



# Comparison of Intrarectal Lidocainated Gel, Intrarectal Ultrasonic Gel and Periprostatic Nerve Blockage concerning Patients' Pain Tolerance

Transrektal Ultrason Eşliğinde Yapılan Prostat Biyopsisinde İntrarektal Lidokainli Jel, İntrarektal Ultrasonik Jel ve Periprostatik Sinir Blokajının Hasta Ağrı Toleransı Açısından Karşılaştırılması

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## ABSTRACT

**Objectives:** Prostate biopsy is the gold standard method used in the diagnosis of prostate cancer. While periprostatic injection of local anesthetic agents during this procedure is the most effective method for reducing pain during the prostate biopsy, there are studies indicating that application of a local anesthetic agent to the rectum is also an effective method. In this study, we compared the effectiveness of intrarectal lidocaine gel (Konix Catheter Gel®), intrarectal ultrasonic gel (Konix Ultrasonic Gel®) and lidocaine administered to the periprostatic region in pain reduction before taking prostate biopsy in our patients with prostate biopsy indication.

**Methods:** In our study, 100 volunteer patients with prostate biopsy indication were included with TUTF\_BAEK2019/203 approval number of Trakya University Faculty of Medicine Ethics Committee. These patients were randomly divided into four groups of 25. Groups were named A, B, C and D. A standard 12-piece prostate biopsy was performed with a tru-cut biopsy needle from all patients. After the procedure, the patient's pain tolerance was evaluated by a different individual. The VAS scale was used to assess pain tolerance.

**Results:** A statistically significant difference was also found between the groups regarding the visual pain scores in all three stages. When STAI-I of the patients participating in this study was compared, there was no significant difference among the four groups. In our study, no significant relationship was found between pre-procedure anxiety and pain during and after the procedure.

**Conclusion:** During prostate biopsies, only periprostatic blockade with lidocaine was not sufficient at the time of introduction of the probe, causing patients to feel pain, therefore, combined with periprostatic blockage with intrarectal lidocaine gel, it has been shown that it increases patient comfort and has the lowest VAS scores in all three stages of biopsy.

**Keywords:** Intrarectal local anesthesia; periprostatic nerve block; prostate biopsy.

## ÖZET

**Amaç:** Prostat biyopsisi prostat kanseri tanısında kullanılan altın standart yöntemdir. Bu işlem sırasında, lokal anestetik maddelerin periprostatik enjeksiyonunun prostat biyopsisi sırasındaki ağrının azaltılmasında en etkili yöntem olduğu bilinmekle birlikte rektuma lokal anestetik madde uygulanmasının da etkili bir yöntem olduğunu belirten çalışmalar mevcuttur. Bu çalışma ile prostat biyopsi endikasyonu olan hastalarımızda TRUS eşliğinde prostat biyopsisi almadan önce intrarektal lidokainli jel (Konix Catheter Gel®), intrarektal ultrasonik jel (Konix Ultrasonic Gel®) ve periprostatik bölgeye verilen lidokainin ağrıyı azaltmadaki etkinliğini karşılaştırıldı.

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**Yöntem:** Trakya Üniversitesi Tıp Fakültesi Bilimsel Araştırmalar Etik Kurulu'nun TUTF-BAEK2019/203 onay numarası ile çalışmamıza Trakya Üniversitesi Tıp Fakültesi Üroloji Kliniği'ne başvuran ve prostat biyopsi endikasyonu olan 100 gönüllü hasta dahil edildi. İşlem öncesi hastaların anksiyete durumunu ölçmek için STAI-I anket formu dolduruldu. Hastalar randomize olarak 25'er kişiden oluşan A, B, C ve D olmak üzere dört gruba ayrıldı. Tüm hastalara 12 parça prostat biyopsisi alınması işlemi uygulandı. İşlem sonrasında hastanın ağrı toleransı vizüel analog skorlaması yapıldı.

