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CLINICAL TRIAL REPORT

The Optimal Doses of Dexmedetomidine Combined with Propofol in Patients in Hysteroscopic Surgery: A Randomized Controlled Trial

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Background: Dexmedetomidine has been reported to be utilized in conjunction with propofol during hysteroscopic surgery. However, both dexmedetomidine and propofol have benefits and side-effects, and the optimal doses of dexmedetomidine when utilized in combination with propofol during hysteroscopic surgery remain unestablished.

Methods: One hundred and fifty patients undergoing hysteroscopic surgery at the affiliated hospital of North Sichuan Medical College were randomly divided into five groups and administered dexmedetomidine at a dose of 0.4 µg/kg, 0.6 µg/kg, 0.8 µg/kg, or 1.0 µg/kg, or saline, prior to anesthesia induction. Before the surgery, propofol was administered via target-controlled infusion using a pump with the Marsh model. The EC_{50} of propofol was determined using an up-and-down sequential method with an adjacent concentration gradient of 1.2 to prevent purposeful movements. Hemodynamic parameters and adverse events related to anesthesia were also evaluated. The duration of the procedure and recovery, the amount of propofol required, and the postoperative recovery characteristics were documented.

Results: The EC50 of propofol was significantly lower in the Dex 0.6, Dex 0.8, and Dex 1.0 groups compared to the S group (p<0.05). As the dose of dexmedetomidine increased, the demand for propofol gradually decreased (p<0.01), whereas the incidence of respiratory depression decreased (p<0.01). Nevertheless, the incidence of bradycardia slightly increased (p=0.02). No significant differences in the incidence of hypotension were observed among the five groups (p>0.05). The patients in the Dex1.0 groups had higher postoperative comfort scores than those in the S group. At both t1 and t2, Ramsay scores were higher in the Dex0.8 and Dex1.0 groups than in the S group (p<0.05). No significant differences were observed in the VAS scores among the five groups.

Conclusion: Dexmedetomidine 0.8 µg/kg offers an optimal balance between propofol-sparing effects, sedation quality, and manageable side effects for hysteroscopic surgery.

Trial Registration: Date of registration: 24/05/2020, registration number: ChiCTR2000033220.

Keywords: propofol, EC50, dexmedetomidine, optimal dose, hysteroscopic surgery

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Background

Hysteroscopic surgery is a minimally invasive approach which presents several merits, such as a relatively brief procedure time, minimal surgical stimulation, and swift recovery.[1–3] Currently, the majority of surgical procedures are performed in 24-hour day surgery centers, where patients demonstrate significantly higher expectations regarding postoperative recovery outcomes.[2,4] Therefore, it is very important to choose appropriate anesthesia. Yet, the optimal anesthesia protocol for hysteroscopic surgery remains to be established.

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Neuraxial anesthesia prolongs postoperative lower limb functional recovery, compromising enhanced rehabilitation, while endotracheal intubation anesthesia fails to meet the time-efficiency requirements of day surgery. So, monitored anesthesia care (MAC) with propofol and opioids is commonly employed for hysteroscopic day-surgery procedures. However, propofol, despite having favorable properties like rapid onset, short duration, fast metabolism, and minimal accumulation, can lead to adverse effects. These include hypotension and respiratory depression, especially at higher doses.[5,6] The adverse effects of propofol are dose-dependent, and reducing the dosage of propofol through the use of adjuvant drugs may help to minimize these side effects.

Dexmedetomidine, a novel highly selective alpha-2 adrenergic receptor agonist, has been widely acknowledged as an effective adjuvant in general anesthesia.[7–9] Bingol Tanriverdi et al[10] reported that dexmedetomidine was capable of providing adequate and safe sedation in hysteroscopic surgery, and was associated with superior analgesia compared to propofol. However, high dose of dexmedetomidine has been demonstrated to be closely associated with hypotension and bradycardia.[11] Several studies demonstrated that the combined use of dexmedetomidine and propofol for sedation was an effective method for suppressing patient movement and reducing the incidence of hypoxemia in hysteroscopic surgery.[12,13]

Now, the dose-relationship between dexmedetomidine and propofol in hysteroscopic surgery remains unclear, and the optimal doses of dexmedetomidine combined with propofol for this procedure are undetermined. To investigate this relationship and determine the most effective dexmedetomidine dosage, we administered varying doses of dexmedetomidine as an adjunct to propofol for sedation and subsequently calculated and compared the EC50 (median effective concentration) of propofol. We hypothesized that higher doses of dexmedetomidine would require lower doses of propofol.

