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Prospective Randomized Controlled Trial Comparing Three Different Ways of Anesthesia in Transrectal Ultrasound-Guided Prostate Biopsy

M. Tobias-Machado, Mauricio J. Verotti, Augusto J. Aragao, Alexandre O. Rodrigues, Milton Borrelli, Eric R. Wroclawski

Section of Urology, ABC Medical School, Santo Andre, Sao Paulo, Brazil

ABSTRACT

Purpose: To make an objective controlled comparison of pain tolerance in transrectal ultrasound-guided prostatic biopsy using intrarectal topic anesthesia, injectable periprostatic anesthesia, or low-dose intravenous sedation.
Materials and Methods: One hundred and sixty patients were randomized into 4 groups: group I, intrarectal application of 2% lidocaine gel; group II, periprostatic anesthesia; group III, intravenous injection of midazolam and meperidine; and group IV, control, patients to whom no sedation or analgesic was given. Pain was evaluated using an analogue pain scale graded from 0 to 5. Acceptance of a repetition biopsy, the side effects of the drugs and complications were also evaluated.
Results: 18/20 (90%) and 6/20 (30%) patients reported strong or unbearable pain in the group submitted to conventional biopsy and topical anesthesia ($p = 0.23$, chi-square = 1.41); whereas those submitted to periprostatic blockade and sedation, severe pain occurred in only 2/60 (3%) patients ($p < 0.001$, chi-square = 40.19) and 3/60 (5%) patients ($p < 0.001$, chi-square = 33.34). Acceptance of repetition of the biopsy was present in only 45% of the patients submitted to conventional biopsy, 60% of those that were given topical anesthesia ($p = 0.52$, chi-square = 0.4), compared to 100% of those submitted to periprostatic anesthesia ($p < 0.01$, chi-square = 15.17), and 95% of those who were sedated ($p < 0.001$, chi-square = 25.97%).
Conclusions: Transrectal ultrasound-guided prostatic biopsy is an uncomfortable experience; however application of periprostatic blockade and intravenous analgesia are associated to higher tolerance of the exam and patient comfort. Low dose sedation by association of intravenous meperidine and midazolam is an emerging and safe outpatient option.

***Key words**: prostate; biopsy; needle; ultrasonography; anesthesia and analgesia*
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INTRODUCTION

From introduction by Hodge et al. in 1989 (1) to 2000, the ultrasound-guided biopsy was usually performed under no kind of anesthesia. Several authors report different indices of pain acceptance during biopsy without anesthesia, 11 to 90% of the patients complaining of some degree of pain during the exam (2,3). It was only after Soloway's report that the growing use of periprostatic blockade in clinical practice gained acceptance (4). In a recent review of the best scientific evidences, Autorino et al. concluded that periprostatic infiltration should be considered the gold standard at the present time (5).

Some authors believe that transrectal probe, a factor not alleviated by periprostatic blockade, is

an important component of pain during prostate biopsy. In this context, the use of sedation for prostate biopsy in outpatient regimen was recently described (6,7).

Our objective was to compare, in a randomized study, the use of periprostatic blockade, topical anesthesia with intrarectal lidocaine gel, intravenous sedation, and the traditional method (without analgesia) in the performance of transrectal ultrasound-guided prostatic biopsy.

MATERIAL AND METHODS

One hundred and sixty patients were submitted to transrectal ultrasound-guided prostatic biopsy from October 2000 to October 2001. The size of sample was calculated by Epi info 2000 considering confidence interval of 95% and significant pain frequency of 30%, based in previous reports (8,9).

Patients included signed the Instrument of Informed Consent of the Study according to the guidance of the Institution's Ethics Committee in Research. All the patients received a single dose of ciprofloxacin and were advised to be with a family member. The patients were randomized into 4 groups by picking their names on envelopes:

Group I (topical anesthesia): Intrarectal application of 20 mL of 2% gel lidocaine hydrochloride 10 minutes prior to the procedure.

