

# The role of cystectomy in elderly patients – a multicentre analysis

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## Introduction

Life expectancy in developed countries is continuously increasing. Hence elderly patients are becoming more common in our clinical practice. Currently, one of the greatest challenges of medicine is balancing the life expectancy of elderly patients against aggressive treatments that carry significant risks.

## Objective

To outline the complications and survival in surgical patients 80 years and over undergoing radical cystectomy for bladder cancer.

## **Patients and Methods**

A review of a radical cystectomy in elderly recorded in four different institutional prospective databases during the period between 1991 and 2014. Clinical and pathologic features, complications and survival were evaluated.

## **Results**

A total of 111 patients were available. Median (range) age 82.2 (80–89) years. Seventeen women and 94 men. Regarding the ASA score, 6 patients were ASA I, 47 patients were ASA II, 49 patients ASA III and 9 ASA IV. Prior to surgery, 48 patients had hydronephrosis. The median (range) creatinine series was 1.1 (0.71–11.1) ng/dL. In 88 cases an ileal conduit was performed, 17 a cutaneous ureterostomy diversion, 5 neobladders and 1 ureterosigmoidostomy case. The median (range) operative time was 230 (120–420) min and a total of

97 patients required blood transfusion. The median (range) hospital stay was 14 (7–126) days. The early and late complication rates were 50.4% and 32%, respectively. A total of 14 patients (12.6%) required surgical reintervention. Eight patients (7.2%) died in the immediate postoperative period. The readmission rate of the series was 27.2%. The mean follow-up of the series was 18 (0.27–134.73) months. During this period 66 patients died, 52 of them due to the tumor. Twelve month tumour progression free survival was 83.9% for  $\leq$ pT1, 70.2% for pT2 and 36% for  $\geq$ pT3, respectively. Twelve month cancer specific survival was 85.6% for  $\leq$ pT1, 75.1% for pT2 and 42.5% for  $\geq$ pT3, respectively.

## Conclusion

Radical cystectomy in elderly population is an aggressive surgical treatment with a significant complication rate, hospital readmission and perioperative mortality rate. Careful selection of patients is essential in order to minimize the complications of this surgery and balance benefits against risks in the elderly population. Tumour progression and cancer specific survival are poor for patients with  $\geq$ pT3 disease. Alternatives such as tri-modality therapy need to be considered within a multidisciplinary approach. More data is required to determine which sub-groups of elderly patients would benefit from a complication, survival and quality of life perspective.

## **Keywords**

radical cystectomy, elderly, complications, survival, bladder tumour, urothelial carcinoma

# Introduction

Bladder cancer (BCa) is a global problem being the ninth most commonly diagnosed cancer worldwide, with more than 380 000 new cases each year and more than 150 000 deaths per year [1,2].

Age is now recognized as the single most important risk factor for the development of cancer; therefore, cancer is considered primarily a disease of the elderly (>65 years) [3,4]. Interestingly, the fastest growing segment of the population is the 80 years and older group, which is

projected to increase in number from 3.7 million in 1996, 5.7 million in 2010, and 18.2 million by 2050 [4].

Because of this strong link between age and cancer, the challenge rests for physicians to optimize outcomes in elderly patients. BCa also is a disease of the elderly, most commonly occurs beyond the 70th year of life [5]. Thus, there is expected to be an increased incidence of BCa in elderly patients who have a reasonable life expectancy.

Radical cystectomy with pelvic lymph node dissection provides the best cancer-specific survival for muscle-invasive BCa [5,6,7], and is the standard treatment, with 10-year recurrence free survival rates of 50–59% and overall survival rates of around 45% [6,8]. In elderly patients, concern has been expressed about the increased morbidity and mortality rates of this surgery. Despite advances in perioperative management with considerable improvements in this field in recent decades complication rates of radical cystectomy remain relatively high against life expectancy is increasing [5,9,10]. Consequently, treatment decisions for elderly patients with muscle invasive or recurrent BCa constitute an important and difficult clinical challenge today and in the foreseeable future.

The aim of this multicentre study is to describe the complications and outcome of surgical patients over 80 years undergoing radical cystectomy for bladder cancer.

## **Patients and Methods**

### **Study Population**

A review of an open radical cystectomy in 111 elderly patients older than 80 years recorded in four different institutional prospective databases during the period between 1991 and 2014: 35 patients from Hospital Clinic in Barcelona, Spain, 32 patients from la Pitié-Salpetrière Hospital in Paris, France, 31 patients from Fundación IVO in Valencia, Spain and 13 from Austin Health Hospital in Melbourne, Australia.

