

## Research Article

## Does music from noise-canceling headphones have a beneficial effect on men undergoing transrectal ultrasound-guided prostate biopsy?

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## ABSTRACT

**Background:** The objective of this study was to evaluate the effect of music with noise-canceling headphones on men undergoing transrectal ultrasound-guided prostate biopsy (TRUSPB) in a prospective randomized study.

**Methods:** From January to February 2020, 94 men underwent TRUSPB at our institution. They were divided into two groups and wore noise-cancelling headphones—group 1 (n = 47) did not listen to music and group 2 (n = 47) listened to music. We examined the patients' clinical characteristics and compared the objective and subjective measurements before and after the procedures. Primary outcomes included vital signs, the State-Trait Anxiety Inventory (STAI, 20–80) scale; and the visual analog scale (VAS, 0–10) for the assessments of pain, satisfaction, and willingness to repeat the procedure.

**Results:** There were no significant differences in patients' characteristics or the prebiopsy status between the groups. Postbiopsy vital signs for objective parameters were statistically similar between the groups; however, the subjective parameters were not. Postbiopsy STAI-state and VAS scores were significantly lower and VAS scores for the patients' satisfaction and willingness to repeat the procedure were significantly higher in Group 2 than in Group 1 ( $p = 0.004$ ,  $p = 0.009$ ,  $p = 0.004$ , and  $p = 0.003$ , respectively). In addition, changes in the STAI-state score before and after the procedure were significant in Group 2 ( $p = 0.001$ ).

**Conclusions:** Music from noise-canceling headphones may have beneficial effects on anxiety, pain, satisfaction, and willingness to repeat the procedure in men undergoing TRUSPB.

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## 1. Introduction

Prostate cancer is one of the most critical health concerns for men.<sup>1</sup> Transrectal ultrasound-guided prostate biopsy (TRUSPB), performed in patients with suspected prostate cancer, has been a standard procedure for the histological diagnosis of prostate cancer.<sup>2</sup> However, TRUSPB can lead to complications such as pain, hematuria, acute urinary retention, urinary tract infection, and life-

threatening sepsis.<sup>2,3</sup> Therefore, TRUSPB could be considered a burdensome procedure that can cause pain and anxiety in patients scheduled for TRUSPB.<sup>4,5</sup>

Music is known to reduce pain, anxiety, and stress by diverting the patient's attention away from negative stimuli and helping them focus on something pleasant and encouraging.<sup>6</sup> Previous studies have demonstrated that music could be an inexpensive, safe, and a potentially nonpharmacological method that has a positive effect on the control of acute and chronic pain, which is accepted by various medical fields as well as urologic interventions.<sup>7,8</sup> A recent study showed that noise causes high levels of both self-reported stress and perceived workload.<sup>9,10</sup>

During TRUSPB, various noises are generated in the space and these can negatively affect the patients. Noise-canceling headphones are designed to attenuate external noise at the ear and the

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technique is more effective at reducing sound.<sup>11</sup> This reduces confounding noise, thereby allowing the user to feel comfortable and better understand speech transmitted to the headphone.<sup>12</sup> Considering these results, we hypothesized that music from noise-canceling headphones could affect men undergoing TRUSPB. Therefore, we aimed to evaluate the effect of music with noise-canceling headphones on men undergoing TRUSPB using subjective and objective parameters.

## 2. Methods

### 2.1. Patients

Overall, 94 patients who underwent TRUSPB and were hospitalized in our institution from January to February 2020 were included. Patients were randomized into the no music group (Group 1,  $n = 47$ ) and music group (Group 2,  $n = 47$ ) with noise-canceling headphones using block randomization. The indications for biopsy included elevated serum prostate-specific antigen (PSA) levels (with or without free PSA levels) or abnormal digital rectal examination findings. Patients were excluded if they had a history of anxiety disorder or other psychiatric diseases. In addition, patients with hearing loss due to difficulty in communication and patients who were unable to complete the biopsy and required questionnaires because of language impairment were excluded. All participants provided written informed consent. The study was carried out in accordance with the Declaration of Helsinki and the Ethical Guidelines for Clinical Studies. This study protocol was reviewed and approved by the institutional review board of the Chonnam National University Hwasun Hospital (IRB approved protocol: No CNUHH-2019-196).

