



Guidelines for Transrectal Ultrasonography-Guided Prostate Biopsy: Korean Society of Urogenital Radiology Consensus Statement for Patient Preparation, Standard Technique, and Biopsy-Related Pain Management

Myoung Seok Lee, MD¹, Min Hoan Moon, MD, PhD¹, Chan Kyo Kim, MD², Sung Yoon Park, MD², Moon Hyung Choi, MD³, Sung Il Jung, MD⁴; Korean Society of Urogenital Radiology (KSUR)

¹Department of Radiology, SMG-SNU Boramae Medical Center, Seoul National University College of Medicine, Seoul, Korea; ²Department of Radiology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea; ³Department of Radiology, The Catholic University of Korea, Eunpyeong St. Mary's Hospital, Seoul, Korea; ⁴Department of Radiology, Konkuk University Medical Center, Konkuk University School of Medicine, Seoul, Korea

The Korean Society of Urogenital Radiology (KSUR) aimed to present a consensus statement for patient preparation, standard technique, and pain management in relation to transrectal ultrasound-guided prostate biopsy (TRUS-Bx) to reduce the variability in TRUS-Bx methodologies and suggest a nationwide guideline. The KSUR guideline development subcommittee constructed questionnaires assessing prebiopsy anticoagulation, the cleansing enema, antimicrobial prophylaxis, local anesthesia methods such as periprostatic neurovascular bundle block (PNB) or intrarectal lidocaine gel application (IRLA), opioid usage, and the number of biopsy cores and length and diameter of the biopsy needle. The survey was conducted using an Internet-based platform, and responses were solicited from the 90 members registered on the KSUR mailing list as of 2018. A comprehensive search of relevant literature from Medline database was conducted. The strength of each recommendation was graded on the basis of the level of evidence. Among the 90 registered members, 29 doctors (32.2%) responded to this online survey. Most KSUR members stopped anticoagulants (100%) and antiplatelets (76%) one week before the procedure. All respondents performed a cleansing enema before TRUS-Bx. Approximately 86% of respondents administered prophylactic antibiotics before TRUS-Bx. The most frequently used antibiotics were third-generation cephalosporins. PNB was the most widely used pain control method, followed by a combination of PNB plus IRLA. Opioids were rarely used (6.8%), and they were used only as an adjunctive pain management approach during TRUS-Bx. The KSUR members mainly chose the 12-core biopsy method (89.7%) and 18G 16-mm or 22-mm (96.5%) needles. The KSUR recommends the 12-core biopsy scheme with PNB with or without IRLA as the standard protocol for TRUS-Bx. Anticoagulants and antiplatelet agents should be discontinued at least 5 days prior to the procedure, and antibiotic prophylaxis is highly recommended to prevent infectious complications. Glycerin cleansing enemas and administration of opioid analogues before the procedure could be helpful in some situations. The choice of biopsy needle is dependent on the practitioners' situation and preferences.

Keywords: Prostate biopsy; Standard technique; Anticoagulant; Antiplatelet; Enema; Antimicrobial prophylaxis; Local anesthesia; Periprostatic neurovascular bundle block; Intrarectal lidocaine gel application; Opioid; Biopsy core; Biopsy needle

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Corresponding author: Min Hoan Moon, MD, PhD, Department of Radiology, SMG-SNU Boramae Medical Center, Seoul National University College of Medicine, 20 Boramae-ro 5-gil, Dongjak-gu, Seoul 07061, Korea.