Tumours were staged and classified according to the TNM classification system of the Union Internationale Contre le Cancer [11]. Data were obtained with institutional review board approval.

Anaesthetic risk was assessed and graded according to the American Society of Anaesthesiologists Physical Status Classification System (ASA score).

Selected patients were hospitalized at least 12 h before surgery to allow intravenous hydration. Perioperative antibiotic therapy and prophylactic anticoagulation were performed following local protocols.

All patients were followed up in 3-month intervals postoperatively for the first year, for the next 2 years in 6 months intervals and if they were disease-free after 3 years, controls were made yearly. Abdominal and pelvic CT Scan was used in the follow-up of these patients. Tumours were considered to be progressing when local or distant metastasis or pathological nodes were developed during the follow-up.

The clinical outcomes were analyzed according to the following definitions: perioperative mortality, any death within 30 days after the surgery; early complication, occurring within 90 days after cystectomy; late complication, occurring >90 days after cystectomy. Complications were classified according to Clavien classification [12].

#### Statistical Analysis

SPSS 12.0 software (SPSS, Inc., Chicago, IL, USA) was used to evaluate mean and median values used for quantitative variables, with the extremes as scatter measures. Absolute and relative frequencies were considered to be qualitative variables. The probabilities of progression free survival and cancer-specific survival were calculated using Kaplan-Meier curves. Statistical differences were identified by the log-rank test. Statistical significance was established at  $\alpha$ -value of 0.05.

## **Results**

The median (range) age of the series is 82.2 (80–89) years. Sex distribution men/women is 94:17. The mean (range) follow-up of the studied population was 18 (0.27–134.7) months. The patients' pathological characteristics are shown in Table 1.

### Preoperative Data

Of the 111 patients included, significant comorbidity was present in 100 patients: 20 (18%) were diabetic, 15 (13.5%) had chronic obstructive lung disease, 48 (43.2%) cardiovascular disease and 21 (18.9%) vascular disease. A total of 29 and 36 patients (26.1% and 32.4%, respectively) were under anticoagulant and antiplatelet treatment, respectively.

Six patients (5.4%) were classified as ASA I, 47 as ASA II (42.3%), 49 as ASA III (44.1%) and 9 as ASA IV (8.2%).

The diagnosis of the tumour was incidental only in 4 patients (3.6%), while all the other patients presented with haematuria. Fifteen patients (13.5%) had a past history of bladder tumour whilst 13 (11.7%) *carcinoma in situ*. Of them 11, received bacillus Calmette-Guerin (BCG) treatment. Seventy patients (63%) underwent a bladder tumour transurethral resection (BT TUR) at least once. Of them, in 39 cases the BT TUR was incomplete. At the moment of diagnosis 48 patients (43.2%) presented with uretero-hydronephrosis. The median (range) creatinine of the series was 1.1 (0.7–11.1) ng/dL. Six patients received neoadjuvant chemotherapy treatment.

#### Table 1 Pathological features of patients with bladder cancer.

	Hospital Clinic of Barcelona	Pitié Salpétrière Hospital of Paris	Fundación IVO of Valencia	Austin Health Hospital of Melbourne	Total <i>n</i> (%)
No of patients	35	32	31	13	111 (100)
Grade					
LG	-	-	-	-	-
HG	31	29	28	12	100 (90.1)
Stage					
pT0	2	0	2	1	5 (4.5)
рТа	1	0	0	0	1 (0.9)
pTis	2	3	1	0	6 (5.4)
pT1	0	1	2	1	4 (3.6)
pT2	4	7	4	3	18 (16.3)
pT3	16	11	15	5	47 (42.3)
pT4	10	10	7	3	30 (27)

#### Surgery

Open radical cystectomy was performed in all patients. Lymphadenectomy was performed in 83 patients (to the level where the ureter crosses the common iliac artery). Regarding the urinary diversion: 88 cases received an ileal conduit (79.3%), 17 a cutaneous ureterostomy (CU) (15.3%), five neobladder (4.5%) and one ureterosigmoidostomy case (0.9%).

The median (range) operative time was 230 (120–420) min and a total of 97 patients (87.4%) required blood transfusion. The median (range) blood loss was 1 000 (300–4 000) ml. The mean (range) hospital stay was 14 (7–126) days. Surgery was predominantly for palliation in 29 (26.1%) of patients having at least one of ongoing haemorrhage, outlet obstruction, renal failure, or pain,

#### Complications

The early complication rate of the series was 50.4% (n = 56) (Table 2). Six patients developed more than one complication. A total of 14 patients (12.6%) required surgical reintervention: seven cases for evisceration, two for hemoperitoneum, two cases of urinary fistula, one case of enteric fistula and two cases of laparotomy for peritonitis. Eight patients (7.2%) died in the immediate postoperative period (before 30 days).

