COMPARISON OF PAIN, QUALITY OF LIFE, LOWER URINARY TRACT SYMPTOMS AND SEXUAL FUNCTION BETWEEN FLEXIBLE AND RIGID CYSTOSCOPY IN FOLLOW-UP MALE PATIENTS WITH NON MUSCLE INVASIVE BLADDER CANCER: A RANDOMIZED CONTROLLED CROSS SECTION SINGLE BLIND STUDY

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Abstract

Objectives: To compare pain, quality of life(QoL), sexual function and lower urinary tract symptoms(LUTS) between rigid(RC) and flexible cystoscopy(FC). Methods: Forty-one patients who were planned control cystoscopies were enrolled the study. At the first cystoscopy, 20 patients(Group 1) and other 21 patients(Group 2) were performed by using flexible(15,5Fr) and rigid cystoscope(15,5Fr), respectively. At the second cystoscopies, the patients in group 1 and group 2 were performed by using rigid and flexible cystosacope, respectively. In all the patients, pain was measured with visual pain scale(VPS) shortly after cystoscopy. Also SF, QoL and LUTS were assessed by using IIEF, SF-36 and MLUTS forms, respectively. Results: While 22 of the patients preferred FC, the other 19 preferred RC(p>0,05). There were no statistically differences between VPS, IIEF, SF-36 and MLUTS scores of the two groups. In multivariate analysis regarding quality of life, although sexual function, pain and cystoscopy type did not affect QoL, voiding symptoms affected independently QoL. After the both cystoscopy type, IIEF, SF-36 and MLUTS scores did not change statistically. Conclusion: The results showed that the effects on pain, sexual function, QoL and LUTS of RC and FC were similar. In general, cystoscopy did not affect negatively on QoL, sexual function and LUTS of the patients.

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symptoms affected independently QoL. After the both cystoscopy type, IIEF, SF-36 and MLUTS scores did not change statistically.

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What is already known about this topic?

Flexible cystoscope is recommended to perform cystoscopy for male patients by EAU guidelines. Because it is more confortable than rigid cystoscopy. However, there are no enough evidences in literature.

What does this article add?

There are no differences between the effects on quality of life and pain of flexible and rigid cystoscopies according to the outcomes of our randomized controllled study(high-evidence level).

Introduction

Cystoscopy is one of the most common outpatient procedures of urologic practice that provides to evaluate lower urinary tract diseases such as various pathologies of urethra, prostate and bladder[(1)]. A Flexible instrument used cystoscopy was first introduced by Tsuchida and Sugawara in 1973. They reported that flexible cystoscopy was a potentially less painful technique than rigid cystoscopy, especially in male patients [(2)]. Since then flexible cystoscopy has been performed routinely in many urology clinics and European Association of Urology guidelines recommend flexible instruments for cystoscopy, particularly in men[(3)]. The guidelines report that flexible cystoscopy with local anesthetic instillation results in better compliance compared to rigid cystoscopy. However the meta-analysis regarding this recommendation do not compare between rigid and flexible cystoscopies. It compares only flexible cystoscopies with and without topical intra urethral anesthetic instillations [(4)].

Only two studies have compared pain and tolerability of male patients during flexible and rigid cystoscopies [(5,6)]. The results of these studies showed that flexible cystoscopy was better tolerated and it caused less pain than rigid cystoscopy by male patients. However the most important limitation of the both studies is that the different diameter instruments were compared. The diameters of the rigid cystoscopes were bigger than the diameters of the flexible cystoscopes in the both studies. The aim of the present study was to compare lower urinary tract symptoms (LUTS), sexual functions and quality of life as well as pain and tolerability between flexible and rigid cystoscopies which had the same diameter in male patients with non-muscle invasive bladder cancer (NMIBC).

Material and Method

A total of 41 male patients with low risk NMIBC were randomized into two groups. The patients were randomized according to the sequence of admittance to our department. The study was designed as cross over experimental. Inclusion criteria was pathologically low risk NMIBC (Ta, G1/low grade, <3cm, primary) after first transurethral resection of bladder tumor (TURBT). Exclusion criteria were T1, G2,3/high grade, carcinoma in situ, recurrence tumor, >3cm and patients who underwent re-TURBT and/or intravesical treatment. The patients (n=20) in Group 1 were performed the first cystoscopy with flexible instrument (15.5 Fr, Karl Storz, Tutlingen, Germany) at third month after TURBT and the second cystoscopy with rigid instrument (15.5 Fr, Olympus Europe Holding GmbH, Hamburg, Germany) at sixth month after TURBT. The patients (n=21) in Group 2 were performed the first cystoscopy with rigid instrument at third month TURBT and the second cystoscopy with flexible instrument at sixth month after TURBT.

