

Relationship Between Entropy-Guided Sevoflurane Administration and End Oxygenator Sevoflurane Concentration in Adult Patients Undergoing Cardiopulmonary Bypass Surgery

Vijay Kumar, Alok Kumar, Krishna Prasad Gourav¹, Bhargava Devarakonda²

Department of Anaesthesia and Critical Care, Armed Forces Medical College, Pune, Maharashtra, ¹Department of Anaesthesia and Critical Care, Postgraduate Institute of Medical Education and Research, Chandigarh, ²Department of Anaesthesia and Critical Care, Army R and R Hospital, New Delhi, India

ABSTRACT

Background: Cardiopulmonary bypass (CPB) during cardiac surgery poses physiological challenges such as altered drug pharmacokinetics. Sevoflurane, a commonly used volatile agent, provides favorable myocardial protection; however, precise dosing during CPB remains difficult. Entropy monitoring, which assesses cerebral and electromyographic activity, offers real-time guidance on anesthetic depth. This study aimed to investigate entropy-guided sevoflurane administration relation with end-oxygenator sevoflurane concentrations, in patients undergoing elective on-pump cardiac surgery.

Materials and Methods: A prospective, randomized controlled trial was conducted in a single tertiary care center affiliated with a teaching hospital, enrolling 74 adult patients scheduled for elective on-pump cardiac surgeries. Participants were randomized into two groups: fixed sevoflurane concentration (1.5% v/v) and entropy-guided sevoflurane titration. Depth of anesthesia was monitored with state entropy (SE) and response entropy (RE), end-oxygenator sevoflurane concentrations, and clinical parameters.

Results: Compared to the fixed-dose group, the entropy-guided group exhibited lower SE and RE values intraoperatively, indicating tighter control of anesthetic depth. Higher sevoflurane dial settings were used initially in the entropy group, resulting in higher end-oxygenator concentrations. Although mean arterial pressure and arterial blood gas parameters remained within acceptable ranges in both groups, VIS was higher in the entropy-guided group, suggesting an increased requirement for vasoactive and inotropic support. There was no statistically significant variation in postoperative mechanical ventilation duration or intensive care unit stay between the two groups.

Conclusion: Overall, entropy monitoring facilitated a precise titration of sevoflurane without adversely affecting immediate postoperative outcomes.

Keywords: Cardiopulmonary bypass, end tidal sevoflurane concentration, entropy, sevoflurane

Address for correspondence: Dr. Alok Kumar, Department of Anaesthesia and Critical Care, Armed Forces Medical College, Pune, Maharashtra, India. E-mail: mipayal07@gmail.com

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INTRODUCTION

Cardiopulmonary bypass (CPB), a pivotal innovation in cardiac surgery since 1953, facilitates complex interventions

by temporarily suspending cardiac and pulmonary function.^[1] While CPB enables life-saving procedures,

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it also induces a systemic inflammatory response syndrome and coagulation imbalances, necessitating meticulous anesthetic management to mitigate endothelial dysfunction, cytokine release, and bleeding risks.^[1,2] To achieve an optimal anesthetic depth during CPB is crucial to prevent intraoperative awareness, a potentially traumatic experience leading to psychological sequelae—while simultaneously avoiding excessive sedation, which can result in cardiovascular depression and delayed recovery.^[1,2] Historically, subjective clinical indicators have guided anesthetic depth assessment, but these methods lack accuracy and reliability, particularly regarding cerebral function and consciousness evaluation.^[3] Recent advancements have introduced objective monitoring techniques, notably entropy monitoring, which analyses cerebral electrical activity via electroencephalogram (EEG) and electromyography to provide real-time, quantitative indices of anesthetic depth. This allows for more precise titration of anesthetic agents and improved patient outcomes.^[4-6] Sevoflurane, a favored inhaled anesthetic agent in cardiac surgery due to its rapid induction and cardioprotective effects, poses challenges in maintaining stable concentrations during CPB due to pharmacokinetic variability and circuit-related alterations.^[7,8] Plasma sevoflurane measurements are impractical for real-time adjustments^[9]; therefore, end-oxygenator sevoflurane concentration measurement emerges as a more viable, non-invasive method for guiding accurate dose adjustments, ensuring optimal agent delivery.^[10]

