

Patient Tolerance During Outpatient Flexible Cystoscopy

A Prospective, Randomized, Double-blind Study Comparing Plain Lubrication and Lidocaine Gel

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Objective: To compare the tolerance of flexible cystoscopy with topical anesthetic versus simple lubrication when the assigned lubricant is instilled 5 min before the exploration.

Material and Methods: A total of 185 consecutive patients were randomly assigned either to simple lubrication (Group 1) or to lidocaine hydrochloride gel (Group 2). Thirteen patients had some kind of difficulty during exploration (stenosis) that required additional manipulation or electrocoagulation for small relapses and were excluded from the final analysis, leaving 172 patients suitable for inclusion. After the intervention, all patients were surveyed regarding their discomfort and pain levels using a verbal scale and a visual analog scale ranging from zero to 10. A χ^2 analysis was performed for comparison of qualitative covariables, and quantitative covariables were compared using Student's *t*-test.

Results: The 172 patients were evenly distributed between the two groups. Of those in Group 1, 89% noted little or no discomfort, compared to 84% in Group 2. Some pain or intense pain was noted by 10% and 16% in Groups 1 and 2, respectively ($p > 0.05$). The average value on the visual analog scale was 2.10 and 1.97 in Groups 1 and 2, respectively ($p > 0.05$).

Conclusion: There are no differences in the perception of discomfort and pain by patients when anesthetic lubricant or simple lubrication are used if the waiting time before the exploration is 5 min.

Key words: cystoscopy, lidocaine, pain, urethra.

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Surveillance after treatment of superficial bladder tumors is performed by means of regular cystoscopy. A rigid cystoscope has traditionally been used, which causes discomfort and pain in the majority of patients (1). Today, flexible cystoscopy allows surveillance to be performed as an outpatient procedure. Because it causes less discomfort to patients and the equipment can be more easily prepared and maintained by ancillary staff, it is now the gold standard for bladder exploration (2). As with any other urethral exploration, passage of the flexible cystoscope requires the urethra to be lubricated. There are a number of products on the market, ranging from simple lubricants to lubricants containing local anesthetic in varying concentrations. Much of the information in the literature on the potential benefits of topical application of local anesthetic before urethral exploration is contradictory.

The objective of this research was to investigate differences in patient tolerance of bladder exploration with the flexible cystoscope using lubricants with and

without local anesthetic. In most studies, tolerance of the cystoscope has been reported 10–15 min after lubrication. However, this is a long waiting time and one that is not applicable in the majority of centers. In this study we shortened the waiting time to 5 min in order to apply our results to daily clinical practice.

MATERIAL AND METHODS

This was a prospective, randomized, double-blind study including 185 consecutive male patients who presented to our center for diagnostic evaluation of lower urinary tract symptoms or microhematuria or for surveillance of superficial bladder tumors. The local ethical committee approved the study.

Having being informed of the study and given their written consent to participate, the patients were randomly assigned to one of two groups (simple randomization was performed using a computer; the

researchers were blinded regarding the assignment) as follows:

- Group 1: sterile urethral lubrication with Johnson & Johnson K-Y[®] lubricant (10 ml applied using a sterile disposable syringe);
- Group 2: urethral lubrication with 2% Xylocaine[®] jelly (lidocaine hydrochloride; Astra Zeneca; direct application of 10–30 ml).

Of the 185 patients, 13 had some kind of difficulty during exploration (stenosis) that required additional treatment or had a small relapse that required electrofulguration (cystodiathermy) and were excluded. Therefore, 172 patients were included in the final analysis (86 in each group).

All patients were explored in the supine position and the urethral meatus was prepared with povidone–iodine dermal solution. The assigned lubricant (20 cm³ for each group) was instilled 5 min before the cystoscopy. A clamp was used to facilitate the dwell time and absorption. Cystoscopy was performed using a 14 F Olympus flexible cystoscope under video-camera guidance. Sterile saline irrigation was used at a pressure of 40 cm H₂O. Three urologists experienced in the technique performed all of the explorations.

