Utilization of Pleth Index in Hysteroscopic Surgery: A Randomized Controlled Trial

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Abstract

Background: When performing hysteroscopic surgery under general anesthesia in non-intubated patients, anesthesiologists and gynecologists face challenges including patient movement and respiratory depression due to variability in the depth of patient anesthesia. Intraoperative modulation of the depth of anesthesia is dictated by clinical practice. In recent years, the noninvasive surgical pleth index (SPI) has been purported to objectively reflect the depth of anesthesia. In the present study, we investigated the performance of SPI monitoring in hysteroscopic surgery.

Methods: Eighty patients scheduled for hysteroscopic surgery under general anesthesia with a laryngeal mask airway (i.e., spontaneous ventilation without a muscle relaxant) were randomly divided into two groups (both n = 40): (1) bispectral index (BIS)- and SPI-monitoring group (BS Group); and (2) BIS-monitoring group (B group). Intraoperative analgesia was provided via target-controlled infusion (TCI) of remifentanil, which was modulated according to the SPI value (target interval, 20–50) in the BS Group or via the anesthesiologist's assessment in the B Group. In both groups, anesthesia was administered to maintain the BIS values between 40–60. Additionally, the incidences and degree of movement, consumption of anesthetic drugs, recovery times, complications, and satisfactory levels were compared between the two groups.

Results: The incidence and degree of bodily movement in the BS Group were significantly lower than those in the B Group ($P < 0.05$). Furthermore, the remifentanil induction dose and recovery time in the BS group were significantly lower than those in the B group ($P < 0.05$). However, there were no significant differences between the two groups with regard to adverse events including nausea, vomiting, and dizziness. Finally, gynecologists had higher satisfactory levels in the BS Group ($P < 0.05$).

Conclusion: SPI- and BIS-guided general anesthesia is clinically feasible in hysteroscopic surgery and leads to both inhibition of intraoperative movement and faster recovery.

Background

Hysteroscopic surgery is a common surgical procedure for abnormal uterine bleeding (AUB), infertility, and uterine pathologies[1]. General anesthesia administered is widely used during hysteroscopic surgery[2, 3]. One notable limitation is bodily movement and respiratory depression[4, 5], which may lead to surgical complications (e.g., uterine perforation[6, 7]). To provide both comfort and safety, general anesthesia with a laryngeal mask airway (LMA; i.e., spontaneous ventilation without a muscle relaxant) may represent an ideal method for hysteroscopic surgery. Unfortunately, opioid overdose associated with postoperative nausea/vomiting (PONV), delayed recovery from anesthesia, pruritus, and dizziness[8] can still occur if analgesic drug administration is guided by conventional analgesic practices.

The surgical pleth index (SPI), initially named the surgical stress index (SSI), is calculated from the heartbeat interval (HBI) and pulse photoplethysmographic amplitude (PPGA) for titration of anesthetic doses, and reflects the degree of intraoperative analgesia/nociception on a scale from 0 (complete

analgesia) to 100 (maximal nociception)[9]. The effectiveness of SPI for quantifying analgesia/nociception during general anesthesia has been demonstrated in many clinical settings, confirming its reliability as an analgesia-monitoring method[10–13].

The present study investigated the utility of SPI- and bispectral index (BIS)-based multimodal monitoring under general anesthesia in patients undergoing hysteroscopic surgeries. To this aim, we recorded adverse events and consumption of anesthetic agents under these conditions. Moreover, we investigated the implications that these monitoring techniques had on the recovery times of patients.

Methods

Before Induction of Anesthesia

This was an observational study of 80 patients undergoing hysteroscopic surgeries at Ningbo First Hospital (Zhejiang, China) from January 2020 to May 2020. The study protocols were approved by the Ethics Committee of Ningbo First Hospital at Zhejiang, China (approval numbers: 2020-R128) and were registered in the Chinese Clinical Trial Registry system (http://www.chictr.org.cn, ChiCTR1900025014). The study adheres to CONSORT guidelines. Patients and gynecologists were blinded to group assignments. All procedures were carried out by the same group of gynecologists.

The inclusion criteria were as follows: (1) aged 18–60 years; and (2) American Society of Anesthesiologists (ASA) classification of I- or II-level. Exclusion criteria were as follows: (1) significant cardiovascular disease or arrhythmia; (2) severe hepatic or renal dysfunction; (3) alcohol or drug abuse; (4) predicted difficult ventilation; (5) pregnancy; (6) moderate-severe anemia (hemoglobin concentration < 90 g/L); or (7) body mass index (BMI) > 35 kg/m^2.

