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Efficacy of Periprostatic Anesthesia according to Lidocaine Dose during Transrectal Ultrasound-Guided Biopsy of the Prostate

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Purpose: The aim of this study was to evaluate the efficacy of periprostatic lidocaine injection according to lidocaine dose during transrectal ultrasound-guided prostate biopsy.

Materials and Methods: The subjects of this study were 92 patients who had undergone transrectal ultrasound-guided 12-core biopsy of the prostate. The patients were randomly assigned to three groups: group 1 (n=31, no lidocaine injection), group 2 (n=30, periprostatic injection of 10 ml 1% lidocaine), and group 3 (n=31, periprostatic injection of 20 ml 1% lidocaine). The patients were assessed for pain by use of a 10-point visual analogue scale (VAS) and for other complications after the procedure.

Results: The mean VAS scores of groups 1 through 3 were 0.93±0.89, 1.32±1.37, and 1.13±1.10, respectively. There were no statistically significant differences between the three groups. However, the mean VAS score of the biopsy pain was 5.0±1.48, 3.93±1.94, and 3.60±2.15, in the same groups, respectively, with statistically significant differences between group 1 and the other groups. Patients in groups 2 and 3 reported significantly less biopsy pain than did group 1 patients (p=0.004, 0.021), with no statistically significant difference in VAS score between groups 2 and 3 (p=0.533). With respect to post-biopsy complications, there were no significant differences in the incidence of hematuria, hematospermia, rectal bleeding, or infection among the three groups.

Conclusions: Periprostatic injection of local anesthesia with lidocaine was associated with significantly less pain than in the absence of anesthesia. Furthermore, a 20-ml dose of lidocaine produced no better pain control than did a 10-ml lidocaine dose for prostate biopsy.

Key Words: *Anesthesia; Biopsy; Prostate*

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INTRODUCTION

Transrectal ultrasound (TRUS)-guided prostate biopsy is the most commonly used procedure for detecting prostate cancer. However, pain is the main morbidity and the main hindrance to the acceptance of TRUS-guided prostate biopsy by patients. Several studies have shown that 19 to 30% of patients experience moderate to severe pain during prostate biopsy [1,2]. There has been a shift recently from the standard sextant biopsy to a 10- to 12-core biopsy protocol to increase the cancer detection rate. This extended biopsy protocol is associated with increased pain, discomfort, and anxiety [3,4]. Two factors usually responsible for pain during prostate biopsy are anal pain due to the ultrasound probe and insertion pain of the needle through the prostate [5].

Currently, there is no universally accepted method of anesthesia for prostate biopsy as evidenced by the numerous methods that have been tried and published in the literature [6-9]. Among the various methods of periprostatic anesthesia, periprostatic lidocaine injection appears to be the most popular. The lidocaine doses for periprostatic anes-

thesia have varied from 2.5 to 20 ml. Several studies have assessed the sites of periprostatic injection. Ozden et al. [7] reported that the effectiveness of periprostatic anesthesia did not differ between basal injection and apical injection. Furthermore, in their study, patients were randomly assigned into three groups depending on the doses of 1% lidocaine applied during periprostatic anesthesia at the basal lesion: 2.5 ml (group 1), 5 ml (group 2), and 10 ml (group 3). In that study, injection of 2.5 or 5 ml did not result in a significant difference in pain control, whereas use of 10 ml of 1% lidocaine produced better pain control.

Because higher doses seem to result in better pain control, at least according to this single study, the effect of doses exceeding 10 ml by basal injection needs to be discerned. To address this shortcoming, we conducted a prospective randomized controlled study to evaluate the efficacy for pain control and tolerability of periprostatic lidocaine injection according to lidocaine doses of more than 10 ml by basal injection during TRUS-guided prostate biopsy.

MATERIALS AND METHODS

1. Patients

This prospective randomized controlled trial comprised a series of 92 consecutive men (median age, 65.4 years; range, 39 to 75 years) with an abnormal prostate-specific antigen (PSA) level (>4 ng/ml) or an abnormal result on a digital rectal examination who underwent TRUS-guided biopsy and prostatic biopsy for the first time between January 2006 and December 2008. Informed consent was obtained from all patients.