We measured the perception of pain and the tolerance of the procedure by the patient using both a visual analog scale (VAS) as previously described (3) and a verbal scale immediately after the examination. Patients were asked about their tolerance of exploration using the following multiple-choice question: what did you feel during cystoscopy? The possible answers were as follows:

- (A) I felt no discomfort
- (B) I felt slight discomfort
- (C) I felt some pain and discomfort
- (D) The exploration was very painful
- (E) The exploration was agonizing.

The question was previously piloted in members of our Department of Urology and in 20 patients undergoing cystoscopy and the terms were subsequently adjusted to improve comprehension.

To ensure that the results of the examination did not influence the patient's perception of pain and tolerance, the results of the cystoscopy (clear or presence of relapse) were discussed following this interview.

Statistical analysis for comparison of covariables between the two groups was performed by means of the χ^2 test for qualitative covariables and Student's *t*-test for quantitative covariables. Data storage and statistical analysis were performed using the SPSS 10.0 statistical program.

Table I. Patient characteristics

Characteristic	Group 1	Group 2
Mean age (years) (SD)	65.31 (7.9)	66.12 (8.5)
Urologist; <i>n</i> (%)		
1	66 (38.3)	63 (36.6)
2	11 (6.3)	14 (8.1)
3	9 (5.2)	9 (5.2)
Type of cystoscopy; <i>n</i> (%)		
Diagnostic	11 (6.3)	8 (4.6)
Follow-up	75 (43.6)	78 (45.3)
Presence of tumor/relapse; <i>n</i> (%)		
No	73 (42.4)	78 (45.3)
Yes	13 (7.5)	8 (4.6)

RESULTS

All patients were males with an average age of 65.7 years (range 38–88 years). There were no differences between the groups in terms of age, the urologist performing the exploration, first exploration versus follow-up cystoscopy or the presence or absence of tumor/relapse (Table I)

Table II shows the perception of discomfort during exploration as reported verbally by the patients and using the VAS. In Group 1, 89.5% chose responses (A) or (B) to the multiple-choice question, as opposed to 83.7% in Group 2. Responses (C) or (D) were chosen by 10.4% in Group 1 and 16.2% in Group 2, and this difference was not statistically significant. No patient in either group chose response (E).

The average scores on the VAS were 2.10 and 1.97 in Groups 1 and 2, respectively and this difference was not statistically significant.

DISCUSSION

In experienced hands, flexible cystoscopy is well tolerated by the majority of patients (1, 2). Vriesema et al. (4) emphasized that, during a follow-up examination for superficial bladder cancer, most patients were satisfied with flexible urethrocystoscopy and would not change it for an alternative non-invasive urinary test with a lower sensitivity. Nevertheless, we need to ensure that the technique is well tolerated in order to continue performing it as an outpatient procedure and

Table II. Distribution of responses to the verbal test and scores on the VAS

Response	Group 1	Group 2
(A) or (B) (%)	89.5	83.7
(C) or (D) (%)	10.4	16.2
(E) (%)	0	0
Mean score on VAS (SD)	2.10 (1.46)	1.97 (1.19)

to reduce to a minimum the number of men who refuse exploration.

This report confirms our belief that simple urethral lubrication is sufficient for the exploration to be well tolerated. The patient experiences minimal discomfort, especially when the procedure is performed by an experienced urologist. Visualization using a video camera allows for minimum contact with the mucosa as the cystoscope passes along the urethra. Possible variables that may have led to bias, such as age, the urologist performing the exploration and the previous experience of the patient with the procedure were distributed homogeneously between the two groups, ensuring that they did not affect the results. Although the presence of tumor relapse should not directly affect tolerance to the procedure, it could alter the patient's perception through emotional mechanisms once informed of the presence or absence of pathology. Tolerance was therefore always tested before the patient was given such oncological information.