**Bulgular:** Gruplar arasında her üç aşamadaki vizüel ağrı skorları arasında da istatistiksel olarak anlamlı fark bulunmuştur. Hastaların işlem öncesi anksiyetelerinin işlem sırasında ve sonrasındaki ağrı arasında çalışmamızda anlamlı ilişki bulunmamıştır. Proben rektuma yerleştirilmesi sırasında duyulan ağrının sadece intrarektal lidokain jel kullanımı ile intrarektal ultrasonik jel ve lidokainli periprostatik blokajın birlikte kullanıldığında duyulan ağrının VAS değerleri arasında anlamlı fark olmadığı görüldü. Prob yerleştirilirken üzerine lubrikan jel sürülmesine rağmen yalnızca periprostatik blokaj yapılan hastaların daha fazla ağrı duydukları ancak biyopsi alımı ve biyopsi sonrası VAS değerlerinin intrarektal ultrasonik jel ve lidokainli periprostatik blokajın birlikte kullanıldığı hastalar ile anlamlı olarak fark taşımadığı saptandı.

**Sonuç:** Prostat biyopsileri sırasında yalnızca lidokain ile periprostatik blokajın probun giriş anında yeterli olmayıp hastaların ağrı duymasına neden olduğu, bu nedenle periprostatik blokajla beraber intrarektal lidokain jel ile kombine kullanılmasının hasta konforunu arttırdığı ve bu kombinasyonun biyopsinin her üç aşamasında da en düşük VAS skorlarına sahip olduğu gösterilmiştir.

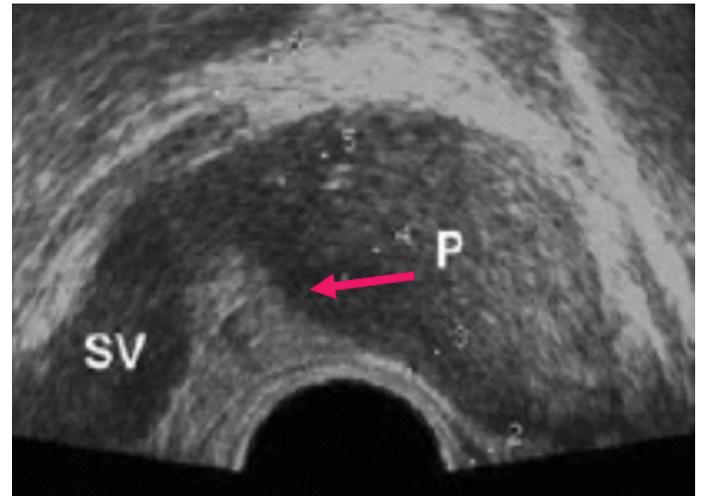
**Anahtar sözcükler:** İntrarektal lokal anestezi; periprostatik sinir blokajı; prostat biyopsi.

Related to rising advances in its diagnosis and treatment, prostate cancer, one of the most common malignancies in men, has received significant attention in recent years. In men, prostate cancer is ranked second in frequency.<sup>[1]</sup> According to previous studies, prostate cancer is the most common urological cancer in our country.<sup>[2]</sup> The first prostate biopsy using Transrectal ultrasonography (TRUS) was applied in 1989 and prostate biopsy with TRUS is the gold standard method used in the diagnosis of prostate cancer for the modern day.<sup>[3]</sup> The studies that are conducted to lessen the pain of the patient during the procedure and make the process more comfortable shown that the most effective method is the periprostatic injection of local anesthetic substances.<sup>[4,5]</sup> In addition to this information, there are other studies suggesting that the application of local anesthetic to the rectum is also an effective method.<sup>[6]</sup>

The prostate is innervated by the branches of the pelvic ganglion, which is consisting of the pelvic (parasympathetic) and hypogastric (sympathetic) nerves. The pelvic plexus innervates the prostate and forms the cavernosal nerves. This plexus runs along the posterolateral border of the prostate, anterior to the rectum, and lateral to the prostatic capsular vessels. This layout is referred to as the neurovascular bundle. Performing the periprostatic nerve block around the neurovascular bundle, rather than the seminal vesicle and prostate junction helps the patient experience less discomfort during the operation.<sup>[7,8]</sup> During prostate biopsy, the biopsy needle does not cause pain in the area above the dentate line where the nerve conduction is, while going through the rectal wall. Therefore, most of the discomfort associated

with prostate biopsy is related to the stimulation of periprostatic nerves localized within the capsule as a result of penetration of the prostatic capsule by the needle (Fig. 1).