Materials and Methods

This study complied with the reporting guidelines outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement and the ethical principles detailed in the Declaration of Helsinki. It received approval from the Ethics Committee of the Affiliated Hospital of North Sichuan Medical College (2020ER080-1) and was registered with the Chinese Clinical Trial Registry on May 24, 2020 (http://www.chictr.org.cn/). The assigned registration number for this study is ChiCTR2003320.

Before study enrollment, written informed consent forms were obtained from all patients. Participants with an American Society of Anesthesiologists (ASA) status of I to II, an age range of 18 to 60 years, and who were scheduled for hysteroscopic surgery from June 2020 to November 2020 were included in this study. Exclusion criteria included patients exhibiting allergies to the test medication, those possessing cardiac conditions such as arrhythmia, bradycardia, atrioventricular block, ischemic heart disease, severe hypertension, heart failure, liver or kidney disease, obstructive sleep apnea syndrome (OSAS), or evidence of chronic illicit drug use.

Patients were randomly allocated to one of five groups, each group of patients receiving a loading dose of dexmedetomidine: 0.4 μg/kg (Dex0.4 group, n=30), 0.6 μg/kg (Dex0.6 group, n=30), 0.8 μg/kg (Dex0.8 group, n=30), 1.0 μg/kg (Dex1.0 group, n=30), or an equal volume of 0.9% saline (S group, n=30). The SPSS software was employed for this randomization process. Patients were ordered based on their surgical sequence and assigned codes from 1 to 150. Following this, random numbers were assigned to each patient and were reorder. The patients were then grouped according to these random numbers order.

When a patient arrived in the operating room, the anesthetist nurse began preparing the test drug, based on the allocation determined via the SPSS software. The nurse then administered the drug into the infusion pump and established a target-controlled concentration of propofol. To minimize potential bias in drug allocation, the nurse concealed the numerical values displayed on the pump's screen. The same anesthetist, who was blind to the treatment allocation, sedated each patient. Importantly, this anesthetist did not participate in patient monitoring or data collection. This approach ensured that both patients and anesthetists remained uninformed about the treatment allocation, thereby maintaining the integrity of the study.

All patients were required to abstain from solid foods for 8 hours and from fluids for 4 hours prior to surgery, and were given phenobarbital sodium 0.1g and N-Butylscopolammonium Bromide 20mg 30 minutes before the procedure began. Upon patient arrival, non-invasive blood pressure, oxygen saturation, and electrocardiogram were continuously monitored, and intravenous access was established in the upper limb. Subsequently, all patients were administered a continuous infusion of lactated Ringer's solution at a rate of 10 mL/kg/h and given lower-flow supplemental oxygen (4 L/min) via a face mask. Before surgery, patients were administered either 0.9% saline or dexmedetomidine which was diluted to a concentration of 4μg/mL for a period of 10 minutes. This was followed by an administration of fentanyl at a dosage of 1.0 μg/kg. The initial target concentration of propofol was set at 3.0μg/mL. Using the Marsh model for target-controlled infusion, propofol was then administered until the end of the surgical procedure.

The surgical procedure commenced once the propofol concentration in the effect chamber and plasma had achieved equilibrium, and the patient exhibited no eyelash reflex. Any purposeful movements of the head or limbs during hysteroscopic surgery were categorized as "responsive". If a patient was deemed "responsive", the target propofol concentration for the subsequent patient would be increased by a factor of 1.2. Additionally, a bolus of propofol at a dosage of 0.5 mg/kg would be administered intravenously as needed until the end of the procedure. Conversely, if the patient remained unresponsive, a lower concentration of propofol would be used for the next patient. Upon completion of the procedure, propofol administration was discontinued. Patients were then transferred to the post-anesthesia care unit (PACU) for continuous monitoring until they regained full consciousness. Patients who achieved a modified Aldrete score exceeding 9 were considered ready for discharge from the PACU.

Hypotension was defined when the Mean Arterial Pressure (MAP) fell below 60 mmHg or decreased by more than 30% from the baseline value. Patients exhibiting hypotension received a treatment of 6 mg ephedrine. Alternatively, respiratory depression, defined as an oxygen saturation (SpO_2) level under 90% or apnea lasting over 15 seconds, was addressed through assisted ventilation. Bradycardia, defined as a heart rate (HR) less than 50 beats per minute, was managed with a 0.5 mg dose of atropine. The dosages of ephedrine and atropine were documented.

