

# Comparison of Sedation between Dexmedetomidine and Propofol During Transesophageal Echocardiography: A Randomized Controlled Trial

## Abstract

**Background:** This study aimed to compare sedation characteristics of dexmedetomidine (Dex) and propofol during transesophageal echocardiography (TEE) in cardiac patients. **Methods:** This clinical trial was conducted on 65 cardiac patients, who underwent TEE in a referral heart hospital. The patients were randomly divided into two groups: Dex ( $n = 34$ ) and propofol ( $n = 31$ ). The depth of sedation in the patients was assessed at 5-min intervals until the end of the TEE examination. The patient, physicians' satisfaction was recorded. Furthermore, blood pressure, heart and respiratory rates, peripheral oxygen saturation, and the bispectral index (BIS) of the patients were measured. The occurrence of apnea, hypotension or bradycardia was documented. **Results:** Demographic variables were similar in both groups. Time from the beginning of sedation to the start of TEE was significantly longer in the Dex group ( $P = 0.01$ ). Duration of the TEE examination was not different between the two groups. Interestingly, the recovery time was shorter in the Dex group than in the propofol group. There were no significant differences regarding patient and physician satisfaction with sedation quality. Hemodynamic profile was mainly similar in both groups. There was a significantly lower BIS level in the Dex group. There was no significant difference in the incidence of apnea or hypotension between the groups. **Conclusions:** Time from the beginning of sedation with Dex was longer than that with propofol. However, Dex was able to provide satisfactory sedation levels, hemodynamic stability, short recovery time, and acceptable patient and practitioner satisfaction during TEE in our cardiac patients.

**Keywords:** Dexmedetomidine, propofol, sedation, transesophageal echocardiography

## Introduction

Sedation in diagnostic and interventional procedures such as transesophageal echocardiography (TEE) is used to alleviate patient discomfort and anxiety and provide amnesia of the experience.<sup>[1]</sup> Furthermore, moderate sedation by creating a calm and cooperative state improves both physician satisfaction and the outcome of the procedure. The American Society of Anesthesiologists (ASA) defines moderate sedation (conscious sedation) as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands accompanied by light tactile stimulation. Usually, the patient's airway is maintained open, and spontaneous ventilation is adequate. In addition, the cardiovascular function is usually preserved.<sup>[2]</sup> Benzodiazepines such as midazolam and propofol are usually used for procedural sedation. However, in cardiac

patients, the cardiovascular and respiratory depressant effects of these drugs, especially when the nonanesthesiology physicians themselves administer these drugs, are the main concern as regards patient safety. Thus, clinicians seek agents capable of retaining hemodynamic stability and airway security more optimally during sedation.<sup>[3,4]</sup>

Dexmedetomidine (Dex) is a highly selective  $\alpha_2$ -adrenergic agonist with anxiolytic and analgesic effects, exerted through the activation of the presynaptic receptors in the central nervous system. Many researchers have investigated the effects of Dex in procedural sedation alone or combination with other sedative drugs such as midazolam and propofol.<sup>[3-10]</sup>

Most studies have evaluated the effects of these drugs by assessing sedation levels with the visual analog scale or the Ramsay scale and anxiety by the Spielberger (trait) test anxiety inventory.<sup>[5,6]</sup> Nonetheless, there is a

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paucity of evidence regarding the sedation quality of Dex compared with other sedatives like propofol as measured with the bispectral index (BIS).

In the present randomized controlled trial, we aimed to assess and compare sedation level, hemodynamic stability, and recovery time between Dex and propofol by using both Ramsay scale and BIS in cardiac patients undergoing diagnostic TEE.

## Methods

### Participants

After the approval of the proposal by the Institutional Ethics Committee, we obtained written informed consent from all the patients and conducted the trial in a referral cardiovascular center. The study was done on cardiac patients who underwent diagnostic TEE in the echocardiography laboratory. The inclusion criterion was age between 18 and 70 years, and the exclusion criteria comprised heart failure (left ventricular ejection fraction  $\leq 30$ ), severe obstructive valvular lesions of heart, allergy to Dex or propofol, contraindication to TEE, severe neurological or mental disorder, heart rate  $\leq 60$  bpm, and tracheal intubation. This clinical trial was registered in the Iranian Registry System ([www.irct.ir](http://www.irct.ir)) with an ID of IRCT2016112731131N1.

