Use of Lidocaine 2% Gel Does Not Reduce Pain during Flexible Cystoscopy and Is Not Cost-Effective

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Purpose: To compare the use of lubricant gel with lidocaine versus lubricant gel without anesthetic in flexible cystoscopy in terms of pain and tolerability.

Materials and Methods: In this observational non-randomized study, 72 patients were divided into two groups. Group 1 included 38 patients in whom lidocaine gel 2% was used and group 2 included 34 patients in whom lubricant gel without anesthetic was administered. The main variables analyzed were score in visual analogue scale (VAS) and score in Spanish Pain Questionnaire (SPQ). Student's *t*-test and Chi-square test were used to compare differences between 2 groups. The *P* values < .05% were considered statistically significant.

Results: Mean age of patients in group 1 was 64.50 ± 12.39 years and 67.79 ± 10.87 years in group 2 (*P* = .23). The distribution according to sex was 29 men and 9 women in group 1 and 25 men and 9 women in group 2 (*P* = .78). The total VAS score was 2.21 ± 2.05 in group 1 versus 1.59 ± 1.61 in group 2 (*P* = .16). In the SPQ, the current intensity value was 1.82 ± 0.86 in group 1 versus 1.53 ± 0.74 in group 2 (*P* = .14), and the total intensity value was 1.92 ± 1.86 in group 1 versus 1.03 ± 1.75 in group 2 (*P* = .04). The cost of gel with lidocaine is 1.25 euro and gel without anesthetic 0.22 euro.

Conclusion: The use of lidocaine gel does not produce benefit in terms of pain relief in flexible cystoscopy and also is costly.

Keywords: cystoscopy; methods; adverse effects; diagnosis; anesthetics; local; lidocaine; therapeutic use; treatment outcome; pain prevention & control; pain measurement.

INTRODUCTION

Flexible cystoscopy is a very useful outpatient technique for studying the urethra and bladder, and especially for diagnosis and management of lower urinary tract diseases. In most cases cystoscopy is performed with local anesthesia. This technique revolutionized the diagnostic area in urology, resulting in the replacement of rigid cystoscopy with flexible cystoscopy in most hospitals.[1] Although the diagnostic cystoscopy procedure can be performed using either rigid or flexible cystoscope, in men it is preferable to use flexible instruments because it is better tolerated, causing less pain and fewer complications.[2] In women, however, indiscriminate use of flexible or rigid cystoscopy is generally well tolerated.[3,4] Overall, cystoscopy is not associated with a high perception of pain, although it is an uncomfortable procedure that usually produces more pain with the first procedure and less pain in subsequent procedures.[5]

Flexible cystoscopy can be performed with or without local anesthetic lubricant (mainly lidocaine). Choosing each, depends primarily on the availability at the hospital and preference of the urologist performing the procedure, since there is no uniformity about whether the use of lubricant gel with or without anesthetic is better. Some studies indicate that the gel with lidocaine reduces moderate to severe pain during the procedure,[5] while others concluded that there is no significant difference in visual analogue scale.[6] The aim of this study was to evaluate the differences in visual analogue scale (VAS) and the Spanish pain questionnaire (SPQ) score in patients undergoing flexible cystoscopy using lubricant gel with 2% lidocaine versus lubricant gel without anesthetic.

MATERIALS AND METHODS

Study Design

This is a non-randomized observational study comparing the use of lidocaine 2% gel versus lubricant gel without anesthetic in patients undergoing simple flexible cystoscopy. Patients were recruited between September and December 2014. The indications for cystoscopy were hematuria, bladder cancer follow-up, lower urinary tract symptoms (LUTS), recurrent urinary tract infections, and others. The procedure was performed by two different urologists with the same level of experi-

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ence in flexible cystoscopy. One urologist used lubricant gel with lidocaine and the other used lubricant gel without anesthetic, following their usual clinical practice. The nurse was blinded for the type of lubricant.

Consecutive patients attending the urology outpatient clinic in the urology department in La Inmaculada Hospital in Huercal-Overa (Almería, Spain) were selected for this study. Inclusion criteria were men or women ≥ 18 years of age with hematuria, bladder cancer follow-up, LUTS, or recurrent urinary infections. Exclusion criteria were patients younger than 18 years old with suspicion for urethral stricture, permanent bladder or suprapubic catheter, ureteral stent, active urinary tract infection, or sensibility problems. All patients were informed about the study and their informed consent was obtained. The Ethics Committee of our Health Area approved the study protocol.