Despite the strong evidence supporting entropy-guided anesthesia,^[4,5] few studies in this area of research have addressed the correlation between the sevoflurane required to maintain the target level of anesthesia using entropy.^[11] This study focuses specifically on investigating the correlation between entropy-guided sevoflurane administration and end-oxygenator sevoflurane concentrations in adult patients undergoing elective on-pump cardiac surgery. The primary objective was to assess the concentration of end-oxygenator sevoflurane in patients receiving entropy-guided sevoflurane administration in comparison to patients receiving standard sevoflurane 1.5% v/v (standard institutional protocol). The secondary objective was to assess the changes in entropy, hemodynamic parameters, and postoperative outcomes in both groups of patients.

MATERIALS AND METHODS

This prospective, randomized controlled trial was conducted at a tertiary care hospital between July 2023 and March 2025, enrolling adult patients

aged 18–60 years scheduled for elective on-pump cardiac surgery. This study was registered under the Clinical Trial Registry of India (CTRI), Registration number-CTRI/2023/11/059847. Institutional ethical clearance was obtained before the trial registration (IEC No. 121/2023 dt 10 Jun 2023). Written informed consent was obtained from all participants. Inclusion criteria included all elective on-pump cardiac surgeries, while exclusion criteria ruled out those with active systemic infection (temperature >38.08°C), diagnosed neurological disorders, pre-existing renal or hepatic dysfunction, emergency surgery, suspected or confirmed genetic syndromes, or those requiring deep hypothermic circulatory arrest. The study involved 74 patients, evenly divided into two groups: Group A: Entropy-guided sevoflurane administration, and Group B: Received fixed sevoflurane concentration (1.5% v/v) administration [Figure 1]. We started in pilot cases, with 1% v/v as per institutional protocol but realized it is insufficient to maintain desired entropy. Subsequently, it was decided to keep the dial setting at 1.5% v/v. These pilot cases were excluded from the study. Randomization of patients was performed with the help of computer-generated random number tables, which were sealed at the start of the study in an envelope to be opened at the time of surgery. This was an open-label randomized trial. The anesthesiologist administering anesthesia was necessarily aware of group allocation because entropy-guided titration required real-time adjustments. However, data recording was performed by a second investigator. Postoperative outcome assessors were blinded to group allocation.

In the operating room, in addition to standard monitoring, entropy electrodes were placed on the patient's forehead after carefully wiping and drying the skin of the forehead with a spirit swab. The response entropy (RE) and state entropy (SE) were monitored using the plug-in module of the E-ENTROPY module, which utilizes the unique and published entropy algorithm, a Datex-Ohmeda innovation (GE Carestation 650 with Tec 7 vaporizer and Carescape B850 monitor, M/s Wipro GE Healthcare Pvt Ltd, GE Med System Co Ltd, Texas, USA). Anesthesia induction included IV etomidate (0.2 mg/kg), IV fentanyl (2 µg/kg), and IV rocuronium (0.6 mg/kg), with intubation and subsequent anesthetic maintenance using air and O₂ (1:1) and sevoflurane. After initial induction and intubation, Group A received entropy-guided sevoflurane titrated to maintain entropy at 40–60, while Group B received a fixed 1.5% v/v sevoflurane as per institutional protocol throughout the surgery. Opioid based analgesia was administered in the form of fentanyl infusion at a rate of 1–2 mcg/kg/h in both groups.

