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Research Article

General Anesthesia versus Sedation in Multi Parametric Magnetic Resonance Imaging (mpMRI) Transrectal Ultrasound Guided (TRUS) Fusion Targeted Prostate Biopsy: A Prospective, Randomized Study

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Abstract

Objectives: Different anesthetic methods have been used in multi-parametric magnetic resonance imaging-guided (mpMRI) transrectal ultrasound guidance (TRUS) fusion-targeted prostate biopsy, but the consensus on the optimal anesthetic approach is not clear. In this study, the anesthesia management, procedural conditions, intraoperative adverse events, complications, discharge criteria, and cancer detection rates of general anesthesia and sedation were compared.

Methods: Participants were randomly divided into general anesthesia (GA) and sedation (S) groups. The primary endpoint of the study was the surgical satisfaction score. The incidence of hypoxia, patient satisfaction, cancer detection rate, anesthetic agent consumption, recovery and hospitalization times, and complication rates were all compared as secondary outcomes.

Results: There was no significant difference in the incidence of hypoxemia in both groups (Group G:0, Group S:2 patients, p=0.494). While there was no significant difference in surgical satisfaction scores (Group GA: 9.48 vs Group S: 9.23, p=0.353). PC detection rates (p=0.809) and complication rates were similar.

Conclusion: With similar surgical conditions, complication incidence, and cancer detection rates, neither anesthesia approach did not provide surgical superiority over the other. The sedation approach, combined with careful monitoring of anesthesia depth, prevented hypoxemia, reduced anesthetic agent consumption, and allowed for faster recovery and discharge, allowing for ambulatory anesthesia.

Keywords: Cancer detection, general anesthesia, sedation, prostate biopsy, surgical conditioning

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In the year 2020, 1,414,259 males of all ages were diagnosed with prostate cancer (PC).[1] It is anticipated to be the second leading cause of cancer-related mortality among males in the United States by 2021.[2] A variety of prostate biopsy methods are performed, İn the identification and treatment of PC. In clinical practice, ten to twelve core biopsies are routinely performed under the guidance of transrectal ultrasonography (TRUS).[3] PC is mostly hypoechoic but can be substantially isoechoic, resulting in a false negative evaluation of TRUS. Furthermore, due to

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the limited sensitivity of ultrasonography US-guided biopsies, the multifocal location of PC causes a considerable percentage of tumors to be missed by US-only evaluation, limiting the ability of the US to identify PC.[4, 5]

However, by enhancing the better resolution of prostate tissue and targeting of prostate needle biopsy, magnetic resonance imaging (MRI) presents possible targets that may lower the false-negative biopsy rate.[6] The European Association of Urology recommends MRI/US fusion-targeted biopsies for persistent PSA elevation following a negative TRUS biopsy in patients with a persistent clinical suspicion of clinical PC.[3]

PB is a painful procedure,[7] and the placement of the movable ultrasonography probe in the anus, as well as the procedure's uncomfortable posture, necessitates anesthesia. Biopsy procedures were performed using various approaches such as local anesthesia techniques (intrarectal, intraprostatic local anesthesia,[8] regional anesthesia techniques, periprostatic nerve block, pelvis plexus block, pudental nerve block, spinal anesthesia,[9] caudal block[10]), sedoanalgesia[10, 11] and general anesthesia.[12, 13]

In our study, we prospectively evaluated the efficacy and safety of general anesthesia and sedation anesthesia techniques in patients who underwent multiparametric(mp) MRI/TRUS fusion-targeted prostate biopsy accompanied by multi-parametric magnetic resonance imaging.