The late complication rate of the series was 32% (n = 33) (Table 2). The hospital readmission rate was 27.2% (n = 28) (Table 3). The number of readmissions was 55. More than two hospital readmissions underwent in 12 patients.

After the surgery 18 patients presented ureterohydronephrosis (five bilateral, nine left side and four right side. Of those last four patients, two of them had uretero-hydronephrosis prior to the surgery). Two and 12 months after the surgery the median (range) creatinine were 1.1 (0.7–4.3) ng/dL and 1.3 (0.7–6.9) ng/dL, respectively.

#### Table 2 Early and late complications according to Clavien classification.

	Early complications (n = 56)	No of patients	Clavien
Medical	Pyrexia of unknown origin	3	Ι
	Blood transfusion	15	II
	Bacteraemia	4	II
	Acute pulmonary edema	1	IV
Surgical	Paralitic ileus	24	Ι
	Pelvic lymphocoele (no intervention)	1	Ι
	Urine fistula (intervention)	2	III
	Enteroanastomosis fistula (intervention)	1	III
	Abdominal haemorrhage (intervention)	2	IV
	Peritonitis (intervention)	2	IV
Wound	Dehiscence (intervention)	7	III
	Late complications (n = 33	>	
Medical	Metabolic imbalance	1	Ι
	Acute renal failure (no requiring dialysis)	1	Ι
	Bacteraemia	12	II
	Pneumonia	3	II
	Hypercalcaemia	1	II
	Deep vein thrombosis	3	II
	Pulmonary embolism	2	IV
	Cardiac disease	2	IV
Surgical	Entero-vaginal fistula	1	III
	Enteric fistula	1	III
	Conversion neobladder to ileal conduit	1	III
Wound	Dehiscence	3	III
	Evisceration peri-stoma	1	III
	Stoma necrosis	1	III

#### Follow-Up and Survival

Mean (range) follow-up was 18 (0.27–134.7) months. The distribution per stage and grade were as follows: five pT0 (4.5%), six pTis (5.4%), one pTa (0.9%), four pT1 (3.6%), 18 pT2 (16.3%), 47 pT3 (42.3%), 30 pT4 (27%), 100 high grade (90.1%). Of those undergoing node dissection (n = 83), 15

Table 3 Hospital readmission causes.

Cause of readmission (n = 28)	No of patients
Sepsis	4
Urinary tract infection	4
Pneumonia	1
Pyrexia	1
Pain	4
Peripheral edema	1
Enteric fistula	2
Vesico-vaginal fistula	1
Entero-cutaneous fistula	1
Performance status deterioration	2
Pleural effusion	1
Nephrostomy tube insertion	4
Diversion change	1

patients (18.1%) had positive nodes while the rest (68 patients) were negative.

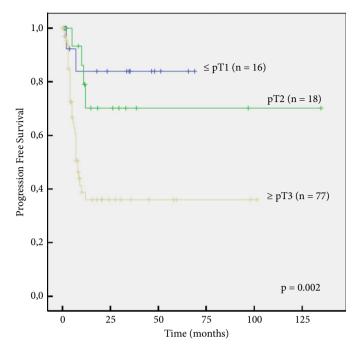
Overall 40 patients (38.8%) developed tumour progression after a mean follow-up of 18 months. Six of them received adjuvant chemotherapy treatment based on the cystectomy pathology. The median (range) time of tumour progression was situated in 6.2 (1–12) months. For pathological stage, 12 month tumour progression free survival was 83.9% for  $\leq$ pT1, 70.2% for pT2 and 36% for  $\geq$ pT3, respectively (*P* = 0.002) (Fig. 1).

During follow-up 66 patients (59.4%) died, 52 of them (47.7%) due to bladder cancer. Two of them were pT0 (3.8%), 1 pT1 (1.9%), 6 pT2 (11.6%), 24 pT3 (46.2%) and 19 pT4 (36.5%). Fourteen patients died from other diseases. The median (range) time of cancer-specific death was 9.3 (2.8–36.7) months. Based on pathological stage, the 12 month cancer specific survival was 85.6% for  $\leq$ pT1, 75.1% for pT2 and 72.9% and 42.5% for  $\geq$ pT3, respectively (*P* = 0.001) (Fig. 2).

