Complications and quality of life in elderly patients with several comorbidities undergoing cutaneous ureterostomy with single stoma or ileal conduit after radical cystectomy

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Objectives

To compare peri-operative outcomes and quality of life (QoL) in a series of elderly patients with high comorbidity status who underwent single stoma cutaneous ureterostomy (CU) or ileal conduit (IC) after radical cystectomy (RC).

Patients and Methods

The clinical records of patients aged >75 years with an American Society of Anesthesiologists (ASA) score >2 who underwent RC at a single institution between March 2009 and March 2014 were retrospectively analysed. After RC, all patients included in the study received an IC urinary diversion or a CU with single stoma urinary diversion. Preoperative clinical characteristics as well as intra- and postoperative outcomes were evaluated and compared between the two groups. In addition, the Bladder Cancer Index (BCI) was used to assess QoL.

Results

A total of 70 patients were included in the final comparative analyses. Of these, 35 underwent IC diversion and 35 CU

single stoma diversion. The two groups were similar with regard to age, gender, ASA score, type of indication and pathological features. Operating times ($P < 0.001$), estimated blood loss ($P < 0.001$), need for intensive care unit stay ($P = 0.01$), time to drain removal ($P < 0.001$) and length of hospital stay ($P < 0.001$) were significantly higher in patients undergoing IC diversion. The number of patients with intra- ($P = 0.04$) and early postoperative ($P = 0.02$) complications was also significantly higher among those undergoing IC diversion. Interestingly, the mean BCI scores were overlapping in the two groups.

Conclusions

The present results show that CU with a single stoma can represent a valid alternative to IC in elderly patients with relevant comorbidities, reducing peri-operative complications without a significant impairment of QoL.

Keywords

bladder cancer, cutaneous ureterostomy, ileal conduit, radical cystectomy

Introduction

Radical cystectomy (RC) with pelvic lymph node dissection is the 'gold standard' treatment for muscle-invasive bladder cancer (BCa) and for selected patients with high-risk non-muscle-invasive disease [1,2]. This surgical procedure can be associated with considerable peri-operative morbidity and mortality, above all in elderly patients with relevant comorbidities [3]. Most of the more dangerous complications observed after RC in elderly patients are directly correlated to

the type of urinary diversion used [2]. Indeed, gastrointestinal complications are frequent in patients who receive an ileal conduit (IC) [3]. Conversely, cutaneous ureterostomy (CU) can be performed quickly, reducing the operating time, the potential risk of bowel complications and metabolic complications in comparison with IC, particularly in the subgroup of elderly patients with advanced disease and limited life expectancy [2]. From a technical point-of-view, in the majority of cases, CU is performed bilaterally using two stomas, which could negatively influence the patients' body

image more than IC [4]. As a consequence, it is a key factor to consider when making surgical decisions, mainly in terms of urinary diversion; however, little information is available in the literature with regard to complications and impact on patient quality of life (QoL) of the different available urinary diversions in the specific subgroup of elderly patients undergoing RC for BCa.

The objective of the present study was to compare peri-operative complications and QoL in two subgroups of patients aged >75 years with high comorbidity status who underwent CU with unilateral stoma or IC after open RC.

Patients and Methods

The clinical records of patients who underwent RC for BCa at a single institution between March 2009 and March 2014 were retrospectively reviewed. Patients aged >75 years at the time of surgery, with an American Society of Anesthesiologists (ASA) score >2, receiving an IC or a CU with single stoma were included in the final analysis. Exclusion criteria were palliative cystectomy for massive bleeding, presence of distant metastases at the diagnosis, neoadjuvant chemotherapy, previous abdominal/pelvic surgery or radiation therapy and simultaneous urethrectomy or nephro-ureterectomy. The following preoperative variables were recorded: age; gender; BMI; ASA score; creatinine; serum protein and haemoglobin levels; indications for RC; and comorbidities. The Charlson comorbidity index was used for assessment of preoperative comorbidity status [5]. Age was not combined with the Charlson comorbidity index. All patients received subcutaneous low-molecular heparin, starting the day before the surgery and antibiotic prophylaxis <1 h before surgical incision. All the surgical procedures were performed by a single expert surgeon. Briefly, RC was performed using a standard intraperitoneal approach in all cases. Pelvic lymph node dissection was performed in all cases. The type of urinary diversion was chosen according to surgeon preference. In patients who received the IC diversion the uretero-ileal anastomosis was performed using Bricker's technique [6]. Ureters were splinted using a mono-J ureteric stent that was removed 3 weeks postoperatively. CU was performed after gentle ureteric mobilization, with preservation of sufficient peri-ureteric connective tissue in order to preserve the blood supply as far as possible. The ureters were spatulated and splinted using mono-J ureteric stents. The left ureter was transposed, avoiding tensions behind the mesosigmoid, in front of the great vessels and through the opening in the retroperitoneal region on the stomal side. The ureters were brought through in a completely extraperitoneal manner in all patients. An abdominal wall hiatus was created through a W-shaped incision. Subcutaneous fat was removed. The fascia was incised, and the muscle and peritoneal layers were perforated with blunt forceps. The distal end of both ureters brought through the abdominal wall were anchored to

