

# Comparing 2% lidocaine gel (Dispogel and Cathejell) in cystoscopy

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## Abstract

**Objective:** Cystoscopy is a common urologic procedure. Analgesics are often used to reduce any pain associated with this procedure. The aim of this study was to investigate the efficacy in reducing pain and the cost-effectiveness of two forms of lidocaine gel in patients undergoing cystoscopy.

**Methods:** In this double-blind, randomized clinical trial, 77 male patients who were referred for double J removal, urethral dilatation, or cystoscopy were enrolled. The patients were divided into two groups: Dispogel and Cathejell. All patients received 20 mL of intraurethral lidocaine gel 2% and cystoscopy was performed 5 minutes thereafter. The primary outcome was the pain score (visual analogue scale, VAS) during and 5 minutes after cystoscopy.

**Results:** There were no statistically significant differences between the VAS scores, blood pressure, and pulse rate in the groups in either observation period. No patient required additional anesthetic agents or sedatives for insufficient pain relief.

**Conclusion:** The results of this study show that the analgesic efficacy of Dispogel and Cathejell in the treatment of pain during and after elective cystoscopy was the same, but Dispogel was more cost-effective.

## Keywords

2% lidocaine gel, Dispogel, Cathejell, cystoscopy, pain, cost-effectiveness, pain score, elective surgery

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## Introduction

Cystoscopy is among the most common urological procedures for evaluating various pathologies such as the urethra, prostate, and bladder and to evaluate lower urinary tract symptoms as well as the lower urinary tract anatomy.<sup>1</sup> The procedure is performed by inserting an optical instrument (cystoscope) into the urethra and bladder. The cystoscope can be metal, rigid, or flexible, and its placement may be associated with restlessness, pain, and discomfort in patients. It can be performed in a doctor's examination room or an operating room using local anesthesia or under an anesthetic (general or sedation).<sup>2</sup>

Cocaine was the first topical anesthetic agent that was reported for cystoscopy in 1884. Historically, a lubricating gel with 2% lidocaine was used as an intraurethral anesthetic, which has been the standard-of-care in men undergoing rigid cystoscopy, and this practice continued after the introduction of a flexible cystoscope.<sup>2</sup> The ideal anesthetic agents used in the urethra for local anesthesia are expected to have no systemic side effects, and they should be inexpensive, fast-acting, and have a sufficient effect during the procedure.<sup>3</sup> Lidocaine-containing gels are the types used as local anesthetics and lubricants in urology clinical practice. Dispogel (DM) and Cathejell (CM) lidocaine anaesthetizing gels are used for catheter lubrication, and they have a local anesthetic effect following instillation into the urethra before catheterization; pain is relieved through an anesthetic effect. Cathejell contains lidocaine hydrochloride as the medically active ingredient and its onset of action is 5 minutes following instillation of the gel. Dispogel is sterile, water-soluble, clear, and tissue-compatible, and it also provides an additional anesthetic effect because it contains lidocaine. Thus, patients are relaxed and iatrogenic injuries resulting from spasticity are minimized.

Several clinical trials have been conducted to determine the most suitable method for making this procedure more tolerable.<sup>1,3</sup> Cystoscopy can be performed in the urologist's examination office using anesthesia, which is less expensive than performing the procedure in an operating room. The aim of this study was to investigate the patient's pain perception and the cost-effectiveness of two different forms of lidocaine gel.

