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Urologic Oncology: Seminars and Original Investigations 38 (2020) 40.e9−40.e15

UROLOGIC ONCOLOGY

Clinical-Bladder cancer

Comparison of standard vs. palliative management for bladder cancer in patients older than 85 years: multicenter study of 317 de novo tumors

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Received 10 May 2019; received in revised form 14 August 2019; accepted 4 September 2019

Abstract

Background: The peak incidence of bladder cancer (BCa) occurs at 85 years but data on treatment and outcome are sparse in this age group. We aimed to compare the outcomes of high-grade nonmuscle invasive BCa (HG NMIBC) and muscle invasive BCa (MIBC) treated with standard therapies vs. palliative management in patients >85 years.

Methods: Retrospective multicenter study of 317 patients >85 years who underwent transurethral resection (TURB) for de novo BCa between 2014 and 2016. Standard management consisted in following EAU-guidelines and palliative in monitoring patients without applying oncological treatments after TURB. Low-grade tumors were not compared because all of them were considered to have followed a standard management.

Results: Median age was 87 years (85−97). ASA-score was as follows: II, 34.7%; III, 52.1%; IV, 13.2%. Pathological examination showed: 86 Low-grade NMIBC (27.1%), 156 HG NMIBC (49.2%), and 75 MIBC (23.7%). Median follow-up of the series was 21 months (3−61) and median overall survival (OS) 29 (24−33). Among HG NMIBC, 77 patients (49.4%) received standard treatments (BCG, restaging TURB) and 79 (50.6%) palliative management. Among MIBC, 24 (32%) received standard management (cystectomy, radiotherapy, chemotherapy) and 51 (68%) palliative. Applying standard management in HG NMIBC was an independent prognostic factor of OS (44 months vs. 24, HR 1.95; *P = 0.013*) and decreased the emergency visit rate (33% vs. 43%). In MIBC, the type of management was not a related to OS (*P = 0.439*) and did not decrease the emergency visit rate (33% vs. 33%). ASA and Charlson-score were not predictors of OS in HG NMIBC (*P = 0.368, P = 0.386)* and MIBC (*P = 0.511, P = 0.665*).

Conclusions: Chronological age should not be a contraindication for applying standard therapies in NMIBC. In MIBC the survival is low regardless of the type of management. The lack of correlation between OS and ASA or Charlson-score raises the necessity of a geriatric assessment for selecting the best treatment strategy.

Key words: Bladder cancer; Elderly; Octogenarians; Palliative management; Transurethral resection of the bladder

1. Introduction

Bladder cancer (BCa) is the ninth most common malignancy worldwide [1], with 118,000 annual new cases and 52,000 deaths per year in Europe [2]. Spain has the highest incidence of BCa in Europe and has one of the highest life expectancies in the world as well [3]. The risk of BCa increases with age and with increasingly aging population in developed countries this disease now poses an important challenge. The median age at diagnosis is 73 years but regarding increase in life expectancy the peak incidence of

Funding: None.
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https://doi.org/10.1016/j.urolonc.2019.09.007
1078-1439/

BCa occurs at 85 years [4,5]. However, the correct management of BCa in the elderly remains controversial.

Although age is an important factor influencing treatment strategy of patients with BCa, there is a lack of evidence-based practice guidelines in the >85 years group. Most decisions are based on chronological age although it is less important than biological age, and many patients are usually managed with more conservative strategies.

The aim of this multicentric study was to analyze the management and outcomes of a consecutive series of patients aged >85 years with de novo BCa. Second, to compare the outcomes between standard therapies vs. palliative management after the initial transurethral resection of the bladder (TURB) in high-grade nonmuscle invasive BCa (HG NMIBC) and muscle invasive BCa (MIBC).

2. Material and methods

2.1. Study population

A retrospective multicenter study of 320 patients older than 85 years with newly diagnosed BCa was performed between 2014 and 2016. Data were collected from 6 Spanish tertiary hospitals. Among all the series, a total of 317 patients who had undergone TURB were selected for the analysis. None of them had history of urothelial carcinoma. Three patients were excluded because they rejected TURB and no pathological data were obtained. Tumors were detected by cystoscopy or ultrasound examination and staged according to the 2009 TNM classification and WHO/International Society of Urological Pathology 2004 guidelines [6,7]. Data about lymphovascular invasion or differentiation was not available because some centers did not routinely report it between 2014 and 2016.

