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Exploring Heart Rate Variability Biofeedback as a Nonpharmacological Intervention for Enhancing Perioperative Care: A Narrative Review

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Abstract

Heart rate variability biofeedback (HRVBF) is a non-invasive therapeutic technique that aims to regulate variability in heart rate. This intervention has promise in mitigating perioperative stress, a critical factor for surgical patient outcomes. This comprehensive review aimed to explore the current evidence on the perioperative role of HRV biofeedback in improving patient outcomes, reducing perioperative stress, enhancing recovery, and optimizing anaesthesia management. A review of the PubMed and Google Scholar databases was conducted to identify articles focused on HRVBF in relation to the perioperative period. Studies were selected using appropriate keywords in English (MeSH). Ample potential applications of HRVBF in clinical anaesthesia have been identified and proven feasible. It is a non-invasive and an easy method an anaesthesiologists has at its disposal with potential utility in reducing perioperative stress, as a tool of optimization of comorbidities, analgesia supplementation and in predicting catastrophic complications. Although HRVBF has the potential to enhance anaesthesia management and improve patient outcomes, several limitations and challenges must be addressed to maximize its clinical utility. Overcoming these obstacles through research and technological advancements will be crucial for realizing the full benefits of HRVBF in perioperative care.

Keywords: Analgesia, autonomic nervous system, biofeedback, breathing, heart rate, perioperative care

Main Points

- This in-depth review examined the latest research on how heart rate variability biofeedback (HRVBF) can help improve patient outcomes, lower perioperative stress, speed recovery, and make the most of anaesthesia management.
- This review discusses the mechanisms, methods, and benefits of HRVBF in the perioperative setting, as well as the challenges and future directions for implementing this technique in clinical practice.
- By targeting autonomic regulation, stress reduction, and resilience enhancement, HRVBF techniques offer a personalized approach to perioperative care that may lead to improved patient comfort, optimized surgical outcomes, and enhanced recovery.

Introduction

Heart rate variability biofeedback (HRVBF) is a non-invasive technique that involves training individuals to regulate their heart rate variability through breathing exercises and relaxation techniques. It has emerged as a promising therapeutic intervention in various clinical settings, including the perioperative period. The significance of perioperative stress on the outcomes of surgical patients is often overlooked.[1] Currently, the main perioperative interventions used to reduce these stress responses are drugs (mainly anaesthetics and painkillers), which can cause a number of problems. Surgery, in addition to anaesthesia and blood transfusion, can cause immunosuppression, leading to infections and other complications.

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The central autonomic network, consisting of complex brain connections, regulates the autonomic nervous system (ANS). HRV is a physiological index that portrays the delicate balance of the ANS. High HRV occurs when the parasympathetic nervous system (PNS) is dominant over the sympathetic nervous system (SNS), indicating good autonomic control. Chronic illnesses such as cardiovascular disease, which often reduce HRV, pose challenges for both patients under anaesthesia and anaesthesiologists.[2] Using a theoretical perspective, several models have been proposed to elucidate the heart-brain connection, revealing its significant effect on psychological responses and overall well-being.[3] Notably, the neurovisceral model outlines the relationship between HRV and emotion, cognition, and mental health by showing how the prefrontal brain and cardiac vagal tone are linked.[4]

Goessl et al.,[5] in their meta-analysis, found a decrease in self-reported stress and improvement in cognitive function, supporting the practical use of HRVBF. While the exact mechanism of HRVBF's effect is still being studied, it has been suggested that enhancing the baroreflex may indicate improved autonomic balance.[6] As researchers looked for strategies to enhance HRV, they found that biofeedback using paced breathing exercises at slow respiratory rates was a potentially effective strategy to help individuals raise vagally mediated HRV values by triggering a parasympathetic response. In general, breathing at a resonance frequency of 4.5-6.5 cycles per minute (HRV) stimulates the resonant properties of the cardiovascular system, resulting in larger heart rate oscillations and, in individuals, higher HRV and other advantageous effects, including improved gas exchange.[7]

Postsurgical patients with postoperative pain can experience multiple ramifications for their health and quality of life. Despite extensive research in this field, predictors of postoperative pain are lacking. HRV has been shown to predict postoperative outcomes and postoperative pain.[8,9] Niu et al.[10] found that patients with a heart rate >70 and low HRV during anaesthesia had a higher risk of postoperative intensive care unit stay.[10] There is a need to include general stress optimization strategies in focusing preoperative stressors beyond the canonical preoperative care workup focused on surgery. Non-pharmacological interventions, in addition to usual perioperative medications, can attenuate somatic and emotional stress. Anaesthesiologists can use HRVBF at the point of care to help prevent overdose because it is an inexpensive, secure, and effective intervention. This comprehensive review aimed to explore the current evidence on the perioperative role of HRVBF in improving patient outcomes, reducing perioperative stress, enhancing recovery, and optimizing anaesthesia management.

Methods

A review of the PubMed and Google Scholar databases was conducted while searching for articles focused on HRVBF in relation to the perioperative period in the last 10 years. Studies were selected using the keywords in English (MeSH) related to "HRVBF", "HRV anaesthesiology", "HRVBF regional anaesthesia", "HRVBF post-operative pain", "HRV cancer pain", and "HRVBF stress". While describing the utility of HRVBF during the perioperative period, articles on adult and paediatric populations were mainly used.

Results

HRV is a Physiological Index that Reflects the ANS Balance

HRV is a physiological index of the delicate balance of the ANS. High HRV was observed when the PNS was predominant over the SNS, indicating good autonomic control. Analysis of HRV revealed irregularities in the activity of ANS and was associated with a higher risk of mortality in individuals with systemic diseases.[11-13] The impact of chronic illnesses, particularly cardiovascular disease, which is often associated with HRV, is widely recognized as a major obstacle for both the anaesthetist and the anaesthesiologist.[2]

The vagal nerve, which is classified as the tenth cranial nerve, is a major regulator of the body system. Indeed, there is a correlation between vagal nerve activity and other possible processes and variables that lead to pain, including age and anxiety. The holistic theory of vagal nerve pain modulation established by Gitler et al.[14] and De Couck et al.[15] emphasizes the protective role of the vagus nerve in several pain-related processes. These mechanisms include inflammation, abnormal SNS activity, and cellular oxidative stress.

In addition, when the ventral periaqueductal gray, a part of the pain brain circuitry, is stimulated at the brainstem level, it leads to a decrease in pain.[16] Further research should investigate whether alterations in brain activity patterns account for the reported association between HRV and pain.

Studies using imaging techniques and resting-state functional connectivity (RSFC) have supported the significance of the relationship between the medial prefrontal cortex and limbic regions in heart rate control.[17,18] Schumann et al.[18] conducted a comparative analysis of RSFC patterns among distinct groups of healthy individuals with varying levels of heart rate regulation in a recent paper. The findings of this study suggest that individuals with slower heart rates have a notable increase in functional connectivity (RSFC) within a functional network encompassing multiple regions of the

central nervous system (CNS) compared with individuals with faster heart rates.

HRV is derived from electrocardiogram (ECG) readings, and HRV variables are collected in both the temporal and spectral domains. Time-domain variables, such as the root mean square of successive deviations between normal heartbeats (rMSSD), are usually the best and fastest way to measure changes in HRV caused by changes in the vagus nerve.[19] rMSSD is the primary characteristic utilized in mobile HRV applications owing to its ease of acquisition and computation using brief time periods.[20]

Mechanisms Through Which HRV Biofeedback Training Affects the ANS

The HRV BF technique incorporates breathing elements and delivers data in the form of a customized digital interface.[21] The individual was positioned on a pulse monitor or ECG lead, and the resulting pulse or ECG tracing, as well as the intervals between beats, were shown on a computer monitor (Figure 1).

Decreased respiration amplifies HRV, and when the breathing rate reaches approximately six breaths per minute, the pattern becomes more pronounced and takes the shape of a sine wave. This phenomenon is commonly referred to as "resonance" or "coherence", and it can be quantified using mathematical methods and visually perceived.[22] The patient is advised to cultivate this pattern through deliberate breathing while also invoking a sense of calm.

It is widely accepted that the resonant pattern is mostly caused by increased heart rate stimulation through vagal mechanisms, namely the "brake and release" response, which occurs in coordination with respiration. It is widely acknowledged that HRV BF promotes breathing by enhancing vagal tone and promoting a calm state. Figure 2 schematizes the various mechanisms of HRVBF.

Specific Physiological and Neural Pathways Involved in HRVBF

The influence of biofeedback on brain function is unclear. Participants stimulated the primary vagal reflexes, specifically the baroreflex by modifying their breathing patterns to enhance heart rate oscillations.[23] The baroreflex is an extremely effective mechanism for regulating heart rate in the immediate term.

HRVBF might improve the input from the vagus nerve, which would then stimulate the cardiovagal brainstem nuclei in a manner similar to direct electrical stimulation. Vagal nerve stimulation affects both the central autonomic network and limbic system by modulating vagal afferent activity.[24] The nucleus of the solitary tract acts as a central hub for integrating sensory information from the periphery.[25] As part of this, signals are sent to the noradrenergic and serotonergic neuromodulator systems, and baroreceptors and lung stretch receptors process the information received.

A recent meta-analysis demonstrated the anxiety-reducing efficacy of both continuous HRVBF and one-time HRVBF.[5,26] One session of HRVBF has been shown to be beneficial for individuals with posttraumatic depression. Physiological coherence refers to the extent to which rhythmic activity within living systems exhibits peace,

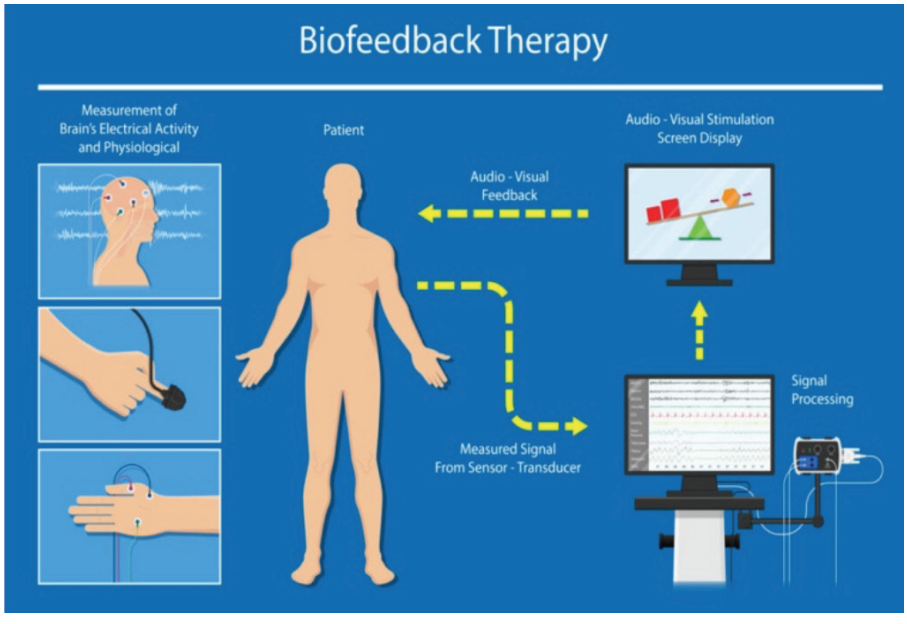

Figure 1. BIOFEEDBACK. Positive Outcomes, Inc. Accessed on May 30, 2024. https://positiveoutcomesllc.com/test-page/

equilibrium, and steadiness within a specific timeframe.[6] The objective of HRVBF is to attain elevated physiological coherence with a higher level of proficiency resulting in such coherence. Scientists have observed that activating vagal afferent pathways during high physiological coherence can change parts of the brain that control emotions. These include the locus coeruleus, orbitofrontal cortex, insula, hippocampus and amygdala.[7]

HRVBF Methods

In their systematic review, Lalanza et al.[22] described different protocols and method-related limitations. They also proposed a checklist to improve protocol quality. The three HRVBF protocols depend on the presence or absence of a previously detected resonant frequency (RF). Breathing in the range of 6.5-4.5 b m for 2 min at a time can detect RF. The participants or patients receive a special device that monitors and displays their heart rate.

1. Biofeedback devices: Specialized biofeedback devices are used to measure variability in heart rate and provide real-time feedback to patients. These devices typically consist of sensors that monitor the heart rate and software that processes the data and presents them in a user-friendly manner. Patients can observe changes in their heart rate variability patterns and learn to modulate their autonomic responses through guided exercises. Few studies have demonstrated that wearable devices display good correlation with ECG-based HRV measurements in terms of comfort, robustness, and non-invasiveness.[27]

2. Breathing techniques: Controlled breathing exercises are fundamental to HRVBF. Patients will be guided to practice slow, deep breathing patterns that can help regulate variability in heart rate and induce a state of relaxation. By synchronizing breathing with specific HRV parameters, patients can enhance their vagal tone and achieve a balanced autonomic state.[28] Deep breathing was found to be useful in lowering preoperative anxiety in 40% of presurgical patients.[29]

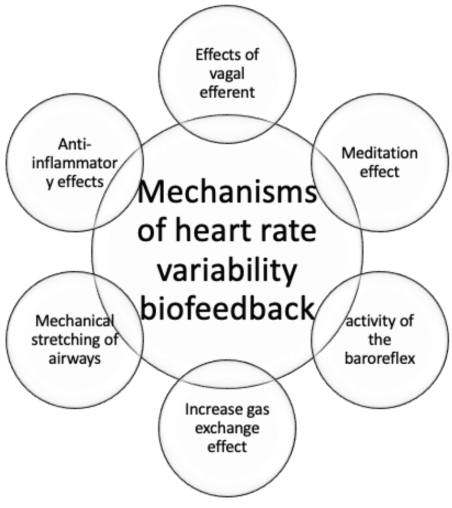

Figure 2. Schematic representation of the various mechanism of HRVBF.

