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Research Article

Comparison of Propofol Sedation and Lidocaine-Propofol Combination in Patients Undergoing Bronchoscopy

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ABSTRACT

Background: This study was conducted with the aim of comparing the sedation rate of Propofol and Lidocaine -Propofol combination in patients undergoing bronchoscopy.
Methods: In this clinical trial study, 60 patients undergoing bronchoscopy were divided into two groups of 30 people, in the first group 1 mg/kg of Propofol and in the second group 1 mg/kg of Propofol together with 1.5 mg/kg of Lidocaine were injected. And the hemodynamic parameters, depth of sedation, consumption of Propofol and midazolam, and pain intensity after the operation were evaluated and compared between two groups.
Results: Patients in the propofol-Lidocaine group had better hemodynamic stability and the trend of sedation score changes was significantly different between the two groups (P=0.042). In terms of pain intensity during recovery, propofol-Lidocaine recipients had less pain intensity (P<0.001). Patients receiving propofol-Lidocaine received less Propofol (P=0.028) and midazolam (P=0.01).
Conclusion: The results of the present study show that the use of injectable Lidocaine with Propofol is associated with more favorable hemodynamic stability, reduction of Propofol consumption, better sedation, and less postoperative pain, so it seems that the use of Lidocaine with Propofol is beneficial. It is preferable to Propofol alone.

Introduction

Although the ideal method of sedation in bronchoscopy has not been determined yet, the known standard method is a combination of a short-acting benzodiazepine with an opioid [1]. The benzodiazepine used is usually midazolam, which was chosen because of its short effect [2], but due to its pharmacokinetic nature, which includes different dose adjustments in offenders, as well as its delayed metabolism, it has led to drug accumulation in 6% of patients. [3] Both of the mentioned factors cause a delay in the improvement and recovery of patients. This issue can reduce the number of examined patients in one day, increase the cost of care and personnel and the need for more care beds. Propofol is a hypnotic and sedative drug that is frequently applied in maintenance and induction of anesthesia. [4] The onset of the fast effect and the anesthetic properties of propofol, along with its quick and easy recovery, make this drug a suitable option for performing procedures. [5] the advantages of using Propofol over midazolam are; Faster effect, better tolerance and faster recovery [6 and 7]. Also, other studies have confirmed the safety of using Propofol in comparison with midazolam-hydrocodone in bronchoscopy and have proven the superiority of Propofol in better recovery [8]. Considering the mentioned advantages, the use of Propofol is increasing to perform bronchoscopy. In contrast to all the mentioned advantages, Propofol is a very strong drug that can cause unwanted drug side effects such as pain at the injection site (more than 10%), headache, hypotension, bradycardia, and transient apnea (between 1-10%)., thrombosis, phlebitis (between 0.1-1%) and in rare cases, abuse leads to addiction or death. [9] Although both

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benzodiazepine-opioid and Propofol methods alone have equal safety and Propofol has better recovery. If the dose of Propofol can be reduced, it is hoped that the unwanted side effects of this drug will also be reduced.

Addition of Lidocaine to Propofol is the approach investigated in this study. Lidocaine is an anesthetic drug that is used as an anesthetic drug of choice in flexible bronchoscopy due to its short effect and safety. [10] The use of local anesthesia in the bronchoscopy process leads to a decrease in stridor and cough. [11, 12] Although some pulmonologists have also used cocaine and bovicaine and confirmed its safety [13], in this study, along with topical Lidocaine, which is routinely used during bronchoscopy, its injectable form was also used.

The aim of local anesthesia using Lidocaine is to achieve satisfactory anesthesia from the lower and upper airways, including the nasal passage, base of the vocal cords, tongue, lower larynx, pharynx and upper larynx, and trachea. [14] Propofol It can also be used as an alternative and better method for benzodiazepines during Lidocaine sedation. Propofol has side effects such as hypotension and pain, bradycardia and transient apnea, so minimizing the dose used can be very beneficial. At the same time, no comprehensive study has assessed the effect of adding Propofol to Lidocaine in creating sedation for bronchoscopy. Therefore, the purpose of designing and implementing this study is to provide a method to reduce the dose of Propofol used and its effectiveness.