Methods

We conducted a prospective, randomized, and comparative study between May and July 2018 after obtaining approval from the Ministry of Health Haseki Training and Research Hospital Ethics Committee. We enrolled 80 patients in the American Society of Anesthesiologists (ASA) physical status 1-2 range, aged 35 to 75 years, who were scheduled for an elective mpMRI/TRUS fusion-targeted prostate biopsy. Our exclusion criteria were high risk of aspiration, allergy to the drugs planned to be used, body mass index >35 kg/m^2 and above, presence of kidney and liver disease, congestive heart failure, respiratory system disease, neurological disease, hemorrhoids, anal fissure and prostatitis, history of chronic pain, alcohol or drug abuse, cognitive impairment or inability to answer questions correctly. Written, informed consent was obtained from the participants. Patients were randomly assigned using the sealed opaque envelope technique to receive general anesthesia (Group GA, n=40) or sedation (Group S, n=40).

Anesthesia Technique

Before the patients were taken to the operating room, they were given 500 ml of crystalloid solution in 20 minutes. Electrocardiography, noninvasive blood pressure, pulse oximetry, and bispectral index (BIS) monitoring were performed after the patient was taken to the operating room. A standardized operating room was established, and normothermia was achieved.

The mean values of heart rate (HR) and mean arterial pressure (MAP) were calculated with three consecutive measurements after premedication with 0.03 mg/kg intravenous (iv) midozolam for all patients preoperatively, and baseline results were calculated.[14]

Patients in group GA were given 1 mg/kg lidocaine, 1 g/kg fentanyl, and 1.5 mg/kg propofol to induce general anesthesia. After adequate depth of anesthesia (BIS value <60) was reached, an appropriately sized Laryngeal Mask Airway (LMA) was placed on the supine participant. The convex surface of the LMA was lubricated and progressed over the hard palate until final insertion was achieved.[15] After that, it was inflated to 60 cmH_2O pressure. Proper placement of the LMA was assessed by the absence of air leak sound during ventilation, the existence of bilateral chest movements, spontaneous filling of the reservoir bag, and the presence of a square capnogram waveform. If the LMA could not be implanted after three attempts, the patient was eliminated from the study via endotracheal intubation and recorded. After LMA placement, the patient was ventilated in volume control mode with FiO_2:0.5, tidal volume: 6-8ml/kg, PEEP:5 cmH_2O, frequency:10-14/min, and end-tidal carbon dioxide: 30-35 mmHg. Anesthesia was maintained with propofol 3-12 mg/kg/hour and remifentanil 0.1-0.3 µg/kg/min, keeping mean arterial pressure (MAP) ± 20% of basal value and BIS value between 40-60.

After an intravenous bolus dosage of 1 mg/kg lidocaine, 1 µg/kg fentanyl, 0.5 mg/kg propofol, anesthesia was maintained with propofol 2-6 mg/kg/hour, and remifentanil 0,05-0,2 µg/kg/min in Group S. The procedure was started when the BIS value was between 60-80. The Richmond Agitation Sedation Scale was used to determine the level of sedation. The Richmond Agitation Sedation Scale was used to determine the level of sedation. If the patient moved and the depth of anesthesia became superficial, an extra bolus dose of propofol (0.4 mg. kg-1) was administered.[16] Four L. min^{-1} oxygen was administered via a face mask to maintain peripheral oxygen saturation (SpO_2) >94%. The patients' spontaneous breathings were preserved. In case of hypoxia (defined as SpO_2< 92%), airway interventions such as chin lift, use of oropharyngeal airway, and use of face mask ventilation were applied, respectively, according to the severity and duration of desaturation to ensure airway patency. Patients who required endotracheal intubation were documented and excluded from the research.

In the preoperative period; antibiotic prophylaxis with 500 mg ciprofloxacin (peroral) twice a day was started 1 day before surgery and continued for 4 days afterward.

In the intraoperative period; 6 ml/kg/hour iv crystalloid solution and 1 gr iv paracetamol 10 minutes before the end of the procedure were administered. HR, MAP, SpO_2, BIS values were recorded at three-minute intervals. Ephedrine 5 mg iv when MAP decreased below 60 mmHg, 0.1 mg nitroglycerin iv when MAP increased above 120 mmHg, 0.5-1 mg atropine iv when HR decreased below 45 bpm was administered. The use of ephedrine, nitroglycerin, atropine was recorded. Intraoperatively, the number of patients that developed hypoxia and required airway intervention was recorded. After the procedure was completed, the operating conditions were evaluated by the surgeon according to the severity of the movement developed in response to the stimulation associated with the intraoperative ultrasound probe or the insertion of the biopsy needle. For this, a 10-point surgical satisfaction scale was used, with 1: very dissatisfied, 10: excellent. The same urologist performed all of the prostate biopsy operations. A transrectal technique was used to collect 12 or more biopsy nuclei from all participants.

