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EFFICACY OF INTRARECTAL LIDOCAINE HYDROCHLORIDE GEL FOR PAIN CONTROL IN PATIENTS UNDERGOING TRANSRECTAL PROSTATE BIOPSY

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ABSTRACT

Objective: To determine the efficacy of intrarectal lidocaine hydrochloride gel in reducing pain in patients undergoing transrectal prostate biopsy.

Materials and Methods: During the period from June to November 2002, 72 patients undergoing transrectal prostate biopsy at an outpatient service were prospectively randomized. Patients were divided into 2 groups. In group 1, 20 mL of 2% lidocaine gel were administered by intrarectal route 15 minutes before biopsy. In group 2 (placebo), 20 mL of ultrasound gel were administered under the same conditions. At the end of the procedure, patients were asked to classify the discomfort degree observed during the procedure through a verbal pain scale. Statistical analysis was performed through qui-square test.

Results: The majority of patients in both groups presented slight pain on the examination, and 26 patients (76.4%) from group 1, and 26 (68.3%) patients from group 2 reported slight pain or no pain at all ($p > 0.05$). Moderate or intense pain was felt by 23.4% of patients in group 1 and 31.5% of patients in group 2 ($p > 0.05$).

Conclusions: We concluded that lidocaine probably exerts a minimal effect on patients' tolerance to pain on transrectal prostate biopsy.

Key words: prostate; biopsy; local anesthesia; lidocaine hydrochloride; gels
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INTRODUCTION

Transrectal biopsy is considered the best diagnostic method for prostate cancer, serving as indicative for staging as well. Due to the grater awareness of the population and the increase in life expectancy, it has been performed with increasing frequency. It is estimated that 500,000 biopsies are performed every year in the USA (1).

Even though 65 to 90% of men report some discomfort during the procedure, biopsies are usually performed without any form of anesthesia (2-4). Pain occurs predominantly when the needle penetrates the prostate capsule and the stroma (4). In some series, approximately 19% of men refused to undergo repeated biopsies without any kind of anesthesia (5).

Recently, it was proposed that rectal administration of a local anesthetic agent, the lidocaine gel, could improve tolerance to prostate biopsy (1,4). The authors conducted a randomized prospective study, aiming to report the efficacy of lidocaine hydrochloride gel for pain control in patients undergoing prostate biopsy.

MATERIALS AND METHODS

During the period from June to November 2002, 72 men undergoing prostate biopsy at the uro-

logic outpatient service of Getúlio Vargas Hospital, were included in the study. All patients had clinical or laboratorial suspicion of prostate cancer. Antimicrobial prophylaxis was achieved with norfloxacin, starting on the previous day and rectal lavage with enema one hour before the procedure.

Among the applied exclusion criteria, we considered patients with sequelae from neurological diseases, previous history of orificial diseases, patients undergoing repeated biopsies, users of analgesic or narcotic drugs, as well as those who were deemed unable to answer the questionnaire.

Patients were randomly distributed in 2 groups. In group 1, 20 mL of 2% lidocaine gel was administered by intrarectal route 15 minutes before biopsy. In group 2 (placebo), 20mL of ultrasound gel was administered under the same conditions. No form of sedation or analgesia was used and all biopsies were performed with the sextant technique.

The biopsies were performed with the patients in lithotomy position. At the end of the procedure, patients were asked to classify the discomfort degree observed during the procedure through a visual pain scale, as follows: 0 – no pain, 1 – slight pain, 2 – moderate pain, and 3 – intense pain.

Statistical analysis was performed through qui-square test, and a p value < 0.05 was considered statistically significant.

RESULTS

During a 5-month period, 72 patients were studied, divided in group 1 (with lidocaine gel, 34 patients), and group 2 (placebo, 38 patients). Mean age was similar between the groups, that is 68.5 years for group 1 and 68 years for group 2 (p = 0.76).

Mean prostate specific antigen (PSA) was 24.4 ng/mL (1.9 - 176) and 15.6 (3.1-100) ng/dL for patients in group 1 and 2 respectively (p = 0.39). Seventeen patients in group 1 (50%) and 20 patients in group 2 (52.6%) presented prostate with normal consistency on the digital rectal examination (p = 0.91). Mean prostate volume as measured by ultrasound was 68.3g (23 - 305) for patients in group 1, and 50.8 g (20 - 140) for patients in group 2 (p = 0.09).

The majority of patients in both groups presented slight pain on the exam (Figure-1). Twenty-six patients (76.4%) in group 1, and 26 patients (68.3%) in group 2 reported slight pain or no pain. Moderate or intense pain was pointed out by 8 (23.4%) patients in group 1 and 12 (31.5%) patients in group 2 (p = 0.29).

Minor complications such as transitory fever, hematospermia and rectal bleeding occurred with similar frequency in both groups. No major complication was observed.

