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Original Research

Comparison between use of fentanyl and rocuronium on outpatient undergoing ultra-short duration gynecologic surgery: a randomized, double-blind, controlled trial

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Abstract

Background: There has been a steady increase in outpatient-based ultra-short duration gynecology surgeries. However, there are no detailed studies on anesthesia regimens for these surgeries. The aim of this study was to compare the effects of low-dose rocuronium and fentanyl single bolus for their suitability with these patients. **Methods**: A total of 60 patients were randomly divided into three groups: a control group (group C, n = 20) that received 3 mL of normal saline; a fentanyl group (group F, n = 19) that received 1 mcg/kg of fentanyl; and a low-dose rocuronium group (group R, n = 20) that received 0.3 mg/kg of rocuronium. We collected hemodynamic data during anesthetic induction and the intraoperative period. We also investigated supraglottic airway (SGA) insertion condition, patient's gross movements, and surgeon's satisfaction. In addition, we evaluated the incidence of postoperative nausea and vomiting, pruritus, first voiding time and discharge time from the postanesthetic care unit. **Results**: Systolic, diastolic, and mean blood pressure were significantly lower in group F after SGA insertion ($p = 0.031$, $p = 0.046$ and $p = 0.048$). SGA insertion conditions scores were significantly worse in group C than in group F and group R for total score ($p < 0.001$). Also, the number of patient movements during surgery and the number of rescue fentanyl injections were significantly higher in group C than group F and group R ($p = 0.005$ and $p < 0.001$). **Conclusion**: Fentanyl administration at 1 mcg/kg has advantages compared with rocuronium and is a more suitable single agent regimen for outpatient-based ultra-short duration gynecology surgeries.

Keywords: Ambulatory anesthesia; Fentanyl; Gynecology surgery; Rocuronium

1. Introduction

Recently, the number of gynecology procedures and surgeries performed in a hospital-based ambulatory setting has been on the rise, and the proportion is increasing [1,2]. Treating these procedures on an outpatient basis is often appropriate as they are relatively non-invasive and of short duration. Additionally, gynecology procedures and surgeries can have less bleeding, less hemodynamic changes and they are mostly performed in healthy outpatients. While many procedures are simple and ultra-short in duration, they can be painful and may require stable positioning (e.g., lithotomy position). Therefore, gynecology procedures and surgeries are regularly performed under locoregional anesthesia or general anesthesia. However, local anesthesia or nerve block as the only anesthetic technique may not be sufficient for laparoscopic or hysteroscopic surgery. In addition, spinal anesthesia or epidural anesthesia (depending on the agents used) may require a prolonged recovery time before patients are ambulatory, making it difficult for them to be discharged on the day of surgery. Therefore, gynecology procedures and surgeries are preferentially performed under general anesthesia with endotracheal intubation or with a supraglottic airway (SGA) device. In this setting the appropriate choice of anesthetic drugs is therefore important: to control perioperative pain effectively, to facilitate airway management, and to enable rapid recovery and discharge after surgery. Anesthesia in this setting should also address pain sensitivity in this population [3] and the high risk of postoperative nausea and vomiting (PONV) [4].

There have been a number of studies examining the effects of neuromuscular blockers or opioids to find appropriate drugs for outpatient surgery. Rocuronium is a suitable neuromuscular blocker for outpatient anesthesia because of its relatively fast onset and short duration of action. In particular, it improves not only endotracheal intubation procedures but also surgical conditions [5,6]. One disadvantage of rocuronium is the possibility of residual paralysis, although this risk has been largely mitigated by the availability of sugammadex [7]. Intravenous fentanyl assists with intubation and surgery, and facilitates postoperative pain management [8]. However, fentanyl can increase the incidence of PONV, decrease respiration drive,

and cause pruritus. As a result, patient discharge could be delayed after ambulatory surgery [9] or furthermore, hospital readmission might be required.

For outpatients undergoing ultra-short duration gynecology surgery, appropriate drugs and dosages will improve patient outcomes and the surgeon's experience. However, there has never been a study in which neuromuscular blockers and opioids are compared in these patients. Therefore, the aim of this study was to look for an optimal drug regimen by comparing the effects of low-dose rocuronium with fentanyl single bolus on hemodynamic changes, SGA insertion conditions, surgeon's satisfaction, and patient's recovery in outpatients undergoing ultra-short duration gynecology surgeries.

