

Inhalation of low-dose desflurane prevents the hemodynamic instability caused by target-controlled infusion of remifentanil and propofol during laparoscopic gynecological surgery: A randomized controlled trial

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Abstract. The objective of the present study was to determine whether the addition of inhaled desflurane is superior to remifentanil-propofol total intravenous anesthesia (TIVA) alone in patients undergoing laparoscopic gynecological surgery. A total of 60 patients who were scheduled to undergo laparoscopic gynecological surgery were prospectively enrolled and randomly allocated to receive either propofol-remifentanil (PR group; n=30) or combined propofol-remifentanil and low-dose desflurane (PRD group; n=30) for the maintenance of anesthesia. Hemodynamics [mean arterial pressure (MAP); heart rate (HR)], recovery parameters and complications were recorded. The results of the present study indicated that the addition of desflurane significantly reduced the amount of propofol and remifentanil that was administered in the PRD group, compared with that in the PR group. MAP and HR were significantly higher at T3 (5 min post-pneumoperitoneum), but significantly lower at T4 (removal of pneumoperitoneum needle) and T5 (post-operation immediately) in the PR group, compared with the PRD group. Moreover, MAP and HR were significantly altered at multiple time points within the PR group; however, they were relatively stable in the PRD group. There were no significant differences in the recovery parameters and complications between the two groups. In conclusion, combining low-dose desflurane with PR may represent an efficient anesthesia regimen to prevent the hemodynamic instability of TIVA in patients undergoing laparoscopic gynecological surgery.

Introduction

Laparoscopic surgery is a widely recommended procedure for excision of gynecological lesions, such as a cyst or cancer of the ovary or the uterine, owing to lower postoperative pain, a better aesthetic result and earlier discharge and recovery compared with laparotomy (1). Laparoscopic surgery is usually performed under general anesthesia, and a target-controlled intravenous infusion of propofol-remifentanil (PR) is the most common anesthetic regimen administered during laparoscopic gynecological surgery (2,3). Previous studies have suggested that this combination allows rapid onset and recovery from anesthesia, and reduces the incidence of complications, such as postoperative nausea and vomiting (PONV), pain, agitation or other various adverse sequelae, thereby improving the quality of recovery (4-6). However, cardiovascular depression and hemodynamic instability, which are potentially fatal, have been reported to develop during the induction of anesthesia (7,8). Therefore, additional anesthetic agents that do not result in cardiovascular depression and hemodynamic instability may be required to be combined with PR.

In addition to intravenous anesthesia, inhaled anesthetics are also another commonly used approach in clinical practice (9). It has been reported that inhaled anesthetics regulate the hemodynamic response of the patients and resulted in muscle relaxation (10). However, inhaled anesthetics have also been indicated to exhibit certain disadvantages, such as prolonged recovery time after surgery and a higher incidence of postoperative agitation, which lessen patient satisfaction (11). Therefore, researchers have been making efforts to identify novel inhaled anesthetics. Desflurane is a novel fluorine halogenated methyl ether and is categorized as an inhaled anesthetic. The blood gas solubility of desflurane is only 0.49, which is lower compared with that of other inhaled anesthetics (such as isoflurane, 1.27; sevoflurane, 0.62; halothane, 2.46) (12), and therefore, allows for a fast alveolar equilibration of desflurane and exhibits rapid onset/recovery characteristics (13-15). Accordingly, we hypothesized that supplementary inhalation of desflurane may not only prevent the adverse effects of cardiovascular depression and hemodynamic instability, but also may not influence the anesthetizing effects of the PR regimen, which has not yet

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been investigated in laparoscopic gynecological surgery, to the best of our knowledge (16).

The purpose of the present study was to determine whether the combination of inhaled desflurane is superior to PR total intravenous anesthesia alone in patients undergoing laparoscopic gynecological surgery, especially with regard to the effects on the hemodynamic stability.

Materials and methods

Patients. The present study was approved by the Ethics Committee of the Second Hospital of Jilin University (Changchun, China; approval no. 2018-010) and registered in the Chinese Clinical Trial Register (trial registration no. ChiCTR1800015017; <http://www.chictr.org.cn/index.aspx>). The objective and methods of the present study were explained to all patients, and written informed consent was obtained. All protocols were performed in accordance with the principles of the Declaration of Helsinki.

