Impact of Patient's Real-Time Visualization during Flexible Cystoscopy: Randomized Controlled Trial

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Objective: To compare the difference in pain score between the patients who visualized their flexible cystoscopy finding on the video monitor and those who did not view the procedure.

Materials and Methods: A prospective randomized controlled trial was conducted at Ratchaburi Hospital between December 2017 and February 2018. Forty male patients undergoing flexible cystoscopy were randomized into two groups. Group A patients (n = 20) were allowed to view their procedure real-time on the video monitor. Group B patients (n = 20) were unable to view the video monitor. All patients recorded their pain on a visual analog scale (VAS) ranging from 0 to 10 after completing the procedure. The blood pressure and pulse were also recorded five minutes before the procedure and immediately after the procedure.

Results: The pain score on the VAS in group A was statistically significantly lower than that in group B (1.0 (0, 2.0) vs. 3.0 (1.0, 5.0), p=0.004). There was no statistically significant difference in the post-procedure systolic blood pressure and pulse between the two groups.

Conclusion: Real-time visualization of flexible cystoscopy finding in male patients made the procedure less painful on the VAS. Therefore, the authors highly recommend this useful technique during flexible cystoscopy.

Keywords: Flexible cystoscopy, Pain, Visual analog scale, Visualization, Video monitor

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Office-based flexible cystoscopy is performed routinely in the urology department. In the past, rigid cystoscopy was the gold standard for diagnostic and therapeutic procedures of lower urinary tract system. Later, flexible cystoscopy has been developed and widely used⁽¹⁾. Compared to rigid cystoscopy, flexible cystoscopy has the advantages of decreasing patient discomfort and eliminating the need for sedation. However, a study demonstrated the patients' experience of measurable pain and morbidity⁽²⁾. The important issue is how to improve patients' comfort. Recently, several studies reported that patients who viewed the monitor during flexible cystoscopy had less pain than those who did not⁽³⁻⁷⁾. Due to the differences in population, such as culture, educational level, and

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Phone: +66-32-719600 ext. 1363 Email: prapornpen@gmail.com economic status, the authors performed a randomized controlled study to determine the impact of real-time visualization of flexible cystoscopy findings on pain in Thai patients.

Materials and Methods

The authors prospectively enrolled male patients undergoing flexible cystoscopy at the Ratchaburi Hospital between December 2017 and February 2018. Indications for flexible cystoscopy were evaluation of hematuria, lower urinary tract symptoms (LUTS) (poor steam of urine, hesitancy, incomplete voiding, terminal dribbling, urgency, frequency, and nocturia), surveillance for bladder tumor, and removal of double-J ureteral stent. The patients with language barriers, visual problems, younger than 18 years old, and requiring additional procedures, including urethral dilation, biopsy, and diathermy of superficial bladder tumor were excluded. Informed consent was obtained from all patients before participation.

The sample size was calculated based on the research by Soomro et al⁽⁵⁾. There were 20 participants

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	Group A (n = 20)	Group B (n = 20)	Total (n = 40)	p-value
	n (%)	n (%)	n (%)	
Age (years), Median (Q1, Q3)	68 (54, 76)	68.5 (62.8, 71.5)	68 (59, 73)	0.779
Indications for cystoscopy				
Surveillance bladder tumor	12 (60.0)	8 (40.0)	20 (50.0)	0.343
Remove double-J stent	4 (20.0)	4 (20.0)	8 (20.0)	0.487
LUTS	3 (15.0)	4 (20.0)	7 (17.5)	1.000
Hematuria	0 (0.0)	2 (10.0)	2 (5.0)	1.000
Others	1 (5.0)	2 (10.0)	3 (7.5)	1.000
Cystoscopy status				
First ever cystoscopy	10 (50.0)	12 (60.0)	22 (55.0)	0.751
Repeated cystoscopy	10 (50.0)	8 (40.0)	18 (45.0)	0.751

Table 1. Demographic data

LUTS=lower urinary tract symptoms

in each group for a 5% type II error (power 95%). Simple randomization with concealment was employed to allocate 40 eligible patients into two groups. Group A patients (n = 20) were allowed to view their procedures in real-time on the video monitor. Group B patients (n = 20), as a control group, did not view the procedure on the video monitor. The randomization was undertaken by a statistician. The subjects were enrolled and assigned to group A or B by the members of the scope team that not involving in the present study.

The procedure was performed at an outpatient surgery unit in supine position by a single urologist using an 8.1Fr flexible cystoscope (Olympus[®] CYF-VHA) and colored video system (Olympus[®] EVIS EXERA III CV-190). All patients received local anesthesia with 10 ml of 2% lidocaine intraurethral and held in place for five minutes before the flexible cystoscopy.