Methods

Trial design and setting

This is a triple-blind clinical trial study, that approved in ethic committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1402.369) and approved in Iranian Registry of Clinical Trial (IRCT) by code: IRCT20160307026950N57. The research was conducted in Alzahra hospital of Isfahan during 2022-2023. The target population was patients with bronchoscopy candidates with physical status (ASA) 1 and 2.

The inclusion criteria were ASA group I, II, bronchoscopy candidates, the age range of 18 - 60 years, and Patient consent to take part in the research. Also, patients using analgesia and opioids 24 hours before the intervention, previous beta-blocker use, allergic to study drugs, patients with severe cardiovascular history, asthma, kidney disease, liver disease and chronic respiratory disease, drug allergies, immunodeficiency, alcohol consumption 24 hours before surgery and patients with muscle weakness were not included in the study. Also occurrence of medical problems after induction that required intervention, and difficult intubation were considered as exclusion criteria.

This study was a triple-blind study, and the patient, the data collector, and the statistical analyst were unaware of the type of drug prescribed. Sampling was done by simple random allocation method.

The sample size was determined by using Epi-Info (CDC) software and regarding the confidence range of 95% and the power of 80% for each group of 30 people and a total of 60 people.

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After the necessary coordination, and with the presence of the researcher at the patient's bedside, the aim of the plan was explained and written consent was received from the patients. For random allocation of patients between two groups, numbers 1-60 were written on 60 cards and put into the box. When the patients entered the study, they were asked to choose a sheet from the box and according to whether they were odd or even, the patient was assigned to one of two groups, 1 and 2.

Intervention

After taking history and recording demographic and basic information and connecting patients to pulse oximeter, ECG, and non-invasive blood pressure, all cases were supported with 2% nasal oxygen. For the first group, the bolus dose of Propofol was calculated and injected at 1 mg/kg. The second group received a bolus dose of 1 mg/kg Propofol plus 1.5 mg/kg Lidocaine intravenously. Two minutes after injecting the bolus dose of drugs, the patient's state of relaxation was checked with sedation score. In the specified scale, the level of sedation in the patient is assessed on a scale from 1 to 5: 1) fully alert and conscious, 2) sleepy, 3) eyes shut but reacting to verbal cues, 4) eyes shut but responding to light physical touch, and 5) eyes shut and unresponsive to light physical touch.

In case of insufficient sedation and Sedation Score less than 5, 70 µg/kg/min Propofol was infused for the patient and the amount of additional drug was recorded in the data collection form. After the procedure ended and the patient regained consciousness, the intensity of pain during the procedure was calculated and recorded based on the VAS scale, where zero is the lowest level of pain and 10 corresponds to the highest intensity of pain that the patient has experienced so far.

Statistical analysis

Finally, data were analyzed by SPSS 26 and using independent sample T-test, Chi-square tests, and Repeated Measures Analysis of Variance, at $P<0.05$.

Results

In this research, 60 patients underwent bronchoscopy in two groups of 30 people receiving 1 mg/kg of Propofol and 1 mg/kg of Propofol and 1.5 mg/kg of intravenous Lidocaine. During bronchoscopy, none of the patients were excluded because of unwanted complications, and 60 patients were analyzed (Figure 1).

According to (Table 1), the two study groups indicated no significant difference in clinical and demographic variables ($P<0.05$).

Examination of the hemodynamic parameters until entering the recovery showed that before the procedure, none of the mentioned variables were significantly different between the groups, but at the 20th minute and the time of entering the recovery, the heart rate (HR) of both groups had a significant difference, and the patients in the Propofol group had a higher HR, but the two groups indicated no significant differences in systolic, diastolic, average blood pressure and blood oxygen saturation percentage at any time. The intragroup analysis showed a significant difference in the alterations in HR parameters and blood oxygen saturation percentage during the study period in both groups, and also in the intergroup analysis, there were significant differences in the trend of HR changes between the two groups. Regarding the sedation score during the research, two groups showed no significant difference before induction and at minute 3, but at minute 10, the variation between the groups was significant and those receiving propofol-Lidocaine had better sedation. At the 20th minute and the time of entering recovery, no significant difference was detected between both groups. According to intra-group analysis, both groups indicated a significant difference in the changes in the sedation score during the research. Regarding intergroup analysis, both groups indicated a significant difference in the changes in the sedation score. (Table 2)

(Figure 2) indicates the alterations in the sedation score during the research.