In accordance with the study by Cooper *et al.*,<sup>[4]</sup> who reported adequate sedation during TEE in 90.9% using Dex and 64.4% with midazolam and considering an  $\alpha$  type error of 0.05 and study power of 80%, we calculated our sample size to be 35 patients in each group (<http://www.stat.ubc.ca/~rollin/stats/ssize/b2.html>). Initially, 70 patients were enrolled in the study; however, because 2 patients declined to participate in the study, a total of 68 patients were finally randomized in Dex ( $n = 34$ ) and propofol ( $n = 34$ ) groups using online randomization software (<http://www.graphpad.com/quickcalcs/randomize2/>). The patients' allocation list was referred to a 3<sup>rd</sup> person and was concealed from the researchers. In the propofol group, one patient did not receive sedation due to an unplanned change in the patient's examination by the echocardiographer, and in two patients propofol was discontinued because of difficult TEE probe insertion. In the Dex group, all 34 patients finished the study, and they were entered into the statistical analyses [Figure 1]. This study was single-blinded, with only the patients being unaware of drug allocation for their sedation.

### Interventions and outcomes

After the patients were scheduled for TEE, allocation of each participant to the Dex or propofol group was performed according to a randomization list by an individual not involved in the study. In all the patients,

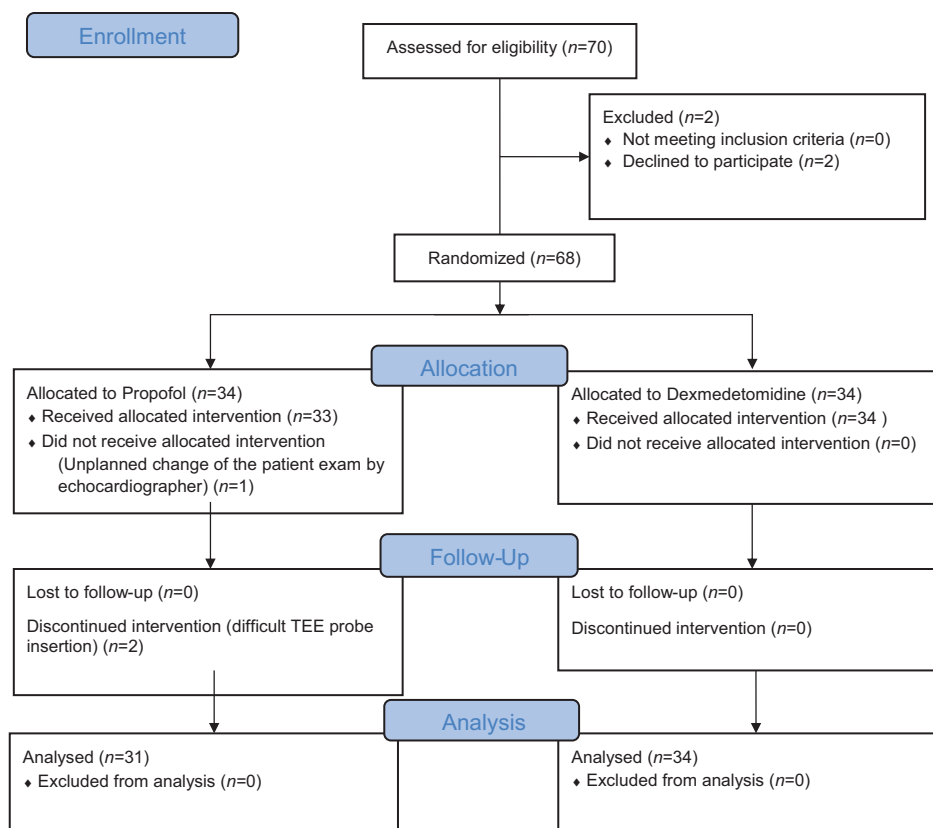


Figure 1: The study flow diagram

local lidocaine (10%) spray was applied until the loss of a triggered gag reflex by a tongue depressor. In the Dex group, the loading dose of Dex (1 µg/kg) was infused over 10 min. After a Ramsay sedation score of 3 was obtained, the TEE probe was inserted, and the echocardiography examination was initiated. The maintenance dose of Dex was 0.1–0.5 µg/kg/h and the patients' sedation level was evaluated at 5-min intervals. When the Ramsay score dropped below 3, 20% was added to the maintenance dose of Dex. In the propofol group, an initial dose of 0.1 mg/kg was administered, and when a Ramsay score of 3 was obtained, the TEE examination was performed. The maintenance dose of propofol was 25–75 µg/kg/min, and it was adjusted according to the patients' sedation level, as was the case in the Dex group.

