$NaHCO_3$-Buffered Lidocaine Gel for Outpatient Rigid Cystoscopy in Men

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Purpose: *The purpose of this study was to explore the effect of $NaHCO_3$-buffered lidocaine gel as a topical anesthetic agent for pain relief for rigid cystoscopy.*
Design: *Prospective randomized controlled trial.*
Methods: *ASA I-II male patients undergoing rigid cystoscopy randomly received 10 mL 2% Carbocaine lidocaine gel with 1 mL 0.9% saline (group 1) or 1 mL 5% $NaHCO_3$ solution (group 2). After 3 minutes exposure, the cystoscope was inserted into the urethra. On receiving the gel, cystoscope insertion, and intravesical observation, pain score was recorded using the visual analog scale.*
Findings: *The gel pH with or without $NaHCO_3$ was 7.20 and 6.41, respectively. The concentration of soluble lidocaine in the gel was stable for 24 hours or more. The visual analog scale score in group 2 was significantly lower (1.3 ± 0.9) than in group 1 (5.28 ± 1.99). No adverse effects were recorded.*
Conclusion: *Alkalized lidocaine gel resulted in successful analgesia for rigid cystoscopy in men without adverse effects.*

Keywords: *topical anesthesia, alkalization, lidocaine gel, cystoscopy.*

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CYSTOSCOPY IS A painful procedure. For outpatients, especially in clinics without a PACU, topical anesthesia is a safe and practical strategy. Lidocaine gel has been widely used as a topical anesthetic for cystoscopy in men, based on its simultaneous roles as a lubricant and local anesthetic. To provide effective pain relief for cystoscopy, some authors have examined the volume,[1] temperature,[2] and instillation time[3] of lidocaine gel as variables, but there are still reports suggesting that it does not reduce, but rather causes pain during urethral delivery.[4]

Pharmacologically, lidocaine is a lipid-soluble amide that enters the hydrophobic component of neural membranes and prevents the transmembrane flow of sodium ions necessary for initiation and propagation of action potentials. Commercial lidocaine cartridges are purposefully formulated as relatively acidic solutions (relative to the physiological pH of 7.4) to enhance the solubility and stability of the anesthetic salts. It is well established that increasing the pH of lidocaine solution with bicarbonate improves its anesthetic potency and facilitates its diffusion by increasing the percentage of the nonionized form.[5-7] In vitro and in vivo studies have both shown that increasing the pH of the local anesthetic solution toward the physiological range improves the quality of neural blockade[7] and results in a more rapid onset time of brachial plexus as well as epidural blockade.[6,8,9]

In this study, we performed a prospective randomized controlled trial to evaluate the efficacy of carbonated lidocaine gel for rigid cystoscopy in male patients.

Methods

Buffering the pH of Lidocaine Gel

At room temperature, 0.5 mL, 1.0 mL, 1.5 mL, 2.0 mL or 2.5 mL of 5% (wt/vol) $NaHCO_3$ solution (Jinyao-Pharm GmbH; Taixin, Tianjin, China) was added to tubes containing 10 mL of 2% lidocaine hydrochloride gel (Jichuan-Pharm GmbH). After thorough mixing, the pH of the buffered gel was measured with a pH detector (Delta 320; Mettler, Shanghai, China) at room temperature (23°C to 25°C). The mixture was kept at room temperature for 24 hours, and the soluble lidocaine in the gel was measured using high-performance liquid chromatography. The measurement was repeated three times, and the median value was taken.

Clinical Observation

Patients with ASA I or II physical status, scheduled for rigid cystoscopy, were recruited after informed consent was obtained, along with approval by the Clinical Research Ethics Committee of The Third Hospital of Hebei Medical University. A random number table was used to divide the patients into two groups: group 1 received 10 mL 2% lidocaine hydrochloride gel + 1 mL 0.9% saline; and group 2 received 10 mL 2% lidocaine hydrochloride gel + 1 mL 5% $NaHCO_3$ solution. Patients who had an episode of hypersensitivity to amide-linked anesthetic agents, a sensory disorder such as spinal cord injury, or using regular analgesics or sedatives were excluded from the study.

No premedication or sedative was administered to the patients in either group. After the patients entered the endoscopy room, heart rate (HR), noninvasive arterial blood pressure, and peripheral oxygen saturation (SPO_2) were monitored with a Philips Hemodynamic System (Philips Corporation, Beijing, China). Blood pressure was measured every 3 minutes, and HR and SPO_2 were determined continuously. The patients were placed in the lithotomy position. After cleaning the penis with iodophor solution, the gel was instilled into the urethra with a 20-mL syringe with no needle. The urethra was closed with a penile clamp, and the penile urethra was massaged so as to squeeze the gel into the posterior urethra. Cystoscopy was initiated after 3 minutes exposure. During the gel instillation, cystoscope insertion, and intravesical observation, an independent person evaluated the patient regarding pain. Subjective pain was assessed using the visual analog scale (VAS) score from 0 to 10, where 0, no pain at all and 10, worst pain imaginable. After removal of the cystoscope, patients were asked whether they were still scared of cystoscopy. HR, blood pressure, and SPO_2 were registered, and patients were questioned whether they had lightheadedness and dizziness.

Statistical Analysis

Statistical analysis was performed with SPSS for Windows, version 13.0. Student *t* test was used