Examining the pain intensity of the patients during the recovery time showed that the propofol-Lidocaine recipients had less pain intensity in all the investigated times during the recovery. According to intra-group analysis, a significant difference was detected in changes in pain intensity from the start of recovery to the 45th minute in both groups. In the intergroup analysis, a significant difference was detected in the changes in pain intensity between the groups, and the propofol-Lidocaine group experienced less pain intensity (Figure 3).

As shown in (Table 3), the pulmonologists expressed significantly greater satisfaction with the propofol-Lidocaine group. Regarding medication dosage, patients in the propofol-Lidocaine group required lower amounts of propofol and midazolam, while there was no notable difference in the amount of fentanyl administered to either group. Additionally, there were no significant differences between the two groups in terms of recovery time, bronchoscopy duration, or anesthesia duration.

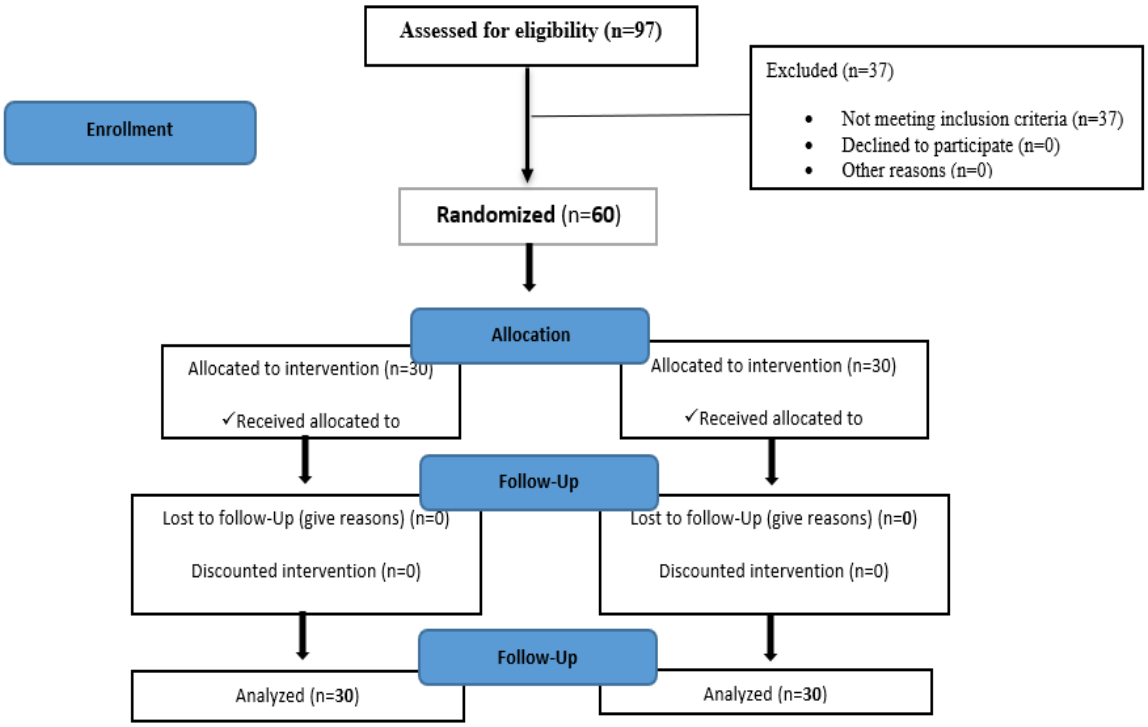

Figure 1- Study flow diagram

Table 1- Demographic and preoperative characteristics of the patients.

Variables		Groups		P
		Propofol + lidocaine	Propofol + lidocaine	
Age (year)		45.2 ± 10.1	53.6 ± 7.2	0.798
Sex N (%)	Male	19(63.3)	24(80)	0.15
	Female	11(36.7)	6(20)	
Weight (kg)		77.4 ± 14.9	79.8 ± 14.2	0.56
ASA	I	28(93.3)	23(76.7)	0.09
	II	2(6.7)	7(23.3)	
Time of bronchoscopy		24.83 ±5.08	25.07 ± 7.07	0.88
Time of anesthesia		33 ± 7.84	32.67 ± 8.72	0.89

P value was calculated using chi square and independent T test. Significance is defined as p<0.05.