Measurements

The concentration of propofol TCI infusion in patients and their response to surgical stimulation were documented. Adverse effects, including hypotension, instances of respiratory depression, and bradycardia were also documented. Moreover, the length of the operation, the recovery time post-anesthesia (defined as the period from discontinuing the propofol infusion until the patient regained consciousness), and the duration of stay in the Post Anesthesia Care Unit (PACU) were documented. To assess comfort levels 30 minutes post-surgery, the Bruggemann Comfort Scale (BCS) was utilized. The Ramsey Scale and Visual Analog Scale (VAS) were used to evaluate sedation levels and pain severity at various intervals: preoperatively (t0), and 30 minutes (t1), 2 hours (t2), 4 hours (t3), and 8 hours (t4) postoperatively.

Statistical Analysis

The up-and-down method was used in our study, which necessitates a sample size of 20–40 patients per group.[12,14] Given that the anticipated incidence of failure at follow-up was roughly 10%, we increased our sample size to 30 cases per group.[14] All data were analyzed using the statistical software SPSS20. Categorical variables were analyzed using either the chi-square (χ^2) test or Fisher's exact test, with all pairwise comparisons undergoing Bonferroni correction. The measurement data, expressed as mean and standard deviation, were evaluated using ANOVA. This was followed by one-way ANOVA with Bonferroni correction and post hoc Bonferroni multiple comparison tests, which helped identify differences in vital signs across the five groups. For data that was not normally distributed, the *U*-test with adjusted p values was applied. Probability-regression analysis was applied to calculate the EC50 of propofol. Statistical significance was set at the $p<0.05$ level.

Results

Following the screening of 178 patients, 150 patients who met the inclusion criteria were enrolled in the study, as illustrated in Figure 1. The baseline characteristics, operative time, and length of PACU stay were outlined in Table 1. No significant differences were observed in the baseline characteristics and operative time and time of PACU stay ($p>0.05$).

The target concentration of propofol required for each patient and their response to hysteroscopic surgery stimulation were depicted in Figure 2. The logistic probability regression analysis was applied to calculate the EC50 and 95%

