



# Assessment of the quality of life and sexual functions of patients followed-up for non-muscle invasive bladder cancer: preliminary results of the prospective-descriptive study

*Kas invaziv olmayan mesane kanseri nedeniyle takip edilen hastalarda yaşam kalitesi ve cinsel fonksiyonların değerlendirilmesi: prospektif-tanımlayıcı çalışmanın ilk sonuçları*

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## ABSTRACT

**Objective:** The aim of this study is to evaluate sexual functions and quality life of patients who are followed-up for non-muscle invasive bladder cancer (NMIBC).

**Material and methods:** Between March 2015-June 2016, 50 patients underwent cystoscopy for NMIBC. At the end of the 1<sup>st</sup> year follow-up patients were assessed for sexual functions using 5-item version of the International Sexual Function Index (IIEF-5) for male and the Female Sexual Function Index (FSFI) for female; for quality of life (QoL) by the European Organisation for Research and Treatment of Cancer-Non-Muscle Invasive Bladder Cancer Quality of Life Questionnaire (EORTC QLQ-NMIBC24) and for emotional status by Beck depression inventory.

**Results:** There were 44 male and 6 female patients with the mean age of 57.6±11.5 years. Twenty patients received intravesical treatment after transurethral resection of bladder tumour (TURBT). The mean Beck (10.7±9.5) IIEF-5 (15.6±5.9), FSFI (19.2±10.9), and the EORTC-QLQ NMBIC 24 (38.2±7.7) scores of the patients were determined as indicated. Among the patients, 42 (84%) of them were not feeling bad about their bladder tumors and 37 (74%) were not worrying about their daily lives. Moreover, 12 (24%) patients were not interested with sexuality, while 27 (54%) of them did not feel comfortable about sexual sincerity. Interestingly, 27 patients receiving intravesical treatment were concerned that the treatment they received for prevention of recurrence and progression of bladder tumor infect their partners during sexual intercourse.

**Conclusion:** NMIBC affects patients' sexual functions and QoL negatively. Therefore during the follow-up of these patients, it is important to inform these patients accurately about their treatments to be applied and predicted complications in the follow up period.

**Keywords:** Bladder cancer; sexual function; quality of life; depression; questionnaire.

## ÖZ

**Amaç:** Bu çalışmanın amacı, kas invaziv olmayan mesane kanseri (KİOMK) nedeniyle takip edilen hastaların cinsel fonksiyonlarını ve yaşam kalitelerini değerlendirmektir.

**Gereç ve yöntemler:** Mart 2015-Haziran 2016 tarihleri arasında 50 hastaya KİOMK nedeniyle sistoskopi yapıldı. Birinci yılın sonundaki takiplerinde, hastaların cinsel işlevlerinin değerlendirilmesi için erkeklerde Uluslararası Cinsel İşlev Endeksinin 5 soruluk versiyonu (IIEF-5) ve kadınlarda Kadın Cinsel İşlev Endeksi (FSFI); yaşam kalitesinin değerlendirilmesi için Avrupa Kanser Araştırma ve Tedavi Organizasyonu - Kas İnvaziv Olmayan Mesane Kanseri Yaşam Kalitesi Anketi (EORTC QLQ-NMIBC24) ve duygusal durumun değerlendirmesi için Beck depresyon envanteri kullanıldı.

**Bulgular:** Hastaların 44'ü erkek, 6'sı kadındı ve ortalama yaş 57,6±11,5 yıl idi. Yirmi hasta mesane tümörü transüretal rezeksiyonu (TURMT) sonrası intravezikal tedavi aldı. Hastaların ortalama Beck skoru 10,7±9,5, ortalama IIEF-5 skoru 15,6±5,9, ortalama FSFI skoru 19,2±10,9 ve EORTC-QLQ NMBIC 24 skoru ise 38,2±7,7 saptandı. Hastalardan 42'si (%84) kendilerini mesane tümörleri hakkında kötü hissetmiyordu ve 37'si (%74) günlük yaşamlarında endişe duymuyordu. Dahası, 27 kişi (%54) cinsel samimiyet konusunda kendini rahat hissetmemesine rağmen, 12 (%24) hasta cinselliğe karşı ilgili değildi. İlginç olan, 27 hastanın

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mesane tümörü nüks ve progresyonunu önlemek için aldıkları intravezikal tedavinin cinsel ilişki sırasında bulaşıcı olduğunu düşünüyor olmalarıydı.