2. Materials and methods

2.1 Patients and randomization

We enrolled female outpatients aged 20 to 65 years, with American Society of Anesthesiologists (ASA) physical status 1 or 2, who were scheduled for ultra-short obstetrics and gynecology surgery. Exclusion criteria were as follows: underweight (BMI $<$18.0 kg/m^2) or overweight (BMI $>$30.0 kg/m^2); ASA physical status 3 or 4; pregnancy; neuromuscular, hepatic or renal disease; being on a medication that influences neuromuscular blockade; history of any allergy to any study drug.

A total of 60 eligible patients were randomly allocated to 3 groups using a computer-generated list (http://www.randomization.com). The control group (group C) was given normal saline 3 mL, the fentanyl group (group F) was given 1 mcg/kg of fentanyl mixed in 3 mL normal saline and the low-dose rocuronium group (group R) was given 0.3 mg/kg of rocuronium mixed in 3 mL normal saline. An anesthesiologist, who was not involved in the clinical care of the patients, prepared the study drugs according to the randomization list.

2.2 Anesthesia

Patients arrived at the operating room without premedication and underwent standard monitoring, including electrocardiography, noninvasive blood pressure measurements, and pulse oximetry. Depth of anesthesia was monitored using a bispectral index score (BIS, an A-2000 BISTM monitor; Aspect Medical Systems Inc., Natick, MA) monitor. After achieving stable baseline hemodynamic data, which included systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), and heart rate (HR), anesthesia was induced in all patients with 2 mg/kg of propofol and maintained with 2–3 vol% sevoflurane to maintain a BIS index of 40–60. The lung was mechanically ventilated and ventilation was controlled to maintain an end-tidal carbon dioxide tension of 30–35 mmHg. Patient temperature was checked via esophageal temperature probe and was maintained at greater than 35 °C.

2.3 Intervention and data collection

After loss of consciousness, each group received the assigned study medication; the control group (group C) was given normal saline 3 mL; the fentanyl group (group F) was given 1 mcg/kg of fentanyl mixed in 3 mL normal saline; the low-dose rocuronium group (group R) was given 0.3 mg/kg of rocuronium mixed in 3 mL normal saline. I-gel® (Intersurgical, Wokingham, UK) as an SGA was inserted by two blinded and skilled anesthesiologists. SBP, DBP, MBP, and HR were recorded before and after SGA insertion. To evaluate the insertion condition, the anesthesiologist recorded whether or not there were gross movements during insertion, and if there was movement, it was recorded according to the cough, jaw relaxation, and limb movement tables using the Viby-Mogensen intubation scoring system [10].

Immediately after the operation started, SBP, DBP, MBP, and HR were recorded. When patient's gross movements were observed during surgery, we recorded the movement, and fentanyl (0.5 mcg/kg) as a rescue drug was administered. When the surgical procedure was completed, we scored the surgeon's satisfaction with the operating conditions as 1, extremely satisfied; 2, satisfied; 3, not satisfied but able to manage; and 4, extremely dissatisfied according to Vinod Bishnoi's scoring system [11]. In addition, the anesthesiologist injected 50 mcg/kg of neostigmine with 10 mcg/kg of glycopyrrolate to group R to reverse the effects of the rocuronium muscle relaxant and 4 mL of normal saline in group C and group F as soon as possible as the patient emerged from anesthesia. I-gel® were extubated in the operating room after confirming verbal obey.

In the postanesthetic care unit, we assessed the incidence and severity of PONV, and pruritis at 30 minutes postoperatively and again at discharge. In addition, we evaluated first voiding time and time interval before patient discharge. We recorded PONV severity using a three-point scale: 1, no PONV; 2, nausea but no vomiting; 3, nausea and vomiting. We recorded pruritus severity using a four-point scale: 1, absent; 2, mild (not troubling the patient); 3, moderate (not disturbing the patient and not requiring treatment); 4, severe (often disturbing the patient and requiring treatment).

2.4 Sample size calculation and statistical analysis

The primary outcome was the mean blood pressure during SGA insertion. Sample size calculation was based on a previous study in which the MBP during SGA insertion after administration of 2.5 mg/kg of propofol was 70 $\pm$ 6.5 mmHg [12]. We considered that with co-administration of rocuronium or fentanyl, a reduction of mean blood pressure by 10% would be statistically significant. Thus, we calculated that 20 patients would be needed in each group, using a two-sided test with 80% power and a two-sided 5% α-error, allowing for 20% dropouts. The statistical values provided in the analysis are either mean $\pm$ standard deviation or num-