Table 2- Mean and standard deviation of hemodynamic parameters of patients before, during and after bronchoscopy in the two groups

Variables	Time	Propofol	Propofol + lidocaine	P
SBP	Base line	129.2 ± 12.6	129.4 ± 13	0.96
	3 mines after	132.6 ± 16.2	130.2 ± 17	0.596
	10 mines after	131.7 ±20.8	126.5 ± 18.4	0.326
	20 min after	127.9 ± 17.8	128 ± 20.3	0.986
	recovery	126.1 ± 15.5	125.6 ± 14.4	0.89
	P**	0.065	0.39	0.77***
DBP	Base line	83.07 ± 11.5	85.3 ± 14.6	0.53
	3 mines after	84.1 ± 14.1	84.3 ± 14.8	0.95
	10 mines after	84.3 ± 14.8	81.1 ± 15.3	0.42
	20 min after	81.4 ± 14.8	82.9 ± 18	0.74
	recovery	81.6 ± 13.8	81.6 ± 12.6	0.99
	P**	0.42	0.67	0.88***
MAP	Base line	94.4 ± 19.4	98.5 ± 11.5	0.37
	3 mines after	98 ± 18.9	99.3 ± 16	0.79
	10 mines after	97.4 ± 13.5	96 ± 16.3	0.73
	20 min after	96.8 ± 15.7	99 ± 18.7	0.67
	recovery	94 ± 21.6	96.8 ± 12.4	0.59
	P**	0.80	0.48	0.56***
SPO2	Base line	94.7 ± 2.4	94.2 ± 2.1	0.36
	3 mines after	91.1 ± 2.6	90.7 ± 3	0.595
	10 mines after	96.8 ± 3.8	95.8 ± 4.9	0.38
	20 min after	94.3 ± 4.7	94.5 ± 4.1	0.87
	recovery	92.3 ± 2.5	92.9 ± 2.4	0.37
	P**	<0.001	<0.001	0.91***
HR	Base line	92.9 ±12.2	81.7 ±8.9	0.94
	3 mines after	96.2 ±11.4	91.3 ± 10	0.09
	10 mines after	98.9 ± 11.1	93.3 ± 11	0.063
	20 min after	102.3 ± 13.8	95 ± 10.1	0.035
	recovery	96.1 ± 12.3	96.1 ± 7.4	0.015
	P**	<0.001	<0.001	0.032***
Sedation score	Base line	1.27 ± 0.58	1.33 ± 0.73	0.70
	3 mines after	3.73 ± 0.98	4.07 ± 0.83	0.17
	10 mines after	4.47 ± 0.86	4.93 ± 0.27	010
	20 min after	4.47 ±0.97	4.64 ±0.99	.52
	recovery	2.53 ± 0.90	2.76 ± 0.97	0.38
	P**	<0.001	<0.001	0.042***

*Significant level of difference between two groups at each point of time according to T-test
**Significant level of changes within each group according to repeated measures ANOVA
***Significant level of the trend of changes between the two groups according to repeated measures ANOVA

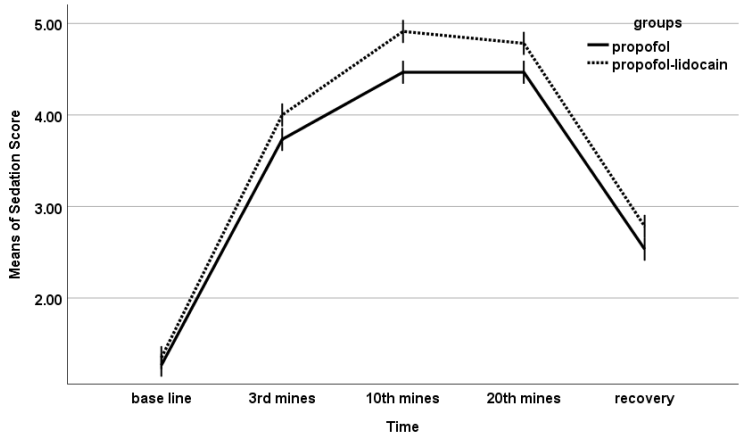

Figure 2- Trend of Changes in the sedation score during the study between the two groups