In the postoperative period; data were evaluated by an independent anesthesiologist blinded to the study groups. If the Modified Aldrete Score (MAS) was 9 or above, patients were transferred from the postoperative care unit (PACU) to the surgical department. In case of postoperative nausea and vomiting, 4 mg ondansetron was administered. Pain score was assessed using the Visual Analogue Scale (VAS; 0, no pain; 1-3, mild pain; 4-6, moderate pain; 7-10, severe pain). If the VAS was 4 or above, a rescue analgesic (dexketoprofen trometamol 25 mg) was administered.

Postoperative pain was evaluated at 15 minutes, 1 hour, and 4 hours. The patients were evaluated for the comfort of the procedure using a 10-point patient satisfaction questionnaire, as 1: very dissatisfied, 10: excellent. Postoperative complications (hematuria, hemospermia, urinary tract infection, fever, rectal bleeding) were recorded. Discharge time was performed if the score was 9 or higher in the modified Post-Anesthesia Discharge Scoring System (MPADSS).[17] In the Modified Post-Anesthesia Discharge Scoring System, evaluation was made in 5 categories out of 10 points. Each category was given a score out of two for vital signs, ambulation, pain, nausea-vomiting, and surgical hemorrhage.

Outcomes

The surgical satisfaction score, which compares working procedurs, is the study's primary outcome. The incidence of hypoxia, patient satisfaction, cancer detection rate, anesthetic agent consumption, recovery and hospitalization times, and complication rates were all secondary outcomes.

Statistical Analysis

The descriptive statistics of the categorical variables in the study are given as numbers and percentages, and the descriptive statistics of the numerical variables are given as mean, standard deviation, median, minimum and maximum. Pearson chi-square and Fisher exact tests were used to investigate relationships between categorical variables. The Shapiro Wilk test was used to determine if the numerical variables conformed to the normal distribution. Student's t test was used for the comparisons of two independent groups in terms of the means of normally distributed variables, and the Mann Whitney U test was used for the mean comparisons of non-normally distributed variables. Two-way repeated Anova model was used to evaluate group effects for differences between periods. The calculations were performed using the SPSS (version 26) package program, with a statistical significance threshold of 0.05.

Results

The eligibility of 151 patients to participate in the study was evaluated. The clinical status of 54 patients did not meet the inclusion criteria of the study, and 17 patients refused to participate. Thus, the remaining 80 patients were randomly assigned to two study groups.

The demographics, clinical data, and prostate features of the participants were similar between groups (Table 1).

Table 1. Clinical data and prostate characteristics of the participants

	GA Group n: 40	S Group n: 40	p
Age (yr)	63.75±7.07	62.83±6.55	0,546
Weight (kg)	77.88±12.35	78.05±9.75	0,944
Body mass index (kg m-2)	26.95±3.36	26.79±2.51	0,803
ASA Classification I/II: n	18/22	19/21	0,823
Comorbidities of patients; n			
Hypertension	18	16	0,651
Diabetes mellitus	5	9	0,239
Coronary artery disease	4	6	0,499
Thyroid disease	3	5	0,456
Prostate characteristics;			
PSA (ng/ml)	10.48±5.98	10.33±7.75	0,470
Mean prostate volume (cm3)	78.50±25.75	75.83±30.97	0,397
Number of cores	14.9±1.84	14.65±1.75	0,519
PI-RADS score, n (%)			0,751
3	10 (25)	11 (27,5)	
4	25 (62,5)	22 (55)	
5	5 (12,5)	7 (17,5)	
Clinically significant PC n(%)	13 (32.5)	12 (30)	0,809

BMI: Body mass index; ASA: American Society of Anesthesiologists; PSA: prostatespecific antigen; PI-RADS: Prostate Imaging-Reporting and Data System; PC: prostate cancer.

