

Is anesthetic gel necessary in outpatient flexible cystoscopy ?

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- Objectives** : *To study the benefit of intraurethral lidocaine jelly instillation before flexible cystoscopic examination regarding patients tolerance to pain compared with the plain lubricant.*
- Research design** : *Randomized prospective study*
- Setting** : *The Outpatient Urologic Clinic at King Chulalongkorn Memorial Hospital*
- Methods** : *We compared the anesthetic effect of 10 cc intraurethral 2 % lidocaine jelly (N= 80) and 10 cc plain lubricant (N = 80) for outpatient flexible cystoscope in male patients. The age, diagnosis, prostatic size and examination time were recorded. After the procedure, the following data of the patient were recorded: level of pain experienced during gel instillation, during cystoscopic examination based on a 100 mm. visual analog scale. A questionnaire on satisfaction of anesthesia, requirement of analgesic drug, willingness to use the same anesthesia for next cystoscopy and requirement of general or spinal anesthesia for next cystoscopy were also recorded.*

Results : *The mean pain score for 2 % lidocaine jelly and plain lubricant groups were 2.93 ± 1.93 and 3.30 ± 1.87 ($p = 0.215$) during gel instillation, while during cystoscopic examination were 3.34 ± 2.18 and 3.34 ± 1.97 ($p = 1.0$). The satisfaction of anesthesia, the requirement of analgesic drug after procedure, the desire of the same anesthesia and number of patients requiring general anesthesia on next procedure were similar in both groups.*

Conclusion : *There was no difference in pain perception in men between 2 % lidocaine jelly and plain lubricant intraurethral instillation before outpatient flexible cystoscope. The plain lubricant is cheaper and faster than applying lidocaine jelly.*

Keywords : *Anesthesia , Flexible cystoscopy.*

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- วัตถุประสงค์** : เพื่อศึกษาถึงประโยชน์ของการให้ยาระงับความรู้สึกเฉพาะที่ในการลดความเจ็บปวดก่อนการส่องกล้องตรวจระบบทางเดินปัสสาวะแบบสายพับงอได้เปรียบเทียบกับการใช้สารหล่อลื่น
- รูปแบบการวิจัย** : การวิจัยเชิงวิเคราะห์แบบไปข้างหน้า
- สถานที่ทำการศึกษา** : แผนกผู้ป่วยนอก ศัลยกรรมระบบทางเดินปัสสาวะ ร.พ.จุฬาลงกรณ์
- ตัวอย่างและวิธีการศึกษา** : แบ่งกลุ่มผู้ป่วยเพศชายที่เข้ารับการส่องกล้องตรวจระบบทางเดินปัสสาวะแบบสายพับงอได้แบบสุ่มเป็น 2 กลุ่ม กลุ่มละ 80 คน โดยกลุ่มที่ 1 จะได้รับการใส่ยาระงับความรู้สึกเฉพาะที่ปริมาณ 10 มล. เข้าในท่อปัสสาวะก่อนการส่องกล้อง และรอระยะเวลาออกฤทธิ์ 5 นาที ก่อนทำการตรวจ ส่วนกลุ่มที่ 2 จะได้รับการใส่สารหล่อลื่นปริมาณ 10 มล. เข้าในท่อปัสสาวะและทำการส่องกล้องตรวจทันที หลังใส่ โดยข้อมูลเปรียบเทียบได้แก่ อายุ การวินิจฉัยโรค ขนาดต่อมลูกหมาก ระยะเวลาการตรวจและให้ผู้ป่วยประเมินระดับความเจ็บปวดในการตรวจ และตอบคำถามภายหลังจากทำการตรวจทันที
- ผลการศึกษา** : ระดับความเจ็บปวดในขณะที่ใส่ยาผ่านท่อปัสสาวะก่อนทำการตรวจในกลุ่มที่ 1 และกลุ่มที่ 2 เท่ากับ 2.93 ± 1.93 , 3.30 ± 1.87 ($p = 0.215$) ระดับความเจ็บปวดขณะทำการตรวจเท่ากับ 3.34 ± 2.18 , 3.34 ± 1.97 ($p = 1$) ความพึงพอใจต่อยาระงับความรู้สึก ความต้องการยาแก้ปวดภายหลังจากการตรวจ ความต้องการที่จะใช้ยาระงับความรู้สึกชนิดเดิม และความต้องการดมยาสลบในการตรวจครั้งต่อไปมีค่าไม่แตกต่างกันทางสถิติในผู้ป่วย 2 กลุ่ม
- สรุป** : ยาระงับความรู้สึกเฉพาะที่มีผลลดระดับความเจ็บปวดจากการส่องกล้องตรวจระบบทางเดินปัสสาวะไม่ต่างกับการใช้สารหล่อลื่นธรรมดาซึ่งมีราคาถูกกว่าและสามารถทำการตรวจได้เร็วกว่า
- คำสำคัญ** : ยาระงับความรู้สึก, การส่องกล้องตรวจระบบทางเดินปัสสาวะ