the fascia and sutured to the skin using absorbable sutures. The stents were then changed every month. The intra- and early postoperative (<30 days after surgery) data from patients in the two groups were recorded and compared. The volume of blood loss was estimated by measuring the volume of suction aspirate and by weighing soaked gauze. Postoperative complications were classified according to the Dindo modified Clavien classification [7]. Patients who were alive at the time of the study received a questionnaire to perform a cross-sectional evaluation of their QoL. An Italian translated version of the Bladder Cancer Index (BCI) was used to assess QoL [8]. For patients managed with non-continent urinary diversion, BCI urinary items assess stoma and appliance function, and are designed to measure symptoms such as urinary leakage and skin irritation that may result from suboptimal stomal placement, retraction and appliance fit [8]. Item responses are based on Likert scales, with domain and sub-domain scores standardized to a 0–100-point scale, on which higher scores correspond to better health states. Descriptive data of continuous variables were expressed as mean and SD values and compared using Student's t-test. Proportions were compared using the chi-squared test or the Yates or Fisher test, when appropriate. P values <0.05 were taken to indicate statistical significance. All statistical analyses were performed using SPSS version 17.0 (SPSS Inc, Chicago, IL, USA) software. The study was approved by the local ethics committee and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave their informed consent before their inclusion in the study.

Results

Overall, a total of 250 RCs were performed within the selected time frame. A total of 70 patients (28%) met the inclusion criteria and were analysed . Of these, 35 (50%) underwent IC diversion and 35 (50%) underwent CU with unilateral stoma diversion. The demographic and clinical characteristics of patients are shown in Table 1. Specifically, the two groups were similar in terms of age, gender, ASA score, BMI, preoperative laboratory tests, comorbidities and pathological features. The mean age of patients undergoing IC and CU was 78.8 and 78.5 years, respectively. The percentage of patients with a diagnosis of muscle-invasive disease in the IC and CU groups was 94.2 and 97.1%, respectively. Seven patients (20%) in the IC group and nine patients (25.7%) in the CU group had an ASA score of 4. The prevalence of cardiovascular disease was 71.4 and 77.1% in the IC and CU groups, respectively, and the prevalence of chronic obstructive airway disease was 42.8 and 51.4% in the IC and CU groups, respectively. Intra- and early postoperative outcomes are shown in Table 2. Operating times ($P = 0.001$), estimated blood loss ($P = 0.001$), need for

intensive care unit monitoring (P = 0.01), time to drain removal (P = 0.001) and length of hospital stay (P = 0.001) were significantly higher in patients undergoing IC diversion. The mean operating time was 225.8 min for the IC group and 149.5 min for the CU group. Twenty-one patients (60%) in the IC group and 10 patients (28.5%) in the CU group required postoperative intensive care monitoring. Similarly, the percentage of patients with intra-operative (P = 0.04) and

early postoperative (P = 0.02) complications was significantly higher among those undergoing IC diversion. The incidence of early postoperative complications is shown in Table 3. Intra-operative complications were: hypotension; decreased oxygen saturation; cardiac arrhythmia; and bleeding. Intraoperative hypotension was defined as a decrease in systolic blood pressure of ≥20% over the basal value, for 15 min. Any abnormalities in cardiac rate, rhythm or conduction, which can be lethal, were considered significant cardiac arrhythmias. A clinically significant decrease in oxygen saturation was defined as SpO2 <90%. The incidence of intra-operative hypotension, decreased oxygen saturation and cardiac arrhythmia was 14.2 and 5.7% (P = 0.42), 11.4 and 2.8% (P = 0.35), 5.7 and 2.8% (P = 1.00) in the IC and CU groups, respectively. The incidence of intra-operative bleeding in the IC and CU groups was 8.5 and 2.8%, respectively (P = 0.60). In two cases, significant bleeding occurred from a branch of the mesenteric artery during ileal resection. Postoperative urinary leakage from the uretero-ileal anastomosis was managed by urinary diversion in all cases.