Group II (periprostatic blockade): Transrectal application of lubricating hydrophilic gel. Ten minutes later, anesthesia was administered by four periprostatic injections of 2.5 mL of 1% lidocaine, guided by ultrasound using a 25 cm x 22 G needle introduced by the biopsy guide. Applications were made bilaterally in the neurovascular bundle region and in the prostatic apex, and biopsy was made ten minutes later (2,4).

Group III (sedation): Intrarectal application of 20 mL of lubricating hydrophilic gel with concomitant intravenous administration of 1.5 mg of midazolam maleate and 2 mg of meperidine hydrochloride, 10 minutes prior to the procedure. All patients received oxygen offered by nasal catheter (1-2 liters/ minute). Material for cardiopulmonary resuscitation and antagonists of benzodiazepine and opioid agents were available on the room.

Group IV (control): Single intrarectal application of 15 mL of lubricating hydrophilic gel 10 minutes prior to the procedure.

All of the biopsies were guided by transrectal ultrasound, using a Dornier 6.5 MHz end-fire probe, obtaining 12 prostatic fragments with an 18 G needle.

After a preliminary analysis of the first eighty procedures, our Institution's Ethics Committee in Research suggested that we abandoned the use of topical anesthesia and placebo (control group). The remaining patients were also randomized through groups II and III, until the total sample of 160 patients was completed.

With the intention of using objective parameters to analyze pain, we made a visual analogue scale graded from 0 to 5 correlating numbers, colors, and intensity of pain (10). After the exam was performed, the pain scale was presented by a different physician (who was not aware of the type of anesthesia used), and the patient was questioned about the presence and intensity of pain during the exam and acceptance of a repetition of the biopsy and the possible side effects of the drugs used.

Patients were reevaluated after 7 days and questions were asked regarding complications of the exam.

For the statistical analysis of pain, patients were regrouped into two groups: those without pain, with very light or light pain, which were considered as individuals with good acceptance of pain; and the cases with moderate, strong, and unbearable pain, where were considered as individuals with poor acceptance of pain in the exam. Statistical analysis was done in the software Epi info 2000® using the chi-square test and the exact Fisher test, with a confidence interval of 95% ($p < 0.05$).

RESULTS

Out of the 160 patients, 20 were included in group I (topical anesthesia), 60 in group II (periprostatic blockade), 60 in group III (sedation), and 20 in group IV (control). Mean age of the patients was 68.77

(± 8.37) years, mean PSA value was 15.19 (± 14) ng/mL, and the prostate volume evaluated by transrectal ultrasound was 35.67 (± 18.20) g, with no statistical difference as to these parameters among the 4 groups ($p > 0.05$), (Table-1).

Among the patients submitted to biopsy without analgesia (group IV), 19 (95%) reported some type of pain, one (5%) reported light pain, 4 (20%) moderate pain, 9 (45%) strong but bearable pain, and 5 (25%) reported unbearable pain (Figure-1).

The pain evaluation in patients submitted to intrarectal anesthesia showed no statistical difference when compared to the control group (Table-2).

In the periprostatic group, 47 (78.33%) reported pain, of which majority reported very light pain or no pain (86.7%) and only 2 patients (3.33%) defined the pain as strong but bearable (Figure-1). No patient complained of unbearable pain and there was a significant reduction of pain when compared to the group, in which no anesthesia was used ($p < 0.001$, chi-square = 40.19), (Table-2).