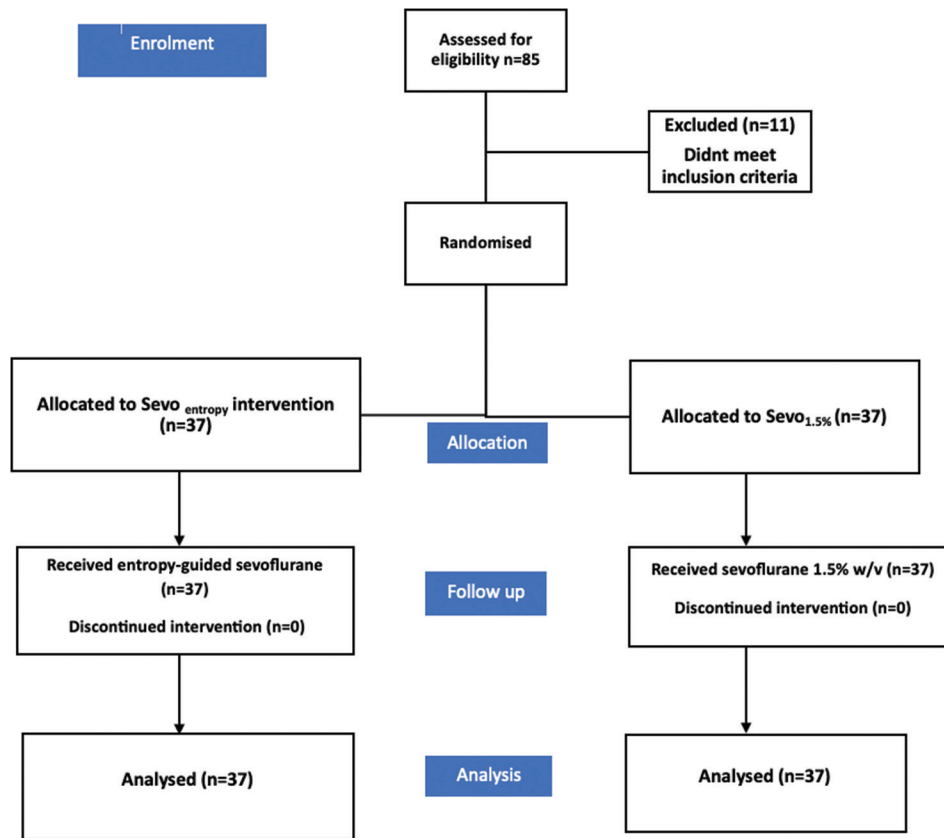


Figure 1: Consort diagram

Coagulation was offset by 400 IU/kg IV unfractionated heparin, aiming at an activated clotting time (ACT) >480 seconds. CPB was instituted as per the institutional protocol using hollow fiber oxygenators (CAPIOX RX-15, Terumo Cardiovascular Systems Corporation, Michigan, USA). Mild hypothermia (32–34°C) was maintained during the CPB. Cardioplegic arrest was induced and maintained by intermittent administration of an antegrade Del Nido cardioplegia solution. Perioperative goal-oriented hemodynamic support was established according to our institutional standards in both the groups. The cardiac surgical team decided upon extubation and postoperative sedation protocols on a case-to-case basis. The rest of the protocol, concerning fluid, inotropes, and diuretics, was targeted to achieve hemodynamic goals adjusted by the treating physician.

Intraoperative parameters, including sevoflurane concentrations, entropy values, hemodynamics (systolic, diastolic and mean arterial pressure [MAP]), CPB flow, sweep gas, and arterial blood gas (ABG) parameters were recorded at regular intervals throughout the procedure, as well as at key peri-CPB time points. The end-tidal anesthetic concentration or end-oxygenator sevoflurane concentration during CPB (ETAC) was monitored

continuously and recorded every ten minutes throughout the procedure [Figure 2]. Postoperatively, patients were followed up in the intensive care unit (ICU), with documentation of vasoactive-inotropic score (VIS), mechanical ventilation (MV) duration, ICU stay, and post-op complications such as AKI, pneumonia, wound infection, arrhythmias, and re-intubation. All patients were interviewed about any memory or recall of intraoperative awareness using the modified Brice questionnaire in the post-operative period before discharge from the ICU.

Statistical analysis

The distribution of the continuous data was tested using the Kolmogorov–Smirnov one-sample test. Continuous variables are expressed as mean $\pm$ standard deviation. Independent two-sample *t*-tests were used to compare continuous variables between the groups, and Chi-square tests were used for categorical variables. For outcomes measured at multiple time points, repeated-measures ANOVA with Tukey's *post hoc* analysis and Greenhouse-Geisser sphericity corrections were used. Sample size estimation was based on preliminary data from 20 patients, comparing sevoflurane administration at a fixed 1.5% v/v concentration (Group A) versus entropy-guided sevoflurane administration (Group B).