It is our belief that other factors not taken into consideration here and in most studies may have a great influence on the tolerance of cystoscopy, including patient anxiety prior to exploration, delicacy of handling during exploration and minimizing the instillation velocity of the gel.

The use and benefits of local anesthetic during urethral manipulation are controversial. Birch et al. (5) reported that 2% lidocaine gel, held in the urethra for 15 min, provided no analgesic advantage over plain lubricating gel. This view was supported by another study (6), which showed no advantage in using either 10 or 20 ml of 2% lidocaine gel instead of plain lubricating gel during flexible cystoscopy. Herr and Schneider (7) evaluated the pain of immediate as opposed to delayed (10–15 min) outpatient cystoscopy in men after instillation of lidocaine gel, finding no difference in pain perception. However, some authors support the benefits of 2% lidocaine gel during flexible cystoscopy. Brekkan et al. (8) and Choong et al. (9) reported a pain relief using lidocaine but noted that 20 ml of anesthetic needed to be maintained for at least 15 min in the urethra, which coincides with the time required for the topical lidocaine to be absorbed (15–60 min). It has been speculated (10–12) that the analgesic benefits obtained in those studies may have been due to a systemic effect of lidocaine absorption into the circulatory system rather than any local topical effect. Recent studies complicate the scenario and the search for the best technique still further: Ho et al. (13) showed that the chemical content of lidocaine gel is the cause of urethral pain before the exploration is done and Wicki et al. (14) warned of the risk of allergy.

The present report has some limitations. By excluding those patients with some type of urethral stenosis it

is impossible to say whether that subgroup would have benefited from the application of lubrication with local anesthetic; however, it should be remembered that this group of patients is particularly difficult to evaluate because of the varied forms of urethral manipulation required. Patients undergoing electrofulguration (cystodiathermy) of small bladder relapses were also eliminated from the study. Although in principle the application of anesthetic in the urethra should not affect tolerance to bladder electrocoagulation, we decided to exclude these individuals from the study because they would have had difficulty distinguishing the discomfort caused by the passage of the instrument from that caused by the bladder fulguration after the exploration/treatment.

One possible criticism of this study might be that exploration was performed after only a 5-min wait after lubrication, rather than after a 10–15-min wait as in the majority of studies. However, this study design enables us to apply our results to daily clinical practice. Generally, patient overload and the availability of resources at our center does not permit this length of time per exploration. Immediate flexible cystoscopy reduces the time that patients spend waiting and saves time in the clinic. In our opinion, this is the case in the majority of centers, in contrast to the scenario presented in most previous studies. Furthermore, as we have already noted, the practical objective of this study was not restricted to cystoscopy performed for urological purposes. We believe that the effect of the passing of the flexible cystoscope resembles the habitual urethral catheterization performed by the emergency services and in hospitalized patients. Probably, the passage of a soft catheter is easier than the passage of a flexible scope with a blunt tip and therefore the former causes less discomfort. To date such probes have been used with no distinction between simple and anesthetic lubrication and no consideration of economic or clinical criteria. The results of this study should help unit officers and managers to develop protocols for the catheterization technique that will entail greater economic savings. The excellent tolerance to exploration using our method (no discomfort or only slight discomfort for 83.7–89.5% of patients) leads us to think that, with a longer wait, the improvement in results and above all the difference between the two groups would still be marginal. In our center the cost of lidocaine gel is €1.80 per patient, compared to €0.84 when a 20-ml syringe filled with plain lubricant is used.

