

## Original Article

# Comparison of intravenous sedation with propofol, dexmedetomidine and midazolam in double-J ureteral stent removal

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**Abstract:** Background: According to the favorable effects of combination therapy to provide better sedation during double-j stent removal and lack of studies investigating the sedative effect of propofol, dexmedetomidine, and midazolam during this procedure. This study aimed to compare the effects of intravenous sedation with propofol, dexmedetomidine and midazolam in double-J ureteral stent removal. Methods: This double-blinded randomized clinical trial was conducted on 120 patients aged 18-72 who underwent double-J ureteral stent removal in Alzahra hospital, Isfahan, Iran from September to November 2021. Patients were randomly divided into 3 groups. In the first group, propofol was titrated with normal saline and was infused with a loading dose of 0.5 mg/kg and a maintenance dose of 1.5-2.5 mg/kg/h. In the second group, Dexmedetomidine was titrated with normal saline and was infused at a dose of 1 µg/kg within 10 min and then continued at 0.45-0.55 µg/kg. In third group, midazolam was titrated was infused with a loading dose of 0.05 mg/kg and a maintenance dose of 0.05 mg/kg/h. 50 mg of fentanyl was also infused in all the groups. If the patients did not reach the desired sedation level, 10 mg ketamine was infused as a rescue sedative agent for all three groups and repeated if needed in all groups. Results: The current study was conducted on 120 patients who underwent double-J ureteral stent removal. The comparison of the sedative effect of midazolam, dexmedetomidine, and propofol showed significant differences among the three groups and was higher in the midazolam group (P=0.018). Between the three groups systolic blood pressure and mean arterial pressure was significantly lower in the propofol group (P=0.002). Heart rate was significantly lower in the dexmedetomidine group during both surgery and recovery time (P<0.001). There was no significant difference among the groups during surgery regarding oxygen saturation (P value =0.84). The intergroup comparison indicates that the mean score of surgeon satisfaction is significantly higher in the midazolam group (P-value =0.039). Conclusion: According to this study midazolam was superior to two other groups and was associated with deeper sedation and higher satisfaction among both patient and surgeon.

**Keywords:** Dexmedetomidine, midazolam, propofol, Double G ureteral stent

## Introduction

Ureteral stent placement is a routine procedure in urologic practice [1]. Various types of stents including metallic ureteral stents and degradable ureteral stents, artificial polymeric stents, and ureteral stents are extensively used in urologic procedures [2].

Ureteral stents especially double-J (D-J) stents are used in endourologic procedures to relieve pain, infection, and obstruction during urologic procedures [2, 3]. The D-J ureteral stent is one

of the most valuable and basic methods used for preventing obstruction of the urinary tract and maintaining its patency following urologic open surgery and endourological procedures [2]. Indications for urethral stenting include: ureteral obstruction, ureteral obstruction due to nephrolithiasis, tumor, or retroperitoneal fibrosis can be uncomplicated, or complicated by urinary tract infection, renal insufficiency, or renal failure [4, 5]. These stents should be removed within a specified time (at post-operative 1 or 2 weeks) by multiple endourologic or

other auxiliary methods [4]. Although there is no guideline for the management of serious problems during this procedure, most patients require analgesia or deep sedation during this procedure [5].

Propofol as an intravenous anesthetic agent with a short half-life is used to maintain anesthesia and to provide sedation during surgical methods [6]. It, a rapidly-acting hypnotic agent, provides rapid onset and recovery times [5]. Nevertheless, propofol use is associated with some adverse effects including hypotension, severe respiratory [5], or cardiovascular depression [7]. Dexmedetomidine, a selective  $\alpha_2$ -adrenergic receptor agonist, has sedative and analgesic characteristics without respiratory depression [5]. The adverse effect of dexmedetomidine is a decrease in heart rate and blood pressure due to sympatholytic effects [5].

Midazolam is a benzodiazepine medication used for procedural sedation, anesthesia, trouble sleeping, and severe agitation and anesthesia [8]. It has a rapid recovery with quick onset; however, due to the long half-life of the drug and its metabolites after repeated doses, excessive sleepiness and psychomotor impairment is happening [9].