A total of 60 adult female patients (median age, 41 years) who were scheduled to undergo laparoscopic gynecological surgery at the Second Hospital of Jilin University (Changchun, China) were enrolled between January 2018 and June 2018. All patients had to meet the following inclusion criteria: i) aged between 18 and 60 years; ii) classified as American Society of Anesthesiologists (ASA) physical status I and II (17); iii) exhibit no heart, lung or brain diseases; iv) exhibit no history of diabetes and hypertension; v) present normal liver and kidney function, electrolytes, blood routine and coagulation test results preoperatively; and vi) present no abnormality in the electrocardiogram and chest X-ray. Patients who exhibited a history of: i) alcohol and/or drug abuse; ii) cardiovascular diseases with cardiovascular agents used and New York Heart Association classification as III or IV (18); iii) bradyarrhythmia (sinus bradycardia, left bundle branch block or third-degree atrioventricular block); iv) abnormal liver and kidney function; and v) allergy to any of the study drugs, were excluded from the present study.

Patients were randomly allocated via a computer-based random distribution to receive either PR or combined PR and desflurane (PRD) for the maintenance of anesthesia.

Anesthetic protocol. Upon arrival to the surgical room, all patients routinely received two-lead electrocardiography, peripheral oximetry, capnography, non-invasive blood pressure and bispectral index (BIS) monitoring. Following pre-oxygenation for 3 min, midazolam at 0.05 mg/kg, fentanyl at 4 μ g/kg, etomidate at 0.3 mg/kg and cisatracurium at 0.15 mg/kg were administered to the patients for the induction of anesthesia. Anesthesia was maintained by an intravenous infusion of propofol and remifentanyl, which were designed to achieve a target effect-site concentration of 2 mg/ml and 4 ng/ml, respectively, via a target-controlled infusion system (Orchestra® Base Primea; Fresenius Vial S.A.S.). Following endotracheal intubation, the patients in the PRD group received inhalation of desflurane at an oxygen flow rate of 2 l/min and an expired end-tidal concentration of 3%.

During the surgery, the concentrations of propofol and remifentanyl were titrated to maintain the mean arterial blood pressure (MAP) within 20% of the baseline values. When

MAP was continuously >10% of the baseline values for 1 min and BIS was >60, the concentration of propofol and remifentanyl was increased by 0.5 μ g/kg and 0.5 ng/ml, respectively; if BIS was 40-60, only the concentration of remifentanyl was increased by 0.5 ng/ml. When MAP was continuously <10% of the baseline values for 1 min and BIS was <40, the concentration of propofol and remifentanyl was decreased by 0.5 μ g/kg and 0.5 ng/ml, respectively; if BIS was 40-60, only the concentration of remifentanyl was decreased by 0.5 ng/ml. When MAP was <20% of the baseline values, ephedrine at 10 mg was administered. If the patient's heart rate (HR) was decreased to <45 beats per minute (BPM), atropine (0.5 mg) was administered.

Postoperatively, the oxygen flow rate of desflurane was adjusted to 6 l/min to promote the removal of desflurane, followed by the removal of the laparoscopic instruments, the suture and the termination of propofol infusion. Atropine (0.01 mg/kg) and neostigmine (0.02 mg/kg) were administered to counteract the cisatracurium-induced neuromuscular block, while flumazenil (0.5 mg) was administered for antagonism of the residual sedative effects of midazolam. No patients received naloxone for awakening. Patients were extubated when the following conditions were met: i) stable autonomic respiratory rhythm; ii) tidal volume >6 ml/kg; iii) peripheral capillary oxygen saturation >95% for 5 min; iv) patient end-tidal carbon dioxide <45 mmHg; and v) recovery of protective reflex and ability to open their eyes on verbal commands, followed by transfer from the operating room to the staffed post-anesthesia care unit. When modified Aldrete Recovery Score was ≥ 9 (19), the patients were discharged to the ward.

Measurement. Hemodynamics, including MAP and HR, were measured upon arrival to the surgical room (T0), immediately at intubation (T1), immediately at operation initiation (T2), 5 min post-pneumoperitoneum (T3), at removal of pneumoperitoneum needle (T4), immediately at post-operation (T5), immediately at extubation (T6), following extubation for 5 min (T7) and 10 min (T8).