Given the innervation of the male urethra, there is little reason to continue using lidocaine hydrochloride gel as a local analgesic agent. The urethra distal to the pelvic floor has a subepithelial plexus of nerves believed to provide sensory information only. These

nerves are presumably the site of action of lidocaine. When a catheter is passed through the urethra, the initial sensations are tactile. When the pelvic floor is reached a crescendo of discomfort or pain is often perceived by the patient. This can be blocked by means of bilateral pudendal nerve blocks, suggesting that the source of such discomfort is the intrinsic rhabdomyosphincter. It is unlikely that intra-urethral lidocaine gel would have a local effect on discomfort because, unless 22 ml of gel was used, the amount used would be insufficient to fill the male urethra beyond the sphincter in all cases.

In conclusion, this prospective, randomized, double-blind trial indicates that flexible cystoscopy is well tolerated, with minimum discomfort to the male patient. The use of local anesthetic fails to improve results when the exploration is performed 5 min after lubrication. If one performs cystoscopy in daily clinical practice after waiting for just 5 min then simple lubrication is sufficient.

REFERENCES

1. Flannigan GM, Gelister JS, Noble JG, Milroy EJ. Rigid versus flexible cystoscopy. A controlled trial of patients' tolerance. *Br J Urol* 1988; 62: 537–40.
2. Herr HW. Outpatients flexible cystoscopy and fulguration of recurrent superficial bladder tumors. *J Urol* 1990; 144: 1365–6.
3. Jaeschke R, Singer J, Guyatt GH. A comparison of seven-point and visual analogue scales. Data from a randomized trial. *Control Clin Trials* 1990; 11: 43–51.
4. Vriesema JL, Poucki MH, Kiemeney LA, Witjes JA. Patient opinion of urinary tests versus flexible urethroscopy in follow-up examination for superficial bladder cancer: a utility analysis. *Urology* 2000; 56: 793–7.
5. Birch BR, Ratan P, Morley R, Cumming J, Smart CJ, Jenkins ID. Flexible cystoscopy in men: is topical anaesthesia with lignocaine gel worthwhile? *Br J Urol* 1994; 73: 155–9.
6. McFarlane N, Denstedt J, Ganapathy S, Razvi H. Randomized trial of 10 ml and 20 ml of 2% intraurethral lidocaine gel and placebo in men undergoing flexible cystoscopy. *J Endourol* 2001; 15: 541–4.
7. Herr HW, Schneider M. Outpatient flexible cystoscopy in men: a randomized study of patient tolerance. *J Urol* 2001; 165: 1971–2.
8. Brekkan E, Ehrnebo M, Malmstrom PU, Norlen BJ, Wirbrant A. A controlled study of low and high volume anaesthetic jelly as a lubricant and pain reliever during cystoscopy. *J Urol* 1991; 146: 24–7.
9. Choong S, Whitfield HN, Meganathan V, Nathan MS, Razack A, Gleeson M. A prospective, randomised, double-blind study comparing lignocaine gel and plain lubricating gel in relieving pain during flexible cystoscopy. *Br J Urol* 1997; 80: 69–71.
10. Axelsson K, Jozwiak H, Lingardh G, Schonebeck J, Widman B. Blood concentration of lignocaine after application of 2% lignocaine gel in the urethra. *Br J Urol* 1983; 55: 64–8.
11. Ouellette RD, Blute R, Jaffee S, Bahde C. Plasma concentrations of lidocaine resulting from instillation of lidocaine jelly into genitourinary tract prior to cystoscopy. *Urology* 1985; 25: 490–1.
12. Eardley I, Broome GD, Murray A, Ramsay JW, Whitfield HN, Wilkinson DJ. Plasma lignocaine levels during transurethral prostatectomy. *Ann R Coll Surg Engl* 1989; 71: 278–80.
13. Ho KJ, Thompson TJ, O'Brien AO, Young MR, McClean G. Lignocaine gel: does it cause urethral pain rather than prevent it? *Eur Urol* 2003; 43: 194–6.
14. Wicki J, Deluze C, Cirafici L, Desmeules J. Anaphylactic shock induced by intraurethral use of chlorhexidine. *Allergy* 1999; 54: 768–9.