We monitored the patients' vital signs – consisting of continuous peripheral pulse oximetry (SpO<sub>2</sub>), heart rate, respiratory rate, and noninvasive (systolic and diastolic) blood pressure every 5 min. In addition, the BIS was measured during TEE and in the recovery room until the patients' full recovery from sedation. The setting equipped with all resuscitation equipment. The occurrence of hypotension (systolic blood pressure <90 mm Hg), respiratory depression (breath rate <8/min), desaturation (SpO<sub>2</sub> <90%), or apnea (cessation of breathing >30 s) was immediately treated accordingly by the anesthesiologist, and the event was recorded. For example, hypotension was treated with a bolus dose of ephedrine (0.1 mg/kg) and a 20% decrease in the infusion dose of Dex or propofol and 100–200 mL of a Ringer's solution infusion. Hemodynamic and respiratory variables as well as the BIS were recorded at baseline and immediately before and after TEE probe insertion at 5-min intervals during the TEE examination and on arrival at the recovery room.

Following the completion of the TEE examination, all the patients were transferred to the recovery room, where standard monitoring was continued (similar to the TEE exam) until the patients became fully awake. The modified Aldrete score was employed to assess recovery in the participants. The criterion for discharge from the recovery room was reaching a modified Aldrete score of 9–10. The other variables measured were the total time of the TEE exam, and time to recovery from sedation.

At the end of the procedure, the echocardiologist, the anesthesiologist, and the patients were asked by a blinded investigator about their level of satisfaction with sedation quality (in terms of patient comfort, respiratory and hemodynamic stability, and speed of recovery). In addition, the patients were inquired about their recollection of the TEE examination and whether or not they would accept this kind of sedation again in the future.

## Statistical analysis

The data were collected and analyzed using SPSS, version 22.0 for Windows (SPSS Inc., IBM Corp, Chicago, Illinois, USA). Adaptation of the data distribution to normal distribution was evaluated with the one-sample Kolmogorov–Smirnov test. The continuous variables were presented as means and standard deviations (SDs) and the categorical parameters as numbers (percentages). The quantitative variables at different time intervals in each group were assessed using the repeated measures analysis of variance. The mean values of the continuous variables were compared between the two study groups using the Independent Samples *t*-test, and the categorical parameters were analyzed using the Chi-square test (with continuity correction or the Fisher's exact test as needed).  $P \leq 0.05$  was considered a statistically significant result.

## Results

In the present study, 68 patients were divided into two groups of Dex and propofol. However, finally, 34 patients in the Dex group and 31 patients in the propofol group completed the procedure and were entered into the statistical analyses. The demographic data of the patients are depicted in Table 1. There were no statistically significant differences in the demographic data, risk factors, and the ASA functional class status between the study groups. Table 2 summarizes sedation status, procedure and recovery times, complication rates, and drug interventions (ephedrine for the treatment of hypotension) in both study groups. Because the administration of the initial dose of Dex took 10 min, the total sedation time in the Dex group was significantly longer than that in the propofol group ( $P = 0.001$ ). Surprisingly, the patients who took Dex awoke earlier than those who received propofol and recovery time (as assessed by using the modified Aldrete score) in the Dex group was shorter ( $P = 0.001$ ).

The hemodynamic parameters, including systolic and diastolic blood pressures and heart rate, were compared during sedation until recovery. As is illustrated in Figure 2, globally, the two study groups had a similar hemodynamic

**Table 1: Demographic parameters of the patients in both study groups**

	Propofol group (n=31)	Dex group (n=34)	<i>P</i>
Sex (male/female)	14/17	14/20	0.942
Age (y)	41.8±16.4	45.2±14.6	0.662
Weight (kg)	69.9±11.2	73.2±16.9	0.362
Height (cm)	165.3±10.1	164.4±17.8	0.804
BMI	26.6±4.9	28.6±3.8	0.377
Diabetes mellitus	2 (6.5%)	2 (5.9%)	1.000
Hypertension	7 (22.6%)	4 (11.8%)	0.406
ASA class (II/III/IV)	6/18/7	2/19/13	0.158

Dex: Dexmedetomidine, ASA: American Society of Anesthesiologists, BMI: Body mass index

profile. However, some statistical differences were observed in the heart rate before TEE probe insertion, in the 5<sup>th</sup> min of the procedure, and at recovery time, but all of them were