Out of the 60 patients submitted to intravenous sedation, 76% reported some degree of pain, most of them with a very light pain or no pain (81.6%) and only 3 (4.99%) related strong or unbearable pain. When compared to the control group, pain reduction

Table 1 – *Distribution of patients according to age, PSA values, and prostatic volume in the 4 groups studied, confirming homogeneity among the samples.*

Group	Mean Age (SD)*	Mean PSA (SD)*	Prostatic Volume* (mean)
I	69.45 (± 9.93)	15.225 (± 14.30)	37.2 (23.2)
II	70.95 (± 8.5)	14.05 (± 13.31)	35.8 (15.8)
III	67.7 (± 7.8)	22.01 (± 23.61)	38.5 (18.3)
IV	69 (± 7.3)	16.47 (± 13.88)	36.5 (17.2)

**p > 0.05*

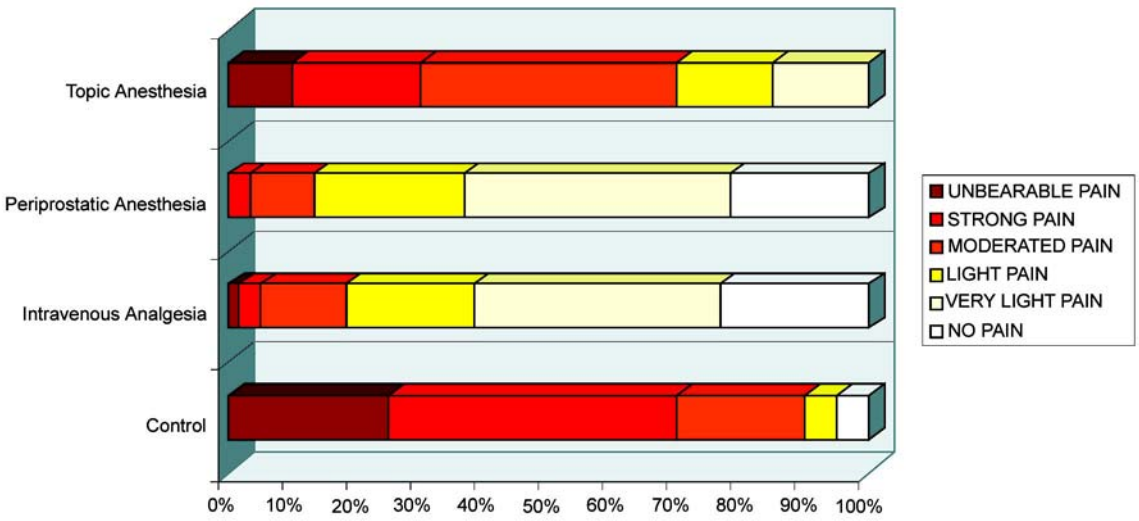

Figure 1 – *Distribution of pain intensity according to the analogue pain scale and modality of analgesia used.*

Table 2 – *Comparison of pain tolerance between the control and the anesthesia groups studied.*

	Good Pain Tolerance N (%)	Poor Pain Tolerance N (%)	p Value
Topical anesthesia (N = 20)	6 (30)	14 (70)	p = 0.23
Periprostatic blockade (N = 60)	52 (86.70)	8 (13.30)	p < 0.001
Sedation (N = 60)	49 (81.60)	11 (18.40)	p < 0.001
Control (N = 20)	2 (10)	18 (90)	
Total	109 (68.10)	51 (31.90)	

was significant (p < 0.001, chi-square = 33.34), (Table-2).

Considering the impact of pain upon acceptance of a possible repetition of the biopsy, 9 (45%) patients of the control group would accept a new biopsy, as well as 12 (60%) patients submitted to topical anesthesia (p = 0.52, chi-square = 0.4), 59 (98.33%) of the periprostatic blockade group (p < 0.001, chi-square = 29.41) and 57 (95%) of the sedation group (p < 0.001, chi-square = 25.97), (Table-3).

The main complications were hematuria (91 patients, 37.91%), rectal bleeding (76 patients, 31.25%), urinary retention (15 patients, 6.25%), febrile UTI (16 patients, 6.66%) and vasovagal reaction (24 patients, 10%). No cardiac or respiratory complication related to the use of the drug was evidenced. No morbidity prevailed among the groups studied (Table-4).

COMMENTS

Advancement in the knowledge of the rich prostatic innervation allowed the clinical use of local anesthesia in urological procedures (11).