**Sonuç:** KİOMK, hastaların seksüel fonksiyonlarını ve yaşam kalitelerini negatif yönde etkilemektedir. Bu nedenle, bu hastaların takibinde uygulanacak tedavilerin ve öngörülen komplikasyonların doğru bir şekilde hastalara anlatılması ve hastaların bilgilendirilmesi önemlidir.

**Anahtar Kelimeler:** Mesane kanseri; seksüel fonksiyon; yaşam kalitesi; depresyon; anket.

## Introduction

Bladder cancer is the fourth most common malignancy in men and eighth in women in the USA and Europe.<sup>[1,2]</sup> Roughly 75% of diagnosed patients have a non-muscle invasive bladder cancer (NMIBC) which is limited to mucosa (Ta, carcinoma in situ (CIS)) and submucosa (T1). According to European Organisation for Research and Treatment of Cancer (EORTC) risk classification, bladder tumor has high rates of recurrence and progression. In the management of NMIBC, intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) or intravesical chemotherapy may be considered depending on risk stratification,<sup>[3-5]</sup> and cystoscopic follow-up is required for many years at regular intervals depending on risk stratification.<sup>[6]</sup>

Hematuria, irritative voiding symptoms, control cystoscopies, follow-up procedures, and uncertainty of having a tumor recurrence have a negative impact on the quality of life (QoL) of NMIBC patients. In addition, QoL is influenced by economic, social, and cultural determinants<sup>[7]</sup> and subjective aspects (work and family areas and sexual function) of the patients.<sup>[8,9]</sup> Although the effect of genitourinary malignancies on sexual dysfunction, defined as a decrease in sexual desire or variability of the sexual response cycle (i.e., excitement, plateau, orgasm, resolution) due to psychogenic or organic causes among men and women can be predicted, while the effect of long-term follow-up of NMIBC and applied multiple procedures on patients' QoL is still unknown. In the literature, QoL data are limited for patients with bladder cancer and primarily focused on muscle-invasive bladder cancer patients.

The aim of this study is to evaluate sexual functions, QoL and depressive symptoms in patients with NMIBC.

## Material and methods

### Study design

This prospective, and descriptive study was conducted in compliance with recognized international standards, including the Ethical Principles For Medical Research Involving Human Subjects of the Declaration of Helsinki. Written informed consent was obtained from patients who participated in this study. Between March 2015 and June 2016, 50 consecutive patients with the diagnosis of primary NMIBC underwent cystoscopic controls at regular intervals according to European

Association of Urology (EAU) NMIBC guideline were prospectively enrolled in the study. Demographic properties and primary tumor characteristics were revealed from the hospital records. At the end of the 1<sup>st</sup> year follow-up, patients were evaluated for male sexual function by International Sexual Function Index (IIEF-5), for female sexual function by Female Sexual Function Index (FSFI), for NMIBC-related QoL by EORTC-NMIBC Quality of Life Questionnaire (EORTC QLQ-NMIBC24) and for emotional status by Beck depression inventory.

Patients with the following characteristics were excluded from the study: incapacity or inability to read the questionnaires; presence of another type of cancer; irregular attempts at sexual intercourse within the last 1 month; presence of systemic diseases which may effect the sexual functions (such as diabetes mellitus, hypertension, cardiac diseases, chronic kidney or liver diseases, neurological and/or psychiatric disorders, etc.), use of drugs which may cause sexual dysfunction (such as antihypertensives, antidepressants, antipsychotics, antiepileptics, etc), smokers and alcohol-users. Finally, 50 patients were allocated for the analysis.