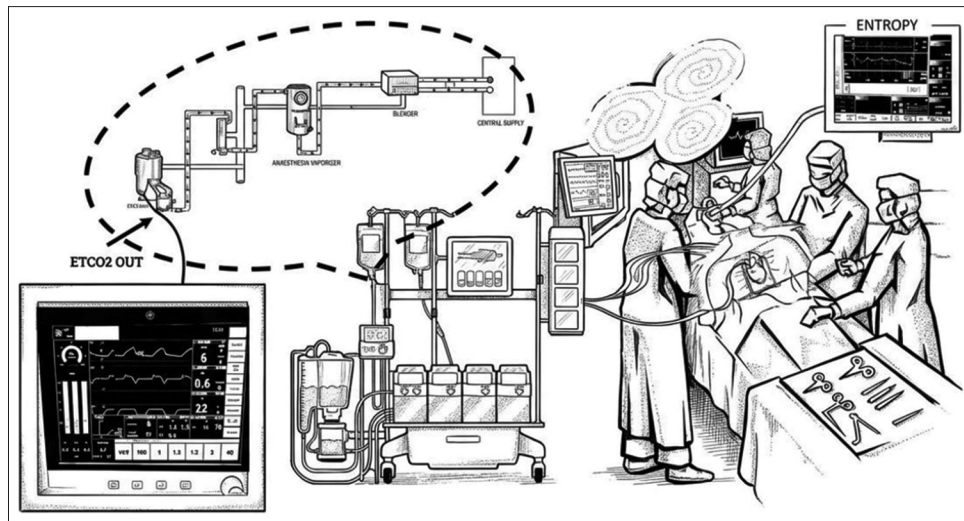


Figure 2: The setup of the vaporizer in relation to the oxygenator and CPB circuit and entropy monitoring. CPB = Cardio-pulmonary bypass

With a mean difference of 8% between groups in sevoflurane administration as measured by ETAC, $\alpha = 0.05$, power = 80%, and equal group sizes, 37 patients were required in each group, totaling 74 participants. Randomization was achieved using a computer-generated sequence, and baseline demographic and clinical data were collected for all the patients. Statistical significance was set at $P < 0.05$. All analyses were performed using the SPSS software (IBM SPSS Statistics version 25, Chicago, IL, USA).

RESULTS

The demographic characteristics of the two groups were not significantly different. CABG was the most common procedure, comprising 44.59% of cases. The distribution of surgical procedures was relatively similar between both the groups ($P = 0.3$), suggesting uniformity in the type of surgeries performed in both groups. Laboratory parameters analyzed at different time points (preoperatively, during CPB, and postoperatively) remained consistent across both groups [Table 1]. The left ventricular ejection fraction (LVEF) improved postoperatively in both groups, although the difference was not statistically significant ($P = 0.091$) [Table 2].

The ANOVA test results for SE and RE showed statistically significant differences across various surgical phases [Figure 3]. Group A exhibited lower SE and RE values throughout the intraoperative period, suggesting higher anesthetic depth with entropy monitoring ($P = 0.01$ and 0.03 , respectively). The dial setting and ETAC were significantly higher in Group A ($P < 0.001$ for both), reinforcing the impact of entropy monitoring on anesthetic administration. Significant differences in MAP were observed at specific

time points. While overall MAP values fluctuated similarly in both groups, the entropy-guided approach led to lower MAP values ($P < 0.001$), suggesting a more vigorous hemodynamic response in the entropy-guided group [Figure 4]. Sweep Gas and CPB Flow did not show statistically significant differences between the two groups, suggesting ventilation strategies and perfusion protocols remained consistent in both groups [Figure 3]. In addition, ABG parameters showed no significant variation, suggesting that the anesthetic approach did not significantly impact the metabolic and respiratory balance significantly.