• Tel: (822) 870-2531 • Fax: (822) 870-3539 • E-mail: mmhoan@gmail.com

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INTRODUCTION

Transrectal ultrasound-guided prostate biopsy (TRUS-Bx) is a standard test for the preoperative diagnosis of prostate cancer and is currently performed widely by radiologists and urologists. In a study of urologists in the United Kingdom, Lee et al. (1) reported numerous differences in the number of biopsy cores, protocols for prebiopsy antibiotic prophylaxis, prebiopsy enemas, and local anesthesia methods among institutions and physicians. In addition, 68% of doctors believe that their training for TRUS-Bx is insufficient (1). In Korea, 12-core biopsy is thought to be widespread at present, but there are variations among operators with respect to the local anesthesia method, prebiopsy antibiotic use, opioid use, and other aspects during TRUS-Bx. However, guidelines for the aforementioned subjects do not yet exist. In the meeting of the Korean Society of Urogenital Radiology (KSUR) in May 2018, the members of the KSUR discussed the actual situations and opinions of the members on topics such as patient preparation and the medicines and methods used for local anesthesia. In this brief article, a consensus report of the aforementioned discussion will be presented with a review of the related literature.

MATERIALS AND METHODS

Composition of the Clinical Guideline Development Group

The KSUR convened a subcommittee consisting of one committee chief and two secretaries for guideline development in 2017. All KSUR members were included as official members of the committee.

Topic Refinement and the KSUR Survey

The subcommittee created several preliminary questionnaires and surveyed the members who attended the regular KSUR monthly meeting in May 2018. Based on these results and feedback, the final questionnaire items were confirmed through discussion with the subcommittee chairman, secretaries, and KSUR president. The survey was conducted using the "Naver Form" survey platform (<https://office.naver.com> as "Naver form" official site, <http://naver.me/50qC8iGw> as our survey page [in Korean]) on January 7, 2019, through January 24, 2019, and responses were solicited from the 90 members registered on the KSUR mailing list as of 2018 (Supplementary Materials).

Database and Literature Search

A comprehensive database search was performed by the subcommittee using the Medline database (accessed at PubMed <https://www.ncbi.nlm.nih.gov/pubmed>) between January 1, 2008 and December 31, 2017. The keywords that were used for the database search were "prostate biopsy," "anticoagulant," "antiplatelet," "enema," "opioid," "antimicrobial," "antimicrobial prophylaxis," "local anesthesia," "pain control," "periprostatic neurovascular bundle block," "lidocaine gel," "biopsy core," "needle gauge," and "needle throw" in combination with publication-type keywords such as "guideline[Publication Type]," "practice guideline[Publication Type]," and "meta-analysis[Publication Type]" or title keywords such as "recommendation*[Title]," "standard*[Title]," and "guideline*[Title]."

Evaluation of the Literature

The subcommittee graded the evidence and classified the strength of the recommendation for each statement. The level of evidence grading and strength of recommendation grading were based on the 2016 Korean evidence-based clinical imaging guidelines by the Korean Society of Radiology and National Evidence-based Healthcare Collaborating Agency (2) (Tables 1, 2).

Table 1. Criteria for Evidence Level for Each Evaluated Study

Level	Content
1	Research satisfying all of following three criteria Criteria 1. Good reference standard Criteria 2. Consecutive patient study Criteria 3. Blind interpretation Systematic review of level 1 Randomized controlled trial or cross-sectional cohort study that compares index test to comparators
2	Research satisfying all of following two criteria Criteria 1. Good reference standard Criteria 2. Consecutive patient study or blind interpretation Systematic review of level 2 Observational studies that compares index test to comparators
3	Without consistently applied reference standards
4	Case-control study Poor or nonindependent reference standard
5	Expert opinion

Adapted from Choi et al. *Korean J Radiol* 2017;18:208-216 (2)

Table 2. Grades of Recommendation Suggested from Korean Clinical Imaging Guidelines

Grading	Content	Definition
A	Recommended	This intervention (examination) has enough evidence to support desired effect and is therefore recommended
B	(Conditional) Recommended	This intervention (examination) has intermediate to sufficient level of evidence to support desired effect Provide intervention (examination) selectively or for specific individuals based on expert judgment
C	Not recommended	This intervention (examination) has enough evidence to support undesired effect and therefore is not recommended (use of this examination is not recommended)
I	No recommendation	This intervention (examination) does not have enough evidence to either support or reject effectiveness and needs further research This intervention (examination) has very low level of certainty for desired effect, and decisions based on this recommendation grading have no meaning