Table 3 – *Acceptance of a possible repetition biopsy. Comparison between control group and analgesia group.*

	Acceptance N (%)	Refusal N (%)	p Value
Topical Anesthesia (N = 20)	12 (60)	8 (40)	p = 0.52
Periprostatic Blockade (N = 60)	59 (98.30)	1 (1.70)	p < 0.001
Sedation (N = 60)	57 (95)	3 (5)	p < 0.001
Control (N = 20)	9 (45)	11 (55)	
Total	137 (85.60)	23 (14.40)	

Table 4 – *Comparison in the incidence of different types of biopsy- related complications among the 4 groups studied.*

Group	Hematuria	UTI (febrile)	Rectal Bleeding	Urinary Retention	Vasovagal Reaction
I	40%	6.66%	30%	5%	8.33%
II	36.66%	5%	33.33%	5%	10%
III	38.33%	6.66%	31.66%	6.66%	10%
IV	36.33%	8.33%	30%	8.33%	11.66%
Total	91 patients	16 patients	75 patients	15 patients	24 patients

Most reports of non-randomized series describe a sextant prostatic biopsy as a procedure with good pain tolerance, with moderate or severe pain in 7-22% (8,9,12).

The main factors related to low pain tolerance during the procedure would be anxiety, increased tonus of the anal sphincter, and the number of biopsies obtained during the procedure (2,9).

The contemporary protocols establish least 10 fragments as a minimum acceptable for prostate biopsy. In our preliminary study with twelve cores, however, 90% submitted to biopsy without any form of anesthesia reported moderate to unbearable pain (2). At that moment, the procedure with no anesthesia was the standard of care. On the initial years of the XXI century, the tendency to improve pain tolerance during the biopsy was documented by a survey that showed that 50% of United States urologists were using some type of analgesia by that time (13).

Today it is accepted that some type of analgesia should be applied to minimize patient discomfort. Determining which option was the most efficient and associated with the less morbidity was the reason for this randomized study.

The contemporary options for analgesia during prostate biopsy are intrarectal topical anesthesia, periprostatic blockade, oral or intrarectal analgesia and endovenous or inhalation anesthesia.

The use of topical anesthesia with intrarectal lidocaine gel in transrectal ultrasound-guided prostatic biopsy seems quite attractive in view of its advantages, such as simplicity, clinical safety, and low cost. However, the data in the literature are scarce and controversial concerning the real value of this method. Issa et al. noted a decrease of 52% to 2% in the complaints of moderate or severe pain using the same anesthetic method (14). Most randomized prospective studies did not find a statistically significant difference between the intrarectal application of 2% lidocaine gel and placebo (12).

Stirling et al. observed that, with respect to the relief of probe- related pain (as opposed to the puncture- related pain), application of lidocaine gel was more efficient than both placebo and periprostatic injection (15).

In our study, 70% complained of moderate to unbearable pain, without a statistical difference when compared to the control group.

After statistical analysis of the first 80 patients and evaluation of the Ethics Research Committee, topical anesthesia and the use of placebo were discontinued in our study.

Of the various methods, periprostatic blockade has been shown to be safe, easy to perform and highly effective (3-5).

In 1996, Nash et al. described the technique of the periprostatic anesthesia for the performance of transrectal ultrasound-guided prostatic biopsy in 64 patients (3).

Initial reports of the University of Miami showed that periprostatic blockade was better than the use of intrarectal lidocaine gel analgesia (16). After that, the application of periprostatic blockade to reduce pain in prostatic biopsy has been gaining more acceptance worldwide, specially in more extensive biopsies (14,17).

Most comparative studies show that periprostatic blockade promotes a significant reduction in pain intensity measured by objective methods when compared to either placebo or topical analgesia with lidocaine gel (14, 15, 18). On the other hand, in a prospective and randomized clinical trial, Mallick et al. did not confirm the superiority of lidocaine infiltration over lidocaine gel (19).

Of all comparative studies, only one challenged the validity of this approach. Wu et al. (20), comparing application of 5 mL of 1% lidocaine or normal sterile saline bilaterally at the extremities of the seminal vesicles in 40 randomized patients, and they did not find any difference in pain complaints between these 2 groups.