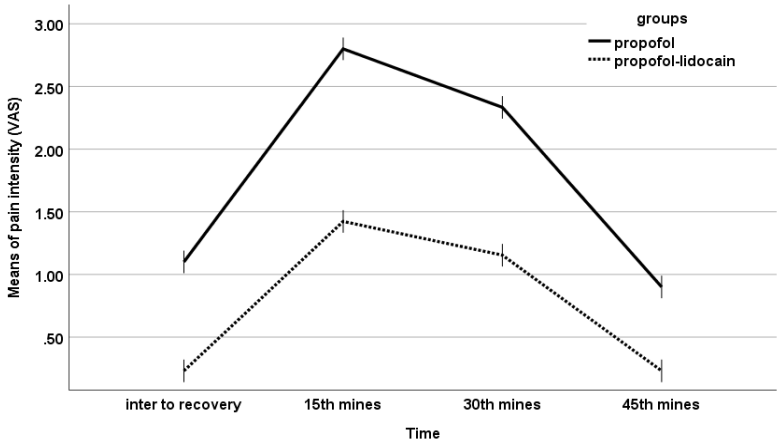

Figure 3- Trend of Changes in the pain intensity during the recovery between the two groups

Table 3- Mean and standard deviation of pain intensity, drugs received recovery, bronchoscopy and anesthesia time in two groups

Variables		Groups		P
		Propofol	Propofol + lidocaine	
Pain intensity (VAS)	Inter to recovery	1.10 ± 0.92	0.22 ± 0.51	<0.001
	15 mines later	2.80 ± 1.63	1.44 ± 1.25	0.001
	30 mines later	2.33 ± 1.37	1.15 ± 0.95	<0.001
	45 mines later	0.9 ± 0.66	0.23 ± 0.51	<0.001
	P**	<0.001	<0.001	<0.001***
Pulmonologist satisfaction		6.30 ± 1.21	7.15 ±1.26	0.012
Mean of Propofol received		108.8 ± 23.9	97.26 ± 11.89	0.028
Mean of Midazolam received		0.58 ± 0.38	0.34 ± 0.10	0.01
Mean of Fentanyl received		10.07 ±6.36	7.30 ± 5.56	0.28
Recovery time		46.04 ± 9.61	45.62 ± 10.56	0.88
Time of bronchoscopy		24.83 ±5.08	25.07 ± 7.07	0.88
Time of anesthesia		33 ± 7.84	32.67 ± 8.72	0.89

Discussion

The occurrence of hemodynamic disorder is one of the serious challenges during procedures under sedation, which can lead to side effects such as tachycardia, hypertension, and arrhythmia by stimulating the central nervous system. Therefore, so far, various studies have been conducted in order to minimize the occurrence of these disorders. Propofol is one of the most common

prescription drugs for inducing sedation, but at the same time, the desired and ideal result in controlling blood pressure and heart rate during procedures such as bronchoscopy has not been achieved. On the other hand, other drugs such as Lidocaine have been introduced to maintain hemodynamic stability during bronchoscopy, but according to studies and experiences, Propofol is considered one of the safest drugs used in sedation, but at the same time, there are few studies about The effect of combining this drug with other drugs in creating sedation has not been done and since the use of sedative drugs such as Propofol is associated with few risks and side effects and can minimize the patient's hemodynamic response during bronchoscopy, this study The aim of comparing Propofol sedation and Lidocaine -Propofol combination in patients undergoing bronchoscopy was achieved.

This study was conducted on two groups of 30 people who received Propofol (1 mg/kg) and Propofol (1 mg/kg) plus intravenous Lidocaine (1.5 mg/kg). According to the initial findings, the two groups were similar regarding demographic and clinical characteristics. There were no significant differences in the basic and hemodynamic variables, as well as the duration of bronchoscopy and anesthesia, and these factors did not have a confounding effect on the study's outcomes. Consequently, the differences noted between the two groups were likely attributable to the type of medication administered.