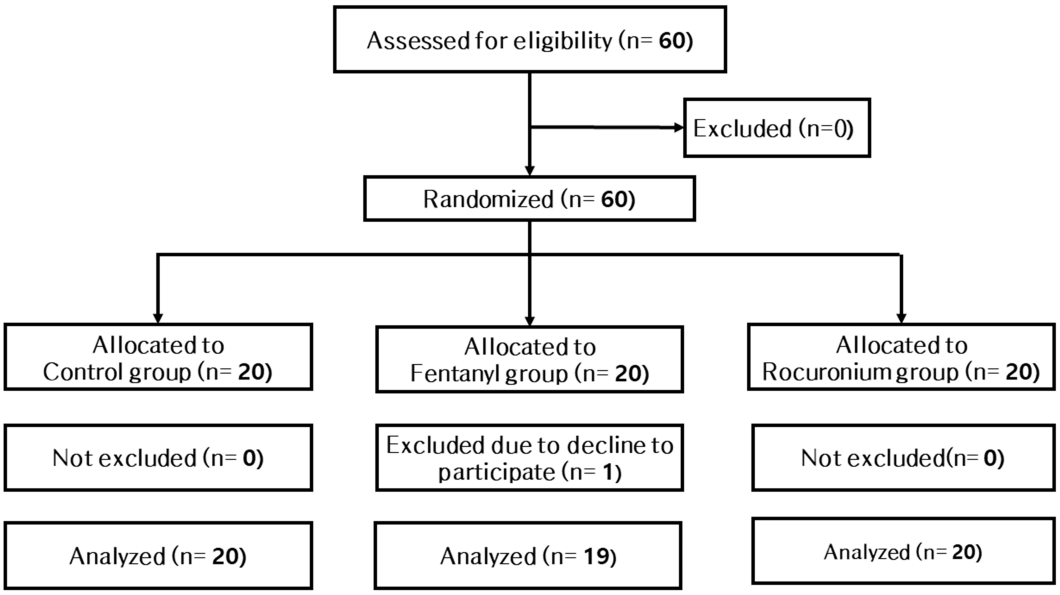

Fig. 1. Flow chart of patient enrollment.

Table 1. Comparison of baseline patient characteristics and surgery characteristics.

Factors	Group C (n = 20)	Group F (n = 19)	Group R (n = 20)	*p*-value
Age (years)	42.3 ± 10.7 [a]	43.6 ± 10.1	41.8 ± 8.6	0.645
Height (cm)	156.2 ± 4.7	159.0 ± 6.8	160.5 ± 6.1	0.098
Weight (kg)	55.2 ± 9.1	58.8 ±10.5	62.3 ± 13.7	0.238
Body mass index (kg/m^2)	22.6 ± 3.7	23.3 ± 4.6	24.2 ± 4.9	0.699
ASA classification (1/2)	11/9 [b]	7/12	7/13	0.370
Duration of surgery (min)	15.5 ± 7.1	13.7 ± 6.0	20.0 ± 10.4	0.132
Duration of anesthesia (min)	44.2 ± 9.7	43.7 ±7.0	49.2 ± 12.0	0.301
Type of surgery				
LEEP	1 (5) [b]	0	1 (5)	
Conization	8 (40)	11 (55)	12 (60)	
Hysteroscopy	11 (55)	8 (40)	7 (35)	

ASA, American Society of Anesthesiologists.
[a] Mean ± Standard Deviation; [b] Number within the group (Percent of the group).

ber within the group and (percent of the group). Statistical difference in nominal data was analyzed by χ^2 test. Statistical differences in continuous data were compared using the Kruskal-Wallis test. SPSS software (version 20.0; SPSS Inc., Chicago, IL, USA) was used for statistical analyses. A p value < 0.05 was considered statistically significant.

3. Results

Sixty patients who underwent ambulatory gynecologic surgery between November 2018 and October 2020 at Korea University Ansan Hospital were enrolled and were randomly allocated into 3 groups. One patient declined to participate during the follow-up period and 59 patients completed the study (Fig. 1). Patients' demographic data and surgery characteristics are presented in Table 1.

After SGA insertion, SBP, DBP, and MBP were significantly higher in group C and group R when compared to group F (Table 2). However, the hemodynamic status of baseline (preoperative), before SGA insertion and immediately after incision was similar in the three groups (Table 2).

