Med. J. Cairo Univ., Vol. 90, No. 8, December: 2673-2681, 2022
www.medicaljournalofcairouniversity.net

A Clinico-Epidemiological Study and Clinical Outcome in Patients with Urinary Bladder Cancer at Assuit University Hospital from 2015-2019 (Hospital Based Study)

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Abstract

Background: Bladder Cancer is the third most common carcinoma after liver and breast in Egypt, the estimated incidence (7.9%) of all cancer new cases and occurs more commonly in developed countries.

Aim of Study: To analyze the clinico-epidemiological characteristics of urinary bladder cancer, identifying factors associated with response, and prognostic factors for overall survival (OS) and disease-free survival (DFS).

Patients and Methods: Ninety five patients with pathologically confirmed bladder cancer (BC) presented to the Clinical Oncology Department, Assiut University Hospital during the period (2015 -2019) were retrospectively reviewed as regards patient's and tumor characteristics, risk factors, management, and pattern of failure.

Results: The mean age was 61 years, with a male predominance in 77/95 (81%) of patients. Smoking was the main risk factor in 62/95 (65%) of patients, and the most common presenting complaint was hematuria in 84/95 (88%) of patients, followed by dysuria in 69/95 (73%) of patients. Transitional cell carcinoma was the most common pathology in 84/95 (88%) of patients, 93/95 (98%) of patients had invasive bladder cancer mainly high grade in 90/95 (95%) of patients. 31/95 (33%) of patients had Stage II followed by Stage III in 27/95 (28%) of patients, 19/95 (20%) of patients were Stage IVb, and 16/95 (17%) of patients were Stage IVa. Median DFS and OS are higher among patients <65, lateral wall of the bladder, low-grade tumor, the lower stage of the tumor, patients treated with radical cystectomy, responded to treatment, with no recurrence and no metastasis.

The significant prognostic variables for DFS in a multivariate cox logistic regression model were dome of bladder site (HR=3.7), anterior wall site (HR=3.8), non-responders to treatment (HR=6.5), and metastatic tumours (HR=4.4). In OS, the significant prognostic variablesalso were dome of bladder site (HR=3.0), anterior wall site (HR=3.3), non-responders to treatment (HR=2.7), and metastatic tumours (HR=5.2).

Conclusion: Epidemiology of bladder cancer was shifted in Egypt with higher incidence of TCC, Patients ›¦65, High-grade tumor, stage III, metastatic or recurrent, non-responded to treatment adversely affecting DFS and OS.

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Key Words: *Urinary bladder cancer – Clinico-epidemiological study.*

Introduction

BLADDER Cancer is the third most common carcinoma after liver and breast in Egypt, the estimated incidence (7.9%) of all cancer new cases and occurs more commonly in developed countries **[1]**.

Bladder cancer incidence increases with age with a strong male predominance of the disease with a 4:1 male-to-female ratio **[2]**.

The observed geographic patterns of bladder cancer incidence appear to reflect the prevalence of tobacco smoking, although infection with Schistosoma haematobium and other risk factors (exposures to aromatic amines and other chemicals in the painting, rubber, or aluminum industries and arsenic contamination in drinking water) may be major causes in some populations **[3,4]**.

Approximately 30% of BC patients present with muscle-invasive bladder cancer (MIBC) **[5]**.

Transurethral resection of the bladder tumor (TURBT) followed by CCRTHis an option for MIBC in patients considered medically unfit for surgery and in those wishing to avoid radical surgery **[6]**.

TURBT is the initial treatment of choice for non-muscle-invasive bladder cancer (NMIBC), with subsequent treatment according to risk stratification **[7]**.

Treatment for patients with metastatic bladder cancer aimed to improve survival in patients with a bad prognosis. Cisplatin-based CTRis the preferred and guidelines-recommended treatment option [8].

Immunotherapy is another treatment option as a first and second-line therapy among in cisplatin-ineligible patients [9].

Our study aims to investigate the clinico-pathological characteristics of urinary bladder cancer and the impact of smoking, age, gender, and the adequacy of treatment on the outcome at Assuit University's clinical-oncology department during the period 2015 till 2019.

Patients and Methods

Our study was carried out at Assuit University Hospital's Clinical Oncology Department from 2015-2019. The Ethics Committee of Assuit University Hospital approved this protocol before data collection (IRB17101267). Data were extracted-from the medical records of 95 patients over 18 years of age diagnosed with pathologically confirmed bladder cancer and analyzed as regard patients and tumor characteristics, risk factors, management, treatment response, and pattern of failure.