We used a computer generated method of block randomization. All participants were divided into two groups (n = 40): (1) bispectral index (BIS)- and SPI-monitoring group (BS Group); and (2) BIS-monitoring group (B group). Upon arrival in the operating room, each patient was monitored via electrocardiography (ECG), noninvasive blood pressure, pulse oximetery with the addition of SPI (CARESCAPE B850 Monitor, GE Healthcare Finland Oy, Finland), and BIS (BIS VISTA, Aspect Medical Systems, Newton, MA, USA). SPI values were covered with a curtain so that they were not visible to the independent anesthesiologist in the B Group.

Before anesthesia induction, baseline values—including heart rate (HR), mean arterial pressure (MAP), SpO_2, BIS, and SPI—were recorded. Tropisetron (5 mg) was administered intravenously for preventing postoperative nausea and vomiting.

Induction of Anesthesia

Induction of anesthesia was titrated with an effect-site target-controlled infusion (TCI) of propofol (Marsh model) and remifentanil (Minto model) at 5.0 μg/mL and 4.0 ng/mL[14], respectively, using a two-

channel TCI pump (Orchestra, Fresenius Vial, Berzins, France).

An LMA (Cookgasair-q, Mercury Company, United States) was inserted when the BIS value decreased to 40–50 (both groups) and the SPI value decreased to 20–30 (BS Group). Then, mechanical ventilation (SIMV mode) was continued and maintained at a tidal volume of 6–8 mL/kg. Ventilation frequency was adjusted to maintain an end-tidal CO_2 of 35–45 mmHg in 100% oxygen. Finally, the propofol infusion was stopped, remifentanil was decreased to 1 ng/mL, and sevoflurane (initially with a minimum alveolar concentration [MAC] of 1.0) was then started immediately.

Maintenance of Anesthesia

In both groups, anesthesia was maintained and continuously adjusted with sevoflurane to retain BIS values between 40–60. Intraoperative analgesia was provided via TCI of remifentanil, which was modulated according to the SPI value in the BS Group or via the anesthesiologist's assessment in the B Group. The remifentanil dose was adjusted by increasing or decreasing the target by steps of 1.0 ng/mL every 2 min to maintain an SPI level between 20–50 until the end of surgery in the BS Group. If the SPI value changed suddenly by more than 10[14], the remifentanil infusion rate was also increased by steps of 1.0 ng/mL, even if the SPI was still within the target range. The remifentanil dose was adjusted to maintain MAP and HR within 20% of baseline values in the B Group (Table 1).

Recovery Period and Feedback

At 3 min before the expected end of surgery, sevoflurane and remifentanil were discontinued, and oxygen at 6 L/min was provided. When the patient met the criteria of eye-opening or providing appropriate responses to verbal commands, the LMA was removed. After confirming stable vital signs, each patient was taken to the post-anesthesia care unit (PACU) with O_2 delivered via a face mask. As a routine early follow-up, telephonic feedback was acquired the next morning.

Recovery time was defined as the period of time between the end of surgery to removal of the LMA. The degree of intraoperative bodily movement was graded with a four-point scale: none; mild, wrist movement only; moderate, elbow or shoulder movement; and severe, whole-body movement, coughing, or breath-holding[15]. A blinded Registered Nurse did the grading.

Endpoints

The primary endpoints of the present study were the degree and incidences of intraoperative bodily movements; secondary endpoints were the recovery times, consumption of anesthetic drugs, and other adverse events including nausea/vomiting, dizziness, and satisfactory scores of patients and gynecologists.

Statistical analysis

We used PASS 11.0 software to calculate the required sample size. A sample size of 26 in each group was determined to be required for a power of 0.90 and an a-value of 0.05. Statistical analysis was performed via SPSS, version 18.0, for Windows (SPSS Inc., Chicago, IL, USA). Parametric data are

expressed as the mean ± standard deviation (SD). Categorical data were compared using χ2 tests or Fisher's Exact tests where appropriate, and parametric data with normal distributions were compared via Student's t tests. Mann–Whitney U tests were used to compare parametric data with skewed distributions. Lastly, P values < 0.5 were considered statistically significant.