2.2. Patients' demographics, perioperative, and oncological outcomes

The following clinical parameters were reported: age, gender, body mass index, ASA-score, Charlson Comorbidity Index (Charlson-score), reason for examination, intraoperative and postoperative complications of TURB (Clavien-Dindo), length of hospital stay after TURB, emergency visits during follow-up, hospital readmissions, clinicopathological staging, tumor management (standard vs. palliative), tumor recurrence, and overall (OS) and cancer-specific survival. Pathological stage was stratified in 3 groups: low-grade (LG) NMIBC, HG NMIBC, and MIBC. Standard management consisted in following the EAU-guidelines recommendations: surveillance in LG NMIBC, BCG instillations and/or restaging TURB in HG NMIBC, and cystectomy, radiotherapy, or chemotherapy in MIBC. Palliative management consisted in monitoring patients and treating them according to their symptoms but without applying oncological or invasive treatments during the follow-up. They could be managed with analgesics, continuous saline bladder irrigation or blood transfusion but without oncological surgery, bladder instillations, radiotherapy, or chemotherapy. In contrast to the standard management group, patients submitted to palliative care were not treated with a scheduled TURB in case of bladder recurrence. The only invasive treatment allowed in the palliative group was the endoscopic management of very symptomatic patients with hematuria and/or urinary retention secondary to blood clots in an emergency setting. Nephrostomy tube placement was considered as invasive treatment and excluded from palliative group.

Patients with HG NMIBC were monitored with cystoscopy-cytology every 3 months for 2 years and every 6 months for 5 years, and low-grade tumors at 3 months and then yearly for 5 years. Patients with MIBC were monitored every 6 months with CT scan for 5 years. Patients in the palliative management group were submitted to cystoscopic or image evaluation during follow-up in order to identify tumor recurrence or progression. This information is important to reach a consensus with the patient and family on the decision of avoiding any invasive procedure in case of complications.

In the first part of the study, we reported the characteristics and outcomes of all patients older than 85 years with de novo BCa. In the second part, we compared the outcomes of the subgroups of patients with HG NMIBC or MIBC managed with standard treatments (guideline-concordant) with those under a palliative management. LG NMIBC cases were excluded from the analysis because all of them were managed according to standard treatment consisting in TURB and surveillance afterwards.

2.3. Statistical analysis

Categorical variables were reported as frequencies and proportions and continuous data were presented as medians and ranges. Mann-Whitney *U* test and chi-square tests were used to compare the difference between continuous and categorical variables, respectively. Univariate and multivariate analyses were carried out using the Cox regression method to evaluate potential prognostic factors. The Kaplan-Meier method was used to estimate survival curves and the log-rank test was used to evaluate the differences in the overall survival between the groups. A P value less than 0.05 was considered to be significant. All of the statistical analyses were carried out using SPSS version 20 (IBM Corp., Somers, NY).

3. Results

3.1. Characteristics and outcomes of patients >85 years with de novo BCa

A total of 317 patients, 242 men (76.3%) and 75 women (23.7%), underwent TURB for de novo BCa. Median patient age was 87 years (85–97). Clinical data, pathological data, and outcomes of all patients of the series are shown in Table 1.