### Questionnaires

A 5-item version of the IIEF-5, developed by Rosen et al.<sup>[10]</sup> and validated in Turkish,<sup>[11]</sup> was used to evaluate sexual dysfunction in males. There are 5 questions on this form, and 1 to 5 points were assigned for each response. The lowest score is 5 and the highest score is 25. The erectile dysfunction status was classified according to the IIEF-5 score as follows: 5-7 severe, 8-11 moderate, 12-16 mild to moderate, 17-21 mild, 22-25 intact erectile function. The FSFI form, developed by Rosen et al.<sup>[12]</sup> and validated in Turkish,<sup>[13]</sup> was used to evaluate sexual dysfunction in females. The FSFI questionnaire consists of 19 questions about sexual activity during the past four weeks, and six subscales. In FSFI questionnaire sum of the scores measures the degree of sexual desire, arousal, lubrication, orgasm, satisfaction and pain (dyspareunia). Each question is scored between 0 or 1 and 6 points. The lowest score is 2 and the highest score is 36 points. State of sexual function according to FSFI scores was classified as follows: >30, good; 23-29 moderate, and <23 poor. EORTC QLQ-NMIBC24 module was used to evaluate the quality of life.<sup>[14]</sup> There are 24 questions each with 4 options in this questionnaire module. Beck depression inventory, developed by Beck et al.<sup>[15]</sup> and validated in Turkish,<sup>[16]</sup> was used to evaluate the severity of depressive symptoms. There are 21 questions on

Clinical Features	Patients (n=50)
Age, year, mean±SD (range)	57.6±11.5 (27-77)
<b>Gender, n (%)</b>	
Male	44 (88)
Female	6 (12)
<b>Tumor grade, n (%)**</b>	
PUNLP	6 (12)
Low	34 (68)
High	10 (20)
<b>Tumor stage, n (%)**</b>	
Ta	26 (52)
T1	17 (34)
Tis	7 (14)
Number of tumors, mean±SD	1.6±1.1
Tumor size, cm, mean±SD	3.6±2.3
<b>Early postoperative chemotherapy, n (%)</b>	
No	10 (20)
Yes	40 (80)
<b>Intravesical treatment, n (%)</b>	
No	30 (60)
Chemotherapy	12 (24)
Immunotherapy	7 (14)
Chemotherapy + Immunotherapy	1 (2)

\*In the presence of multiple tumor pathologies, the grade of the highest grade of the tumor was taken into consideration. \*\*In the presence of more than one tumor pathology, the highest stage of the tumor was eliminated. SD: standard deviation; PUNLP: papillary urothelial neoplasm of low malignant potential

this self-report form with answers each scoring 0 to 4 points. Depression severity was classified as follows: 1-10 minimal, 11-16 mild, 17-20 borderline, 21-30 moderate, 31-40 severe, and >40 extreme.

### Statistical analysis

Statistical analysis were performed with Statistical Package for the Social Sciences version 21.0 (IBM SPSS Statistics; Armonk, NY, USA). The data were expressed as mean standard deviation, number and percentage according to the type of variables. Normality tests (Shapiro-Wilk test,  $p>0.05$ ) were performed to evaluate the distributions of numeric variables.

Questionnaires	Scores
IIEF-5, mean±SD	15.6±5.9
FSFI, mean±SD	19.2±10.9
BECK, mean±SD	10.7±9.5
EORTC QLQ-NMIBC 24, mean±SD	38.2±7.7

IIEF-5: 5-item version of the International Sexual Function Index; FSFI: The Female Sexual Function Index; EORTC QLQ-NMIBC24: European Organisation for Research and Treatment of Cancer-Non-Muscle Invasiv Bladder Cancer Quality of Life Questionnaire

### Results

There were 44 (88%) male and 6 (12%) female patients with a mean age of 57.6±11.5 years. Forty patients received chemotherapy during early postoperative period and twenty (40%) patients received various forms of intravesical treatments (intravesical chemotherapy, n=12; 7 patients intravesical immunotherapy with BCG, n=7; intravesical chemotherapy and immunotherapy, n=1 after transurethral resection of the bladder tumour (TURBT). The demographic characteristics of the patients are shown in Table 1. The mean scores of the patients' questionnaires are shown in Table 2. According to the mean scores of these surveys, mild-moderate erectile dysfunction was found in men (IIEF-5: 15.6±5.9; mild-moderate (12-16)), sexual dysfunction in women (FSFI: 19.2±10.9; poor (<23)), severe depression in patients (Beck: 10.7±9.5; mild (11-16)).