HRVBF, Heart rate variability biofeedback.

3. Visual and auditory feedback: Biofeedback devices often provide visual or auditory cues to help patients regulate their heart rate variability. For example, patients may be instructed to match their breathing rate with a visual representation of their heart rate variability on a screen or by following auditory cues, such as tones or sounds that change based on their physiological state.[30] Muzzi et al.[31] evaluated the effects of intraoperative auditory stimulation on postoperative pain in children undergoing adenotonsillectomy. The researchers found a clinically significant reduction in postoperative pain and emergence delirium in children.

4. Guided imagery and relaxation techniques: Incorporating guided imagery and relaxation techniques into HRVBF sessions can enhance the effectiveness of the intervention.[32] Patients may be guided to visualize calming scenes or engage in progressive muscle relaxation exercises to promote relaxation, reduce anxiety, and improve their overall emotional well-being during the perioperative period.[33,34] It can be used as a complementary treatment to postoperative pain management in all patients.

Benefits of HRVBF in the Perioperative Setting

1. Stress reduction: Research suggests that HRVBF can effectively reduce perioperative stress and anxiety levels in surgical patients by promoting relaxation, enhancing parasympathetic activity, and mitigating the physiological stress response to surgery and anaesthesia. The authors found significantly higher preoperative anxiety in day care (34%) and inpatients (38.3%) posted for day care surgery.[35] Amalan et al.[36] investigated HRV-based stress detection and demonstrated similarity in patients' pre-surgery stress. Use has been demonstrated in obstetric patients for stress reduction in the postpartum period and in patients undergoing the first in vitro fertilization with embryo transfer.[37] van der Zwan et al.[38] examined how well self-hel pphysical activity (PA), mindfulness meditation (MM), and HRVBF helped 76 healthy volunteers deal with stress and its associated symptoms.[38] They found that HRVBF was as good as PA and MM for reducing stress and associated symptoms. Reduced stress levels not only improve patient comfort but may also positively impact surgical outcomes and recovery. A meta-analysis by Pizzoli et al.[21] showed that HRVBF is effective for improving mental well-being. HRVBF was used to effectively reduce blood pressure in 43 prehypertensive patients by Lin et al.[39] We can extrapolate

the study findings to hypertensive patients who undergo elective surgery in a pre-anaesthetic clinic to utilize HRVBF as a non-pharmacological intervention to optimize blood pressure and hence improve patient outcomes. HRVBF is associated with decreased stress levels in peripartum women, highlighting its potential as an adjuvant treatment for stress management during the peripartum period.[40] Moreover, in patients with cardiovascular disease, HRVBF has been linked to lower rates of all-cause readmissions, improved 6-min walk test results, and reduction in blood pressure.[41] HRVBF can be an effective tool to mitigate perioperative stress levels and improve overall well-being.

2. Pain management: HRVBF has shown promise as a complementary approach to perioperative pain management. By changing autonomic function, raising vagal tone, and encouraging relaxation, HRVBF techniques can help lower pain perception, opioid use, and postoperative pain medication needs, leading to better pain control and faster recovery.

These studies have shown that patients with postoperative pain have lower HRV.[42,43] The authors did not keep track of the pain score trends, which limited the study limitations due to their sampling methods (cross-sectional design). This systematic review supports an inverse relationship between HRV and pain, as shown in pragmatic studies.[44] This study also validates a CNS modulatory basis for the effects of vagal nerve stimulation on pain.

Anderson et al.[45] conducted a prospective observational study of 65 patients scheduled for laparoscopic cholecystectomy. They found that changes in the high-frequency HR variability index indicated changes in the balance between pain and analgesia.[45] Intraoperative titrate analgesia may help individual patients. Girishan Prabhu et al.[46] aimed to compare the efficacy of nature-based virtual reality (VR) and HRVBF in reduce surgical postoperative pain and anxiety. They randomly enrolled 30 patients undergoing total knee arthroplasty into three groups: control, video-assisted HRVBF, and VR with HRVBF. They found that both groups had greater PNS activity levels, and VR with HRVBF mitigated pain more than VR with HRVBF alone ($P < 0.01$). It would be beneficial to identify patients with anxiety during the preoperative period using appropriate questionnaires. It becomes the responsibility of the anaesthetist to take care of the stress, as it can have various far-reaching consequences, even in the postoperative period. VR interventions, often combined with other techniques, such as active communication and HRVBF, can effectively reduce pain and anxiety in children and adolescents undergoing various medical procedures, including surgery.[47,48]

3. Anaesthetic management: The potential impact of HRVBF on optimizing anaesthetic management during the perioperative period is worth noting. HRVBF interventions improve hemodynamic stability, anaesthesia depth modulation, and perioperative outcomes by changing vagal tone, physiological coherence, and autonomic balance. This approach has improved patient safety and perioperative care. Patients who experienced the adaptive VR-based HRVBF environment reported significant decreases in preoperative anxiety and postoperative pain after VR intervention.[49]

The depth of anaesthesia is an essential component of standard anaesthesia monitoring to prevent intraoperative awareness. It ensures safe and high-quality anaesthesia, thereby decreasing anaesthesia-related complications. HRV correlates well with anaesthesia depth.[50] Zhan et al. [50] developed an ingenious method for distinguishing various states of anaesthesia based on HRV-derived features in combination with a deep neural network.

High-frequency HRV as a marker of nociception-analgesia balance is a better choice than other usual hemodynamic changes.[51] Analgesia nociception index (ANI) and high-frequency variability index monitors (Mdoloris Medical Systems) were used to consider the HRV value.[52] The major limitation of this study is that ANI in the awake state is not conclusive because of the profound effect of the patient's emotional status.

4. Recovery and rehabilitation: Preliminary evidence suggests that HRVBF interventions could play a significant role in facilitating postoperative recovery and rehabilitation.[53,54] By promoting adaptive stress responses, enhancing resilience, and supporting physiological coherence, HRVBF may facilitate faster recovery, improved functional outcomes, and enhanced overall well-being during the postoperative period. Additionally, HRV-BF has shown promise in decreasing anxiety, improving HRV, and enhancing vasomotor function in patients with alcohol dependence, thereby complementing standard rehabilitative care.[55] A systematic review by Burlacu et al.[41] demonstrated the beneficial effects of HRVBF on various cardiovascular diseases. HRVBF can be complementary to improving postoperative outcomes in cardiac patients who undergo cardiac and non-cardiac surgery.

There is a positive relationship between increased HRV and traumatic brain injury recovery following biofeedback, including improvements in cognitive and emotional functioning and physical symptoms, such as headaches, dizziness, and sleep problems.[56,57] Anaesthesiologists, in collaboration with surgical and psychological teams, facilitated the rehabilitation of postsurgical patients using HRVBF.[58] Oncological patients frequently undergo resection for recurring tumors, especially head and neck and breast cancer. It is beneficial to reduce stress and anxiety levels to help anaesthesiologists better manage pain and achieve better functional outcomes. HRVBF can help alleviate

chronic pain in cancer survivors.[59-61] HRVB training can improve HRV coherence ratios among cancer survivors, thereby improving cancer-related symptom management.

Challenges, Limitations, and Future Directions for the Implementation of HRVBF Training in Clinical Settings

Although variability in HRVBF holds promise in the management of anaesthesia, there are several limitations and challenges associated with its use in clinical practice. Some key limitations of the proposed model include the following.

1. Training and expertise: Implementing HRVBF in anaesthesia management requires specialized training from healthcare providers, including anaesthesiologists and nursing staff. Not all medical professionals have the necessary expertise to effectively interpret HRV data and integrate it into anaesthesia care. This could potentially limit the widespread adoption of HRVBF in the clinical setting.[61] Low compliance rates in the study group and poor feasibility are some methodological limitations that researchers can face.[62]

2. Equipment and technology: HRVBF typically relies on the use of specialized equipment and technology to monitor and analyze HRV. Access to such devices may be limited in certain healthcare settings, particularly in resource-limited environments or in smaller facilities. The cost of acquiring and maintaining this technology could also be a barrier to its widespread implementation. Ectopic beats, other abnormal heart rhythms, lines, movements, or electromyogram artifacts are just a few examples of factors that can make it difficult to accurately detect RR intervals.[63] When conducting HRV data collection, studies should consider factors such as noise, temperature, illumination, humidity, time, and participant postures. It is crucial to have a strategy in place for preventing artifacts and analyzing data before commencing an HRV study. Complex, non-categorical values can impede the routine clinical application of HRV.[8] Li et al.[64] presented a technique that uses white noise to mimic the interference that wearable technology can experience in everyday situations to assess the accuracy of these devices. Further research is required in this field.

3. Standardization and guidelines: There are currently no standardized protocols and guidelines for the use of HRVBF in anaesthesia management. The absence of clear recommendations on how to incorporate HRV data into clinical decision-making may hinder its effective and consistent application across different healthcare settings.[65] Further research is needed to establish best practices and evidence-based guidelines for HRVBF in anaesthesia care.

4. Patient variability: Individual differences in patient responses to HRVBF may pose challenges in its application in anaesthesia management. Not all patients benefit equally from this technique, and factors such as age, comorbidities, and baseline physiological state can influence the effectiveness of HRVBF interventions. According to the results of a cohort study involving 167,548 people (aged 6 months to 93 years), HRV sharply decreased with age until approximately 60 years of age, at which point it stabilized.[66] Conversely, Lehrer et al.[67] found that age-associated obliteration of biofeedback changes on HRV had no effect on the efficacy of the HRVBF method in their research population involving geriatric asthmatic patients. Tailoring HRV biofeedback to each patient's unique characteristics and needs is essential to maximize its benefits.

5. Interpretation and integration: Interpreting HRV data and integrating them into clinical decision-making processes can be complex and time-consuming. Anaesthesiologists and healthcare providers must have the knowledge and skills to effectively analyze HRV parameters and translate this information into actionable insights for optimizing anaesthesia management. This process may require additional resources and training to ensure accurate and meaningful HRVBF.

6. Ethical and privacy concerns: The collection and analysis of physiological data through HRVBF raises ethical considerations related to patient privacy and data security. Safeguards must be in place to protect patient information and ensure compliance with data protection regulations. Healthcare providers must also communicate transparently with patients regarding the purpose and implications of HRVBF.

In summary, although HRV biofeedback has the potential to enhance anaesthesia management and improve patient outcomes, several limitations and challenges must be addressed to maximize its clinical utility. Overcoming these obstacles through research, education, and technological advancements will be crucial for realizing the full benefits of HRV biofeedback in perioperative care.

Future Directions

Individualized training programs are essential for optimizing the benefits of HRVBF during the perioperative period. Healthcare providers can tailor biofeedback protocols according to each patient's specific needs, considering factors such as baseline HRV levels, medical history, and surgical procedure. Customized training programs can enhance patient engagement and adherence to HRVBF intervention.

HRVBF can be integrated into anaesthesia management protocols to optimize perioperative patient outcomes. A Perioperative care model is suggested for the use of HRVBF for patient management (Figure 3). Anaesthesiologists can use HRV data to adjust anaesthetic dosages, monitor patient stress levels, and personalize anaesthetic care based on individual

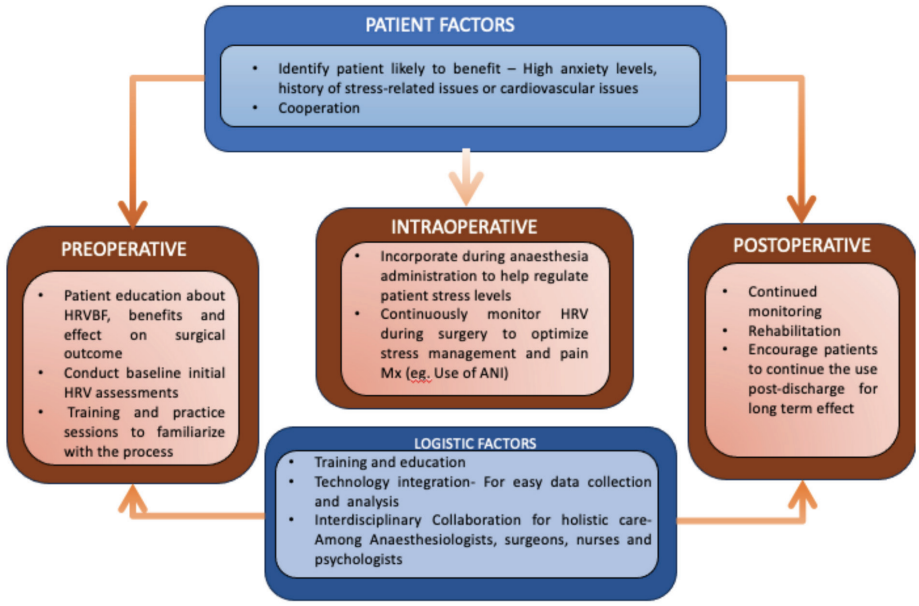

Figure 3. Perioperative care model for the use of HRVBF for patient management.

ANI, analgesia nociception index; HRVBF, Heart rate variability biofeedback.

autonomic responses. Collaboration between anaesthesia providers and biofeedback specialists is essential for the seamless integration of HRVBF into perioperative care.

Continuation of HRVBF during the postoperative period can promote recovery, reduce pain, and enhance patient well-being. Follow-up sessions and remote monitoring can help patients sustain positive outcomes and effectively manage postoperative stress.

Conclusion

While the accuracy of this approach may be uncertain in this scenario, if anaesthesiologists possess a tool capable of consistently evaluating HRV in real time may potentially employ it to adjust management. In conclusion, HRVBF is a valuable tool for perioperative care, improving patient outcomes, recovery, and anaesthesia management. By targeting autonomic regulation, stress reduction, and resilience enhancement, HRVBF techniques offer a personalized approach to perioperative care that may improve patient comfort, optimize surgical outcomes, and enhance recovery. To maximize HRVBF and advance personalized care in the perioperative setting, more research and clinical integration are needed. These improvements will ultimately lead to better patient outcomes and higher quality of care in surgical practice.

