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Comparison of Pudendal Nerve Blockade, Tenoxicam Suppository and Rectal Lidocaine Gel Anesthesia for Transrectal Ultrasound-Guided Biopsy of the Prostate

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Aim: We assessed the safety and efficacy of three different local anesthesia methods (pudendal nerve blockade, tenoxicam suppository and rectal lidocaine gel) before transrectal ultrasound (TRUS)-guided biopsy of the prostate in this study.
Materials and Methods**:** In our prospective and controlled study, 136 consecutive patients were randomized into four groups: men in group 1 (n=41) received no anesthesia, group 2 (n=30) received intrarectal 10 cc 2% lidocaine gel 10 mins before biopsy, group 3 (n=31) received 20 mg tenoxicam suppository 30 mins before biopsy and pudendal nerve blockade was performed in group 4 (n=34) 10 mins before biopsy using 10 ml of 1% lidocaine. The patients were asked to grade the pain when TRUS probe was inserted and during the biopsy procedure using a 11-point linear visual analog scale (VAS) and their pain scores were noted.
Results**:** There were statistically significant differences among four groups regarding the mean VAS scores during probe insertion (p=0.024) and biopsy (p=0.012). This significance was provided by the difference between the group 1 and 4 (p=0.015 for probe insertion and p=0.022 for biopsy with Tukey test). No statistically significant difference was found among the pain scores of group 1, 2 and, 3 during probe insertion and biopsy.
Conclusions: Pudendal nerve blockade was effective in reducing pain both during the biopsy procedure and probe insertion, while suppository tenoxicam and rectal lidocaine gel had no significant anesthetic effect.
Key Words: Prostate Biopsy, Anesthesia, Pain, Pudendal Nerve Blockade, Tenoxicam Suppository

Transrektal Ultrasonografi Kılavuzluğunda Prostat Biyopsisi İçin Pudental Sinir Bloğu, Supozituar Tenoksikam ve Rektal Lidokain Jel Anestezisinin Karşılaştırılması

Amaç: Bu çalışmada transrektal ultrasonografi (TRUS)-kılavuzluğunda prostat biyopsisi öncesi kullanılan üç farklı lokal anestezi yönteminin (pudental sinir bloğu, supozituar tenoksikam ve intrarektal lidokain jel) etkinlik ve güvenilirliği araştırıldı.
Materyal ve metot: Prospektif ve kontrollü olan çalışmamızda toplam 136 hasta 4 gruba randomize edildi; grup 1'deki (n=41) hastalara anestezi uygulanmadı, grup 2'deki (n=30) hastalara biyopsiden 10 dk önce intrarektal 10 cc %2'lik lidokain jel, grup 3'deki (n=31) hastalarabiyopsiden 30 dk önce 20 mg supozituar tenoksikam, grup 4'deki (n=34) hastalara biyopsiden 10 dk önce 10 ml %1'lik lidokain kulanılarak pudental sinir bloğu uygulandı. Vizüel analog skala (VAS) kullanılarak hastalardan prob girişi ve biyopsi sırasındaki ağrıyı derecelendirmeleri (0-10 puan) istendi.
Bulgular: Prob girişi (p=0.024) ve biyopsi (p=0.012) sırasındaki ortalama VAS skorları incelendiğinde 4 grup arasında istatistiksel olarak anlamlı fark mevcuttu. Bu sonuç grup 1 ve 4 arasındaki farktan kaynaklanıyordu (Tukey testinde prob girişi sırasında p=0.015 ve biyopsi sırasında p=0.022). Grup 1, 2 ve 3 arasında prob girişi ve biyopsi sırasındaki ortalama VAS skorları bakımından istatistiksel olarak önemli fark yoktu.
Sonuç: Pudental sinir bloğu prob girişi ve biyopsi sırasındaki ağrıyı azaltmada etkili olurken supozituar tenoksikam ve intrarektal lidokain jelin önemli anestetik etkisine rastlanmamıştır.
Anahtar Kelimeler: Prostat Biyopsisi, Anestezi, Ağrı, Pudental Sinir Bloğu, Supozituar Tenoksikam

Introduction

Although transrectal ultrasound (TRUS)-guided prostate biopsy is still the gold standart procedure for prostate cancer diagnosis, 70% to 85% of patients complain about some degree of pain and discomfort during the procedure.[1] This problem may lead aborting the biopsy procedure before taking enough tissue specimens for some patients. Therefore it is important to achieve a less painful and comfortable prostate

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biopsy. Multiple insertions of biopsy needle into the prostate gland and anal discomfort of TRUS probe are main factors creating pain during prostate biopsy.[2] There are plenty of studies aiming to achieve a pain-free prostate biopsy and trying to find out the most effective method. Intrarectal anesthetic gels, unilateral pudendal nerve blockade and diclofenac suppository were used to achive analgesia/anesthesia for TRUS-guided prostate biopsy.[3-5] There have been no previous studies of tenoxicam suppository or bilateral pudendal nerve blockade prior to TRUS-guided prostate biopsy.