The mean (range) follow-up was 42.7 (12–72) months. The number of patients alive at the time of the analysis was 32 in the IC group and 30 in the CU group.

Data on QoL outcomes were available in 30 patients (85.7%) who received IC diversion and in 28 (80%) who underwent CU diversion. QoL results overlapped in the two groups (Table 4). In both groups, higher scores were recorded in the urinary function and urinary bother domains, while lower scores were recorded in the sexual function and sexual bother domains.

Discussion

The present study showed that, in elderly patients with relevant comorbidities, CU with a single stoma minimizes the risk of peri-operative complications without a negative impact on QoL in comparison with IC. These data should be taken

Table 1 Demographic and clinical characteristics of the study population according to study group.

	IC, N=35	CU, N=35	P
Mean ± SD age, years	78.8 ± 1.8	78.5 ± 2.1	0.25
Gender, n (%)			
Male	33 (94.2)	31 (88.5)	0.66
Female	2 (5.7)	4 (11.4)	
ASA score, n (%)			
3	28 (80)	26 (74.2)	0.56
4	7 (20)	9 (25.7)	
Mean ± SD BMI, kg/m^2	26.0 ± 1.3	26.5 ± 1.5	0.08
Mean ± SD haemoglobin level, g/dl	12.2 ± 1.1	12.1 ± 1.7	0.45
Mean ± SD total serum proteins, g/dl	7.3 ± 0.7	7.1 ± 0.6	0.08
Mean ± SD creatinine level mg/dl	1.1 ± 0.4	1.2 ± 0.6	0.08
Indication for RC, n (%)			
Muscle-invasive disease	33 (94.2)	34 (97.1)	1.00
Non-muscle-invasive disease refractory to intravesical immunotherapy	2 (5.7)	1 (2.8)	
Comorbidity, n (%)			
Cardiovascular disorders	25 (71.4)	27 (77.1)	0.78
Chronic obstructive airway disease	15 (42.8)	18 (51.4)	0.63
Diabetes mellitus	9 (25.7)	13 (37.1)	0.43
Ulcer disease	5 (14.2)	7 (20)	0.75
Liver disease	3 (8.5)	2 (5.7)	1.00
Chronic kidney disease*	8 (22.8)	10 (28.5)	0.78
Upper urinary tract obstruction, n %	3 (8.5)	5 (14.2)	0.7
Mean ± SD CCI	5.2 ± 0.8	4.9 ± 0.8	0.21

ASA, American Society of Anesthesiologists; CCI, Charlson comorbidity index; CU, cutaneous ureterostomy; IC, ileal conduit; RC, radical cystectomy. *Defined in accordance with International Classification of Diseases-9 criteria.

Table 2 Intra-operative, early postoperative and pathological data according to study group.

	IC, N=35	CU, N=35	P
Mean ± SD operating time, min	225.8 ± 72.3	149.5 ± 35.1	<0.001
Mean ± SD intra-operative EBL, mL	510.5 ± 106.8	380 ± 93	<0.001
Patients transfused, n (%)	15 (42.8)	6 (17.1)	0.03
Need for intensive care monitoring, n (%)	21 (60)	10 (28.5)	0.01
Mean ± SD length of intensive care monitoring, days	2.5 ± 0.9	2.2 ± 0.7	0.16
Mean ± SD time to drain removal, days	6.2 ± 2.4	3.7 ± 0.9	<0.001
Mean ± SD length of hospital stay, days	13.2 ± 1.7	8.8 ± 1.0	<0.001
Pathological stage, n (%)			
Organ-confined disease (≤pT2, pN0)	24 (68.5)	21 (60)	0.45
Extravesical disease (> pT2, or >pN0)	11 (31.4)	14 (40)	
Patients with intra-operative complications, n (%)	9 (25.7)	2 (5.7)	0.04
Patients with early post-operative complications, n (%)	20 (57.1)	10 (28.5)	0.02

CU, cutaneous ureterostomy; EBL, estimated blood loss; IC, ileal conduit.

Table 3 Complications according to study group.