2. Procedure

Patients were randomly assigned to three groups by using the restricted randomization method to achieve balance in group size. The random-number table was drawn up by the urologist and an appropriate anesthetic procedure was assigned to each number.

Group 1 received 10 ml of 2% lidocaine gel instilled rectally as a control. Group 2 received 10 ml of 1% lidocaine at the bilateral basal periprostatic lesions following rectal installation of 10 ml of 2% lidocaine gel. Group 3 received 20 ml of 1% lidocaine at the bilateral basal periprostatic lesions after 10 ml of 2% lidocaine gel was instilled rectally. Patients were unaware of their group assignment.

All patients had suppository enemas the day before and on the day of the biopsy and received intravenous antibiotics on the day before the biopsy and oral antibiotics for 7 days after the biopsy. All biopsies were performed by one individual using a 9.5 MHz HD 11 XE (Philips, New York, NY, USA). Each patient was placed in the left lateral decubitus position during the prostate biopsy. Periprostatic lidocaine injections were performed near the junction of the seminal vesicle with the base of the prostate with an 18-gauge AceCut biopsy needle (TSK Laboratory, Tochigi, Japan). The accuracy of the block was determined by detecting the collection of local anesthetic fluid on TRUS. Each biopsy was performed 5 minutes after the lidocaine injection. The 12-core biopsies were obtained by using an automatic, spring-loaded device with an 18-gauge needle. All patients underwent an equal number of biopsies. After the biopsy procedure, the patients completed a questionnaire regarding the level of pain they experienced during probe insertion and biopsy. The pain score was assessed by using a 10-point linear visual analogue scale (VAS; 0 for no pain, 10 for excruciating pain). After discharge, complications such as hematuria, hematospermia, rectal bleeding, and infection were determined by interviewing each patient on his next visit to the hospital.

3. Statistical analysis

Statistical analysis was performed by using SPSS ver. 12.0 (SPSS, Inc., Chicago, IL, USA). The groups were compared statistically by use of the Kruskal Wallis test. Various parameters that could be related to the degree of pain during the prostate biopsy (VAS score, patient's age, prostate volume, PSA, and the detection of cancer) were statistically analyzed by Pearson correlation test. Pain scores were compared between groups by use of Wilcoxon's signed ranks test. Statistical significance was defined as a p-value ≤ 0.05.

RESULTS

The mean age of the patients was 64.0±11.7 years, their mean prostate volume was 49.0±22.5 ml, and their mean PSA level was 11.0±14.6 ng/ml. There were no statistically significant differences in baseline characteristics between

TABLE 1. Patients' characteristics

Characteristic	Group 1	Group 2	Group 3	p-value[a]
No. of patients	31	30	31	
Age (yr)	64.3±9.8	65.2±14.0	62.4±11.3	0.472
Prostate volume (ml)	43.4±15.5	56.7±30.3	47.2±17.8	0.331
PSA (range, ng/ml)	13.1 (74.7)	12.2 (87.2)	11.0 (89.4)	0.261
Detection of carcinoma	11	10	8	0.693

Values are presented as mean±SD.
Group 1, control; group 2, periprostatic injection of 10 ml of lidocaine; group 3, periprostatic injection of 20 ml of lidocaine.
[a]:Kruskal Wallis test.

the three groups (Table 1). With respect to the correlation between VAS score and each parameter, such as age, prostate volume, PSA, and the detection of cancer, there were no statistical significances in Pearson's correlation test (Table 2). The mean pain VAS scores during probe insertion were 0.93±0.89, 1.32±1.37, and 1.13±1.10 in groups 1, 2, and 3, respectively, and there were no statistically significant differences between the three groups (Table 3). The mean pain VAS scores during prostate biopsy were 5.0±1.48, 3.93±1.94, and 3.60±2.15 in groups 1, 2, and 3, respectively (Table 3). Patients in groups 2 and 3, who received a periprostatic injection of 1% lidocaine, reported significant pain reduction compared with the control group (p=0.004, 0.021). However, there was no statistically significant difference in VAS score between groups 2 and 3 (p=0.533) (Fig. 1).

