Effectiveness of intraurethral lubricant in pain reduction during rigid cystoscopy in men

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■ ABSTRACT

Background: Different general and pharmacological measures have been described in an attempt to provide an effective local anesthetic for performing rigid cystoscopy as a relatively quick procedure and avoiding the use of more invasive methods of anesthesia.

Objective: The study objective was to develop an effective anesthetic lubricant for intraurethral instillation of urological instrumentation.

Materials and Methods: An experimental study was carried out on male patients scheduled to undergo rigid cystoscopy. Lubricant with and without anesthetic ingredient was applied and pain response was evaluated with the Visual Analog Pain Scale (VAPS) upon completion of cystoscopy. Statistical data analysis was carried out using variance analysis (ANOVA).

Results: Mean age of patients was 62 years and there were no statistical differences between study groups. VAPS pain response was significantly lower in patients who had received the anesthetic lubricant prior to cystoscopy.

Conclusions: The use of anesthetic gel lubricant safely and effectively reduced pain in patients undergoing rigid cystoscopy.

Key words: Lidocaine gel, intraurethral instillation, rigid cystoscopy, pain, visual analog pain scale.

■ RESUMEN

Objetivo: Desarrollar una preparación de lubricante anestésico eficaz para la aplicación intrauretral en las instrumentaciones urológicas. Material y métodos: Estudio experimental. Se incluyeron pacientes masculinos con indicación de cistoscopia rígida, se les aplicó lubricante con y sin la preparación anestésica; al término de la cistoscopia se valoró la respuesta al dolor mediante la escala visual análoga del dolor (EVA), el análisis estadístico de los datos se realizó mediante análisis de varianza (ANOVA).

Resultados: La edad promedio de los pacientes en el estudio fue de 62 años, sin diferencias significativas entre los grupos de estudio. La respuesta al dolor mediante la EVA fue significativamente menor en los pacientes sometidos a cistoscopia rígida que recibieron la preparación del lubricante con el anestésico local.

Conclusiones: La utilización de gel lubricante anestésico disminuye el dolor en pacientes sometidos a cistoscopia rígida en forma eficaz y segura.

Palabras clave: Gel de lidocaína, aplicación intrauretral, cistoscopia rígida, dolor, escala visual análoga de dolor, México.
INTRODUCTION

Intense and prolonged pain is capable of triggering a series of potentially adverse psychological and physiological responses in patients with limited cardiovascular and respiratory reserves. Psychologically there can be anxiety and fear, sleep deprivation and a sensation of vulnerability. These changes intensify each other and increase pain. In addition to prolonging pain they can result in responses of rage and resentment and the protraction of emotional alterations, especially in children.

Pain in the elderly patient is an important cause of delirium. Physiologically, there is a systemic and local response with inflammatory, autonomic, endocrine and immunological changes. The specific role of pain in this response is not well defined because the effects of pain per se cannot be separated from those produced by tissue destruction. The interpretation of research on this problem is also difficult because nociceptive stimuli are only one of the activators of the stress response (SR) and pain is almost always accompanied with other SR activators.

Response can be thought of as an afferent arch, a central integration and an efferent arch. Information about the exact nature of efferent factors and their central integration is limited but hormonal and metabolic changes have been studied in detail.

The neural pathway is the principal triggering mechanism, with segmental and also suprasegmental responses that stimulate bulbar, hypothalamic and limbic centers. There are local tissue factors, with the liberation of intracellular substances, whose characteristics have been studied intensely in recent years, but there is still no clear picture of their relative role. The complement and cascade of coagulation, fibrinolysis, and total local liberation of mediators such as histamine, serotonin, prostaglandin, interleukin and others is activated. Local inflammatory response is important for cicatrization and for fighting infection.

In addition to endocrine and metabolic changes, pain and a variety of other responses produce alterations at different levels.

RESPIRATORY RESPONSE

Pain in the chest or abdomen, especially the upper half, produces an increase in abdominal and intercostal muscle tone during exhalation and also an alteration in diaphragmatic function. The result is a decrease in thoracic distensibility, inability to breathe profoundly or cough with force. In many cases, all this leads to secretion retention, atelectasis and eventually to pneumonia, hypoxemia and hypercapnia.

CARDIOVASCULAR RESPONSES

There is tachycardia and an increase in systolic output, myocardial work and oxygen consumption. There is vasoconstriction with an increase in peripheral resistance and a decrease in venous capacity (high blood pressure). The decrease in physical activity increases venous stasis and platelet aggregation resulting in a greater risk of deep vein thrombosis and eventually pulmonary thromboembolism.