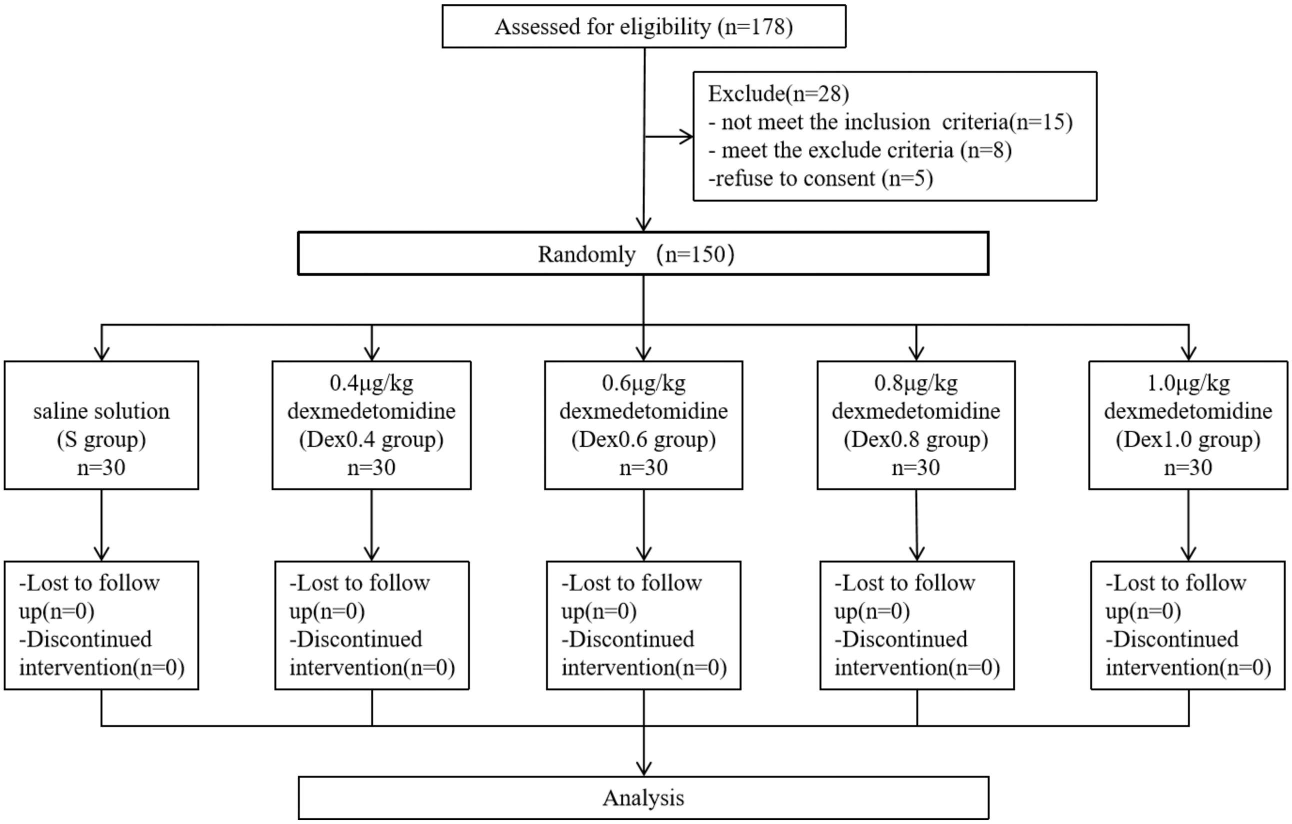

Figure 1 Participant flow diagram.

confidence interval (95% CI) of propofol for each group. The results revealed the following EC50 values for propofol: 3.79 (3.21–4.69) μg/mL in the S group, 3.05 (2.34–3.97) μg/mL in the Dex 0.4 group, 2.90 (1.39–2.8) μg/mL in the Dex 0.6 group, 2.25 (2.08–2.44) μg/mL in the Dex 0.8 group, and 2.09 (1.39–2.80) μg/mL in the Dex 1.0 group. The Dex 0.6, Dex 0.8, and Dex 1.0 groups exhibited a significantly lower EC50 of propofol than the S group ($p<0.05$) (refer to Figure 3).

Comparing propofol dosages, no significant difference emerged between the Dex0.4 group and the S group ($p>0.05$). However, the Dex0.6, Dex0.8, and Dex1.0 groups required significantly less propofol than the S group ($p<0.001$). Additionally, the Dex0.8 and Dex1.0 groups used less propofol than the Dex0.4 group ($p<0.001$). The propofol dosages in the Dex0.6, Dex0.8, and Dex1.0 groups did not significantly differ from each other ($p>0.05$) (refer to Figure 3).

At 30 minutes post-surgery, the Dex1.0 group exhibited significantly higher BCS scores than the S group ($p<0.05$). Notably, the Dex0.6, Dex0.8, and Dex1.0 groups had a significantly prolonged recovery time compared to the S group, with the Dex1.0 group exceeding the Dex0.4 group significantly ($p<0.05$; refer to Table 2).

Table 1 Demographic Data and Patients' Characters

	S Group (n=*30*)	**Dex0.4 Group (n=*30*)**	**Dex0.6 Group (n=*30*)**	**Dex0.8 Group (n=*30*)**	**Dex1.0 Group (n=*30*)**	***p* value**
Age (yrs)	36.0±8.2	36.2±9.4	35.7±8.3	37.5±9.6	36.1±8.5	0.950
Height (cm)	158.9±4.3	157.1±6.7	159.8±6.7	158.7±5.0	159.4±3.6	0.284
Weight (kg)	54.8±6.2	55.6±6.8	55.3±7.1	56.6±6.9	54.8±5.1	0.811
ASA status (I/II)	8/22	8/22	10/20	9/21	9/21	0.978

Note: Data presented as mean±SD or n.