Records were made on intraoperative intake, estimated blood loss, intraoperative urine output, consumption of remifentanyl and propofol and the time of operation, anesthesia, eye-opening on verbal commands, extubation, orientation recovery and achievement of a modified Aldrete recovery score (19) ≥ 9 .

Observer's Assessment of Alertness and Sedation (OAA/S) score was assessed preoperatively and postoperatively to predict the sedation status, which was rated on a 5-point scale as follows: 5, alert; 4, lethargic; 3, awakened by voice; 2, awakened by shaking; and 1, deep sleep (20). The Sedation-agitation scale (SAS) was evaluated at T6 and T8 to predict the agitation status, which was rated on a 7-point scale, with a ≥ 5 score diagnosed as emergence agitation (21). Postoperative pain was assessed using the visual analogue scale [VAS; range, 0-10 (0 represents no pain and 10 represents the worst imaginable pain)] (22) at T8 and 1 h after the operation. VAS >4 indicated the occurrence of postoperative pain. Intravenous fentanyl (0.1 mg) was the first-line rescue analgesic, and pethidine (50 mg) was used as the second-line rescue analgesic on demand. All scores were assessed by the same anesthesiologists in a blinded fashion to the grouping of the trial.

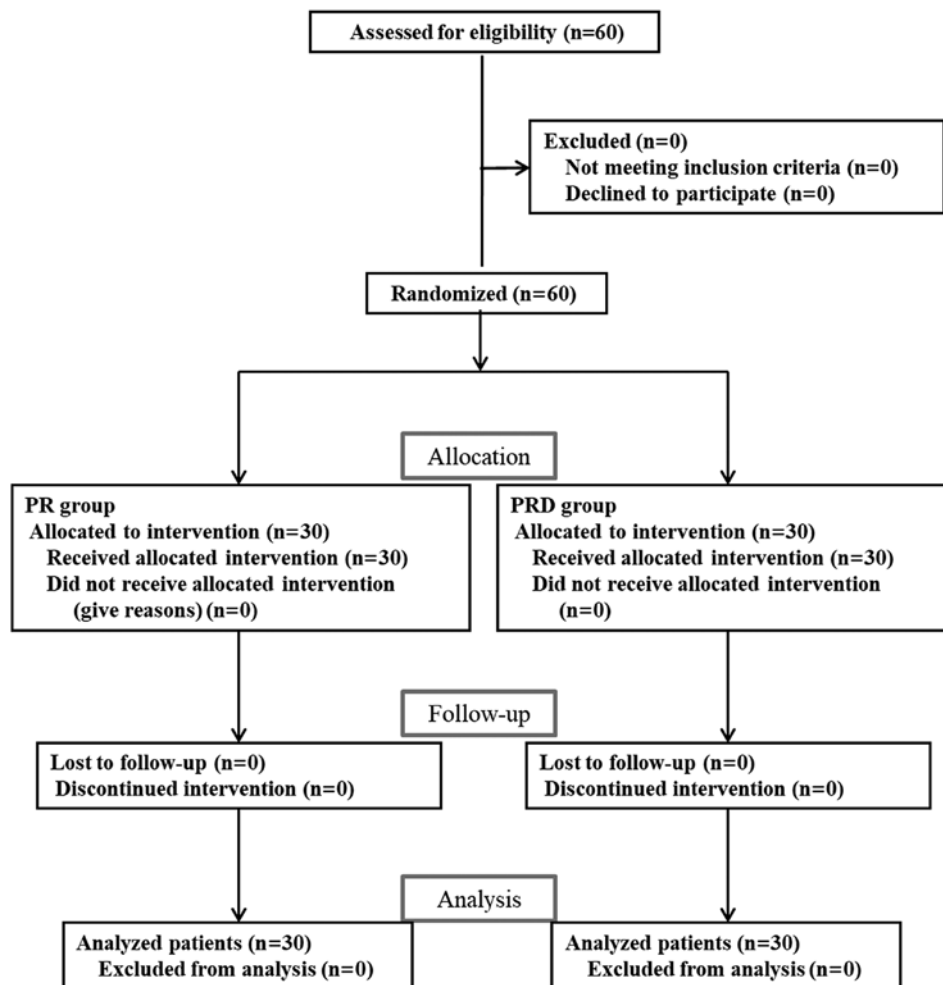


Figure 1. Flow diagram of the present study.