Ethics

Author Contributions: Surgical and Medical Practices - N.R.; Concept - N.R.; Design - N.R.; Analysis and/or/Interpretation - N.R., S.S.; Literature Review - N.R., S.S.; Writing - N.R., S.S.

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Cesarean Sections Under Spinal Anaesthesia: Comparison of Varying Doses of Dexmedetomidine Combined with 0.75% Hyperbaric Ropivacaine: A Double-Blind Randomized Trial

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Abstract

Objective: The primary aim of this study was to evaluate the effects of 5 µg, 7.5 µg, and 10 µg doses of dexmedetomidine added to hyperbaric 0.75% ropivacaine on the duration of analgesia during cesarean section. Furthermore, the onset of sensory and motor block, hemodynamics, sedation, and adverse effects were investigated.

Methods: A total of 120 full-term parturients scheduled for cesarean section under spinal anaesthesia were randomized into three groups. Group RD5 received intrathecal hyperbaric 0.75% ropivacaine 15 mg (2 mL) plus dexmedetomidine 5 µg (0.5 mL), group RD7.5 received intrathecal hyperbaric 0.75% ropivacaine 15 mg (2 mL) plus dexmedetomidine 7.5 µg (0.5 mL), and group RD10 received intrathecal hyperbaric 0.75% ropivacaine 15 mg (2 mL) plus dexmedetomidine 10 µg (0.5 mL). Sensorimotor blockade characteristics, analgesia duration, hemodynamic variables, and adverse events were documented. Student's t-test and the chi-square test were used for data analysis.

Results: In groups RD5, RD7.5, and RD10, the onset of sensory block was 2.96±1.32 min, 2.26±1.50 min, and 1.96±0.93 min, respectively, while the onset of motor block was 9.63±0.11 min, 8.63±0.58 min, and 6.40±0.14 min, respectively. The duration of analgesia was significantly prolonged in group RD10 compared with groups RD7.5 and RD5 (483.43±76.21 vs. 398.74±73.59 vs. 362.58±79.87 min, respectively, P=0.001). Group RD10 also exhibited significantly higher incidences of sedation, bradycardia, and vomiting.

Conclusion: We conclude that increasing dexmedetomidine doses decreases the onset of sensory and motor blockade while prolonging analgesia duration in a dose-dependent manner.

Keywords: Analgesia, cesarean section, dexmedetomidine, ropivacaine, spinal anaesthesia

Main Points

- Currently, subarachnoid block is the ideal anaesthesia option for lower-segment cesarean section deliveries.
- The main limiting factor of spinal anaesthesia is the relatively short duration of anaesthesia and analgesia, which can be overcome by adding adjuvants to intrathecal ropivacaine.
- Our goal is to ascertain the ideal intrathecal dexmedetomidine dose as an adjuvant to 0.5% hyperbaric ropivacaine for prolonging post-operative analgesia without significant adverse effects in parturients.

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Introduction

The ideal option for cesarean section is spinal anaesthesia, provided that there are no contraindications.[1] One of the very common adverse effects of spinal anaesthesia is hypotension, which is closely related to maternal and neonatal morbidity and mortality. Numerous studies have indicated that the incidence of spinal-induced hypotension can be reduced by reducing the dosage of intrathecal local anaesthetic agent.[2,3] However, this reduction in anaesthesia dosage is associated with shorter anaesthesia and analgesia durations. To overcome these disadvantages, various adjuvants, such as opioids, epinephrine, α2 agonists, etc., are recommended.[4]

In recent times, hyperbaric ropivacaine heavy has gained popularity owing to its lower potential for central nervous and cardiac toxicity compared with bupivacaine heavy. However, ropivacaine exhibits less potency, and the motor block duration is shorter than that of bupivacaine.[5] As a result, spinal anaesthesia using hyperbaric ropivacaine is primarily reserved for cesarean sections.[6] Numerous studies have explored the efficacy of intrathecal ropivacaine in combination with adjuvants such as fentanyl and sufentanil for cesarean delivery.[7,8]

Dexmedetomidine exhibits eightfold higher affinity for alpha 2 receptors in contrast to clonidine, and it is a selective alpha 2 agonist. In clinical practice, dexmedetomidine is widely used as an additive in local, regional, and general anaesthesia. Although dexmedetomidine has been approved by the Food and Drug Administration for intravenous (i.v) sedation in the intensive care unit, it has recently become a popular adjuvant to local anaesthetic agents. When dexmedetomidine is used in combination with local anaesthetics in subarachnoid block, it elongates the timespan of sensory and motor blocks, as well as postoperative analgesia, without causing significant sedation.[9]

There has been a lack of extensive research comparing the effects of dexmedetomidine, when used as an adjuvant, in different doses with intrathecal ropivacaine during cesarean section. Therefore, this study aimed to analyze the efficacy of varying doses of dexmedetomidine as an additive to 0.75% hyperbaric ropivacaine. In this study, we hypothesized that the inclusion of dexmedetomidine as an adjuvant to intrathecal 0.75% hyperbaric ropivacaine during cesarean section could enhance intraoperative blockade conditions, extend analgesic duration in the post-operation period, and maintain minimal impact on motor block while presenting negligible side effects.

In this randomized trial, our primary aim was to evaluate the effects of 5 µg, 7.5 µg, and 10 µg doses of dexmedetomidine added to hyperbaric 0.75% ropivacaine on the duration of analgesia in parturients scheduled for cesarean section. Furthermore, the onset of sensory and motor block, hemodynamics, sedation, and adverse effects were investigated.

Methods

This prospective, double-blind (patient and assessor-blinded) randomized trial was conducted from November 2023 to April 2024. This research was approved by the Institutional Ethics Committee of Government Medical College, Kadapa (approval no.: ACAD./E3B/2022-2023, dated: May 27, 2023), and the trial was registered in the Clinical Trials Registry-India (register no.: CTRI/2023/10/059021; URL: https://ctri.nic.in/ Clinical trials). This study was conducted in accordance with the guidelines of the Declaration of Helsinki (2013).

One hundred twenty full-term parturients aged 21-32 years, with American Society of Anesthesiologists (ASA) physical status II, who were scheduled for lower-segment cesarean delivery with subarachnoid block were included after waiving written informed consent. Exclusion criteria comprises gestational age <36 weeks; parturients with body mass index (BMI) >35 kg m^{2-1}, history of more than one previous cesarean delivery, placenta previa, ruptured membranes, intrauterine growth restriction, hypertension or pre-eclampsia, diabetes or gestational diabetes, and any contraindications to regional anaesthesia, such as bleeding disorders or local site infection.

Block randomization was performed using a computer-generated block random number table to randomly assign 120 full-term parturients into one of the three groups (Figure 1). The allocation sequence was concealed within sealed envelopes and opened by a senior resident who was not involved in the investigation. The study solutions were prepared under sterile conditions in advance and enclosed within masked 3 mL syringes according to randomization to maintain blinding. The treatment group remained unknown to the anaesthesiologist monitoring the patient, collected data, and administered the block. The three groups were designated as follows: group RD5, which received intrathecal 0.75% hyperbaric ropivacaine 2 mL plus dexmedetomidine 5 µg (diluted in 0.5 mL normal saline); group RD7.5, which received intrathecal 0.75% hyperbaric ropivacaine 2 mL plus dexmedetomidine 7.5 µg (diluted in 0.5 mL normal saline); and group RD10, which received intrathecal 0.75% hyperbaric ropivacaine 2 mL plus dexmedetomidine 10 µg (diluted in 0.5 mL normal saline).

As per institutional protocol, all patients were given 150 mg of oral ranitidine the night before surgery and were usually fasted prior to surgery. Standardized monitoring, including oxygen saturation (SpO2), pulse rate, systolic and diastolic non-invasive blood pressure, and electrocardiogram measurements, was performed during the perioperative

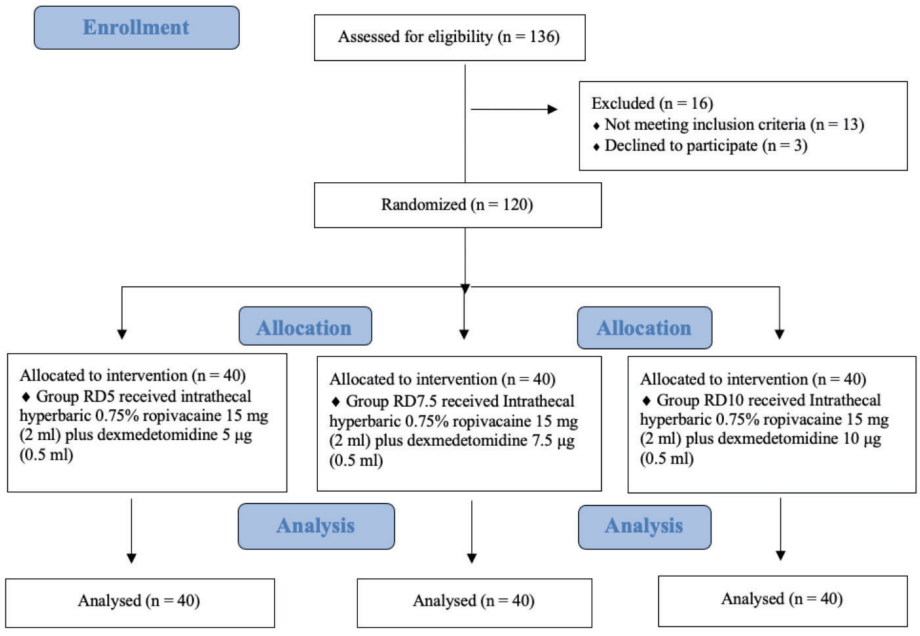

Figure 1. Consort diagram demonstrating the randomization.

phase. Intravenous access was established using an 18/20-G cannula, with all patients receiving a preload of 10 mL kg^{-1} of crystalloid solution. Pantoprazole 40 mg and ondansetron 4 mg were administered intravenously. Spinal anaesthesia was administered in the sitting position using a 26-G Quinke needle under strict aseptic and antiseptic precautions in the L3-L4 intervertebral space. All patients received 2.5 mL of the drug, regardless of their study group. After intrathecal injection, patients were positioned supine, and their vital signs [heart rate, systolic blood pressure (SBP), DBP, and SpO2] were recorded at 2, 5, 10, and 15 min intervals until the surgery concluded, followed by every 30 min for 6 hours during the postoperative period. A SBP below 90 mmHg or a drop of more than 20% from the basal systolic pressure was referred to as hypotension. Hypotension was managed with a bolus of 100 µg of i.v phenylephrine, and repeated if necessary. Bradycardia, which was defined as a heart rate below 60 beats per minute, was managed with i.v atropine (0.6 mg).

An 18-G epidural needle was gently inserted along the medioventral line to assess the degree of sensory block loss due to pinprick. The onset time was defined as the duration from drug administration into the subarachnoid space until the achievement of the T10 sensory block level. The length of the sensory block was defined as the time interval between the onset and two-segment regression of the block. The lower limb motor block level was determined using the Modified Bromage Score.[10]

The motor block onset time was defined as the time interval between spinal drug administration and the achievement of a Modified Bromage Score of 1. The length of spinal analgesia was defined as the time interval from intrathecal injection to the first time the patient required postoperative analgesia. Analgesic effectiveness was assessed by visual analogue scale (VAS), ranging from 0 to 10 cm scores (0=no pain, 10=most severe pain) recorded on marked paper strips intraoperatively every 15 minutes and postoperatively every half-hour until the first rescue analgesic was administered. Rescue analgesia (1 gm i.v paracetamol) was administered if the VAS score exceeded 3. Adverse events, like sedation, postoperative nausea and vomiting were recorded and treated accordingly. Sedation levels were evaluated using the modified Ramsay sedation scale.[11]

Statistical Analysis

Power analysis was conducted based on the findings of a prior study by Kapinegowda et al.,[12] which demonstrated that dexmedetomidine can decrease the onset time of sensory and motor blockade while prolonging the duration of anaesthesia and analgesia in a dose-proportional fashion. Based on these results, with 5% type 1 error and 80% power, a minimum sample size of 37 patients per group was required. To validate the results, we included 40 patients in each group. Using Statistical Package for the Social Sciences (SPSS, IBM, Armonk, NY, USA) version 23.0 for Windows, data was analyzed. Continuous and categorical variables are represented as mean [standard deviation (SD)]

and frequencies (percentages), respectively. To determine the association between quantitative continuous variables, one-way ANOVA followed by Bonferroni's multiple comparison test was used. To assess the association between qualitative variables, the chi-square test followed by pairwise comparison was used. *P* value of <0.05 was considered statistically significant.

Results

One hundred and thirty-six patients were evaluated for acceptability, and 120 patients were equally distributed among the study groups through randomization. Sixteen patients were not included in the randomization process because they either declined to provide consent or did not meet all eligibility criteria. Figure 1 illustrates the patient flow in the investigation according to Consolidated Standards of Reporting Trials recommendations.

Age, height, weight, BMI, gestational age, fetal delivery duration, and surgery duration were comparable between the three groups (Table 1). No statistically significant differences were observed in baseline hemodynamic variables among the three study groups ($P > 0.05$).

The onset of sensory and motor blocks was significantly quicker in group RD10 than in groups RD7.5 and RD5. There was a dose-related significant curtailment of the mean time to the highest sensory block (mean ± SD, 2.96±1.32, 2.26±1.50, and 1.96±0.93 min; $P < 0.001$) and mean time to the highest motor block (5.96±0.72, 5.60±1.16 and 5.43±1.075 min; $P < 0.001$) with increasing dexmedetomidine doses of 5, 7.5, and 10 µg, respectively. The time required to reach the highest level of sensory block was statistically insignificant across the groups (P=0.402). However, the time taken for two-segment sensory regression was significantly different among the groups: 97.26±33.67 min in group RD5, 119.18±34.27 min in group RD7.5, and 127.46±31.24 min in group RD10 (P=0.014). This difference indicates an earlier regression in group RD5 compared with groups RD7.5 and RD10 (Group RD5 < Group RD7.5 < Group RD10) (Table 2).