Examination of hemodynamic parameters from pre-anesthesia to the time of recovery showed no significant difference in blood pressure and percentage of oxygen saturation between the groups, but a significant difference was detected in HR between the two groups, and the patients receiving propofol-Lidocaine significantly decreased the heart rate. have had a lower Also, the patients receiving propofol-Lidocaine had a better level of sedation. In this context, a study conducted by Akhundzadeh et al. in 2021 aimed to compare the sedative effects of a propofol-ketamine combination with that of propofol-ketamine combined with Lidocaine spray during endoscopy. A total of 154 patients scheduled for endoscopy were randomly assigned to two groups. In the first group, 0.5 mg/kg of propofol was administered along with 0.5 mg/kg of ketamine, while the second group received 2 puffs of 10% Lidocaine spray, totaling 20 mg. Subsequently, both groups were given 0.5 mg/kg of propofol and 0.5 mg/kg of ketamine, followed by an additional 2 puffs of 10% Lidocaine spray, amounting to 20 mg. The researchers then assessed and compared sedation levels, apnea, nausea, and other clinical findings in the patients. The findings indicated that patients who received the combination of propofol, ketamine, and Lidocaine experienced higher sedation levels. There was no significant difference in systolic blood pressure between the two groups; however, the heart rate during the anesthetic administration was significantly lower in the group receiving propofol, ketamine, and Lidocaine. [14] These results align with ours. In the study conducted by Moftakher et al., 138 patients scheduled for outpatient endoscopy were assigned to two groups. The first group received 0.5 mg/kg of propofol and 0.5 mg/kg of ketamine, while the second group was given 0.5 mg/kg of ketamine, 0.5 mg/kg of propofol, and 1.5 mg/kg of Lidocaine. The researchers recorded and compared hemodynamic changes, sedation levels, as well as instances of nausea and vomiting among the patients. The results indicated no significant differences in heart rate or mean arterial blood pressure between the two groups. Additionally, the sedation levels were similar in both groups. The study concluded that the addition of intravenous Lidocaine to the propofol-ketamine combination enhances clinical outcomes and reduces side effects. [15] In a study by Amini et al., the effectiveness of a combination of low-dose propofol, ketamine, fentanyl, midazolam, and Lidocaine was compared to a standard combination of propofol and fentanyl for achieving deep sedation. The results indicated that the combination of low-dose fentanyl, ketamine, midazolam, propofol, and Lidocaine was more effective in inducing deep sedation than the usual dosages of propofol and fentanyl. In another study by Naghibi et al., it was found that administering either lidocaine or dexamethasone did not significantly reduce postoperative cognitive disorders. However, given that the use of dexamethasone is restricted in cataract surgery patients due to various underlying health conditions, lidocaine is considered the preferable option for these individuals. [17].

Our findings showed that patients receiving propofol-Lidocaine had less pain during recovery, which is consistent with the results of Akhoundzadeh and Jabal Ameli's study [17, 14].

Our results indicated that in the group receiving propofol-Lidocaine, the rate of receiving Propofol and Midazolam was significantly lower, which aligns with the results of Moftakher et al. [18]. In a study in 2020, Chen and colleagues investigated the effect of intravenous Lidocaine in reducing the consumption of Propofol in elderly patients undergoing colonoscopy, and no significant difference was detected in the total amount of Propofol consumed, but the amount of supplemental Propofol was significantly less in the Lidocaine group [19].]. Hu et al. examined the effect of intravenous Lidocaine in elderly patients receiving gastroscopy, and the use of Lidocaine significantly reduced the dose of Propofol in the subjects. [20] Jing Liu and colleagues have investigated the safety and efficacy of intravenous Lidocaine in sedation during ERCP, and the results of the study have shown that intravenous Lidocaine caused a significant reduction the amount of Propofol consumed during ERCP [21], which The results of this study on the amount of Propofol consumed are consistent with our results. In any case, our results show that the use of

injectable Lidocaine at the rate of 1.5 mg/kg along with 1 mg/kg of Propofol has better hemodynamic stability, reducing the consumption of Propofol and sedative, as well as less pain intensity afterwards. It is associated with practice, but due to the limitations that existed in this study, including short follow-up time, no control group, and a small sample size, more relevant studies should be conducted.

Conclusion

Our results show that adding injectable Lidocaine to Propofol for bronchoscopic sedation is associated with more benefits. The items investigated in this study included hemodynamic parameters, intensity of sedation, patient's pain level, pulmonologist's satisfaction level and the amount of additional medication. Patients in the injectable propofol-Lidocaine group had better sedation and the pain caused by the procedure was lower in them, the pulmonologist was more satisfied with sedation in this group and the need for additional medication was less. Considering that Propofol is a safe drug for maintaining the patient's hemodynamics, the patient's hemodynamics underwent less changes with the help of injectable Lidocaine. All these cases show that the use of injectable Lidocaine along with Propofol can be more beneficial for patients and the medical system.

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