There was no significant difference between HR and MAP parameters in all time periods of the GA and S groups, respectively (p=0.411, p=0.401). While SpO2 levels were lower in group S, BIS levels were higher in all time periods except the baseline (p<0.001, p=0,009, respectively). Intraprocedural hemodynamic variables for both groups are presented in Figures 1-3. Intraoperative BIS values are presented in Figure 4. There was no significant difference in the incidence of intraoperative adverse events between the groups (Group GA: %17.5% vs. Group S: 15%, p=0.762) (Table 2). Anesthetic agent consumption was also observed to be higher in group GA (p<0.001) (Table 2). While biopsy and anesthesia times were similar, PACU and orientation times were longer in Group GA (<0.001). There was no evidence of awareness in any of the patients. Postoperative pain scores and rescue analgesic requirements (p=1,00) were evaluated as similar. While the incidence of postoperative nausea and vomiting was similar between the groups, sore throat was more common in Group GA (Group GA: % 25 vs Group S: % 2.5, p=0,003) (Table 2). While there was no significant difference in surgical satisfaction between the two groups (Group GA: 9.48 vs Group S:9.23, p=0,353), Group S had a higher patient satisfaction score (Group GA: 8.57 vs Group S: 9.2, p=0.006) (Table 3). There was no clinically significant difference in PC detection rates between groups (Group GA: 32.5% vs Group S: 30%, p=0.809) (Table 1). The incidence rates for each complication were similar between the groups (Table 2). Hospitalization was considered longer in Group GA (Grup GA:8 hours vs Grup S 6.4 hours, p=0.018) (Table 2).

Discussion

Our findings revealed that both anesthetic techniques provide equal working conditions in mpMRI/TRUS fusion-targeted prostate biopsy, although general anesthesia is associated with a longer recovery time, longer hospitalization stays, and lower patient satisfaction.

The TRUS-guided biopsy is part of the standard diagnostic approach for PC, which is one of the most frequent cancers in men. However, due to its limited sensitivity and specificity, clinicians are questioning this approach alone, and it leaves its place to new modalities. To circumvent the limitation of cancer detection, mpMRI/TRUS fusion software-based targeted biopsy allows performing targeted biopsy of lesions detected in MRI. By combining preoperative MR imaging with intraoperative TRUS by the urologist, the excellent diagnostic accuracy of MRI is used to diagnose PC. Using the fusion device also automates the process of recording MRI and US images together.[18] The mpMRI/TRUS

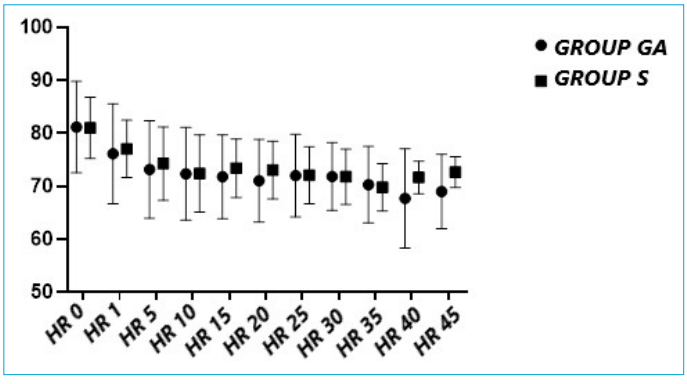

Figure 1. Heart Rates (HR) during the operation.