With respect to the incidence of complications after prostate biopsy, the three groups did not show significant differences (Table 4). One patient experienced temporary vasovagal syncope and recovered after conservative management with intravenous fluid therapy. All complications resolved with conservative management.

DISCUSSION

Although well tolerated by most men, 65 to 90% of patients reportedly have discomfort during TRUS-guided prostate biopsy [7,10,11]. One study reported that 64% of patients who underwent TRUS-guided prostate biopsy reported anxiety concerning pain before the procedure, with 20% of patients experiencing severe post-biopsy pain [4]. Pain during TRUS-guided prostate biopsy can occur during transrectal probe insertion and when the needle pierces the capsule of the prostate through the rectal wall. Lidocaine gel is usually instilled transrectally for pain reduction, but its efficacy when instilled transrectally is controversial [8,12,13].

Several nerve block methods have been investigated for better pain control. These include periprostatic injection, prostatic injection, apical anesthetic injection, and prostate plexus anesthetic injection [6]. Among them, the most commonly used method is periprostatic injection of anesthetics into the sites around the neurovascular bundle between the seminal vesicle and periprostatic tissue [6,11,14].

The technique of periprostatic injection into the basal lesion of the prostate was adapted for local anesthesia in the present study. In the process of periprostatic injection for local anesthesia, confirmation of the appropriate injections is important to maximize the anesthetic effects for pain relief during prostate biopsy. The hypoechoic wheal (the collection of local anesthetic fluid between the rectal

TABLE 2. Correlation between biopsy pain score (VAS) and each parameter

Parameter	Biopsy pain score (VAS) (r)	p-value[a]
Age (yr)	-0.009	0.934
Prostate volume (ml)	-0.064	0.542
PSA (ng/ml)	0.110	0.294
Detection of carcinoma	-0.040	0.702

VAS, visual analogue scale; PSA, prostate-specific antigen.
[a]:Pearson's correlation test.

TABLE 3. Comparison of pain score between groups

	VAS score[a]	p-value[c]	VAS score[b]	p-value[c]
Groups 1 & 2				
1	0.93±0.89		5.0±1.48	
2	1.32±1.37	0.574	3.93±1.94	0.004
Groups 1 & 3				
1	0.93±0.89		5.0±1.48	
3	1.13±1.10	0.349	3.60±2.15	0.021
Groups 2 & 3				
2	1.32±1.37		3.93±1.94	
3	1.13±1.10	0.712	3.60±2.15	0.533

Values are presented as mean±SD.
VAS, visual analogue scale.
[a]:VAS score during rectal probe insertion, [b]:VAS score during prostate biopsy, [c]:Wilcoxon's signed ranks test.

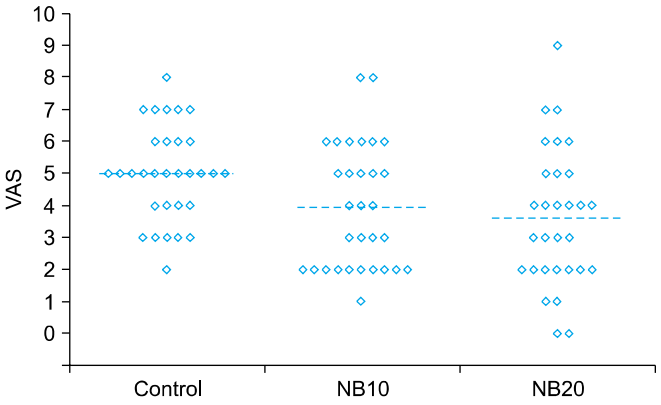

FIG. 1. The dotted line indicates the mean value of the visual analogue scale (VAS) in each group. NB, nerve block.

TABLE 4. Complications after transrectal ultrasound guided prostate biopsy

	Group 1	Group 2	Group 3
Hematuria	6 (19)	5 (17)	4 (13)
Hemospermia	1 (3)	0 (0)	2 (6)
Rectal bleeding	1 (3)	0 (0)	1 (3)
Infection	3 (10)	1 (3)	1 (3)
Syncope	0 (0)	1 (3)	0 (0)

Values are presented as number (%).
Group 1, control; group 2, periprostatic injection of 10 ml of lidocaine; group 3, periprostatic injection of 20 ml of lidocaine.

