Original Article

Comparison of cooled and room temperature lidocaine gel in reducing urethral discomfort during cystoscopy

Thongchai Chansirirattanakul, Tanet Thaidumrong, Vorapot Choonhaklai, Viroj Chittchang, Somkiat Pumpaisanchai, Nattapong Wongwattanasatien, Sermsin Sindhubodee, Chawawat Kosrisirikul, Matchima Huabkong, Somjith Duangkae

Division of Urology, Department of Surgery, Rajavithi Hospital, Bangkok, Thailand

Key words:
lignocaine gel, cystoscopy

Abstract

Objective: Prospective randomized controlled trial study to compare pain scores between room temperature and cooled 2% lidocaine gel during instillation and cystoscopy.

Material and method: Male patients who had indications for cystoscopy between September 2017 and December 2017 at Rajavithi Hospital were included in this study. They were prospectively randomized into 2 groups. Group I received 10 ml of 2% lidocaine hydrochloride gel at 4°C and Group II received 10 ml of 2% lidocaine hydrochloride gel at room temperature (22°C). After instillation of the gel and at the end of cystoscopy, patients were immediately asked to score their pain level using a NUMERIC RATING SCALE (NRS) FOR PAIN.

Result: A total of 70 male patients were enrolled in the study and randomized into 2 groups. There were no significant differences in age and number of previous cystoscopies between the 2 groups. The pain scores were analyzed using the Mann-Whitney U test. Pain perception scores during gel instillation were not statistically different between the groups. (P = 0.496). Pain perception scores during cystoscopic procedures in group I were statistically lower than in group II (P<0.05).

Conclusion: Transurethral cooled 2% lidocaine gel significantly reduced pain during cystoscopy when compared with the instillation of room temperature 2% lidocaine hydrochloride. However, it did not significantly reduce pain perception scores during gel instillation.

Corresponding author: Thongchai Chansirirattanakul
Address: Division of Urology, Department of Surgery, Rajavithi Hospital, Bangkok, Thailand
E-mail: Gimmongy@hotmail.com

นิพนธ์ต้นฉบับ

เปรียบเทียบระดับความปวดระหว่างการใช้ยาชาเฉพาะที่แบบเจลที่มีอุณหภูมิเย็นและแบบอุณภูมิปกติ ในผู้ป่วยที่ทำการส่องกล้องทางเดินปัสสาวะ

ธงไชย ชาญสิริรัตนกุล, ธเนศ ไทยดำรงค์, วรพจน์ ชุณหคล้าย, วิโรจน์ จิตต์แจ้ง, สมเกียรติ พุ่มไพศาลชัย, ณัฐพงศ์ วงศ์วัฒนาเสถียร, เสริมสิน สินธุบดี, ชววรรธน์ โกสีย์ศิริกุล, มัชฌิมา ฮวบกอง, สมจิตร ดวงแข

หน่วยศัลยศาสตร์ระบบปัสสาวะ กลุ่มงานศัลยกรรม โรงพยาบาลราชวิถี กรุงเทพฯ

คำสำคัญ:
ยาชาเฉพาะที่แบบเจล
ส่องกล้องทางเดินปัสสาวะ

บทคัดย่อ

ผู้ป่วยและวิธีการศึกษา: ผู้ป่วยเพศชายที่เข้ารับการส่องกล้องทางเดินปัสสาวะในโรงพยาบาลราชวิถี ตั้งแต่เดือน กันยายน พ.ศ. 2560 จนถึง ธันวาคม พ.ศ. 2560 จากนั้นทำการสุ่มแบ่งผู้ป่วยออกเป็น 2 กลุ่ม โดยผู้ที่อยู่ในกลุ่มที่ 1 จะได้รับยาชาอุณหภูมิเย็น (4 องศาเซลเซียส) และผู้ป่วยในกลุ่มที่ 2 จะได้รับยาชาอุณหภูมิห้อง (22 องศาเซลเซียส) หลังจากนั้นจะทำการสอบถามคะแนนความปวดของผู้ป่วย 2 ช่วง คือช่วงระหว่างใส่ยาชา และหลังทำการส่องกล้องเสร็จ

ผลการศึกษา: ผู้ป่วยเพศชายที่เข้าร่วมงานวิจัยทั้งหมด 70 คน จากนั้นทำการสุ่มออกเป็น 2 กลุ่ม ไม่มีความแตกต่างด้านอายุและประสบการณ์การเข้ารับการส่องกล้องทางเดินปัสสาวะของทั้ง 2 กลุ่ม การเปรียบเทียบข้อมูลคะแนนความปวด โดย Mann-Whitney U test ผลการศึกษาพบว่า ในกลุ่มที่ใช้ยาชาที่มีอุณหภูมิเย็นจะมีระดับคะแนนความปวดระหว่างการทำการส่องกล้องทางเดินปัสสาวะน้อยกว่ากลุ่มที่ได้ยาชาอุณหภูมิห้อง ในขณะที่ระดับคะแนนความปวดระหว่างการใส่ยาชานั้น ไม่พบความแตกต่างระหว่างทั้ง 2 กลุ่ม