Eighty-four percent of the patients was not feeling bad about their bladder tumor and 74% of them was not worrying about their daily life. However 64% of the patients never worried about their future health, and 66% of them were not concerned about the results of examinations. Moreover, 24% of the patients were not interested with sexuality, despite 54% did not feel comfortable about sexual sincerity, and 20% of them were not sexually satisfied. Interestingly, 57% of the patients receiving intravesical treatment were concerned that the treatment they received for bladder might infect their partners during sexual intercourse, while 19% of them reported no such concerns. The EORTC QLQ-NMIBC24 questionnaire outcomes of the patients are shown in Table 3.

### Discussion

In NMIBC patients, irritative symptoms due to cystoscopic follow-up and intravesical treatments, and risk of tumor recurrence have a negative impact on their QoLs. In recent studies, QoL of the patients with bladder cancer has been investigated by researchers.<sup>[17,18]</sup> Although, most studies on sexual dysfunction and other aspects of QoL have focused on cystectomy patients,

**Table 3. EORTC QLQ-NMIBC 24 questionnaire results**

	Not at all 1	A Little 2	Quite a bit 3	Very much 4
<b>During the past week</b>	<b>% of patients</b>			
Have you had to urinate frequently during the day?	8.5	46.8	27.7	17.0
Have you had to urinate frequently at night?	38.3	42.6	6.4	12.8
When you felt the urge to pass urine, did you have to hurry to get to the toilet?	38.3	31.9	17.0	12.8
Was it difficult for you to get enough sleep, because you needed to get up frequently at night to urinate?	61.7	25.5	6.4	6.4
Have you had difficulty going out of the home, because you needed to be close to a toilet?	76.6	19.1	0	4.3
Have you had any unintentional release (leakage) of urine?	72.3	25.5	0	2.1
Have you had pain or a burning feeling when urinating?	72.3	23.4	2.1	2.1
Did you have a fever?	95.7	4.3	0	0
Did you feel ill or unwell?	83	14.9	0	2.1
Did you have trouble arranging your life around the repeated bladder treatment appointments (cystoscopies or instillations)?	74.5	19.1	6.4	0
Did you worry about having repeated bladder treatments (cystoscopies or instillations)?	76.6	10.6	8.5	4.3
Were you worried about your health in the future?	61.7	19.1	10.6	8.5
Did you worry about the results of the examinations and tests?	66	23.4	6.4	4.3
Did you worry about possible future treatments?	57.4	29.8	10.6	2.1
Did you have a bloated feeling in your abdomen?	76.6	14.9	8.5	0
Have you had flatulence or gas?	44.7	38.3	10.6	6.4
To what extent were you interested in sex?	23.4	29.8	38.3	8.5
To what extent were you sexually active (with or without sexual intercourse)?	23.4	36.2	27.7	12.8
For men only: (n=44) Did you have difficulty gaining or maintaining an erection?	47.7	22.7	18.2	11.4
For men only: (n=44) Did you have ejaculation problems (e.g. dry ejaculation)?	70.5	18.2	9.1	2.3
Have you felt uncomfortable about being sexually intimate?	53.2	34	8.5	4.3
Have you worried that you may contaminate your partner during sexual contact with the bladder treatment you have been receiving?	47.9	25	22.9	4.2
To what extent was sex enjoyable for you?	19.1	29.8	31.9	19.1
For men only: (n=6) Did you have a dry vagina or other problems during intercourse?	40	20	20	20
Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.				

