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GENERAL UROLOGY

Original Article

2% Lidocaine gel or plain lubricating gel: Which one should be used in male flexible cystoscopy?

Erkeklerde fleksibl sistoskopide hangi jeli kullanalım: %2 lidokainli jel ya da düz kayganlaştırıcı jel

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ABSTRACT

Objective: To investigate and compare the effects on pain of intraurethral 2% lidocaine gel and plain lubricating gel in male patients underwent flexible cystoscopy.

Material and methods: The data of 220 male patients who underwent flexible cystoscopy between March 2012 and August 2014 were retrospectively analized. The patients were divided into 2 groups according to using intraurethral gel types. Group I included 120 patients who were underwent flexible cystoscopy with 2% lidocaine gel and Group II was consisted from 100 patients who underwent flexible cystoscopy with plain lubricating gel. The groups were compared according to postprocedure data including pain score, procedure time and age of patients.

Results: The mean age of the patients in Group I was 50.02±11.87 years while that in Group II was 52.03±13.37 years (p=0.492). The mean procedure times were 6.02±0.787 and 6.28±0.689 minutes in Group I and Group II respectively (p=0.061). Pain perception scores were not statistically different between the groups (Group I: 3.10±0.980, Group II: 3.34±0.789, p=0.132).

Conclusion: Use of intraurethral 2% lidocaine gel has no advantage over plain lubricating gel in regard to pain control during flexible cystoscopy in men.

Keywords: Flexible cystoscopy; lidocaine gel; pain; plain lubricating gel.

ÖZ

Amaç: Bu çalışmada fleksibl sistoskopi uygulanan erkek hastalarda düz kayganlaştırıcı jel ile %2 lidokainli jelin ağrı üzerine etkilerini araştırmayı amaçladık.

Gereç ve yöntemler: Mart 2012 ve Ağustos 2014 tarihleri arasında fleksibl sistoskopi uygulanan 220 erkek hastanın kayıtları retrospektif olarak incelendi. Hastalar kullanılan jel türüne göre 2 gruba ayrıldı. Grup I'deki 120 hastaya %2 lidokainli jel, grup II'deki 100 hastaya düz lubrikan jel kullanılmıştı. Gruplar ağrı skorları, prosedür süresi ve hasta yaşı açısından karşılaştırıldı.

Bulgular: Grup I'deki hastaların ortalama yaşı 50,02±11,87 yıl iken grup II'de 52,03±13,37 yıldı (p=0,492). Ortalama işlem süresi grup I'de 6,02±0,787 ve grup II'de 6,28±0,689 dakikaydı (p=0,061). Gruplar arasında ağrı skorları arasında istatistiksel olarak fark yoktu (grup I: 3,10±0,980, grup II: 3,34±0,789, p=0,132).

Sonuç: Erkeklerde fleksibl sistoskopide %2 lidokainli jel kullanımı ile düz lubrikan jel kullanımının ağrı kontrolünde benzer etkileri olduğunu gördük.

Anahtar kelimeler: Ağrı; düz kayganlaştırıcı jel; flexibl sistoskopi; lidokainli jel.

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Introduction

Office based cystoscopy is an easy, safe, and effective method for the diagnosis of lower urinary tract symptoms (LUTS) and follow-up of urological malignancies.[1] Before the mid 1990s, all cystoscopies used to be done with rigid cystoscope.[2] The first flexible cystoscopy was performed in 1981 by Wilbur using flexible choledochoendoscope and now flexible cystoscope is used extensively in many centers.[3,4] Both rigid and flexible cystoscopy is associated with some extent of pain and discomfort to the patient but the flexible cys-

toscopy has significantly decreased the pain and discomfort associated with the procedure.

