

# Which Anaesthesia should be Recommended for Prostate Biopsy?

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## ABSTRACT

**Objective:** Although transrectal ultrasound-guided prostatic biopsies are associated with significant discomfort and pain, most urologists do not use any kind of anaesthesia. We therefore compared the efficacy of two local anaesthetics, namely, the rectal administration of lidocaine gel and lidocaine periprostatic infiltration prior to biopsies.

**Design and Methods:** Three hundred and fifty-six randomized patients received either 15 mL of 2% lidocaine gel administered intrarectally ten minutes before prostate biopsies in group 1 (180 patients) or 10 mL of 1% lidocaine given under ultrasound guidance in two periprostatic injections of 5 mL, four minutes before the biopsies in group 2 (176 patients). A visual analogue scale (VAS) was used to assess the pain score during anaesthesia (VAS 1), during the biopsies (VAS 2) and 30 minutes after them (VAS 3).

**Results:** Patients receiving lidocaine gel experienced statistically less pain than the lidocaine injection group for mean VAS 1 (0.1 vs 1.4,  $p < 0.0001$ ) and mean VAS 3 (0.8 vs 1.4,  $p < 0.001$ ) but VAS 2 showed no statistically significant difference (2.0 vs 2.1). No major morbidity was noted with either anaesthetic.

**Conclusion:** Rectal administration of lidocaine gel is both safe, simple and effective and results are more satisfactory than with lidocaine periprostatic infiltration.

## ¿Qué Anestesia debe Recomendarse para la Biopsia de la Próstata?

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## RESUMEN

**Objetivo:** Aunque las biopsias prostáticas transrectales guiadas mediante ultrasonido se asocian con considerable malestar y dolor, la mayoría de los urólogos no usa cualquier tipo de anestesia. Por lo tanto, comparamos la eficacia de dos anestésicos locales, a saber, la administración rectal de gel de lidocaína y la infiltración con lidocaína del área periprostática antes de las biopsias.

**Diseño y métodos:** Trescientos cincuenta y seis pacientes randomizados recibieron o bien 15 mL de lidocaína en gel al 2%, administrada intrarectalmente diez minutos antes de las biopsias de la próstata en el grupo 1 (180 pacientes); o alternativamente 10 mL de lidocaína al 1% administrada bajo la guía de ultrasonido en dos inyecciones periprostáticas de 5 mL, cuatro minutos antes de las biopsias en el grupo 2 (176 pacientes). Se usó una escala analógica visual (EAV) para evaluar el grado de dolor durante la anestesia (EAV 1), durante las biopsias (EAV 2) y 30 minutos después de realizarlas (EAV 3).

**Resultados:** Los pacientes que recibieron lidocaína en gel, experimentaron menos dolor estadísticamente, que el grupo de la inyección de lidocaína, para la VAS 1 media (0.1 frente a 1.4,  $p < 0.0001$ ) y VAS 3 media (0.8 frente a 1.4,  $p < 0.001$ ). Sin embargo, la VAS 2 no mostró diferencia significativa alguna en términos estadísticos (2.0 frente a 2.1). No se vio morbosidad de consideración con ninguno de los anestésicos.

**Conclusión:** La administración rectal de gel de lidocaína es tan segura y simple como efectiva, y siendo los resultados más satisfactorio que aquellos producidos con la infiltración periprostática de lidocaína.

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## INTRODUCTION

More than a decade after the description by Hodge *et al* (1) of the technique for detecting prostate cancer, transrectal ultrasound (TRUS) guided prostate biopsy currently takes an

important place in the urologist's armamentarium. It is considered as a minor procedure, well tolerated by most patients and frequently performed without analgesia or anaesthesia in a majority of medical centres (2–4). General anaesthesia is provided rarely, only for patients who are undergoing a large number of prostate cores or those opposed to any local anaesthesia. Although no consensus exists, it is now demonstrated that the standard technique of sextant core biopsies is not sufficient and a larger number of biopsies should be obtained (5). Despite the use of small bioptic needles and special spring-action biopsy guns, about 12.5% to 24% of the men undergoing TRUS guided prostate biopsies indicate that the procedure is uncomfortable, ranging from mild discomfort to severe pain (6, 7), and discomfort increases concomitantly with the number of biopsies. Many studies have dealt with the reduction of discomfort during that procedure but led to conflicting results. Lidocaine gel has proved itself in many outpatient procedures such as cystoscopy or sigmoidoscopy. It has been suggested that intrarectal lidocaine gel may be a suitable form of anaesthesia before prostate biopsy (8) due to its easy mode of administration. Most studies aimed at demonstrating the efficacy of lidocaine infiltration under ultrasound guidance. Soloway and Obek (4) confirmed that three 5 ml injections of 1% lidocaine given on either side of the prostate were efficient. In the same way, Taverna *et al* (9) showed that a single injection of 10 mL 1% lidocaine was sufficient. Similar results were published by Schostak *et al* (10), Kaver *et al* (11), Leibovici *et al* (12) or Bulbul *et al* (13). Conversely, Wu *et al* (14) did not find any benefit in lidocaine infiltration in a comparison with placebo.