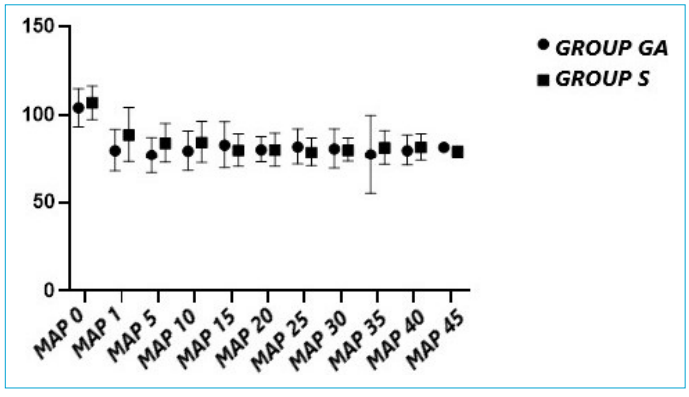

Figure 3. Mean Arterial Pressures (MAP) during the operation.

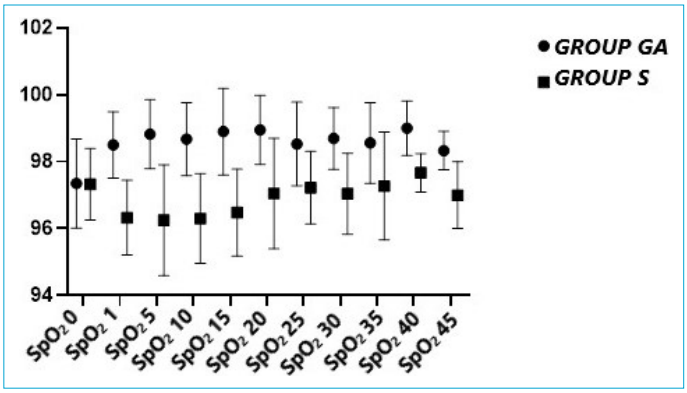

Figure 2. Peripheral oxygen saturations (sPO_2) during the operation.

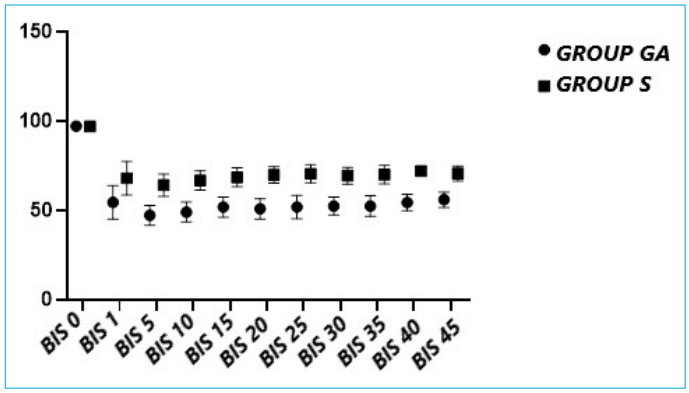

Figure 4. Bispectral Indexes (BIS) during the operation.

Table 2. Perioperative data, advers events and urological complications

	GA Group n: 40	S Group n: 40	p
Duration of procedur (min)	25.53±8.55	25±9.3	0,572
Duration of anesthesia (min)	30.85±9.04	29.35±9.68	0,261
Orientation time (min)	9.65±2.82	7.3±2.33	< 0.001
PACU discharge time (min)	13.05±5.96	9.03±3.41	< 0.001
Total propofol consumption (mg)	296.63±88.24	215.5±52.21	< 0.001
Remifentanil consumption (µg)	206±72.06	152.38±44.28	< 0.001
PONV n (%)	2 (5)	3 (7.5)	0,644
Sore throat n (%)	10 (25)	1(2.5)	0,003
İntraoperative advers event n (%)	7(17.5)	6(15)	0,762
Hypoxia (SpO_2< %92)	0 (0)	2(5)	
Hypotension (MAP <60 mmHg)	4 (10)	1 (2.5)	
Hypertension (MAP >120 mmHg)	2 (5)	2 (5)	
Arrhythmia	0	0	
Bradycardia (heart rate < 45 bpm)	1(2.5)	2 (5)	
Use of rescue analgesic n(%)	4 (10)	5 (12.5)	1,00
Complications n (%)			
Hematuria	9 (22.5)	8 (20)	0.785
Hemospermia	4 (10)	5 (12.5)	1,00
Fever	2 (5)	3 (7.5)	1,00
Urinary tract infection	4 (10)	3 (7.5)	1.00
Rectal bleeding	5 (12.5)	6 (15)	0.745
Hospitalization time (h) (MPADSS≥ 9)	8±4.91	6.4±3.77	0.018

PONV: Post-operative nausea-vomiting; MPADSS: A Modified Postanaesthetic Discharge Scoring System.