สรุป: การใช้ยาชาเฉพาะที่แบบเจลที่มีอุณหภูมิเย็นจะช่วยลดความปวดระหว่างทำการส่องกล้องทางเดินปัสสาวะเมื่อเปรียบเทียบกับการใช้ยาชาที่มีอุณหภูมิห้อง แต่ความปวดในช่วงระหว่างการใส่ยาชาเฉพาะที่แบบเจลนั้น ไม่แตกต่างกันทั้ง 2 กลุ่ม

ผู้นิพนธ์หลัก: ธงไชย ชาญสิริรัตนกุล
ที่อยู่: หน่วยศัลยศาสตร์ระบบปัสสาวะ กลุ่มงานศัลยกรรม โรงพยาบาลราชวิถี กรุงเทพฯ
E-mail: Gimmongy@hotmail.com

Introduction

Cystoscopy is one of the most common procedures in urology. Among general patients, pain which may occur during the process of treatment is their main concern. Flexible cystoscope was developed and is available in some urology clinics. However, the use of a rigid cystoscope is still the standard because it is less expensive, easier to handle and maintain, and has a better visual field than flexible scope. The common disadvantage of rigid cystoscope is pain; therefore, it is essential to find a solution to reduce the pain associated with using rigid cystoscope.

Topical lidocaine gel has emerged as the anesthetic agent of choice based on its simultaneous role as a lubricant and local anesthetic. Numerous studies have examined the volume, temperature and instillation time of lidocaine gel as variables and yet no standard regimen has been established. Rajiv Goel et al[1] conducted a prospective randomized study comparing pain during instillation with lidocaine gel at room temperature and at 4°C, and the results demonstrated that gel at 4°C can significantly reduce the initial discomfort associated with instillation of 2% lidocaine hydrochloride into the male urethra.

This prospective randomized study was conducted in order to compare pain during instillation and during the procedure with lidocaine gel at room temperature (22°C) and at 4°C.

Material and method

This study was conducted in Rajavithi Hospital from September 2017 to December 2017. The subjects were 70 male patients who had indications to undergo cystoscopy. For those who had urinary retention, stricture urethra, allergy to lidocain, received any analgesic medication prior to the procedure, and needed additional procedures such as urethral dilatation, bladder mass biopsy, ureteral or urethral catheterization, were excluded. The study was approved by the ethics and research committee of Rajavithi Hospital. Written informed consent to participate in the study was obtained from all participants.

Cystoscopy was performed in an office setting in Rajavithi Hospital. The participants were randomized into 2 groups. The study group (n=35) was given 10 ml cooled temperature 2% lidocaine gel and the control group (n=35) was given 10 ml room temperature (22°C) 2% lidocaine gel. After transurethral instillation for 10 minutes, cystoscopy was performed by 2nd year urology residents of the Division of Urology, Department of Surgery, Rajavithi Hospital, using a Karl Storz-Endoscope, 27026 U, Cystoscope-Urethroscope sheath, 17 Fr and Karl Storz-Endoscope, 27005 BA Hopkins II Forward-Oblique Telescope 30°.

The severity of pain was assessed in 2 periods during the transurethral instillation of 2% lidocaine gel into the urethra, and immediately at the end of the cystoscopy procedure (Fig. 1).

An 11-point (0 to 10) Numerical Rating Scale (NRS) was used to assess the severity of pain (0: no pain, 10: worst possible pain).

The Mann-Whitney U test was used to compare pain scores. P-value less than 0.05 was considered significant. The statistical analysis software used was the Statistical Package for Social Sciences (SPSS).

Results

Patient characteristics are shown in Table 1. The mean age of the cooled temperature 2% lidocaine gel group was 60.4 years, whereas the mean age of the room temperature 2% lidocaine gel group was 64.4 years. The mean number experienced in cystoscopy was 3.6 and 4.4 in the cooled temperature 2% lidocaine gel group and in the room temperature 2% lidocaine gel group, respectively. There were no significant differences in patient age and number of previous cystoscopies between the 2 groups.

The distribution of pain scores during instillation in the cooled temperature group and the room temperature group are given in Table 2.