Postoperatively, the highest VIS in the first 12 hour on arrival to the ICU was also recorded to assess the requirement for inotropic support. Group A had significantly higher VIS scores than Group B, indicating an increased need for vasoactive and inotropic support. This suggests a greater hemodynamic challenge in Group A, which may be attributed to differences in anesthetic depth control or perioperative management strategies. Postoperative outcomes such as the length of ICU stay and MV duration were also analyzed. However, statistical analysis revealed that there was no significant difference between the two groups in terms of MV duration or length of ICU stay ($P > 0.05$ for both). This suggests that while entropy-guided anesthesia contributed to intraoperative lower pressures, it did not significantly impact postoperative recovery time in terms of ventilation duration or ICU stay [Table 2]. None of the patients in our study reported any awareness during the interview using the modified Brice questionnaire after extubation.

DISCUSSION

Our study found that in both groups, SE and RE values

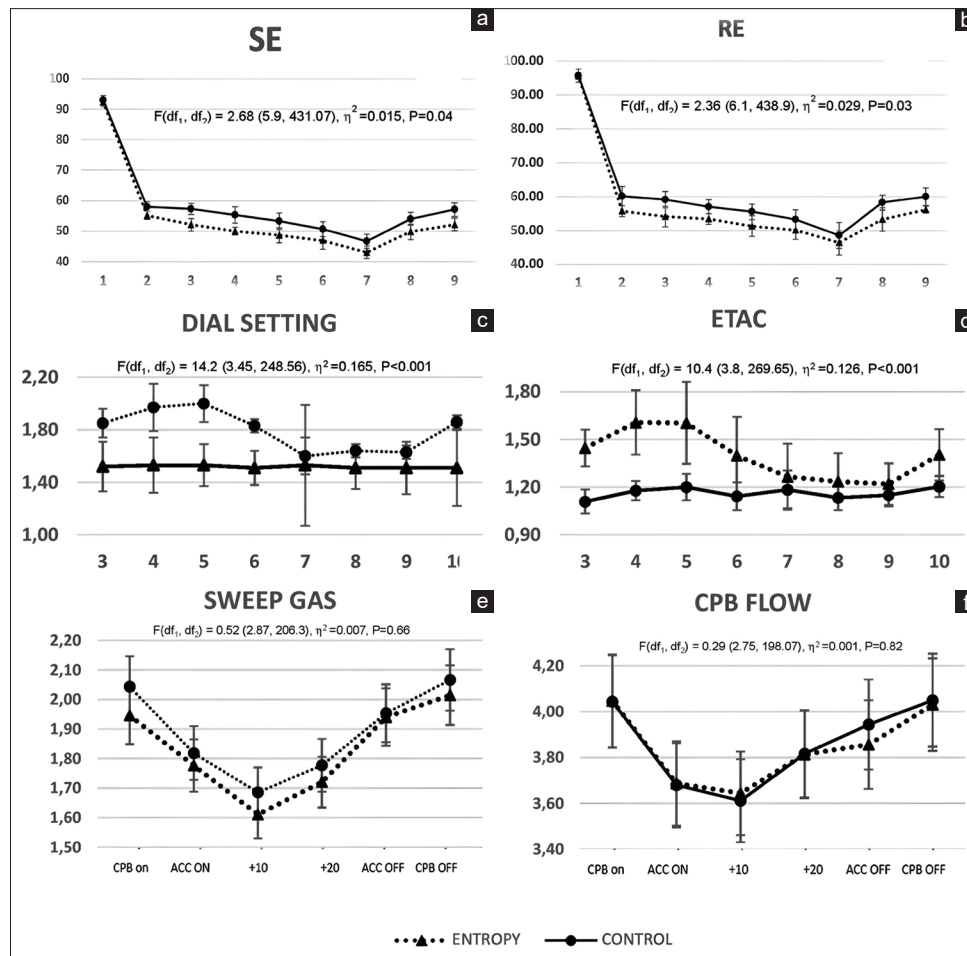


Figure 3: ANOVA result comparing various parameters between the two groups. 1) Baseline, 2) Before induction, 3) At induction, 4) Skin incision, 5) Sternotomy, 6) Starting CPB, 7) Aortic cross clamp, 8) Aortic cross clamp removal, 9) Termination of CPB, and 10) Post CPB. (a) State entropy (SE), (b) Response entropy (RE), (c) Sevoflurane vaporizer dial setting, (d) End oxygenator concentration (ETAC), (e) Sweep gas flow, and (f) Cardiopulmonary (CPB) flow. CPB = Cardio-pulmonary bypass