The sensory reclamation time was greatest in group RD10 compared with groups RD7.5 and RD5 (RD10 > RD7.5 > RD5). The times required for total sensory reclamation (Table 2) was 328.83±63.41 min in RD5, 345.13±66.38 min in RD7.5, and 421.21±94 min in RD10 which is statistically highly significant ($P \leq 0.001$).

Motor blockade onset was observed in RD10 at 6.40±0.14 min, RD7.5 at 8.63±0.58 min, and RD5 at 9.63±0.11 min. Motor block onset was earlier in RD10 than in both RD7.5

Table 1. Demographic Data

Variable	RD5 (n = 40)	RD7.5 (n = 40)	RD10 (n = 40)	*P* value
Age (years)	26.9±5.1	25.2±6.4	25.8±4.7	0.552
BMI (kg m^{-2})	23.04±2.50	23.05±2.81	22.91±2.74	0.663
Gestational week (weeks)	38.6±1.1	38.2±1.4	37.8±1.9	0.069
Fetal delivery time (min)	23.7±5.2	24.0±3.7	23.6±4.7	0.124
Duration of surgery (min)	57.2±10.3	58.0±9.1	60.4±13.9	0.194

Data are expressed as mean ± SD.
SD, standard deviation; BMI, body mass index

Table 2. Properties of Subarachnoid Blocks

Variable	RD5 (n = 40)	RD7.5 (n = 40)	RD10 (n = 40)	*P* value
Time of onset of sensory block (min)	2.96±1.32	2.26±1.50	1.96±0.93	0.025
Time to achieve maximum Level of the sensory block (min)	5.96±0.72	5.60±1.16	5.43±1.075	0.402
TTSSR (min)	97.26±33.67	119.18±34.27	127.46±31.24	0.014
TCSR time to complete Sensory recovery (min)	328.83±63.41	345.13±66.38	421.21±94.6	<0.001
Total duration analgesia (min)	362.58±79.87	398.74±73.59	483.43±76.21	<0.001
Time to rescue analgesia (min)	417.42±68.05	451.68±64.11	537.86±73.30	<0.001
Time of onset of motor blockade (min)	9.63±0.11	8.63±0.58	6.40±0.14	<0.001
Total duration of motor blockade (min)	331.93±83.67	364.23±82.39	411.23±84.41	0.046

TCSR, time to complete sensory recovery; TTSSR, time taken for two-segment sensory regression

Table 3. Comparison of Adverse Events

Side effect	Group RD5, n (%)	Group RD7.5, n (%)	Group RD10, n (%)	*P* value
Sedation score (>3)	11 (27.5%)	15 (37.5%)	18 (45%)	0.044
Bradycardia (HR <50 bpm)	6 (15%)	12 (30%)	19 (47.5%)	0.020
Hypotension (MAP <60 mmHg)	5 (12.5%)	5 (12.5%)	12 (30%)	0.364
Vomiting	0	0	2 (5%)	0.024

Values are illustrated as number of patients.
HR, heart rate; MAP, mean arterial pressure

Table 4. Neonatal Umbilical Cord Blood Air and Apgar Scores

Parameter	Group RD5	Group RD7.5	Group RD10	*P* value
PH	7.34 (7.32, 7.37)	7.36 (7.33, 7.38)	7.34 (7.32, 7.37)	0.464
PO_2	30.0 (22.5, 35.0)	32.0 (26.0, 39.0)	31.0 (21.0, 37.5)	0.491
PCO_2	43.0 (39.0, 46.5)	46.0 (39.0, 48.5)	43.0 (39.0, 47.0)	0.820
1 min Apgar	9.0 (8.0, 9.0)	8.5 (8.0, 9.0)	9.0 (8.0, 9.0)	0.061
5 min Apgar	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)	9.0 (9.0, 10.0)	0.368

Data are expressed as medians

and RD5 (RD10 < RD7.5 < RD5), which was statistically significant ($P \leq 0.001$).

The total motor blockade duration in RD10 was a comparatively prolonged duration of 411.23±84.41 min, than RD7.5 (364.23±82 min) and in RD5 was (331.93±83.67 min), which was statistically significant (*P*=0.046).

Similarly, the total duration of analgesia was significantly longer in RD10 (537.86±73.30 min) than in RD7.5 (451.68±64.11 min) and RD5 (417.42±68.05 min), which was statistically significant ($P \leq 0.001$). The findings indicated that the dosage had a direct impact on the total duration of motor blockade; the more the dosage, the more prolonged the block.

Adverse effects, such as sedation, bradycardia, and vomiting, were higher in patients with RD10 than in those with RD7.5 and RD5 (Table 3). However, regarding the incidence of hypotension, no significant difference was observed between the groups (*P*=0.364). Bradycardia was well managed with a solitary dose of 0.6 mg atropine sulfate i.v and did not recur. Without further deterioration, hypotension was managed with a 200 mL bolus of isotonic i.v fluids and a bolus of 100 µg of i.v phenylephrine, and repeated if necessary. Notably, a significantly greater number of patients in group RD10 exhibited a maximum sedation score (>3) than those in groups RD7.5 and RD5 (*P*=0.044).

There were no significant differences in neonatal Apgar scores or analyses of umbilical cord blood gas, which included pH, partial pressure of oxygen, and partial pressure of carbon dioxide among the groups ($P > 0.05$) (Table 4).

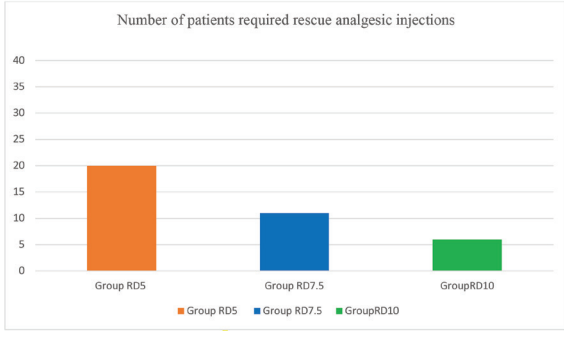

Figure 2. Rescue analgesic demand in postoperative period (*P*=0.037).

Discussion

In this randomized prospective research, it was observed that administering 5 µg, 7.5 µg and 10 µg of dexmedetomidine with 0.75% hyperbaric ropivacaine for spinal anaesthesia in parturients scheduled for elective lower uterine segment cesarean section accelerated the onset of sensory and motor blockade, prolonged the duration, and enhanced postoperative analgesia in a dose-dependent manner. A comparatively smaller number of patients (15%) in group RD10 required i.v paracetamol [1 gm i.v] as a rescue analgesic than those from group RD7.5 (27.5%) and group RD5 (50%) (Figure 2). Bradycardia incidence was elevated in the RLD10 group (47.5%) compared with the RD7.5 and RD5 groups. Higher dexmedetomidine doses also led to increased sedation (*P*=0.044).

Dexmedetomidine is a centrally acting α2 adrenergic agonist that is eight times more selective than clonidine.

It is a safe and useful adjuvant in a variety of anaesthetic and analgesic protocols. It has sedative, sympatholytic, and analgesic effects.[13] It does not include stabilizers or additives and is offered as a solution without preservatives. It prolongs motor and sensory blockade by local anaesthetics when administered intrathecally as an adjuvant, thereby providing supraspinal analgesia. This could be a consequence of the synergistic or cumulative effect of various modes of action of different local anaesthetics. The principal focus of this study was to evaluate the potency and safety of dexmedetomidine at three different doses when combined with 0.75% hyperbaric ropivacaine in achieving adequate intraoperative anaesthesia and elongation of analgesia duration during spinal anaesthesia.

In several experimental and clinical studies, dexmedetomidine was successfully used in neuraxial blocks without inducing neurological deficits. Its intrathecal administration in humans has been advocated for concentrations ranging from 2.5 µg to 15 µg in conjunction with numerous local anaesthetics.

In this study, the onset of sensory and motor blockade was observed to occur sooner with a high dose of dexmedetomidine (10 µg) than with dexmedetomidine doses of 7.5 µg and 5 µg. These findings align with those of Halvadia and Patel,[14] who reported that subarachnoid administration of dexmedetomidine, in conjunction with hyperbaric 0.5% bupivacaine, accelerated the onset of sensory and motor block onset. In the present prospective study, we also observed a significant and consistent lengthening of the duration of sensory and motor block with increasing subarachnoid dexmedetomidine dosage. Sudheesh et al.[15] also reported a similar finding, where the authors compared doses of 3 µg and 5 µg of dexmedetomidine combined with 0.5% bupivacaine (4 mg) in 50 patients who underwent ambulatory surgeries for perianal diseases. They observed significant dose-related escalation in both sensory and motor block durations.

Another study by Modir et al.[16] concluded that the duration of analgesia was prolonged in parturients who received a higher dose of dexmedetomidine (7.5 µg) in 2.5 mL of heavy 0.75% ropivacaine compared with 2.5 and 5 µg of dexmedetomidine in spinal anaesthesia. They also found that the addition of 7.5 µg of dexmedetomidine to intrathecal 0.75% ropivacaine heavy produced stable haemodynamic parameters and block characteristics compared with lower intrathecal dexmedetomidine doses in patients scheduled for cesarean section. However, likely complications, such as falls in both blood pressure and heart rate, should be taken into account simultaneously. These results are similar to those of our study.

The total analgesia duration showed a dose-dependent relationship across groups RD5 (362.58±79.87 min), group RD7.5 (398.74±73.59 min), and RD10 (483.43±76.21 min), which was statistically significant ($P \leq 0.001$). Prior studies have noted significant dose-dependent differences among the groups, indicating similar findings.[17,18] In a comparative study by Gupta et al.,[19] the influence of three doses of dexmedetomidine (dexmedetomidine 2.5 µg, 5 µg, and 10 µg) combined with 15 mg of bupivacaine heavy 0.5% was studied and assigned into three groups (n = 30) on patients undergoing elective lower limb and abdominal surgeries. As in previous investigations, they examined both sensory and motor blockade properties and also differential analgesia, (the differential analgesia is defined as the interval between the end of the motor blockade and the first analgesic demand).[20] Researchers discovered that an increase in intrathecally administered dexmedetomidine dosage from 2.5 µg to 10 µg led to increases in motor block, sensory block, and analgesia durations of 41.28%, 67.28%, and 208.37%, respectively. Prolonged analgesia duration has the advantage of reducing the incidence of complications of postoperative pain (e.g., the risk of neuro-sensitization, delayed wound healing, prolonged hospitalization), thereby minimizing chronic pain and prolonged motor blockade-related issues, such as deep venous thrombosis, reduced mobilization, and pulmonary embolism.

Keplinger et al.[21] studied the dose dependency of dexmedetomidine when combined to ropivacaine in peripheral nerve blockade. In this investigation, 22.5 mg of only ropivacaine (R) or in combination with 50 µg (RD50), 100 µg (RD100), or 150 µg (RD150) of dexmedetomidine was administered as an ulnar nerve block to each subject. A significant increase was observed in the mean duration (SD) of analgesia with dexmedetomidine when administered at increasing doses: R = 8.7 h, RD50 = 16.4 h, RD100 = 20.4 h, and RD150 = 21.2 h. Additionally, there was a dose-dependent increase in sedation. These outcomes are consistent with our results. Adding dexmedetomidine potentiated the analgesic effect of 0.75% hyperbaric ropivacaine in spinal anaesthesia in a dose-related manner. In this study, a lower number of patients in the RD10 group required i.v paracetamol as rescue analgesia compared with groups RD5 and RD7.5 ($P < 0.05$). Our observations are consistent with those of Bi et al.[22]. Similarly, Kapinegowda et al.[12] also observed that i.v diclofenac sodium (aqueous base) 75 mg was administered as a rescue analgesic in the subarachnoid 0.5% heavy bupivacaine combined with the 10 µg dexmedetomidine group compared to 7.5 µg and 5 µg dexmedetomidine groups for infra umbilical surgeries.[13]

In this study, adverse effects, especially sedation, bradycardia, and vomiting, were exhibited at a notably higher frequency in group RD10 than in groups RD5 and RD7.5. The occurrence of hypotension did not exhibit statistical significance across the three groups. These adverse reactions are typically manageable. Dexmedetomidine's sedative

characteristics of dexmedetomidine stem from its lipophilic properties, leading to systemic absorption upon intrathecal administration. Significant sedation was observed with larger doses of dexmedetomidine (1.5 µg kg^{-1}) in conjunction with caudal ropivacaine compared with plain ropivacaine for postoperative analgesia in pediatric ambulatory surgeries.[23] However, this did not result in patient discharge delays.

Study Limitations

We only included healthy individuals with ASA II in our study. The effects of intrathecal in patients with ASA III and IV and those with comorbidities have not yet been studied. Another limitation was that participants with a BMI >35 kg m^{-2} and age >32 years were not included in our study. Therefore, the findings cannot be applied to pregnant women. Furthermore, a lengthy postoperative follow-up was lacking in our investigation to identify possible neurological problems. Despite these limitations, it is important to highlight that this study produced several important findings. Additionally, prospective studies are required to determine the efficacy of various dexmedetomidine doses as adjuvants in neuraxial block for parturients undergoing lower segment cesarean section.

Conclusion

Adding 10 µg of dexmedetomidine to hyperbaric 0.75% ropivacaine in spinal anaesthesia results in a prolonged analgesic effect compared with doses of 7.5 µg and 5 µg. Additionally, the higher dosage enhances the onset and extends the duration of sensorimotor blockade. However, higher dexmedetomidine doses result in a higher incidence of sedation and bradycardia, necessitating close monitoring.