COMMENTS

Transrectal biopsy is an essential part of the diagnostic of prostate cancer. A significant amount of patients who undergo transrectal biopsy consider the procedure uncomfortable (2,3). The pain associated with prostate biopsy occurs predominantly when the needle penetrates the prostate capsule into the stroma, but the maintenance and positioning of the

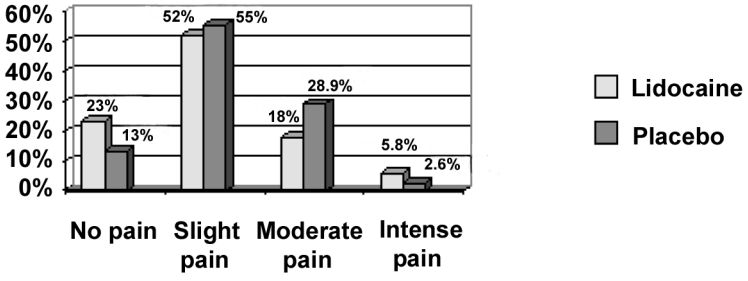

Figure 1 – *Tolerance to pain in transrectal prostate biopsy in patients who were (group 1) or were not (group 2) given intrarectal lidocaine gel.*

ultrasound probe or of the examiner's finger can also contribute to the reported discomfort (4).

Recently, studies demonstrated that the prostatic nervous supply derives from the inferior hypogastric plexus, located just above the seminal vesicles, and from this point, it provides fibers that run in a plane between the prostate and the rectum. These nerves are located inferior and laterally to the prostate and represent its main nervous supply. On the other hand, the anterior and supra-lateral surfaces do not appear to have significant innervation (6,7).

Lidocaine is a widely used local anesthetic agent, and its efficacy and safety have already been proven in many applications (8,9). Several studies have shown conflicting results concerning the use of topic and injectable anesthesia for pain control in patients undergoing prostate biopsy.

Berger et al. (2003), in a double-blind, placebo-controlled, randomized prospective study assessed the effect of periprostatic infiltration of local anesthetic in 100 men undergoing transrectal prostate biopsy. They divided the patients in 2 groups of 50 subjects. They applied 10 mL of 2% lidocaine solution in the first group, and 10 mL of placebo (0.9% NaCL) in the second group. After the biopsy, patients were evaluated according to a visual pain scale in order to analyze the presence of discomfort. Patients who received local anesthesia presented significantly lower pain scores when compared to patients from the placebo group ($p = 0.001$). The lidocaine injection did not cause adverse effects. The authors recommend to routinely using this anesthetic during the procedure (10). However, this recommendation is not consensual, since other studies have shown conflicting results. Cevik et al. (2002), in a similar randomized prospective study, assessed another 100 patients in 2 groups, who were given lidocaine or saline solution. No statistical difference was observed in the pain score between groups, and thus, the intrarectal lidocaine injection was not considered superior to placebo for pain control in patients undergoing prostate biopsy (11).

Penetration of lidocaine gel through the rectal mucosa was experimentally confirmed (12), and a local effect on the autonomic innervation of the rectal mucosa was proposed as a mechanism for the reduction in pain and discomfort caused by biopsy (13). A prospective randomized study assessed the safety and efficacy of intrarectal lidocaine gel in 50 patients undergoing prostate transrectal biopsy. Patients were distributed in 2 groups with similar characteristics and received 10 mL of intrarectal lidocaine gel or ultrasound gel 10 minutes before the procedure. A visual pain scale (ranging from 0 to 10) was used, and it was found that the mean score between patients who used intrarectal lidocaine gel was 2 (ranging from 1 to 5), versus 5 (ranging from 1 to 7) for the control group ($p = 0.00001$). These authors recommend the routine use of lidocaine gel during the procedure (1).

Later, another study (14) compared the efficacy of intrarectal lidocaine gel for pain control. In this trial, 360 patients were randomized in 2 groups of 180 subjects, and were given 10 mL of lidocaine or placebo (ultrasound gel) 10 minutes before biopsy. No other form of analgesia was used. A 10-point visual scale was used to analyze the pain level. The mean pain score during biopsy was 2 (ranging from 0 to 8), and 3 (ranging from 1 to 10) in groups 1 and 2 respectively ($p = 0.0001$). The authors concluded that the use of lidocaine gel is safe, simple and effective for reducing the pain associated with transrectal prostate biopsy (14).

The combined use of periprostatic block with lidocaine injection and intrarectal lidocaine gel has been referred in literature as well. A prospective randomized study investigating the efficacy of adding intrarectal lidocaine gel in patients undergoing transrectal prostate biopsy with periprostatic block concluded that these patients showed significant improvement in analgesia when compared with the group submitted to periprostatic block alone or with the group who ingested tramadol (15).

However, other authors did not confirm the efficacy of this method while assessing the use of intrarectal lidocaine gel in a prospective controlled study with 109 patients. They administered 15 mL of intrarectal 2% lidocaine gel 15 minutes before the procedure in group 1 (study group), and 15 mL of ultrasound gel in group 2 (placebo). The authors observed that the majority of patients in both groups, presented slight pain or no pain. Moderate or intense

pain was reported by 12.5% of patients in group 1 and 11.3% of patients in group 2 (p = 0.39) (4).

Similarly, we observed in our sample that patients who underwent rectal administration of lidocaine gel presented similar levels of pain when compared with the placebo group, especially if we consider those patients who reported slight pain. However, due to the small number of patients who complained of intense pain (2 patients in group 1 and only 1 patient in group 2), a larger sample is required in order to draw conclusions that are more definitive. Thus, we conclude that lidocaine probably exerts a minimal effect on the patients' tolerance to transrectal prostate biopsy.

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