A prospective randomized trial comparing lidocaine and lubrificating gel on pain level in patients undergoing transrectal ultrasound prostate biopsy

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Purpose: *To compare patient reported pain during TRUS guided biopsies using intrarectal lidocaine gel versus lubrificating gel.*

Materials and methods: *From May 2000 to May 2001, 360 men undergoing transrectal prostate biopsy were enrolled in this study. Patients were randomized into two groups. In group 1, 180 patients received 10 cc of 2% intrarectal lidocaine gel (Xylocaine® 2% jelly, Astra Pharma Inc.) 5 to 10 minutes before the procedure and in group 2, 180 patients received 10 cc of lubricating gel. No other sedation or analgesia was given. Pain level immediately after the last biopsy was assessed using a 10-point linear visual analog pain scale.*

Results: *The median pain score during transrectal prostate biopsy was 2 (range 0 to 8) and 3 (range 1 to 10) in groups 1 and 2, respectively ($p = 0.0001$). Only minor complications occurred and complication rates were not significantly different between the groups.*

Conclusion: *Rectal administration of lidocaine gel is safe, simple and effective for reducing the pain level associated with transrectal prostate biopsy.*

Key Words: prostate cancer, transrectal ultrasound, anesthesia, pain

Introduction

Transrectal ultrasound guided prostate biopsy has become the standard procedure for diagnosing prostate cancer. Generally biopsies are taken without any form of anesthesia, although 65% to 90% of men report discomfort during transrectal prostate biopsy.[1,2] Pain occurs especially when the needle penetrates the prostatic capsule and stroma.[3] Although prospective randomized studies have been done in order to evaluate the possible efficacy of rectal administration of lidocaine gel for pain control during transrectal ultrasound (TRUS) with prostate biopsy, the results are controversial. In one study of 109 patients undergoing TRUS, 56 patients received intrarectal lidocaine gel.[4] The authors found that lidocaine has

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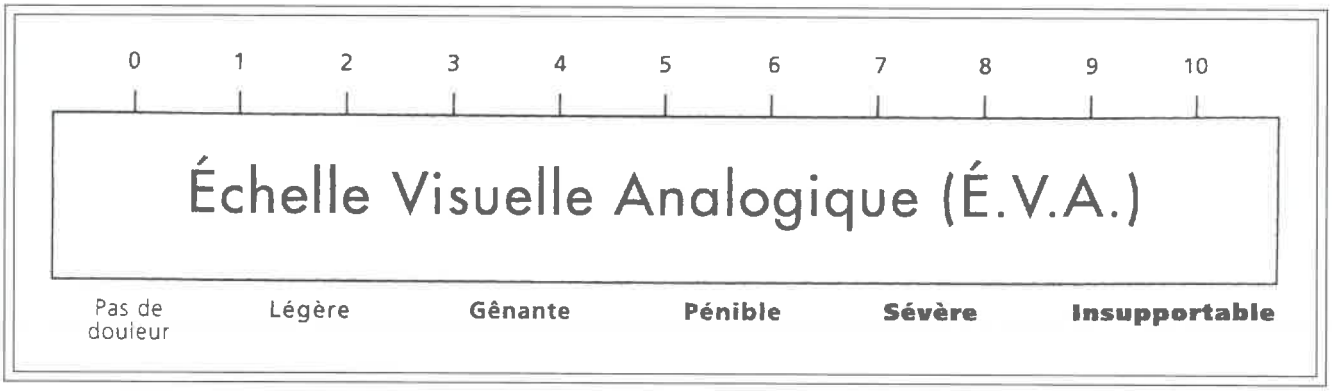

Figure 1. Visual analog pain scale

no impact on the tolerance to prostatic biopsy. In a smaller study, Issa et al[5] found that intrarectal lidocaine gel to be a simple, safe and efficacious method of providing satisfactory anesthesia in 50 men (25 in each group) undergoing transrectal prostate biopsy. Based on their results they recommend the routine administration of intrarectal lidocaine gel in all patients undergoing TRUS.

In order to further determine the possible role of intrarectal lidocaine gel during TRUS we compared the pain level of patients of intrarectal lidocaine gel to pain levels of patients receiving lubrificating gel during TRUS with prostate biopsy.

Materials and methods

From May 2000 to May 2001, 360 men undergoing transrectal prostate biopsy were enrolled in this study. All patients invited to participate accepted. Indications for transrectal prostate biopsy included an abnormal prostate on digital rectal examination and/or elevated serum prostate specific antigen (PSA). There were no exclusion criteria except allergy to lidocaine or the concomitant use of analgesic and narcotic medications.

