



The Effect of Flexible and Rigid Cystoscopy on Quality of Life, Pain Perception and Lower Urinary Tract Symptoms: A Prospective Randomized Study

Fleksible ve Rijid Sistoskopinin Hayat Kalitesi, Ağrı Skoru ve Alt Üriner Sistem Semptomları Üzerine Etkisi: Prospektif Randomize Bir Çalışma

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ABSTRACT

Objective: To compare the effects of flexible and rigid cystoscopy on quality of life, pain perception and lower urinary tract symptoms.

Material and Methods: A total of 168 patients with bladder tumor history were prospectively randomized to flexible and rigid cystoscopy arms. For the quality of life assessment, a cancer specific module was administered just before and one week after cystoscopy. The expected and experienced pain was recorded by a visual analogue scale before and immediately after the procedure. Lower urinary tract symptoms were assessed using the International Prostate Symptom Score before and 2, 7 and 30 days after the procedure.

Results: Of the 168 patients, 140 were eligible for the study and responded to the questionnaires. Of these, 69 and 71 patients were from the flexible and rigid arms, respectively. The mean visual analogue scale scores after the procedure were significantly lower for the flexible arm compared to the rigid arm (2.57 ± 1.83 and 4.48 ± 2.18 , respectively, $p < 0.01$). Patients undergoing flexible cystoscopy experienced less pain than they expected in contrast to the patients in the rigid arm ($p < 0.01$). Quality of life parameters did not change after cystoscopy in the two groups ($p < 0.01$). Lower urinary tract symptoms scores increased insignificantly on the second day in both arms and returned to baseline on the seventh day.

Conclusion: Flexible cystoscopy, caused less pain than rigid cystoscopy. However quality of life scores were not different in the two groups indicating that stress and anxiety may affect these parameters more than the pain experienced during the procedure.

Key Words: Quality of life, Flexible cystoscopy, Pain, Lower urinary tract symptoms

ÖZ

Amaç: Fleksible ve rijid sistoskopinin; hayat kalitesi, ağrı skorlaması ve alt üriner sistem semptomları üzerine etkilerini karşılaştırmak.

Gereç ve Yöntemler: Mesane tümörü öyküsü olan 168 hasta, prospektif olarak fleksible ve rijid sistoskopi kollarına randomize edildi. Yaşam kalitesi değerlendirmesi için, sistoskopi öncesinde ve bir hafta sonrasında kanser spesifik bir modül kullanıldı. Beklenen ve yaşanan ağrı, işlem öncesinde ve hemen sonrasında görsel bir analog skala ile kaydedildi. Alt üriner sistem semptomları, prosedürden önce ve prosedürden 2,7 ve 30 gün sonra Uluslararası Prostat Semptom Skoru ile değerlendirildi.

Bulgular: Çalışmaya katılan 168 hastadan, 140'ı uygun bulunarak değerlendirildi. Sırasıyla, 69 ve 71 hasta fleksible ve rijid kollarıydı. İşlem sonrası yaşanan ortalama ağrı skorları, fleksible kol için rijid kola kıyasla anlamlı derecede düşüktü (sırasıyla, $2,57 \pm 1,83$ ve $4,48 \pm 2,18$, $p < 0,01$). Fleksible sistoskopi uygulanan hastalar, rijid sistoskopi kolundaki hastalardan farklı olarak, beklediklerinden

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daha az ağrı yaşadılar ($p < 0,01$). Hayat kalitesi parametreleri iki grupta da sistoskopi sonrasında değişmedi ($p < 0,01$). Alt üriner sistem semptomları her iki kolda da, ikinci günde istatistiksel anlamsız derecede yükseldi ve yedinci günde başlangıç değerlerine geri döndü.

Sonuç: Fleksible sistoskopi, rijid sistoskopiye oranla daha az ağrıya neden oldu. Bununla birlikte; hayat kalitesi skorlarının her iki grupta da farklı olmayışı, stres ve kaygının bu parametreleri, prosedür sırasında yaşanan ağrıdan daha fazla etkileyebildiğini düşündürmektedir.