GASTROINTESTINAL AND URINARY RESPONSES

There is a decrease in gastrointestinal tone, gastric emptying delay, a decrease in bladder and urethral tone and a greater probability of urinary retention.

Intense pain can modify spinal and central nerve excitability leading to an increase in the sensitive area and threshold changes. This is the same as saying that pain itself can increase pain (1,2).

LOCAL ANESTHESIA IN URETHRAL INSTRUMENTATION

Pain during intraurethral instillation of lubricant with anesthetic. Ho and colleagues carried out a study comparing pain perceived by patients during intraurethral instillation of simple lubricating gel and instillation of gel with anesthetic (lidocaine), showing that there was pain perception in the second group (3).

Thompson and Goel studied whether lidocaine gel lubricant temperature affected initial pain perception during intraurethral instillation. The authors found significantly less pain with the use of lidocaine gel at 4°C.

Other authors reported less pain when intraurethral lidocaine gel was instilled over a period of 10 seconds as opposed to a period of 2 seconds (4-9).

EFFICACY OF INTRAURETHRAL ANESTHETIC LUBRICANT DURING CYSTOSCOPY

Study conclusions in this area are contradictory. Of five reviewed studies, three conclude that intraurethral anesthetic gel is not a pain controller that is superior to simple gel. However, two of these studies were carried out using flexible cystoscope. (10-12) The other two studies report an advantage to using anesthetic gel when using 21F rigid cystoscope. (13-16).

INTRAURETHRAL LUBRICANT VOLUME

Brecklan and colleagues studied whether the applied volume of lidocaine gel conditioned pain perception
during cystoscopy. The authors found no significant reduction in pain perception between two study groups of women. Men were divided into subgroups of over or under 55 years of age. Twenty cubic centimeters of lidocaine gel were used in patients under 55 years of age and pain was perceived as greater. In the group over 55 years of age pain perception remained unchanged (5).

**IDEAL TIME NECESSARY FOR ANESTHETIC LUBRICANT TO TAKE EFFECT**

Making sure the anesthetic gel is topically exposed to the urotheilum for the correct amount of time is another relevant theme and a penile clamp is a valid application option. Choong and colleagues evaluated different amounts of time for gel exposition to the urotheilum and found just over 15 minutes to be the most adequate (8).

**ANESTHETIC ALKALINIZATION WITH SODIUM BICARBONATE**

Henry and colleagues studied lidocaine alkalization with sodium bicarbonate in 1:1 proportions as a local anesthetic for bladder mucosa. Taking into consideration urine and alkaline pH acid, they concluded that alkalization for intravesical instillation was crucial. Alkalization increases the lipid proportion of the formula, increasing its absorption, thus improving penetration and achieving a deeper local anesthesia sufficient for performing bladder mucosa resection and fulguration (11).

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**TOLERATION EFFECT FROM ALLOWING THE PATIENT TO OBSERVE THE PROCEDURE**

Amit and colleagues studied the impact that allowing patients to visualize the procedure while explaining the flexible cystoscopy study to them in real time has on pain perception. They concluded it was beneficial and pain was reduced 40% (14).

**MATERIALS AND METHODS**

A randomized, experimental double-blind study was carried out. The study population was a group of active and retired military patients belonging to the Instituto de Seguridad y Servicios de las Fuerzas Armadas de México (ISSFAM) who received medical attention at the Urology Service of the Hospital Central Militar. The study group consisted of 45 patients treated with lubricant and local anesthetic and the control group consisted of 20 patients. Male patients programmed for out-patient diagnostic cystoscopy with no anesthesia were included in the study. All patients participated voluntarily and signed letters of informed consent.

Female patients, patients having undergone previous cystoscopic study, patients requiring urethral meatus dilatation prior to cystoscopy due to non-compliant urethral meatus, patients with a history of allergy to any of the anesthetic components (lidocaine, bicarbonate and water-based gel) and any patient who did not accept study inclusion protocol were all excluded from the study.

The anesthetic lubricating gel was prepared by mixing together a water-based lubricating gel, lidocaine at 10% and sodium bicarbonate in a sterile glass container stored in a refrigerator at 4°C. Intrarethral instillation was carried out with a sterile 20 cc syringe with no needle. The water-based lubricant was stored at the same temperature in its original container and applied in standard fashion.

Cardiac frequency, blood pressure and oxygen saturation were registered and the patient was placed in the lithotomy position. The genitals were washed with 0.9% saline solution and surgical soap. Intrarethral 10-second instillation of 20cc of anesthetic gel or placebo gel was carried out with a syringe with no needle. Visual Analog Pain Scale (VAPS) was applied in relation to gel instillation. Rigid cystoscopy with 17F cystoscope with 30° lens was performed by the same urologist using the standard technique. The patient was watching the procedure in real time while the urologist simultaneously explained the process. Modified VAPS (numerical classification) was applied upon cystoscopy completion (20).