All procedures were performed in the same manner: supine (men) or lithotomy (women) position, skin and genital preparation with povidone iodine, and introducing an 18 French (F) flexible cystoscope using gel with lidocaine or gel without anesthetic. A total of 72 patients were recruited and divided into two groups: group 1 included 38 patients who underwent flexible cystoscopy with lubricant gel with lidocaine 2%. Group 2 included 34 patients who underwent flexible cystoscopy with lubricant gel without anesthetic.

Main Variables

The main variables studied after the procedure were the pain score evaluated using visual analogue scale (VAS) and Spanish pain questionnaire (SPQ).[7] The SPQ is consisting of two parts: current intensity value (0-14 points) and total intensity value (0-5) and VAS is measured as mild pain (0-3), moderate pain[4-7], or intense pain[8-10]. Others variables analyzed include sex, age, reason for cystoscopy, results of cystoscopy and cost.

Statistical Analysis

For a study population of 150,000 inhabitants, taking a precision of 5% and (1-α) of 95%, and 5% of dropout rate, at least 72 patients are needed. Statistical analysis was performed using Student's *t*-test for analysis of qualitative and quantitative variables and Chi-squared test for analysis of dichotomous variables. A multivariate analysis was performed by binary logistic regression model. Normality of variables was checked using Kolmogorov-Smirnov test and analysis of variance with Levene's test was also performed. Statistical significance was set as $P < .05$. Analyses were performed with Statistical Package for the Social Science (SPSS Inc, Chicago, Illinois, USA) version 17.0 for Windows.

RESULTS

Seventy-two patients were included in the study with a mean age of 64.50 ± 12.39 years in group 1 and 67.79 ± 10.87 years in group 2 ($P = .23$). The sex ratio (men:-women) was 29:9 in group 1 and 25:9 in group 2 ($P = .78$). The body mass index in group 1 was 28.7 ± 5.6 kg/m^2 and in group 2 27.9 ± 4.9 kg/m^2, with no statistically significant difference. About educational level, in group 1, 35% presented university studies, 40% medium studies and 25% basic studies and in group 2, 40% had university studies, 40% had medium studies and 20% had basic studies with no differences. In occupational status, in group 1, 25% were employed and 75% were retired, and in group 2, 20% were employed and 80% were retired, with no significant differences. The reason and results of cystoscopy are shown in **Table 1**. The main pain score based on VAS was 2.21 ± 2.05 in group 1 versus 1.59 ± 1.61 in group 2 ($P = .16$). In the SPQ, the current intensity value was 1.82 ± 0.86 in group 1 versus 1.53 ± 0.74 in group 2 ($P = .14$), and the total intensity value was 1.92 ± 1.86 in group 1 versus 1.03 ± 1.75 in group 2 ($P = .04$). These data are depicted in **Figure**. In group 1, 24 patients presented a VAS ≤ 2 (mild pain) versus 26 patients in group 2, which had no statistically significant difference ($P = .221$). In a multivariate analysis by binary logistic regression including age, sex, occupational status, body mass index and education level, no significant relation have been observed (**Table 2**).

Table 1. Main reasons for and results of cystoscopy. No significant differences were observed in reasons for cystoscopy and results of cystoscopy analyzed with Chi-square test.

Variables	Group 1 (n = 38)	Group 2 (n = 34)
Reasons for cystoscopy, no.		
Bladder cancer follow up	19	20
Hematuria	8	6
LUTS	8	1
Others	3	7
Results of cystoscopy		
Normal	18	18
Bladder cancer	10	6
Edema / swelling	3	1
Trabecular bladder	0	1
Others	7	5

DISCUSSION

Some studies have analyzed the role of anesthetic lubricant in rigid and flexible cystoscopy tolerability. The studies have shown no differences in pain and tolerability between immediate and delayed placement of flexible cystoscopy after intraurethral anesthetic installation.[8,9] In the study by Herr and colleagues[8] with 288 patients undergoing flexible cystoscopy, they observed

Table 2. Multivariate analysis by binary logistic regression using different independent variables related to use lubricant with or without local anesthesia. No significant differences were observed.

Variables	Punctuation*		Gel	*P* Value
Sex	.253		1	.615
Age	1.812		1	.178
Body mass index	2.620	1	.106	
Education level	.013	1	.910	
Occupational status	.194	1	.660	
Global statistics	4.967	5	.420	

* Punctuation is a result coefficient of multivariate analysis that appears with SPSS program.