Statistical analysis:

Data analysis was performed using a statistical package for the social science (IBM-SPSS) version 26.0 software. Qualitative data were expressed a frequency and percent. Mean ± SD or median and range were used to express data according to their distribution. Chi-square and Fisher Exact tests used to compare proportions between groups. Disease-free survival and overall survival were tested by the Kaplan-Meier method using the Log rank test and Kaplan-Meier curves. Univariate cox regression analysis was performed to evaluate possible prognostic factors for DFS and OS and significant variables entered in a multivariate cox regression analysis. Univariate Logistic regression analysis was performed to evaluate possible predictors for overall response among patients with bladder cancer and significant variables entered in a multivariate Logistic regression analysis, the level of significance was considered at p-value <0.05.

Results

*Patient's characteristics:*The mean age of the enrolled patients was 61 years. Out of those patients, about 32/95 (34%) were ≥65 years old,with a male predominance in 77/95 (81%) of patients. Smoking was the main risk factor in 62/95 (65%) of patients, followed by bilharzia in 28/95 (30%) of patients. The most common presenting complaint was hematuria in 84/95 (88%) of patients, followed by dysuria in 69/95 (73%) of patients (Table 1).

Disease characteristics: Regarding the site, the lateral wall of the bladder was the most frequently affected site by the tumour in 58/95 (61%) of patients. Transitional cell carcinoma was the most common pathology in 84/95 (88%) of patients.

Ninety-eight percent of patients' MIBC Most of the lesions were high grade in 90/95 (95%) of patients. Stage II in 31/95 (33%) of patients was followed by Stage III in 27/95 (28%) of patients, Stage IVb in 19/95 (20%) of patients, and Stage IVa in 16/95 (17%) of patients (Table 2).

Lines of treatment and clinical response:

Ninety-one percent of patients complete their line of treatment,67/86 (78%) of patients were non-metastatic bladder cancer, and 19/86 (22%) of patients were metastatic bladder cancer. Response to treatment in patients with non-metastatic bladder cancer was evaluated in 64 patients as three patients died after treatment and before evaluation. 36/67 (54%) of patients received neo-adjuvant CTR in the form of cisplatin/gemcitabine followed by CCRTH with a response rate of 76% and radical cystectomy in 29/67 (43%) of patients with a response rate of 93% [8/67 (12%) of patients received neo-adjuvant CTR followed by radical cystectomy with response rate in 100%, 15/67 (22%) patients did radical cystectomy followed by adjuvant CTR with response rate in 87% of patients and 6/67 (9%) patients did radical cystectomy without adjuvant CTR with response rate in 100%].

Response to treatment in patients with metastatic bladder cancer was evaluated in 19/86 patients. PR was observed in 16%, SD in 63%, and DP in 21 % of patients.

In non-metastatic bladder cancer, recurrence was observed in 14/64 (22%) of patients, mainly distant recurrence in 12/64 (19%) of patients (mainly non-regional lymph node in 5/64 (8%) of patients, and bone in 4/64 (6% of patients).

Factors associated with response:

In univariate logistic regression analysis, lateral site of tumour (OR=7.69), lower stage of tumour (stage II: OR=8.74, stage III: OR=7.22), non-metastatic tumours (OR=20.9), and patients treated with radical cystectomy (OR=72) were the significant predictors associated with response. These significant variables were entered into a multivar-

iate logistic regression model and the significant variables in this model which had the highest influence on response were lateral site of bladder tumour (AOR=8.01) and non-metastatic tumour (AOR=17.88) (Table 3).

Prognostic factors related to disease free survival (DFS):

In univariate cox regression analysis: DFS is higher among patients <65 years old, lateral wall of the bladder, low grade tumor, lower stage of tumor, patients treated with radical cystectomy, responded to treatment, with no recurrence and no metastasis.

These significant variables were entered into a multivariate cox logistic regression model and the significant prognostic variables in this model which had the highest influence on DFS were dome of bladder site (HR=3.7), anterior wall site (HR=3.8), non-responders to treatment (HR=6.5) and metastatic tumours (HR=4.4) (Table 4) and Fig. (1).

Prognostic factors related to overall survival (OS):

In univariate cox regression analysis, median OS is higher among patients <65 years old, lateral wall of the bladder, low grade tumor, lower stage of tumor, treated with radical cystectomy, and who responded to treatment with no recurrence and no metastasis.