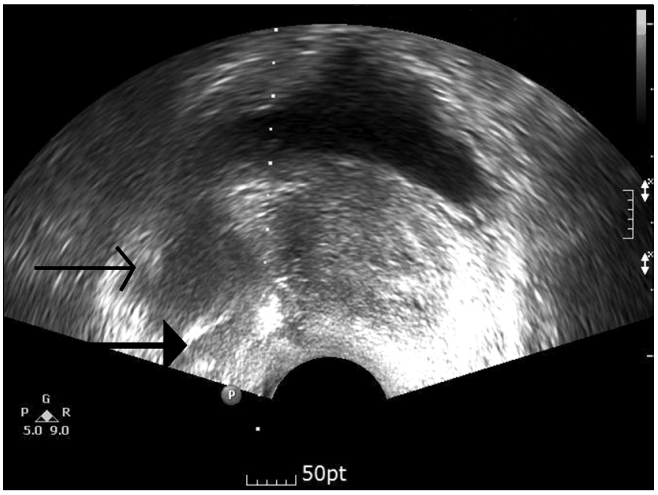

FIG. 2. Transrectal prostate ultrasonographic image (sagittal view). The ultrasonic wheal (collection of lidocaine) is seen as a hypoechoic space (arrow head). The narrow arrow indicates the seminal vesicle.

wall and the prostate detected by TRUS during periprostatic injection) is the key point for determining proper local injection [11,14] (Fig. 2). Since Nash et al. [15] reported the efficacy of periprostatic anesthesia during prostate biopsy, numerous studies have also reported the effectiveness of a periprostatic nerve block. Schostak et al. [6] reported no significant difference in pain control between those receiving an injection of a total of 20 ml of 1% lidocaine into the apical and basal lesions and the group injected with a total of 10 ml of 1% lidocaine only into the basal lesions. Trucchi et al. [16] showed that an injection of 20 ml of 1% carbocaine near the junction of the seminal vesicle with the base of the prostate achieves better pain control than does 20 ml of 1% lidocaine.

Whereas most studies to date have demonstrated good efficacy of periprostatically injected lidocaine during prostate biopsy, there is no information or consensus about the efficacy of dose escalation of lidocaine for pain relief or of the optimal dosage of lidocaine, especially concerning injection into the junction between the seminal vesicle and the base of the prostate. Presently, we assessed the efficacy of periprostatic anesthesia according to the dosage of lidocaine during TRUS-guided prostate biopsy. No statistically significant differences were evident in the VAS score between group 2 (10 ml of 1% lidocaine) and group 3 (20 ml of 1% lidocaine). This result suggests that 10 ml of lidocaine was enough to induce maximum prostatic anesthesia. Therefore, 10 ml of 1% lidocaine was judged to be sufficient for pain control.

The rate of post-procedural infection is about 14.4% of all complications. In particular, the septic condition after prostate biopsy can be life-threatening. According to Obek et al. [17], periprostatic anesthesia is associated with a higher incidence of infectious complications and is due to the extra punctures and infiltration through a highly colonized rectum into a highly vascularized space. However, Song et al. [11] and Lee et al. [18] showed that periprostatic anesthesia was not associated with a higher rate of infectious complications. Our study concurs with these prior findings. Furthermore, other complications such as hematuria, hematospermia, and rectal bleeding were resolved with conservative management.

Our study had several limitations. The first concerns are the study design and the statistical power related to sample size; the lack of a placebo group and the small sample size may have influenced the statistical results. A second limitation was that we could not determine the optimal dosage of lidocaine for periprostatic anesthesia; we only know that there was no significant difference between the group that received 10 ml and the group that received 20 ml lidocaine for periprostatic anesthesia.

CONCLUSIONS

For pain control during prostate biopsy, the combination of periprostatic nerve block and lidocaine gel provides better pain control than does lidocaine gel alone. Furthermore, 20 ml of lidocaine for periprostatic nerve block does not achieve better pain control than 10 ml of lidocaine. To determine the optimal dose of lidocaine for periprostatic anesthesia, further well-designed, placebo-controlled prospective studies involving larger populations will be needed.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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