Although there have been some previous studies in this regard [10-13], there are limited data regarding the comparison of intravenous sedation of propofol, dexmedetomidine, and midazolam for the removal of double-J ureteral stent. There also has been no comprehensive study in our country. Thus, this study aimed to assess the comparison of intravenous sedation with propofol, dexmedetomidine, and midazolam for the removal of double-J ureteral stent.

### Methods and material

#### *Study design*

This double-blinded randomized trial was conducted on 120 patients who underwent double-J ureteral stent removal in Alzahra hospital from September to November 2021. The current study was approved by the Ethical Committee of Isfahan University of Medical Sciences and registered at the Iranian Registry of Clinical trials (code: IRCT202109-13052458N1).

#### *Inclusion and exclusion criteria*

The current study was conducted on patients aged 18-72 with ASA (the American Society of Anesthesiologists) physical status 1 and 2, and informed written consent to participate in the study. Patients with symptoms of lower urinary tract before the procedure, urethral obstruction and prostatitis during cystoscopy, Prostatitis or stenosis of the urethra during cystoscopy, Kidney failure (serum creatinine  $>1.5$  mg/dL), acute upper respiratory tract infection, chronic pain syndrome, mental disorder and difficulty in communication, history of chronic use of sedatives, alcohol and narcotics, bradycardia (heart rate less than 50 beats per minute), Systolic blood pressure less than 90 mm Hg, taking a sedative or analgesic 24 hours before surgery were not included in the study. The patients were excluded from the study if the procedure was changed to general anesthesia and if the patients were intubated.

The protocols and objectives of the study were explained to the participants and written informed consent was obtained.

#### *Interventions*

Before surgery, the patients were randomly divided into three groups to receive fentanyl plus dexmedetomidine, midazolam, or propofol, using the permutation blocks method.

The demographic characteristics and medical condition of all the participants were recorded by an anesthesiologist blinded to the groups.

Hemodynamic parameters before, during, and after surgery, sedation level, complication and adverse events during surgery, and recovery time, patient and surgeons' satisfaction levels were evaluated and recorded by the anesthesiologist and compared in the three groups.

Hemodynamic parameters were defined as systolic and diastolic blood pressure, and mean arterial blood pressure. These parameters were assessed using a sphygmomanometer. Sedation level was measured every 5 minutes during surgery using a Ramsay sedation scale classified 1-6 (1= anxious, 2= calm, 3= lethargic, 4= confused and responsive to auditory stimuli, 5= sluggish response to auditory stimuli, 6= No response to painful stimuli). When

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the patients achieved desired sedation (score 3), based on Ramsay Sedation the procedure commenced [14].

The complication of anesthesia including nausea, vomiting, bradycardia, apnea, laryngospasm, and restlessness during surgery and recovery was recorded. In addition, in case of any cardiovascular complication during surgery and recovery, it was recorded during the appropriate treatment.

### *Randomizing and blinding*

A double-blind randomization was performed in this study. Before the surgery the patients were randomly allocated into three groups via the permutation blocks method. Both the patients and the data collectors were unaware of the drug grouping and the blind observer who was unaware of the patients' drug grouping collected patient's data during the intervention and in recovery.

### *Anesthetic procedure*

Before induction of anesthesia, a 5 ml/kg lactate ringer solution was infused to prevent hypotension. Oxygen was administered at a rate of 4-6 liters/min through the nasal cannula in the operation room and recovery room. Patients in the three groups received sedatives at the same time. Systolic and diastolic blood pressure, heart rate and arterial oxygen saturation were recorded before surgery and every 5 minutes during surgery and every 10 minutes during the recovery period. Blood pressure was measured using a sphygmomanometer. Arterial blood oxygen saturation and heart rate were measured by a pulse oximetry device.

In the first group, propofol was titrated with normal saline and was infused with a loading dose of 0.5 mg/kg and a maintenance dose of 1.5-2.5 mg/kg/h. Moreover, 1 cc of fentanyl (50 micrograms) was infused. In the second group Dexmedetomidine was titrated with normal saline and was infused at a dose of 1 µg/kg within 10 min and then continued at 0.45-0.55 µg/kg. Moreover, 1 cc of fentanyl (50 micrograms) was infused. In the third group, midazolam was titrated was infused with a loading dose of 0.05 mg/kg and a maintenance dose of 0.05 mg/kg/h. Moreover, 1 cc of fentanyl (50 µg) was infused. If the patients did not

reach the desired sedation level, 10 mg ketamine was infused as a rescue sedative agent for all three groups and repeated if needed.