The height, weight and socio-demographic data of all patients were recorded before the first cystoscopy. All of the patients filled in the International Index of Erectile Function (IIEF) and the Short Form-36 (SF-36) questionnaires before and the third month after the first and second cystoscopy, and the International Consultation on Incontinence Questionnaire-Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) before and the first week after the cystoscopies. The IIEF is used to assess the male sexual function and consists

of 15 items divided into 5 subscales including erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. The SF-36 is used to indicate the health status of particular populations and to measure the impact of clinical and social interventions. The ICIQ-MLUTS consists of 13 items, evaluating 6 storage symptoms and 5 emptying symptoms as well as frequency and nocturia questions. The validation and reliability studies of Turkish version of the IIEF [(7)], SF-36[(8)] and ICIQ-MLUTS [(9)] were made by Turkish Society of Andrology, Kocyigit et al. and Mertoglu et al., respectively. Microscopic urinalyses of the patients were made the first week after the cystoscopies.

Prior to the cystoscopy, 10mL of the %2 lidocaine gel was instilled in the urethra. After 10 minutes, cystoscopy was carried out with the patient in the dorsolithotomy position by the same surgeon (O.U.). The patients were blinded by a drape to the type of cystoscope being used. An independent person presented the patients with a visual analog scale (VAS) and asked to mark their pain status after shortly the procedure. The VAS consisted of a 10-cm horizontal line (0 being no pain and 10 being the worst pain imaginable). After the second cystoscopy, the patients were asked which cystoscope they preferred. Informed consent was obtained from all the patients who participated in the study and Local Ethics Committee approved the study protocol (No: 20478486-98). The patients' enrolment algorithm has been illustrated in Figure 1.

Statistical analyses were performed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA). All the data of the two groups were compared using the Mann Withney U Test. Also the data of the first cystoscopies of each group were compared with the data of the second ones using the Wilcoxon Signed Ranks Test. The changes of scores after the procedures in the both groups were calculated as well. These changes were analyzed for assessing the effect on VAS, IIEF, MLUTS and SF-36 scores of cystoscopy type by using the Multiple Linear Regression. The impacts on LUTS, sexual function, quality of life and pain of type of cystoscopy were evaluated using multivariate analysis. A p value less than 0,05 was considered statiatically significant.

Results

The mean age and body mass index and the professional status of the patients in group 1 and 2 were statistically similar (Table 1). After the second cystoscopies, 19 of all the patients preferred rigid cystoscope and the other 22 patients preferred flexible one (p=0.42). The mean VAS values of all the patients in the study at the first and second cystoscopies were 2.26 $\pm$ 0.83 and 2.02 $\pm$ 0.79, respectively (p=0.17). The mean VAS values of the groups at the first and second cystoscopies were given in the Table 2. There were no statistically significant differences between the mean IIEF, ICIQ-MLUTS, SF-36 and their subgroup scores of group 1 before and after the procedures (Table 3). Similarly, there were no statistically significant differences between the scores of group 2 (Table 3).

The changes of VAS, IIEF, MLUTS and SF-36 scores after the cystoscopies in the both groups were calculated. The effect on these score changes of cystoscopy type was analyzed and the results of the Multiple Linear Regression Test showed that type of cystoscope and sequence of cystoscopy did not influence (p>0.05). The findings are summarized in Table 4.