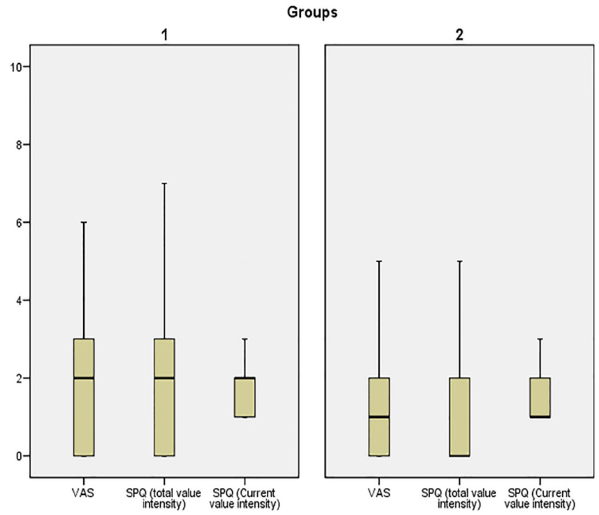

Figure. Comparison of Visual Analogue Scale (VAS) score and in Spanish pain questionnaire (SPQ) scores between two groups show no benefit for lubricant gel with lidocaine 2% in the flexible cystoscopy procedure.

that neither immediate nor delayed cystoscopy after the instillation of intraurethral lidocaine gel interfered with the results of the VAS. Losco and colleagues[9] agreed with Herr and co-workers' conclusion,[8] in that performing flexible cystoscopy immediately or delaying after the instillation of local anesthetic gel does not change the perception of pain by the patient.

Indeed, the controversy of whether or not intraurethral instillation with lidocaine improves tolerability and pain is ongoing. Studies have shown some benefit of lidocaine gel versus plain lubricating gel,[5,10] while others have shown no benefit in using an anesthetic except adding to the cost of the procedure.[11-13] Borch and colleagues[10] showed that intraurethral instillation of lidocaine 2% gel reduced pain compared to plain lubricating gel in patients undergoing cystoscopy. Similarly, Aaronson and colleagues[5] showed reduction in moderate to severe pain with the use of lidocaine gel compared to not using any local anesthetic. On the other hand, studies by Kobayashi and colleagues[10,11] demonstrated no benefit from the use of an anesthetic gel; moreover, the anesthetic gel may produce a more painful sensation in the patient. The study of Palit and colleagues[13] demonstrated that most patients undergoing flexible cystoscopy with lignocaine gel or lubricant gel without anesthetic, gave a score in VAS of < 3, with no significant differences between them. In the study by Chen and colleagues,[6] a score in VAS of 2.8 versus 2.6 was observed among patients undergoing flexible cystoscopy using lubricant gel with lidocaine 2% versus lubricant gel without anesthetic, respectively, with no statistically significant difference. In our study, the results demonstrate that the use of lubricant gel with lidocaine 2% give no benefit during the procedure and actually produces more pain based on SPQ (total intensity value). In fact, most patients in our study commented that the lubricant anesthetic gel produced a stinging sensation in the urethra. Also, the use of lubricant gel with lidocaine increased the cost of the procedure: the individual cost of lubricant gel with anesthetic is 1.25 euro and lubricant gel without anesthetic is 0.22 euro. As we know, there have been different studies assessing the tolerability of the procedure using intraurethral gel with local anesthetic versus no anesthetic. Some of the studies show the benefit of using local anesthetic gel, while in others no significant differences are observed. In our study, lubricant with lidocaine did not produce any benefit and added to the cost of the procedure. Therefore, we do not recommend its use. Other techniques, drugs or maneuvers have been used to reduce pain and improve tolerability during the cystoscopy procedure such as increased hydrostatic pressure during cystoscopy,[14] inhaled nitrous oxide,[15] and self-viewing during cystoscopy.[16-18] They appear to be effective, but they have yet to become popular and are not routinely used.

We know that our study have some limitations such as the number of patients and non-randomized manner, so it is necessary to design a randomized clinical trial with one surgeon and blinded to lubricant to avoid bias and to obtain a definitive conclusion.

CONCLUSIONS

As a conclusion of this study, the use of lubricant gel without anesthetic is recommended when performing flexible cystoscopy, as it is not associated with more pain sensation in comparison with lidocaine, in addition it is more cost effective than lidocaine gel.

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CONFLICT OF INTEREST

None declared.

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