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Research Article

Comparison of Ciprofol-nalbuphine and Propofol-nalbuphine Sedation During Painless Abortion: A Randomized Controlled Trial

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Abstract

Objective: Despite the widespread use of propofol for painless abortion, it is frequently associated with cardiopulmonary adverse events. Ciprofol, a novel intravenous anesthetic agent, demonstrates a more favorable respiratory and hemodynamic stability profile. The aims of this study were to evaluate the efficacy and safety of ciprofol-nalbuphine combination in mitigating cardiopulmonary complications and enhancing recovery following painless abortion procedures. Methods: A total of 120 patients scheduled for elective painless abortion, aged 18-39 years, ASA physical status I or II, were selected. They were randomly divided into a Propofol-Nalbuphine group (PN group, n = 60) and a Ciprofol-Nalbuphine group (CN group, n = 60) using a random number table. Anesthesia was induced by intravenous injection of nalbuphine 0.1 mg/kg, followed 3 minutes later by intravenous injection of propofol (2 mg/kg, PN group) or ciprofol (0.4 mg/kg, CN group). Anesthesia was maintained by continuous intravenous infusion of propofol or ciprofol. The incidence of cardiopulmonary adverse reactions (respiratory depression, hypotension, bradycardia), changes in heart rate (HR), mean arterial pressure (MAP), and pulse oxygen saturation (SpO_2) at different time points were observed. Additionally, drug dosage, induction time, operative time, recovery time, injection pain, postoperative uterine contraction pain, and surgeon satisfaction were compared between the two groups. Results: Compared with PN, CN demonstrated a lower incidence of cardiopulmonary adverse reactions (15% vs. 40%, $P < 0.05$) and shorter recovery time (2.8 ± 1.8 vs. 1.9 ± 0.8 min, $P < 0.05$). The CN group also had reduced injection pain (3.3% vs. 16.6%) and intraoperative body movement (10% vs. 20%) (both $P < 0.05$). Surgeons reported higher satisfaction scores with CN (8.9 ± 1.0 vs. 8.0 ± 1.0, $P < 0.001$). MAP decreased after induction in both groups, with no intergroup difference ($P > 0.05$). Anesthesia induction time, operative time, and postoperative uterine contraction pain did not differ significantly between groups ($P > 0.05$). Conclusion: Intravenous anesthesia using ciprofol 0.4 mg/kg combined with nalbuphine 0.1 mg/kg is safe and effective for painless abortion. It offers advantages such as fewer cardiopulmonary adverse events, faster recovery, and less injection pain, making it worthy of clinical application and promotion.

Keywords

Ciprofol, Nalbuphine, Propofol, Abortion

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1. Introduction

Surgical abortion is a widely utilized medical intervention for terminating pregnancies in their early stages. Due to the pain and emotional distress typically involved, many patients choose to undergo the procedure with pain management options [1]. As a result, there is a strong demand for anesthetic agents that must offer rapid onset, adequate sedation, superior analgesia, brief recovery, and few side effects. Propofol is commonly used for anesthesia in painless abortion procedures due to its advantages of rapid onset, quick metabolism, and high clearance rate [2]. However, its adverse effects such as respiratory depression, hypotension, and injection pain have attracted widespread clinical attention [3]. Ciprofol (HSK3486) is a novel 2, 6-disubstituted phenolic derivative. Based on the structural framework of propofol, the addition of a cyclopropyl group enhances its binding affinity to the γ-aminobutyric acid type A (GABA-A) receptor [4, 5], thereby inducing sedative and anesthetic effects in the central nervous system [6]. Although the pharmacokinetic characteristics of ciprofol are comparable to those of propofol, studies have shown that the incidence of adverse events such as respiratory depression, hypotension, and injection pain is significantly lower with ciprofol than with propofol [7]. Nalbuphine, as a μ-receptor antagonist and κ-receptor agonist, offers advantages such as effective visceral pain suppression and a lower incidence of postoperative nausea and vomiting (PONV) compared to other opioids [8].