## Discussion

Currently, one of the greatest challenges of medicine is balancing the life expectancy of elderly patients against aggressive treatments that carry significant risks. The ultimate goal with bladder cancer is having a treatment that has reduced morbidity and that extends life with acceptable quality of life. Radical cystectomy has been the standard treatment for patients with muscle invasive bladder cancer [13]. Elderly patients have long been recognized as a highrisk surgical group, with age traditionally considered to be a determinant factor for surgical outcome, especially postoperative complications. The morbidity of radical cystectomy is clearly lower than in previous decades, which is probably due to refinements of surgical techniques as well as the improvement of anaesthesia and perioperative protocols into routine clinical practice [14,15]. However, morbidity still remains high in the postoperative period.

Fig. 1 Kaplan-Meier progression free survival curve.



Historically, due to the poor results with combined cystoscopic resection, radiation and chemotherapy in nonselected cases, a number of authors have investigated the use of cystectomy in the elderly (see Table 4). Interestingly, many series of radical cystectomy in patients over 75 years are published in the literature [5], but few of them included only patients over 80 years and have generally included a limited number of patients so they have not been large enough to draw conclusive findings (Table 4). Consequently, our study is a relevant multi-institutional series with 111 cases. In terms of modern tri-modality (multimodality) therapy, consisting of more aggressive cystoscopic resection, chemo-radiation with regular cystoscopic follow-up and salvage cystectomy if appropriate on failure, little data exists in the elderly [13]. This alternate treatment strategy will be discussed in subsequent sections.

The present study focused on evaluating the patients' complications and disease outcome in order to confirm the aggressive impact of radical cystectomy in an elderly population. Perioperative mortality rates across series have varied widely from 0% to 14%, among the 2 637 unique patients (Table 4). In the current study the perioperative mortality rate was 7.2%, consistent with other reports in the literature. Complications rates have varied widely between cystectomy series in elderly patients, from 17% to as high as 67% (see Table 4). It would be very difficult to make comparisons, because the series all differ considerably in how a complication was defined, whether or not late complications were included, and how long the patients were followed.



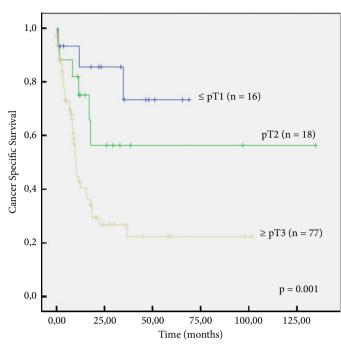


 Table 4
 Overview of reported perioperative mortality and complication rates in over 80 years old patients undergoing radical cystectomy.

References	No of patients	30-day ortality rate (%)	Early/late complication rate (%)
Izquierdo et al.	111	7.2	50.4/32
Tachibana et al. [17]	9	0	67
Ogawa et al. [18]	9	0	33/-
Orihuela and	7	14	-
Cubelli et al. [19]			
Stroumbakis et al. [20]	44	4.5	51
Lance et al. [21]	33	0	60.6 (overall)
Yamanaka et al. [24]	72	4.2	30.6/20.8
Liguori et al. [22]	20	5	35
Mendiola et al. [23]	49	9.5	57/17
Zakaria et al. [32]	275	5.8	33.1/-
Leveridge et al. [33]	657	6	30/36
Schiffmann et al. [34]	1 382	7.7	-
Nguyen et al. [35]	61	0	31/44

Nevertheless, the complication rates in the current series is similar to the wider literature in younger patients [5,9,10] and fits well within the range of early complication rates (30– 57%) and late complication rates (17–44%) reported by other somewhat comparable series (Table 4). In eight of those thirteen series, the number of elderly patients was <50, making the statistical power of the studies low [16–23]. Hence one of the most comparable study to the current series is the Yamanaka et al. [24] with 72 patients. They reported a 4.2% perioperative mortality rate, 4.2% reoperation rate, 30.6% and 20.8% of early and late complication rate, respectively. Our results concluded, 7.2% perioperative mortality rate, 12.6% reoperation rate, 50.4% and 32% of early and late complication rate, respectively. Patients' comorbidity could justify the differences. It is well known that older adults are more likely to have chronic diseases [15,25]. The study by Malavaud et al. [26] showed that the only independent predictor of complications after cystectomy was the patient's ASA score. In our series 90% of the patients presented comorbidities, in fact only six patients were ASA I. A higher rate of the earlier complications probably is related to the higher rate of comorbidities in the elderly and the higher late complication rate may be hypothesized that this is due to the higher overall survival in our elderly population and, thus, longer follow-up and more opportunity to develop a late complication. Hence accurate patient selection is essential.