Table 1
Clinical data, pathological data, and outcomes of all patients

	All patients ($n = 317$)
Age (y), median (range)	87 (85–97)
Gender, *n* (%)	
Male	242 (76.3)
Female	75 (23.7)
BMI, median (range)	26.8 (19–38)
ASA-score, *n* (%)	
II	110 (34.7)
III	165 (52.1)
IV	42 (13.2)
Reason for examination, *n* (%)	
Hematuria	262 (82.9)
Incidental	44 (13.9)
Charlson-score, median (range)	5 (1–14)
pT stage, *n* (%)	
pTx	20 (6.3)
pTa	111 (35)
pT1	106 (33.4)
CIS	5 (1.6)
≥ pT2	75 (23.7)
Pathological stratification, *n* (%)	
LG NMIBC	86 (27.1)
HG NMIBC	156 (49.2)
MIBC	75 (23.7)
Lymph node metastases, *n* (%)	11 (3.5)
Distant metastases, *n* (%)	9 (3)
TURB intraoperative complications, *n* (%)	7 (2.2)
TURB postoperative complications, *n* (%)	64 (20.2)
Clavien-Dindo, *n* (%)	
I–II	43 (13.5)
III–IV	21 (6.7)
Emergency visits, *n* (%)	102 (32.2)
Hospital readmissions, *n* (%)	33 (10.4)
Hospital stay (days), *n* (%)	3 (1–60)
Bladder recurrence, *n* (%)	87 (27.8)
Metastatic recurrence, *n* (%)	41 (12.9)
Death of bladder cancer, *n* (%)	69 (26.5)
Death, *n* (%)	174 (54.9)

ASA-score = American Society of Anesthesiologists physical classification; BMI = body mass index; HG NMIBC = high-grade nonmuscle invasive bladder cancer; LG NMIBC = low-grade nonmuscle invasive bladder cancer; MIBC = muscle invasive bladder cancer; TURB = transurethral resection of the bladder.

Among all patients, 110 (34.7%) were ASA-score II, 165 ASA III (52.1%), and 42 ASA IV (13.2%). Pathological analysis reported 86 cases (27.1%) of LG NMIBC, 156 (49.2%) of HG NMIBC, and 75 (23.7%) of MIBC. A total of 64 patients (20.2%) had postoperative complications after TURB, of whom 16 (5%) were Clavien I, 27 II (8.5%), 19 III (5.9%), and 2 IV (0.6%). Most of low-grade complications (I–II) consisted in urinary infection, urinary retention or blood transfusion, and high grade (III–IV) in endoscopic management of hematuria. The median length of hospital stay was 3 days (1–60).

With a median follow-up of 21 months (3–61), bladder recurrence occurred in 87 patients (27.8%) and metastatic recurrence in 41 (12.9%). Median time between TURB and bladder recurrence was 16 months (3–60) and metastatic recurrence 19 months (3–33). Among 101 patients in the standard group, 47 (46%) underwent a scheduled TURB for bladder recurrence. Only 23 (17%) of 130 patients under palliative management were treated endoscopically in an emergency setting due to hematuria or urinary retention.

A total of 174 patients (54.9%) died, of whom 69 (26.5%) of BCa. The median OS was 29 (24–33) months for all 3 series, 41 (32–49) months for LG NMIBC, 31 (25–36) for HG NMIBC, and 13 (10–15) for MIBC.

3.2. Comparison of standard treatments vs. palliative management in HG NMIBC and MIBC

Table 2 showed clinicodemographic characteristics and outcomes of patients according to pathological stage. After TURB, all of the LG NMIBC cases were monitored in accordance to EAU guidelines without adjuvant treatments. Among 156 HG NMIBC, 77 patients (49.4%) received standard adjuvant treatment and 79 (50.6%) a palliative management. Adjuvant treatment consisted in; restaging-TURB + BCG in 15 patients (13 pT1, 2 pTa), BCG alone in 53 patients (32 pT1, 4 pTx, 15 pTa, and 2 CIS) and restaging-TURB alone in 9 pT1. The decision for proposing BCG instillations were subjective and no specific criteria were used in the departments. BCG schedule consisted in induction alone for 47 patients (69%) and with maintenance for 21 (31%). We reported 7 cases (11.5%) of BCG low-grade complications. Regarding the 75 cases of MIBC, 24 (32%) received standard treatments, and 51 (68%) a palliative management. Standard therapies in MIBC were cystectomy in 15 patients, trimodal therapy in 4 (cisplatin based), and radiotherapy in 5 (4 whole-bladder irradiation with 60–65 Gy and 1 hypofractioned with 50–57.7 Gy). Among 15 cystectomies, postoperative complications occurred in 12 (80%), of whom 8 (53%) were Clavien I–II and 4 III–IV (27%). The type of urinary diversion was a cutaneous ureterostomy in 14 (93%) cases and ileal counduit in 1 (7%).