Clavien grade	Type of complication	IC, n (%)	CU, n (%)	P
I	Prolonged ileus	9 (25.7)	2 (5.7)	0.04
	Fever	9 (25.7)	2 (5.7)	0.04
	Wound infection	7 (20)	4 (11.4)	0.5
	Pelvic lymphocele	2 (5.7)	1 (2.8)	1.00
	Disorientation	6 (17.1)	4 (11.4)	0.73
II	Gatrointestinal bleeding	3 (8.5)	0 (0)	0.23
	Pelvic haematoma	1 (2.8)	1 (2.8)	0.47
	Cardiac arrhythmia	4 (11.4)	4 (11.4)	0.70
	Myocardial infarction	1 (2.8)	1 (2.8)	0.47
	Pyelonephritis	6 (17.1)	3 (8.5)	0.47
IIIa	Wound dehiscence	2 (5.7)	2 (5.7)	0.60
	Urinary leakage from the uretero-ileal anastomosis	5 (14.2)	0 (0)	0.06
	Pelvic hematoma	1 (2.8)	1 (2.8)	0.47
IVa	Pneumonia	3 (8.5)	2 (5.7)	1.00
V	Death	1 (2.8)	1 (2.8)	0.47

CU, cutaneous ureterostomy; IC, ileal conduit.

Table 4 Mean bladder cancer index scores according to study group.

	IC (n=30)	CU (n=28)	P
Urinary			
Function	82.4	81.7	0.56
Bother	84.3	85.5	0.61
Bowel			
Function	75.2	74.5	0.92
Bother	76.7	77.1	0.85
Sexual			
Function	18.5	17.2	0.63
Bother	46.7	48.5	0.65

CU, cutaneous ureterostomy; IC, ileal conduit.

into consideration during the preoperative counselling with the aim of improving the decision-making process.

Elderly patients with BCa represent a challenge category with a progressively increasing epidemiological relevance [3]. If elderly patients diagnosed with invasive BCa are left untreated, most will die from the disease and not from a competing age-related illness [3,9–12]. Moreover, the effects of locally advanced disease, such as pain, bleeding and upper collecting system dilatation, can evolve into severe general conditions such as anaemia, fatigue, renal insufficiency, requiring frequent palliative treatments and hospitalization.

Obviously, in frail patients surgical procedures should be performed quickly to reduce the risk of complications. In this context, the choice of urinary diversion is a relevant factor.

To date, only few studies have reported their experience with RC in high-surgical-risk elderly patients with special focus on the type of urinary diversion [3,13,14]. Moreover, none of these studies has addressed the issue of QoL in such patients. IC is the usual urinary diversion of choice also in elderly

patients with BCa [15]. CU is a less popular form of urinary diversion. Both techniques imply the use of external bags to collect the urine, which can lead to a negative effects on body image. Each technique has its inherent advantages and disadvantages. CU is the simplest and less invasive form of urinary diversion. Moreover, CU does not require intestinal violation and allows a convenient approach to the upper urinary tract. The main drawback of CU is stomal stenosis, which has been observed more often with this procedure than in intestinal stomas, and requires lifelong changes of the ureteric stents [3]. IC does not require permanent ureteric stenting, but complications related to gastrointestinal tract violation are frequent. The incidence of complications after RC in the elderly has been reported to vary from 28 to 64% [16]. Most complications (41–72%) are medical [16]. Surgical complication rates vary from 8 to 35% [16]. The wide variations in the reported frequency and spectrum of complications is mainly attributable to the heterogeneity of the reporting systems and the different lengths of follow-up periods after surgery. Results from the present study in elderly, high-risk patients with BCa undergoing RC have shown better intra- and early postoperative outcomes when a CU with unilateral stoma diversion was performed rather than an IC urinary diversion.

Obviously, the ability to minimize operating time and intra-operative blood loss in patients with substantial comorbidities may help to reduce postoperative complications [3,17]. The present results showed significantly lower operating times and intra-operative blood loss in patients undergoing RC, followed by CU with unilateral stoma creation, and these results are in accordance with previously published data [3]. Deliveliotis et al. [3] reported significantly lower mean operating times (131 vs 251 min; $P < 0.001$), mean blood loss (387 vs 490 mL; $P < 0.001$) and need for blood transfusions (24.1 vs 56%; $P < 0.025$) in patients undergoing CU than in those undergoing IC [3]. Interestingly, the incidence of intra-operative complications in the present study was low in both groups, although significantly lower in patients undergoing CU diversion. Similarly, Deliveliotis et al. [3] reported a significantly lower incidence of intra-operative complications in patients undergoing CU urinary diversion than in those undergoing IC urinary diversion (13.7 vs 40%; $P < 0.035$). The lower incidence of intra-operative complications in the present series may be explained in part by the fact that patients with a history of pelvic surgery, radiotherapy and neoadjuvant chemotherapy, which have been reported to increase technical difficulties during surgery, were excluded [18]. In a recent study by Wuethrich et al. [19], the 90-day complication rate was higher among patients aged >75 years who underwent open RC and CU urinary diversion than in those undergoing IC urinary diversion (56.7 vs 63.6%). Most results on such complication rates derive from single-centre and retrospective studies which have potential selection