Results

A total of 80 patients completed the study, and six patients had to be excluded due to violations of the study protocol (i.e., four patients received vasoactive drugs, while two patients experienced intraoperative arrhythmias). Ultimately, 36 patients were included in the BS Group and 38 patients were included in the B Group (Fig. 1). The demographics of the patients were similar between the two groups (Table 2).

Anesthetic consumption

The propofol induction dose was comparable between the two groups (2.14 ± 0.29 mg/kg in the BS group vs. 2.17 ± 0.34 mg/kg in the B group; mean difference [MD] = − 0.0397; 95% confidence interval [CI] [− 0.1849, 0.1054], $P > 0.05$). In contrast, the remifentanil dose was significantly lower in the BS group compared to that in the B group (remifentanil induction dose: 0.80 ± 0.28 vs. 1.05 ± 0.26 μg/kg, respectively; MD = − 0.2447, 95% CI [− 0.369, − 0.119], $P < 0.001$; intraoperative total remifentanil dose: 1.07 ± 0.33 vs. 1.29 ± 0.35 μg/kg, respectively; MD = − 0.22, 95% CI [− 0.3763, − 0.0631], $P = 0.007$).

Recovery time

The time to remove the LMA in the BS Group was 4.91 ± 0.92 min, which was significantly shorter than the 5.61 ± 1.42 min in the B Group (MD = − 0.70, 95% CI [− 1.26, − 0.13], $P = 0.016$).

The incidence of complications

No statistically significant differences were found between the two groups regarding the incidences of PONV, dizziness, or intraoperative awareness ($P > 0.05$).

The incidences and severity gradings of intraoperative bodily movements were significantly lower in the BS Group than in the B Group ($P < 0.05$). There was only one mild case in the BS Group. In contrast, nine cases in the B Group included three mild cases and two moderate cases, as well as one severe case that interrupted the surgical procedure. Logistic regression demonstrated an association between longer operative duration and a higher incidence of intraoperative bodily movement in the B Group (OR, 1.087; 95% CI, 1.015–1.165) (Tables 3 and 4).

Satisfaction with anesthesia and surgery

Patient satisfaction with anesthesia and surgery was similar between the groups ($P > 0.05$), but gynecologists had higher satisfaction levels in the BS Group compared to those in the B Group ($P < 0.05$) (Table 5).

Hemodynamic data and monitoring indexes

MAP, HR, SPI, and BIS values at five different time points are provided in Table 6. The groups did not differ at any of the measuring times ($P > 0.05$).

Discussion

Hysteroscopic surgery has become an established and widely practiced minimally invasive approach for treating intrauterine pathologies including endometrial polyps, submucous fibroids, uterine septa, intrauterine adhesions, and retained products of conception[1]. Outpatient hysteroscopy involves short, minimally painful procedures with thinner instruments (< 5-mm hysteroscopes[16]), and generally does not require anesthesia. However, some non-anesthetized patients who have anxiety or who have previously undergone failed surgical procedures cannot tolerate the pain of cervical dilatation, which may lead to vasovagal syndrome (a 0.21–30% incidence[17]) during this procedure. Hysteroscopic surgery with scopes > 5 mm (10 mm, generally) requires cervical dilatation, which may cause bleeding, cervical laceration, and uterine perforation. To promote patient comfort and safety, the method of anesthesia is often general anesthesia with an LMA, spontaneous ventilation, and no muscle relaxation. However, complications such as intraoperative bodily movements, postoperative nausea/vomiting, and delayed recovery can still occur as a result of conventional analgesic practices that are based on somatic or autonomic responses including lacrimation, bodily movements, sweating, and hemodynamic changes. Recently, it has been confirmed that modulation of neurotransmission from dorsal afferent neurons into the dorsal horn of the spinal cord, as well as effects on the spinal reflex arc from the dorsal horn to ventral-horn motor neurons, represent mechanisms of action of anesthetics. Accordingly, intraoperative bodily movements of patients have been demonstrated to indicate insufficient analgesia rather than insufficient muscle relaxation[18].

Consequently, it is important to accurately monitor the depth of anesthesia, inhibit intraoperative bodily movements, and increase the cost-effectiveness of surgeries. Several commercial devices have been developed and are available for reflecting the depth of analgesia. Most of these devices analyze autonomic responses during noxious stimulation. SPI monitoring is a unique approach because it only requires general-anesthesia monitoring and does not require any additional consumables[19]. SPI has been widely studied perioperatively, where it has been demonstrated to be an objective, non-invasive, continuous, and reproducible method for reflecting analgesic depth during general anesthesia. A recent meta-analysis reported that SPI-guided analgesia resulted in lower opioid consumption and shorter times to tracheal extubation[13]. However, there have been no reports on the application of SPI in hysteroscopic surgery utilizing an LMA.