Ethics

Ethics Committee Approval: This research was approved by the Institutional Ethics Committee of Government Medical College, Kadapa (approval no.: ACAD./E3B/2022-2023, dated: May 27, 2023).

Informed Consent: Written informed consent was obtained from all participants.

Author Contributions: Surgical and Medical Practices - S.R.N., S.C.; Concept - S.R.N., S.C.; Design - S.R.N., S.C.; Data Collection and/or Processing - V.B., S.Kani.; Analysis and/or/Interpretation - S.K., S.S.; Literature Review - S.R.N., S.C.; Writing - S.R.N., S.C.

Declaration of Interests: The authors declare no conflicts of interest.

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Evaluation of Operating Room Staff Awareness of Environmental Sustainability and Medical Waste Management

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Abstract

Objective: This study aims to identify the obstacles to recycling and environmental sustainability habits in a university hospital's operating room (OR) environment in Turkey and lay the groundwork for potential solutions.

Methods: A questionnaire was used to measure current views among the 140 OR staff members aged 20-54 years. The survey assessed awareness and behaviors of recycling at home and in the OR, as well as awareness of environmentally safe anaesthesia practices.

Results: Half of the participants believed that ORs significantly affected their carbon footprint, and most agreed that these environmental effects could be reduced. The primary barriers to recycling were inadequate knowledge, negative staff attitudes and insufficient services. Notably, 76% of participants paid attention to segregating OR waste, yet many lacked formal education about the environmental impact of their practices. Approximately 89% agreed that the environmental effects of ORs could be further reduced, with education being a critical need.

Conclusion: The healthcare sector's contribution to carbon emissions and waste production is significant, especially in ORs. The lack of education regarding ecological implications is concerning. Implementing standardized training programs and enhancing recycling services can substantially reduce the environmental impact of ORs, highlighting the need for a more sustainable healthcare system.

Keywords: Anaesthetics, carbon footprint, environment, global warming, operating rooms, recycling

Main Points

- This study identified critical barriers in medical facilities that hinder the implementation of sustainable waste management, including inadequate staff training, employee disinterest and a lack of accessible recycling services.
- A pivotal finding is the absence of standardized environmental education in healthcare education. This underscores the urgent need for comprehensive and integrated training programs in medical schools.
- Enhanced environmental practices, especially in operating rooms, emerge as a potential area for improvement, focusing on the need for better education and recycling services.
- This research highlights the critical role of educational initiatives in environmental sustainability and emphasizes examining the actual conditions of medical workplaces to drive change.
- Comparisons with international studies illustrate common challenges in achieving environmental sustainability in healthcare, regardless of country or medical setting.

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Introduction

The increasing occurrence of global warming necessitates an urgent reassessment of environmental policies across all sectors, including healthcare. The healthcare industry, which is a significant contributor to carbon emissions, bears a substantial environmental footprint. Citing a University of Chicago study, the healthcare sector in the United States accounts for 8% of the nation's total greenhouse gas emissions.[1] Hospitals, with their energy consumption being 2-3 times higher than a residential building of comparable size, also generate approximately 5.9 tons of waste annually. Notably, operating rooms (ORs) are responsible for approximately 21% of this waste.[2] Given that infectious waste requires specialized handling, such as incineration and chemical treatment, misclassification and improper management can exacerbate environmental damage.

This study explores current attitudes and practices concerning recycling and environmental sustainability within OR settings, along with a comparative analysis with prior studies to identify areas for improvement and understand how regional differences may impact these practices.

Methods

This cross-sectional study was conducted at a single center, involving 140 participants from OR staff (including anaesthesiologists, surgeons, residents, nurses and cleaning staff) to medical students at Ankara University. Ethical committee approval was secured prior to the study from the Ankara University Faculty of Medicine, Human Research Ethics Committee (approval no.: İ4-165-19, date: 10.10.2019). Participants were provided survey forms and informed consent documents. Survey forms were recycled after digitization.

Our inclusion criteria were anyone who consented to participate in this study and of any age and gender who disposes of waste from the OR, consisting of anaesthesiologists, surgeons, residents, nurses, cleaning staff, and medical students. The criteria for exclusion were forms lacking essential demographic details like age, gender, and occupation, as well as forms where more than 20% of the survey questions were left unanswered. For additional information, refer to the study flowchart.

Before the analysis, we grouped occupations based on the observed waste generation amount and similar educational backgrounds into four main groups to simplify the analysis: Doctors (Anaesthesiologists/Surgeons), Nurses/Technicians (Anaesthesia Nurses/Technicians, OR Nurses), medical students, and cleaning staff.

Out of 18 questions we prepared for our survey (the full survey form is included in the Appendix 1), we questioned basic demographic information such as age, gender, occupation, and years the participant practiced. We also examined the following:

Awareness and behaviors related to recycling at home or OR, understanding of environmentally safe anaesthesia practices and behaviors.

Likert scales were used to assess participants' beliefs about ORs' environmental impact, the potential for minimizing this effect through waste management and energy consumption reduction, and willingness to alter their work practices to reduce these impacts.

We assigned five specific questions to those working in anaesthesia practice (anaesthesiologists and anaesthesia technicians). These questions inquired about whether sevoflurane or desflurane is safer for the environment, the ways in which these gases harm the environment, whether a low or high fresh gas flow is more environmentally safe, and whether participants have received training on the environmental effects of anaesthesia practice, including the source of this training. Additionally, we asked about the three most significant barriers they encountered in their work, their interest in receiving education about recycling in the OR, and an open-ended question regarding their desired changes in the OR to better protect the environment.

Statistical Analysis

An initial sample size of 110 was selected randomly to assess the effect of sample size, and a power calculation was performed using G*Power 3.1.9.2. A minimum participant count of 60 was determined to be statistically significant with a 95% power and an $\alpha = 0.05$ error probability.

The survey data were managed in a spreadsheet format and analyzed using SPSS v11.5. Continuous data were tested for normal distribution, and various statistical tests (t-test & Mann-Whitney U test for comparisons between two groups, ANOVA & Kruskal-Wallis variance analysis for comparing more than two groups) were employed to analyze the data. Pearson's chi-square test or Fisher's exact test was used to compare nominal variables. P=0.05 was accepted as the threshold for statistical significance.

Results

Among the 140 participants, we excluded 8 participants with incomplete demographics and forms. The participants were between 20 and 54 years old, with a median age of 28, and the gender distribution was 66% female to 34% male (Table 1).

Fifty-six percent of the participants believed that ORs have an essential effect on the carbon footprint and global warming, whereas 44% expressed no opinion. Twenty-one percent said they frequently recycled at home, 30.3% sometimes did, and 24.2% rarely recycled at home (Table 2).

Eighty-nine percent of the participants agreed that OR environmental effects can be further decreased, and 73% stated that while working in the OR, they try to take measures to reduce the ecological impact of ORs.

Seventy-six percent of participants reported paying attention to segregating OR waste, whereas 14.6% rarely or never do. When asked about the preferred anaesthetic agent, most doctors (90%) and 64% of the anaesthesia technicians stated sevoflurane. Three-quarters of the participants knew sevoflurane was the safest anaesthetic agent compared with desflurane;[3,4] however, 27% stated they needed more information.

Forty-eight percent of the anaesthesia nurses/technicians believe that low-flow desflurane is the environmentally safest practice. At the same time, 75% of the physicians believe that low-flow sevoflurane is the safest, which we found statistically significant between the occupational groups (Table 3, $P < 0.001$).

Half of the doctors and 79.3% of the nurses/technicians expressed that they had no prior education about the effects of anaesthesia practices on the environment. Only 60% of the anaesthesia care providers had previous education on this topic. Within this group, 42% had information from a colleague, 18% from curricular sources, 9% from conferences, and 24 from other sources.

The most frequently reported barriers to OR recycling were inadequate knowledge (82.6%), negative staff attitudes toward recycling (75%), insufficient recycling services (44.6%), and time constraints (46.2%). Nearly all (95.5%) participants believed that education about OR recycling is necessary.

Based on the 63 responses, essential suggestions to lessen the environmental impact of ORs include prioritizing waste management and efficient handling of sterilization solutions, enhancing education and awareness through staff training and informative materials, improving OR infrastructure like ventilation systems, fostering a change in staff attitudes toward environmental practices and boosting operational efficiency by reducing workload and optimizing resource use such as electricity.

Table 1. Demographic Data (n=132)

	Median (years)	Range (years)
Age	28	20-54
Years in practice	4	0.33-30
Gender	**Frequency (n)**	**Percentage (%)**
Female	87	65.9
Male	45	34.1
Occupational group	**Frequency (n)**	**Percentage (%)**
Doctors	46	34.8
Nurses/Technicians	45	34.1
Cleaning staff	15	11.4
Medical students	26	19.7

Table 2. Do You Segregate Recyclable Waste at Home? (n=132)

	Frequency (n)	Percentage (%)
Always	9	6.8
Often	28	21.2
Sometimes	40	30.3
Rarely	32	24.2
Never	23	17.4

Discussion

In recent years, environmentally safe medical and anaesthesia practices have gained increasing attention. Multiple organizations have published guides and statements highlighting the importance of minimizing the environmental impact of clinical practice and personal life. Most highlighted recommendations include the use

Table 3. Which Anaesthesia Practice is Safe for the Environment? (n=55, $P < 0.001$)

		Low-flow sevoflurane	High-flow sevoflurane	Low-flow desflurane	High-flow desflurane	No opinions
Doctors	Frequency (n)	21	1	5	0	1
	Percentage (%)	75.0%	3.6%	17.9%	0.0%	3.6%
Nurses/Technicians	Frequency (n)	5	0	13	1	8
	Percentage (%)	18.5%	0.0%	48.1%	3.7%	29.6%
Total	Frequency (n)	26	1	18	1	9
	Percentage (%)	47.3%	1.8%	32.7%	1.8%	16.4%

of environmentally safer medications (local anaesthetics and nerve blocks being the safest option), equipment, ultra-low fresh gas rates when using inhaled agents, and reduction and reuse of materials, when possible, without compromising patient safety. Incorporating environmental education within the medical curriculum and emphasizing that conducting medical research itself can also increase the carbon footprint.[5-7]

Our study surveyed environmental awareness in a single center, revealing significant barriers to reducing the carbon footprint of ORs. Only half of the respondents recognized the ecological effects of ORs, and nearly all acknowledged the importance of recycling. Recognition of the importance of recycling is a positive indicator that healthcare professionals are willing to engage in sustainable practices. However, limited awareness of the broader ecological impacts of OR indicates the need for more comprehensive educational initiatives. Additionally, half of the participants cited time constraints, highlighting the need for changes that integrate sustainable practices into the workflow without adding to the workload. Providing dedicated staff and ensuring that sustainable practices are efficient and rationalizing waste segregation processes so that there are no uncertainties when managing or generating waste can help address these issues.

Although most respondents claimed to segregate OR waste, the need for proper education raises concerns about the effectiveness and safety of OR methods. Notably, 16% of patients were admitted to seldom segregating OR waste, highlighting the need for stringent waste segregation practices for infection control and health safety, especially in large hospitals with substantial waste generation.

Our study identified significant barriers to recycling in ORs, which is consistent with previous research. The most frequently reported obstacles were inadequate knowledge (82.6%), negative staff attitudes (75.0%), insufficient recycling services (44.6%) and time constraints (46.2%). Nearly all participants (95.5%) agreed that education about OR recycling is necessary. These findings were similar to those of McGain et al.[8], where half of 780 fellows from the Australian and New Zealand College of Anesthetists reported inadequate recycling facilities as a primary barrier, alongside negative staff attitudes (17%) and inadequate information on recycling (16%). Similarly, Petre et al.[9] found that while nearly all the 426 Canadian anaesthesiologists were willing to recycle at work, only 30% did so, citing a lack of support from hospital leadership (63%) and insufficient education (62%) as major barriers. The high willingness to recycle contrasted sharply with the low implementation rate, underlining the need for systemic support and appropriate educational initiatives.

Our study further revealed that only 35% of the participants had received any education on recycling, with a mere 21% having received formal education from the curriculum and conferences. This percentage compared to less than half (42.6%) of Petre et al.'s[9] respondents who had received prior formal training. These educational gaps highlight the necessity for comprehensive and structured training programs to raise awareness and competence in sustainable practices.

Most of the nurses and technicians had no prior experience in their daily practices. While many agree that low fresh gas flow is safer, they consider low-flow desflurane to be the safer option for the environment compared with sevoflurane, avoiding high-impact anaesthetics such as desflurane and nitrous oxide is essential due to their substantial climate impact and limited clinical benefits.[5]

Moreover, our participants provided suggestions that they think minimize the environmental impact of ORs, including prioritizing waste management, enhancing education and awareness, improving OR infrastructure, fostering positive staff attitudes, and optimizing resource use such as electricity. These recommendations resonate with the current guidelines and reinforce the idea that multifaceted approaches are needed to address the environmental impact of ORs.[5,6]

Incorporating environmental sustainability into formal anaesthesia education and research programs is vital. Anaesthesia providers should lead sustainability initiatives within healthcare organizations and collaborate with industry to enhance environmental practices. It is important that educational and policy initiatives must consider the realities of the OR environment, such as high patient turnover, and focus on practical, achievable training programs.

Study Limitations

This study is limited by its single-center, small-scale nature, which may not represent the diversity of anaesthesiologists' practices across Turkey. Non-response bias and acquiescence bias could also have influenced the results. Multi-center and more extensive scale studies are needed to gain a more comprehensive and accurate representation of workplace habits and barriers in Turkey.