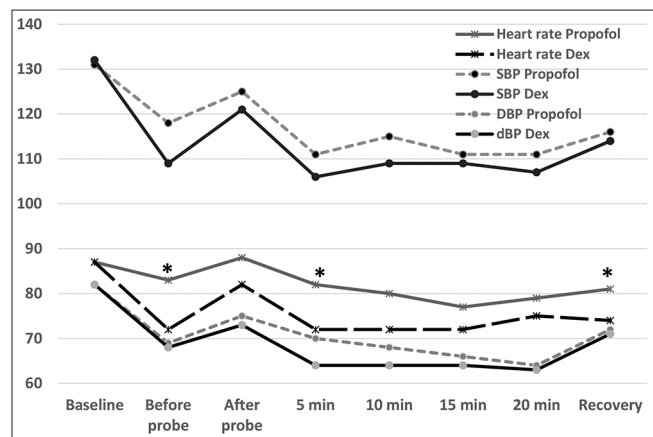


Figure 2: Hemodynamic changes during transesophageal echocardiography in the propofol and dexmedetomidine groups. X-axis: MmHg, Y-axis: transesophageal echocardiography time trend

Table 2: Sedation and procedure times and complication rates and drug interventions in the study groups

	Propofol group (n=31), n (%)	Dex group (n=34), n (%)	P
Time from sedation to TEE (min)	2.8±0.8	12.6±3.2	0.001
Duration of TEE (min)	16.5±5.8	18.9±7.8	0.172
Recovery time (min)	5.5±3.1	3.0±0.8	0.001
Apnea	2 (6.5)	0	0.432
Hypotension	0	1 (2.9)	0.902
Total complications	2 (6.5)	1 (2.9)	0.935
Drug intervention (ephedrine for hypotension)***	0	6 (17.6)	0.043
Intervention number (1/2/3)	0	3/1/2	0.110

\*\*\*One patient with SBP <90 and 5 patients with SBP 90–100 mmHg that ephedrine administered on echocardiologist to prevent hypotension. Dex: Dexmedetomidine, TEE: Transesophageal echocardiography, SBP: Systolic blood pressure

within normal limits. Peripheral oxygen saturation in the Dex group was minimally higher than that in the propofol group during sedation, but all the values were higher than 96.5%. There were significant differences in the respiratory rate in the 5<sup>th</sup> and 10<sup>th</sup> min of the procedure between the two groups; nevertheless, all the respiratory rate values were within normal limits (11–14 breaths/min).

In this study, in addition to routine monitoring, we assessed sedation depth during TEE using the BIS. In general, the patients who received Dex had lower BIS values (70–80) than those who received propofol (80–85); however, only in the 10<sup>th</sup> min of the procedure was this difference statistically significant.

Regarding cardiorespiratory complications, we encountered 2 (6.5%) cases of apnea in the propofol group and no respiratory depression in the Dex group (P = 0.432). Furthermore, in the Dex group, hypotension (systolic blood pressure <90 mm Hg) was observed in 1 (2.9%) patient, who was treated with 0.1 mg/kg of ephedrine. There was no case of hypotension in the propofol group. In the Dex group, five patients had a systolic blood pressure between 90-100 mm Hg and the echocardiologist asked the anesthesiologist to administer ephedrine to prevent more blood pressure fall. All the drug interventions were recorded, and they are summarized in Table 2.

One of the main goals of the current study was to evaluate sedation quality by assessing satisfaction with sedation during TEE from the perspective of the echocardiologist, the anesthesiologist and – more importantly – all the patients. We graded the satisfaction rate from bad (grade 0) to excellent (grade 4) and found that generally there were no statistically significant differences in the satisfaction levels between the two groups in the views of the echocardiologist, the anesthesiologist, and the patients [Table 3].

### Discussion

In this study, we found that Dex is a suitable sedation drug in cardiac patients undergoing diagnostic TEE exam.

Table 3: Echocardiologist, anesthesiologist, and patient satisfaction with sedation during transesophageal echocardiography

Satisfaction rate (grading)	Echocardiologist		Anesthesiologist		Patients	
	Propofol group (n=31)	Dex group (n=34)	Propofol group (n=31)	Dex group (n=34)	Propofol group (n=31)	Dex group (n=34)
Bad (0)	2	0	0	0	0	1
Not bad (1)	0	1	0	0	0	1
Fair (2)	1	1	3	1	2	4
Good (3)	1	4	2	3	2	2
Perfect (4)	27	28	26	30	27	26
P		0.321		0.509		0.635
Mean values of grading	3.65±1.05	3.74±0.67	3.74±0.63	3.85±0.44	3.81±0.54	3.50±1.02
		0.678		0.409		0.142

Dex: Dexmedetomidine, TEE: Transesophageal echocardiography

Dex was able to provide satisfactory sedation levels, hemodynamic and respiratory stability, short recovery time, and acceptable patient and practitioner satisfaction during TEE in comparison with propofol. We encountered only 2 (6.5%) cases of apnea in the propofol group and 1 (2.9%) case of hypotension in the Dex group; even so, with respect to all the cardiorespiratory complications, there was no statistical difference between the two groups [Table 2].