In our present study, the remifentanil dose was modulated according to SPI values in the BS Group, whereas it was modulated via the anesthesiologist's assessment in the B Group. Our results demonstrated that SPI-guided analgesia reduced intraoperative bodily movements. The risk of bodily movements increased with the length of surgery in the B Group. We strongly suggest that BIS- and SPI-monitoring is necessary in long-time hysteroscopic surgery (> average length of surgery, approximately

18 min). We also demonstrated that SPI-guided analgesia was associated with a reduction in the consumption of remifentanil in hysteroscopic surgery. We found that this reduction was more pronounced during anesthesia induction.

Sevoflurane is a commonly used volatile anesthetic that exhibits rapid pharmacokinetic properties. Schraag et al.[20] reported that the time to respiratory recovery and tracheal extubation were shorter with sevoflurane than with propofol. Moreover, SPI-guided analgesia has been demonstrated to be effective during general anesthesia with volatile anesthetics (e.g. sevoflurane) as well as total intravenous anesthesia[10]. Hence, we chose sevoflurane rather than propofol in our present study to induce faster recovery. A limitation of our present study was that we were unable to calculate sevoflurane consumption[21]. Different anesthetic regimens have divergent impacts on SPI guidance. However, our present study indicated that SPI-guided analgesia can provide effective analgesia during sevoflurane-remifentanil anesthesia.

We found that there were no differences with regard to PONV and dizziness between the two groups in our present study. There are two possible reasons for these results. First, the incidence of complications was very low in our present study. Second, our sample sizes may have been too small to detect any significant effects. No intraoperative awareness was reported in our study. Additionally, no postoperative sore throat was reported. Despite patient satisfaction being similar between the two groups, gynecologists were more satisfied with general anesthesia under dual BIS- and SPI-monitoring in hysteroscopic surgery compared to that of BIS monitoring alone. However, it is noteworthy that many factors affect patient satisfaction[22].

Individual titration of analgesics—especially opioids—has improved via the application of SPI and BIS monitoring, which has consequently benefited patient outcomes. Therefore, clinical practices should be updated so that they may best integrate these improvements during surgeries.

Conclusion

In conclusion, SPI- and BIS-guided general anesthesia with an LMA, spontaneous ventilation, and without a muscle relaxant is clinically feasible in hysteroscopic surgery and leads to inhibition of intraoperative bodily movements and faster recovery.

Abbreviations

SPI
Surgical pleth index; BIS:Bispectral index; TCI:Target-controlled infusion; AUB:Abnormal uterine bleeding; LMA:Laryngeal mask airway; PONV:postoperative nausea/vomiting; SSI:Surgical stress index; HBI:Heartbeat interval; PPGA:Pulse photoplethysmographic amplitude; ASA:American Society of Anesthesiologists; BMI:Body mass index; ECG:Electrocardiography; SpO_2:Pulse oximetry; HR:Heart rate;

MAP:Mean arterial pressure; MAC:Minimum alveolar concentration; PACU:Post-anesthesia care unit; SD:Standard deviation.

Declarations

Acknowledgments

Not applicable.

Authors' contributions

YL designed this study. YL, HC, ZJ, and LY conducted the trials. ZJ, LY, and LY analysed data. YL and ZJ interpreted the data. YL and ZJ drafted the paper. All authors read and approved the final version of the manuscript.

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Availability of data and materials

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

Ethics approval and consent to participate

The study protocols were approved by the Ethics Committee of Ningbo First Hospital at Zhejiang, China (approval numbers: 2020-R128) and written informed consent was obtained from all subjects participating in the trial. The trial was registered in the Chinese Clinical Trial Registry system (http://www.chictr.org.cn, ChiCTR1900025014, Principal investigator: Lifeng Yao, Date of registration: 2019-08-07).

Consent for publication

Not applicable.

Competing Interest

The authors report that there are no conflicts of interest.

