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Comparison of pain intensity between lidocaine gel and intraurethral tramadol with lidocaine gel during rigid cystoscopy in men

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Abstract

Background: Local anesthesia as lidocaine gel has long been used for cystoscopy using a rigid cystoscope. Recently, tramadol was discovered to also have a local anesthetic effect.

Objectives: We aimed to examine the difference in pain intensity between intraurethral injections of tramadol combined with lidocaine gel and sole lidocaine gel during cystoscopy.

Methods: A prospective comparative study was conducted in Kathmandu Medical College and Teaching Hospital, Kathmandu among 120 males who underwent rigid cystoscopy. All patients were divided into 2 groups, in which group 1 was given a combination of tramadol and lidocaine gel urethral injection 10 minutes before rigid cystoscopy, whereas group 2 was given lidocaine gel urethral injection 10 minutes before rigid cystoscopy. Patient tolerance during the procedure was assessed using visual analogue pain scale score. The scores were recorded three times, first during the entrance of the cystoscope, then during cystoscopy, and finally 15 minutes after removal of the cystoscope.

Results: The visual analogue pain Scale score at the commencement of the procedure, middle of the procedure, and 15 minutes after removal of the cystoscope in lignocaine group was 3.90 ±1.003, 5.75 ± 1.24 and 3.34 ± 1.024 respectively. Similarly, visual analogue pain scale score at the commencement of the procedure, middle of the procedure, and 15 minutes after removal of the cystoscope in lignocaine and tramadol group was 3.43 ±1.079, 5.5 ±1.33 and 2.73± 1.23 respectively. Mean pain scores in all stages were found to be significantly lower in the patients who received lidocaine and tramadol at the entrance of cystoscope, during cystoscopy and 15 min after end of cystoscopy as shown by p-value of 0.03, 0.028 and 0.03 respectively.

Conclusion: The combination of intraurethral tramadol and lidocaine gel can significantly decrease pain during rigid cystoscopy in men more effectively than sole intraurethral lidocaine gel.

Key words: Cystoscopy; Lignocaine gel; Tramadol; Visual Analogue pain Scale score.

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INTRODUCTION

Cystoscopy is a widely used diagnostic procedure that can typically be carried out in a urology office. It serves as an effective tool for diagnosing various urologic conditions and can also offer therapeutic benefits in certain situations.[1,2] Local anesthesia as lidocaine gel has long been used for cystoscopy using a rigid cystoscope.[3] The rigidity of the cystoscope sheath can cause discomfort or even pain because of the friction between the sheath and the walls of the urethra or bladder mucosa. This discomfort might lead to the premature termination of the procedure, potentially resulting in missed diagnosis.[4,5]

Lidocaine 2% gel is a local anesthetic that works by disrupting signal transmission in neurons. It achieves this by blocking the fast voltage-gated sodium channels in the neuronal cell membrane, which are crucial for action potential propagation.[6] Tramadol, a synthetic analog of 4-phenylpiperidine, is an analgesic used to treat moderate to severe pain. Its mechanism of action in the central nervous system helps manage pain without typically causing respiratory or cardiovascular side effects[7] However, recently tramadol was discovered to also have a local anesthetic effect.

Therefore, we aimed to examine the difference in pain intensity between intraurethral injections of tramadol combined with lidocaine gel and sole lidocaine gel during cystoscopy.

METHODOLOGY

This is an experimental study conducted at the Department of Urology, Kathmandu Medical College and Teaching Hospital, Nepal over a period of six months (from January 2022 to June 2023) after taking ethical approval from Institutional Review Committee (Ref. 30122022/03). As most of the cystoscopy was done for stent removal post stone surgery, sample size calculation was done using prevalence rate of renal stone in Asian population from study by Yu Liu et al.[8] as 8%. The sample size formula, n = z2pq/e2 was used. Considering p = 0.5 (50%); z = 1.96 at 95% confidence level; q = 1-p; and e = 0.05 at 5% margin of error, the sample size calculated was 113.4≈114. A total of 120 male patients above 18 years with ASA status 1 and 2, undergoing rigid cystoscopy were enrolled in each study group. Patients allergic to tramadol or lignocaine were excluded from the study. Informed consent was taken from all the participants, and they were allocated in experimental group (lidociane gel plus tramadol) and control group (lidocaine alone). All patients were divided into 2 groups, in which group 1 was given lidocaine gel urethral injection 10 minutes before rigid cystoscopy whereas group 2 was given a combination of tramadol and lidocaine gel urethral injection 10 minutes before rigid cystoscopy. Patients who have undergone rigid cystoscopy on the odd days of the calendar were assigned to lignocaine gel group, and the patients undergoing cystoscopy on the even days of the calendar were assigned to tramadol and lidocaine gel group.

Prior to the procedure, complete history was taken, and physical examination was done. During the process of cystoscopy, patient was examined in lithotomy position and urethral meatus and surrounding parts were sterilized with povidone iodine.

Group 1 was injected with 10 ml of 2% w/v (300 mg) lidocaine gel (Lox Jelly 2%, Neon Laboratories Limited) mixed with 2 ml normal saline through the external urethral meatus using a 20cc syringe. Group 2 was injected with 10 ml of 2% lidocaine gel mixed with 100 mg of tramadol dissolved in 2 ml normal saline through the external urethral meatus using a 20cc syringe. After the injection, a clamp was placed posterior to the coronary sulcus for 10 minutes to prevent ejection and to facilitate dwell time for lubricant penetration and absorption into the tissue. After 10 minutes of instillation of assigned lubricant gel patients were subjected for cystoscopy using a Karl Storz 19 Fr cystoscope. Sterile saline irrigation was used during the process. Operator were unaware of the analgesics provided.