### 2.2. Pre- and Post-TRUSPB objective and subjective parameter assessments

Patient characteristics include age, body mass index, medical history, biopsy history, the International Prostate Symptom Score, International Index of Erectile Function (IIEF-5) score, and Aging Male Symptoms (AMS) score, PSA, serum testosterone level, maximal flow rate, and postvoid residual urine volume were investigated. Blood samples were obtained in the morning (between 8 and 10 a.m.) under the same protocol in all patients.

Objective parameters such as systolic blood pressure (SBP), diastolic BP, heart rate, respiratory rate, and arterial oxygen saturation were recorded before and after the procedure, respectively. As subjective parameters, the prebiopsy State-Trait Anxiety Inventory (STAI)-state and STAI-trait scores were investigated the day before the procedure, and the postbiopsy STAI-state score was measured immediately after the biopsy in the ward. STAI was used to assess patient anxiety, which is a self-reported anxiety inventory that contains two separate 20-item multiple-choice subscales that measure trait (baseline) and state (situational) anxiety. The overall score ranges from 20 to 80: the higher the score, the higher the level of anxiety.<sup>13</sup> The visual analog scale (VAS) was also used to quantify pain levels on a scale of 0 to 10, with 0 indicating “no pain” and 10 indicating “the worst pain imaginable.” The postprocedural questionnaire also included overall satisfaction of the prostate biopsy experience on a scale of 0 to 10 and a rating on willingness to undergo the procedure again if needed on a scale of 0 to 10.

### 2.3. TRUSPB procedure

All TRUSPB were performed by the same radiologist at our institution to obtain 12 core biopsies under the same protocol. Rectal swab samples were obtained within 2 weeks before the

administration of antibiotics and TRUSPB, and povidone-iodine rectal cleansing was carried out just before the biopsy. All the patients were given intravenous pethidine HCl (pethidine HCl, 25 mg/0.5 mL/A) once just before the biopsy. They were also asked to take oral acetaminophen 650 mg tablet twice a day for 3 days starting from the day of the biopsy. A 5.0 to 7.5 MHz transrectal ultrasound transducer was inserted through the anus. A biopsy needle was inserted through the steering device attached to the transducer. For a biopsy, an 18-gauge automatic biopsy gun (ACECUT; CIVCO Medical Solutions, Kalona, IA, USA) was used, and the needle length was 20 cm, the cutting notch was 1.6 cm, and the stroke length was 22 mm. The path of the biopsy needle was visualized through the electronic guideline provided in the ultrasound (US) image. Two cores were collected from each of the six regions of the prostate (right upper, right middle, right lower, left upper, left middle, and left lower), and a total of 12 tissues were obtained. Immediately after obtaining the tissue, the prostate was compressed for a few minutes with a US probe to prevent bleeding.

### 2.4. Application (provision) of music

The music to be provided to the patient was determined by checking the genre and volume of the patient's preferred music the day before TRUSPB. All patients wore noise-canceling headphones (Bose QuietComfort 35 II Wireless Bluetooth Headphones, Bose, Framingham, MA, USA) before starting the biopsy at the procedure room. Only after the procedure assistant checked whether music was provided or not after randomization, the preferred music was provided to the patients with the desired type and volume in the music group. The radiologist performed the biopsy without recognizing whether or not to provide music. Music continued to be provided until the procedure was over and before moving to the ward. Owing to the concern of lacking interaction between the patient and the radiologist when listening to music, all patients were notified in advance to raise their hand at any time during the procedure if they wanted any interaction with the physician.

### 2.5. Statistical analysis

Statistical analyses were performed using SPSS version 20.0. (IBM Corp., Armonk, NY, USA). Continuous variables were reported as mean values with standard deviations; categorical variables were presented as frequencies (%). Comparative analysis between two groups was performed using the chi-square test for categorical data and independent t-test for continuous data as applicable. Statistical significance was assumed when the  $p$  value was less than 0.05 ( $p < 0.05$ ) for all analyses.