Discussion

A lot of studies have evaluated the adverse effects of cystoscopy in the literature. However, most of them have investigated the management of pain and discomfort in the patients who underwent cystoscopy[(10-12)]. A few studies have compared between rigid and flexible cystoscopies but the diameters of the cystoscopes in these studies were not equal [(5,6)]. Cicione et al also reported the lack of studies regarding comparison of these cystoscopies in literature [(13)]. In a multi-center prospective study, Seklehner et al performed rigid cystoscopy for 150 patients and flexible cystoscopy for other 150 patients [(5)]. They reported that the patients undergoing flexible cystoscopy were more frequently free of pain than the patients undergoing rigid cystoscopy. Consequently, they suggested that flexible instrument for diagnostic cystoscopy caused less pain than rigid instrument in male patients. However the most important limitations of their study were that the study was multi-institutional and the diameters of rigid cystoscopes (17.7 and 16 Fr) were bigger than flexible ones (16.5, 16 and 15.5 Fr). The two limitations might influence the results of the study regarding the negative effect of rigid cystoscopy on the pain of the patients. The present study was single-institutional and the

cystoscopies were performed by the same surgeon. Also the diameters of rigid and flexible cystoscopes were equal. The result of our study showed that the mean VAS values of the patients undergoing the first rigid cystoscopies were statistically similar to the patients undergoing the first flexible ones. The second cystoscopies were performed using cross sectional design of the instruments. There was no statistically difference between the VAS values of the patients in the second cystoscopies (Table 2). There was also no difference between the mean VAS values of all patients in the first and second cystoscopies. Overall, the findings of our study showed that the pain levels of patients during cystoscopy were not affected by type of instrument or the cystoscopy experience of patient.

The other study compared between rigid (n=60) and flexible (n=60) cystoscopies in the male patients with bladder cancer[(6)]. The results of this study indicated that flexible cystoscopy was less pain procedure and better tolerated than rigid cystoscopy by men with bladder cancer. However the different diameter instruments were used for cystoscopy in this study. Diameters of rigid and flexible cystoscopes were 20 and 15Fr, respectively. The most important limitations of previous two studies were that diameters of instruments were not equal and cystoscopies did not performed by the same surgeon. Our study was a prospective randomized cross-sectional single blind study and cystoscopy procedures were performed by the same urologist. LUTS, quality of life and erectile function as well as pain of male patients after rigid cystoscopy were compared with male patients undergoing flexible cystoscopy. After the second cystoscopies all of the patients were asked which instrument they preferred. While 22 patients preferred flexible instrument, the other 19 patients preferred rigid one (p=0.42). When the patients were divided into two groups according to the instrument using the first cystoscopy, there were no statistically differences between the choices of the patients.

Sexual functions of the patients in our study were evaluated by using IIEF form. The mean IIEF total and EF scores of the patients in the two groups before the both first and second cystoscopies were statistically similar to the scores after the cystoscopies (Table 3). These findings showed that cystoscopies using flexible or rigid instruments did not influence the erectile function of patients. LUTS of the patients were evaluated as two different groups including "voiding" and "incontinence" by using ICIQ-MLUTS form. The mean voiding and incontinence scores of the patients before and after the both first and second cystoscopies were statistically similar independently of cystoscope type (Table 3). The findings regarding quality of life were similar to the results associated with LUTS and erectile function. Overall, the results of our study indicated that flexsible or rigid cystoscopies did not effect adversely the LUTS, quality of life and erectile function of the patients.

Finally, when all parameters of the present study including age, quality of life scores, LUTS and sexual function scores of the groups, and type of cystoscopy were analyzed by using multivariate tests, no relationships between types of cystoscopy and other parameters were found. A limitation of our study was small sample size. Further large sample studies should confirm the finding of the present study.

Conclusion

Consequently, the findings of our study showed that there were no differences between the effects of rigid and flexible cystoscopies on pain, sexual function, LUTS and quality of life in patients with NMIBC. Also cystoscopy did not influence the quality of life, sexual function, and LUTS of patients independently of cystoscope type. We suggest that cystoscopy may be performed easily using both rigid and flexible instruments in follow-up of patients with NMIBC as an outpatient procedure.

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Ethical standards

The Local Ethics Committee approved the study protocol.

Conflict of interest

There are no conflicts of interest to be stated for the corresponding author and all co-authors.

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Table 1. The mean age and body mass index, the professional status and education levels of the patients in group 1 and 2.

		Group 1 (n=20) Mean ± SD	**Group 2 (n=21) Mean ± SD**	**P value**
Age (years)	Age (years)	63.40 ± 7.08	64.23 ± 7.87	0.72
BMI (kg/m^2)	BMI (kg/m^2)	27.37 ± 2.78	26.81 ± 3.87	0.59
		n (%)	**n (%)**	
Profession	Retired	17 (85)	17 (81)	0.79
	Officer	1 (5)	1 (6)	
	Worker	0 (0)	1 (6)	
	Farmer	2 (10)	2 (12)	

		Group 1 (n=20) Mean ± SD	Group 2 (n=21) Mean ± SD	P value
Education	Primary school	6 (30)	5 (24)	0.42
	Secondary school	1 (5)	2 (12)	
	High school	12 (60)	13 (58)	
	University	1 (5)	1 (6)	

BMI: Body mass index.