Adapted from Choi et al. *Korean J Radiol* 2017;18:208-216 (2)

Consensus Achievement

The Delphi method was used for formal consensus in accordance with previously published guidelines (2-4). Twenty-six council members of the KSUR, including some of the subcommittee members, were asked to provide their level of agreement with each draft recommendation using a voting scale of 1–9 during the regular monthly meeting of the KSUR in March 2019 (where 1 denoted strong disagreement and 9 denoted strong agreement). Each voting score was allocated to one of three groups: 1–3 (disagreement), 4–6 (neutrality), and 7–9 (agreement). Consensus was defined as $\geq 75\%$ of participants providing a score within the 7–9 range (agreement).

Summary of Literature Review with Consensus Statements

The following recommendations for patient preparation, standard technique, and biopsy-related pain management during TRUS-Bx are summarized in Table 3.

Patient Preparation

Anticoagulation: Stop or Continue before Biopsy?

Bleeding appears as hematuria, rectal bleeding, or hematospermia, and is a common complication of TRUS-Bx; bleeding has been reported in as many as 84% of patients who undergo TRUS-Bx (5). Thus, antiplatelet medications (aspirin, clopidogrel, nonsteroidal anti-inflammatory drugs [NSAIDs], and so on) and anticoagulation medications (heparin, warfarin, and so on) are generally required to be administered before TRUS-Bx to lower the risk of bleeding complications (6). The Canadian Urologic Association guideline on prostate biopsy methodology recommends that

antiplatelet agents be stopped 1 to 2 weeks before TRUS-Bx and that anticoagulants be stopped 4 to 5 days prior (6). The Society of Interventional Radiology Consensus guideline for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions (SIR guidelines) (7, 8) stratifies percutaneous interventional procedures into three categories according to the risk of bleeding, difficulty of detection, and control of bleeding: Category 1, procedures with a low risk of bleeding or where any bleeding is easily detected and controllable; Category 2, procedures with a moderate risk of bleeding; and Category 3, procedures with a significant risk of bleeding that is difficult to detect and control. Most intra- or retroperitoneal biopsies are classified as Category 2 according to SIR guidelines, and TRUS-Bx may also be classified in this category. The SIR guidelines suggest a 5-day course of regular-dose aspirin, clopidogrel, and warfarin before Category 2 procedures with confirmation that the PT-INR is under 1.5 and the platelet count is over 50000/ μL (or correction to these values).

Patients who continue taking low-dose aspirin without interruption do not show a significant increase in hemorrhage or hematuria after TRUS-Bx (9, 10). For warfarin, no statistically significant difference has been reported in the severity of postbiopsy bleeding between patients who were continuously administered before and after biopsy and those who discontinued the drug (11). However, this study had limitations, including its nonrandomized design; variability in biopsy type (patients undergoing either 6- or 4-core biopsies); the possibility of life-threatening hemorrhagic complications that may have been missed due to the small sample size; the potential for recall bias, as complications were entered retrospectively 10 days after the biopsy; and the inclusion of patients