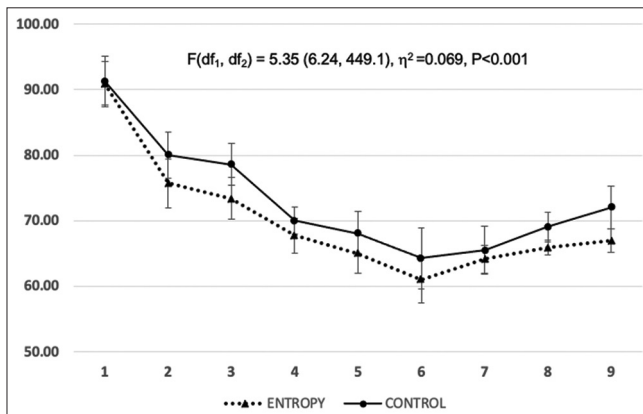


Figure 4: Mean arterial pressure (MAP) comparison in two groups: ANOVA result. 1) Baseline, 2) Before induction, 3) At induction, 4) Skin incision, 5) Sternotomy, 6) Starting CPB, 7) Aortic cross clamp, 8) Aortic cross clamp removal, and 9) Termination of CPB. CPB = Cardio-pulmonary bypass

were consistently maintained within the target range, with lower values in the entropy-guided sevoflurane group. We

kept the entropy close to 50 (range 40–60) in the entropy group, while the entropy in the fixed dial setting group was observed to remain between 50 and 60. A significant decrease in RE and SE after skin incision, reaching their lowest at peak hypothermia, and then rising again during rewarming and skin closure has been observed.^[12] In Group A (entropy-guided sevoflurane administration), both the vaporizer dial setting and ETAC were significantly higher compared to Group B (fixed sevoflurane concentration of 1.5% v/v). Throughout the intraoperative period, Group A also showed consistently lower SE and RE values, along with lower MAP and significantly higher VIS values than Group B. Collectively, these results imply that Group A achieved a deeper level of anesthesia, but required higher vaporizer settings and significantly greater hemodynamic support. This observation contrasts with several studies that reported that EEG-based monitoring system-guided anesthesia reduces overall sevoflurane consumption compared to titration based on clinical parameters.^[5,6] The

Table 1: Demographic and baseline parameters

Parameters	Total	Entropy group	Control group	t/χ^2 [#]	P
Number of patients	74	37	37		
Age (years)	54.8±10.6	54.9±15.8	58.2±12.6	0.54	0.59
Gender					
Male	52 (70.3%)	25 (67.6%)	27 (72.9%)	0.26 [#]	0.61
Female	22 (29.7%)	12 (32.4%)	10 (27.0%)		
Body surface area (m ²)	1.54±0.56	1.56±0.15	1.63±0.13	0.42	0.81
EUROSCORE II	1.13±0.27	1.15±0.28	1.12±0.77	0.41	0.88
CPB duration (min)	145.5±34.6	142.2±35.6	146.5±34.8	0.42	0.87
Aortic cross-clamp time (min)	89.9±17.5	87.2±17.6	92.7±12.6	0.59	0.58
Surgical procedure (n) (%)					
AV replacement	13 (17.6%)	3 (8.1%)	10 (25%)	4.71 [#]	0.31
AVR	2 (2.7%)	1 (2.7%)	1 (2.7%)		
CABG	33 (44.6%)	21 (56.8%)	12 (32.4%)		
DVR	9 (12.2%)	4 (10.8%)	5 (13.5%)		
MVR	17 (22.9%)	8 (21.6%)	9 (24.3%)		
Baseline laboratory parameters					
Hemoglobin (mg/dL)	11.7±0.8	11.2±0.8	12.1±0.8	0.34	0.74
ACT (sec)	119.6±8.9	118.4±6.7	121.3±17	1.9	0.06
Arterial blood gas analysis					
pH	7.37±0.05	7.38±0.03	7.37±0.04	0.69	0.49
pO ₂	130.4±16.2	131.5±17.4	128.8±14.5	0.74	0.46
pCO ₂	34.3±3.6	34.49±4.0	34.2±3.0	0.31	0.76
Lactate	1.03±0.4	1.07±0.4	1.01±0.5	0.61	0.54
LVEF (%)	61.4±4.6	59.9±5.6	62.8±4.3	0.82	0.42