**STATISTICAL ANALYSIS**

Mean, standard deviation and standard error were calculated for each group. Student t test for independent samples was used to compare two different samples and decide if they belonged to the same population or not. Multiple means were compared using variance analysis (ANOVA) that corresponded to a completely random single factor experimental design. When ANOVA showed significant differences, Newman-Keuls test was employed. Differences were considered statistically significant when \( P < 0.05 \).

**RESULTS**

Table 1 shows the parameters that were analyzed in both study groups – patients receiving lubricating gel with and without anesthetic who underwent rigid cystoscopy. There were no significant differences related to age (Image 1). Intrarethral instillation of the lubricant produced a 1.2 pain response according to VAPS (0-10 scale). Although it was not statistically significant there tended to be a lower pain response in the group receiving the anesthetic lubricant (Image 2).
DISCUSSION

The data reported in the literature states that cystoscopy in male patients is a common but painful procedure that generally requires intravenous sedation. Anesthetic aid implies risk to the patient and is not always feasible due to the amount of anesthetic procedures performed and lack of specialized personnel – factors which often delay diagnosis and treatment of urological disease.

The lack of specialized personnel in anesthesia and the number of cystoscopies programmed in our hospital were the motivating factors for our decision to prepare an efficient anesthetic lubricating gel to be used in rigid cystoscopy.

The data published in the literature about the use of these types of preparations are contradictory. From a total of 5 articles on pain evaluation during intraurethral instillation of lidocaine lubricant, 3 of them concluded that there was no reduction of pain comparing groups with and without lidocaine. However, two of those studies were carried out using flexible cystoscopy. And the other two studies reported that anesthetic gel was advantageous in relation to pain when 21F rigid cystoscopy was performed (12, 15, 17–19). Ho and colleagues reported an increase in pain perception in patients who received anesthetic lubricant (3). In the present study we found pain perception to be significantly less in patients who received lidocaine lubricating gel when 17F cystoscope was used than in the control group.

Other authors have reported less pain in intraurethral lidocaine gel application when instillation is carried out in 10 seconds rather than in 2 seconds (4, 9). In the present study all instillations were carried out in 10 seconds.

Brecklan and colleagues studied whether lidocaine gel volume affected pain perception during cystoscopy. The authors found no significant reduction in pain perception among the female study groups. Male patients were divided into subgroups of over and under 55 years of age. In the application of 20cc of lidocaine gel there was an increase in pain perception in the group under 55 years of age while there was no difference in pain perception in the group over 55 years of age (5). In the present study, 20cc of gel was in contact with tissue for 15 minutes. Chooong and colleagues evaluated different anesthetic gel time exposures to urethral urothelium, finding 15 minutes to be the most adequate (8). Amit and colleagues studied the impact that letting the patient watch the procedure in real time while receiving simultaneous explanation of the flexible cystoscopy has on pain perception. They concluded that it has a beneficial effect and diminished pain by 40% (14). In the

<table>
<thead>
<tr>
<th>Parameters analyzed</th>
<th>Control Group (n = 20)</th>
<th>treated Group (n = 45)</th>
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<tbody>
<tr>
<td>Age</td>
<td>62.8 ± 4.62</td>
<td>61.66 ± 2.45</td>
</tr>
<tr>
<td>Pain during intraurethral instillation of lubricant with anesthetic (VAPS)</td>
<td>1.2 ± 0.27</td>
<td>0.57 ± 0.08**</td>
</tr>
<tr>
<td>Efficacy of intraurethral lubricant with anesthetic during cystoscopy (VAPS)</td>
<td>7.4 ± 0.31</td>
<td>2.88 ± 0.12***</td>
</tr>
</tbody>
</table>

VAPS= Visual analog pain scale
** P< 0.0047
*** P<0.0001

** Image 3** shows post-rigid cystoscopy VAPS in patients who received anesthetic lubricant to be significantly lower than that of the control group.

** Table 1.** Means ± SD and n are shown for groups with intraurethral instillation of lubricating gel with and without local anesthetic.
present study all patients were allowed to watch their procedures in real time while simultaneously having the cystoscopy explained to them. No adverse events were observed in our study.

**CONCLUSIONS**

Our local anesthetic lubricating gel preparation is a practical, efficient and safe alternative as an anesthetic aid in the performance of rigid cystoscopy in men.

**BIBLIOGRAPHY**