The number of factors may cause discomfort in the prostate biopsy process. For instance, the entry of the TRUS probe into the rectum and its internal motions, the size and form of the USG probe, the penetration of the Trucut needle into the rectal wall and the prostate capsule, and the pain endured during the core biopsies.<sup>[9]</sup> In addition to these factors, various studies have shown that pre-biopsy anxiety increases pain being felt both during and after the procedure.<sup>[10]</sup> Patients are more likely to tighten the anal sphincters during biopsy due to anxiety, and this state makes it more challenging for the probe to enter and move in the rectum. Moreover, due to anxiety, the



**Figure 1.** The opening between the vesicle and the prostate. Periprostatic Blockage Area.

contraction of the anal sphincter may cause the probe tip to go under the linea dentate; thus, the pain felt by the patient during the procedure increases.

In the light of this information, we compared the effectiveness of intrarectal lidocaine gel, intrarectal ultrasonic gel and lidocaine given to the periprostatic area during TRUS guided procedure in reducing pain in patients with prostate biopsy indication. Unlike similar studies, we investigated the effects of anxiety on pre-biopsy pain during and after the procedure.

## Methods

In our study, 100 volunteer patients with prostate biopsy indication were included with TUTF\_BAEK2019/203 approval number of Trakya University Faculty of Medicine Ethics Committee. These patients were randomly divided into four groups of 25. Groups were named A, B, C and D. Patients with active anal and rectal disease, a history of using analgesic and narcotic drugs, and patients with previous TRUS or prostate biopsy were excluded from this study.

Patients had B.T. Enema the night before the operation. To minimize the effects of anxiety caused by waiting until the biopsy, patients were called at 11:00 a.m. and taken to the surgical room at 12:00 p.m. Patients were informed about anxiety before the surgery and the STAI-I questionnaire was performed to assess patients' pre-biopsy anxiety.

- Patients in group A were placed in the optimal position (lateral decubitus) 15 minutes before the procedure, and 12 mL lidocaine gel (Konix Catheter Gel) was applied to the intrarectal area.
- Patients in group B were administered 10 mL of lidocaine containing two ampoules of JETMONAL 2%/5 ml to the periprostatic area five minutes before the procedure. During the procedure, gel was applied to the probe to allow the probe to enter the rectal area
- The patients in group C were positioned 15 minutes before the procedure, and intrarectal ultrasonic gel (Konix

Ultrasonic Gel) was used. In addition, 10 mL of lidocaine containing two ampoules of JETMONAL 2%/5 mL was applied to the periprostatic area five minutes before biopsy.

- Patients in group D were placed in the optimal position 15 minutes before the procedure, and 12 mL lidocaine gel (Konix Catheter Gel) was applied to the intrarectal area. Five minutes before the procedure, 10 mL of lidocaine containing two ampoules of JETMONAL 2%/5 mL was applied to the periprostatic area (Table 1).

A standard 12-piece prostate biopsy was performed with a tru-cut biopsy needle from all patients. All biopsies were performed by the same urologist using the same ultrasound device (Esaote MyLab 40). After the procedure, the patient's pain tolerance was evaluated by a different person. The VAS scale was used to assess pain tolerance.

The patients' VAS scores at the time of insertion of the ultrasound probe (VAS1), during the procedure (VAS2) and one hour after the procedure (VAS3) were recorded.

## Results

The mean age for all patients involved in this study was 57.4 years, the mean PSA value was 7.22 ng/ml and the mean of the prostate volume was 48.2 mL.

Differences between prostate volumes which were not normal distributed between groups, total PSA and VAS1, VAS2 and VAS3 values were investigated by the Kruskal Wallis test. To find the groups that made a significant difference between the groups, the post-hoc Tamhane test was conducted.