Patients received antibiotic prophylaxis (ciprofloxacin or levofloxacin) before and after the biopsy. No bowel preparation was given prior to the procedure.

Informed and consenting patients were randomized into two groups. Group 1 received 10 cc of 2% lidocaine intrarectally 5 to 10 minutes before the biopsies. Group 2 received 10 cc of lubricating gel (placebo) in the same manner. Only patients were blinded to the gel used. Patients were all placed in the left lateral decubitus position and had a digital rectal examination at the beginning of the procedure.

TRUS guided prostate biopsies were done using a Brüel and Kjaer 7 MHz rectal probe. An average of eight (6 – 11) biopsy cores were obtained from the prostate, including at least three from each lobe (apex, mid and base), using an automatic spring loaded biopsy gun and 18 gauge needles. There was no difference in the average number of biopsies performed in each group. Immediately after the last biopsy, patients were asked by the nurse to grade the discomfort and/or pain level experienced during the procedure using a 10-point linear visual analog pain scale, VAS Figure 1. The question was phrased in the same manner in all cases to minimize any bias during data collection. All patients were monitored during and after the procedure for possible complications. A 7-day follow up was made by phone to evaluate any adverse events (hematospermia, hematuria, rectorragia, dysuria, voiding difficulty, infections). Statistical analyses were performed by using the Student test to compare pain scores between the two groups. The infection and traumatic rates in these two groups was analyzed using the chi-squared test.

Results

From May 2000 to May 2001, 360 men were enrolled in this study. 180 patients were randomized into group 1 and 180 into group 2. The mean age and PSA serum levels were similar in each group Table 1. Figure 2 shows the distribution of the pain scores. Patients receiving lidocaine gel had significantly less pain than the control group ($p = 0.0001$). The percentage of patients scoring 5 and over on the VAS questionnaire in the lidocaine and in the lubricating group was 12.2% and 26.7% respectively.

Only two cases of septicemia (0.55%) were reported, one in each group. There were no clinically nor statistically significant differences regarding

TABLE 1. **Patients demographic, infection and traumatic rates in both groups**

	Group 1 2% lidocaine gel	Group 2 lubricating gel	p value
Number of patients	180	180	-
Patients age (yr)	65	68	-
Mean PSA levels (ng.ml)	9.41	11.02	0.4762
Mean pain score (range)	2.62 (0-8)	3.32 (0-10)	0.0001
Median pain score	2	3	0.0001
Urosepsis	1	1	> 0.99
Hematospermia (%)	106 (58.8)	107 (59.4)	0.4
Hematuria (%)	119 (66.1)	122 (67.8)	0.3
Rectorragia (%)	35 (19.4)	32 (17.7)	0.2

PSA: prostatic specific antigen

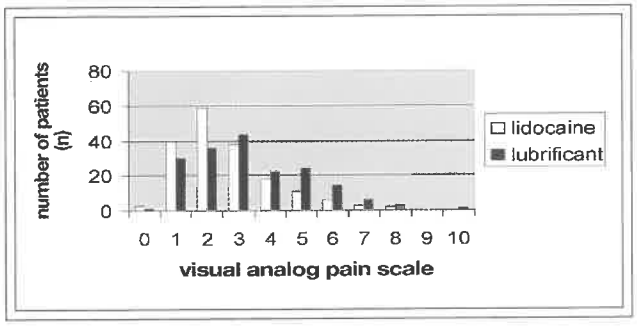

Figure 2. Pain score of lidocaine versus lubricating

minor traumatic complications between both groups of patients. Minor complications subsided within 4 weeks after the procedure.

Discussion

Our results concur with the Emory University experience.[5] However in the present study we enrolled a much larger number of patients (360) and we restricted our exclusion criteria to a minimum in order to better assess the overall efficacy of intrarectal lidocaine gel.

Previous studies[4,5] have assessed the efficacy of lidocaine gel in selected patients.

However multiple exclusion criteria were used in these studies and we believe this could have biased the conclusions of these studies. We believe exclusion criteria such as hemorrhoids, anal fissures, chronic prostatitis or neurological conditions are too restrictive since a great proportion of patients have rectal conditions.

A periprostatic nerve block before ultrasound guided prostate biopsy has shown to dramatically decrease discomfort.[3,6] This approach is more invasive and less convenient than intrarectal lidocaine gel and may be reserved for selected cases.

Conclusions

Our study confirms that intrarectal lidocaine gel applied topically is simple, safe and effective in patients undergoing transrectal ultrasound guided prostate biopsy. □

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