## Methods

After approval by the Faculty Ethics Committee, male patients 18 to 65 years of age who were scheduled to undergo American Society of Anesthesiologists (ASA) I-II and elective cystoscopy were enrolled into the study. Patients who refused the procedure or demanded general anesthesia, who had a history of allergy to local anesthetic agents, who had used analgesics in the last 24 hours, those who use analgesics regularly, those with a history of chronic pain, and those who were not eligible for local anesthesia were excluded from the study. A visual analogue scale (VAS) was used as the standard method to evaluate the pain levels. The cystoscopy procedure and the VAS (0=no pain and 10=the most severe pain) were explained to all patients in the preoperative period. Patients who agreed to participate in this research provided written informed consent while making necessary preparations for cystoscopy and before study procedures were performed. Noninvasive blood pressure, electrocardiogram (ECG), and peripheral oxygen saturation data were obtained from the patients, and those who were not premedicated were taken to the operation room. Vital functions of all patients were recorded after intravenous vascular access, and patients were randomized to one of the following two groups: Cathejell (12.5 g disposable tube, CM group) or Dispogel

(12.5 g disposable tube, DM group). Patients undergoing lithotomy had the required surgical sterilization procedures performed followed by administration of 2% lidocaine gel based on their experimental group. The lidocaine gel was placed into the urethra 5 minutes before the procedure. A penile clamp was used to prevent backflow of the substance administered to the urethra and to ensure better penetration into the tissue to provide standardization. The patient was blinded to the drug that was used. Cystoscopy was performed using a sterilized 1940 F rigid cystoscope (Karl-Storz Inc., Tuttingen, Germany) with 40 cm of water pressure. The degree of pain was evaluated during and after cystoscopy using a VAS scale. Patients with a VAS score >4 were treated with 1 mg/kg of intravenous fentanyl and 2 mg of midazolam and these patients were excluded from the study after the pain had resolved. All patients were followed up postoperatively at the end of the procedure and those with stable vital functions who felt fine were sent to the urology clinic. Additionally, during the planning phase of the current study, we obtained the cost of Dispopel and Cathejell from at least three suppliers to determine cost effectiveness.

### Statistical analyses

Statistical analyses were performed using SSPS version 16.0 for Windows computer software (SSPS, Chicago, IL, USA). The normality of the variables within the groups was measured using the Shapiro–Wilk test. Differences between groups were evaluated using an independent sample *t*-test and the Mann–Whitney *U*-test. Paired sample *t*-tests and the Wilcoxon test were used for intergroup repeating tests where appropriate. The Yates corrected  $\chi^2$  test was used for category changes in the groups. Differences between the groups used were determined using the Fisher's

**Table 1.** Patient Demographic Characteristics.

Variable	DM Group (n = 38)	CM Group (n = 42)	P value
Age (years)	64 ± 1	65 ± 0.2	0.523
Prostate volume (mL)	64 ± 2.5	62 ± 4.1	0.741
Duration of procedure (min)	48 ± 3.5	51 ± 5.2	0.425
BMI (kg/m <sup>2</sup> )	23 ± 4.4	22 ± 6.1	0.637

Data are presented as the mean ± SD. DM group, lidocaine 2% (Dispopel 12.5 g); CM group, lidocaine 2% (Cathejell 12.5 g); BMI, body mass index.

exact test. A *p* value of less than 0.05 was considered to be statistically significant. Data are expressed as the mean ± standard deviation (SD) or numbers (n).

### Results

There were 72 male patients who were undergoing elective cystoscopy (age range, 18–65 years) enrolled into the study. The demographic characteristics, prostate volume, and duration of the procedure were similar (Table 1). Table 2 presents a comparison of the average 2% lidocaine gel and pain scores between the groups. There was no statistically significant difference between the groups in terms of VAS scores in all observation periods. No statistically significant relationship was observed between DM and CM groups. No patients required additional anesthetic agents or sedatives for insufficient pain relief, and no participants displayed a major complication except some injection-related effects such as urethral pain and hemorrhage. Additionally, the cost of Dispopel and Cathejell was obtained from at least three suppliers before starting the study. We found that Cathejell was almost two-times more expensive than Dispopel.