Regarding the intrarectal administration of lidocaine gel, Desgrandchamps *et al* (6) did not find any benefit with this gel considering that similar VAS pain score data were obtained in the placebo group. Issa *et al* (8) comparing the intrarectal administration of lidocaine gel 10 minutes before TRUS guided prostate biopsy with a control group deprived of anaesthesia, came to the conclusion that the instillation of gel to diminish pain was a simple, safe and effective method of anaesthesia.

Since we are convinced that there should be anaesthesia, the need was to find the best way of anaesthetising prior to prostate biopsy. Thus, we compared the efficacy of rectally instilled lidocaine gel with periprostatic ultrasound guided infiltration of lidocaine in a prospective randomized trial.

#### PATIENTS AND METHODS

Between July 2002 and September 2003, 356 consecutive men who underwent TRUS prostate biopsy in the Department of Urology at the University Hospital of Pointe à Pitre, Guadeloupe, in the French West Indies, were entered into this study which had previously received the approval of a local ethics committee.

Indications for biopsy included an abnormal digital rectal prostate examination or transrectal ultrasound scan

and/or elevated prostate specific antigen (PSA) (> 4 ng/mL). Lidocaine allergy, haemorrhagic diathesis, anticoagulation therapy and an inability to rate a visual analogue scale (VAS) were the exclusion criteria. Patients received an enema and 200 mg ofloxacin the night before and two hours prior to the procedure.

Once informed consent was obtained, patients were randomized into two groups. All patients were examined in the left lateral decubitus position. The TRUS guided biopsies were performed using a Hitachi Victora system with a 6.5 MHz probe. In Group 1, 15 mL of 2% lidocaine gel was administered intrarectally ten minutes before the prostate biopsies, as described by Desgrandchamps *et al* (6). Patients belonging to Group 2 received periprostatic 5 mL injections of 1% lidocaine four minutes prior to the biopsies *via* a 22-gauge 20-cm Skinny needle with Chiba tip 2. Lidocaine was administered between Denonvillers' fascia and the periprostatic fascia overlying the prostate. Prostate biopsies were undertaken with an 18-gauge, 20 cm spring-loaded biopsy needle.

Before the examination, patients received a VAS which was explained to them. The assessment ranges from 0 (no pain) to 10 (unbearable pain) and was measured during anaesthesia (VAS 1), immediately after (VAS 2) and 30 minutes (VAS 3) after the biopsy procedure. Patients were reviewed by the urologist three weeks after biopsy and data were recorded. Rectal bleeding, gross haematuria, haemospermia, dysuria, fever and any other complication following the biopsy were also noted.

Results were analyzed and the differences between the groups in VAS pain score were compared using the Student-t-test. A chi-square test was also used to compare the proportion of complications in the different groups. A p value less than 0.05 was considered statistically significant.

#### RESULTS

Among the 356 men, 180 were randomized to receive lidocaine gel intrarectally (Group 1) and 176 to be infiltrated by lidocaine (Group 2). Each patient underwent ten core biopsies (five on each lobe). A lower number of cores were chosen when the diagnosis of prostate cancer was obvious on abnormal DRE and/or by a high PSA level. A higher number of cores was obtained for the patients who had had a previous prostate biopsy. The two groups were similar with respect to age, PSA, prostate volume, findings of the digital rectal examination, previous prostate biopsy, number of cores and pathological findings at needle biopsy (Table 1).

Regarding the VAS pain scores, a significant difference existed between the two groups for VAS 1 and VAS 3, with an advantage for the intrarectal lidocaine gel group. During the biopsy procedure, the lidocaine gel led to lower pain score values than in Group 2 but no statistical significant difference was noted (Table 2). Mild pain or no pain was experienced by the vast majority of the patients in each group (Figs. 1–3). An advantage in the intrarectal lidocaine gel group (Group 2) was statistically demonstrated with less pain

Table 1: Characteristics of study groups

Parameter	Group 1 (Gel)	Group 2 (Injection)	p value
Patients (n)	180	176	
Age (year)			
Mean $\pm$ SD	68.1 $\pm$ 8.6	69.9 $\pm$ 9.5	NS
PSA (ng/mL)			
Mean $\pm$ SD	21.1 $\pm$ 71.8	21.8 $\pm$ 74.0	NS
Prostate volume (cm <sup>3</sup> )			
Mean $\pm$ SD	47 $\pm$ 29	46 $\pm$ 28	NS
Previous prostate biopsy (%)	24 (13%)	26 (15%)	NS
Normal DRE (%)	88 (49%)	95 (54%)	NS
Number of cores			
Mean $\pm$ SD	10 $\pm$ 0.6	10 $\pm$ 0.9	NS
Cancer on biopsy (%)	88 (49%)	95 (54%)	NS

SD = Standard deviation; NS = Non-significant; PSA = prostate specific antigen; DRE = digital rectal examination