## 3. Results

### 3.1. Patient characteristics

Demographic data and preoperative characteristics for all enrolled patients are summarized in Table 1. Patients were divided into the no music group (Group 1,  $n = 47$ ) and music group (Group 2,  $n = 47$ ) with noise-canceling headphones. The patient's mean age was  $70.6 \pm 8.8$  years, and body mass index was  $24.8 \pm 3.3$  kg/m<sup>2</sup>. The number of patients with a history of hypertension, diabetes mellitus, and nonurologic cancer was 41 (43.6%), 22 (23.4%), and 23 (24.5%), respectively. The mean serum PSA level was  $14.6 \pm 26.0$  ng/mL, and 52 (55.3%) patients were diagnosed with prostate cancer. The mean serum testosterone level was  $3.2 \pm 1.1$  ng/mL. The IIEF-5 and AMS score was  $10.2 \pm 7.3$  and  $38.1 \pm 12.1$ , respectively. There was no statistically significant difference in the patient characteristics between the no music group and music with noise-canceling

**Table 1**  
Patients' characteristics and prebiopsy status comparison between the two groups (n = 94)

Variables	Total	Group 1 (n = 47)	Group 2 (n = 47)	p value
Age (years)	70.6 ± 8.8	70.7 ± 8.6	70.4 ± 9.1	0.862
Body mass index (kg/m <sup>2</sup> )	24.8 ± 3.3	24.3 ± 3.3	25.4 ± 3.2	0.127
Hypertension (%)	41 (43.6)	20 (42.6)	21 (44.7)	0.835
Diabetes mellitus (%)	22 (23.4)	9 (19.1)	13 (27.7)	0.330
Cancer history (%)	23 (24.5)	10 (21.3)	13 (27.7)	0.472
Biopsy history (%)	22 (23.4)	8 (17.0)	14 (29.8)	0.144
Prostate-specific antigen (ng/mL)	14.6 ± 26.0	12.2 ± 16.8	17.1 ± 32.7	0.377
Testosterone (ng/mL)	3.2 ± 1.1	3.2 ± 1.2	3.1 ± 1.1	0.679
Total IPSS score	13.4 ± 8.1	14.6 ± 6.9	12.3 ± 9.0	0.185
Voiding symptom	7.8 ± 5.4	8.4 ± 4.5	7.2 ± 6.2	0.274
Storage symptom	5.7 ± 3.3	6.1 ± 3.1	5.2 ± 3.4	0.149
Maximal flow rate (mL/sec)	14.5 ± 6.9	14.9 ± 6.9	14.0 ± 7.0	0.519
Postvoid residual urine (mL)	54.9 ± 62.5	51.8 ± 58.4	58.1 ± 66.8	0.631
IIEF-5 score	10.2 ± 7.3	9.4 ± 7.5	11.0 ± 7.1	0.294
AMS score	38.1 ± 12.1	38.8 ± 13.6	37.4 ± 10.5	0.565
Objective parameters				
Systolic BP (mmHg)	121.8 ± 13.7	122.5 ± 11.7	121.1 ± 15.6	0.612
Diastolic BP (mmHg)	74.3 ± 9.8	75.5 ± 8.9	73.1 ± 10.7	0.234
Heart rate (beats/min)	69.5 ± 7.6	69.9 ± 7.7	69.1 ± 7.5	0.636
Respiratory rate (breaths/min)	19.9 ± 0.6	19.9 ± 0.6	19.9 ± 0.6	1.000
Arterial oxygen saturation (%)	96.4 ± 1.4	96.4 ± 1.4	96.4 ± 1.4	0.885
Subjective parameters				
STAI-state score	46.0 ± 6.2	45.9 ± 7.5	46.2 ± 4.7	0.843
STAI-trait score	42.8 ± 7.2	42.5 ± 8.2	43.1 ± 6.2	0.681
Prostate volume	41.2 ± 19.8	42.4 ± 22.0	40.0 ± 17.5	0.556
Postbiopsy Pca diagnosis (%)	52 (55.3%)	24 (51.1)	28 (55.3)	0.407

IPSS, international prostate symptom score; IIEF, international index of erectile function; AMS, aging males' symptoms; BP, blood pressure; STAI, state-trait anxiety inventory; Pca, prostate cancer.

headphones group including prebiopsy objective and subjective parameters. Patients did not present with postbiopsy infectious complications or needed readmission. Three patients (2 patients in Group 1, and 1 patient in Group 2) who visited earlier than the scheduled date presented with intermittent gross hematuria which relieved spontaneously after a few days of medication.