These significant variables were entered into a multivariate cox logistic regression model and the significant prognostic variables in this model which had the highest influence on OS were dome of bladder site (HR=3.0), anterior wall site (HR=3.3), non-responders to treatment (HR=2.7) and metastatic tumours (HR=5.2) (Table 5) and Fig. (1).

Table (1): Characteristics of patients with bladder cancer.

Variables	N=95	%
Age (years):		
<65	63	66.3
≥65	32	33.7
Mean ± SD (range)	60.66±6.35 (37-70)	
Gender:		
Male	77	81.1
Female	18	18.9
Occupation:		
Farmer	53	55.8
Worker	24	25.3
Housewife	18	18.9
Risk factors:		
Smoking:		
Smoker	62	65.3
Nonsmoker	33	34.7
Bilharziasis:	28	29.5
Symptoms:		
Hematuria	84	88.4
Dysuria	69	72.6
Frequency	36	37.9
Urge incontinence	35	36.8
Lower abdominal pain	40	42.1

Data were expressed as frequency and %.

Table (2): Tumor characteristics in patients with bladder cancer.

Variables	N=95	%
Site:		
Lateral	58	61.1
Anterior	20	21.1
Posterior	9	9.5
Dome of bladder	8	8.4
Pathology:		
TCC	84	88.4
SCC	10	10.5
Adenocarcinoma	1	1.1
Invasiveness:		
Invasive	93	97.9
Noninvasive	2	2.1
Grading:		
Low grade	5	5.3
High grade	90	94.7
Staging:		
I	2	2.1
II	31	32.64
III	27	28.42
IV a	16	16.84
IV b	19	20.0

Data were expressed as frequency and %.

Table (3): Predictors associated with response in patients with cancer bladder.

Variables	Univariate		Multivariate	
	OR (95% CI)	*p*-value	AOR (95% CI)	*p*-value
Site:				
Dome of bladder	Reference		Reference	
Lateral	7.69 (1.33-44.49)	0.023	8.01 (1.06-40.67)	0.023
Anterior	2.85 (0.41-19.64)	0.286	3.90 (0.41-37.43)	0.286
Posterior	2.50 (0.29-21.39)	0.403	6.74 (0.48-25.03)	0.403
Staging:				
IV	Reference			
II	8.74 (2.54-30.01)	0.001		0.001
III	7.22 (2.07-25.14)	0.002		0.002
Metastasis:				
Metastatic	Reference		Reference	
Non-Metastatic	20.92 (5.28-82.77)	<0.001	17.23 (3.88-76.67)	<0.001
Lines of treatment:				
Systemic Chemotherapy	Reference			
Radical cystectomy	72.0 (10.8-100.04)	<0.001		<0.001
Neoadjuvant with CCRT	16.76 (3.74-74.97)	<0.001		<0.001

Logistic regression analysis. OR: Odds ratio. AOR: Adjusted odds ratio. 95% CI: 95% confidence interval.

Table (4): Prognostic factors related to disease-free survival (DFS) in patients with cancer bladder.

Variables	Disease-free survival (DFS)					
	Median DFS (95%CI)	*p*-value	Univariate		Multivariate	
			HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age:						
<65	53.0 (35.3-70.7)	<0.001	Reference			
≥65	15.0 (1.47-28.5)		4.9 (2.0-12.2)	<0.001		
Site:						
Lateral	56.0 (49.6-62.4)	0.001	Reference		Reference	
Anterior	21.0 (9.2-52.2)		2.9 (1.1-7.6)	0.029	3.8 (1.16-12.52)	0.027
Posterior	21.0 (14.0-49.1)		1.98 (0.4-9.0)	0.376	3.3 (0.64-16.87)	0.151
Dome of bladder	4.0 (3.9-13.7)		5.35 (2.1-13.9)	0.001	3.7 (1.22-10.94)	0.020
Grading:						
Low	64.0 (56.2-71.8)	0.003	Reference			
High	44.0 (16.0-71.9)		7.2 (1.1-30.42)	0.05		
Staging:						
II	44.0 (24.2-63.8)	0.021	Reference			
III	38.6 (26.4-50.7)		1.3 (0.4-3.3)	0.544		
IV	23.1 (15.1-31.1)		3.7 (1.4-10.2)	0.011		
Main lines of treatment:						
Radical cystectomy	59.0 (52.1-65.9)	<0.001	Reference			
Neoadjuvant followed by concurrent chemo-radiation	37.0 (19.3-54.7)		5.2 (1.4-19.0)	0.013		
Systemic chemotherapy	4.0 (2.8-5.2)		31.3 (6.1-60.2)	<0.001		
Response to treatment:						
Responder	56.0 (48.8-63.2)	<0.001	Reference		Reference	
Non responder	21.0 (5.3-36.7)		8.0 (3.2-20.3)	<0.001	6.5 (2.2-19.2)	0.001
Recurrence:						
Yes	18.0 (2.97-33.0)	0.006	3.3 (1.3-8.4)	0.011		
No	53.0 (34.6-71.4)		Reference			
Metastasis:		<0.001				
Non metastatic	53.0 (28.9-77.0)		Reference		Reference	
Metastatic	4.0 (2.5-5.4)		9.2 (2.9-28.9)	<0.001	4.4 (1.1-16.6)	0.031