Although the addition of periprostatic injection brings the theoretical possibility of higher bleeding and infection risks, most papers that adopt periprostatic blockade report that the procedure is safe when compared to the placebo group (21).

Other attempts for reducing the pain related to prostate biopsy are the use of oral and intrarectal non- steroidal anti-inflammatory agents and opioids like tramadol alone or in combination with other analgesics modalities.

Diclofenac administered as a suppository resulted in significantly less pain than placebo when administered 1 h prior to the biopsy procedure (22) and the combination of lidocaine periprostatic blockade with Diclofenac suppository provides additional pain relief during and after prostatic biopsy (23).

Tramadol 1.5 mg/kg in 100 mL of saline as an intravenous infusion given 30 min prior to the biopsy procedure was compared to placebo and periprostatic nerve block in a randomized study (24,25). Tramadol was found to be superior to placebo and not statistically different from periprostatic block, although a visual analogue scale indicated slightly more pain.

Application of intravenous analgesia during transrectal biopsy has been poorly reported and no comparative study with periprostatic blockade has been described so far. Some physicians do not do this procedure at the office, because an adequate hospital and anesthesiology support is needed.

The study of Peters et al. (7) remains the only one to address the use of propofol for sedation during prostate biopsy. They found significantly reduced discomfort, especially for patients who need repeated prostatic biopsies. The authors also emphasized the need for a cost analysis; obviously, propofol anesthesia needed operating theatre conditions and an anesthesiologist.

However, some recent papers show that this modality is safe and can be performed in the office. Manikandan et al. showed that nitrous oxide inhalation and periprostatic lidocaine infiltration provide significant pain relief during transrectal guided biopsy of the prostate in the outpatient setting and the techniques are effective, safe and inexpensive, but lidocaine may be better tolerated than nitrous oxide (6).

In the present study, we utilized a schedule previously described in ambulatory procedures to minimize cardiorespiratory events (26). The choice of the midazolam and meperidine combination is justified, as it allows a sedating and relaxing effect on the muscle tonus (benzodiazepine), which is important for the probe-related pain component, in addition to their analgesic effect (opiate). Such combination has also the advantage of reducing the side effects related to each single drug. Many patients may also benefit from the amnesia occurring after the procedure.

We should point out that in the adoption of this scheme of intravenous anesthesia, we chose doses that did not present relevant risks of undesirable side effects (26). With the anesthetic support available, it is possible to use such drugs in higher doses, probably decreasing or even eliminating complaints of pain during the exam.

The majority of patients submitted to this low-dose sedation scheme reported a significant reduction of pain, when compared to the control group. In our series, we have not observed any ventilatory or hemodynamic side effect with the dosage used.

Another criterion to check on the efficiency of local anesthesia is the subjective impression of the patient confronted with the need to repeat the biopsy. Such criterion reinforces the concept of benefit achieved both by using the periprostatic blockade or intravenous sedation.

CONCLUSION

Periprostatic local anesthesia and low-dose sedation reduce the painful sensation in an effective and safe way, improving tolerance to the exam and acceptance of a possible repetition biopsy without additional morbidity. Low dose sedation can reduce the anal tonus and induces amnesia in some patients.

CONFLICT OF INTEREST

None declared.

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Correspondence address:
Dr. Marcos Tobias-Machado
Rua Graúna, 104 / 131
São Paulo, SP, 04514-000, Brazil
E-mail: tobias-machado@uol.com.br

EDITORIAL COMMENT

The authors are to be congratulated for their article reporting interesting data from a prospective randomized study comparing three different ways of anesthesia in transrectal ultrasound (TRUS) guided prostate biopsy. They concluded that periprostatic nerve blockade (PNB) and low-dose sedation withy midazolam and meperidine are both safe and effective in this setting, whereas anesthetic gel instillation did not provide any benefit to the patients.