SGA insertion condition scores were significantly worse in group C than in group F and group R for coughing ($p < 0.001$), jaw relaxation ($p = 0.001$), limb movement ($p = 0.004$) and total score ($p < 0.001$) (Table 3). The number of patient movements during surgery was significantly higher in group C ($p = 0.005$), and the number of rescue fentanyl injections was also significantly higher in group C ($p < 0.001$) (Table 3). Surgeons' satisfaction scores with the operation conditions were not significantly different among the three groups but in group F and group R, the surgeon was more satisfied with the operation condition than group C (Table 3).

During the patients' stay in the postanesthetic care unit, the incidence of dizziness, PONV, and pruritus were

Table 2. Comparison of hemodynamic data among the three groups.

Factors	Group C (n = 20)	Group F (n = 19)	Group R (n = 20)	*p*-value
Preoperative SBP (mmHg)	135.5 ± 18.3 [a]	132.32 ± 18.0	129.3 ± 19.6	0.662
Preoperative DBP (mmHg)	82.7 ± 7.2	82.95 ± 11.0	81.3 ± 15.6	0.776
Preoperative MBP (mmHg)	105.3 ± 8.9	104.74 ± 14.3	100.0 ± 18.3	0.541
Preoperative HR (/m)	81.7 ± 20.3	83.74 ± 19.8	76.4 ± 17.8	0.600
Before-SGA insertion SBP (mmHg)	121.6 ± 16.5	117.79 ± 17.0	115.6 ± 18.7	0.574
Before-SGA insertion DBP (mmHg)	76.8 ± 10.7	74.84 ± 11.8	75.3 ± 15.9	0.804
Before-SGA insertion MBP (mmHg)	98.9 ± 11.9	96.05 ± 13.5	95.2 ± 16.9	0.523
Before-SGA insertion HR (/m)	87.5 ± 14.7	83.21 ± 15.3	82.5 ± 13.1	0.403
After-SGA insertion SBP (mmHg)	123.5 ± 15.3	109.74 ± 14.4 [c]	127.1 ± 27.7	0.031 [c]
After-SGA insertion DBP (mmHg)	80.9 ± 15.3	68.84 ± 16.0 [c]	82.4 ± 23.2	0.046 [c]
After-SGA insertion MBP (mmHg)	99.8 ± 14.7	88.42 ± 14.9 [c]	103.5 ± 25.5	0.048 [c]
After-SGA insertion HR (/m)	89.9 ± 8.6	85.58 ± 13.8	94.4 ± 10.7	0.082
After incision SBP (mmHg)	121.8 ± 19.8	119.21 ± 14.8	125.0 ± 22.6	0.747
After incision DBP (mmHg)	80.0 ± 13.8	80.94 ± 12.1	83.2 ± 21.5	0.977
After incision MBP (mmHg)	97.8 ± 17.0	97.89 ± 13.4	102.4 ± 20.6	0.823
After incision HR (/m)	92.3 ± 13.8	90.58 ± 16.5	95.5 ± 14.5	0.695

DBP, Diastolic blood pressure; HR, Heart rate; MBP, Mean blood pressure; SBP, Systolic blood pressure; SGA, Supraglottic airway.

p value < 0.05 is considered statistically significant.

[a] Mean ± Standard Deviation; [b] Number within the group (Percent of the group); [c] $p < 0.05$ compared with group C and group R.

similar among the three groups (Table 4). In addition, first voiding time, and discharge time from the unit were similar among the three groups (Table 4).

4. Discussion

This study shows that when combined with anesthesia using sevoflurane, fentanyl had a number of advantages for the patient relative to a control group or to a patient group receiving rocuronium. During SGA insertion, the fentanyl group had significantly more stable hemodynamics (smaller increases in SBP, diastolic DBP, mean MBP, and HR). In addition, because fentanyl provides similar intraoperative conditions and recovery profiles to rocuronium, fentanyl combined with sevoflurane is an appropriate anesthetic regimen for outpatients undergoing ultra-short gynecology surgery.

In obstetrics and gynecology procedures and surgeries, like other kinds of surgeries, the proportion of ambulatory surgery has been increasing [1,2,13]. Initially, it was limited to simple procedures, but now even laparoscopic surgery is actively performed in ambulatory patients [14]. This is because, along with the development of surgical equipment and surgical techniques, the quality of management of ambulatory patients has been improved. In order to promote and to facilitate ambulatory surgery in obstetrics and gynecology, safe and efficient anesthesia methods should be sought. Drug sensitivity varies from person to person, and there are cases in which anesthesiologists are reluctant to use multiple drugs. Therefore, it is necessary to use a well-defined and validated regimen that prevents nausea and vomiting [4], reduces perioperative pain [15], promotes a smooth postoperative recovery, and allows rapid discharge, paying attention to the fact that the target patient group is female.