Cox regression analysis 95% CI (confidence interval). HR (HR: Hazard ratio). Median disease-free survival by Log rank test.

Table (5): Prognostic factors related to overall survival (OS) in patients with cancer bladder.

Variables	Overall survival (OS)					
	Median OS (95%CI)	*p*-value	Univariate		Multivariate	
			HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age:						
<65	54.0 (37.9-70.1)	0.011	Reference			
≥65	19.0 (18.1-19.9)		2.7 (1.21-6.1)	0.015		
Site:						
Lateral	56.7 (45.4-67.9)	<0.001	Reference		Reference	
Anterior	26.2 (11.9-40.5)		3.9 (1.8-8.9)	0.001	3.3 (1.3-8.7)	0.015
Posterior	33.3 (21.3-45.4)		1.9 (0.4-8.6)	0.394	3.4 (0.69-17.1)	0.132
Dome of bladder	25.6 (13.4-37.7)		4.5 (1.8-11.4)	0.002	3.0 (1.1-8.9)	0.042
Grading:						
Low	65.0 (62.9-67.1)	0.05	Reference			
High	43.0 (21.2-64.8)		3.3 (0.9-12.0)	0.074		
Staging:						
II	54.0 (36.7-71.3)	<0.001	Reference			
III	49.2 (35.5-62.8)		1.3 (0.5-3.2)	0.585		
IV	13.0 (9.5-16.5)		7.2 (2.9-17.9)	<0.001		
Lines of treatment:						
Radical cystectomy	65.0 (56.2-73.8)	<0.001	Reference			
Neoadjuvant followed by concurrent chemo-radiation	48.0 (32.6-63.4)		2.7 (1.1-7.3)	0.050		
Systemic CTH	10.0 (7.6-12.4)		21.3 (6.3-40.6)	<0.001		
Response to treatment:						
Responder	64.0 (56.9-71.0)	<0.001	Reference		Reference	
Non responder	19.0 (12.0-25.9)		7.1 (2.9-17.5)	<0.001	2.7 (1.1-5.8)	0.044
Recurrence:						
Yes	22.0 (17.1-26.9)	0.05	2.1 (0.9-5.0)	0.086		
No	58.0 (45.7-70.3)		Reference			
Metastasis:						
Non metastatic	54.0 (37.9-70.1)	<0.001	Reference		Reference	
Metastatic	10.0 (7.6-12.34)		8.3 (3.5-19.9)	<0.001	5.2 (1.62-16.22)	0.005

Cox regression analysis 95% CI (confidence interval).
HR (HR: Hazard ratio).
Median disease-free survival by Log rank test.