Table 2: Comparison of the VAS pain score

Score	Group 1 (Gel)	Group 2 (Injection)	p value
VAS 1 (before biopsy)			
Mean $\pm$ SD	0.1 $\pm$ 0.1	1.4 $\pm$ 2.4	< 0.0001
Range	0 – 1.1	0 – 8.4	
VAS 2 (during biopsy)			
Mean $\pm$ SD	2.0 $\pm$ 3.8	2.1 $\pm$ 3.7	NS
Range	0 – 8.5	0 – 8.5	
VAS 3 (after biopsy)			
Mean $\pm$ SD	0.8 $\pm$ 1.2	1.4 $\pm$ 1.8	< 0.001
Range	0 – 3.8	0 – 4.8	

SD = Standard deviation; NS = Non-significant

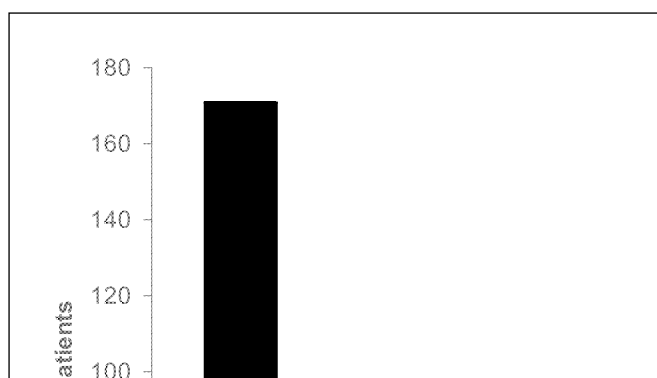


Fig. 1: VAS 1 evaluation

for the mean VAS 1 and 3 pain score values, but though the mean VAS 2 pain score was lower in Group 1, no statistically significant difference existed in this measurement (Table 2).



Fig. 2: VAS 2 evaluation

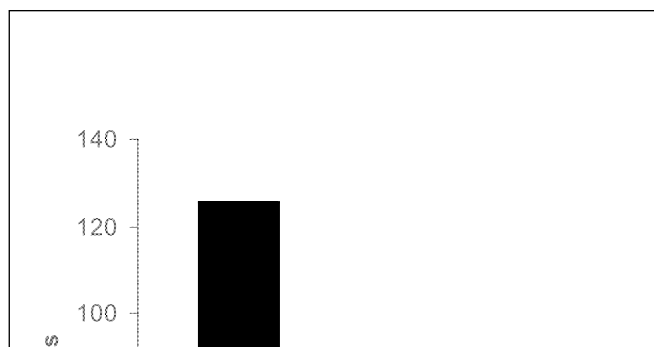


Fig. 3: VAS 3 evaluation

The incidence of adverse reactions and complications was low and similar in Groups 1 and 2. None of the patients developed any anaesthetic complication such as rectal wall haematoma, excessive rectal bleeding or systemic lidocaine toxicity. During the biopsy procedure, only one patient, in Group 1, complained of postural dizziness but orthostatic vital signs proved normal. All the patients were examined three weeks after the procedure. Three (2%) patients in Group 1 and four (2%) in Group 2 complained of prolonged haematuria. A lengthy haemospermia was noted for four cases (2%) in Group 1 and two (1%) in Group 2. No other complication was noted. None of the patients complained of acute urinary retention, persistent rectal haemorrhage or fever.

## DISCUSSION

Transrectal ultrasound prostatic biopsy has evolved into a standard procedure for diagnosing prostate cancer. Though improvements in the biopsy procedure have been introduced over the years, pain and discomfort still remain the most common side effects. This does not mean that general anaesthesia should be used routinely for TRUS guided prostate biopsy. Recently, various types of local anaesthesia have been proposed to reduce the pain and decrease the discomfort associated with prostate biopsy. The different attempts investigating the use of anaesthesia endeavour to maintain a VAS pain score of 0 to 4, which corresponds to a rating of mild pain. In this study, the VAS pain score data appear to be

relatively low (less than 3 for the mean data). It appeared that the patients who had definitive malignant pathological findings had less pain during biopsy than those with lesions. Complications after anaesthesia or biopsy were rare. As generally described in the literature, no major complication was found, the most common minor complications being haematuria or haemospermia.

The present study revealed the efficacy of lidocaine for the first time in a randomized trial. This finding did not corroborate with that of Alavi *et al* (15) nor those of Lynn *et al* (16), who demonstrated the superiority of intrarectal lidocaine infiltration. However, Stirling *et al* (17) recently confirmed that both techniques proved effective.

The authors believe that prostate biopsy in the absence of anaesthesia is painful and that anaesthesia should therefore be offered to any male undergoing TRUS prostate biopsy. The preferred local anaesthesia is the endorectal administration of lidocaine. Local anaesthetic with intrarectal application of lidocaine is simple to administer and takes only a few seconds for rectal administration of lidocaine and requires only a ten-minute delay before biopsy. This mode of anaesthesia is safe and effective in reducing discomfort.

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