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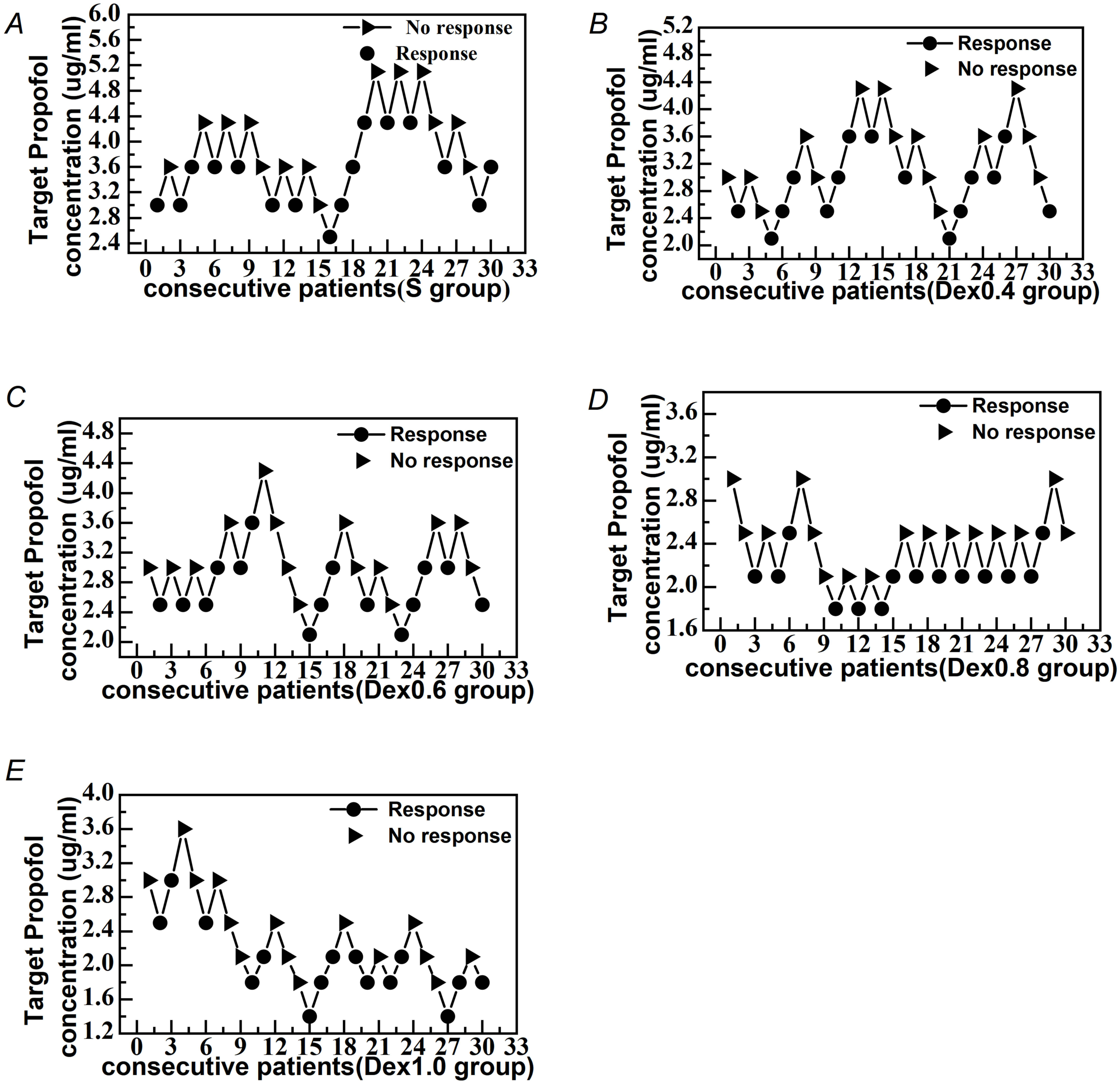

Figure 2 Target propofol concentration in S group (**A**), Dex0.4 group (**B**), Dex0.6 group (**C**), Dex0.8 group (**D**) and Dex1.0 group (**E**). The responses shown were determined using the modified Dixon up and down method.

The incidences of incidences were as follows: 33% in the S group, 30% in the Dex0.4 group, 26.7% in both the Dex0.6 and Dex0.8 groups, and 20% in the Dex1.0 group. No significant differences were observed among the groups concerning hypotension incidence and ephedrine dosage. Respiratory depression incidences were 53.3%, 46.4%, 33.3%, 13.3%, and 10.0% in the S, Dex0.6, Dex0.8, and Dex1.0 groups, respectively (χ^2=21.333, p<0.001). For respiratory depression, the Dex0.8 (χ^2=10.8, p=0.002) and Dex1.0 (χ^2=13.01, p=0.001) groups had significantly lower incidences than the S group, and the Dex1.0 group was significantly lower than the Dex0.4 group (χ^2=9.9, p=0.003). Bradycardia treatment was required for one patient each in the S, Dex0.4, and Dex0.6 groups, five in the Dex0.8 group, and seven in the Dex1.0 group (χ^2=10.164, p=0.02). However, no significant differences were found among the groups after pairwise comparisons (refer to Table 3).