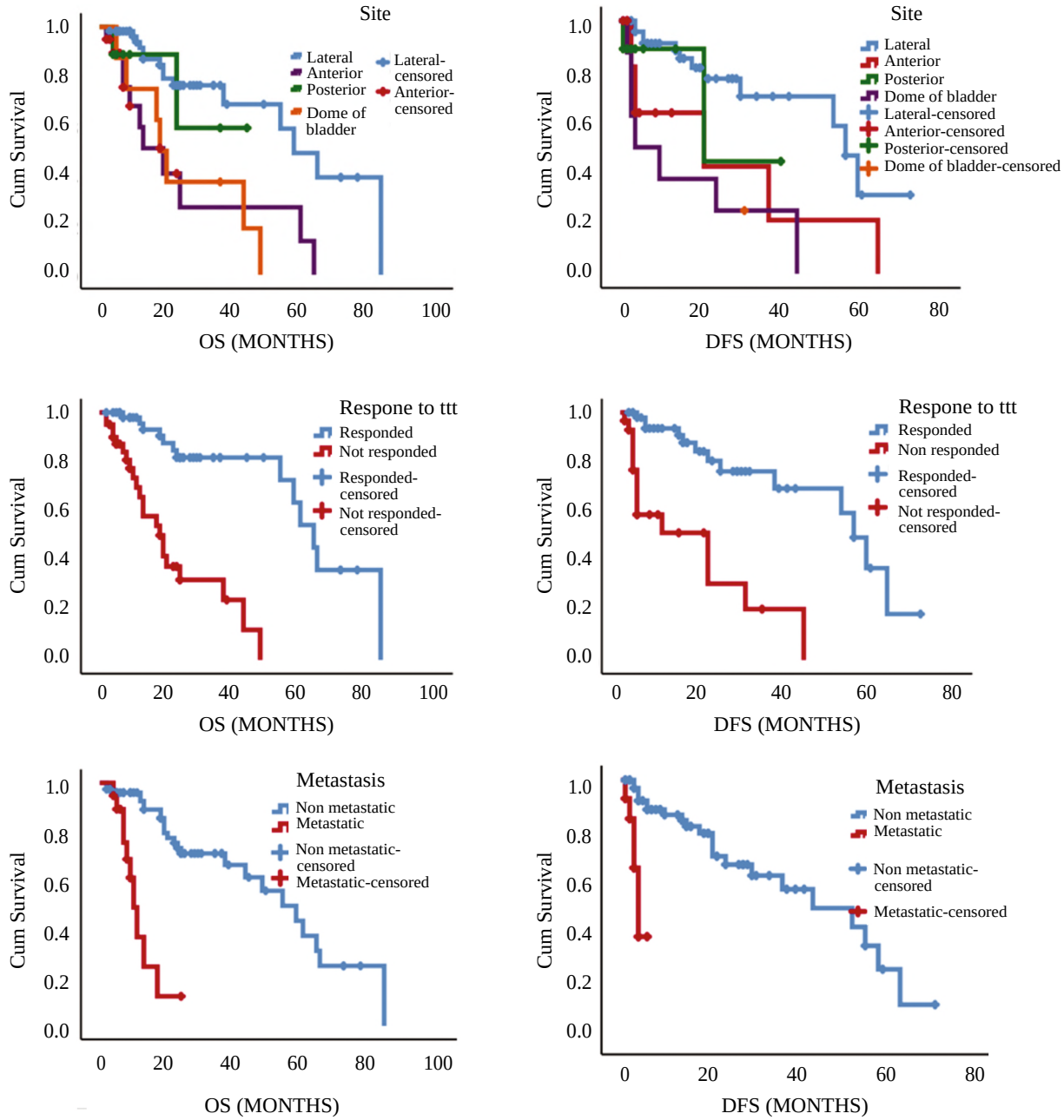

Fig. (1): Kaplan Meir curves for DFS and OS in patients with bladder cancer.

Discussion

The mean age of patients in our study was 61 years, with a male predominance in 81 % of patients, which agrees with that reported by Ferlay J, et al. (2020) **[10]**.

Smoking is the main risk factor in 65% of patients with a lower bilharziasis incidence in 30% of patients due to the eradication of bilharziasis. This agrees with that reported by Amr S et al. (2012) as the frequency of TCC increased from 22% in 1980 to 73% of bladders diagnosed in 2005, while SCC decreased from 78% of diagnosed bladder tumours in 1980 to 27% of diagnosed bladder tumors, so Egypt is becoming more "Westernized" in terms of its bladder carcinoma subtypes **[11]**.

Hematuria is the most common presenting symptom in 88% of patients in our study, which agrees with that reported by Khadra M.H et al. (2000) **[12]**.

In our study, transitional cell carcinoma was the most common pathology in 88 % of patients, which agrees with that reported by Mushtaq J et al. (2019) that 90% of bladder cancer cases, espe-

cially those in the developed world, arise from urothelial cells **[13,14]**.

In our study, 98% of patients had an invasive tumor, which could be attributed to nearly all non-muscle invasive bladder cancers being managed at urology and referred to us when they become invasive. In our study, the response rate was 93% in patients treated by radical cystectomy versus 78% in patients treated by CCRTH, which agrees with Milowsky M.I. et al. (2019) who reported that neoadjuvant CTR followed by radical cystectomy is the current treatment of choice in MIB **[15,16]**, and CCRTH could be a treatment option in medically unfit patients or patients refusing surgery. As reported by Booth CM et al., 2014 **[17]**. A better response to treatment was observed in early-stage patients with significant p-values, which agrees with Rink M et al. (2012), who reported that the outcome of bladder cancer is closely associated with the stage of disease at presentation **[18,19]**.