In various studies done by Banihashem *et al.*,<sup>[11]</sup> Jung *et al.*,<sup>[12]</sup> and Cooper *et al.*,<sup>[4]</sup> Dex conferred acceptable sedation in different procedures in comparison with midazolam and/or opioids without increase in respiratory depression or oxygen desaturation rates.

Cho *et al.*<sup>[13]</sup> reported a high sedation score with Dex compared with remifentanyl in atrial fibrillation ablation with catheter. Recovery times were similar in both groups. Koruk *et al.*<sup>[14]</sup> and Elseri *et al.*<sup>[15]</sup> found a short recovery time with Dex in comparison with ketamine and propofol, respectively, which is concordant with our study.

We found no statistically significant difference in the satisfaction rates between the Dex and propofol groups. In contrast, Banihashem *et al.*<sup>[11]</sup> showed high satisfaction rates with Dex compared with midazolam as reported by their echocardiologist and patients with transient ischemic attack undergoing TEE. In the study by Cho *et al.*,<sup>[13]</sup> the patients reported similar satisfaction rates in the Dex and remifentanyl groups, but the echocardiologists reported more satisfaction with the Dex group.

In general, Dex is similar to other sedatives in achieving sufficient levels of sedation – with comparable rates of respiratory depression, oxygen desaturation, and hemodynamic stability.<sup>[4-16]</sup> The main drawback of Dex is that its starting dose takes a long time to infuse (10 min), which may be deemed too long. Indeed, the echocardiologist may find it tiresome to begin a TEE examination with Dex. Furthermore, Dex may not be suitable in short-time procedures and clinics with a high patient turnover. What is more, an infusion pump must be available for administering Dex (although, it is needed for propofol infusion). Apropos patient anxiety, both propofol and Dex can efficiently lessen anxiety levels during magnetic resonance imaging, but Dex takes longer to confer adequate sedation.<sup>[5]</sup>

The BIS monitor is an electroencephalographic-based method of assessing the level of consciousness by the analysis of an algorithm to make a weighted index. In general, deeper anesthesia is related to lower BIS values. The BIS shows higher amplitudes with lower frequencies; this rule, however, does not apply to ketamine, N<sub>2</sub>O, and Dex.<sup>[17]</sup> In sedation with ketamine, we inversely observe a higher frequency oscillations and thus, a higher BIS, and despite high BIS values, the patient may not be awake. Inversely, in sedation with Dex, slow waves oscillations are seen, and we observe low BIS values while the

patient responds and can be readily aroused with minor stimulations.<sup>[17]</sup> To put it briefly, the BIS value may not chime in with the clinical level of sedation.<sup>[18,19]</sup>

We found no significant differences in the cardiorespiratory complication rates between the Dex and propofol groups. A number of studies have reported similar findings and found no differences in apnea and hypotension rates between patients taking Dex and those receiving propofol.<sup>[20-23]</sup> Still, some investigators have reported more hypotension and bradycardia associated with Dex,<sup>[24-26]</sup> while others have observed fewer complications with Dex.<sup>[27-29]</sup> This discordance in the complication rates among various studies could be related to differences in patient populations, doses of the drugs used, and times and methods of Dex administration.

There are limited evidences comparing Dex and propofol in short cardiac procedures. In a recent investigation, Mayr and colleagues compared these two agents for sedation in transcatheter aortic valve implantation procedure. They concluded, DEX was related with lesser PaCO<sub>2</sub> levels and lower requests for vasopressor drugs, making it a favorable alternative to propofol for sedation during TAVI.<sup>[30]</sup>

## Conclusions

We conclude that Dex is a suitable sedation drug in cardiac patients undergoing diagnostic TEE. Dex provides adequate sedation levels while maintaining hemodynamic and respiratory stability, short recovery time, and acceptable patient and practitioner satisfaction during TEE such as propofol. Although Dex group needed significantly more time to achieve target sedation. We found no statistical differences between our two study groups vis-à-vis all cardiorespiratory complications. The BIS value may not chime in with the clinical level of sedation with Dex.

## Limitations

The main limitation of this study is performing it in a single center on referred with cardiac diseases referring echocardiography laboratory that limits generalization of the findings to other patients in the different clinical setting. Another limitation of this study could be limited number of participant, so some nonsignificant results may be result from the somehow low sample size.

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## Conflicts of interest

There are no conflicts of interest.

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