Cystoscopy is one of the most common examination in urologic outpatient clinics. It was used for diagnostic and follow up of various urologic conditions such as hematuria, bladder outlet obstruction, surveillance of bladder tumor after treatment. Pain is the important factor for patients who were examined, especially in men. Many clinical trials have been conducted to improve patient's tolerance from the procedure. In the middle of the 20th century, intraurethral instillation of anesthetic gel was introduced to relieve pain perception during examination in rigid cystoscopy. Recently, flexible cystoscopy has the gold standard of examination. Smaller caliber and flexible tip produce less pain compare to conventional rigid cystoscopy. Primary, topical anesthetic gel was usually instilled intraurethral and waited for 5-10 minutes before scope insertion.⁽¹⁾ Later, many reports were published about the necessary of anesthesia before flexible cystoscopy; however, no conclusion has been achieved.

In our and other busy outpatient clinic, many patients received cystoscopic examination daily. Sometimes, the timing was limited. Some patients were examined less than 5 minutes after anesthetic gel instillation. By observational and many reports, pain perception was not difference between patients who waited for 5-10 minutes and less than 5 minutes before examination

We conducted a prospective randomized trial comparing between intraurethral lidocaine jelly and plain lubricant gel to determine the necessary of topical anesthesia in outpatients flexible cystoscopy.

Material and Methods

The study protocol was approved by the

Research Ethics Committee of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. In November 2006, we performed a pilot study in 20 patients (10 patients in each group). The pain score by visual analogue scale (VAS) during cystoscopic examination was 3.8 ± 1.81 in study group and 2.9 ± 1.68 in control group. We calculated the sample size from the following equation (two independent groups).

$$\begin{aligned} n/gr &= 2 \times (Z_{\alpha/2} + Z_{\beta})^2 \times \sigma^2 / (X_1 - X_2)^2 \\ \sigma^2 &= \text{Pooled Variance} \\ &= \frac{(n_1 - 1) S_1^2 + (n_2 - 1) S_2^2}{n_1 + n_2 - 2} \\ \alpha &= 0.05 \\ \beta &= 0.10 \\ Z_{\alpha/2} &= 1.96 \text{ (Two Tail)} \\ Z_{\beta} &= 1.28 \\ n/gr &= 79 \end{aligned}$$

From December 2006 to November 2007, male patients who underwent outpatient flexible cystoscope under various objectives were eligibled for entry into the study. After providing written informed consent, they were randomized into two groups : group 1 (study group) and group 2 (control group) according to the table of random numbers. Patients were excluded based on the following criteria : 1) having a sensory disorder from neurological deficit; 2) their pain perception could not be evaluated such as having very old age or having brain disease; and 3) patients with urethral stricture and undergoing urethral dilation.

A total of 160 consecutive men were recruited to the study and randomized into group 1 (N = 80) and group 2 (N = 80), 15 patients were excluded by the criteria.

Patients were placed in the dorsal lithotomy position. The penis was prepared with chlorhexidine

solution. In group 1, the patients were instilled 10 cc K-Y jelly (Johnson & Johnson) intraurethral in 10 seconds by syringe and the examination was began immediately. In group 2, patients were instilled 10 cc of 2 % xylocaine jelly (Astra Zenaca) intraurethral in 10 seconds by syringe, which was retained in the urethral for at least 5 minutes by a penile clamp, then examination was done. The same urologist instilled the gel and performed all cystoscopies. Video cystoscopy is performed using a 14 Fr. Flexible cystoscope (Olympus Visera CYA-VA). After the procedure, diagnosis, prostatic size and examination time were recorded by the urologist. The patients were asked to record their level of pain perception during gel instillation and cystoscopic examination by using 100 mm. visual analog scale (a score 0 on the scale was equated to no pain whereas and 100 to the worst pain). The questionnaire on satisfaction of anesthesia, the requirement of analgesic drug, willingness to use

the same anesthesia in the next cystoscopy and requirement of general or spinal anesthesia for next cystoscopy were also recorded.

The pain scale was compared statistically by using independent T – test and the demographic data (patients characteristics and patients satisfaction) using Chi-square test. All test were 2 – tailed with statistical significance at $p < 0.05$.

Results

A total of 175 patients were enrolled in the study. Fifteen patients were excluded by the criteria 160 patients were recruited. All patients completed the study questionnaire, 80 were randomized to each group. The two groups were well – matched in terms of number and demographic data (age, diagnosis, history of previously cystoscopy, prostate size and examination time). (Table 1)

Table 1. Patients characteristics.