Table 2. The mean VAS values of the groups at the first and second cystoscopies.

	Group 1 (n=20) Mean ± SD	Group 2 (n=21) Mean ± SD	p value
First cystoscopy	Flexible	Rigid	0.73
	2.20 ± 0.83	2.33 ± 0.85	
Second cystoscopy	Rigid	Flexible	0.18
	2.20 ± 0.76	1.85 ± 0.79	

VAS: Visual analog scale. Mann Withney U test was performed.

Table 3. The mean IIEF, ICIQ-MLUTS, SF-36 and their subgroup scores of the patients in group 1 and 2 before and after the cystoscopies.

	Rigid Cystoscopy	Rigid Cystoscopy	Rigid Cystosc
	Group 1 (n=20) Before cystoscopy Mean ± SD	Group 1 (n=20) After cystoscopy Mean ± SD	Group 1 (n= p value
IIEF- EF	14.20 ± 9.05	13.60 ± 10.05	0.17
IIEF- Total	36.45 ± 20.08	34.50 ± 21.34	0.16
ICIQ-MLUTS-Voiding	3.55 ± 4.90	3.40 ± 4.46	0.76
ICIQ-MLUTS-Incontinence	3.45 ± 5.23	3.30 ± 5.02	0.95
SF-Physical	83.73 ± 13.90	83.32 ± 14.17	0.88
SF-Mental	74.52 ± 15.00	75.98 ± 13.76	0.58
SF- Physical functioning	79.50 ± 21.02	83.25 ± 20.08	0.40
SF-Role functioning/ physical	90.00 ± 40.06	92.50 ± 36.36	0.70
SF-Pain	91.60 ± 13.32	88.00 ± 17.08	0.37
SF-General health	71.10 ± 14.53	67.63 ± 16.89	0.22
SF-Energy/ Fatigue	63.75 ± 16.37	62.25 ± 17.35	0.38
SF- Social functioning	88.75 ± 19.40	87.50 ± 20.27	0.70
SF-Role functioning/ emotional	80.00 ± 29.41	90.00 ± 36.03	0.10
SF-Mental health	65.60 ± 18.73	64.20 ± 17.19	0.76

IIEF: International Index of Erectile Function, EF: Erectile Function, ICIQ-MLUTS: International Consultation on Incontinence Questionnaire-Male Lower Urinary Tract Symptoms, SF: Short Form

Wilcoxon Signed Ranks Test was performed.

Table 4. The effect of cystoscopy type on the change of the Physical and Mental Quality of life score of the patient, before and after the cystoscopy: Multiple Linear Regression analyses.

	Physical Quality of Life	Physical Quality of Life	Physical Quality of Life	Mental Q
	Standardized Coefficient	t	Sig.	Standard

	Physical Quality of Life	Physical Quality of Life	Physical Quality of Life	Mental Q
	Beta		Std. Error	Beta
Intercept		.02	.98	
(Constant)				
Type of the cystoscopy	-.09	-.76	.44	
Covariates				
IIEF total score difference	.17	1.38	.17	.25
MLUTS-voiding score difference	.66	5.38	.00	.42
VAS score difference	.08	.64	.52	.20
BMI	.11	.90	.37	.23
Age	-.10	-.84	.40	-.05
The sequence of cystoscopy				.22

Dependent Variable: QOL Physical Dimension Score difference (Physical Summary Dimenison of the SF-36) Adjusted R Square= 0.43. QOLMental Dimension Score difference (Mental Summary Dimenison of the SF-36) Adjusted R Square= 0.21

CONSORT 2010 Flow Diagram

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`Figure 1. CONSORT 2010 Flow Diagram.pdf` available at https://authorea.com/users/353510/articles/493051-comparison-of-pain-quality-of-life-lower-urinary-tract-symptoms-and-sexual-function-between-flexible-and-rigid-cystoscopy-in-follow-up-male-patients-with-non-muscle-invasive-bladder-cancer-a-randomized-controlled-cross-section-single-blind-study

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