The 5-year overall survival (OS) rate for patients with MIBC is 50%-70% **[20,21]**; high-risk disease, T3-T4a or lymph node-positive disease, carries an estimated 5-year survival of only 10%-40% **[22]**.

In a univariate analysis of our study, patients with high grade tumours, stage III or IV, metastatic or recurrent, and non-responders to treatment were found to be significant independent poor prognostic factors affecting DFS and OS in patients with bladder cancer, which agrees with what was reported by many authors that treatment end-results were affected by prognostic factors like stage, grade, and nodal involvement **[23,24,25]**.

In multivariate analysis among the prognostic factors with $p < 0.1$ on univariate analysis, tumour site (anterior wall HR was 3.8, posterior wall HR was 3.3, and dome of bladder HR was 5.35), response to treatment (non-responder HR was 8.03) and the presence of metastasis (metastatic HR was 9.2) were found to be statistically significant factors affecting DFS and OS, which agrees with that reported by Mao W et al. (2019) that the presence of metastasis affects OS **[26]**. But didn't agree with that reported by Edge S et al. (2010) who reported tumour grade affects OS **[27]**. Also didn't agree with that reported by Rahul Dutta et al. (2016) that urachal and dome locations have relatively favorable survival and oncological outcomes **[28]**.

Conclusion: Epidemiology of bladder cancer was shifted in Egypt with higher incidence of TCC, Patients > 65, High-grade tumor, stage III, metastatic or recurrent, non-responded to treatment adversely affecting DFS and OS.

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دراسة سريرية وبائية فى المرضى الذين يعانون من سرطان المثانة البولية فى مستشفى أسيوط الجامعى من ٢٠١٥ - ٢٠١٩ دراسة قائمة على المستشفى

الملخص : الهدف من العمل هو تحليل الخصائص السريرية الوبائية لسرطان المثانة البولية، وتحديد العوامل المرتبطة بالخلو من المرض والبقاء على قيد الحياة خالية من الأمراض بالاستجابة، والعوامل التنبؤية للبقاء على قيد الحياة بشكل عام فى قسم الأورام بمستشفى جامعة أسيوط خلال الفترة بمراجعة ملفات مريضاً مصاباً بسرطان المثانة المؤكدة خلال الفترة (٢٠١٥–٢٠١٩) بأثر رجعى فيما يتعلق بخصائص المريض والورم وعوامل الخطر والعلاج ونمط الفشل.

النتائج : كان متوسط العمر ٦١ عاماً مع غلبة الذكور فى ٥٩/٧٧ (٨١٪ من المرضى). كان التدخين عامل الخطر الرئيسى ٩٥/٦٢ (٦٥٪ من المرضى) وكانت الشكوى المقدمة الأكثر شيوعاً هى البول الدموى فى ٩٥/٨٤ (٨٨٪ من المرضى) تليها عسر البول فى ٧٥/٦٩ (٧٢٪ من المرضى). كان سرطان الخلايا الانتقالية أكثر الأمراض شيوعاً فى ٩٥/٨٤ (٨٨٪ من المرضى)، وكان ٩٥/٩٣ (٩٨٪) من المرضى يعانون من سرطان المثانة مخترق العضلات بشكل رئيسى فى ٩٥/٩٠ (٩٥٪ من المرضى). المرحلة الرابعة ٩٥/٣٥ (٣٧٪ من المرضى)، ٩٥/٣٣ (٣٣٪ من المرضى) لديهم المرحلة الثانية والمرحلة الثالثة فى ٩٥/٢٧ (٢٨٪ من المرضى) وكان الخلو من المرض والبقاء على قيد الحياة أعلى بين المرضى عمرهم <٦٥ سنة، والجدار الجانبى للمثانة، والورم منخفض الدرجة، والمرحلة الدنيا من الورم، والمرضى الذين عولجوا باستئصال المثانة الجذرى، واستجابوا للعلاج، دون تكرار ولا ورم خبيث.

الاستنتاج : تغير نوع خلايا سرطان المثانة من الخلايا الحرشفية إلى الخلايا الانتقالية فى مصر وأن سرطان المثانة عالى الدرجة، المرحلة الثالثة، النقيلى أو المتكرر، غير المستجيب للعلاج، يؤثر سلباً على الخلو من المرض والبقاء على قيد الحياة.