In female patients, cystoscopy is generally associated with mild discomfort, and the need for intraurethral anesthesia does not usually arise. Moreover, because of the short female urethra, the efficacy of intraurethral anesthesia by numerous means of topical application is limited and difficult to standardize. In contrast, men may experience more discomfort during cystoscopy due to longer urethra. Cocaine was reported as the first topical anesthetic agent for cystoscopy in 1884.[5,6] Historically, a lubricating gel with 2% lidocaine used as an intraurethral anesthetic has been a standard of care in men undergoing rigid cystoscopy; however, with introduction of the flexible cystoscope, the need for intraurethral anesthesia in men has been questioned.[7]

The primary objective of this study was to determine whether intraurethral lubricating gel containing 2% lidocaine results in lower average pain scores compared with the plain lubricating gel in men undergoing flexible cystoscopy.

Material and methods

The medical records including ages, type of lubricants, type of procedures, procedure times and the pain score during procedure of 220 male patients who underwent flexible cystoscopy between March 2012 and August 2014 were retrospectively analyzed. This study was carried out in accordance with Helsinki Declaration. 2% Lidocaine gel (Aqua Touch Jelly; İstem Medikal, Ankara, Turkey) was used to the patients and cheaper plain lubricating gel (Vazelin Likit; Tıpkimsan, İstanbul, Turkey) was used whenever lidocaine gel was not obtained. All data were compared after patients were divided into two groups (Group I: lubricating gel containing 2% lidocaine with a 11 mL syringe and Group II: plain lubricating gel with a 5 mL syringe). The indications for cystoscopy were LUTS, bladder/upper urinary tract cancer surveillance, haematuria and incontinence. Exclusion criteria were urethral stricture, presence of a sensory disorder such as a spinal cord injury and simultaneous scheduling of another procedure (like bladder biopsy) along with cystoscopy. Before the cystoscopy, all patients provided informed consent and no antibiotics were given as prophylaxis. Patients were placed in dorsolithotomy position and after the skin preparation with iodine solution; lidocain gel or plain lubricating gel were instilled into the urethra. Flexible cystoscopy was performed immediately after 5 ml plain lubricating gel instillation. 11 mL 2% lidocaine gel was applied intraurethrally followed by application of a penile clamp across the distal penis and the procedure was performed after 5 minutes. Temperature of the instillation gels was maintained at 4°C using a standard fridge. Experienced urologists performed the cystoscopy by using the 15.5 French flexible cysto-urethroscope (Storz, Tuttlingen, Germany). The cystoscopies were done by three urological surgeon. Following the cystoscopy, the medical records of the patients were kept and each subject was asked by an experienced urology nurse to rate how painful during the procedure according to a visual pain scale from 0 (no pain) to 10 (agonizing pain). All patients received single dose oral first generation cephalosporin after procedure.

Statistical analysis

All statistical evaluations were performed by the Statistical Package for Social Sciences software for Windows, version 15.0 (SPSS Inc; Chicago, IL, USA). The student's t-test was used for analysis of results and expressed as mean ± standard deviation (SD). A p value of <0.05 was considered statistically significant.

Results

A total of 220 male patients with LUTS, haematuria, bladder/upper urinary tract cancer surveillance and incontinence undergoing flexible cystoscopy at the outpatient clinic were included in the study. Group I contained 120 and Group II contained 100 patients. The mean age of the patients in Group I was 50.02±11.87 years (range 18-79 years) while that in Group II was 52.03±13.37 years (range 19-77 years). The difference was statistically not significant (p=0.492). The mean pain score in Group I was lower (3.10±0.980) than that in Group II (3.34±0.789) but this difference was also statistically not significant (p=0.132). The mean procedural times were 6.02±0.787, and 6.28±0.689 minutes in Group I and Group II respectively (p=0.061). None of the patients in the both groups needed analgesic in post cystoscopy period and no adverse reactions occurred during and after the procedures. The comperative data of groups are summarized in Table 1.