Conclusion

As the healthcare sector increasingly recognizes the environmental impact of inhalation agents, the current lack of education about their ecological implications has become a critical concern. In our study, most participants showed an interest in education, and nearly all expressed that they had yet to receive formal education on this issue. Standardized and repeatable curricula should be implemented in residency training programs; simulation-based programs can also help increase recycling awareness and behavior. With improved

training and accessibility to recycling services, along with the widespread adoption of consistent recycling behaviors among OR staff, minor changes in daily practice can significantly reduce the impact of ORs on carbon emissions and waste production, fostering an eco-friendlier healthcare system.

Ethics

Ethics Committee Approval: Ethical committee approval was secured prior to the study from the Ankara University Faculty of Medicine, Human Research Ethics Committee (approval no.: İ4-165-19, date: 10.10.2019).

Informed Consent: Participants were provided survey forms and informed consent documents.

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Original Article
Airway Management

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Comparison of Tracheal Intubation Using the Air-Q ILA and LMA Blockbuster Among Adults Undergoing Elective Surgery: A Randomized Controlled Trial

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Abstract

Objective: Air-Q intubating laryngeal airway (ILA) is associated with a 58-77% success rate in blind intubation. The newer laryngeal mask airway (LMA) blockbuster is specially designed to facilitate easier endotracheal intubation and may have a higher success rate. The current study aimed to compare the success rate of endotracheal intubation using the Air-Q ILA and LMA blockbuster.

Methods: After ethics committee approval and informed written consent, 140 adult patients with normal airways who were scheduled for elective surgery under general anaesthesia requiring endotracheal intubation were recruited for this randomized controlled trial. Blind endotracheal intubation was performed using the Air-Q ILA in group A and the LMA blockbuster in group B with special maneuvers and/or tubes in the second attempt. Fibreoptic bronchoscope (FOB) guidance was used in the third attempt if required. The primary outcome was the success rate of intubation without FOB assistance. The number of attempts for supraglottic airway (SGA) insertion, the time taken for SGA insertion, and the overall intubation time was also noted.

Results: The success rate of intubation without FOB guidance was significantly higher in group B than in group A [91.4% vs 55.7%; relative risk (RR) 1.68; (95% confidence interval (CI) 1.34, 2.11); p<0.0001]. The number of attempts for SGA insertion was similar in groups A and group B [87% vs 90%; RR 1.03; (95% CI-0.92, 1.16); p=0.60]. The times for successful SGA insertion and endotracheal intubation were also similar between the groups.

Conclusion: The LMA blockbuster offers a significantly higher success rate for endotracheal intubation without FOB guidance than the Air-Q ILA in adult patients with normal airways. However, an increased success rate was achieved with the use of a specially designed flexible endotracheal tube and maneuvers.

Keywords: Airway management, bronchoscopy, endotracheal intubation, glottis, laryngeal mask airway

Main Points

- Laryngeal mask airway blockbuster has a significantly higher success rate for blind endotracheal intubation than Air-Q intubating laryngeal airway in adult patients with a normal airway. However, the fiberoptic bronchoscopic glottic view, intubation time, and incidence of sore throat are similar.

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Introduction

Supraglottic airway (SGA) devices can be used as primary airway devices for ventilation or as conduits for intubation. It also provides a route for oxygenation in failed intubation, and those with a gastric port can facilitate the drainage of gastric contents.[1] In difficult airways, a fibreoptic bronchoscope (FOB) may be considered the gold standard for intubation if available, and intubation through SGA can be a reasonable alternative in appropriate cases.[2] Although intubation through SGA should be ideally guided by FOB, in a resource-limited setting, this approach may need to be performed without FOB assistance. Therefore, an SGA with a high blind intubation success rate is clinically significant.

Laryngeal mask airway (LMA) blockbuster, a novel SGA, has a short airway tube that matches the oropharyngeal curve, a guidance device at the laryngeal end that directs the endotracheal tube (ETT) toward the glottis, and comes with its designated wire-reinforced ETT with a soft tip that facilitates intubation. It has been found to have a 90-94% intubation success rate in initial studies compared with the 66% success rate of LMA Fastrach.[3,4] Air-Q intubating laryngeal airway (ILA) has a shorter and wider airway tube, has a removable connector, and comes with a stabilizing stylet to facilitate intubation. However, the intubation success rate through the Air-Q ILA has been 58-77% in comparative trials with the LMA Fastrach.[5-7]

The initial promise of LMA blockbuster was derived from smaller studies, and intubation success between LMA blockbuster and Air-Q ILAs was not compared directly. Therefore, this study compared the LMA blockbuster and Air-Q ILAs. The primary outcome was the success rate of blind intubation without FOB assistance, and the secondary outcomes were i) time to intubation, ii) success rate of SGA insertion, iii) FOB glottic view, and side effects like sore throat and blood on SGA removal. We hypothesized that the LMA blockbuster will have a higher success rate for blind intubation due to specific modifications to aid intubation and the availability of a specially designated ETT compared with the Air-Q ILA.

Methods

This single-center, randomized, controlled trial was conducted at a tertiary care academic institution in India from October 2019 to April 2021. Permission was obtained from the Institutional Ethics Committee of All India Institute of Medical Sciences (ref no.: IECPG-446/27.06.2019), and the protocol was registered in a publicly accessible clinical trial registry database of India (www.ctri.nic.in; CTRI/2019/10/021623) before the recruitment of the first patient. Written informed consent was obtained from each patient.

Study Population

One hundred and forty adult patients aged between 18 and 75 years with either sex and American Society of Anesthesiologists physical status I or II, who underwent elective surgery under general anaesthesia requiring endotracheal intubation, were recruited in this study. Patients with respiratory or pharyngeal pathologies, cervical spine disease, potentially difficult airway and patients at risk of regurgitation were excluded from the study.

Randomization and Blinding

Patients were randomized according to a software-generated random number table in the two study groups. In group A, the Air-Q ILAs and in group B, the LMA blockbuster was used for securing the airway and as a conduit to intubation. Allocation was concealed using the sealed envelope technique. The anaesthesia team in the operating room opened the envelope and followed the previously mentioned procedure. The independent investigator noted all outcome data. Complete blinding was not possible for obvious reasons. The operator who performed SGA placement and subsequent intubation was blinded to the FOB view. The postoperative outcome assessor was also blinded to group allocation.

Anaesthesia Protocol

All patients underwent a routine pre-anaesthesia assessment and were kept nil per oral for 8 hours for solids and 2 hours for water before surgery. In the operating room, an intravenous line was started, and routine monitoring, i.e. electrocardiography, pulse oximeter, non-invasive blood pressure, and capnography was performed. Patients were pre-oxygenated for 3 min, and anaesthesia was induced using intravenous Fentanyl (2 µg kg^{-1}) and Propofol (2.0-2.5 mg kg^{-1}). Neuromuscular blockade was achieved with atracurium at 0.5 mg kg^{-1}, and after 3 min, a randomly assigned SGA was inserted.

In group A, the appropriate size of Air-Q ILAs was chosen according to the patient's weight [size 2.5 (30-50 kg), size 3.5 (50-70 kg), size 4.5 (70-100 kg)]. Cuffed polyvinyl chloride (PVC) ETTs of sizes 6.5, 7.0, and 8.0 were selected for Air-Q ILA 2.5, 3.5, and 4.5, respectively. The ETTs were pre-warmed and lubricated with 2% lignocaine jelly. An Air-Q ILA was inserted using an inward and downward pressure using the curvature as a guide until resistance was felt, and the cuff was inflated to a cuff pressure of 60 cm H_2O using a cuff pressure manometer.

In group B, size 3 LMA Blockbuster was used in patients weighing 30-50 kg, size 4 for 50-70 kg and size 5 for 70-100 kg. Cuffed PVC ETTs of sizes 6.5, 7.0, and 7.5 were selected for LMA Blockbusters of sizes 3, 4, and 5, respectively. The ETTs were pre-warmed and lubricated with 2% lignocaine jelly. The LMA blockbuster was directed into the pharynx

using the curvature until resistance was encountered. The four-way connector was held with both thumbs, and the LMA Blockbuster was moved up and down to achieve adequate ventilation.

If the SGA was not successfully placed in the first attempt, the index finger of the left hand was placed behind the mask and flexed forward to guide the SGA into the pharynx. A mandibular lift was used for the third attempt to facilitate SGA insertion. If the SGA was not successfully placed in three attempts, the trachea was intubated using direct laryngoscopy. SGA placement was confirmed by observing an adequate chest rise and the appearance of square wave capnography. After confirmation of SGA placement, a FOB was performed to note the glottic view. Thereafter, the connector was removed, and the previously lubricated ETT was inserted into the airway tube, which was gently advanced further to intubate the trachea. The position was confirmed by auscultation and capnography. If the first attempt was unsuccessful, the ETT was withdrawn from the airway tube, and the manufacturer's recommendations were used in the second attempt. In group A, the Air-Q ILA was withdrawn 5-8 cm and reinserted with a mandibular lift, and a bougie was inserted into the airway tube with the coude tip facing upwards.[6] External laryngeal manipulation was performed to guide the bougie into the larynx if required, and subsequently, the lubricated PVC ETT was advanced over the bougie. For the second attempt in group B, the dedicated flexible ETT provided with the LMA Blockbuster was used after lubrication with lignocaine jelly, external laryngeal manipulation, and rotation of the ETT, if required. If intubation was unsuccessful after the second attempt in both groups, FOB guidance was used for the third attempt. If the third attempt was also unsuccessful, the trachea was intubated using a direct laryngoscope.

Anaesthesia trainees who had previously performed at least 50 similar procedures performed SGA placement and subsequent intubation. Patients were ventilated with 100% oxygen between attempts if necessary. If SpO_2 decreased to 90% or less during the procedure, direct laryngoscopy and intubation were performed. Subsequent anaesthesia management was performed at the discretion of the anaesthesia team.

Data Collection

Baseline and demographic data at enrollment and outcome data were recorded. The primary outcome was blind intubation success rate without FOB assistance (combined success rate of first and second attempt), and the secondary outcomes were;

i) Success rate of SGA placement,

ii) SGA insertion time: from the time the device entered the mouth until the appearance of the capnograph waveform. If no carbon dioxide was detected or the seal was inadequate, the device was removed. The time of the second/third attempt was recorded similarly, and the insertion time was considered the sum of all attempts.

iii) ETT insertion time: from the time of insertion of the ETT through the SGA until the appearance of the capnograph waveform. If no carbon dioxide was detected, the ETT was removed. The time of the second/third attempt was recorded similarly, and the insertion time was considered the sum of all attempts.

iv) Time for removal of SGA and blood on SGA: The SGA was removed after confirmation of successful intubation. The time needed to remove the SGA was recorded as the time from the initial disconnection of the ETT from the breathing circuit until reconnection and verification of the capnography waveform. Upon removal of the SGA, a note was made for any visible blood on the device, which indicated trauma to the upper airway.

v) Glottic view under FOB guidance: This was classified as per Brimacombe et al. into four grades: Grade 1: a globtic aperture seen completely without any obstruction, Grade 2: a globtic aperture seen partially but visual obstruction <50%, Grade 3: Glottic aperture barely seen and visual obstruction >50%, and Grade 4: a globtic aperture invisible.[8] Grades 1 and 2 were considered favorable.

vi) An adverse airway event was defined as an oxygen desaturation of 90% or less, significant airway trauma, or other major adverse event.

vii) The incidence of postoperative sore throat (POST) was assessed 0, 1, 6, and 24 hours after surgery.

Sample Size Estimation and Statistical Analysis

Based on previous studies, we assumed a success rate of intubation of 58% with Air-Q and 90% with Blockbuster LMA.[5,9] Considering the 80% power of the study and type 1 error as 0.05, 62 patients were required in each group. However, anticipating a dropout rate of 10%, we included 70 patients in each group.

Results

In total, 140 patients were recruited and analyzed (Figure 1). Demographic and baseline data were comparable between the groups (Table 1). Successful unassisted intubation was possible in 64 out of 70 patients in group B (91.4%) and 39 out of 70 patients in group A (55.7%) ($P < 0.001$). The overall intubation success rate was 100% in both groups. SGA placement success rates were similar between the groups (Table 2). Only 3 patients in group A and 1 patient in group B required a third attempt for SGA insertion.

The time to SGA insertion and intubation were comparable between both groups (Table 2). A favorable glottic view (combination of grades 1 and 2) was observed in 81% in the Air-Q ILA group and 77% in the LMA Blockbuster group (*P*=0.53).

The presence of blood on the SGA was observed in 24 patients on Air-Q ILA and 15 patients on LMA Blockbuster, and the incidence of POST at all time points was comparable between the groups (Table 3).

Table 1. Patient Demographics; Mean (SD)

Group	Air-Q ILA (n=70)	LMA Blockbuster (n=70)	Significance
Age (years)	40.37±14	40.31±14	0.981
Female (%)	41 (58.6)	49 (70)	0.108
Weight (kg)	61 (9)	57(8)	0.032
BMI (kg m^{-2})	22.9±2	22.4±2	0.255
Height (cm)	163±10	160±9	0.108

Data expressed as mean±SD or number (percentage)
SD, standard deviation; ILA, intubating laryngeal airway; LMA, laryngeal mask airway; BMI, body mass index.