Anahtar Sözcükler: Hayat kalitesi, Fleksible sistoskopi, Ağrı, Alt üriner sistem semptomları

INTRODUCTION

Bladder cancer is a common disease in developed countries. More than 70% of bladder cancers present as non-muscle invasive disease characterized by a high risk of recurrence and cystoscopy is still the gold standard method in the diagnosis and follow-up of these patients (1). Flexible cystoscopy (FC) under local anesthesia has become an alternative to rigid cystoscopy (RC) since its introduction (2). Although performed as an outpatient procedure, cystoscopy is invasive and often described as an unpleasant procedure with potential side effects. FC has decreased most of the disadvantages and especially pain perception of RC. This study was designed to clarify whether these improvements in instrumentation have an impact on the quality of life (QOL), pain perception and lower urinary tract symptoms (LUTS).

MATERIALS and METHODS

The study was designed as a randomized prospective study evaluating the differences between the changes in the quality of life, pain and lower urinary tract symptoms by the flexible and rigid cystoscopy procedures. During this study, 168 patients underwent cystoscopy in our outpatient clinics for investigation of hematuria and routine controls of non-muscle invasive bladder cancer. Patients were randomized to flexible and rigid arms. Local ethics board approval was obtained before the study.

Some of the patients had a history of previous cystoscopies, so we defined three groups according to the history as “group 1: 0-5 cystoscopies”, “group 2: 5-10 cystoscopies” and “group 3: >10 cystoscopies”. Only rigid instruments had been used in all of the previous cystoscopies so the effects on the presumed pain remained equal in both groups. Before the procedure, the patients were asked to answer the Quality of Life Questionnaire C-30 (QLQ-C30) and the International Prostate Symptom Score (IPSS). Preoperatively, patients noted the Visual Analogue Scale (VAS) score for the pain they presumed they would feel during the procedure.

We used a 17 F rigid cystoscope (Karl Storz GmbH, Germany) and 15 F flexible cystoscope (Karl Storz GmbH, Germany) for instrumentation and 6 cc 2% lignocaine gels for lubrication and local anesthesia.

After the operation, the pain score was noted on VAS. Prepaid enveloped forms of QLQ-C30 and IPSS were given to patients. They filled the questionnaire forms at the intervals required and sent them back 4 weeks later. The postoperative QLQ-C30 form was filled on the first week, and the IPSS form on the 2nd day, 1st week and 4th week. The data of 140 patients who had returned their forms were evaluated. Cystoscopy findings were recorded and suspected cases were recommended biopsy and TUR-BT under general anesthesia. Quality of life assessments of 14 patients who had TUR-BT were excluded from the study data set.

For statistical analysis, we used the Statistical Package for Social Sciences (SPSS) version 11.0 software. Wilcoxon signed rank (for VAS scores), Mann-Whitney U (VAS score) and Kruskal-Wallis (QOL, IPSS) tests were applied when the data set population was assumed to be abnormally distributed or in the ordinal scale. For normally distributed qualitative analysis, we used the chi-square test. The differences were considered significant when $p < 0.05$.

RESULTS

Of the 168 patients, 140 who returned questionnaires were eligible for the study. Of the 140 patients, 117 (85%) were male and 23 (15%) were female. Of the 117 men, 59 patients were randomized to the flexible and 58 to the rigid arm; of the 23 women, 10 patients were randomized to the flexible and 13 to the rigid arm. The procedure was the first cystoscopy for 13 (9%) patients; 58 (39%) had undergone 1-5, 35 (24%) had undergone 5-10, and 55 (37%) had undergone more than 10 cystoscopies.

Mean postoperative VAS scores for the RC and FC arms were 4.48 and 2.57 respectively ($p < 0.01$). In the FC arm, the patients had less pain than they presumed they would have (4.77 vs. 2.57, $p < 0.01$). In the RC arm, the patients had more pain than they had expected (4.48 vs. 3.83, $p = 0.01$). Only 16 patients (22%) expressed less pain compared to their previous cystoscopy experiences. The cystoscopy history of the patients did not have any significant effect on the pain scores in both arms ($p = 0.74$ and $p = 0.42$). Figure 1 shows the expected and experienced VAS scores for both arms, before and after the procedure.

Fourteen patients (8 in the flexible and 6 in the rigid arm) who had new bladder tumors and went on to

have endoscopic surgery were excluded from the QOL assessments. Preoperative mean health and QOL scores for the FC arm were 40.11 and 10.07 and these values were 39.88 and 10.19 respectively after the procedure ($p=0.76$ and $p=0.81$ respectively). In the RC arm, these values were 36.57 and 11.57 preoperatively, and 36.86 and 11.06 postoperatively ($p=0.38$ and $p=0.31$). Table I shows the changes in QOL and mean health for both arms.