### 3.2. Pre- and post-TRUSPB objective and subjective parameters

The comparison of postbiopsy objective and subjective parameters between the two groups was summarized in Table 2. The systolic BP, diastolic BP, and heart rate were increased in both groups after the procedure. However, the respiratory rate and arterial oxygen saturation were comparable in the groups. There was no significant difference between the two groups in the

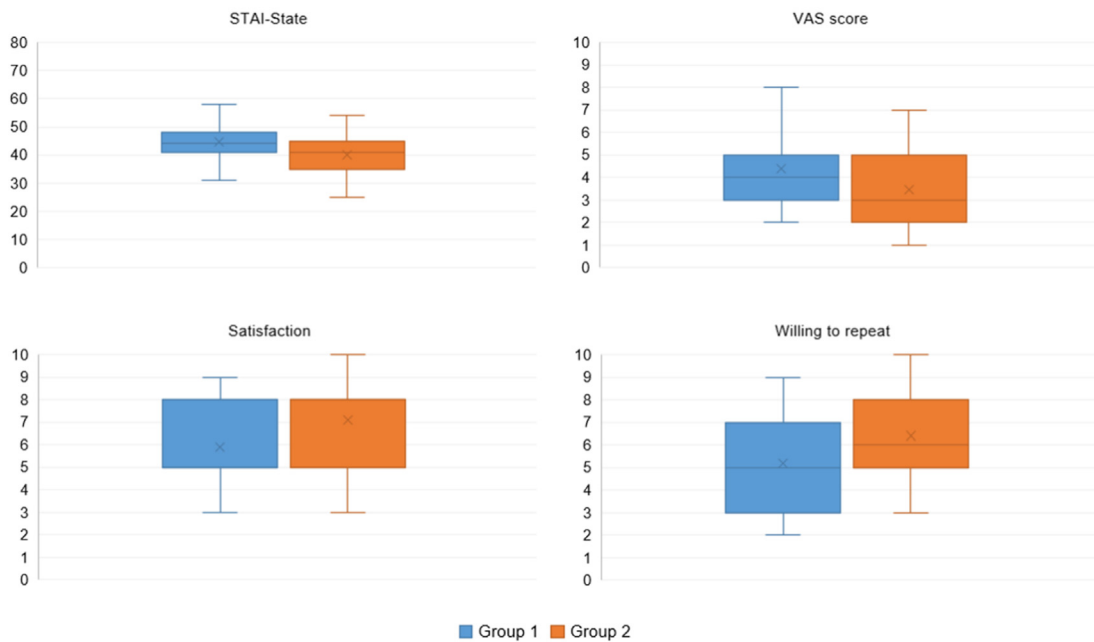
postprocedural objective parameters ( $p > 0.05$ ). However, the postprocedural subjective parameters were different.

The mean score of postbiopsy subjective parameters including the STAI-state, VAS, satisfaction, and willingness to repeat biopsy was  $42.4 \pm 7.9$ ,  $3.9 \pm 1.8$ ,  $6.5 \pm 2.0$ , and  $5.8 \pm 2.0$ , respectively (Fig. 1). The postbiopsy STAI-state score showed significantly lower in group 2 than group 1 ( $p = 0.004$ ). The difference was consistently significant in the change of STAI-state score before and after the biopsy between both groups ( $p = 0.001$ ). Postbiopsy VAS scores for pain were lower, and VAS scores for the patients' satisfaction and willingness to repeat the procedure were higher in Group 2 than in Group 1 ( $p = 0.009$ ,  $p = 0.004$ , and  $p = 0.003$ , respectively).