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Tables

Table 1 Criteria of remifentanil modulation

Observation indexes	BS Group	B Group
Underdosed analgesic	SPI value > 50 for more than 5 sec or Δ SPI >10	MAP > 120% of baseline or > 100 mmHg, HR >100 beats/min, bodily movement
Remifentanil modulation	Increasing the target by steps of 1.0 ng/mL every 2 min	
Adequate anesthesia	SPI value (20–50) and BIS value (40–60)	
Overdosed analgesic	SPI value < 20 for more than 5 sec	MAP < 80% of baseline or < 60 mmHg, HR < 45 beats/min
Remifentanil modulation	Decreasing the target by steps of 1.0 ng/mL every 2 min	

Table 2 Demographic properties of patients included in the study

Demographic data	BS Group (*N* = 36)	B Group (*N* = 38)
Age, yr	42.2 ± 9.5	40.5 ± 9.6
Height, cm	159.5 ± 4.4	159.3 ± 4.4
Weight, kg	58.8 ± 10.8	57.1 ± 8.2
Body mass index, kg/m^2	23.15 ± 4.02	22.49 ± 2.90
ASA I/II, *N*	28/8	33/5
Hemoglobin concentration, g/L	125.8 ± 16.1	124.5 ± 13.6
Duration of surgery, min	18.2 ± 9.8	18.5 ± 12.2

Table 3 The incidences of adverse events

Observation indexes	BS Group	B Group	*P*-value
	(*N* = 36)	(*N* = 38)	
Intraoperative bodily movement, %	1 (2.8)	8 (21.1)	0.029*
NO	35 (97.2)	30 (78.9)	
YES	1 (2.8)	8 (21.1)	
Postoperative nausea and vomiting (PONV), %	2 (5.6)	4 (5.5)	0.676
NO	34 (94.4)	34 (89.5)	
YES	2 (5.6)	4 (10.5)	
Dizziness, %	3 (8.3)	2 (5.2)	0.666
NO	33 (91.7)	36 (94.8)	
YES	3 (8.3)	2 (5.2)	
Intraoperative awareness, %	0 (0)	0 (0)	
NO	36 (100)	38 (100)	
YES	0 (0)	0 (0)	
*Statistically significant.			

Table 4 Severity grading of bodily movements

	BS Group	B Group	*P*-value
	(*N* = 36)	(*N* = 38)	
Severity grading of bodily movements			0.016*
none, *N* (%)	35 (97.2)	30 (79)	
mild, wrist movement only, *N* (%)	1 (2.8)	5 (13.2)	
moderate, elbow or shoulder movement, *N* (%)	0 (0)	2 (5.3)	
severe, whole-body movement, cough, or breath-holding, *N* (%)	0 (0)	1 (2.6)	
Statistical significance was analyzed by a two-sided Fisher's exact test. *Statistically significant.			

Table 5 Satisfaction with anesthesia and surgery

Satisfactory Levels	Patient		Gynecologists	
	BS Group	B Group	BS Group	B Group
Poor, %	1 (2.7)	2 (5.3)	0 (0)	1 (2.6)
Good, %	6 (16.7)	8 (21.0)	1 (2.8)	7 (18.4)
Excellent, %	29 (80.6)	28 (73.7)	35 (97.2)	30 (79.0)
P-value	0.469		0.017*	

Statistical significance was analyzed by a two-sided Fisher's exact test. *Statistically significant.

Table 6 MAP, HR, SPI, and BIS values at five time points

Observation indexes	BS Group (*N* = 36)	B Group (*N* = 38)
MAP (mmHg)		
T_0	87.1 ± 8.8	86.6 ± 10.1
T_1	72.5 ± 7.0	70.1 ± 8.0
T_2	74.8 ± 8.4	72.5 ± 9.0
T_3	76.5 ± 9.3	74.3 ± 8.8
T_4	77.1 ± 8.0	77.2 ± 9.2
HR (beats $min^{-1)}$		
T_0	79.0 ± 12.7	76.5 ± 11.0
T_1	68.4 ± 10.0	64.4 ± 8.6
T_2	68.3 ± 10.6	65.6 ± 9.4
T_3	68.4 ± 9.5	65.1 ± 9.6
T_4	68.8 ± 11.4	65.8 ± 11.5
SPI value		
T_0	77.1 ± 9.2	
T_1	26.8 ± 4.2	
T_2	34.1 ± 9.0	
T_3	32.5 ± 8.6	
T_4	35.9 ± 11.9	
BIS value		
T_0	96.2 ± 2.0	95.3 ± 2.5
T_1	43.8 ± 5.1	44.0 ± 5.9
T_2	46.8 ± 9.7	44.5 ± 10.7
T_3	47.1 ± 7.8	49.6 ± 7.2
T_4	52.3 ± 8.1	50.0 ± 6.0

SPI and BIS values, as well as the mean arterial pressure (MAP) and heart rate (HR), were recorded at five-time points: (T_0, baseline) before induction; (T_1) immediately before LMA insertion; (T_2) at the start of surgery; (T_3) 5 min after the start of surgery; and (T_4) at the end of surgery.