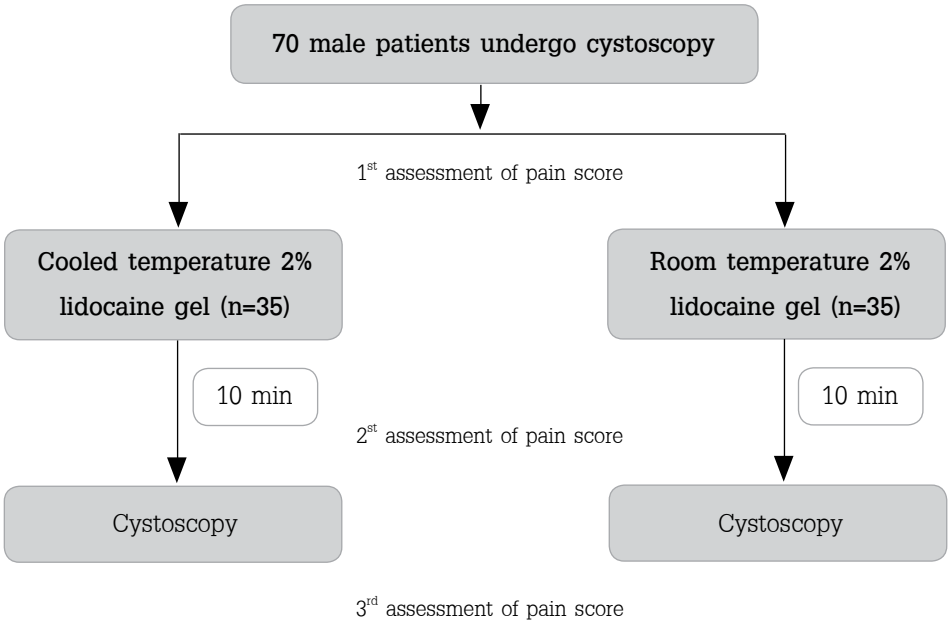

Fig 1. The study design

Table 1. Patient characteristics

	cooled temperature group (n=35)	room temperature group (n=35)	P-value
Mean age (years)	60.4 (+/- 13.79)	64.4 (+/- 11.56)	0.190
Mean number experienced in cystoscopies (n)	3.6 (+/- 4.3)	4.4 (+/- 5.07)	0.483

Table 2. The pain scores during instillation of the cooled temperature 2% lidocaine gel group and room temperature 2% lidocaine gel group

Pain score (during instillation)	Cooled lidocaine gel	Room temperature lidocaine gel
0	2 (5.7 %)	6 (17.1%)
1	9 (25.7%)	6 (17.7%)
2	8 (22.9%)	9 (25.7%)
3	6 (17.1%)	5 (14.3%)
4	6 (17.1%)	6 (17.1%)
5	3 (8.6%)	3 (8.6%)
7	1 (2.9%)	0 (0 %)
Total	**35 (100%)**	**35 (100%)**

The distribution of pain scores during cystoscopy of the patients in the cooled temperature group and the room temperature group are given in Table 3.

The data presented in Table 4 show that the pain scores during gel instillation were not statistically different between the groups (P=0.496). Pain perception scores during the procedure in the cooled temperature 2% lidocaine gel group were statistically lower than in the room temperature 2% lidocaine gel group (P<0.05).

Table 3. The pain scores during cystoscopy of the cooled temperature 2% lidocaine gel group and the room temperature 2% lidocaine gel group.

Pain score (during cystoscopy)	Cooled lidocaine gel	Room temperature lidocaine gel
0	1 (2.9 %)	1 (2.9%)
1	1 (2.9 %)	2 (5.7%)
2	5 (14.3%)	1 (2.9%)
3	5 (14.3%)	4 (11.4%)
4	10 (28.6%)	6 (17.1%)
5	10 (28.6%)	10 (28.6%)
6	2 (5.7%)	8 (22.9%)
7	1 (2.9%)	2 (5.7%)
8	0 (0%)	1 (2.9%)
Total	**35 (100%)**	**35 (100%)**

Table 4. The Comparison of pain scores in the cooled temperature 2% lidocaine gel group and the room temperature 2% lidocaine gel group.

	Pain score (Cooled lidocaine gel)	Pain score (Room temperature lidocaine gel)	P-value (<0.05)
During instillation 2% Lidocaine gel	2	2	0.496
During cystoscopy	4	5	0.037

The pain scores are shown in the format of median

Discussion

Outpatient cystoscopy is one of the most common procedures performed in the urology practice. A rigid cystoscopy is still commonly used in office urology today since a flexible cystoscopy has some disadvantages, such as a higher cost, lower quality of visual field, and it is more difficult to operate than the rigid cystoscopy.[2] In their studies on pain associated with cystoscopy, Muezzinoglu T et al[3] and Taghizadeh AK et al[4] reported that they had found no strong correlation between patient experience with the operation and pain scores. In the study by Choong S et al[5], the results show that urethral instrumentation using topical urethral anesthesia can be a painful and frightening experience, especially for younger patients.