Discussion

Outpatient cystoscopy is one of the most common procedure performed in urology practice and it is usually well tolerated.[8] The data reported in the literature explains that rigit cystoscopy in male patients is a painful procedure that generally requires intravenous sedation. Flexible cystoscopy is an easy, safe and effec-

Table 1. Demographic and clinical data of study groups.*

	Group I (n=120) (2% Lidocaine gel)	Group II (n=100) (Plain lubricating gel)	p
Age (years)	50.02±11.87 (18-79)	52.03±13.37 (19-77)	0.492
Procedural time (minute)	6.02±0.787	6.28±0.689	0.061
Pain scores (0-10)	3.10±0.980	3.34±0.789	0.132

*Data are presented as mean ± standard deviation

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tive procedure and in comparison to rigid cystoscopy it causes less pain, well tolerated and associated with less post procedure symptoms.[9] However some patients complain of discomfort and many studies showed that plain lubricating gel and anesthetic lubricating gel were used to lessen these symptoms.[10] The principal advantages of flexible cystoscopy are the ease of performance due to smaller calibre instruments, improved global visualisation of the bladder especially in men presumably due to urethral length and the angle required to inspect the bladder, enhanced patient comfort and tolerability.[8,11]

Two percent lidocaine have been used as an intraurethral local anesthetic in urology practice since 1949.[12] It has a medium potency and a medium duration of action. Miscellaneous studies have been done on different aspects of intraurethral instillation of lidocaine for men undergoing cystoscopy including concentration rates, volumes, exposure times and temperatures of the gel.

Holmes et al.[13] have reported that instillation of 20 ml lidocaine gel is superior to 10 mL. Conversely, McFarlane et al.[14] found no difference in pain reduction between instillation of 10 mL and 20 mL of anesthetic gel for flexible cystoscopy in men. The other study reported a mean urethral volume of 16 mL in awake male by assessing the volume of gel required to pass through the bladder neck on ultrasonography.[15] Thus 10ml of anesthetic gel seems to be insufficient to completely lubricate the the whole urethra in male patients. In the present study, we instilled 11 mL of 2% lidocaine gel.

It is controversial the optimum indwelling time necessary for the anesthetic effect of lidocaine after intraurethral instillation. Choong et al.[16] evaluated different amounts of time for gel exposition to the urethral mucosa and found just over 15 minutes to be the most adequate. In a current study, significant treatment effect was observed with only 10 mL of the lidocaine gel applied for approximately 15 minutes.[17] Herr et al.[18] study showed no difference in pain relief between flexible cystoscopy performed immediately after lidocaine gel instillation and after 15 min delay. Prescribing information as the onset of action of lidocaine gel is about 3-5 minutes.[19] It is a common practice in busy outpatient clinics to perform cystoscopy within 5 minutes after the intraurethral instillation of lidocaine gel.[20] In our study, 2% lidocaine gel stayed in all patients' urethra for 5 minutes based on prescribing information.

Khan et al.[21] reported that delivering intraurethral lidocaine gel during 10 seconds resulted in less pain than a delivery rate of 2 seconds. We slowly delivered intraurethral lidocaine and plain lubricating gel in all patients. Thomson, Goel et al.[22,23] reported that cooling the lidocaine gel to 4°C significantly reduced the discomfort compared to the same agent at 22°C. However, Bhomi et al.[2] reported cooled lidocaine gel at 4°C has no advantage over room temperature lidocaine gel for decreasing pain perception during rigid cystoscopy. In the present study, anesthetic agent and plain lubricating gel were kept at a temperature of 4°C in the standart fridge.