Based on its unique pharmacological properties, the synthetic opioid nalbuphine represents a promising analgesic choice for painless abortion procedures [9]. While clinical trials and meta-analyses have indicated that ciprofol is associated with lower rates of respiratory depression, hypotension, and injection pain compared to propofol in the context of painless gastrointestinal endoscopy [3, 6], it remains uncertain whether combining nalbuphine with ciprofol confers a clear benefit over its combination with propofol for painless abortion, due to the absence of relevant comparative studies. Therefore, we conducted a trial to compare the effects of nalbuphine combined with either propofol or ciprofol for anesthesia in painless abortion, aiming to inform clinical anesthetic selection. We postulated that the combination of ciprofol and nalbuphine could potentially improve procedural safety and expedite recovery after abortion. Although the safety of ciprofol as a single agent in gastroscopy and colonoscopy has been documented [10], there is a scarcity of high-quality clinical data on the efficacy and safety of the ciprofol-nalbuphine combination for sedation in abortion. To investigate this, we performed a head-to-head comparison between ciprofol and propofol for moderate sedation during abortion, with a focus on cardiopulmonary complications and recovery parameters.

2. Material and Methods

Design and patients

This single-center, randomized, controlled clinical trial was conducted at the Wuxi Huishan District People's Hospital, Jiangsu Province, China. This study was approved by the Ethics Committee of Huishan District People's Hospital in Wuxi (Approval No: HYLL (YJ)-2025003). The study was performed in full compliance with the ethical standards set forth by the Declaration of Helsinki (1975 revision). Written informed consent was a mandatory requirement for all participants before the commencement of any study-related procedures.

The study enrolled 120 patients who were scheduled for elective painless abortion, aged 18-39 years. Using a random number table, participants were allocated to either the PN group (n = 60) or the CN group (n = 60). Eligibility requirements consisted of: American Society of Anesthesiologists (ASA) physical status class I-II, respiratory rate 12-18 breaths/min, heart rate 50-100 beats/min, systolic blood pressure (SBP) 90-180 mmHg, diastolic blood pressure (DBP) 60-100 mmHg, and room-air SpO_2 above 95%. Exclusion criteria were: known hypersensitivity to propofol, ciprofol, or nalbuphine; anticipated difficult airway; significant psychiatric illness or emotional instability; compromised cardiopulmonary function (e.g., severe hypertension, myocardial ischemia, heart failure, second-degree atrioventricular block, or severe chronic obstructive pulmonary disease); hepatic or renal impairment; and any other condition considered clinically unsuitable for inclusion by the investigators.

Anesthesia Management

The randomization was performed in a 1:1 ratio using a computer-generated sequence, assigning patients to either the ciprofol or propofol group, with no stratification applied. Allocation concealment was ensured through sequentially numbered, sealed opaque envelopes. Upon opening the envelope, the assigned anesthetic agent was administered by the attending anesthesiologist according to a predetermined sedation protocol designed to maintain patient safety. In the operating room, patients were placed in the lithotomy position. Standard monitoring was established, including non-invasive blood pressure, electrocardiogram, and SpO_2. Prior to the procedure, all patients received supplemental oxygen at 3 L/min via nasal cannula, which continued until full recovery of consciousness following the procedure.

Prior to study drug administration, all patients received a bolus of 0.1 mg/kg nalbuphine (Nalbuphine Hydrochloride Injection, 10 mg/2 ml; Yangtze River Pharmaceutical Industry Co., Ltd., China) intravenously over 15 seconds. Following this, patients were randomized to receive an initial induction dose of either 0.4 mg/kg ciprofol or 2.0 mg/kg propofol (both from HaiSiKe, Liaoning, China). The anesthesiologist administered the induction agent intravenously over 30 seconds. Sedation depth was monitored with the Modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale [11]. Abortion commenced once adequate sedation was attained, defined

as an MOAA/S score of ≤ 3. Throughout the procedure, MOAA/S scores were recorded at two-minute intervals. If body movements were observed, maintenance sedation was provided as bolus supplements: 0.1 mg/kg ciprofol in the ciprofol group or 0.5 mg/kg propofol in the propofol group. A desaturation event was defined as a decrease in SpO_2 below 90% lasting more than 10 seconds, prompting immediate airway interventions such as jaw thrust or bag-mask ventilation. If hypoxemia persisted or oxygen saturation failed to improve, manual ventilation was instituted. Pharmacological support with atropine, ephedrine, and/or inotropes was administered in response to hypotension (SBP < 90 mmHg) or bradycardia (HR < 50 beats per minute). Hemodynamic deviations were defined as follows: hypotension and hypertension were respectively defined as a decrease or increase of ≥ 20% in either MAP or SBP relative to baseline values. Bradycardia was defined as a HR ≤50 beats per minute. Hypoxemia was characterized by a SpO_2 below 90% lasting for more than 10 seconds. Following the painless abortion procedure, patients were monitored continuously in the post-anesthesia care unit (PACU). The Aldrete score [12] was recorded at two-minute intervals, and transfer from the PACU to the observation area was permitted after three consecutive readings of ≥ 9 were obtained. Eligibility for final discharge was determined using the Modified Post-Anesthesia Discharge Scoring System (MPADSS), with a score of 10 required across five domains: vital signs, ambulation, nausea/vomiting, pain, and intraoperative bleeding [13].