Postoperative nausea was defined as a subjectively unpleasant sensation associated with an awareness of the urge to vomit, whereas an episode of vomiting was defined as vomiting (forceful expulsion of gastric contents from the mouth) and retching (spasmodic, labored and rhythmic contractions of the respiratory muscles without expulsion of gastric contents). When the patients either vomited or retched, 0.3 mg ramosetron was injected intravenously as a rescue treatment, if treatment was requested. In addition, other postoperative complications, including respiratory depression, shivering and bradycardia, were also recorded.

Statistical analysis. The sample size was calculated using GraphPad InStat version 3.0 software (GraphPad Software, Inc.). The calculation revealed that 27 subjects per group were required to achieve a power of 90% with a type I error of 0.05. To allow for a dropout rate of up to 10%, 30 subjects were designed to be enrolled in each group. Categorical data are presented as number (%) and are compared between groups using χ^2 test or Fisher's exact test. Non-Gaussian continuous data are presented as the median (minimum-maximum) and are compared between groups using the Mann-Whitney U test. Normally distributed continuous data are presented as the mean \pm SD and are compared between groups using two-sample independent Student's t-test. A mixed-design repeated

measures ANOVA followed by Bonferroni's multiple comparisons test was used to compare MAP and HR within (different time points) and between PR and PRD groups. $P < 0.05$ was considered to indicate a statistically significant difference. Statistical analysis was performed using SPSS v23.0 software (IBM Corp.).

Results

Study population. Between January 2018 and June 2018, 60 patients were enrolled in the present study, and no dropout occurred. These 60 patients were subsequently randomly allocated to receive PR or combined PRD for the maintenance of anesthesia, with 30 patients in each group (Fig. 1). No significant differences were observed between the two groups with regard to the patients' demographics, including age, body weight, ASA classification and the cause of the laparoscopic gynecological surgery, indicating that both groups were comparable (Table I).

Impact on perioperative characteristics. Surgery and anesthesia were uneventful in all patients. The perioperative characteristics were also recorded and compared. The results indicated no significant differences were observed in the intra-operative intake, estimated blood loss, intra-operative urine

Table I. Demographic data of the population of the present study.

Variables	PR group (n=30)	PRD group (n=30)	P-value
Mean age \pm SD, years	41.46 \pm 10.97	38.87 \pm 9.63	0.333
Mean weight \pm SD, kg	62.23 \pm 7.34	59.80 \pm 5.00	0.139
Median height (minimum-maximum), cm	160 (151-170)	160 (155-169)	0.834
ASA physical status, n (%)			0.756
I	6 (20.0)	7 (23.3)	
II	24 (80.0)	23 (76.7)	
Type of surgery, n (%)			0.873
Ovarian cystectomy	6 (20.0)	7 (23.3)	
Hysterectomy	9 (30.0)	10 (33.3)	
Myomectomy	15 (50.0)	13 (43.3)	

PR, propofol-remifentanyl; PRD, PR and low-dose desflurane; ASA, American Society of Anesthesiologists.

Table II. Patients' perioperative characteristics.

Variables	PR group (n=30)	PRD group (n=30)	P-value
Intra-operative intake, ml	500 (300-800)	500 (300-800)	0.515
Estimated blood loss, ml	100 (50-300)	55 (50-300)	0.271
Intra-operative urine output, ml	100 (50-280)	90 (50-350)	0.847
Operation time, min	70 (50-150)	65 (40-169)	0.853
Anesthesia time, min	99 (65-165)	85 (75-185)	0.911
Consumption of anesthetics			
Cisatracurium, mg	14 (12-35)	12.5 (12-25)	0.242
Remifentanyl, mg	1.56 (0.96-4.36)	0.90 (0.20-2.88)	<0.001
Propofol, mg	358.33 \pm 100.18	212.33 \pm 62.85	<0.001

Non-Gaussian continuous data are presented as the median (minimum-maximum); normally distributed continuous data are presented as the mean \pm SD. PR, propofol-remifentanyl; PRD, PR and low-dose desflurane.