Characteristic	Group 1	Group 2
1. Mean age (yr)	64.96 ± 15.24	64.30 ± 13.47
2. Indication for cystoscopy (N)		
- bladder tumor	31	27
- LUTS	19	23
- hematuria	11	11
- remove DJ stent	8	9
- stricture urethra	5	7
- others	6	3
3. Previously cystoscopy (N)	49	42
4. Prostatic size (N)		
- 1/2 VF	30	23
- 1 VF	30	36
- 1 1/2 VF	13	17
- ≥ 2 VF	7	4
5) Examination time (N)		
- ≤ 2 min.	68	68
- > 2 min.	12	12

The mean \pm standard deviation of pain score during gel instillation was 3.3 ± 1.87 and 2.93 ± 1.93 in group 1 and 2 respectively ($p = 0.215$). The pain score during cystoscopic examination was 3.34 ± 1.97 and 3.34 ± 2.18 in group 1 and 2 respectively ($p = 1$). No significant difference was detected in both groups. (Table 2)

The number of patients who were satisfied with the anesthesia, the requirement of analgesic drug after the examination, the willingness to use the same anesthetic agent for the next cystoscopy and number of patients who need general anesthesia were not different in both groups. (Table 3)

Discussion

Outpatient cystoscopy has been well accepted by patients. The use of flexible cystoscope for male patients is superior than conventional rigid

cystoscope due to the invasiveness. Various studies for the necessity of the topical anesthetic gel have been performed the results were not concluded. Some studies reported no difference in pain perception between lidocaine jelly and plain lubricant.⁽²⁻⁴⁾ Another study concluded that anesthetic gel instillation has no advantage compared to no gel instillation.⁽⁵⁾ However, some studies reported the certain advantages of the anesthetic gel.⁽⁶⁻⁷⁾

Because the plain lubricant content is more sticky than lidocaine jelly, we used the pain during gel instillation to compare the results of this factor. One study reported instillation of plain lubricant cause it produced less pain than instillation of 2 % lidocaine jelly.⁽⁸⁾ The amount, rate of delivery, exposure time and temperature of the anesthetic gel were discussed in a previous study.

Table 2. Pain scores of the patients.

Time of recording	Group 1	Group 2	p - value
During gel instillation	3.3 ± 1.87	2.93 ± 1.93	0.215
During cystoscopic examination	3.34 ± 1.97	3.34 ± 2.18	1

Table 3. Questionnaires

Number of patients (n)	Group 1 (n=80)	Group 2 (n=80)	p- value
1. Satisfied the anesthetic agent	77	74	0.493
2. Required the anesthetic drug after examination	25	19	0.376
3. Need the same anesthetic on next examination	71	72	1
4. Need general anesthesia on next examination	3	4	1

Regarding the amount of the instillation gel, one study reported no difference in pain reduction between 10 and 20 cc of anesthetic gel.⁽⁹⁾ In our study, we thought that a larger amount of gel might result in greater pain during the instillation. We used 10 cc gel in this study. Regarding the exposure time of gel on the urethral mucosa, Herr *et al.*⁽¹⁰⁾ demonstrated that no difference in pain perception between immediate and delay 10 – 15 min. cystoscope after gel instillation. On the immediate examination, anesthetic gel was not yet absorbed into urethral mucosa, so the anesthetic gel might not be necessary for the examination. Regarding the rate of delivery, Khan *et al.*⁽¹¹⁾ concluded that 10 seconds delivery of gel was more comfortable than 2 seconds, so in this study we instilled gel on 10 seconds. Thompson *et al.*⁽¹²⁾ demonstrated that cooling (4 °C) the anesthetic gel significantly reduced the discomfort associated with its instillation compared with gel at 22 °C and 40 °C. In our study, because the limitation on preparation we used gel at the room temperature (25 °C)

There are many factors that may influence pain perception, i.e., the skill of examiner and patients may be desensitized by repeated experience of examination or aging. In this study, we believed that these factors did not affect the results of the study because the parameters of both groups were well matched.

Although anesthetic gel instillation may reduce pain after cystoscope, pain and dysuria after cystoscope was not evaluated in this study. At least, the results of our study suggests that anesthetic gel instillation has no advantage on pain relief during cystoscopic procedures.

In our opinion, it appears that the impact of

intraurethral anesthetic gel on pain relief has become less significance in the era of flexible cystoscope with smaller size and gentle insertion under direct vision with good lubrication, although it actually has some degree of pain – reducing effect.⁽⁵⁾

The advantage of immediate flexible cystoscope is that the procedure is well tolerated by the majority of the patients. It reduced the time that patients were waiting on table. It can also decrease patient anxiety and saves time in the outpatient clinics especially the busy ones. However, the cost of lidocaine jelly is two times more expensive than plain lubricant.

Conclusion

This study indicates that intraurethral lidocaine jelly can't provides advantage in term of pain perception compared to plain lubricant in outpatient flexible cystoscopy. Plain lubricant also decrease the cost and time of the examination.

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