Outcome Measures

The primary endpoint was the incidence of cardiopulmonary adverse events, which included hypotension, bradycardia, and hypoxemia. The secondary endpoints included the time of induction, surgical duration, time to awakening; total dosage of ciprofol, propofol, and nalbuphine; incidence of injection pain, dreaming, uterine pain; and operator satisfaction.

Calculation of sample size

PASS 15.0.5 (NCSS, LLC, Kaysville, USA) was utilized for sample size calculation.

In gynecological surgery, the incidences of anesthesia-related adverse events during general anesthesia induction with propofol and ciprofol were reported as 48.3% and 20.0%, respectively [14]. Using a 1:1 allocation ratio, with a two-sided significance level (α) of 0.05 and a power (1-β) of 0.9, and accounting for an estimated dropout rate of 10%, the calculated sample size required was 120 patients, with 60 participants assigned to each group.

Statistical analysis

Statistical analysis was performed using SPSS version 22.0 (IBM, Armonk, NY, USA). The normality of continuous variables was evaluated with the Shapiro-Wilk test. Normally distributed variables are presented as mean ± standard deviation (SD) and were compared using the independent two-sample t-test. Non-normally distributed variables are summarized as median (range) and were analyzed using the Mann-Whitney U test. Categorical variables are expressed as frequencies and percentages, and were compared using the chi-square (χ^2) test or Fisher's exact test, as appropriate. A two-sided *P*-value of less than 0.05 was defined as statistically significant.

3. Results

3.1. Trial Population and Baseline Characteristics

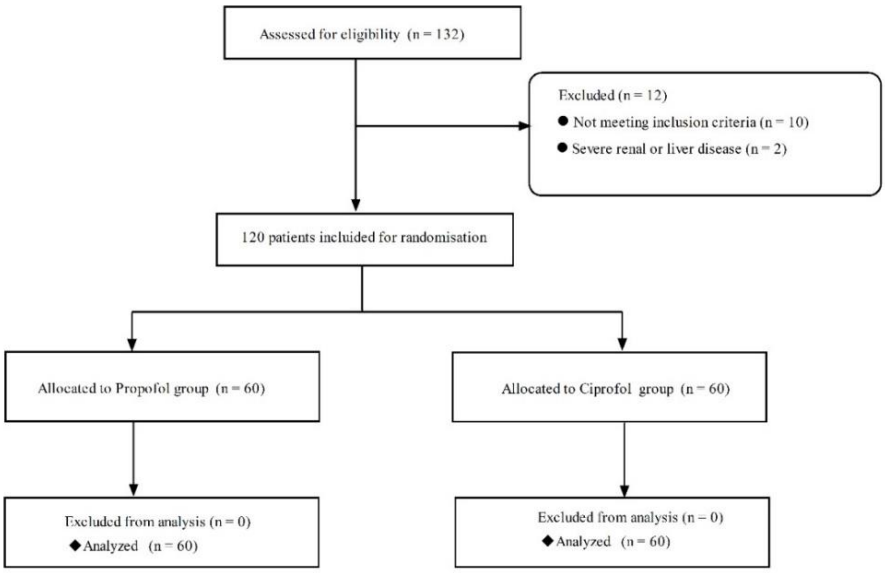

Figure 1. *CONSORT Flow Diagram.*

Between March 2025 and October 2025, a total of 120 patients scheduled for painless abortion at Huishan District People's Hospital, Xinglin College of Nantong University, were assessed for eligibility. After applying the predefined exclusion criteria, eligible participants were enrolled and randomly assigned to receive sedation with either ciprofol or propofol (Figure 1). No statistically significant differences were observed between the two groups in baseline demographic, clinical, or procedural characteristics. ($P > 0.05$) (Table 1).

Table 1. *Patient demographics and baseline values.*

Variable	Group PN (n = 60)	Group CN (n = 60)	χ2/ t	*P*-value
Age (years old)	31.8±5.5	31.7±4.8	0.035	0.972
Height (cm)	160.9± 5.3	160.8±5.8	0.909	0.909
Weight (kg)	57.6±9.2	59.4±8.0	1.169	0.245
BMI (kg/m2)	22.1±3.1	22.9±2.9	1.413	0.160
ASA physical status			0.229	0.632
I grade	55	56		
II grade	5	4		

Note: Data were presented as mean (SD) or n (%), as appropriate; SD = standard deviation.