AV: Aortic valve, AVR: Aortic valve replacement, MVR: Mitral valve replacement, CABG: Coronary artery bypass graft, DVR: Double valve replacement, ACT: Activated coagulation time, LVEF: Left ventricular ejection fraction, ETCO₂: End-tidal carbon dioxide, CPB: Cardio-pulmonary bypass

Table 2: Postoperative parameters

Parameters	Total	Entropy group	Control group	t/χ^2 [#]	P
Laboratory parameters					
Hemoglobin (mg/dL)	12.1±0.8	11.9±0.7	12.2±0.8	0.35	0.73
ACT	113.8±6.1	112.9±3.8	115.1±12	0.2	0.81
Arterial blood gas analysis					
pH	7.4±0.03	7.4±0.04	7.39±0.03	0.13	0.9
pO ₂	113.7±57.1	113.6±57.3	111.6±55.9	0.15	0.88
pCO ₂	37.9±3.4	38.24±3.7	37.72±3.3	0.57	0.57
Lactate	1.88±0.4	1.93±0.5	1.85±0.5	0.59	0.55
LVEF (%)	61.1±3.8	61.05±3.8	66.21±3.9	0.11	0.91
VIS	24.5±1.6	28.9±1.4	21.7±2.3	54.3	0.0001*
MV duration (h)	2.4±0.37	2.13±0.34	2.8±0.42	0.89	0.15
ICU stay (d)	4.4±1.3	4.24±1.21	4.6±1.32	0.67	0.42

ACT: Activated coagulation time, LVEF: Left ventricular ejection fraction, ICU: Intensive care unit, MV: Mechanical ventilation, VIS: Vasopressor inotropic score

discrepancy between our findings and those of previous studies may be attributed to methodological differences, variations in patient populations, cardiopulmonary bypass-led hemodilution, and hypothermia, which could influence the required anesthetic concentrations.^[13] The sevoflurane requirements increase during the rewarming phase of hypothermic CPB, with a predictable pattern correlating with temperature rise.^[14]

In cardiac surgery, maintaining a minimum alveolar concentration (MAC) of 1 is often challenging because patients are highly susceptible to hemodynamic instability. Moreover, the precise MAC requirements during CPB are not well established. During CPB, the delivery of volatile anesthetic agents through the oxygenator can be monitored

by measuring the agent concentration in the oxygenator exhaust.^[2,15] However, these readings may become inaccurate if the exhaust is connected to an anesthetic gas scavenging system, potentially due to the room-air admixture.^[9,16] In our setup, we did not use a scavenging system. Therefore, we consider the end-oxygenator concentration of sevoflurane to be a reliable reflection of the actual anesthetic delivery during CPB.

EEG based monitoring such as entropy monitoring is a widely used non-invasive methods for assessing the depth of anesthesia. However, these modalities have been primarily been validated under normothermic conditions, and their accuracy during hypothermia remains uncertain. Hypothermia can independently suppress EEG activity

and induce unconsciousness, potentially leading to misleading entropy values. However, a study by Dewandre *et al.*^[17] reported that BIS values were not significantly affected by mild hypothermia. In our study, we specifically included patients undergoing mild hypothermic CPB to avoid potential inaccuracies in entropy readings that may occur at moderate to deep levels of hypothermia. Sevoflurane requirements increase with temperature during rewarming, and this relationship is predictable. Entropy-guided titration facilitated consistent anesthetic depth despite hypothermic conditions, thus minimizing intraoperative variability.^[18]