Tenoxicam has systemic anti-inflammatory and analgesic properties. It is easily administrated in suppository form and its absorption after rectal administration is approximately 80%. It is useful for acute pain relief.[6] Tenoxicam suppository might provide local analgesia and procedural pain relief in additon to its systemic benefits.

Pudendal nerve blockade were performed unilaterally using 10 mL of 1% lidocaine before TRUS-guided prostate biopsy and found effective in reducing the pain at both biopsy and probe manipulation.[7] We aimed to achieve further anesthetic effect without increasing the dose of lidocain but performing the procedure bilaterally as originally defined.

We have designed a randomized, prospective and controlled clinical trial to investigate the safety and efficacy of pudendal nerve blockade, tenoxicam suppository and intrarectal lidocaine gel for TRUS-guided biopsy of the prostate.

Materials and Methods

A total of 136 consecutive patients underwent TRUS-guided prostate biopsy because of abnormal digital rectal examination findings and/or high prostate spesific antigen (PSA) levels were included in our study. Active painful conditions of rectum, prostate and anus (eg. hemorrhoid, anal fissure, acute prostatitis, prostatodynia), bleeding diathesis, treatment with aspirin or anticoagulants and allergy to lidocain or tenoxicam were exclusion criteria from the study. Patients using any analgesic or narcotic medication were excluded from the study to prevent the interference with pain evaluation. Patients with previous prostate biopsy history and neurological conditions were also excluded from the study to minimize influence on pain perception due to experience or altered sensation. Proflactic oral ciprofloxacin 500 mg was given all patients twice daily for 5 days starting the day before biopsy. Self-administrated fleet enema was used for bowel cleansing. All patients fully informed about the procedure and consent forms were provided.

Patients were randomized into 4 groups. Group 1 (n=41) served as controls and no analgesia/anesthesia was given. Group 2 (n=30) received intrarectal 10 cc 2% lidocaine gel 10 mins before biopsy. Group 3 (n=31) received 20 mg tenoxicam suppository 30 mins before biopsy. Pudendal nerve blockade was applicated to group 4 (n=34) by the same anesthesiologist 10 mins before biopsy. TRUS imaging was performed with the patient in the left lateral decubitus position using a Hitachi EUB 420 ultrasound system with 6.5 MHz biplane probe (Hitachi, Tokyo, Japan). After transverse and sagital imaging, prostate volumes were calculated using the software of ultrasound device. Ten biopsy cores were obtained from the prostate gland, including 5 from each lobe (apex, midgland, base, lateral and far lateral) using an automatic spring-loaded biopsy gun with an 18 gauge biopsy needle. Patients were asked to grade the pain when TRUS probe was inserted and during the biopsy procedure using a 11 point linear visual analog scale (VAS) from 0 (no discomfort) to 10 (severe pain). Pain scores obtained real time were recorded to the patients files.

Pudendal nerve blockade was performed manually by modified perineal approach without any radiologic guidance. The patients placed in left lateral decubit position with knees and hips flexed. After perineal cleaning with iodine solution and proper wrapping, ischial tubercle was palpated and a 27 gauge hypodermic needle was inserted perpendicularly to the skin surface till touching the ischial tubercle. And then the needle retracted 1 cm and advanced 6-7 cm 20° laterally and 45° distally for reaching to the ischiorectal fossa. After aspiration, 5 mL of 1% lidocaine was injected. And then the same procedure was performed to the opposite side. Confirmation of exact location of pudendal blockade was done by checking the cutaneous anesthesia of pudendal nerve territory by pin-prick. The procedure rarely took longer than 5 minutes. Prostate biopsy was performed 10 minutes after the nerve blockade. SPSS 13.0 package software program was used for performing data analysis. One-way ANOVA and Tukey test were used to compare the mean VAS scores of the groups. p values less than 0.05 were accepted as statistically significant**.**

Results

The mean age of total 136 patients was 68.1 ± 7.9 years, mean serum PSA level was 30.5 ± 93.6 ng/mL and mean prostatic volume was 56.6 ± 30.2 mL. There was no significant difference among the groups in regard to mean patient age, serum PSA and prostatic volume (Table 1).

There was a statistically significant difference among the groups in regard to mean VAS score during biopsy (p=0.012) and probe insertion (p=0.024) (Table 2). This

significance was provided by the difference between the group 1 and 4 (p=0.022 for biopsy and p=0.015 for probe insertion with Tukey test). No statistically significant difference was found among the pain scores of group 1, 2 and, 3 during biopsy and probe insertion.