Table 3. Summary of KSUR Guidelines

Recommendation	Grade	Evidence Level	Mean Agreement Score*
Patient preparation			
Anticoagulants and anti-platelet agents should be discontinued at least 5 days prior to procedure, and platelet counts and PT-INR levels should be monitored and adjusted to levels appropriate for procedure (PT-INR < 1.5; platelet count > 50000/ μ L)	A	1	8.0
Cleansing enema can be administered to improve sonic window during biopsy or to lower potential infectious biopsy risk. Standard bowel preparation method should be rectal enema	B	2	7.5
Antimicrobial prophylaxis is recommended to reduce risk of post-biopsy infectious complications	A	1	8.4
Postbiopsy duration of antibiotics is still controversial; however, KSUR members typically use course of 5 days or less after biopsy	I	5	7.2
Biopsy-related pain management			
PNB is highly recommended to lower patient discomfort associated with TRUS-Bx	A	1	7.8
IRLA can be used as ancillary method to decrease discomfort during TRUS-Bx. In particular, IRLA is recommended to be used in combination with PNB	B	1	7.1
Opioids are not usually recommended for pain relief during biopsy. However, use of opioids can be considered for anxiolysis ¹	B	2	6.8
Other considerations			
Use of 12-core biopsy scheme that incorporates apical and far-lateral cores is highly recommended because it appears to be optimal for CDR, NPV, and pathology concordance	A	1	7.8
Length of biopsy specimen must be sufficiently long; 11.9 mm or more is suggested	B	2	7.8

*Mean agreement score: mean value of agreement score from 26 council members of KSUR for each recommendation (score 1 denoted strong disagreement and score 9 denoted strong agreement), ¹This recommendation may be controversial since consensus was not fully achieved (% of respondents with agreement score \geq 7: 73.1%). CDR = cancer detection rate, IRLA = intrarectal lidocaine gel application, KSUR = Korean Society of Urogenital Radiology, NPV = negative predictive value, PNB = periprostatic neurovascular bundle block, TRUS-Bx = transrectal ultrasound-guided prostate biopsy

on warfarin, which may have led to an underestimation of the severity of the hemorrhagic complications (6). A randomized prospective trial revealed that continuing low-dose aspirin in men undergoing TRUS-Bx did not increase the incidence of mild bleeding complications, although it prolonged the duration of self-limiting hematuria and rectal bleeding; thus, its effect on severe bleeding must be evaluated further (12). Therefore, there is a risk to not stopping the anticoagulant or antiplatelet based on the above studies.

All KSUR members who responded to the questionnaire stopped anticoagulants before TRUS-Bx. Approximately 76% (22 of 29) of the responding members ceased anticoagulants 1 week before the procedure. Similarly, almost all respondents except one doctor stopped antiplatelet drugs before TRUS-Bx. Most respondents (86%, 25 of 29) paused the antiplatelet drugs 1 week before the procedure.

Recommendation
 Before TRUS-Bx, anticoagulants and anti-platelet

agents should be discontinued at least 5 days prior to the procedure, and platelet counts and PT-INR levels should be monitored and adjusted to levels appropriate for the procedure (PT-INR < 1.5; platelet count > 50000/ μ L).

- Grade A recommendation
- Evidence level 1
- Mean agreement score: 8.0 (range, 5–9)
- % of respondents with agreement score \geq 7: 88.5% (23/26)

Cleansing Enema

The main effect of the prebiopsy glycerin enema is emptying the stool from the rectum to improve the sonic window and prevent unnecessary shadowing (6). There is still controversy regarding the effectiveness of enema in preventing infection after biopsy. The incidence of postbiopsy bacteremia is lower in patients given an enema than in those who received no enema, independent of antibiotic administration; however, the bacteremia is asymptomatic (13). Carey and Korman (14) reported that the prebiopsy enema was not of significant benefit and

only increased the cost and inconvenience to the patient. However, several published studies subsequently reported that prebiopsy enema could reduce infectious side effects (15-17). Mechanical bowel preparation, such as with polyethylene glycol (PEG) solution intake, has an effect of lowering infectious side effects similar to that of a glycerin enema; however, patients considered the PEG preparation to be less comfortable (18).

All members of the KSUR who responded to the questionnaire administered an enema just before TRUS-Bx.

Recommendation

There is no strong evidence to recommend for or against the use of an enema before TRUS-Bx; however, an enema can be administered to improve the sonic window during the biopsy or to lower the potential infectious biopsy risk. The standard bowel preparation method should be rectal enema.