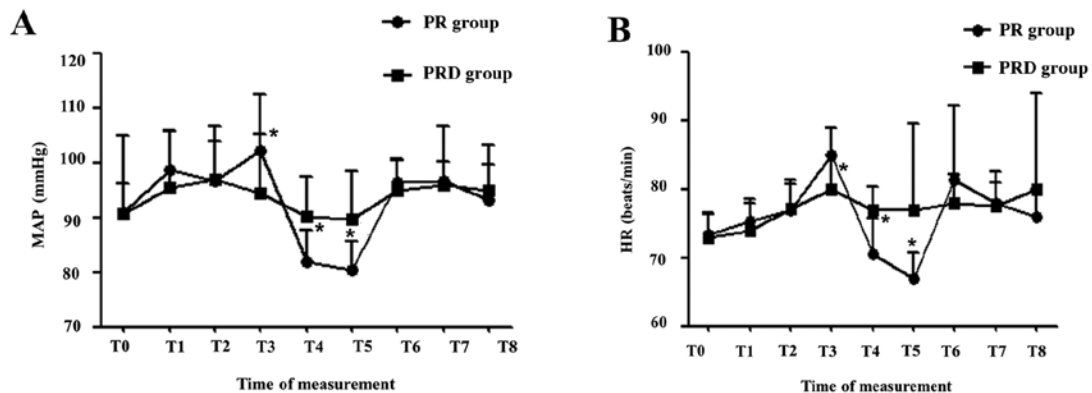


Figure 2. Hemodynamic responses to various stimuli during the perioperative period. (A) MAP. (B) HR. T0, upon arrival to the surgical room; T1, immediately at intubation; T2, immediately at operation initiation; T3, 5 min post-pneumoperitoneum; T4, removal of pneumoperitoneum needle; T5, immediately post-operation; T6, immediately at extubation; T7, 5 min following extubation; T8, 10 min following extubation. *P<0.05 vs. PRD group. PR, propofol-remifentanyl; PRD, PR and low-dose desflurane; MAP, mean arterial blood pressure, HR, heart rate.

output, operation time and anesthesia time between the two groups, but the addition of desflurane significantly decreased

the consumption of propofol and remifentanyl (Table II), indicating that the incidence of PR-induced complications, such

Table III. Hemodynamic alterations at different points for each group.

Hemodynamic parameter	Time point	PR group (n=30)	PRD group (n=30)
MAP	T0	91.00±5.09	90.73±14.32
	T1	98.63±6.99 ^a	95.47±10.49
	T2	96.60±7.34	96.93±9.71
	T3	102.10±10.24 ^{a,c}	94.33±10.92
	T4	82.03±5.58 ^{a-d}	90.17±7.25 ^c
	T5	80.50±5.05 ^{a-d}	89.77±8.59 ^c
	T6	96.50±3.98 ^{a,e,f}	95.00±5.63
	T7	96.60±10.05 ^{e,f}	95.97±4.20 ^{e,f}
HR	T0	73.30±3.03	73.00±3.55
	T1	75.30±3.17 ^a	74.00±3.91
	T2	77.00±4.39 ^a	77.23±3.46 ^{a,b}
	T3	85.03±3.96 ^{a-c}	80.00±4.91 ^{a,b}
	T4	70.63±5.12 ^{b-d}	77.00±3.35 ^a
	T5	67.00±3.80 ^{a-d}	76.87±12.67
	T6	81.33±10.75 ^{a,e,f}	78.00±4.18 ^a
	T7	78.00±4.56 ^{a,d,f}	77.57±3.41 ^a
	T8	76.00±3.85 ^{d-f}	79.87±14.12

T0, upon arrival to the surgical room; T1, immediately at intubation; T2, immediately at operation initiation; T3, 5 min post-pneumoperitoneum; T4, removal of pneumoperitoneum needle; T5, immediately post-operation; T6, immediately at extubation; T7, 5 min following extubation; T8, 10 min following extubation. ^aP<0.05 vs. T0; ^bP<0.05 vs. T1; ^cP<0.05 vs. T2; ^dP<0.05 vs. T3; ^eP<0.05 vs. T4; ^fP<0.05 vs. T5; ^gP<0.05 vs. T7. MAP, mean arterial blood pressure; HR, heart rate; PR, propofol-remifentanyl; PRD, PR and low-dose desflurane.