When the results were evaluated for LUTS, there was no increase in IPSS scores on the 2nd day for both groups ($p=0.18$ and $p=0.22$ respectively). However, at the end of first week, the IPSS scores decreased significantly compared to the second day ($p=0.00$ and $p=0.04$ respectively). Changes in the IPSS scores over time are shown in Table II while Figure 2 shows the graphic of changes during the 4 weeks.

DISCUSSION

Cystoscopy is the gold standard procedure used in both the diagnosis and follow up bladder cancer. As non-muscle invasive bladder tumors constitute 75-85% of all transitional cell cancers, the need for regular cystoscopy during follow-up will continue unabated.

One of the goals in the management should be reducing the stress caused by the procedure itself. Although this stress differs individually and is hard to define accurately, studies for upgrading the quality of life should target mainly this issue. Seklehner et al. reported that, prior to cystoscopy 30.2% of patients were anxious and 24.8% depressive while in the post-examination period the anxiety declined to 24.5% but depression was unchanged (24.4%). They also showed that anxiety and depression levels were unaffected

Table I: Effect of flexible and rigid cystoscopy on Quality of Life assessed with QLQ-C30.

	Global Health			Quality of Life		
	Flexible	Rigid	p*	Flexible	Rigid	p*
Before Cystoscopy	40.11±10.98	36.57±8.46	0.18	10.07±2.83	11.17±2.42	0.30
After Cystoscopy	39.88±10.51	36.86±6.93	0.53	10.19±2.94	11.06±2.53	0.90
p*	0.76	0.38		0.81	0.31	

* Wilcoxon Signed Ranks test.

Table II: Effect of flexible and rigid cystoscopy on IPSS Scores.

	IPSS			
	Before	2 nd day	1 st week	4 th week
Flexible	7.76±7.26	8.02±6.67	6.54±5.79	6.50±5.90
Rigid	7.78±6.31	7.93±5.97	7.56±5.80	7.67±6.28
p*	0.85	0.16	0.24	0.27

* Wilcoxon Signed Ranks test.

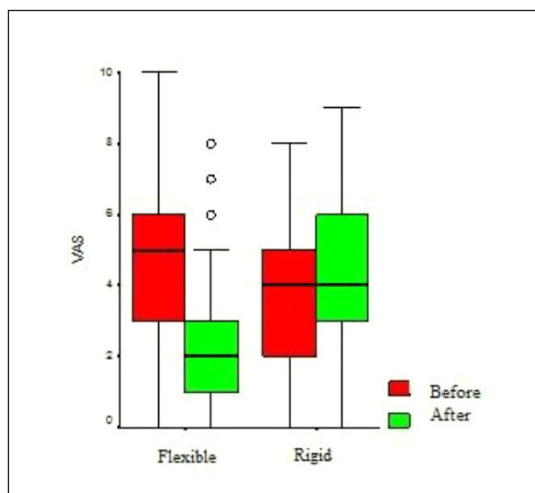


Figure 1: VAS scores in the flexible and rigid arms, before and after the procedure.

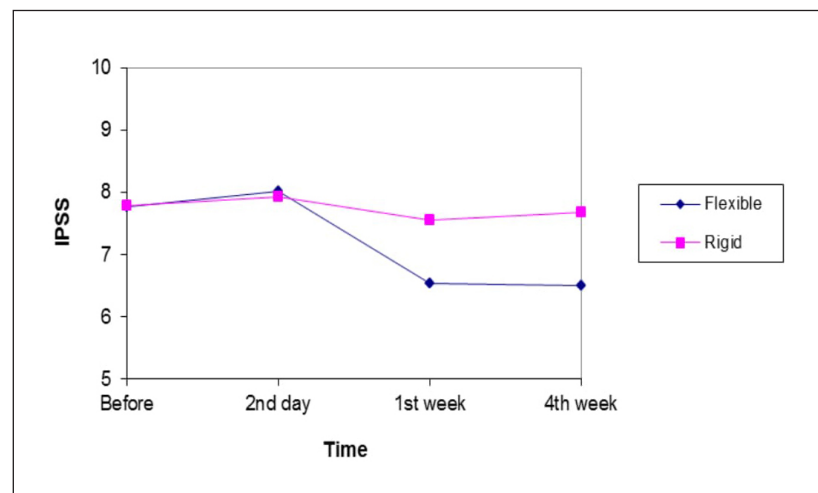


Figure 2: Graphic of changes in IPSS scores within time in the flexible and rigid arms.