biases. Because of substantial heterogeneity among study populations, direct comparisons of results are impossible and the discrepancies in results underline the need for further research in this field.

The number of patients requiring intensive care monitoring was also significantly lower among those undergoing CU with unilateral stoma creation. Deliveliotis et al. [3] reported a significantly lower need for intensive care monitoring (7.4 vs 32%; $P < 0.032$) in patients undergoing CU urinary diversion than in those undergoing IC urinary diversion.

Before 1990, peri-operative mortality after RC was very high and ranged from 2.4 to 15% in large series (>100 patients) [17]. During the past decade the mortality rate has decreased to 0–3.9% [17]. Peri-operative mortality in elderly patients undergoing RC with IC or CU urinary diversion has been reported to vary between 0 and 10% [18]. Similarly to previously published series, we did not report intra-operative mortality [3,20]. Early postoperative mortality in the present series was within the published ranges.

The average hospital stay after RC in the literature ranged between 7 and 34 days [21].

The mean hospital stay reported in the present study in both groups is consistent with the available literature data [3,20]. Deliveliotis et al. [3] reported significantly lower mean hospitalization times (8.6 vs 16.09 days; $P < 0.001$) in patients undergoing CU urinary diversion than in those undergoing IC urinary diversion. Consistent with previously published data, the mean length of hospital stay for patients who underwent IC urinary diversion was significantly higher than for those undergoing CU [3]. Taken together, the intra-operative and early postoperative advantages we reported in the group of patients undergoing CU urinary diversion are of great clinical relevance in an older and comorbid patient.

There is a growing interest in evaluating QoL in patients with BCa who undergo RC and urinary diversion. It is commonly held by urological surgeons that there are QoL differences among various forms of urinary diversions [22], but no study has conclusively shown that one form of diversion is superior to another in terms of QoL in elderly patients [22]. Saika et al. [23] compared the health-related QoL of elderly patients after RC for BCa. They found no significant differences among urinary diversion subgroups (IC, CU or orthotopic urinary reservoir) in any area of the QLQ-C30, a QoL questionnaire . The BCI is a novel BCa-specific QoL questionnaire presented by Wei et al. [24]. Robust reliability and validity evaluation provided strong evidence for the reliability of the BCI along the entire spectrum of therapies for superficial and invasive BCa regardless of sex. In the present study we used the BCI, for the first time, in elderly, high-risk patients undergoing RC with IC or CU diversion. The results showed that the two

groups scored similarly in all the function and bother domains (urinary, bowel, sexual).

The present study has several limitations. It was an observational, retrospective, non-matched pair study and the BCI questionnaire is not validated for Italian-speaking patients; therefore, it was not possible to perform a baseline QoL evaluation of analysed patients. Moreover, some minor postoperative complications could be missed and the relatively small sample size might have resulted in low statistical power for some of our analyses. Although long-term complications, such as stent-related complications, were not evaluated by the present study, its findings show that chronic ureteric stenting does not affect the QoL of patients with BCa undergoing CU urinary diversion compared with those undergoing IC urinary diversion.

In conclusion, this comparative study showed that, in elderly patients with high disease burden, CU with a single stoma can represent a valid alternative to IC as it can lead to substantial benefits in overall patient management in the intra- and early postoperative period without a negative impact on QoL. Considering that CU is the easier and quicker urinary diversion, this option should be strongly considered and discussed when an elderly patient with relevant comorbidities is being considered for RC from an oncological point-of-view.

Conflict of Interest

The authors declare that there are no conflicts of interest.

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Abbreviations: ASA, American Society of Anesthesiologists; BCa, bladder cancer; BCI, bladder cancer index; CU, cutaneous ureterostomy; IC, ileal conduit; QoL, quality of life; RC, radical cystectomy.