Univariate and multivariate analysis of potential predictors of OS after stratifying by pathological stage are shown in Table 3. ASA-score and Charlson-score were not related to OS in none of the groups. Applying standard treatments was an independent prognostic factor of OS in HG NMIBC and decreased the emergency visit rate (33% vs. 43%). Patients with HG NMIBC managed under guideline-concordant recommendations had a median OS of 44 months (31–56.9) compared to 24 months (20.5–27.4) in those under palliative management (HR 1.95 CI 95% 1.15–3.3; *P = 0.013*) (Fig.1). Regarding MIBC, the median OS of patients under standard management was 17 months (10.6–23.3) compared to 11 months (7.2–14.7) in palliative (HR 1.24 CI 95% 0.71–2.14; *P = 0.439*) (Fig. 1) and no differences were found in the emergency visits rate (33% vs. 33%). The subgroup of patients managed with standard therapies had similar clinicodemographic characteristics than those under palliative management. In both HG NMIBC and MIBC, there were not significant differences between the type of management

Table 2
Clinical data, pathological data, and outcomes according to pathological stage

	LG NMIBC ($n = 86$)	HG NMIBC ($n = 156$)	MIBC ($n = 75$)	P
Age (y), median (range)	87 (85–96)	88 (85–97)	88 (85–94)	*0.209*
Gender, *n* (%)				*0.508*
Male	69 (80.2)	115 (73.7)	58 (77.3)	
Female	17 (19.8)	41 (26.7)	17 (22.7)	
BMI, median (range)	25.9 (19–35)	27 (19–36)	26.8 (20–38)	*0.122*
ASA-score, *n* (%)				*0.813*
II	31 (36)	56 (35.9)	23 (30.7)	
III	42 (48.8)	79 (50.6)	44 (58.7)	
IV	13 (15.2)	21 (13.4)	8 (10.7)	
Charlson-score, median (range)	5 (1–13)	5 (1–14)	5 (1–14)	*0.616*
Lymph node metastases, *n* (%)	0 (0)	0 (0)	11 (14.6)	*<0.001**
Distant metastases, *n* (%)	0 (0)	0 (0)	9 (12)	*<0.001**
TURB intraoperative complications, *n* (%)	2 (2.3)	3 (1.9)	2 (2.7)	*0.934*
TURB postoperative complications, *n* (%)	13 (15.1)	35 (22.4)	16 (21.3)	*0.268*
Emergency visits, *n* (%)	17 (19.8)	60 (38.5)	25 (33.3)	*0.024**
Hospital readmissions, *n* (%)	2 (2.3)	19 (12.2)	12 (16)	*0.011**
Hospital stay (days), *n* (%)	2 (1–60)	3 (1–34)	4 (1–27)	*0.648*
Guideline-concordant management, *n* (%)				*<0.001**
Yes	86 (100)	77 (49.4)	24 (32)	
No	0 (0)	79 (50.6)	51 (68)	
Bladder recurrence, *n* (%)	25 (29.8)	48 (31)	14 (18.9)	*0.146*
Metastatic recurrence, *n* (%)	4 (4.6)	15 (9.6)	22 (29)	*0.150*
Death of bladder cancer, *n* (%)	14 (21.2)	24 (18.9)	36 (46.3)	*<0.001**
Death, *n* (%)	38 (44.2)	76 (48.7)	60 (80)	*<0.001**

ASA-score = American Society of Anesthesiologists physical classification; BMI = body mass index; HG NMIBC = high-grade nonmuscle invasive bladder cancer; LG NMIBC = low-grade nonmuscle invasive bladder cancer; MIBC = muscle invasive bladder cancer; TURB = transurethral resection of the bladder.
Italic font indicates statistical significance.
* Variables at $P < 0.05$.