by the patient's previous experience with cystoscopy or history of non-muscle invasive bladder cancer (3). The most important factor determining anxiety is the pain during cystoscopy (4). Previously cystoscopy related pain was evaluated with 10-point visual analog self-assessment scale and reported to be ranging from 2.5 to 4.5 points for flexible and 2.8 to 5.1 points for rigid instrument use (4-7). Krajewski et al. showed the superiority of flexible CS over the rigid one in terms of pain perception, but also in sexual satisfaction or anxiety levels in male patients who were under cyclic surveillance because of NMIBC (8). We have demonstrated significant reduction of pain in the FC arm (2.57 ± 1.83 vs. 4.48 ± 2.18 , $p < 0.01$). The majority of patients undergoing FC (87%) indicated that they felt less pain than they had expected. On the other hand, 56% of the patients in the RC group felt more pain than they had expected. Although we have expected to see a reduction in the individual patient's perception of pain with several cystoscopy sessions, we have not seen any significant change as the number of cystoscopies experienced by the patient increased. In fact, this result may be interpreted as the patients seeing every cystoscopy as a new session and new challenge; therefore using flexible instruments will cause less pain in every follow-up session. As the implementing doctor's experience directly affects the level of pain during cystoscopy, all procedures in our study were performed by a single doctor. One important factor in favor of the flexible cystoscope is its diameter (15 inches vs. 17 inches).

Using flexible instruments in cystoscopy should reduce the need for general anesthesia. This should provide the patient a sense of being investigated as an outpatient procedure instead of undergoing surgery. Causing less pain is needed for increasing the rate of local anesthesia. Intraurethral 2% lignocaine gel application 25 minutes prior to cystoscopy was reported to decrease pain significantly (9). According to some authors, wiping lubricant aquagel on the external surface of the flexible cystoscope did not make any significant difference in pain compared to intraurethral local anesthetic instillation (10,11).

Unlike other types of cancer, studies on quality of life issues with non-muscle invasive bladder tumors are scant. Existing studies have mostly focused on intravesical therapy, transurethral resection and the effects of urinary diversion. A few studies investigated the sole effect of cystoscopy on QOL. Stav et al. performed RC under local anesthesia to 100 patients and evaluated them at the end of the second week with SF-36; they reported no significant change compared to preoperative scores of QOL (7).

A more recent study showed that the cystoscopy type did not affect the quality of life and pain parameters although flexible instrumentation was a potentially less painful technique than rigid cystoscopy (12). Also in our study, QOL parameters evaluated in the postoperative 1st week with QLQ-C30 were not significantly different than the preoperative scores for both groups. The two groups were similar when compared on general health and quality of life basis. Therefore our main focus should be on preoperative anxiety. Moseholm et al. showed that patients undergoing diagnostic evaluations for cancer experience a high rate of anxiety and decreased quality of life prior to the diagnosis, using QLQ C30 (13). Ellis et al. found the prevalence of anxiety and depression in patients undergoing flexible cystoscopy to be increased according to the general population of similar age and the procedure-related worry and pain rates were generally low in their study (14). These findings suggest that stress and anxiety may affect the QOL parameters more than the pain of the procedure itself.

Although Stav et al. reported that LUTS were increased in the first two days and returned to baseline in two weeks after rigid cystoscopy, we found no difference in IPSS scores before and two days after cystoscopy for both arms (7). The later evaluation at 4 weeks also showed no significant change in either group. Similar results were reported by Üçer et al. who stated that both flexible and rigid cystoscopy do not change IPSS scores statistically (12).

It should be noted that there is no validated questionnaire for non-invasive bladder cancer yet, but some studies are ongoing for developing a validated instrument to measure disease specific QOL on patients treated with local therapy. The Bladder Cancer Index (BCI) is a new questionnaire and responsive to treatment related functional and QOL differences, and can be used clinically and in research to quantify patient centered outcomes in bladder cancer survivors (15). New research with specific instruments will provide additional information and understanding concerning the outcomes experienced by bladder cancer survivors.

CONCLUSION

Pain felt during FC is significantly lower than in RC. However, QOL parameters remain similar in both methods of instrumentation suggesting that stress and anxiety may affect these parameters more than the pain experienced during the procedure. Flexible cystoscopy is an efficient and comfortable method that can be used for office based examination of the lower urinary tract.

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