QoL evaluation in NMIBC was noticed to optimize health care services and to quantify the negative effects of disease. The aim of measuring of QoL in clinical trials is to give information to

patients and their physicians about the effect of treatments on QoL.<sup>[19,20]</sup> This information can supplement clinical outcome data in decision making.

A recent study has examined sexual dysfunction and its psychosocial correlates among a sample of NMIBC patients.<sup>[21]</sup> Results of the study, the physical manifestations of sexual dysfunction (ED and ejaculatory problems) among men and vaginal dryness among women, were reported for more than one-half of sexually active NMIBC patients. The study also demonstrated significant psychological and emotional findings.<sup>[21]</sup> The study showed that treatments affected relationship between patients and their partners. Also patients worried about harming their partner through sexual contact following NMIBC treatment. In a national survey study, 1550 women and 1455 men were evaluated and physical symptoms of sexual dysfunction (e.g., difficulty achieving orgasm) were reported by approximately 35% of the participants.<sup>[22]</sup> Previous researches also suggest that NMIBC treatment is associated with at least transient sexual dysfunction.<sup>[23,24]</sup>

In a prospective study, Yoshimura et al.<sup>[25]</sup> studied the impact of TURBT on QoL of the patients with NMIBC. Physical problems were indicated with the first TURBT, but when the fourth TURBT was performed, patients apparently adapted to frequent interventions, although their general QoL was still affected. The study shows that TURBT has a significant impact on QoL. The exact impact of intravesical treatment on QoL remains controversial. A previous research on the effect of NMIBC on QoL of the patients demonstrated that intravesical treatment could decrease the QoL,<sup>[26]</sup> but the results from another similar research did not support that conclusion.<sup>[27]</sup> In our study, there was a major concern felt by 57% of patients undergoing intravesical treatment related that medicine might harm their partners during sexual intercourse.

Until recently IIEF-5 and FSFI scores have not been evaluated for QoL and sexual function in patients with NMIBC. However, EORTC questionnaires have been evaluated in many studies on bladder cancer for years.<sup>[28]</sup> In the 1990s, the EORTC quality of life group developed modules for bladder cancer, the QLQ-BLS24 for NMIBC and the QLQ-BLM30 for muscle-invasive bladder cancer.<sup>[14]</sup> The Danish version of EORTC QLQ-NMIBC24 has been tested and the subscales were confirmed in Danish patients, suggesting its usefulness in Scandinavian patients. The questions related to urinary problems and future worries were the most important issues.<sup>[29]</sup> As in the Blazeyby study,<sup>[28]</sup> the questions relating to sexual function had too many missing data and were therefore of little use in this study.<sup>[29]</sup> In our study, mild-moderate erectile dysfunction was found in men according to IIEF-5 score; mild-moderate sexual dysfunction was found in women according to FSFI score and mild depression was found in all patients according to Beck score. Also, according to EORTC QLQ-NMIBC24 questionnaire outcomes, 84% of the patients were not feeling bad about their bladder tumor, 74% of them were not worrying about their

daily life, while 64% of them never worried about their future health, and 66% of the patients were not worrying about the results of examinations. Twenty-four percent of the patients were not interested with sexuality, and 38% were interested, 54% of patients did not feel comfortable about sexual sincerity, and 20% of the study participants were not sexually satisfied. This study showed that bladder cancer was effective on mental health and impaired sexual function. Our results should help clinicians to inform the patients about NMIBC and progression of the disease.

There are some limitations of this study. Firstly, the study population is very low. But, it is a prospective study and the study is still going on. In this article we would like to share our preliminary results. Secondly, due to the design of this study (descriptive study), we have no control group. Third, we haven't recorded the hormonal parameters, blood fasting glucose and serum lipid profiles which may effect the sexual function.

In conclusion, NMIBC negatively affects the QoL of the patients. During the follow-up of these patients, it is important that they are informed accurately and in detail about the diseases and the treatments to be applied. The expectations about the psychological and social lives of the patients with NMIBC should be taken into consideration and treatment alternatives for these complaints should be discussed with them.

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**Ethics Committee Approval:** Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

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