In summary, complication rates in this series were not particularly higher than in other series (see Table 4) nor when compared to series with younger patients [27]. This is important as this helps clarify the suitability of doing cystectomy in the elderly population. Techniques that may assist in limiting complications include more minimally invasive surgery such as partial cystectomy if appropriate or extraperitoneal cystectomy. Less aggressive urinary diversion such as cutaneous ureterostomy (CU) may also represent a good surgical option in these cases. In general, CU does not require bowel manipulation or isolation and is far simpler and less time-consuming compared with ileal conduit or continent reservoir, with a shorter hospital stay, less blood loss and lower complication rates even in the elderly [28,29]. Alternately, as already alluded to, tri-modality treatment remains an alternative with likely fewer complications and should be considered if feasible and likely to achieve the desired goals in any individual patient [13]. However, no data comparing the two approaches is easily drawn from the literature. Given the poor survival rates in this series, such a multidisciplinary approach has significantly more credence. As with surgery, careful patient selection is the key, such as focusing on smaller burden tumours that have less haemorrhage and in patients with poorer performance status. The other caveat being that they are closely monitored and offered salvage cystectomy and/or diversion if appropriate.

The other major objective of this study is to clarify the impact of radical cystectomy on the survival of the elderly patients. After a mean follow-up of 18 months, 38.8% of the patients developed tumour progression with a median time situated in 6.2 months. Twelve months tumour progression free survival was 83.9% for  $\leq$ pT1, 70.2% for pT2 and 36% for  $\geq$ pT3, respectively (*P* = 0.002). The Yamanaka et al. [24] paper reported a 36.2% of tumour progression rate, consistent with our study. Regarding cancer specific survival, 46.8% of patients dead because of the tumour with a median time situated 9.3 months. For pathological stage, 12 months cancer specific survival was 85.6% for  $\leq$ pT1, 75.1% for pT2 and

42.5% for  $\geq$ pT3, respectively (*P* = 0.001). The paper of Yamanaka et al. [24] showed similar cancer survival curves by stage. The poor cancer specific survival in this group of patients may reflect the more advanced pathological stage in elderly population. In addition, the significant difference in cancer specific survival between these three groups with  $\leq$ pT1 disease, pT2 disease, and importantly in patients aged over 80 years old with  $\geq$ pT3 was worrisome.

Despite the poor results in cancer specific survival in patients with  $\geq pT3$  disease, it is tempting to state that arguably there is likely no other superior alternative treatment to cystectomy. Historically, the prognostic outcome of our study appears to be evidently superior to those achieved in the elderly patients who received radiotherapy for BCa [19,30]. The study by Holmang et al. [30] with 74 BCa patients treated with radiotherapy concluded that radiation is associated with high local recurrence and serious complication rate. Granted the longterm follow up of radiation series is limited, and those in the elderly essentially do not exist, but this must be tempered against modern tri-modality therapy; where there is a greater focus on complete cystoscopic resection better planned radiation and chemotherapy with regular follow-up and salvage surgery available. Issues remain in that chemotherapy treatment could offer benefit to these patients but very often their performance status does not allow such treatment. Also, in these patients, surgical treatment may be more helpful in terms of quality of life and palliating, than in terms of curative aspects. Highlighting this, around a quarter of the patients predominantly had surgery for palliation in this study. More quality of life studies and cost analyses are required to conclude whether surgery or a trimodality approach offers the best palliation. Nonetheless, the importance of discussing these patients in multidisciplinary meetings is essential so that all modalities are considered should be 'standard of care' and cannot be underestimated [31].

Limitations of the study are that this is a review of a database and may have the bias associated with such an approach. Also, there remains an inability to comment on functional or quality of life measures, which are important outcomes following cystectomy. However, this multicentre study represents a significant and varied population performed by experienced but different urologists across large tertiary hospitals.

In summary, the current results support the concept that radical cystectomy and urinary diversion can be offered and could be a reasonable treatment alternative in carefully selected elderly patients. Advanced age by itself no longer constitutes an absolute contraindication to major surgery but it is mandatory to limit the extent of the surgical procedure according to the tolerability of the patient.

## Conclusions

Radical cystectomy in elderly population is an aggressive surgical treatment with a significant complication rate, hospital readmission and perioperative mortality rate. Careful selection of patients is essential in order to minimize the complications of this surgery and balance benefits against risks in the elderly population. Tumour progression and cancer specific survival are poor for patients with  $\geq$ pT3 disease. Alternatives such as tri-modality therapy need to be considered within a multi-disciplinary approach. More data is required to determine which sub-groups of elderly patients would benefit from a complication, survival and quality of life perspective.

## **Conflict of Interest**

All authors have no conflicts to disclose.

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