Table 3. Patient and Surgery satisfaction score

	GA Group	S Group	p
Patient satisfaction score	8.57±1.08	9.2±0.97	0,006
Surgery satisfaction score	9.48±0.64	9.23±0.97	0,353

fusion-targeted prostate biopsy ensures that biopsies are taken from suspicious lesions rather than being taken at random. In a prospective study by Mozer et al., a higher rate of clinically significant PC was detected in MRI/TRUS-fusion targeted biopsies in the first round of biopsies compared to standard extended 12-core biopsy.[19]

It is the most correct approach to perform the procedure under anesthesia because of the discomfort caused by the ultrasound probe and the pain caused by the puncture of the prostate capsule and parenchyma with the biopsy needle. It suggests that patient tolerance may be more difficult due to the longer procedure times of mpMRI/TRUS fusion-targeted prostate biopsy compared to standard TRUS biopsy. In the study of Peyromaure et al. in which they evaluated pain and morbidity after a 10-core biopsy protocol under the guidance of transrectal ultrasound, 47.6% of 275 patients described the procedure as painful, 67.9% as mildly painful, and 33.8% as uncomfortable but not painful.[20] In the current prostate biopsy practice in the Australian and New Zealand Urological Society, 73% of clinicians used IV sedation or GA for analgesia, 39.9% used peri-prostatic local anesthetic infiltration, and 8.1% used intrarectal local anesthetic gel.[21] In previous studies, they used peripheral nerve blocks, topical anesthesia, spinal anesthesia, and general anesthesia to manage anesthesia during prostate biopsy procedures.[11, 12, 22] However, there is no clear consensus on the best anesthesia approach. The present study is the first in the literature to compare sedation and general anesthesia.

The two anesthetic approaches were compared in terms of intraoperative adverse events, surgical condition, complications, cancer detection rates, and discharge criteria. Anesthetic agent consumption was found to be lower in the SA group than in the GA group (total propofol and remifentanil consumption; p<0.001) When the duration of the post anesthesia care unit was compared, it was observed that the SA group was recovered in a shorter time (Group GA 13.05±5.96 vs Grup S9.03±3.41, p<0.001). The length of hospital stay was recorded as longer in the GA group (Group GA 8±4.91 vs Group S 6.4±3.77, p=0.018). Daskaya et al. compared general anesthesia and sedation

in septolastic surgery and found that the GA group had longer hospitalization times.[23] In our study, a deeper level of anesthesia is required to tolerate the LMA used in the GA group, to suppress spontaneous breathing and to ensure immobility. On the contrary, in the SA group, a more superficial anesthesia level is required compared to general anesthesia to maintain the respiratory impulse. The difference in the depths of anesthesia between the two groups caused more anesthetic agent consumption and delayed recovery in the GA group.

The distribution of intraoperative adverse events was similar between the groups (p=0.762). There was no significant difference in the incidence of hypoxemia in both groups (p=0,494). The most significant problems encountered during sedation include hypoxemia, hypoventilation, and apnea. Hypoxia can be avoided by preserving the spontaneous respiratory impulse and maintaining airway patency. To prevent propofol-induced airway obstruction and hypoxia during sedation, it has been recommended to keep BIS values above 75.[24] The role of BIS monitoring should be considered in maintaining an optimal level of sedation and maintaining a patent airway. The fact that hypoxemia development indices were similar in our study suggests that BIS monitoring contributed. The sore throat was more common in the GA group (25% vs 2.5%, p=0.003). The frequency of sore throat after using LMA® Classic has been documented to range between 2.6 and 42 % in the literature.[25, 26] The development of sore throat varies depending on the placement technique of the LMA® Classic, the number of trials, and the cuff pressure. The sore throat was less common in the sedation group because no supraglottic airway device was used.