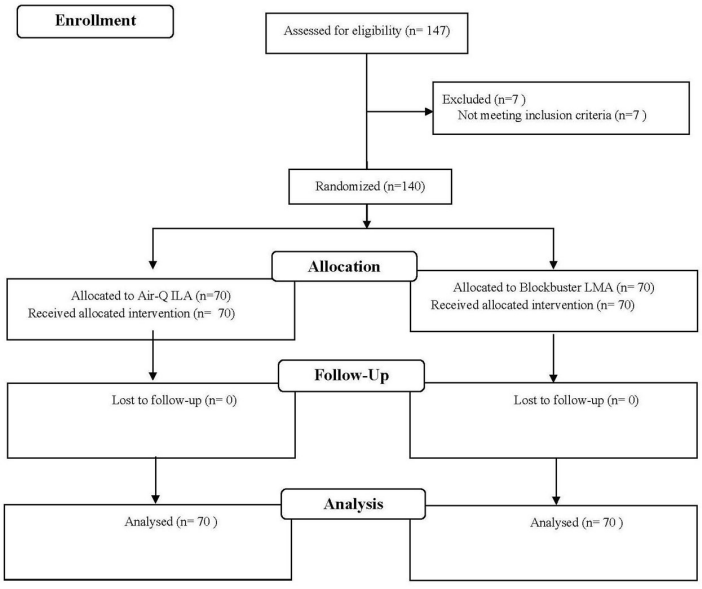

Figure 1. CONSORT flow diagram

ILA, intubating laryngeal airway; LMA, laryngeal mask airway

Table 2. Number of Attempts and Time to SGA Insertion and Intubation in the Groups Air-Q ILA and Blockbuster LMA. Values are Presented as Median (IQR)

		Air-Q ILA (n=70)	LMA Blockbuster (n=70)	Significance
Success rate of blind intubation		39 (55.7%)	64 (91.4%)	0.0001
Intubation success in 1st attempt		33 (47.1%)	39 (55.7%)	
Intubation success in 2nd attempt		6 (8.6%)	25 (35.7%)	
Intubation success in 3rd attempt (FOB guided intubation)		31 (44.3%)	6 (8.6%)	
Time to intubation (seconds)		43 (20-122)	31.5 (23-45)	0.122
Success rate of SGA placement	1st attempt	61 (87.1%)	63 (90%)	0.759
	2nd attempt	6 (8.6%)	6 (8.6%)	
	3rd attempt	3 (4.3%)	1 (1.4%)	
SGA insertion time (seconds)		29 (22-35)	27 (21-32)	0.198
SGA removal time (seconds)		38 (30-43)	35 (30-41)	0.341

Table 2. Continued

		Air-Q ILA (n=70)	LMA Blockbuster (n=70)	Significance
Glottic view grading (8)	Grade 1	49 (70%)	32 (45.7%)	0.004
	Grade 2	8 (11.4%)	22 (31.4%)	
	Grade 3	7 (10%)	13 (18.6%)	
	Grade 4	6 (8.6%)	3 (4.3%)	

Data expressed as frequency (percentage) or median (IQR)
SGA, supraglottic airway; ILA, intubating laryngeal airway; LMA, laryngeal mask airway; IQR, interquartile range; FOB, fibreoptic bronchoscope.

Table 3. Blood on the SGA and Postoperative Sore Throat

		Air-Q ILAs (n=70)	LMA Blockbuster (n=70)	Significance
Blood in the SGA		24 (34%)	15 (21%)	0.065
Sore throat	1 h	29 (41%)	19 (27%)	0.054
	6 h	13 (18.5%)	8 (11%)	0.172
	12 h	4 (6%)	3 (4%)	0.50
	24 h	3 (4%)	3 (4%)	0.660

Data expressed as number (percentage)
SGA, supraglottic airway; ILA, intubating laryngeal airway; LMA, laryngeal mask airway

Discussion

In the present study, we observed a higher intubation success rate without FOB assistance in the LMA Blockbuster group compared with the Air-Q ILA. However, the first attempt intubation success rate, SGA insertion success rate, favorable FOB glottic view, intubation time, and incidence of sore throat were similar.

In the present study, the success rate of blind intubation was significantly better with the LMA Blockbuster (91.4%) compared with the Air-Q ILA (55.7%) [relative risk- 1.64; (95% confidence interval) (1.31, 204); $P < 0.0001$]. This is similar to the reported high success rate of blind intubation through LMA Blockbuster by Endigeri et al.[3] (90%) and Singh[4] (94%). However, the success rate of blind intubation with Air-Q ILA was 55.7% only, and FOB guidance was required in the remaining 44.3% of patients. This result is similar to the pilot study by Bakker et al.[5] where only a 58% success rate was achieved for blind intubation in the first attempt. They attributed the low success rate to the absence of an ETT with Air-Q ILA and the learning curve. Karim and Swanson[6] observed a 77% success rate for blind intubation in two attempts with the Air-Q ILA and 99% with the LMA Fastrach. They attributed the better success rate of intubation with the LMA Fastrach to the specialized tube available as compared to the standard ETT with the Air-Q ILA. Similar to Karim and Swanson[6], we have used special manoeuver and bougie guidance for intubation through AirQ-ILA in the second attempt, which marginally improved the success rate compared with the first attempt.

It is interesting to note that the first attempt success rate was similar in both groups when we used a PVC ETT tube, and the success rate improved markedly in the LMA Blockbuster after the use of the specially designed ETT. Mohan et al.[9] reported success rates of 84% and 96% with PVC ETT and specially designed ETT through LMA Blockbuster. However, in view of such improvements in success rates in both groups in the second attempt, though marginal in Air-Q ILA and marked in LMA Blockbuster, we suggest that a specially designed ETT with rotating/twisting movements during advancement should be used in LMA Blockbuster,[10] and bougie guidance with a described maneuver should be used in Air-Q ILA in the first attempt itself for the best results if blind intubation is attempted.[6]

Moreover, the unavailability of an appropriate Air-Q ILA size could have contributed to a lower intubation success rate through the latter. In our experience, size 3.5 seemed to be too large and size 2.5 too small for some patients, especially females weighing around 50 kg. This could lead to misalignment and subsequent intubation difficulties.

In the present study, all patients were successfully intubated in the final FOB guided attempt. Similarly, Karim and Swanson[6] reported a 96.7% success rate in FOB-guided intubation using air-Q ILA. Samir and Sakr[11] also reported a 96.7% success rate in FOB-guided intubation using Air-Q ILA in patients with limited cervical spine instability. El-Ganzouri et al.[12] found blind intubation success rates of 70% and FOB-guided intubation success rates of 97.5% through Air-Q ILAs with a shorter insertion time. Both SGA devices should be considered useful for FOB-guided endotracheal intubation because it was finally possible to intubate all cases using the FOB.

Although favorable glottic views were similar between the groups (81% in Air-Q ILA and 77% in LMA Blockbuster), grade 1 glottic views were observed in 70% of the Air-Q cases and only 45% of the LMA Blockbusters cases. Despite

the comparatively poor glottic view, the LMA Blockbuster achieved a higher success rate for blind intubation. Similarly, Endigeri et al.[3] observed full FOB view of the glottis in 43% of cases, partial glottic view in 30%, and only epiglottis in 20%, but achieved a 90% blind intubation success rate. This suggests that LMA Blockbuster may facilitate successful intubation despite the poor glottic view. A multitude of factors, including a short airway tube with >95° angulation which aids exit of ETT at 30° acute angle from the laryngeal mask with the help of a guidance ramp at the laryngeal end, and specially designed soft-tip ETT with rotation movement may facilitate blind intubation through LMA Blockbuster.[13]

In the present study, the first-pass insertion success rates were 87% for the Air-Q ILAs and 90% for the LMA blockbusters. This is very similar to previous studies. Neoh and Choy[7] observed a 96% success rate, Galgon et al.[14] reported an 88% success rate in the first attempt for Air-Q ILA insertion, whereas Endigeri et al.[3] found a 90% success rate with Blockbuster LMA.

The mean times to successful SGA insertion in the first attempt were 29 s in the Air-Q ILA and 27 s in the LMA blockbuster. Galgon et al.[14] observed that the mean insertion time for the Air-Q ILA was 20 s, and in the study by Karim and Swanson[6], the mean insertion time for the Air-Q ILA was 27 sec. Endigeri et al.[3] reported a mean insertion time of 12 s for the LMA Blockbuster. The overall mean time to SGA insertion was 37 s in the Air-Q ILA group and 33 s in the LMA Blockbuster group.

In the current study, the median cumulative time for ETT insertion was 43 s in the Air-Q ILA and 31 s in the LMA Blockbuster. This was statistically not significant; however, could be clinically meaningful. A similar trend was observed in previous studies. The mean time for intubation using the LMA Blockbuster was 18 s according to the study by Endigeri et al.[3]. Karim and Swanson[6] reported a mean intubation time of 35 s using Air-Q ILA.

The incidence of POST was 41% and 27% in the Air-Q ILA and LMA blockbuster groups, respectively, 1 h after surgery, and it reduced to 4% in both groups at 24 h. Neoh and Choy[7] reported 51% sore throat with Air-Q ILA. The increased incidence of POST could be attributed to multiple attempts in the Air-Q ILA group and the use of PVC tubes in the first attempt in the LMA Blockbuster group.

The important strengths of the present study include a larger sample size than that of previously published literature; complete follow-up with no data loss and a more pragmatic design with the use of commonly available PVC ETT and assessment of blind intubation success rate considering the relevance and wider application of this technique in resource-poor settings where difficult airway patients may need to be managed without FOB.

Study Limitations

The limitation of our study could be the lack of inclusion of obese patients and other patients with difficult airway, where the study could be more relevant. The current findings need to be validated in those scenarios in further randomized controlled trials.

Conclusion

LMA Blockbuster offers a significantly higher success rate of endotracheal intubation without FOB guidance than Air-Q ILA in adult patients with normal airways. However, an increased success rate in the LMA Blockbuster was achieved with the use of a specially designed, dedicated flexible ETT and external maneuvers.

Ethics

Ethics Committee Approval: Permission was obtained from the Institutional Ethics Committee of All India Institute of Medical Sciences (ref no.: IECPG-446/27.06.2019), and the protocol was registered in a publicly accessible clinical trial registry database of India (www.ctri.nic.in; CTRI/2019/10/021623) before the recruitment of the first patient.

Informed Consent: Written informed consent was obtained from each patient.

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Original Article
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Comparative Efficacy of Intraoperative Patient State Index vs. Bi-Spectral Index in Patients Undergoing Elective Spine Surgery with Neuromonitoring Under General Anaesthesia: A Randomized Controlled Trial

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Abstract

Objective: Various electroencephalogram-based monitors have been introduced to objectively quantify anaesthesia depth. However, limited data are available on their comparative clinical efficacy in various surgical procedures. Therefore, we planned this study to compare the relative efficacy of patient state index (PSI) vs. Bi-spectral index (BIS) assessment in patients undergoing elective spine surgery under general anaesthesia.

Methods: This prospective, parallel-group, single-center study included patients undergoing major spine surgery with neuromonitoring. Patients were randomized into two groups, i.e., group B (undergoing surgery under BIS monitoring) and group P (undergoing surgery under PSI monitoring). The primary objective was to compare the time to eye opening after stopping anaesthetic drug infusions.

Results: The mean propofol dose required for induction in group B was 130.45±26.579, whereas that in group P, it was 139.28±17.86 (*P* value 0.085). The maintenance doses of propofol and fentanyl required for surgery were also comparable between the groups. Time to eye opening was 12.2±4.973 in group B and 12.93±4.19 in group P, with a *P* value of 0.2664 (U-statistic-684.50).

Conclusion: The intraoperative PSI and BIS had similar clinical efficacy in terms of the dose of propofol required for induction, time of induction, maintenance dose of propofol and fentanyl, time of eye opening, and recovery profile in patients undergoing elective spine surgery under neuromonitoring.

Keywords: Consciousness monitors, electroencephalogram, intravenous anaesthesia, intraoperative monitoring, neuroanaesthesia, spine

Main Points

- Both Bi-spectral index (BIS) and patient state index (PSI) have been used and validated for monitoring the depth of anaesthesia but have not been extensively studied in patients requiring intraoperative neuromonitoring.
- Our study found that using either BIS or PSI resulted in similar clinical efficacy in terms of intraoperative anaesthetic consumption and postoperative recovery in patients requiring intraoperative neuromonitoring.
- Therefore, either of the two approaches can be used to monitor the depth of anaesthesia during the intraoperative period in this group of patients.

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Introduction

The assessment and maintenance of adequate anaesthesia depth has remained an important clinical consideration for anaesthesiologists.[1] Inadequate depth of anaesthesia can lead to intraoperative awareness, whereas excessive use of anaesthetics can cause delayed awakening and wastage of anaesthetic drugs. Clinical parameters, like heart rate, blood pressure, and lacrimation, provide subjective assessments but are grossly inadequate for quantifying the depth of anaesthesia. Recently, various electroencephalogram (EEG) based monitors have come into use to objectively quantify the depth of anaesthesia.[2] Most of these monitors use the frequency and wavelength of specific EEG waveforms and provide an assessment of depth in the form of a number ranging from 0 to 100.[2]

The most commonly used EEG-based anaesthesia depth assessment monitor is the Bi-spectral index (BIS). BIS was the first monitor approved by the Food and Drug Administration for this purpose.[3] It uses a single-channel frontal EEG and assesses awareness considering various parameters like frequency, phase, and power spectrum, as a dimensionless number. The normal range for BIS for adequate depth of anaesthesia is 40-60. Its mathematical algorithm responds rapidly to changes in EEG frequency and thus provides rapid evaluation of anaesthesia depth.[4]

The patient state index (PSI) is a more recent depth of anaesthesia monitor that relies on 4-channel EEG following advanced artifact removal.[5] The normal range of PSI for adequate depth of anaesthesia is 25-50. Compared with conventional EEG monitoring, PSI signals are shown to be less affected by electromyography (EMG) and thus may be better in patients in whom EMG may interfere with an adequate assessment of depth of anaesthesia. Studies have also shown that compared with PSI, BIS reacts faster to changes in sevoflurane concentration.[6] However, after a thorough search of the literature, we were not able to find any studies comparing BIS with PSI in patients undergoing spine surgery under total intravenous anaesthesia, in terms of the anaesthetic dose used for induction and maintenance, recovery profile, and incidence of complications like awareness and recall under anaesthesia. Therefore, this study was planned by us to compare the relative efficacy of PSI vs BIS assessment in patients undergoing elective spine surgery under general anaesthesia.