3.2. Anesthetic Use and Sedation-related Time

Table 2. *Consumption of anesthetics and sedation-related time.*

Variable	Group PN (n = 60)	Group CN (n = 60)	χ2/ t	P-value
Nalbuphine dose (mg)	5.5±0.9	5.7±0.8	0.895	0.372
Sedative-agent dose (mg)				
Induction dose (mg)	108.3±15.3	28.6±4.4		
Total dose (mg)	121.6±25.7	31.6±5.7		
Time				
Induction (Second)	47.8±5.1	49.1±5.4	1.394	0.166
Operation (min)	6.5±1.9	6.9±2.1	1.276	0.205
Recover (min)	2.8±1.8	1.9±0.8	3.503	0.001

There were no statistically significant differences between the two groups in terms of anesthesia induction time, surgical duration, or nalbuphine dosage ($P > 0.05$). However, the recovery time was significantly shorter in the CN group compared to the PN group ($P < 0.05$) (Table 2).

3.3. Primary and Secondary Outcomes

Compared to the PN group, the CN group demonstrated a significant reduction in the incidence of intraoperative cardiopulmonary adverse events and injection pain ($P < 0.05$). Operator satisfaction scores were markedly higher in the CN group than in the PN group ($P < 0.001$). No statistically significant differences were observed between the two groups regarding other perioperative adverse events ($P > 0.05$) (Table 3).

Table 3. *Adverse events.*

Outcomes	Group PN (n = 60)	Group CN (n = 60)	χ2/t	*P*-value
Primary outcome				
Hypotension	13 (21.6%)	3 (5.0%)	5.841	0.016
Bradycardia	9 (15.0%)	5 (8.3%)	1.294	0.255
hypoxemia	2 (3.3%)	1 (1.6%)	0.000	1.000
Total incidence rate	24 (40.0%)	9 (15.0%)	9.404	0.002
Secondary outcome				
Injection pain	10 (16.6%)	2 (3.3%)	4.537	0.033
Body movement	20 (33.3%)	10 (16.6%)	4.444	0.035
Dreaming	22 (36.6%)	18 (30%)	0.600	0.439
Uterine pain	19 (31.6%)	20 (33.3%)	0.038	0.845
Fatigue	2 (3.3%)	3 (5.0%)	0.000	1.000
Gynecologist satisfaction	8.0±1.0	8.9±1.0	4.497	＜0.001

3.4. Hemodynamics

No statistically significant differences were observed between the two groups in MAP, HR, or SpO_2 (Table 4).

Table 4. *Hemodynamics between the two groups.*

Variable		Group PN (n=60)	Group CN (n=60)	t	P-value
MAP (mmHg)	T1	90.4±12.2	90.2±13.1	0.086	0.931
	T2	71.5±11.0	74.8±11.3	1.588	0.115
	T3	82.7±15.7	87.2±16.0	1.561	0.121
	T4	87.5±14.9	91.6±16.2	1.446	0.151
	T5	86.6±13.9	90.5±14.45	1.534	0.128
HR (beats/min)	T1	79.9±9.3	83.5±13.3	1.721	0.088
	T2	72.0±8.1	72.6±10.2	0.336	0.738
	T3	69.2±8.2	70.1±9.1	0.568	0.571
	T4	68.6±8.3	69.9±8.7	0.836	0.405
	T5	71.7±8.1	73.9±8.3	1.503	0.136
SpO_2 (%)	T1	99.4±0.5	99.4±0.5	0.172	0.864
	T2	98.9±0.7	98.8±1.3	0.680	0.498
	T3	98.9±0.9	98.9±0.7	0.492	0.668
	T4	98.9±0.4	98.8±0.7	0.303	0.762
	T5	99.0±0.5	99.1±0.5	0.885	0.378

Note: T1: Before anesthesia induction, T2: After anesthesia induction, T3: During cervical dilation, T4: End of surgery, T5: Upon leaving the recovery room.

4. Discussion

Our study focused on the combination of ciprofol and nalbuphine for painless abortion sedation for the first time. The findings substantiated the protocol's promise, verifying its capacity to reliably produce target sedation, decrease the incidence of respiratory complications, and foster improved hemodynamic stability.