There have been studies assessing local anesthesia or nerve block for outpatients. However, local infiltration needs a large amount of local anesthetic [1], there is a risk of complications due to systemic absorption, and additional sedation may be required [2]. Several nerve blocks, including the Transversus Abdominis Plane Block, have also been studied [3–5]. Nerve block was effective for postoperative pain control. However, since nerve block as the only anesthetic technique was insufficient, spinal anesthesia or general anesthesia was performed in these studies. Although there is a case report using peripheral nerve block as the only anesthetic technique [6], both patients in this study complained of urinary discomfort. Urinary discomfort is more likely to occur in gynecologic procedures operating near the bladder. In addition, there is no research on whether nerve block can replace general anesthesia. Lastly, in the case of spinal anesthesia or epidural anesthesia [7,8], patients may take considerable time to become ambulatory, so it may be difficult to be discharged on the day of surgery. Additionally, in laparoscopic surgery, the patient may feel referral shoulder pain and may suffer from dyspnea due to pneumoperitoneum. Therefore, general anesthesia is preferred to enable same-day discharge, reduce patient discomfort, and perform surgery in a stable state.

Table 3. Comparison of SGA insertion conditions and intraoperative conditions.

Factors	Group C (n = 20)	Group F (n = 19)	Group R (n = 20)	*p*-value
Coughing	2.0 ± 1.1 [a]	1.2 ± 0.4	1.0 ± 0.0	0.000 [c]
Jaw relaxation	2.1 ± 0.9	1.4 ± 0.6	1.4 ± 0.6	0.010 [c]
Limb movement	2.5 ± 1.1	1.9 ± 1.1	1.4 ± 0.7	0.004 [c]
Total SGA insertion conditions score	6.5 ± 2.3	4.5 ± 1.9	3.8 ± 1.0	0.000 [c]
Fentanyl rescue frequency	14 (70) [b]	3 (15.7)	1 (5)	0.000 [c]
Gross movement at skin incision	5 (25)	0 (0)	0 (0)	0.005 [c]
Surgeon satisfaction score	1.4 ± 0.8	1.1 ± 0.5	1.0 ± 0.0	0.068

p value < 0.05 is considered statistically significant.

[a]Mean ± Standard Deviation; [b] Number within the group (Percent of the group); [c]$p <$ 0. 05 compared with group C.

Table 4. Comparison of postoperative pre-release conditions.

Factors	Group C (n = 20)	Group F (n = 19)	Group R (n = 20)	*p*-value
Dizziness	1 (5) [b]	4 (21.1)	3 (15)	0.334
PONV at 30 mins	1.1 ± 0.3 [a]	1.1 ± 0.2	1.1 ± 0.2	0.783
PONV at discharge	1.0 ± 0.0	1.1 ± 0.2	1.0 ± 0.0	0.349
Pruritis at 30 mins	1.0 ± 0.0	1.0 ± 0.0	1.0 ± 0.0	1.000
Pruritis at discharge	1.0 ± 0.0	1.0 ± 0.0	1.0 ± 0.0	1.000
First voiding time (min)	219.7 ± 58.7	224.3 ± 61.3	216.4 ± 60.5	0.772
Discharge time (min)	270.8 ± 26.9	285.5 ± 48.2	281.6 ± 31.3	0.522

PONV, Postoperative nausea and vomiting.

p value < 0.05 was considered statistically significant.

[a]Mean ± Standard Deviation; [b] Number within the group (Percent of the group).

There are no detailed studies about anesthesia regimens suitable for ambulatory surgery in patients undergoing gynecological surgery. However, in the existing paper about this [16], application of local anesthetic at the surgical incision site, SGA insertion for airway management, and rapid emergence and discharge were recommended. It was also encouraged to use drugs that have hemodynamic stability effects. In the present study, we also evaluated whether rocuronium-induced neuromuscular block could bring about hemodynamic stability equivalent to low-dose fentanyl. In our study, low-dose fentanyl improved the conditions during SGA insertion as reported in a previous study [17] which studied patients undergoing other types of surgery. In another study [18], 0.2 mcg/kg of sufentanyl, an effective dose equal to 2 mcg/kg of fentanyl, was shown to improve SGA insertion condition. This study also showed that even a smaller dose could be effective and equally effective to rocuronium administration. Fentanyl administered at 1 mcg/kg was helpful for hemodynamic stability in SGA insertion as shown in a previous study [19] and as confirmed in our present study. Our study showed that fentanyl administered at 1 mcg/kg used for induction prevented movement during surgery equivalent to rocuronium and the case of additional fentanyl administration there was not a significant difference between group F and group R. This is similar to the previous study where fentanyl administered during induction prevented movement during surgery [20]. While the previous study gave fentanyl 100 mcg in about 30 minutes of surgery, our study gave fentanyl 1 mcg/kg in less than 20 minutes of surgery. In other words, this study once again demonstrated the usefulness of low dose of fentanyl with very short surgery duration and also indicated that it could lead to increased surgeon's satisfaction scores.