as hemodynamic instability, may be reduced. This hypothesis was verified by the measurement of MAP and HR, which indicated that both MAP (Fig. 2A) and HR (Fig. 2B) were significantly higher at T3, but significantly lower at T4 and T5 in the PR group compared with the PRD group. In addition, within the PRD group, the MAP and HR were generally stable, with significant alterations only between a few time points (Table III). By contrast, significant differences in MAP and HR were observed at multiple time points within the PR group (Table III).

Impact on postoperative outcomes. Furthermore, postoperative recovery parameters and adverse events were also recorded and are presented in Tables IV and V. The results indicated that the two groups were comparable in eye-opening time, extubation time, orientation recovery time, time to achieve Aldrete score ≥ 9 , OAA/S score and SAS score (Table IV). No significant difference was observed in the number of patients who experienced complications, including bradycardia, hypotension, agitation, PONV, nausea, vomiting and pain, between the two groups. The number of patients requiring rescue anti-

emetic and postsurgical analgesia also did not differ between the two groups (Table V).

Discussion

Intravenously infused propofol and inhaled desflurane are two commonly used anesthetics that can be combined with the ultra-short-acting μ -opioid receptor agonist remifentanyl for the induction and maintenance of anesthesia during surgery. However, which combination is optimal remains unclear, and may be attributed to certain disadvantages of each anesthetic (23-27). For example, Cho *et al* (23) reported that tissue oxygen saturation was higher in the desflurane group compared with that in the propofol group at 30 and 60 min of ventilation. The recovery slope during the vascular occlusion test, reflecting microvascular reperfusion adequacy, was also higher in the desflurane compared with that in the propofol group during surgery (23). Mahli *et al* (24) reported that the general mean values of MAP and HR for the PR group were higher compared with that of the desflurane-remifentanyl group (89.3 mmHg and 72.4 BPM vs. 77.1 mmHg and 69.5 BPM, respectively). These findings indicated that desflurane-remifentanyl anesthesia may be associated with an improved microcirculation and hemodynamic stability compared with PR anesthesia (24). Yoo *et al* (6) demonstrated that the incidence of nausea in the post-anesthetic care unit (22.6 vs. 6.5%; P=0.001) and at 1-6 h postoperatively (54.8 vs. 16.1%; P=0.001) was significantly higher in the desflurane-remifentanyl compared with that in the PR group. Zaballos *et al* (25) reported that the desflurane-remifentanyl group received an increased amount of fentanyl as rescue analgesia compared with the PR group (200±65 vs. 113±38 μ g). Gritti *et al* (26) and Gozdemir *et al* (27) demonstrated that the recovery times for spontaneous ventilation, extubation, time to awakening, eye opening and ability to provide name and date of birth were shorter in the PR group compared with those in the desflurane group. These results suggested that PR may be more effective for recovery and associated with a decreased number of complications. Moreover, the concentration of each anesthetic was higher when only propofol or desflurane was used, resulting in non-negligible adverse outcomes (such as unstable hemodynamic responses and PONV) in the clinic (28). Therefore, we hypothesized that a combination of three drugs (desflurane, propofol and remifentanyl) in lower doses may prevent their respective shortcomings and achieve improved anesthetizing effects. Although a previous study has recommended the supplementation of intravenous anesthesia with desflurane, it has not compared the effects of PR and PRD, but only compared the PRD with the desflurane group (16). Therefore, this is the first time, to the best of our knowledge, that a study compared the anesthetizing effects of a combination of lower-dose desflurane with PR. The results of the present study indicated that the PRD group not only exhibited a similar recovery potential and complications (such as low PONV) to the PR group, but also maintained stable hemodynamics. Although three drugs were used, the combined cost may be similar for the patients, as the dose of PR was significantly decreased in the PRD compared with the PR group, and the price of propofol and desflurane has been reported to be similar (29,30).