Discussion

TRUS-guided prostate biopsy is the gold standart procedure for diagnosis of prostate cancer. The procedure is quite fast, safe and frequently used in daily urologic practice. Pain and discomfort are mainly derived from ultrasonic probe manipulation and multiple needle insertions.[2,4] However, a significant proportion of patients consider this procedure uncomfortable and sometimes painful. Therefore, it is advocated that it should be carried out under some forms of general or local anesthesia/analgesia.[8]

General anesthetics, opioids, unilateral pudendal nerve or periprostatic blocks, intrarectal lidocain gels, suppository or oral nonsteroid anti-inflammatory drugs are used for this purpose[9] On the other hand, some urologists still believe that analgesia or anesthesia is unnecessary for TRUS-guided prostate biopsy.[10]

Using intrarectal gels containing lidocaine have variable results. According to Issa et al. 2% lidocaine gel was found effective for providing satisfactory anesthesia.[3] However there were several studies stating that it was not superior to placebo.[11,12] Also in our study, intrarectal lidocaine gel administration did not show any significant analgesic effect over control and tenoxicam suppository groups during both probe insertion and biopsy.

Other suggested method of analgesia is suppository anti-inflammatory drugs. For that purpose diclofenac was used and found to be effective.[5] We used another suppository anti-inflammatory drug tenoxicam before TRUS-guided biopsy of prostate. Tenoxicam is a thenothiazine derivative of the oxicam class of non-steroidal anti-inflammatory drugs. It is available in oral, suppository and injectable forms and acts both locally and systemically.

There is no benefical local effect when it is used orally and parenterally. The suppository form is available as 20 mg and it gives effective pain relief for a long duration.[6] In our study, we did not observe any significant analgesic effect of tenoxicam suppository over control during both biopsy and probe insertion.

Pelvic floor muscles and organs are innervated by the pudendal nerves.[13] Pudendal blockade is necessary for some urologic and anorectal procedures to be done successfully.[14]

Using the pudendal nerve block for an analgesic option in patients undergoing minor gynecologic, urological and anococcygeal operations is not new.[15] As our knowledge, it was not used for the prostate biopsy before, except the unilateral pudendal blockade study of Adsan et al.[4] Pudendal block is also used in the neurolytic block for intractable pelvic pain, urodynamic studies of sphincteric function, penile prosthetic surgery and in the diagnosis of neurogenic impotence.[15,16]

Computed tomography, ultrasound, and C-arm guided methods have been used to perform pudendal block more precisely.[17-19] However, those have the need for expensive equipment, long procedural time and high cost. So, we think that they are not suitable for daily office procedures.

According to our observations, modified perineal approach without any radiological guidance is successful enough to reach the pain reduction in hands of a qualified clinician. Adsan et al. performed pudendal block unilaterally for relief of all pain during TRUS guided biopsy of the prostate and found effective.[4]
We think that pudendal blockade should be performed

Table 1. The mean patient age, serum PSA level and prostatic volume of the groups.

	Group 1 (n=41)	Group 2 (n=30)	Group 3 (n=31)	Group 4 (n=34)	p value*
Age (year)	69.1±7.5	70.5±8.5	64.7±6.7	67.8±8.0	0.06
PSA (ng/mL)	21.2±30.8	66.7±185.1	20.0±28.8	17.1±18.8	0.11
Prostate volume (mL)	59.4±33.9	63.6±32.5	58.0±23.8	46.1±25.4	0.10

* One-way ANOVA

Table 2. The mean visual analog scale scores of the groups.

	Group 1 (n=41)	Group 2 (n=30)	Group 3 (n=31)	Group 4 (n=34)	p value*
During probe insertion	3.56± 2.11	2.67 ± 1.76	2.65± 1.45	2.1± 2.7**	0.024
During biopsy	4.0 ± 2.39	2.47 ± 2.41	3.52± 2.15	2.3± 2.9***	0.012

*One-way ANOVA

** Significant differences between group 1 and 4 (p=0.015, Tukey test)

*** Significant differences between group 1 and 4 (p=0.022, Tukey test)

bilaterally as classically defined. Because the pudendal nerves are bilateral and the biopsy cores are taken bilaterally during the prostate biopsy procedures. In our study, 5 patients experienced transient parestesia of the perineum and penis. No other side-effects or complications (such as haematoma formation, intra-vascular injection, drug idiosyncrasy, faecal soiling) were observed in relation to the block. Shafik et al. reported an additional branch of the pudendal nerve termed as the accessory nerve, innervating the levator ani, perineal muscles and perineal skin.[20] Double innervation of the levator ani muscle and external sphincter (one from accessory pudendal branch, one from the inferior rectal nerve) might provide added protection against faecal incontinence.

Conclusion

According to our results, pudendal nerve blockade seems to be an efficient and safe analgesic method for TRUS-guided biopsy of the prostate. We did not observe any significant analgesic effects of tenoxicam suppository and intrarectal lidocaine gel applications. Pudendal nerve blockade provide efficient patient comfort by reducing pain both during probe insertion and biopsy procedure.

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