Data are expressed as mean ± SD. *Statistically significant.

Figures

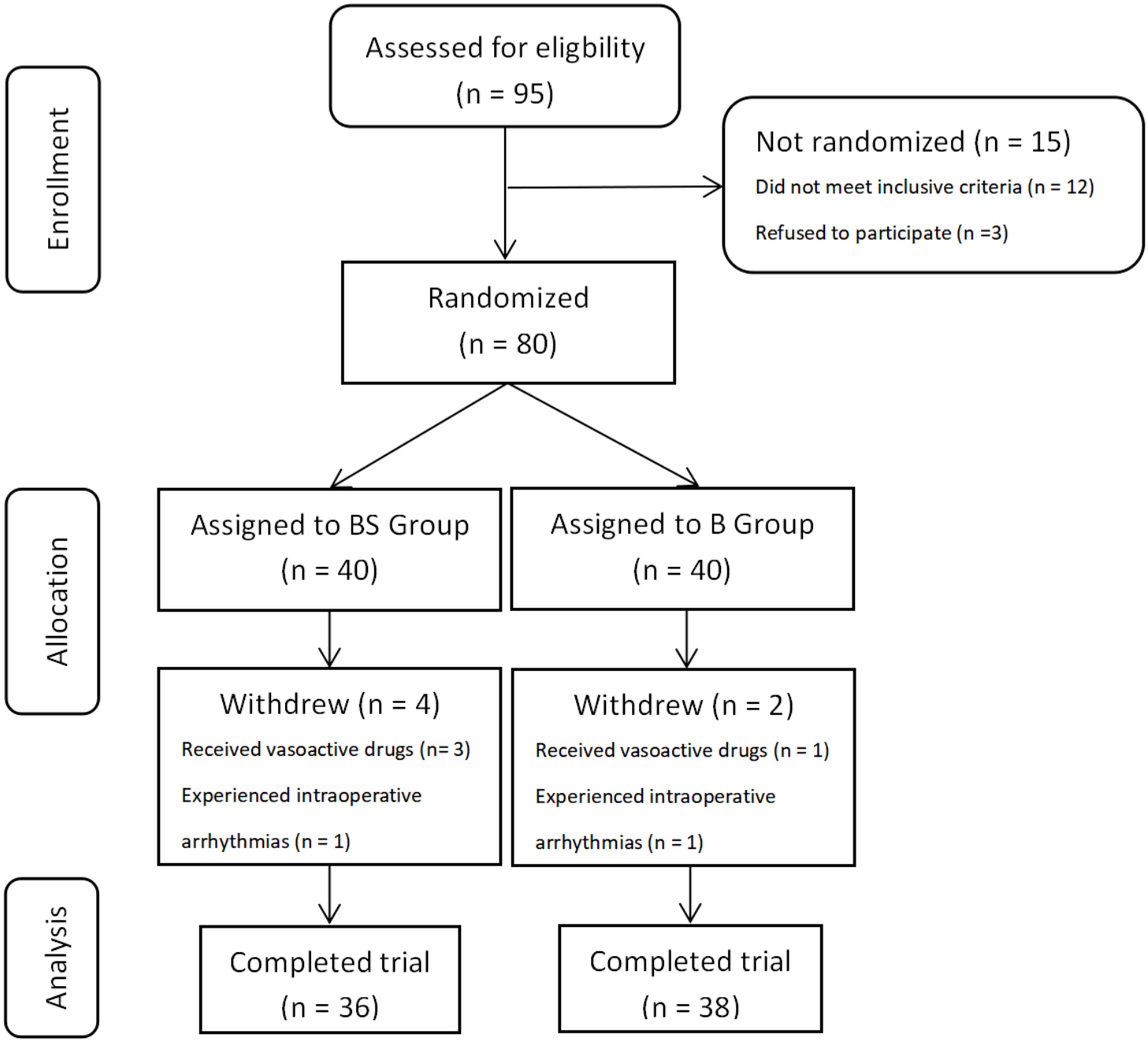

Figure 1

Flow chart of the study

Supplementary Files

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