- Grade B recommendation
- Evidence level 2
- Mean agreement score: 7.5 (range 4-9)
- % of respondents with agreement score \geq 7: 80.1% (21/26)

Antimicrobial Prophylaxis

Antimicrobial prophylaxis reduces the risk of bacteriuria, bacteremia, and clinical infections after TRUS-Bx (19, 20). Prophylactic antibiotic therapy for 1 day or even single-dose prophylactic antibiotic therapy is known to lower the risk of infectious complications to 1% or less (21, 22). Fluoroquinolone and first-, second-, and third-generation cephalosporins are recommended for TRUS-Bx, and prophylactic antibiotics should be given 1-2 hours before the procedure (19, 20, 23). The administration route (oral, intramuscular, or intravenous) does not influence the effect of the antibiotics. The postbiopsy duration of antibiotics is still controversial (6). A retrospective multicenter study (24) reported that a combination of single-dose gentamicin intramuscular injection before biopsy and three-day levofloxacin oral administration after biopsy reduced the infectious complication rate by up to 90% compared to the administration of postbiopsy antibiotics only.

Most KSUR members who responded to the questionnaire (86%, 25 of 29) used antibiotic prophylaxis before TRUS-Bx. The most frequently used antibiotics were third-generation cephalosporins, followed by quinolones and second-generation cephalosporins. Postbiopsy antibiotic use

was also surveyed, and almost all members who responded (90%, 26 of 29) administered antibiotics up to 1 week after the procedure. One member who did not use prophylactic antibiotics administered postbiopsy antibiotics (3rd generation cephalosporins) 1 week after the biopsy.

Recommendation

Antimicrobial prophylaxis is recommended to reduce the risk of postbiopsy infectious complications.

- Grade A recommendation
- Evidence level 1
- Mean agreement score: 8.4 (range 6-9)
- % of respondents with agreement score \geq 7: 92.3% (24/26)

The postbiopsy duration of antibiotics is still controversial; however, KSUR members typically use a course of 5 days or less after biopsy.

- Grade I recommendation
- Evidence level 5
- Mean agreement score: 7.2 (range 2-9)
- % of respondents with agreement score \geq 7: 80.1% (21/26)

Biopsy-Related Pain Management

Periprostatic Neurovascular Bundle Block

The factors affecting pain in TRUS-Bx patients vary, and the intensity of the pain is known to be influenced by the size of the ultrasound probe and the number of biopsies.

The pain that occurs when an ultrasonic transducer is inserted is known as somatic pain when the anal canal under the dentate line, which has a rich sensory nerve distribution, is expanded by the transducer. The rectal mucosa is insensitive to pain, but the prostate capsule and prostate parenchyma are very sensitive to pain, which is known to spread through the periprostatic neurovascular bundle.

Periprostatic neurovascular bundle block (PNB) was usually performed using a Chiba needle or a long spinal needle (7-inch, 22-gauge), with direct injection of 5 mL of 1-2% lidocaine in the region of the prostatic vascular pedicle at the base of the prostate just lateral to the junction between the prostate and seminal vesicle (24). To date, PNB has been the best proven method for reducing pain in TRUS-Bx and has been shown to reduce pain (with statistical significance) in a series of meta-analyses comparing non-anesthetic control and placebo

(25, 26). PNB has also been shown to provide similar pain control compared to sedoanalgesia (intravenous midazolam and fentanyl) or intravenous tramadol. However, PNB is a preferable method in TRUS-Bx since it is much more practical in outpatient clinics and relatively free from the side effects of midazolam, fentanyl, or tramadol.

Most KSUR members who responded to the questionnaire adopted PNB for pain management during TRUS-Bx (79%, 23 of 29).

Recommendation

PNB is highly recommended to lower patient discomfort associated with TRUS-Bx.