Table IV. Post-anesthesia recovery parameters.

Variables	PR group (n=30)	PRD group (n=30)	P-value
Eye-opening time, min	7.00±1.97	7.40±1.61	0.392
Extubation time, min	10.00±2.44	10.70±2.32	0.259
Orientation recovery time, min	12.43±2.18	13.47±2.32	0.080
Time to achieve Aldrete score ≥9, min	15.97±2.55	16.53±2.54	0.393
OAA/S, n (5/4)			0.401
Preoperatively	30/0	30/0	
1 h post-operation	30/0	29/1	
SAS, n (0-4/5-7)			0.492
Extubation	30/0	28/2	
10 min after extubation	30/0	30/0	

PR, propofol-remifentanyl; PRD, PR and low-dose desflurane; OAA/S, Observer's Assessment of Alertness and Sedation; SAS, sedation-agitation scale.

Table V. Incidence of postoperative adverse reactions.

Variables	PR group (n=30)	PRD group (n=30)	P-value
Hypotension, n (%)	2 (6.7)	0 (0)	0.492
Bradycardia, n (%)	5 (16.7)	2 (6.7)	0.424
Agitation, n (%)	0 (0.0)	2 (6.7)	0.492
PONV, n (%)	1 (3.3)	1 (3.3)	1.000
Nausea, n (none/mild/moderate/severe)	29/1/0/0	29/1/0/0	1.000
Vomiting, n (%)	0 (0.0)	0 (0.0)	1.000
Rescue antiemetic, n (%)	0 (0.0)	0 (0.0)	
VAS, n (0-3/4-6/7-10)			
10 min after extubation	30/0/0	30/0/0	1.000
1 h post-operation	27/3/0	22/8/0	0.098
Pain, n (%)	3 (10.0)	8 (26.7)	0.095
Postsurgical analgesia, n (%)			
None	27 (90.0)	22 (73.3)	0.098
Fentanyl	3 (10.0)	8 (26.7)	
Fentanyl + pethidine	0 (0.0)	0 (0.0)	

PR, propofol-remifentanyl; PRD, PR and low-dose desflurane; PONV, postoperative nausea and vomiting; VAS, visual analogue scale.

Several limitations to the present study exist. Firstly, although the power analysis indicated that the number of patients who were required in the present study was sufficient, the population size was relatively small and this was a single-center study. This may be an underlying reason explaining statistically non-significant differences in postoperative adverse reactions between the PRD and PR groups and the lower PONV observed (1/30 patients, 3.3%) compared with previous reports (20-50%) (4,31,32). Secondly, the enrolled patients were relatively young and whether the conclusion is similar in an older population requires further validation. Thirdly, a desflurane-remifentanyl control group should have been included. Fourthly, only one kind of surgery, such as ovarian cystectomy, should be included in future trials, in

order to more easily control the operation and anesthesia time and reduce its influence on the postoperative pain. For example, the fact that the incidence of pain was relatively higher in the PRD compared with that in the PR group may be attributed to the increased number of patients (3/8) who underwent myomectomy among the patients with pain. Fifthly, a cost analysis with the use of the three agents was not a part of the present study. Finally, more outcomes, including the incidence of intraoperative awareness and body movement, and mechanism parameters, such as alterations in the stress response (catecholamines, noradrenaline, adrenaline, adrenocorticotropic hormone and cortisol) or inflammation factors (interleukin-6, tumor necrosis factor- α , C-reactive protein and nitric oxide) (33,34) should be recorded to comprehensively

assess the anesthetizing effects of lower-dose desflurane combined with PR.

The present study suggested that combining low-dose desflurane with PR may represent an efficient anesthesia regimen to prevent the hemodynamic instability of total intravenous anesthesia for patients undergoing laparoscopic gynecological surgery.

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Availability of data and materials

All data generated or analyzed during the present study are included in this published article.

Authors' contributions

PZ and XS participated in the conception and design of the study. PZ and YC collected the data and performed the statistical analysis. LS was involved in the interpretation of the data. PZ drafted the manuscript. XS revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The present study was approved by the Ethics Committee of the Second Hospital of Jilin University (Changchun, China; approval no. 2018-010) and written informed consent was obtained from all patients.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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