**Table 2**  
Comparison of postbiopsy parameters between the two groups

Variables	Total	Group 1 (n = 47)	Group 2 (n = 47)	p value
Objective parameters				
Systolic BP (mmHg)	137.3 ± 15.4	140.2 ± 15.2	134.5 ± 15.2	0.071
Postbiopsy change	15.5 ± 13.0	17.7 ± 13.4	13.4 ± 12.4	0.113
Diastolic BP (mmHg)	80.1 ± 10.2	81.1 ± 9.6	79.2 ± 9.1	0.367
Postbiopsy change	5.9 ± 5.4	5.6 ± 5.9	6.1 ± 5.0	0.651
Heart rate (beats/min)	72.2 ± 9.7	75.4 ± 9.1	73.0 ± 10.3	0.233
Postbiopsy change	4.8 ± 6.8	5.6 ± 6.8	3.9 ± 6.9	0.241
Respiratory rate (breaths/min)	20.0 ± 0.1	20.0 ± 0.1	20.0 ± 0.0	0.320
Postbiopsy change	0.1 ± 0.6	0.1 ± 0.6	0.1 ± 0.6	0.862
Arterial oxygen saturation (%)	96.6 ± 2.1	96.4 ± 2.4	96.7 ± 1.9	0.412
Postbiopsy change	0.1 ± 2.4	-0.1 ± 2.5	0.3 ± 2.4	0.425
Subjective parameters				
STAI-state score	42.4 ± 7.9	44.7 ± 8.3	40.1 ± 6.8	0.004
Postbiopsy change	-3.6 ± 5.8	-1.2 ± 6.1	-6.1 ± 4.5	0.001
VAS score	3.9 ± 1.8	4.4 ± 1.5	3.5 ± 1.9	0.009
Satisfaction	6.5 ± 2.0	5.9 ± 2.0	7.1 ± 1.8	0.004
Willing to repeat biopsy	5.8 ± 2.0	5.2 ± 2.0	6.4 ± 1.9	0.003

BP, blood pressure; STAI, state-trait anxiety inventory; VAS, visual analog scale.



**Figure 1.** Box plots of postbiopsy subjective parameters between the two groups. Box plots show postbiopsy subjective parameters including STAI-state (Trait Anxiety Inventory), VAS (visual analog scale), satisfaction, and willingness to repeat biopsy between the two groups. The postbiopsy STAI-state score and the postbiopsy VAS score for pain show significantly lower in Group 2 than Group 1 ( $p = 0.004$  and  $0.009$ , respectively), and VAS scores for the patients' satisfaction and willingness to repeat the procedure are significantly higher in Group 2 than in Group 1 ( $p = 0.004$  and  $0.003$ , respectively).

#### 4. Discussion

The effect of music on vital signs and arterial oxygen saturation, which was evaluated as a measure of the objective parameter in our study of providing music via noise-canceling headphones to men undergoing TRUSPB seems to be limited. However, through subjective data, it was confirmed that it positively reduces anxiety and pain. It also shows positive effects on the satisfaction and willingness to repeat biopsies of patients who received music through noise-canceling headphones.

A prostate biopsy is essential for histologic diagnosis of prostate cancer, and increasing rates of PSA testing are leading to more biopsies.<sup>1</sup> Problematic postbiopsy complications can lead to increased anxiety, distinct from distress related to the diagnosis of prostate cancer.<sup>14</sup> Therefore, patients undergoing TRUSPB are inevitably sensitive to pain, and in accordance with a previous study by Chopra et al., about 20% of patients who underwent TRUSPB experienced unacceptable pain.<sup>15</sup> Local anesthesia using lidocaine for pain relief in TRUSPB was attempted.<sup>16</sup> However, local anesthesia is still not commonly used, and sedatives and analgesics are generally used in real practice to reduce anxiety and pain.<sup>17</sup>

The biological mechanisms involved in the interconnection between the physiological effects of anxiety and pain perception are well known.<sup>18,19</sup> Anxiety triggers the activation of the sympathetic nervous system. It stimulates the neuronal release of acetylcholine, promoting epinephrine and norepinephrine release from the adrenal cortex, and increases pain perception by activating the adrenaline response by epinephrine.<sup>20</sup> Music can reduce the dosage of sedatives and analgesics because it can reduce the perception of discomfort by activating the cingulo-frontal cortex associated with pain control by reducing anxiety and distraction.<sup>7,21</sup> The combination of drugs and noninvasive, nonpharmacological interventions may be an effective way to reduce patient anxiety and pain immediately after surgery or procedure.<sup>22</sup> A recent meta-

analysis study to compare and evaluate music interventions' effectiveness in patients with cancer reported that music interventions could have beneficial effects on anxiety, pain, fatigue, and quality of life.<sup>23</sup>