- Grade A recommendation
- Evidence level 1
- Mean agreement score: 7.8 (range 5–9)
- % of respondents with agreement score \geq 7: 84.6% (22/26)

Intrarectal Lidocaine Gel Application

The main function of the gel applied to the anal canal during TRUS-Bx is to reduce the pain caused by the expansion of the anal canal by enhancing anal compliance and lowering the friction between the probe and anal canal. Lidocaine-containing gels are expected to reduce somatic pain more effectively by dampening the sensation of the anal canal and by adding local anesthetic effects to the surrounding prostate capsule and parenchyma via absorption through the rectal mucosa (26). However, the effects of intrarectal lidocaine gel application (IRLA) have been reported to be widely variable; of 17 randomized controlled trials, 12 reported no difference in pain relief between conventional ultrasound gel and lidocaine gel, and 5 described IRLA as reducing the pain in TRUS-Bx, relative to the effect of conventional gel (27). In comparison with

IRLA, PNB is known to have the same effect (24) and shows more effective pain relief (25-29). In particular, the use of both PNB and IRLA simultaneously is described as being more effective than single treatment (25).

Four of 29 (14%) KSUR members who responded to the questionnaire used IRLA only, and 6 doctors among the respondents used a combination of PNB and IRLA for pain management during TRUS-Bx (21%, 6 of 29).

Recommendation

IRLA can be used as an ancillary method to decrease discomfort during TRUS-Bx. In particular, IRLA is recommended to be used in combination with PNB.

- Grade B recommendation
- Evidence level 1
- Mean agreement score: 7.1 (range 3–9)
- % of respondents with agreement score \geq 7: 84.6% (22/26)

Opioid Analogues

Among opioid analogues, meperidine (pethidine) and fentanyl are commonly used in Korea. Generally, fentanyl is more effective and faster-acting than meperidine, but its effective duration is shorter, and it is more expensive. Among side effects, respiratory depression, nausea, and vomiting show similar frequencies between the two drugs, but the rate of cardiovascular side effects is slightly higher for meperidine. Simple comparisons are listed in Table 4.

Opioid analogues are mainly used as an adjunct to PNB because narcotic analgesics reduce anxiety (anxiolytics) (28). There is no evidence that the analgesic effect of opioid analogues is superior to that of PNBs when injected intravenously, and the analgesic effects of opioids are inferior to those of PNBs when injected intramuscularly (27, 29, 30). Although fentanyl offers no additional benefit

Table 4. Pharmacological Properties of Meperidine and Fentanyl

	Time of Onset (Intravenous Injection) (min)	Time of Maximum Effect (min)	Duration Time (min)	Metabolism and Excretion	Antagonist	Side Effects	Capacity and Price (KRW)
Meperidine	3–6	5–7	60–180	Metabolized in liver, excreted through kidney	Naloxone	Respiratory suppression, nausea, vomiting	25 mg/0.5 mL (209) 50 mg/1 mL (314)
Fentanyl	1–2	3–5	30–60	Metabolized in liver, excreted through kidney	Naloxone	Respiratory suppression, nausea, vomiting	100 µg/2 mL (2071) 500 µg/10 mL (9954)

over PNB monotherapy when used with PNB, it should be considered for reducing patient anxiety (28).

Only two KSUR members (6.8%) who responded to the questionnaire used opioid analgesics, and all used opioids as a complement to PNB and/or IRLA. No respondent used opioids as the sole method of pain management during TRUS-Bx.

Recommendation

Opioids such as meperidine or fentanyl are not usually recommended for pain relief during biopsy. However, the use of opioids can be considered for anxiolysis. This recommendation may be controversial since a consensus was not fully achieved (% of respondents with agreement score ≥ 7 : 73.1%).