### *Assessment of variables*

Sedation level was measured every 5 minutes during surgery using the Ramsay sedation scale. If the Ramsay sedation score was lower than 3, a rescue dose of 10 mg Ketamin was injected and repeated if needed. The frequency of injected rescue dose was recorded by the anesthesiologist.

Apnea was defined as the cessation of respiratory effort for more than 20 seconds or less than 20 seconds which was associated with cyanosis or bradycardia. Bradycardia was defined as a 20% decrease in heart rate and tachycardia was defined as a 20% increase in heart rate. Hypotension was defined as a 20% decrease in blood pressure and hypertension was defined as a 20% increase in blood pressure. Hypoxemia was defined as oxygen saturation of less than 90%.

### *Outcome assessments*

The duration of surgery and the length of stay in recovery were measured in terms of minutes.

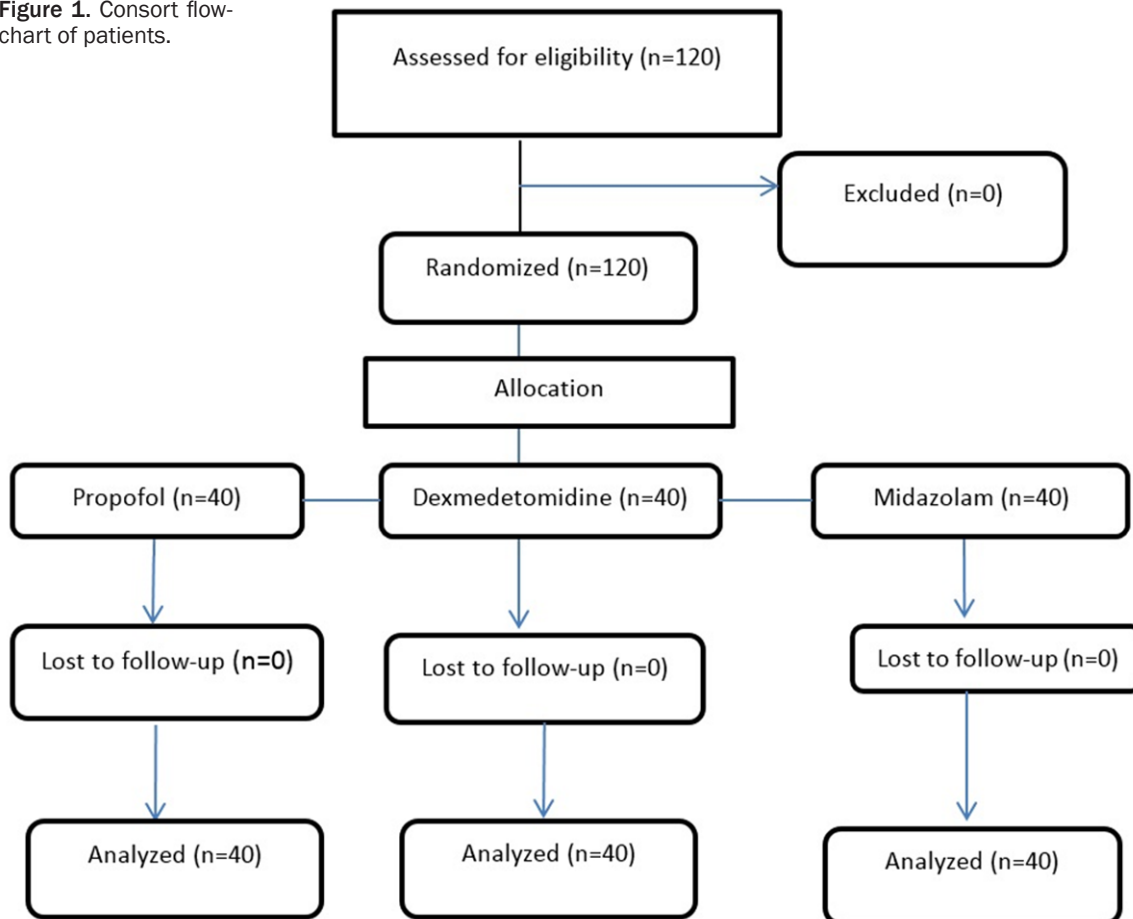
The length of stay in recovery was defined from the time of entry into recovery and the time of discharge from the recovery room when achieved Aldrete score of 9-10. The Modified Aldrete Score assesses patient activity, respiration, blood pressure, consciousness, and color. Each is scored from 0 to 2. A score >9 is required for discharge [15]. At the end of surgery and before discharge, the patients' and surgeons' satisfaction was assessed using a 5-point Likert scale as follows: 1. Very satisfied; 2. Satisfied; 3. Unsure; 4. Dissatisfied; 5. Very dissatisfied.