During the last 5 years, there has been a growing awareness on the need of adopting anesthesia in clinical practice when performing a TRUS guided prostate biopsy. As a proof of this phenomenon, there have been an increasing number of reports in this field during this period in the urological literature.

Although most of the morbidity associated with the procedure involves minor complications, patients perceive it as traumatic and worrisome. It is every urologist's experience that anxiety is common in men undergoing prostate biopsy and 2 important issues that should be considered are the age of the patients, that are more and more young, and the adopted biopsy protocols, that are more and more extensive in order to improve prostate cancer detection. In this respect, it has been determined that age had a significant independent effect on pain perception and younger patients had significantly more pain than older ones. Interestingly, the authors have been adopting (12 core scheme) an extensive prostate biopsy protocol, in line with the policy of most urology departments worldwide nowadays. On the other hand in most of the previous published reports, the number of cores obtained per patient ranged from 6 to 10.

Two main factors are usually responsible for pain during prostate biopsy: anal discomfort due to the ultrasound probe and insertion of needles through the prostate gland. In this report the authors provide a specific evaluation of these 2 main portions of the biopsy procedure. In addition, it is interesting to note that they did not find any difference during probe insertion and biopsy punctures when submitted to PNB. In our experience we found the patients suffering from probe insertion even after PNB, whereas they feel comfortable with the biopsy portion of the procedure. General anesthesia may overcome the pain issue during TRUS prostate biopsy, but it should be considered that it is not without risk and it

could have a significant impact on manpower and financial resources, since most of general anesthetics obviously require operation theatre conditions with increasing cost. In this respect the suggestion from the authors of the present report is interesting since the use of low dose sedation offers the possibility of an office procedure.

Different groups proposed different amounts of anesthetic medium and different injection sites for local anesthesia during prostate biopsy. Nash et al initially suggested bilateral injections at the junction of the base of the prostate and seminal vesicles. We found this technique to be safe, easy and effective. Soloway & Obek (reference 4 in the article) proposed 2 additional injections on each side, one beside the apex and one between the apex and the base. The technique adopted by the authors of this report consists of two injections for each lobe, one at the base, one at the apex. We are presently adopting one single injection per lobe at the apex level, as already suggested by others.

Interpreting the results in terms of pain and discomfort during TRUS guided biopsy remains subjective and there are no standardized criteria to define whether a given procedure is well tolerated or not. Pain is a complex perceptual experience that remains difficult to quantify. Different methods have been described for this purpose and this fact represents a bias that should be considered when analyzing the outcome from the different experiences. In the last decades the VAS has proven to be satisfactory for the subjective measurement of pain intensity. It is independent of language after instruction, provides a sensitive measure and enables statistical comparison. In some cases, besides the VAS, patients were given specific questionnaire to be completed. The authors suggested using a grading scale correlating numbers, colors and pain intensity. This option took into account the known difficulty of pain evaluation, owing the subjectivity of the symptoms and the intellectual level of some patients.

PNB requires 1 or extra needle punctures and it can be expected that these extra punctures may increase complications. It has been showed that increasing the number of injections had no effect on hemorrhagic complications. The authors did not find any significant complications after either PNB or sedation. Also in our experience the rate of complications is more related to the number of cores taken than the injection of anesthetics.

The theoretical concern of increased scarring from injection in the neurovascular bundles has not been reported to make nerve-sparing prostatectomies more difficult. This remains an open issue since reports specifically addressing this issue have not been published yet.

All urologists should be urged to introduce anesthesia in their clinical practice as a routine part of the procedure, whatever the patient characteristics and biopsy scheme. Among the various methods, PNB has shown to be safe, easy to perform, highly effective. It can be considered the gold standard at the moment, even if the optimal technique remains to be established.

Dr. Rocco Damiano
Magna Graecia University
Catanzaro, Italy
E-mail: damiano@unicz.it

Dr. Ricardo Autorino
Second University, Naples, Italy

E. P. Zukovski
Consultant Radiologist, PR, Brazil