- Grade B recommendation
- Evidence level 2
- Mean agreement score: 6.8 (range 5–9)
- % of respondents with agreement score ≥ 7 : 73.1% (19/26)

Other Considerations

Number of Biopsy Cores and Length and Diameter of the Biopsy Needle

According to the American Urologic Association white paper (31) and the Canadian Urological Association on Prostate Biopsy Methodology (5), a 12-core biopsy scheme including the prostate apex and bilateral far lateral peripheral zones is recommended as the standard TRUS-Bx protocol. In comparison with the standard sextant biopsy, the 12-core biopsy scheme increases the cancer detection rate (CDR), increases the negative predictive value (NPV) to lower the ratio of recurrent biopsy, and shows a similar rate for diagnosing cancer (i.e., the difference in rate is not clinically significant). These reports also indicated that there are no additional benefits in terms of CDR and NPV to performing biopsy with more than 12 cores.

The size of the biopsy needle is usually 18-gauge, and there are studies reporting that an increase in the size of the core to a 16-gauge does not cause any side effects or differences in CDR (32). The length of the core has a great effect on the CDR (32, 33), and one study recommended that the length of the core be greater than 11.9 mm (33). Therefore, there could be no significant difference in CDR between the 16-mm and 22-mm biopsy needles. However, the aforementioned studies compared the length of cores

obtained by a fixed single-length biopsy needle, and there are no studies comparing CDR or complication rates among different biopsy needle gauges and lengths. Further studies are needed on this issue.

Most KSUR members who responded to the questionnaire (90%, 26 from 29) chose the 12-core method for TRUS-Bx. One respondent used the 10-core method. Two respondents chose 'others'; one answered that he or she obtained 10 or 12 cores depending on the situation, and the other responded that he or she obtained an additional 2 cores from the transitional zone, making 14 cores in total.

The most commonly used gauge and throw combination for the biopsy gun was the 18G 22-mm (15 of 29, 51.7%) needle, followed by the 18G 16-mm needle and 16G 16-mm biopsy needle. Four respondents chose "others" and left a comment stating "mixed use of 18G 16-mm and 18G 22-mm according to prostate size."

Recommendation

The use of a 12-core biopsy scheme that incorporates apical and far-lateral cores is highly recommended because it appears to be optimal for CDR, NPV, and pathology concordance.

- Grade A recommendation
- Evidence level 1
- Mean agreement score: 7.8 (range 5–9)
- % of respondents with agreement score ≥ 7 : 92.3% (24/26)

Although the gauge and length of the biopsy needle seem irrelevant in CDR, the length of the biopsy specimen must be sufficiently long; 11.9 mm or more is suggested.

- Grade B recommendation
- Evidence level 2
- Mean agreement score: 7.8 (range 5–9)
- % of respondents with agreement score ≥ 7 : 88.4% (23/26)

CONCLUSION

The KSUR guideline development subcommittee presented a consensus statement with a literature review for topics including patient preparation, pain management, and biopsy scheme planning for TRUS-Bx. We recommend the 12-core biopsy scheme with the PNB \pm IRLA local anesthesia method as the standard protocol for TRUS-Bx. Anticoagulants and antiplatelet agents should be discontinued at least 5 days prior to the procedure, and antibiotic prophylaxis is highly

recommended to limit infectious complications. Glycerin cleansing enemas and administration of opioid analogues before the procedure could be helpful in some situations. The choice of gauge and length of the biopsy needle is dependent on the practitioners' situation and preferences.

Supplementary Materials

The Data Supplement is available with this article at <https://doi.org/10.3348/kjr.2019.0576>.

Conflicts of Interest

The authors have no potential conflicts of interest to disclose.

ORCID iDs

Min Hoan Moon

<https://orcid.org/0000-0003-2448-2895>

Myoung Seok Lee

<https://orcid.org/0000-0001-5285-4874>

Chan Kyo Kim

<https://orcid.org/0000-0003-0482-1140>

Sung Yoon Park

<https://orcid.org/0000-0003-0996-7595>

Moon Hyung Choi

<https://orcid.org/0000-0001-5962-4772>

Sung Il Jung

<https://orcid.org/0000-0002-4588-209X>

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