Patients recorded their pain feeling on a 100-mm visual analog scale (VAS) ranging from 0 to10 as a pain score (PS) after the procedure was completed. No pain was defined as a score of 0, mild pain as a score of 1 to 3, moderate pain as a score of 4 to 7, and severe pain as a score of 8 to $10^{(8)}$. The blood pressure and pulse were measured five minutes before the procedure and immediately after the procedure. The patients' age, number of times for cystoscopy, indications for cystoscopy, duration of procedure, and preference of next time flexible cystoscopy (choose whether to visualize the monitor or not) were also documented. The information was collected and assessed by the scope team members who were not involved in the procedure.

The data were analyzed using SPSS[®] version 22.0 (SPSS Inc., Chicago, IL, USA). Results were described as mean and standard deviation (SD) for normally distributed data and median and interquartile range for non-normally distributed data. The VAS was compared between groups using the Mann-Whitney U test. The independent-samples t-test was used to determine the differences in systolic blood pressure and pulse between the two groups. The classification of pain was analyzed using Fisher's exact test. All tests were 2-sided with p-value less than 0.05 to consider statistically significant.

All procedures performed in the study involving human participants were in accordance to the ethical standards of the Institutional Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The present study was approved by the Ratchaburi Hospital Ethical Committee, protocol number COA-RBHEC 040/2017.

Results

The overall patient demographic data are shown in Table 1. The median of patient age was 68 (59, 73) years old. Most patients had flexible cystoscopy for surveillance bladder tumor (50%), followed by double-J stent removal (20%), evaluation of LUTS (17.5%), and hematuria (5%). Patient demographic data was well-balanced between the groups. The ratio of patients who had previous cystoscopy in both groups was comparable (50% versus 40%).

Clinical outcomes are shown in Table 2. The mean duration of the procedure in group A and

	Group A (n = 20)	Group B (n = 20)	Total (n = 40)	p-value
Duration of procedure (minutes), Mean±SD	5.0±1.0	4.7±1.2	4.8±1.1	0.335
Pain score, Median (Q1, Q3)	1.0 (0, 2.0)	3.0 (1.0, 5.0)	1.0 (0.5, 3.0)	0.004*
First ever cystoscopy	1.0 (0, 2.1)	3.8 (1.5, 6.8)	1.0 (2.3, 4.3)	0.003*
Repeated cystoscopy	0.8 (0, 1.5)	1.0 (0.1, 3.4)	1.0 (0, 3.0)	0.460
Classification of pain				
No pain (PS=0)	6 (30.0)	2 (10.0)	8 (20.0)	0.235
Mild pain (PS=1-3)	14 (70.0)	11 (55.0)	25 (62.5)	0.514
Moderate pain (PS=4-7)	0 (0.0)	7 (35.0)	7 (17.5)	0.008
Severe pain (PS=8-10)	0 (0.0)	0 (0.0)	0 (0.0)	
Pre-procedure				
Pulse (beats/minute), Mean±SD	75.7±13.2	75.1±15.0	75.4±14.0	0.894
SBP (mmHg), Median (Q1, Q3)	137.0 (128.5, 153.5)	128.5 (122.3, 135.8)	131.5 (125.3, 145.3)	0.153
Post-procedure, Mean±SD				
Pulse (beats/minute)	75.2±15.0	77.9±13.9	76.5±14.4	0.552
SBP (mmHg)	137.2±14.1	135.0±17.4	136.1±15.7	0.663
Next time cystoscopy preference, n (%)				
Visualization	14 (70.0)	9 (45.0)	23 (57.5)	0.201
Non visualization	6 (30.0)	11 (55.0)	17 (42.5)	0.201

SD=standard deviation; PS=pain score; SBP=systolic blood pressure



Figure 1. The pain score in group A was statistically significantly lower than that in group B (p=0.004).

group B was 5.0 ± 1.0 and 4.7 ± 1.2 minutes (p=0.335), respectively. The median PS on the VAS was 1.0 (0, 2.0) in group A and 3.0 (1.0, 5.0) in group B (p=0.004) (Figure 1). The patients in group A who were allowed to view the video monitor experienced significantly less pain, especially, the patients who underwent their first cystoscopy (group A, 1.0 (0, 2.1) versus group B, 3.8 (1.5, 6.8), p=0.003). According to the classification of pain, most patients from both groups had mild pain (14 patients in group A and 11 patients in group B). In group A, six patients experienced no pain, as compared with two patients in group B. None of the patients in group A experienced moderate pain, as compared with seven patients in group B. None of the patients in both groups had severe pain. There was no statistically significant difference in post-procedure pulse (75.2±15.0 versus 77.9±13.9, p=0.550) and systolic blood pressure (137.2 ± 14.1) versus 135.0±17.4, p=0.663) between groups. In group A, 14 of 20 patients chose to watch the video monitor for the next time flexible cystoscopy. However, 9 of 20 patients in group B who did not see the procedure preferred to view the monitor while performing this procedure next time.