A statistically significant difference was found between the VAS1, VAS2 and VAS3 probe scores of the patients involved in the analysis, and it was noted that the type of analgesic used during the biopsy affected the patients' comfort and biopsy tolerance during the operation ( $p < 0.001$ ,  $p < 0.001$ ,  $p < 0.001$ ) (Table 2).

In the post-hoc test performed to investigate the group that made the difference in the visual pain scores (VAS1) of the

Table 1. Patient groups and applied anesthesia methods

Patient Group	Periprostatic blockage	Intrarectal lidocaine gel	Intrarectal ultrasonic gel
A	-	+	-
B	+	-	-
C	+	-	+
D	+	+	-

Table 2. Comparison of visual pain scores by groups

	Group A	Group B	Group C	Group D	$\chi^2$	p
VAS 1	5.96±1.10	7.08±19.0	5.76±1.30	4.12±4.12	27.574	<0.001
VAS 2	6.16±1.55	4.60±2555	3.84±1.40	2.64±2.64	35.841	<0.001
VAS 3	3.12±1.30	2.32±1.03	1.64±1.15	0.72±1.02	25.333	<0.001

Table 3. Post-hoc test comparison of visual pain scores during probe insertion

	Group A	Group B	Group C	Group D
Group A	-			
Group B	0.005	-		
Group C	0.993	0.002	-	
Group D	<0.001	<0.001	<0.001	-

compared patient groups during probe insertion, the findings showed that group D had a statistically significant and lower VAS score than all of the other groups ( $p<0.001$ ,  $p<0.001$ ,  $p<0.001$ ).

While gel was used on the probe, it was found that group B, without intrarectal gel, had a statistically significant and higher VAS1 score than other groups ( $p=0.005$ ,  $p=0.002$ ,  $p=0.001$ ).

There was no statistically significant difference between VAS1 scores of groups A and C.

It was observed that during probe placement, the patients who were using only intrarectal lidocaine gel and the patients who underwent periprostatic blockage with lidocaine and intrarectal USG gel, experienced pain to a similar degree (Table 3).

In the post-hoc test performed to investigate the group that made the difference in the visual pain scores of the compared patient groups during the biopsy procedure, the findings showed that group D had a statistically significant and lower VAS2 score than all groups ( $p<0.001$ ,  $p<0.001$ ,  $p=0.031$ ). It was observed that there was a statistically significant and higher VAS2 score in group A, the group without periprostatic blockage, than in other groups ( $p=0.001$ ,  $p<0.001$ ,  $p<0.001$ ). There was no statistically significant

Table 4. Post-hoc test comparison of visual pain scores during probe insertion

	Group A	Group B	Group C	Group D
Group A	-			
Group B	0.001	-		
Group C	<0.001	0.228	-	
Group D	<0.001	<0.001	0.031	-

Table 5. Post-hoc test comparison of visual pain scores during probe insertion

	Group A	Group B	Group C	Group D
Group A	-			
Group B	0.114	-		
Group C	0.001	0.180	-	
Group D	<0.001	<0.001	0.026	-

difference between the VAS2 scores of the B and C groups (Table 4).

It was determined that group D had a statistically significant and lower VAS3 score than all groups in the post-hoc test conducted to examine the group that made a difference in the visual pain scores of the comparable patient groups one hour after the biopsy ( $p<0.001$ ,  $p<0.001$ ,  $p=0.026$ ).

The findings showed that group A had a statistically significant and higher VAS3 score ( $p=0.001$ ). There was no statistically significant difference between the VAS3 scores of the B and C groups (Table 5).

No significant difference between the four groups was observed when analyzing the STAI-1 of the patients included in the sample. No significant relationship was found in our study between the patients' anxiety before the procedure and the pain that was experienced before and after the procedure (Table 6).

Table 6. Comparison of STAI-1 scores by groups

	Group A	Group B	Group C	Group D	$\chi^2$	p
STAI-1	40.16±2.88	40.00±3.24	39.84±2.39	40.60±3.57	-1.672	0.614

## Discussion

The gold standard method for the diagnosis of prostate cancer today remains the prostate biopsy taken under TRUS. Reducing the pain that patients experience during biopsy provides convenience to the physician during the operation and improves the compliance of the patient during the biopsy and when re-biopsy is necessary.