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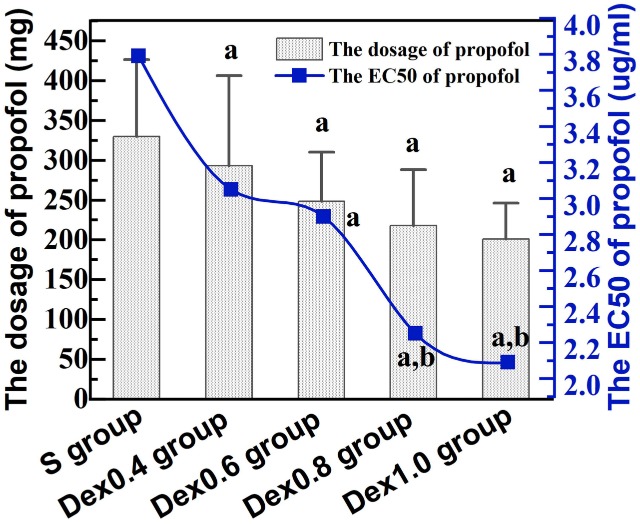

Figure 3 The EC50 and dosage of propofol in group S group, Dex0.4 group, Dex0.6 group, Dex0.8 group, and Dex1.0 group respectively; a p< 0.05 vs the S group, b p< 0.05 vs the Dex0.4 group.

Within each group, Ramsay scores at t1 exceeded those at t0 (p<0.001), while the Dex0.6, Dex0.8, and Dex1.0 groups had higher scores at t2 than at t0 (p<0.05). Between groups, Ramsay scores at t0 were similar (p>0.05). However, patients' Ramsay scores at t1 and t2 in the Dex0.8 and Dex1.0 groups were higher than in the S group (p<0.05), and scores at t1 were higher in the Dex1.0 group than in the Dex0.4 and Dex0.6 groups (p<0.05) (refer to Figure 4).

At 30 minutes post-surgery, three patients in the S group and one in the Dex0.6 group required analgesics. Despite this, there was no significant difference in VAS scores among the groups (p>0.05). However, VAS scores significantly dropped at t3 and t4 compared to t1 (refer to Figure 5).

Table 2 The Duration of the Operation, the Length of Stay in the PACU, the Recovery Time, and BCS Score of the Patients

	S Group (n=*30*)	Dex0.4 Group (n=*30*)	Dex0.6 Group (n=*30*)	Dex0.8 Group (n=*30*)	Dex1.0 Group (n=*30*)	*p* value
Operation time (min)	19.4±8.4	19.8±9.8	19.3±7.2	20.6±11.2	19.5±7.7	0.978
Duration of PACU* (min)	41.9±10.9	43.8±11.2	42.6±9.7	38.6±9.8	37.6±11.2	0.117
Recovery time (min)	5(2)	5(3)	7(3) ^{a}	7(4) ^{a}	8 (4) ^{ab}	<0.001
BCS$^{\#}$ score	2.4±1.2	2.8±0.9	3.0±1.1	3.1±1.0	3.2±0.9 ^{a}	0.034

Notes: Data presented as median (*IQR*: inter quartile range) or mean±SD,* post anesthesia care unit,$^{\#}$ Bruggemann comfort scale. ^{a} *p*<0.05 vs S group; ^{b} *p*<0.05 vs Dex 0.4 group.

Table 3 The Side Effect and the Dose of Vasoactive Drugs

	S Group (n=*30*)	Dex0.4 Group (n=*30*)	Dex0.6 Group (n=*30*)	Dex0.8 Group (n=*30*)	Dex1.0 Group (n=*30*)	*p value*
Adverse effects						
Hypotension, n (%)	10(33.3)	9(30.0)	8(26.7)	8(26.7)	6(20.0)	0.85
Bradycardia, n (%)	1(3.3)	1(3.3)	1(3.3)	5(16.7)	7(23.3)	0.02
Respiratory depression, n (%)	16(53.3)	14(46.4)	10(33.3)	4(13.3) ^{a}	3(10.0) ^{ab}	<0.001
Vasoactive drugs						
Ephedrine (mg)	3.2±5.1	3.0±4.6	2.2±3.8	1.8±3.2	1.2±2.4	0.51
Atropine (mg)	0(0)	0(0)	0(0)	0(0)	0 (0.12)	0.03

Notes: Data presented as n(%) or median(*IQR*), ^{a} *p*<0.05 vs S group; ^{b} *p*<0.05 vs Dex 0.4 group.