Table 3
Univariate and multivariate analysis for predicting overall survival according to pathological stage

	HG NMIBC		MIBC	
	Univariate P	Multivariate HR (95% CI); P	Univariate P	Multivariate HR (95% CI); P
Age	*0.001*	1.11 (1.02–1.21); *0.011**	*0.881*	
Gender	*0.921*		*0.720*	
BMI	*0.014**	*0.137*	*0.721*	
ASA-score	*0.368*		*0.511*	
Charlson-score	*0.386*		*0.665*	
Tumor management (standard vs. palliative)	*<0.001**	1.95 (1.15–3.3); *0.013**	*0.439*	
cT	*0.52*		*0.176*	
cN	*0.532*		*0.116*	
cM	*0.398*		*0.255*	

ASA-score = American Society of Anesthesiologists physical classification; BMI = Body Mass Index; CI = confidence interval; HR = hazard ratio.
Italic font indicates statistical significance.
* Variables at $P < 0.05$.

groups in regarding gender, ASA-score, and cTNM. The only exceptions were that median Charlson-score was higher in the standard group of HG NMIBC, and median patient age was slightly lower in the standard group of both HG NMIBC and MIBC (Table 4).

4. Discussion

Age is the most important risk factor for developing BCa. Recent data revealed that the peak incidence of BCa in developed countries is in the 85 to 95 years age group [8]. Despite these trends, there is a lack of evidence about the management of BCa in the elderly. The huge interindividual variability between very elderly patients makes the clinical decisions more difficult than in their younger counterparts and more tools are needed to decide the optimal management in each case.

Regarding the clinicopathological staging in the elderly, we found a similar distribution as in the literature (75% of HG tumors, 23% of MIBC) [9]. In spite of the advanced