Discussion

The present study demonstrated that the male patients who viewed the video monitor during flexible

cystoscopy had less pain on the VAS. Clements et $al^{(3)}$, Patel et al⁽⁴⁾, Soomro et al⁽⁵⁾, Zhang et al⁽⁶⁾, and Koenig et al⁽⁷⁾ reported that watching the procedure on video screen is a useful tool for reducing the discomfort experienced during flexible cystoscopy. This statement is supported by the present study results. In contrast, Cornel et al⁽⁹⁾ stated that the pain experienced by male patients undergoing flexible cystoscopy is not strongly influenced by watching the procedure. Similarly, the study by Kesari et al⁽¹⁰⁾ reported that there was no effect of watching the monitor on anxiety and pain in the patients undergoing rigid cystoscopy. The data from the present study showed that the patients with repeated cystoscopy had lower PS than the patients who had cystoscopy for the first time. In addition, there was a significant difference in PS between groups in the patients with first ever cystoscopy, as the study by Zhang et al⁽⁶⁾ reported, but the difference in PS in repeated cystoscopy patients was not significant. Kobayashi et al⁽¹¹⁾ stated that further improvements in decreasing the pain of flexible cystoscopy might not be possible due to overall minimal discomfort. This statement is confirmed by the authors' results, as most patients had no pain or mild pain, which is consistent with previous published studies.

Pain is a subjective feeling and VAS is a tool to quantify the pain. To verify pain objectively, the authors also assessed changes in pulse and blood pressures pre- and post-procedure as an established measure of cardiovascular regulation and autonomic function⁽¹²⁾. The present study shows no significant difference in the post-procedure pulse and systolic blood pressure between groups, as demonstrated by the study of Zhang et al⁽⁶⁾. On the contrary, Soomro et al⁽⁵⁾ reported that there was a statistically significant difference in the pre- and post-procedural pulse rate; however, the systolic blood pressure pre- and postprocedure remained the same.

Position of patients while the flexible cystoscopy is performed have no impact on pain. Zhang et al⁽⁶⁾, Koenig et al⁽⁷⁾, and Cornel et al⁽⁹⁾ performed flexible cystoscopy in lithotomy position. On the other hand, Soomro et al⁽⁵⁾ performed this procedure in supine position, same as the present study. Both lithotomy^(6,7) and supine position⁽⁵⁾ show less PS in visualized group. In term of indications for cystoscopy, Patel et al⁽⁴⁾, Zhang et al⁽⁶⁾, and Cornel et al⁽⁹⁾ included the patients with diagnostic procedure only, whereas Soomro et al⁽⁵⁾ and the present study included patients with wider range of indications, including therapeutic intervention such as removal of double-J stent. The authors found that the difference in PS between the diagnostic and therapeutic procedures was not statistically significant, which is consistent with the report by Soomro et al⁽⁵⁾. Although the mean duration of the procedure in the present trial was relatively shorter than the previous studies, the difference between the two groups was not significant, similar to previous published studies.

Most patients allowed to view the monitor preferred to watch the procedure the next time. Interestingly, almost half of patients in the nonvisualized group decided to view the monitor if they had to undergo flexible cystoscopy again. The result is useful in case of the patients that are under surveillance for bladder tumor and undergoing repeated flexible cystoscopy to improve patients comfort and satisfaction.

The possible limitation in the present study is the inability to blind subjects or surgeon. This may lead to potentially more careful manipulation in one group than in the other.

Conclusion

Allowing male patients to view the procedure of flexible cystoscopy on a real-time monitor significantly decreases PS, especially in the first ever cystoscopy. The authors recommend using this simple technique for reducing discomfort experienced during the procedure.

What is already known on this topic?

Although several studies⁽³⁻⁷⁾ reported that the patients who viewed the monitor during flexible cystoscopy had less pain than those who did not, two studies^(9,10) showed that pain experienced is not influenced by watching the procedure. However, the effect on pain experienced by male patients watching their flexible cystoscopy has not been established in Thailand.

What this study adds?

This study demonstrated that Thai male patients who viewed the video monitor during flexible cystoscopy had less pain on the VAS. Moreover, there was a significant difference in pain between groups in the patients with first ever cystoscopy. Most patients who viewed the monitor prefer to watch the procedure the next time. Therefore, the authors encourage urologists to use this technique to improve patients' comfort, especially in the first-time cystoscopy.

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Conflicts of interest

The authors declare no conflict of interest.

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