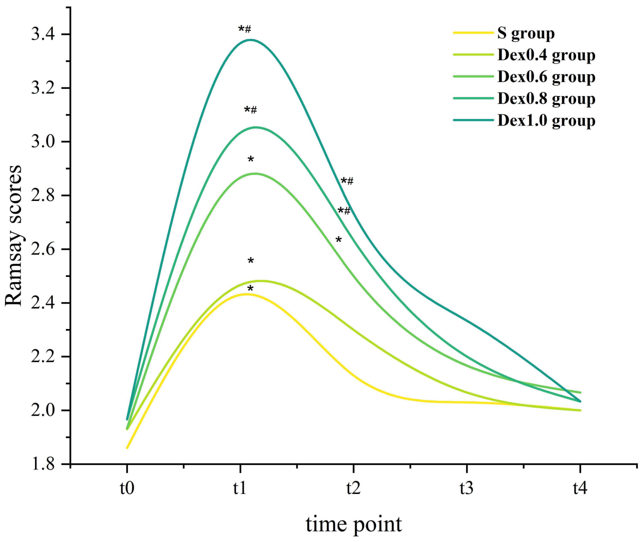

Figure 4 The Ramsay score after surgery. *p<0.05 vs t0, $^{\#}$p<0.05 compared to the S group; t0: preoperatively, t1:30 minutes postoperatively, t2: 2 hours postoperatively, t3:4 hours postoperatively, and t4:8 hours postoperatively.

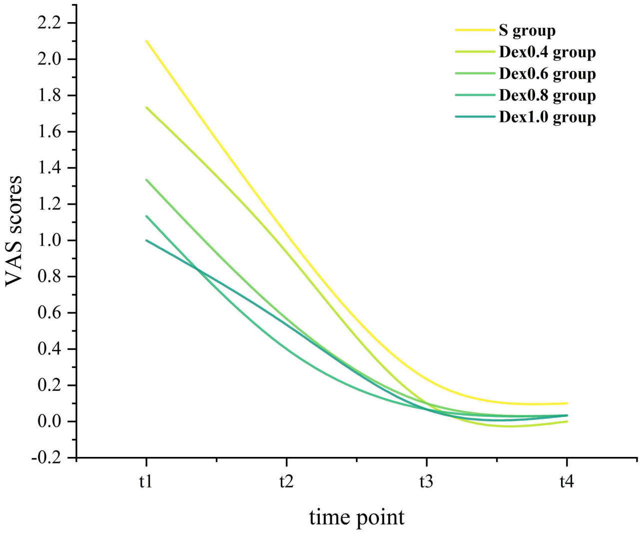

Figure 5 The VAS score after surgery, t1: 30 minutes postoperatively, t2: 2 hours postoperatively, t3:4 hours postoperatively, and t4:8 hours postoperatively.

Discussion

Our study demonstrated that dexmedetomidine significantly reduced the EC50 of propofol in a dose-dependent manner during hysteroscopic surgery while mitigating respiratory depression and enhancing recovery quality. However, the synergistic effect plateaued at higher doses, accompanied by increased risks of bradycardia and recovery delay.

Our results demonstrated that different loading doses of dexmedetomidine (0.4, 0.6, 0.8, and 1.0 μg/kg) significantly reduced the EC50 of propofol by 19%, 23%, 40%, and 44%, respectively, with corresponding decreases in propofol dosage (10%, 24%, 33%, and 38%). These findings align with those presented by Zhao et al,[15] who reported that a dexmedetomidine loading dose markedly lowered propofol's EC50 before anesthesia induction. Moreover, the findings of Li H's study demonstrated that dexmedetomidine doses of 0.75 μg/kg and 0.5 μg/kg significantly reduced the required propofol dosage in patients undergoing hysteroscopic submucosal myomectomy.[16] These results suggest that a synergistic pharmacological interaction exists between dexmedetomidine and propofol. Notably, no statistically significant differences were observed in either EC50 values or propofol requirements between the Dex0.8 and Dex1.0 groups, suggesting the existence of a ceiling effect for dexmedetomidine's propofol-sparing action.

Additionally, higher dexmedetomidine doses were associated with a lower incidence of respiratory depression (defined as apnea >15 seconds or SpO_2 <90%). This aligns with Makoto et al,[17] who observed reduced respiratory depression in children undergoing MRI with dexmedetomidine-propofol coadministration. Moreover, a study[18] observed a significant decrease in the incidence of respiratory depression in patients receiving 0.5μg/kg dexmedetomidine combined with propofol compared to those who received propofol alone during hysteroscopic surgery. The reduction may stem from dexmedetomidine's dose-dependent decrease in propofol requirements, as propofol alone can induce respiratory depression via loss of airway tone, reduced respiratory rate, and diminished tidal volume.[6,17,19] Importantly, dexmedetomidine itself does not suppress respiratory drive,[7] making it a valuable adjunct for minimizing propofol-related respiratory compromise.