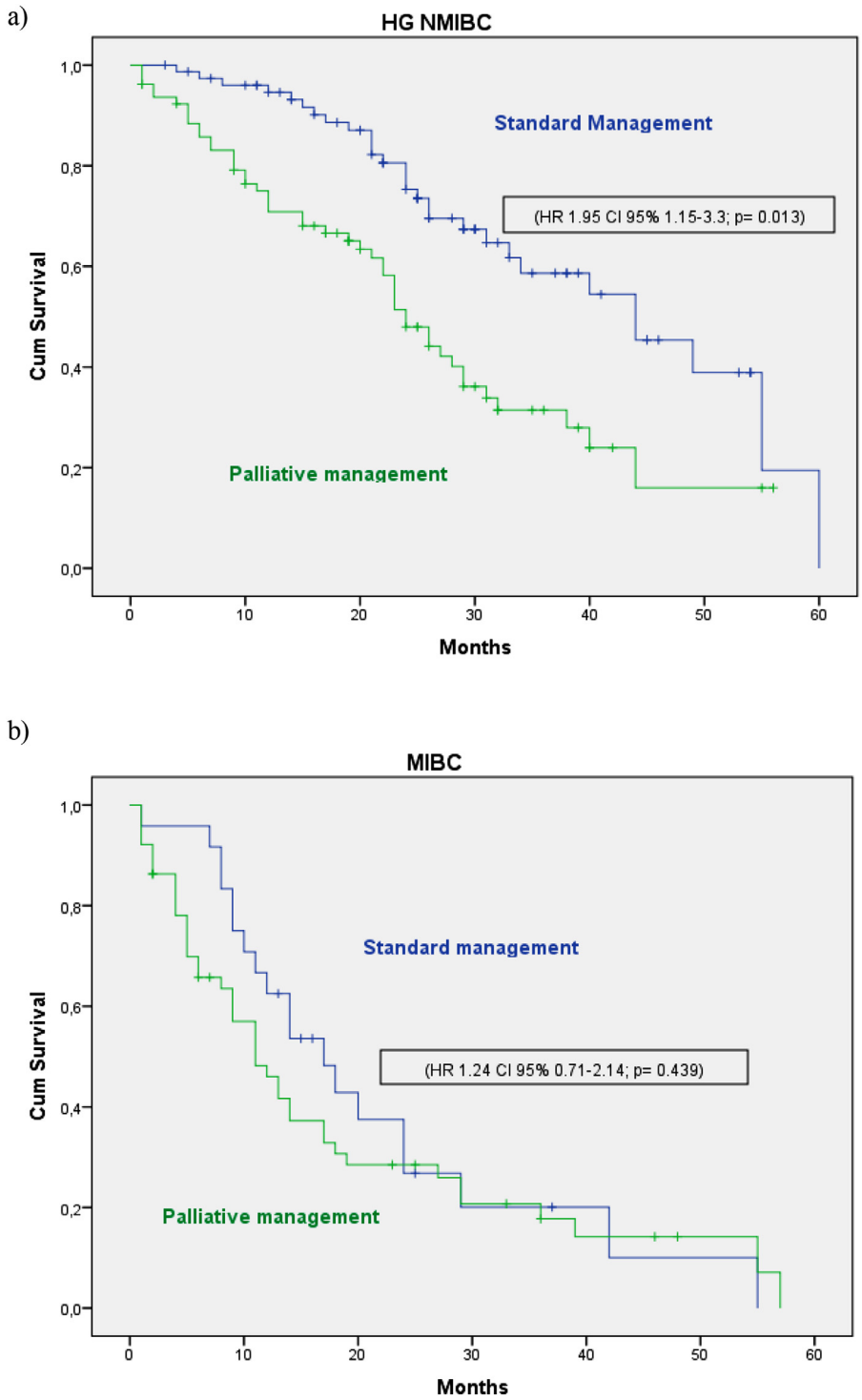

Fig. 1. Kaplan-Meier curves depicting cumulative proportion of all cause of death. Standard management vs. palliative management in HG NMIBC (A) and MIBC (B). HR and Log-rank test *P* values were reported.

chronological age, almost all patients of our study were initially managed with TURB. This procedure is generally well tolerated with low risk of serious complications [4]. We found that 83% of patients with newly diagnosed BCa had hematuria at the time of the diagnosis. For that reason, we usually consider performing TURB to all de novo tumors not only to avoid the risk of progression but also to reduce the risk of hematuria and other symptoms that could impact on their quality of life.

It has been suggested that differences in outcomes between elderly and their younger counterparts may be due to the administration of less aggressive and effective

Table 4
Clinicodemographic characteristics according to pathological stage and type of management

	HG NMIBC ($n = 156$)			MIBC ($n = 75$)		
	Standard ($n = 77$)	Palliative ($n = 79$)	*P*	Standard ($n = 24$)	Palliative ($n = 51$)	*P*
Age (years)	87 (85–96)	88 (85–97)	*0.04**	86 (85–93)	88 (85–94)	*0.007**
Gender			*0.931*			*0.795*
Male	57 (74)	58 (73.4)		19 (79.2)	39 (76.5)	
Female	20 (26)	21 (26.6)		5 (20.8)	12 (23.5)	
BMI	28 (19–36)	26 (20–35)	*0.012**	27 (20–33)	26 (20–38)	*0.994*
ASA-score			*0.745*			*0.752*
II	27 (35.1)	29 (36.7)		6 (25)	17 (33.3)	
III	38 (49.4)	41 (51.9)		15 (62.5)	29 (56.9)	
IV	12 (15.6)	9 (11.4)		3 (12.5)	5 (9.8)	
Charlson-score	6 (1–14)	5 (1–11)	*0.01**	5 (1–11)	5 (1–14)	*0.989*
cT			*0.484*			*0.279*
cT0	18 (23.4)	23 (29.1)		0 (0)	0 (0)	
cT1	59 (76.6)	56 (70.9)		1 (4.2)	3 (5.9)	
cT2	0 (0)	0 (0)		16 (66.7)	35 (68.6)	
cT3-4	0 (0)	0 (0)		7 (29.2)	13 (25.5)	
cN			*0.263*			*0.467*
cNx	67 (87)	63 (79.7)		0 (0)	0 (0)	
cN0	10 (13)	16 (20.3)		20 (83.3)	44 (86.2)	
cN1-2	0 (0)	0 (0)		4 (16.7)	7 (13.8)	
cM						*0.219*
cMx	67 (87)	63 (79.7)	*0.263*	0 (0)	0 (0)	
cM0	10 (13)	16 (20.3)		23 (95.8)	43 (84.3)	
cM1	0 (0)	0 (0)		1 (4.2)	8 (15.7)	

ASA-score = American Society of Anesthesiologists physical classification; BMI = body mass Index; HG NMIBC = high-grade nonmuscle invasive bladder cancer; MIBC = muscle invasive bladder cancer.