**Figure 1** shows the consort flowchart of patients.

### *Statistical analysis*

The obtained data were entered into the Statistical Package for Social Sciences (SPSS) (version 19, SPSS Inc., Chicago, IL). Quantitative data were reported as mean ± standard deviation and qualitative data as frequency distribution (percentage). Analysis of Variance (ANOVA),

**Figure 1.** Consort flow-chart of patients.



and Chi-square were used to analyze the data. *P*-value <0.05 was considered as the significance threshold.

**Results**

*Study population*

Totally, 120 eligible patients entered the study and were randomly allocated into three groups of 40.

The mean age of patients in 3 groups including propofol, dexmedetomidine and midazolam were 45.4±11.11, 49.5±10.23, and 50.3±10.16 years, respectively (*P*=0.085). Moreover, 66 patients (55%) were men and 54 patients (45%) were women.

*Patient's characteristics*

Regarding class 1 ASA, 23 patients were in the propofol group, 32 patients were in the dexme-

detomidine group, and 23 patients were in the midazolam group.

Operative details of patients before, during and after the procedure in the study group, values are presented in **Table 1**. The comparison of the mean Ramsay score showed a significant difference among the three groups during surgery (*P*=0.018) and was higher in the Midazolam group.

Before surgery there was no significant difference between the three groups regarding hemodynamic variables (*P*>0.05).

*Hemodynamics*

During surgery systolic blood pressure and mean arterial blood pressure were significantly different (*P*-value =0.002) and were lower in the propofol group. Moreover, heart rate was significantly different among the three groups (*P*<0.001), and was lower in the dexmedetomi-

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**Table 1.** Operative details of patients before, during and after the procedure in the study groups, values are presented as mean  $\pm$  SD and n (%)

Variable	Propofol, N=40	Dexmedetomidine, N=40	Midazolam, N=40	P value
<b>Before surgery</b>				
Systolic blood pressure	121.5 $\pm$ 18.3	123.02 $\pm$ 10.35	126.6 $\pm$ 9.46	0.2*
Diastolic blood pressure	76.7 $\pm$ 11.8	76.9 $\pm$ 9.5	79.4 $\pm$ 9.5	0.42*
Mean arterial pressure	89.6 $\pm$ 11.5	90.2 $\pm$ 9.1	92.9 $\pm$ 11.8	0.36*
Arterial oxygen saturation	95.5 $\pm$ 7.3	97.7 $\pm$ 3.8	97.3 $\pm$ 2.1	0.1*
Heart rate	65.9 $\pm$ 6.4	68.2 $\pm$ 8.17	68.9 $\pm$ 9.3	0.2*
<b>During surgery</b>				
Ramsay score	4.49 $\pm$ 0.28	4.47 $\pm$ 0.36	4.61 $\pm$ 0.31	0.018*
Systolic blood pressure	111.09 $\pm$ 2.02	114.80 $\pm$ 2.13	114.13 $\pm$ 2.12	0.002*
Diastolic blood pressure	68.14 $\pm$ 1.62	73.99 $\pm$ 4.04	69.78 $\pm$ 1.51	0.051*
Mean arterial pressure	80.87 $\pm$ 1.32	84.25 $\pm$ 1.35	82.42 $\pm$ 1.98	0.002*
Arterial oxygen saturation	97.48 $\pm$ 0.70	97.37 $\pm$ 1.89	97.72 $\pm$ 1.31	0.84*
Heart rate	67.44 $\pm$ 0.85	65.30 $\pm$ 1.03	68.42 $\pm$ 0.69	<0.001*
Hypotension	14 (35)	3 (7.5)	8 (20)	<0.001**
Hypertension	3 (7.5)	0	0	<0.001**
Tachycardia	4 (10)	4 (10)	3 (7.5)	<0.001**
Bradycardia	5 (12.5)	21 (52.5)	7 (17.5)	<0.001**
<b>After surgery and recovery</b>				
Systolic blood pressure	120.40 $\pm$ 1.45	78.20 $\pm$ 0.58	119.10 $\pm$ 0.77	0.33*
Diastolic blood pressure	74.93 $\pm$ 1.85	89.38 $\pm$ 1.66	75.40 $\pm$ 1.40	0.007*
Mean arterial pressure	87.95 $\pm$ 2.16	97.71 $\pm$ 0.19	87.68 $\pm$ 1.35	0.26*
Arterial oxygen saturation	97.90 $\pm$ 0.28	66.26 $\pm$ 0.89	98.11 $\pm$ 0.09	0.23*
Heart rate	68.00 $\pm$ 1.19	75.75 $\pm$ 1.47	69.75 $\pm$ 1.18	<0.001*
Complication	0	3 (7.5%)	0	<0.001**
Nausea	0	15 (37.5%)	7	<0.001**
Vomiting	0	4 (10%)	0	<0.001**
Chills	3 (7.5%)	0	3 (7.5%)	<0.001**