Opioid use in surgery is associated with many complications including PONV, respiratory depression, prolonged sedation, urine retention, ileus, increased postoperative pain, and tolerance. Therefore, in recent studies, opioid-free anesthesia has been recommended in female patients who undergo breast or gynecologic surgery [21,22]. However, these studies also suggest that the use of low-dose opioids can be helpful for intubation, extubation, and pain control without significant adverse effects on patients. Common complications with ambulatory surgery include bleeding and postoperative pain. Laparoscopic surgery can result in pain at or near the surgical site as well as remote locations [23]. Proper pain control is therefore an essential part of patient management. In previous studies [17–20], fentanyl doses of 1–2 mcg/kg were used, and in this study, a fentanyl dose of 1 mcg/kg was used. At this dose of fentanyl there was no difference observed in the occurrence of complications among the three groups.

Rocuronium is known to facilitate airway management with procedures such as intubation and extubation, and to reduce movements during surgery with improved surgical outcomes. In this study, a low dose of rocuronium, consistent with the patient's ultra-short surgery, was administered to one cohort. The rocuronium patients had better SGA insertion conditions than the control group, but showed a similar effect to the fentanyl group. It has been shown that SGA insertion works effectively without muscle relaxants, being less invasive relative to endotracheal intubation [24]. This is consistent with our study where group R did not show significantly better SGA insertion condition compared to group F. Rocuronium is well known for improving surgical conditions by providing deep neuromuscular blockade [25]. However, in this study, rocuronium did not show an improved surgical condition when compared to fentanyl. Most of the operations targeted in this study were of very short duration and were minimally invasive and would therefore not benefit from deep neuromuscular blockade as compared with more invasive procedures such as open abdomen surgery or laparoscopic surgery.

This study had several limitations. Firstly, the depth of anesthesia was measured using BIS, but the reliability of the BIS values among the three groups may be different. If neuromuscular blockers are not used as in our groups C and F, BIS values may be inaccurate and BIS values may rise due to electromyogram activity [26–29]. Therefore, surgery may not have been performed under similar depth of anesthesia, or recovery may not have occurred from a similar depth of anesthesia. Secondly, this study was based on the minimum number of patients to provide statistical significance and was carried out in a single institution. The sample size was not sufficient for the detection of a difference in hemodynamic status immediately after SGA insertion and SGA insertion conditions. Thirdly, we tried to use drugs that were most advantageous as single agents at low dose. This is in contrast to the guidelines for ambulatory anesthesia that recommend a multimodal approach. Finally, although postoperative pain is one of the common causes of re-hospitalization after ambulatory anesthesia the operations targeted in this study involved very short-duration surgeries with minimal incisions resulting in little postoperative pain. Thus, in this study, a follow up of postoperative pain was not performed, and the effect of the various study conditions on postoperative pain is not known.

In conclusion, to our knowledge, the present investigation is the first study, which suggests a detailed anesthetic regimen for patients undergoing ultra-short ambulatory obstetrics and gynecology surgery. We found that when combined with sevoflurane, fentanyl at a dose of 1 mcg/kg produced similar SGA insertion condition, intraoperative conditions, and recovery profiles when compared with rocuronium at a dose of 0.3 mg/kg. The fentanyl group additionally had significantly more stable hemodynamics (smaller increases in SBP, diastolic DBP, mean MBP, and HR) during SGA insertion. Furthermore, prospective and randomized study about the minimum capacity per kg will be needed and it will be helpful as it can be used for patients with various weights.

Author contributions

ESC, KSL and WYK designed the research study. DSK, YJC, TJM, YSL, KJM, and JHK performed the research. ESC analyzed the data. ESC, KSL and WYK wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Institutional Review Board of Korea University Ansan Hospital (Gyeonggi-do, Korea; approval on November 1, 2018, B2018AS0239). And the clinical registration number of the trial is KCT0004285.

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Conflict of interest

The authors declare no conflict of interest.

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