Data are shown as median (range) or *n* (%).

Italic font indicates statistical significance.

* Variables at $P < 0.05$.

therapies in the elderly [4]. A study about BCa in octogenarians showed that 42% of NMIBC patients were managed with adjuvant treatments after TURB and 43% of MIBC with a potentially curative therapy approach [10]. Regarding HG NMIBC, we found that age and the type of management were independent prognostic factors of OS. Although chronological age alone should not be viewed as a contraindication for standard treatments, only 50% of patients with HG NMIBC were managed with guideline-concordant treatments in our study. The identification of frail patients who may not be suitable for standard therapies could be difficult in some cases [11]. Eredics et al. recently found a strong correlation between OS and ASA in nonagenarians patients with BCa. They recommended following a palliative management in ASA IV patients aiming to minimize hospitalization and ensuring an adequate quality for the remaining life span [12]. In our study, neither ASA nor Charlson were related to OS among HG NMIBC patients. Furthermore, ASA was equally distributed between treatment groups and median Charlson was higher in the standard management group. For that reason, the better outcomes reported in patients under standard treatments might not be influenced by the differences in comorbidities between the groups. In spite of the slight difference seen in the median age of the groups, the type of management was still an independent prognostic factor of OS in the multivariate analysis. Due to the long survival of NMIBC patients, we recommend to consider the same tumor management as that offered to younger patients. Applying adjuvant treatments to these patients could reduce the risk of progression and tumor-related symptoms as well as improve survival. Although we did not report any serious BCG side effect, most departments avoided the administration of maintenance therapy due to increased risk of complications.

On the other hand, only 32% of MIBC were managed with standard therapies in our study. There were a nonsignificant and slight difference in OS between MIBC managed with standard treatments and those under palliative management (17 vs. 11 months). Although this lack of differences could be influenced by the small number of patients treated with standard therapies, as the survival was low in both treatment groups, we recommend managing these patients with more conservative strategies. Novotny et al. found that ASA was a better predictor of 90-day mortality after radical cystectomy than Charlson and recommended to incorporate this tool into daily clinical practice [13,14]. As in HG NMIBC, we found that none of these tools were related to OS in MIBC. For that reason with think that frail patients with MIBC should be evaluated with a more accurate geriatric assessment in order to select the best treatment strategy. Several tools as G8

screening had been developed but they are not routinely used in the urological community [15,16]. Due to the high complication rate and perioperative mortality rate of cystectomy in octogenarians [17], this procedure was rarely used at the 6 institutions of our study and should be only proposed to patients with an excellent physiological status. Alternatively, recent data about octogenarians with MIBC found that chemoradiation is a treatment with survival equal to that of surgery alone [18]. Finally, cTNM of MIBC was not related to OS probably due to the low number of metastatic patients, the analysis of OS and not cancer-specific survival, and the high overall mortality rate regardless of clinical stage (80%).

The results of this study might be useful for several reasons. First, most patients with de novo BCa aged >85 years had hematuria at the time of the diagnosis and were initially managed with TURB. This is generally a safe procedure with a low rate of high-grade complications. Second, we found a strong correlation between OS and the type of management in HG NMIBC and we suggest following standard therapies even for those of an advanced age. Regarding MIBC, although we could not conclude that standard therapies should not be used, we recommend to consider more conservative strategies due to the low survival of the patients regardless of the type of management. Finally, ASA and Charlson-score failed to predict OS in these age-group patients and they should be individually evaluated with a more accurate geriatric assessment.

The present study is limited by its retrospective nature. Another limitation is because of the differences between the institutions in regarding the criteria to decide the type of management, the surgical experience, postoperative management, and follow-up. However, the 6 Spanish departments that participated in the study belong to high-volume tertiary centers with similar experience in this field. Furthermore, a standardized geriatric assessment tool and quality of life questionnaires were not systematically used.

5. Conclusions

Chronological age should not be a contraindication for applying standard therapies in NMIBC. In MIBC the survival is low regardless of the type of management. The lack of correlation between OS and ASA or Charlson-score raises the necessity of a geriatric assessment for selecting the best treatment strategy.

Conflict of interest

None declared.

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