This study confirmed that both ciprofol (0.4 mg/kg) and propofol (2 mg/kg), when used for induction in combination with nalbuphine (0.1 mg/kg) and titrated for maintenance based on MOAA/S scores, were effective in completing the abortion procedure. However, the ciprofol-nalbuphine regimen demonstrated advantages including fewer cardiopulmonary adverse effects, shorter recovery time, and a lower incidence of injection pain. In this study, the incidence of hypotension was 21.6% in the NP group, compared to only 5.0% in the NC group, indicating that ciprofol exhibits better efficacy in reducing cardiopulmonary adverse effects, which is consistent with previous studies [11, 15]. It demonstrated that propofol-nalbuphine sedation for Endoscopic retrograde cholangiopancreatography significantly reduced respiratory depression and procedural interruption compared with propofol-fentanyl, likely attributable to the unique pharmacodynamics of nalbuphine [16]. In a randomized, double-blind colonoscopy trial, a ciprofol dose of 0.4-0.5 mg/kg provided comparable sedative efficacy to 2.0 mg/kg of propofol, with no statistically significant differences in safety outcomes between the two groups [17]. Compared to ciprofol, propofol was associated with a higher incidence of hypotension during induction due to its sympatholytic effects [18]. The findings of this study also indicated a higher intraoperative hypotension rate in the NP group than in the NC group, although the difference was not statistically significant. A possible explanation for this observation is that intravenous administration of nalbuphine prior to general anesthesia induction reduced the required induction dose of propofol. The occurrence of anesthesia-related hypotension and sinus bradycardia may be linked to the GABA-ergic modulatory mechanism of propofol within the autonomic nuclei of the brainstem, which exerts inhibitory effects on both chronotropic regulation and vasomotor tone maintenance [19].

It has been reported in the literature that propofol was associated with a relatively high incidence of injection pain, reaching up to 52.4% [7]. In the present study, however, the incidence was only 16.6%, which may be attributed to the analgesic effect provided by the preemptive intravenous administration of nalbuphine. Meanwhile, the lower concentration (1%) of the lipid emulsion in ciprofol contributes to its increased hydrophobicity, which is another factor explaining its reduced incidence of injection pain [20]. Lower incidence of injection pain with ciprofol administration was theorized to correlate with heightened patient satisfaction scores. Previous studies have shown that in anesthesia for painless gastrointestinal endoscopy using nalbuphine combined with propofol, the ED50 and ED95 of nalbuphine are 0.078 mg/kg and 0.162 mg/kg, respectively [21]. Given that the duration and surgical stimulation during painless abortion were typically shorter and less intense than those during painless gastrointestinal endoscopy, the dosage of nalbuphine was set at 0.1 mg/kg in this study. This study found an induction time of approximately 50 seconds with 0.4 mg/kg ciprofol, which is notably shorter than the 63.4-second onset time reported by Gao et al [11]. This difference may be related to the preemptive administration of nalbuphine. The satisfaction of surgeon primarily depends on the patient's intraoperative cooperation (absence of involuntary movements) and an efficient workflow (short recovery time and expedited turnover). In this study, the incidence of intraoperative body movement reactions in the PN group was twice that in the CN group, which explains why the satisfaction level among obstetricians and gynecologists was lower in the PN group compared to the CN group. The results of this investigation found that the incidence of dreaming was 36.6% in the PN group and 30% in the CN group, a difference that was not statistically significant and consistent with the findings of Zhou et al [22]. Consequently, it cannot be inferred that dreaming leads to higher patient satisfaction, as intraoperative dreams are influenced by multiple factors including the type of anesthetic agent, depth of anesthesia, age, gender, and preoperative psychological state [23].

The limitations of this study include: (1) The exclusion of obese individuals, combined with a relatively young cohort, likely contributed to a lower observed incidence of upper airway obstruction; (2) Routine blood glucose monitoring was not performed before the abortion procedure, as hypoglycemia can also lead to hypotension; (3) Conducted at a single center, this study had inherent limitations regarding the external validity of its conclusions; (4) The adverse effects of sedative medications after discharge were not systematically evaluated.

Abbreviations

ASA	American Society of Anesthesiologists
BMI	Body Mass Index
DBP	Diastolic Blood Pressure
HR	Heart Rate
MAP	Mean Arterial Pressure
MOAA/S	Modified Observer's Assessment of Alertness/Sedation
PACU	Post-Anesthesia Care Unit
PONV	Postoperative Nausea and Vomiting
SpO_2	Pulse Oxygen Saturation
SBP	Systolic Blood Pressure

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Data Availability Statement

All original data will be available when contact the correspondence author by email.

Conflicts of Interest

The authors declare that they have no competing interests.

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