While dexmedetomidine improved respiratory outcomes, its effects on hemodynamic stability were less pronounced. Propofol typically induces hypotension by reducing sympathetic activity and vascular tone.[5,6,20] Although prior studies suggest dexmedetomidine enhances hemodynamic stability,[21] we observed no significant intergroup differences in hypotension incidence, despite reduced propofol demands in dexmedetomidine groups. This implies that dexmedetomidine's hypotensive effects, mediated via central α-2A receptor activation, sympathetic suppression, and vasodilation,[22] may offset the benefits of lower propofol doses.

In the postoperative period, higher dexmedetomidine doses correlated with elevated Ramsay sedation scores, peaking at 30 minutes post-surgery before gradually declining. No patient exceeded a Ramsay score of 5, confirming enhanced sedation without deep sedation. Appropriate sedation plays a crucial role in alleviating anxiety, mitigating discomfort from unnecessary movement, enhancing overall comfort, and maintaining hemodynamic stability in the postoperative period. Furthermore, 1.0 µg/kg dexmedetomidine significantly improved BCS scores at 30 minutes postoperatively, likely due to its NREM sleep-like sedation, analgesic properties, and reduced opioid-related side effects.[23,24] We utilized the Visual Analogue Scale (VAS) to evaluate pain, with the results revealing no significant disparities among the five groups. This finding is indicative of the mild pain experienced post-hysteroscopic surgery, comparable to menstrual cramps.

However, dexmedetomidine significantly impacted heart rates. Dexmedetomidine significantly reduced heart rates, with higher doses (0.8–1.0 µg/kg) increasing bradycardia incidence and atropine requirements. Although Dex0.6-Dex1.0 groups had longer recovery times than the saline group, PACU stay duration remained comparable. The findings from the study by Li H et al[16] indicated that a dexmedetomidine dose of 0.75 µg/kg may lead to delayed recovery, and significant reductions in heart rate and blood pressure. Consequently, they recommended using a 0.5 µg/kg dose of dexmedetomidine in combination with propofol. However, it should be noted that their study employed laryngeal mask general anesthesia, whereas our research utilizes MAC technique, necessitating particular attention to respiratory depression risks. Additionally, the average heart rate in above study remained above 60 bpm, the study did not report that the patients received 0.75 µg/kg dexmedetomidine need atropine to correct bradycardia. Moreover, we found that their mean recovery time was significantly longer than in our study, likely attributable to the higher doses of opioids used and the continuous infusion of dexmedetomidine during surgery, both of which can prolong the time of recovery. Given these findings, we recommend not exceeding 0.8 µg/kg dexmedetomidine for hysteroscopic surgery, with close hemodynamic monitoring.

Our study also presents some limitations. Firstly, Bispectral Index (BIS) monitoring was unavailable due to financial constraints; however, no cases of intraoperative awareness occurred, as confirmed by postoperative interviews with each patient. Secondly, the Dixon-Massey sequential method limited sample size, necessitating larger trials to confirm dexmedetomidine's benefits.

Conclusion

In conclusion, dexmedetomidine effectively reduces propofol requirements and improves sedation quality in hysteroscopic surgery, with doses 0.8 µg/kg showing the most benefit. However, higher doses (>0.8 µg/kg) should be used cautiously due to prolonged recovery and bradycardia risk. Dexmedetomidine 0.8 µg/kg may represent the optimal balance between efficacy and safety in this setting.

Abbreviations

EC50, Median effective concentration; ASA, American society of Anesthesiologists; BCS, Bruggemann comfort scales; OSAS, obstructive sleep apnea syndrome; PACU, post anesthesia care unit; HR, heart rate; MAP, mean arterial pressure; TCI, target-controlled infusion; MAC, Monitored anesthesia care; 95% Cl, 95% confidence interval.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate

This study complied with the reporting guidelines outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement and the ethical principles detailed in the Declaration of Helsinki. It received approval from the Ethics Committee of the Affiliated Hospital of North Sichuan Medical College (2020ER080-1) and was registered with the Chinese Clinical Trial Registry on May 24, 2020 (http://www.chictr.org.cn/). The assigned registration number for this study is ChiCTR2003320.

Before study enrollment, written informed consent forms were obtained from all patients. Patients satisfying the following inclusion criteria were enrolled in the study: American Society of Anesthesiologists (ASA) status I to II, age ranging from 18 to 60 years, and those scheduled for hysteroscopic surgery.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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