Lidocaine first entered clinical practice in 1949[6]. Lidocaine is a lipid-soluble amide base capable of entering the hydrophobic components of neuronal cell membranes and preventing the transmembrane flow of sodium ions necessary for the initiation and propagation of nerve signal action potential[7]. Khan et al[8] demonstrated that the slow administration of gel (over 10 seconds) resulted in decreased urethral discomfort during instillation. In this study, the gel was delivered in both groups over a period of 10 seconds rather than the usual practice. After the instillation of lidocaine gel, we waited about 10 minutes before starting cystoscopy. Burke D et al[9] showed evidence that reducing norciceptor temperature will lead to reduced nociceptor responsiveness and therefore a reduced perception of pain.

Some studies have shown that changing the temperature of the local anaesthesia could reduce pain during instillation. While no benefit was demonstrated when warm (40°C) lidocaine gel was delivered into the male urethra [10], cooled lidocaine hydrochloride solution at 4°C significantly reduced discomfort during instillation because a reduced temperature leads to reduced nociceptor responsiveness, and thus reduced discomfort associated with the instillation of the cooled gel.

In this study, the effect of the cooled lidocaine gel (4°C) on cystoscopy-related pain was evaluated and compared with room temperature (22°C) lidocaine gel. The pain was evaluated using the numeric rating scale (NRS). NRS has good sensitivity and is appropriate in clinical practice as a result of its simplicity.[11] From the results, no significant decrease of pain was seen during the instillation period between the 2 groups, which contradicts the previously mentioned study. However, pain scores during the procedure in the cooled temperature 2% lidocaine gel group were statistically lower than in the room temperature 2% lidocaine gel group. We cannot explain this unexpected result, but it may imply that the effect from the cooled temperature could have led to the reduced nociceptor responsiveness of the urethral surface when we manipulated the rigid cystoscope.

This study has some limitations. There are several factors that can affect the pain score during cystoscopy, such as prostate size, skill of the surgeon, and personal pain tolerance. Different surgeons with different skills may be the cause of the uneven severity of pain. For better accuracy and data reliability, a single surgeon is required.

Conclusion

Transurethral cooled 2% lidocaine gel significantly reduced pain during cystoscopy when compared with the instillation of normal temperature 2% lidocaine hydrochloride. However, it did not significantly reduce pain perception scores during gel instillation. A larger study is needed in order to assess the effectiveness of this technique.

References

1. Goel R, Aron M. Cooled lignocaine gel: does it reduce urethral discomfort during instillation? International urology and nephrology. 2003;35: 375-377.
2. Yoshimura R, Wada S, Kishimoto T. Why the flexible cystoscope has not yet been widely introduce?: a questionnaire to Japanese urologists. Int. J. Urol. 1999;6:549-559.
3. Muezzinoglu T, Ceylan Y, Temeltas G, Lekili M, Buyuksu C. Evaluation of pain caused by urethrocystoscopy in patients with superficial bladder cancer: a perspective of quality of life. Onkologie 2005;28:260-264.
4. Taghizadeh AK, El Madani A, Gard PR, Li CY, Thomas PJ, Denyer SP. When does it hurt? Pain during flexible cystoscopy in men. Urol. Int. 2006;76:301-303.
5. Choong S, Whitfield HN, Meganathan V et al. A prospective, randomized, double-blind study comparing lignocaine gel and plain lubricating gel in relieving pain during flexible cystoscopy. Br J Urol 1997;80:69-71.
6. Gordh T. Xylocaine: a new local analgesic. Anaesthesia 1949; 4: 4-9.
7. Rogers HJ, Spector RG, Trounce JR. Local anaesthetics. In Rogers HJ, Spector RG, Trounce JR, eds, A Textbook of Clincal Pharmacology, 1st edn, Chapt 11, London: Hodder and Stoughton, 1985:343-344.
8. Khan MA, Beyzade B, Tau W et al. Effect of the rate of delivery of lignocaine gel on patient discomfort perception prior to performing flexible cystoscopy. Urol Int 2002;68:164-167.
9. Burke D, Mogyoros I, Vagg R, Kiernan MC. Temperature dependence of excitability indices of human cutaneous afferents. Muscle Nerve 1999;22:51-60.
10. Thompson TJ, Thompson N, O'Brien A et al. To determine whether the temperature of 2%lignocaine gel affects the initial discomfort which may be associated with its instillation into the male urethra. BJU Int 1999;84:1035-1037.
11. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J. Clin. Nurs. 2005;14:798-804.