Considering the hemodynamic instability commonly encountered during cardiac surgery, especially during CPB, it is standard practice to use a lower MAC of volatile anesthetics. Typically, a dial concentration range of 1%–2% is used during CPB. However, such lower MAC values may increase the risk of intraoperative awareness. Overreliance on BIS monitoring during CPB is common, but BIS has failed to prevent awareness in large studies.^[19] To address this, we used entropy monitoring to guide anesthetic depth and derive an appropriate average MAC to minimize the risk of awareness. Our findings showed that the vaporizer dial concentration and ETAC were significantly higher in entropy-guided sevoflurane administration, indicating that a fixed dial concentration of 1.5% may be insufficient to maintain an entropy value near 50. Despite this, the entropy values in group 2 remained within the recommended range, which may explain the absence of intraoperative awareness in both groups. However, our sample size was too small to detect any incidences of awareness. Importantly, the SE and RE values in the entropy-guided group were consistently maintained within the target range, indicating a more controlled and predictable depth of anesthesia with reduced variability.

ABG analysis showed no significant differences between the groups in pH, pO₂, or pCO₂, indicating that both anesthetic techniques maintained stable respiratory and metabolic profiles. Higher doses of inhalational agents are associated with lower MAP owing to their dose-dependent vasodilatory effects and myocardial depression, a finding that was also observed in our study. In the entropy-guided group, we noted a modest reduction in MAP, accompanied by a significant increase in the VIS score, suggesting a greater need for pharmacological cardiovascular support. This difference may be attributed to the higher vaporizer dial concentrations required in group 1 to maintain the target entropy values. Although entropy monitoring aids in maintaining a stable depth of anesthesia and reducing the risk of intraoperative awareness, it does not directly address

inotropic or vasoactive requirements.^[5,12,14] In contrast, some studies have suggested that BIS monitoring may be more effective in improving hemodynamic stability.^[18] Higher VIS requirements in the entropy-guided group likely reflect the higher sevoflurane concentrations required to achieve the entropy targets.

This study has multiple methodological and clinical strengths that enhance the credibility and translational potential of the findings. The foremost among these is the comprehensive temporal analysis of entropy indices, ETAC, and MAP trajectories across the discrete phases of CPB. A particularly impactful element of this study is the integration of the VIS; a parameter not extensively explored in prior anesthesia literature within this context. This study substantiates and extends the existing literature demonstrating the clinical utility of entropy-guided sevoflurane titration for optimizing anesthetic depth within the complex physiological context. The present study revealed that entropy-guided titration resulted in higher sevoflurane dial settings and higher end-oxygenator concentrations without significant improvement in postoperative outcomes compared with a fixed dial setting.

Our results were contrary to earlier assertions positing a reduced requirement for vasoactive support under targeted anesthetic depth paradigms. These variations are plausibly attributable to the hemodynamic effects of marginally elevated sevoflurane concentrations. Notably, these alterations did not culminate in deleterious clinical sequelae, as no statistically significant differences emerged in arterial blood gas profiles, postoperative ventilatory duration, or ICU length of stay.^[20,21]

Nevertheless, several limitations of this study warrant consideration. The relatively modest sample size constrains the statistical power and limits external generalizability. Moreover, the single-center design introduces the potential for institutional biases, thereby restricting the extrapolation of results to diverse operative environments. Additionally, the anesthetists were not blinded to neither the entropy values nor the allocation group, which could have introduced a performance bias in anesthetic titration.

In summary, this study provides robust support for the integration of entropy monitoring alongside ET-sevo measurements as a means of refining anesthetic administration during high-complexity cardiac procedures. This dual-modality approach enables the timely, data-driven modulation of inhalational agents in response to fluctuating intraoperative physiology. Further multicenter investigations

with expanded patient cohorts are recommended to validate and potentially generalize these findings across diverse surgical and institutional settings.

Key points

- The study highlights the feasibility and clinical value of integrating entropy monitoring with sevoflurane measurements to refine anesthetic delivery in cardiac surgery.
- Entropy-guided sevoflurane during bypass demonstrates lower state entropy (SE) and response entropy (RE) values.
- Entropy-guidance shows tighter anesthetic depth control with higher vaporizer settings and end oxygenator anesthetic values.
- Entropy monitoring enabled precise, real-time anesthetic titration without adverse effects on postoperative outcomes such as intensive care unit (ICU) stay, ventilation duration, or awareness.

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Conflicts of interest

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

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