Some studies have been reported regarding the effect of music conducted during TRUSPB. In the randomized trial performed by Vignesh et al., the anxiety and pain reduction effects of music during TRUSPB were not confirmed, and there was no difference in the group receiving or not receiving music in the vital sign, satisfaction, and willingness for repeat biopsy.<sup>24</sup> Cho et al. reported that anxiety decreased in the group receiving music, but the pain score did not show any difference between the group receiving and not receiving the music.<sup>25</sup> Headphones were not applied to men who had TRUSPB in the studies above. In a study by Chang et al. that applied music through headphones, pain and anxiety were significantly reduced in the group receiving music. Patient satisfaction and willingness to repeat the biopsy were also higher in the group receiving music. Heart rate and SBP measured after biopsy were significantly lower in the group receiving music.<sup>26</sup> In a case-control study conducted by Chiu et al., pain and anxiety were significantly lower in the group of which the music was provided through the headphones. The heart rate and SBP did not show statistically significant differences in the group receiving and not receiving music.<sup>27</sup>

Noise-canceling headphones can be useful in conveying music as it reduces confusion noise and helps users better understand the sound passing through the headphones.<sup>28</sup> Tsivian et al. divided patients who received TRUSPB into three groups, 1) without noise-canceling headphones and music; 2) only wore noise-canceling headphones without music; 3) wore noise-canceling headphones with music. The vital sign showed no difference between the three groups. In the group with music using the noise-canceling headphones, reduced pain and anxiety was demonstrated compared with other groups. It was concluded that the music affected anxiety

and pain reduction and that using only a noise-canceling headphone did not affect anxiety and pain reduction.<sup>29</sup> Similarly, in the present study, our results showed a significant reduction of pain and anxiety in the group receiving music through noise-canceling headphones. Positive results were also found in patient satisfaction and willingness to repeat biopsy. However, there were no significant results for blood pressure, heart rate, respiratory rate, and arterial oxygen saturation. Previous and the present study showed the music using a direct medium could make the effect of providing music stronger than otherwise.

Our study has several notable strengths compared with previous studies that evaluated the effect of music during TRUSPB. Previous studies have used lidocaine gel or lidocaine injection to relieve prebiopsy pain.<sup>24-27,29</sup> However, lidocaine's effectiveness may vary from patient to patient, which can be insufficient to explain the pain-reducing effects of music. However, because local anesthesia with lidocaine has not been performed in our study, the effects of music can be better explained. Also, noise-canceling headphones are worn in all patients, and the operator is blinded, reducing possible bias caused by the operator. Also, we provided the music in which the patient selected the genre and volume previously. It seemed to have a positive effect on the subjective parameters in our study by predetermining the desired music type and volume, but further research is needed.

However, the present study also has several limitations. It was a study with a relatively small sample size conducted at a single institution in Asia. Because the degree of pain may vary by region and race, large-scale studies in various regions are needed in the future.<sup>30</sup> The patient's anxiety or pain at each stage of the procedure was not evaluated. Because noise-canceling only eliminates continuous sound, it is limited in removing sudden noise, so it may have been difficult to completely block the sound of the biopsy gun from the patient. The present study could not confirm the effects of noise-canceling headphones alone without music because all patients were applied the noise-canceling headphones to obtain a blind state during the procedure. The objective parameters we evaluated were limited to vital signs and arterial oxygen saturation. Future studies are needed to devise additional tools to recognize anxiety and pain; these tools could indicate the patient's subjective and objective changes immediately and accurately ensure the influence of music. However, our results are worthwhile because this is the first study in Asia with noise-canceling headphones, which showed evidence of the positive effect of music on men undergoing TRUSPB.

## 5. Conclusions

Our study suggests that music from noise-canceling headphones may have beneficial effects on anxiety, pain, satisfaction, and willingness to repeat the procedure in men undergoing TRUSPB. Further studies are necessary to find an additional approach to reduce the discomfort during TRUSPB.

## Funding

None.

## Ethics statement

For human study: The present study protocol was reviewed and approved by the Institutional Review Board of Chonnam National University Hwasun Hospital (Reg. No. CNUHH-2019-196). Informed consent was submitted by all subjects when they were enrolled.

## Conflicts of interest

All authors have no conflict of interest to declare.

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