### Discussion

The analgesic efficacy of DM and CM in the treatment of pain during and after

**Table 2.** Comparison of pain, blood pressure, and pulse rate between groups.

Variable	DM Group (n = 38)	CM Group (n = 42)	P value
<b>VAS</b>			
during procedure	3.7 ± 1.2	3.8 ± 0.9	0.521
after procedure	2.2 ± 0.4	2.1 ± 0.5	0.624
<b>BP (mmHg)</b>			
change	13 ± 1.3	12 ± 1.2	0.365
before procedure	11 ± 2.4	12 ± 2.1	0.412
after procedure	14 ± 2.8	13 ± 1.9	0.252
<b>PR (beats/min)</b>			
before procedure	79 ± 2.5	82 ± 1.5	0.561
after procedure	78 ± 4.6	83 ± 2.4	0.458

Values are presented as the mean ± standard deviation (SD). DM group, lidocaine 2% (Dispogel 12.5 g); CM group, lidocaine 2% (Cathejell 12.5 g); VAS, visual analog scale; BP, blood pressure; PR, pulse rate.

elective cystoscopy was the same in this prospective randomized study. This method is also cost-effective because of a shorter operative time with DM. Cystoscopy is the most common surgical procedure used in urology clinics. When performed under local anesthesia, a flexible cystoscope may be used to reduce patient anxiety and procedure discomfort.<sup>4</sup> Local anesthetics are drugs that reversibly block impulse conduction when they come into contact with nerve fibers and when the anesthetic is used at an appropriate concentration. Local anesthetics affect the nerve fiber membrane and the membranes of all inducible cells in a dose-dependent manner.<sup>5</sup> The gel form of lidocaine-containing materials is used as local anesthetic and lubricants in urology practice.<sup>6</sup> However, cystoscopy is performed as an outpatient treatment using 2% lidocaine gel under local anesthesia in clinics that are not equipped for the high clinical workload and general anesthesia.<sup>7</sup> Various studies have been performed on the necessity of local anesthesia in men undergoing cystoscopy and the amount, exposure time, and

temperature of the anesthetic gel have been well discussed in previous reports. The experience of the surgeon performing the procedure also seems to affect the degree of pain felt during cystoscopy, as does the patient's previous experience with cystoscopy. Schede and Thuroff evaluated the effect of lidocaine gel on analgesia during endoscopic procedures in a retrospective study, and they concluded that the best result is obtained when 20 to 30 mL of the gel is injected into the urethra.<sup>8</sup> A meta-analysis in 2009 showed that lidocaine gel reduced moderate to severe pain during flexible cystoscopy.<sup>9</sup> In the present study, there was no significant difference in the patients' estimation of pain in the DM and CM groups. However, DM was found to be a cost-effective analgesic. Chen et al.<sup>10</sup> showed that lidocaine gel is a cost-effective analgesic method that dramatically reduces the need for analgesic use and hospitalization after cystoscopy.

The optimum indwelling time that is necessary for the lidocaine gel anesthetic effect to be reached in the urethra before starting the procedure remains controversial. The Prescribing Information for Xylocaine<sup>®</sup> indicates that the onset of lidocaine gel action is about 3 to 5 minutes.<sup>11</sup> It is a common practice to perform cystoscopy within 5 minutes after the intraurethral instillation of lidocaine gel in busy outpatient clinics.<sup>12</sup> In our study, DM and CM gel remained in the urethra of all patients for 5 minutes based on the Prescribing Information.<sup>11</sup>

This study has some limitations. First, this was a single center study with a relatively small sample size. Second, the patients in this study were observed for a short period of time and none of the participants displayed a major complication except some injection-related effects. However, based on the literature review, this study is the first clinical double-blind study to evaluate the role played by DM

and CM anesthesia in urologic procedures. It is recommended that future studies are performed with larger sample sizes. This method can also be used in other endoscopic procedures such as urethral stone removal and internal urethrotomy.

The findings of the present study suggest that DM and CM significantly reduce pain perception immediately after cystoscopy and that DM is more cost-effective than CM. Thus, the proposed method can be used as an effective method of pain control during cystoscopy, thereby reducing the need for anesthesia. Studies with larger sample sizes should be performed in the future.

### Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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