Group S had a higher level of patient satisfaction (8.57 vs 9.2, p=0.006). It is thought that more frequent sore throat monitoring, delayed recovery times and longer hospital stays contributed to the lower satisfaction in the general anesthesia group.

According to the severity of the movement that may emerge in response to the intraoperative surgical stimulation, surgical satisfaction was rated as similar in both groups (p=0,353). Satilmis et al. found that surgeon satisfaction was significantly lower in the sedation group due to the increased head and leg movements associated with patient discomfort during periods of increased surgical stimulus in a study comparing the effects of sedation and general anesthesia in the surgically assisted rapid palatal expansion (Group S excellent 53.3% vs Group GA excellent 100%).[27] Immobility is required to ensure optimal procedure conditions. The presence of movement will result in a failure to get a biopsy from the targeted lesion, repeated biopsy attempts, prolongation of the operation time, and an increase in the possibility of infection. More superficial anesthetic levels in the sedation approach, compared to general anesthesia, contribute negatively to keeping the patient motionless during the procedure. SA is an anesthetic approach in which anesthesiologists demonstrate their skills, requiring a level of anesthesia deep enough to keep the patient still to maximize the comfort of the surgery while maintaining the spontaneous respiratory impulse. This was achieved by standardizing the depth of anesthesia with sedation scales and BIS monitoring of the patients. The reason why our findings were similar to those of Satilmis et al.'s study is that we provided the level of deep anesthesia with BIS monitoring without suppressing respiration. Thus, we also maintained immobility during the procedure.

The incidence of complications did not differ significantly between the groups (Hematuria p=0.785, Hemospermia p=1, Fever p=1, Urinary tract infection p=1, Rectal bleeding p=0.745). In recent research comparing MRI targeted biopsy versus traditional biopsy for the diagnosis of PC, the MRI focused biopsy group had fewer complications.[28]

Complications with similar rates mentioned in the review of Loeb et al. in which they examined the complications arising from prostate biopsy were also seen in our study. [29] Clinically significant PC detection rates in both groups were comparable with the literature and were statistically insignificant (32.5% vs 30%, p=0.809).

In a randomized study by Kasivisvanathan et al. in which they compared MRI-targeted and standard prostate biopsy and investigated clinically significant cancer detection rate, they detected a higher rate of clinically significant cancer in the MRI-targeted biopsy group (38% vs. 26%). Risk assessment with MRI and the use of MRI-targeted biopsy were considered superior to transrectal ultrasonography-guided biopsy in those at clinical risk for PC.[28] As the procedure was carried out under comparable surgical conditions, this suggests that the incidence of complications and cancer detection were similar.

Conclusion

With similar surgical conditions, complication incidence and cancer detection rates, neither anesthesia approach did not provide surgical superiority over the other. Hypoxemia was avoided by providing an optimal level of sedation and maintaining respiratory drive with BIS monitoring. The sedation approach enabled ambulatory anesthesia by reducing the anesthetic agent consumption with close monitoring of the depth of anesthesia, thus providing faster recovery and discharge. Furthermore, it was superior in the sedation approach, with a minimal incidence of sore throat and high patient satisfaction.

Disclosures

Ethics Committee Approval: This study was approved by the Ministry of Health Haseki Training and Research Hospital Ethics Committee (Decree No: 738/ Date: 11.03.2019).

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – H.U.; Design – H.U., S.K.; Supervision – H.U., S.K; Materials – H.U., S.K.; Data collection and/or processing – H.U.; Analysis and/or interpretation – H.U., S.K.; Literature search – H.U., S.K.; Writing – H.U., S.K.; Critical review – H.U.

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