There was no significant relationship between the degree of pain felt before and during the biopsy of patients with elevated anxiety before the biopsy procedure ( $p=0.614$ ). While Saraçoğlu's research showed that patients with high pre-biopsy anxiety encountered more pain throughout the operation, the anesthesia method used during the procedure could be effective in getting this result.<sup>[10]</sup> The fact that the pain felt as the probe is inserted into the rectum at the beginning of the biopsy would not significantly increase the VAS score when only intrarectal lidocaine is used may be attributed to the lubricant effect of the gel together with the local anesthetic effect, whereas the VAS1 value was significantly higher in the patient group, who had only periprostatic blockade than the other groups. VAS2 and VAS3 scores of the patient group who were biopsied using only intrarectal lidocaine gel were higher than the other groups showed that periprostatic blockade was significantly effective in reducing pain.

In the study conducted by Issa et al., the patients were divided into two groups. 10 ml of 2% lidocaine gel was applied intrarectally to one group, and intrarectal anesthesia was not applied to the other group. As a result of the study, they reported that VAS scores in patients who underwent intrarectal anesthesia were lower than patients who were not anesthetized.<sup>[11]</sup>

In the placebo-controlled studies in which intrarectal lidocaine gel anesthesia was examined in the prostate biopsy performed by Chang et al., they divided the patients into two groups in which intrarectal 2% lidocaine gel or ultrasonic hydrophilic gel was applied. Their intent was to evaluate the degree of pain felt by the patients. It was stated in this research that, unlike our study, intrarectal gel application with lidocaine alone did not provide statistically significant analgesia compared to the ultrasonographic gel application.<sup>[12]</sup> Raber et al. evaluated 200 patients who used intrarectal lidocaine gel and placebo before biopsy in their study. It was reported that in the group anesthetized with lidocaine gel, there was a statistically significant decrease in pain during insertion of the

probe into the rectum and during the procedure compared to the placebo group. The complication rates were similar.<sup>[13]</sup> In a study of Alevi and et al., 150 patients were divided into two groups. They applied a periprostatic blockade with lidocaine to one group and an intrarectal lidocaine gel to the other group. VAS values of patients who underwent periprostatic blockade with lidocaine were significantly lower, this result is seen in our study as well.<sup>[14]</sup> In conclusion, the pain felt during a prostate biopsy is important to increase the comfort of the patients during the procedure and the patient's compliance when re-biopsy is required.<sup>[15]</sup> In Ün et al.'s study, with the number of 793 patients, it was observed that patients who experienced pain because of insufficient anesthesia during the procedure were unwilling to re-biopsy.<sup>[16]</sup>

## Conclusion

In our study, the findings showed that periprostatic block was not sufficient, while the probe was being inserted and induced pain on patients, the combined use of intrarectal lidocaine gel with periprostatic block improved patient comfort, and this combination had the lowest VAS score in all three phases of the biopsy. For this purpose, for patient compliance, we suggest that intrarectal lidocaine gel along with periprostatic block should be applied to patients with prostate biopsy indications. While patients with high levels of pre-biopsy anxiety reported more pain during and after the procedure in different studies, it was found in our research that the state of anxiety did not significantly influence the pain during and after the procedure. By increasing the number of patients, new studies can be conducted by measuring anxiety at different moments during the biopsy process of patients, and different results can be found according to these studies.

### Disclosures

Ethics Committee Approval: TUTF-BAEK2019/203 approval number of Trakya University Faculty of Medicine Ethics Committee.

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Authorship Contributions: Concept – M.O.A, G.Ç.; Design – M.O.A, G.Ç.; Supervision – G.Ç, H.A, T.A, E.A.; Materials – M.O.A.; Data collection &/or processing – M.O.A., G.Ç.; Analysis and/or interpretation – M.O.A., G.Ç.; Literature search – M.O.A, G.Ç.; Writing – M.O.A.; Critical review – M.O.A., G.Ç.

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