\*ANOVA test, \*\*Chi square test.

dine group. There were no significant differences between the three groups regarding diastolic blood pressure and oxygen saturation during surgery ( $P$ -value  $>0.05$ ).

During recovery time heart rate was significantly different and was lower in the dexmedetomidine group compared to propofol and midazolam with  $P$ -value =0.00. There were no significant differences regarding systolic blood pressure and mean arterial pressure and oxygen saturation among the three groups ( $P$ -value  $>0.05$ ) during recovery time.

### Complications and further assessments

There were no significant differences between the groups regarding complications except for

bradycardia which was significantly higher in Dexmedetomidine ( $P<0.05$ ).

As shown in **Table 2**, there was no significant difference among the three groups regarding the number of rescue doses ( $P$ -value =0.4) the frequency of 2 doses of Ketamine (rescue dose) in propofol, dexmedetomidine and midazolam groups were 7.5%, 7.5%, and 0%, respectively. The rest of the patients (25 patients) didn't receive any rescue dose.

As shown in **Table 3**, although there was no significant difference among the 3 groups in terms of patient satisfaction, the highest rate of patient satisfaction was related to midazolam with a mean of 1.6 $\pm$ 0.81. In addition, the highest rate of surgeon satisfaction was relat-

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**Table 2.** Rescue dose of Ketamine during surgery

Rescue dose	Propofol Frequency (n=40)	Dexmedetomidine Frequency (n=40)	Midazolam Frequency (n=40)	P-value*
1 doses	30 (75%)	27 (67.5%)	32 (80%)	0.4
2 doses	3 (7.5%)	3 (7.5%)	0	

\*Chi square.

**Table 3.** Comparison of patient's satisfaction in different groups

Group	Propofol Frequency (n=40)	Dexmedetomidine Frequency (n=40)	Midazolam Frequency (n=40)	P value*
patient	1.3±0.81	1.2±0.6	1.6±0.81	0.057
surgeon	2.32±0.94	1.7±1.01	2.39±1.2	0.039

\*ANOVA test.

ed to midazolam with a mean of 2.39±1.2 (P=0.039).

### Discussion

In the current study, the sedative quality of propofol, dexmedetomidine, and midazolam was evaluated and compared in double-j stent removal surgery. In this study, the comparison among the three groups showed significant differences regarding Ramsay's score during surgery, and was higher in the midazolam group. This finding may suggest that midazolam can cause deeper sedation. Wang and colleagues reported that although the sedative mechanism of dexmedetomidine and midazolam was different; there was no significant difference between the two groups regarding the depth of sedation, which was in contrast with our study. Wang and colleagues believed that both medicines provide a good sedative effect on patients who underwent surgery [16]. Jakob and colleagues evaluated the effect of midazolam and dexmedetomidine or propofol for sedation during mechanical ventilation and observed that no preference was observed between these groups regarding sedation [17]. Although the studies reported acceptable sedative effects the difference was not significant and the findings were inconsistent with our study.