Patient's tolerance during the procedure was assessed by an assistant who was blinded and was using Visual Analogue pain Scale (VAS) score. Scores are based on self-reported measures of symptoms that are recorded with a single handwritten mark placed at one point along the length of a 10-cm line that represents a continuum between the two ends of the scale—"no pain" on the left end (0 cm) of the scale and the "worst pain" on the right end of the scale (10 cm).[9] The scores were recorded three times, first during the entrance of the cystoscope, then during cystoscopy, and finally 15 minutes after removal of the cystoscope.

All patients were examined for post-procedure nausea, vomiting, and hallucinations and were kept in observation at recovery room till one hour after the procedure. All patients were discharged with tablet paracetamol as per requirement.

Data were analyzed using the statistical package for social sciences, SPSS version 27. The continuous variables were analysed by using the independent t-test.

RESULTS

Total 120 male patients were included in the study. The mean age of the patient undergoing rigid cystoscopy was 40.2 ±14.18 with the range from 16 to 78 years. Various indications for cystoscopy are shown in Table 1.

The mean age of patients in lidocaine gel group was 40.65 ± 14.28 years while in lignocaine plus tramadol group was 39.75 ±14.08 years. There was no significant difference between the 2 groups in terms of age. (Table 2)

The mean cystoscopy time in the lidocaine only group was 6.02 ±1.18 minutes while it was 5.78 ± 0.97 minutes

in lidocaine plus tramadol group which was comparable as shown by the p value of 0.107. (Table 2)

The VAS score at the commencement of the procedure, middle of the procedure, and 15 minutes after removal of the cystoscope in both groups were measured. Mean pain scores in all stages were found to be significantly lower in the patients who received lidocaine and tramadol as shown in Table 3. In all groups, no episodes of severe pain were noted that necessitated stopping the procedure.

DISCUSSION

Rating acute pain using a VAS is an essential part of pain assessment. It is widely recognized that cystoscopy often causes some level of discomfort, regardless of the instrument used, prompting the use of various methods to alleviate it. To make rigid cystoscopy more tolerable, several anesthetic options are available. For instance, a lubricating gel containing 2% lidocaine is frequently applied prior to the insertion of transurethral instruments, serving both as a lubricant and a local anesthetic. However, topical lidocaine gel is absorbed slowly and may not be fully effective.

In this study, when evaluating the effectiveness in both the groups, lignocaine gel + tramadol group performed better than single lignocaine gel group in term of improved VAS score during entrance of cystoscope, during cystoscopy and 15 minutes after end of cystoscopy. This finding was supported by a study done by Cahyo Wijayanto et al, who concluded that the combination of intraurethral tramadol and 2% lidocaine gel significantly decrease pain during DJ stent removal more effectively than sole intraurethral 2% lidocaine gel based on the Wong-Baker pain scale.[10]

Moharari et al. also revealed that instillation of lidocaine gel in conjunction with ketamine in the urethra could decrease pain perception, helping men undergo outpatient rigid cystoscopy more comfortably.[10]

Opioids have long been the mainstay for post-operative pain relief. Recent studies have similarly shown the efficacy of localized opioids such as tramadol .[12]

Khajavi et al studied sixty male candidates who underwent diagnostic cystoscopy using tramadol and lignocaine gel. He also found out the median values of pain numerical rating score significantly lower in the intervention group (tramadol and lidocaine gel) at the time of insertion of probe of cystoscope, 10 min after the insertion of the cystoscope, and at the end of cystoscopy as compared to control group. Mean total pain score was 35·5±1·57 in the control group compared to 29·4 ± 2·39 in the intervention group which showed that pain in the intervention group was significantly lower than the control group (P=0·037).This finding was similar to our study which showed VAS score during entrance of cystoscope, during cystoscopy and 15 minutes after end of cystoscopy was significantly less in intervention group. [13]

Table 1: Indications of cystoscopy

Indications	n (%)
Lower Urinary Tract Symptoms	29 (41.4)
DJ stent removal	26 (37.1)
Surveillance of bladder tumor	7 (10.0)
Hematuria	5 (7.1)
Others	3 (4.3)

Table 2: Age and duration of cystoscopy

Variables	Lidocaine gel (mean± SD)	Lidocaine gel plus Tramadol (mean ±SD)	p= value
Age (In years)	40.65 ± 14.28	39.75 ± 14.08	0.77
Duration of cystoscopy (minutes)	6.01 ± 1.16	5.83 ± 0.95	0.106

Table 3: Comparison of Mean Visual Analogue Scale (VAS) Score

VAS score	Lidocaine gel (mean± SD)	Lidocaine gel plus Tramadol (mean ±SD)	p-value[a]
Entrance of cystoscope	3.90 ±1.003	3.43 ±1.079	0.03*
15 min after end of cystoscopy	3.34 ± 1.024	2.73± 1.23	0.03*

[a] Independent sample t-test, *p-value significant at <0.05

This study considers limited number of samples and study period. Other limitations of this study were the assessment of post-procedural pain which was only evaluated in the short term. The consistency in the findings of study outcomes (pain, opoid use, urologist satisfaction) can also show the clinical importance of these results. The link between the blood concentrations of tramadol and the resulting analgesic effects were also not evaluated in this study.

CONCLUSION

The combination of intraurethral tramadol and lidocaine gel can significantly decrease pain during rigid cystoscopy in men more effectively than sole intraurethral lidocaine gel.

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