Randomized studies of the 2% lidocaine gel versus plain lubricating gel in men undergoing flexible cystoscopy report miscellaneous findings. While some authors report significantly less pain in the 2% lidocaine gel arm relative to the plain lubricating gel, others report no significant differences in pain perception in the two groups (Table 2).[7,13,14,16,17,24-27] A meta-analysis reported that there was not a statistically significant difference in mean pain scores between the lidocaine and the plain lubricating gel group.[28] Conversely, in another meta-analysis, lidocaine

Table 2. The studies of 2% lidocaine gel versus plain lubricating gel in men undergoing flexible cystoscopy

Study	Groups	Mean PS (0-10)	p
Borch et al.[17]	- 10 mL lidocaine; 15 minutes	2.04	<0.001
	- 10 mL plain gel; 15 minutes	3.38	
Chitale et al.[24]	-11 mL lidocaine; time not stated	2.00	>0.05
	- 11 mL plain gel; time not stated	2.20	
Chen et al.[25]	- 20 mL lidocaine; 15 minutes	2.80	0.06
	- 20 mL plain gel; 15 minutes	2.50	
Rodriguez-Rubio et al.[26]	- 10-30 mL lidocaine; 5 minutes	2.00	>0.05
	- 10 mL plain gel; 5 minutes	2.10	
Palit et al.[27]	- 11 mL lidocaine; 15 minutes	2.60	>0.05
	- 10-15 mL of plain gel; <5 minutes	2.50	
McFarlane et al.[14]	- 10 mL lidocaine gel; 15 minutes	3.90	
	- 20 mL lidocaine gel; 15 minutes	3.60	0.406
	- 20 mL plain gel; 15 minutes	4.70	
Holmes et al.[13]	- 20 mL lidocaine; 10 minutes	1.80	<0.001
	- 20 mL plain gel; 10 minutes	3.10	
	- 10 mL lidocaine; 10 minutes	2.70	0.190
	- 10 mL plain gel; 10 minutes	2.50	
Choong et al.[16]	-20 ml lidocaine; 5 minutes	3.30	>0.05
	-20 mL plain gel; 5 minutes	3.70	
	-20 mL lidocaine; 25 minutes	1.80	<0.01
	-20 mL plain gel; 25 minutes	4.60	
Birch et al.[7]	-10 mL lidocaine; 15 minutes	1.20	>0.05
	-10 mL plain gel; 15 minutes	1.40	

PS: pain score

was associated with higher probability of experiencing less than moderate pain compared with the plain lubricating gel.[29]

Patel et al.[30] reported that the men viewing cystoscopy on the video monitor experienced an approximately 40% decrease in the pain level compared to those who did not view the procedure on the monitor. Unfortunately, we could not make our patients view the procedure because of the absence of video monitor in our office.

Some adverse effects as allergy to lidocaine had been reported. The adverse effects to lidocaine were not observed for none of our patients. However, we think that the usage of plain lubricating gel decreases the adverse effects to lidocaine.

In comparatively many studies up to now, it has been observed that the pain tolerance and pain threshold of old patients are higher. Cannot been analyzed statistically of pain scores according to age groups is one of the limitations of our study.[31] The results of our study indicate that any significant difference between groups using lubricating gel containing 2% lidocaine or plain lubricating gel in terms of procedure time and rate of pain described during the flexible cystoscopy was not found. But total time of the procedure takes longer time for the patients used lidocaine gel because of a five minutes waiting. Our patients' pain scores were low, which suggests that flexible cystoscopy with 2% lidocaine gel or plain lubricating gel are a well tolerated procedure. Perception of the pain may be widely varied among the patients. So, 2% lidocaine gel and plain lubricating gel ideally should have been compared by each individual. In other words, the study should have designed as crossover trial. But our study could not have designed as crossover trial because of being retrospective study. It is the other one of the limitations of our study. Therefore, further crossover trials are needed to identify ideal intraurethral agent that would make cystoscopy more tolerable.

In conclusion, flexible cystoscopy is easier, safer, more comfortable and more convenient to patients in comparison to rigid cystoscopy. It can be performed with a local anastetic gel or plain lubricating gel. Using plain lubricating gel is safe, fast and cheaper than lidocaine gel. Our study suggests that the pain experienced with the plain lubricating gel is no greater than that experienced with 2% lidocaine gel. The plain lubricating gel is as effective as 2% lidocaine gel and its regular use should be advocated for flexible cystoscopy in urology outpatient clinic.

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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