Koruk and colleagues assessed the sedative effect of midazolam (0.05 mg/kg, 10 min before the procedure) and dexmedetomidine (1 µg/kg for 10 min) in combination with propofol in endoscopic retrograde cholangiopancreatography and found the comparable sedative effects of dexmedetomidine propofol combina-

tion than midazolam-propofol [18]. Jung and colleagues evaluated the therapeutic effect of propofol and midazolam in endoscopic retrograde cholangiopancreatography and demonstrated better sedation of propofol than midazolam [19]. It seems that the difference between studies was due to various doses of medication, and types of surgery. Huang and colleagues assessed the effect of midazolam and dexmedetomidine for the sedation of patients with non-invasive ventilation failure and demonstrated that midazolam led to a deeper level of sedation [20] and this finding was consistent with our study.

In the current study, the hemodynamic characteristics before the surgery were not significantly different. The comparison of hemodynamic and respiratory variables among the 3 groups showed that systolic blood pressure and mean arterial pressure was significantly different and was lower in the propofol group during surgery. In addition, the heart rate difference was significant and was lower in the dexmedetomidine group during surgery and recovery time. There was no significant difference between propofol, dexmedetomidine and midazolam groups regarding oxygen saturation. Koruk and colleagues compared the hemodynamic variables in patients receiving dexmedetomidine and midazolam and showed that no significant difference was seen between the two groups regarding hemodynamic variables [18]. Jung and colleagues exhibited no difference in blood pressure, or oxygen saturation between the two groups of patients receiving propofol and midazolam [19]. Murad and colleagues assessed the efficacy of propofol and dexmedetomidine

on hemodynamic variables in cardiac patients undergoing transesophageal echocardiography and demonstrated that mean arterial pressure value was approximately similar in two groups indicating a more steady hemodynamic profile during the study [21]. The result of our current study are inconsistent with those of Murad and colleagues and Jung and colleagues. Different result can be due to different procedure and different doses used.

There were significant differences among the groups regarding complications during surgery and recovery the most reported complication during surgery was bradycardia and was significantly higher in dexmedetomidine. Cardinale and others evaluated Bradycardia in Critically Ill Patients Receiving Dexmedetomidine and Fentanyl and reported that using a combination of fentanyl and dexmedetomidine can cause significant bradycardia. This finding is consistent with our study [22].

The comparison of the 3 groups in terms of satisfaction showed that even though the difference was not significant, the highest level of patient satisfaction was related to midazolam. In addition, the comparison of surgeon satisfaction showed a significant difference among the three groups and was higher in the midazolam group. Kim and colleagues assessed the patients who underwent cystoscopic ureteral stent removal under midazolam and propofol and observed less pain and a higher satisfaction rate in patients receiving midazolam than propofol [5], which was consistent with our study. Barends and colleagues evaluated the effect of dexmedetomidine versus midazolam in procedural sedation and reported that dexmedetomidine was associated with a higher operator and patient satisfaction compared to midazolam [23]. The finding of this study was inconsistent with our study. Corbett and colleagues assessed the effect of dexmedetomidine and propofol and reported that despite the advantages of dexmedetomidine to improve overall patient satisfaction, the two medicines provide a similar answer to pain control. Dossa and colleagues assessed the effect of propofol versus midazolam for sedation in colonoscopy and reported that both propofol and midazolam led to high patient satisfaction and seems to be safe for use in colonoscopy [24]. It seems that the type of surgery and different doses of medi-

cation was the reason for differences between studies.

The main limitations of our study were the restricted study population and not comparing our data to a control group. Conducting this study in a single center was another shortcoming of this study. However, our data are clinically valuable and could be used in future research. We recommend that multicentric studies on larger populations should be conducted.

### Conclusion

This study demonstrated that although the quality of sedation was acceptable in all three groups during double-j stent removal surgery, midazolam was superior to the other two groups and was associated with deeper sedation and higher satisfaction between both patient and surgeon. However, further studies and a larger sample size are recommended.

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### Disclosure of conflict of interest

None.

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