Methods

This was a prospective, parallel-group, single-center randomized control study approved by the Institutional Ethical Committee of All India Institute of Medical Sciences, Rishikesh (Uttarakhand) (decision no.: AIIMS/IEC/19/749, date: 12.04.2019) and registered in the clinical trial registry (CRTI) of India (CTRI/2021/12/038503). We followed the Helsinki Declaration of 1964, revised in 2013. The inclusion criteria for this study were age 18-70 years and American Society of Anesthesiologists class I or II who underwent major spine surgery with neuromonitoring under general anaesthesia. The exclusion criteria included patients with clinically significant cardiovascular, respiratory, hepatic, renal, or metabolic disease, alcohol or drug abuse, use of regional/neuraxial blocks for intraoperative analgesia, neurological or psychiatric disorders, and use of antiepileptic or other centrally acting drugs.

Informed written consent was obtained from all patients before enrollment in this study. A computer-generated randomization sequence was used to randomize patients into groups B and P based on simple randomization and 1:1 allocation. Group B patients underwent spine surgery under BIS monitoring [BIS LOC2 channel (Coviden)], maintaining a BIS value between 40 and 60 during the intraoperative period, and group P patients underwent spine surgery under PSI monitoring [SEDLine on Root monitor (Masimo)], using a range of 25-50 for anaesthesia. Baseline awake mean arterial pressure (MAP), heart rate, and BIS/PSI were noted in both groups. After that, patients were anesthetized with propofol at an infusion of 30 mg kg^{-1} hr^{-1} i.v. until there was loss of response to the eyelash reflex and desired BIS/PSI values were achieved in the respective groups. A maintenance infusion of propofol was started at 2 mg kg^{-1} hr^{-1} and titrated to maintain a BIS value of 40-60 in group B and a PSI value of 25-50 in group P. Subsequently, fentanyl 2 μg kg^{-1}, vecuronium 0.1 mg kg^{-1}were given, and intubation was performed after 3 min of positive pressure ventilation in both groups.

No further vecuronium dose was administered. Surgery was performed under continuous infusion of propofol and fentanyl (started at 1 μg kg^{-1} hr^{-1}) titrated to maintain BIS/PSI values in the above-mentioned range in both groups. MAP, heart rate, MAC, and BIS/PSI were recorded after induction, intubation, and surgical incision on an hourly basis until completion of surgery. Postoperatively, patients were administered neostigmine and glycopyrrolate for relaxation reversal, and BIS/PSI values were noted at the time of eye opening and extubation. The modified Observer's Assessment of Alertness and Sedation (mOAAS) was noted before and after extubation. Time to eye opening after switching off the propofol infusion was noted in both groups. Patients were also assessed for intraoperative awareness or recall immediately and 24 hours after surgery.

The primary objective of this study was to compare the time to eye opening after stopping anaesthetic drug infusions in both groups. The secondary objectives were to compare the dose of propofol required for induction, time of induction, total maintenance dose of propofol and fentanyl used intraoperatively, mean heart rate and MAP in both groups,

mOAAS score at emergence, and relative incidence of complications (mentioned below) in both groups.

We noted complications like intraoperative awareness and recall, bradycardia, tachycardia, hypertension, and hypotension. Any intraoperative event occurrence confirmed by OT staff was defined as intraoperative awareness and recall. A heart rate of less than 50 min^{-1} was defined as bradycardia, whereas a heart rate of more than 100 min^{-1} was defined as tachycardia. Hypotension was defined as a fall in the MAP by more than 25% from the baseline value or any value of less than 55 mmHg. Similarly, hypertension was defined as MAP >100 mmHg or a rise >25% from the baseline value. In cases of bradycardia, in. atropine 0.6 mg of inj. atropine was used. For hypotension inj,. mephentermine 6 mg i.v. was used. For hypertension and tachycardia, an fentanyl bolus of 0.5 µg kg^{-1} i.v. was used.

Study Sample Size

Since there have been no similar studies in the past comparing the time of eye opening after stopping anaesthetic drug infusions with BIS and PSI, we used an effect size of 0.6 (medium effect size using Cohen's convention). The sample size was calculated using G*Power software version 3.1.9.7, comparing two different means using a one-tailed analysis. To achieve 80% power of the study with an alpha error of 0.05, we need to have 36 participants per group. Therefore, we included 40 patients in each group (a total of 80 patients) to compensate for any dropouts.

Statistical Analysis

The data was analyzed using Statistical Package for the Social Sciences (SPSS v23, IBM Corp.). Mean ± standard deviation was used for continuous data, and number/ percentage was used for categorical data. To compare two groups, we used the unpaired t-test, if the data were normally distributed or Mann-Whitney test, if the data were skewed. A *P* value of < 0.05 was considered statistically significant.

Results

We included 89 patients in our study. Of these, two patients refused to participate in the study, three had significant comorbidities, one was a known alcoholic, one received erector spinae plane block, and two were on anticonvulsants. Therefore, we enrolled 80 patients in our study (Figure 1).

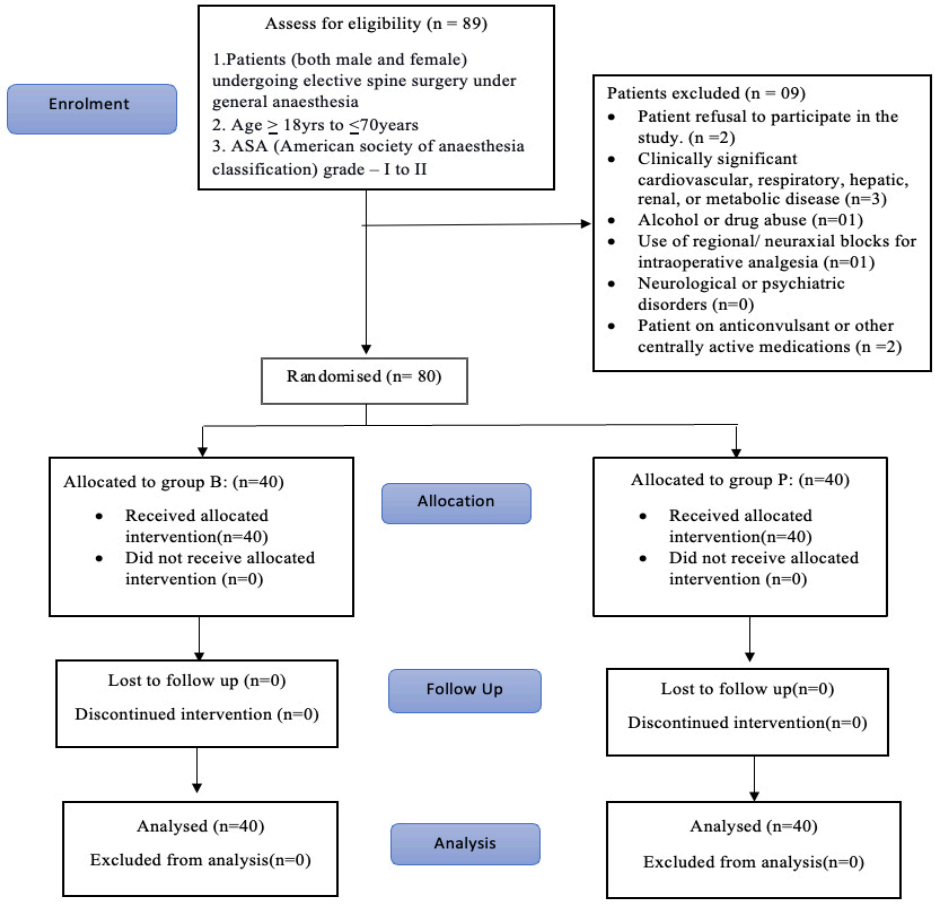

Figure 1. CONSORT Flow Diagram

The demographic characteristics of the patients in both groups were comparable (Table 1). The mean durations of anaesthesia and surgery were also similar between the groups (Table 1).

The mean dose of propofol (in mg) required for induction in group B was 130.45±26.579, while in group P, it was 139.28±17.86 (*P* value 0.085). The time (minutes) required for induction was 4.025±0.9046 in group B and 4.23±0.3824 in group P, with no statistically significant difference (*P* value 0.1907). The mean heart rate (Table 2) and MAP (Table 3) were analyzed intraoperatively at different time points, and no significant difference was noted in the two groups at any time point. The mean PSI and BIS values were within the acceptable range for both groups (Figure 2) at all time points.

The maintenance doses of propofol and fentanyl required for surgery were also comparable between the groups (Table 4). Time to eye opening was 12.2±4.973 in group B and 12.93±4.19 in group P, with a *P* value of 0.2664 (U-statistic-684.50). The mOAAS scores were also comparable in both groups. The mean mOAAS score before extubation in group B was 1.95±0.8458, whereas that in group P, it was 1.6±0.7442, and the difference was not statistically significant (*P* value 0.0530). After extubation, the mean mOAAS score was 3.225±0.6197 in group B and 3.3±0.6485 in group P, and the difference was again found to be statistically non-significant (*P* value 0.5984).

The incidences of various complications in both groups were comparable. In group B, four patients had bradycardia, three had tachycardia, five had an episode of hypotension, and two had an episode of hypertension. In group P, five

Table 1. Demographic Profile of the Patients in Group B and Group P

Parameter	Group B	Group P	*P* value
Age; years	44.2±17.96	48.525±15.39	0.256‡
Sex; M:F	25:15	24:16	--
BMI*; kg m^{-2}	26.44±4.43	25.74±4.85	0.502‡
ASA† grade; I:II	25:15	31:9	--
Duration of surgery; hours	4.47±1.29	4.49±1.13	0.78§ (U-statistic-768.00)
Duration of anaesthesia; hours	5.04±1.33	4.97±1.18	0.94§ (U-statistic-791.50)

Values are mean ± SD or number (proportion)
*BMI, body mass index; †ASA, American Society of Anesthesiologists; ‡t-test; §Mann-Whitney U test; M:F, male:female.

Table 2. Mean Heart Rates in Groups B and P During the Intraoperative Period

Parameter	Group B	Group P	*P* value
	Mean ± SD	Mean ± SD	
Before induction	73.92±6.61	75.1±5.4	0.294* (U-statistic-691.50)
After induction	73.05±5.26	73.95±6.45	0.234* (U-statistic-676.50)
After intubation	81.65±7.33	79.45±6.86	0.339* (U-statistic-700.50)
At incision	79.23±6.29	76.53±5.99	0.0633* (U-statistic-607.50)
1 hour	72.63±6.25	73.95±6.45	0.1485* (U-statistic-650.00)
2 hours	72.63±5.39	73.85±5.33	0.346* (U-statistic-702.50)
3 hours	72.56±6.44	73.31±6.78	0.621†
4 hours	72.77±6.24	72.18±6.58	0.719†
5 hours	72.82±6.34	70.81±8.52	0.446†
6 hours	84.57±7.28	82.56±12.75	0.715†
7 hours	79.4±7.4	81±13.09	>0.999* (U-statistic-9.50)
Before extubation	84.15±8.98	87.3±8.43	0.097* (U-statistic-628.50)
After extubation	77.83±5.03	79.4±5.28	0.169* (U-statistic-659.00)

Values are mean ± SD
*Mann-Whitney U test; †t-test; SD, standard deviation.

patients had bradycardia, three had tachycardia, four had hypotension, and three reported hypertension. No patient exhibited no intraoperative awareness or recall during the surgery.

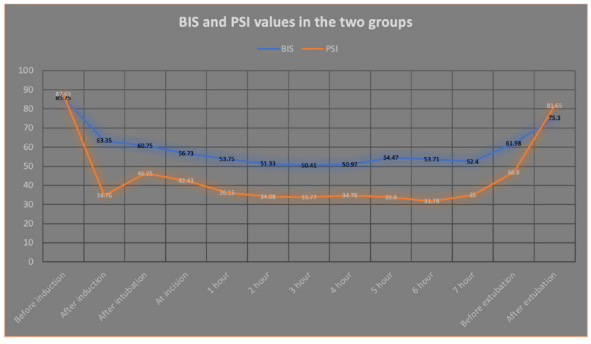

Figure 2. Mean intraoperative BIS vs PSI values in the two respective groups

BIS, Bi-spectral index; PSI, patient state index.

Discussion

We conducted a randomized controlled trial of patients undergoing major spine surgery with neuromonitoring under general anaesthesia. Patients were comparable in terms of demographic profile and duration of surgery and anaesthesia. The dose of propofol required for induction was lower in group B than in group P, but the difference was not statistically significant. Similarly, there was a statistically non-significant difference in the time required for anaesthesia induction, which was less in group B. We did not find any statistically significant difference in mean heart rate and MAP between the groups during the intraoperative period. Similarly, the maintenance doses of propofol and fentanyl were similar between the groups. After surgery, the time to eye opening was similar in both groups. The mean mOAAS score was higher in group B at the time before extubation, but the difference was not statistically significant. After extubation, the mOAAS score was comparable in both groups. The relative incidence of various complications was also comparable in both groups.

Table 3. Mean Arterial Pressure in Groups B and Group P During Intraoperative Period

Parameter	Group B	Group P	*P* value
	Mean ± SD	Mean ± SD	
Before induction	72.25±5.001	75.425±9.109	0.26* (U-statistic-683.50)
After induction	73.85±5.691	76.375±7.458	0.143* (U-statistic-648.50)
After intubation	80.475±11.431	79.95±10.891	0.98* (U-statistic-797.00)
At incision	79.075±10.341	77.925±8.748	0.729* (U-statistic-764.00)
1 hour	77.225±6.945	75.975±7.458	0.413* (U-statistic-715.50)
2 hours	75.65±6.822	73.825±6.621	0.316* (U-statistic-696.00)
3 hours	74.103±5.651	74.846±7.618	0.943* (U-statistic-753.00)
4 hours	75.2±7.993	73.812±7.785	0.582* (U-statistic-440.50)
5 hours	76.35±7.729	75.47±9.716	0.779†
6 hours	76.86±7. 358	71.56±12.381	0.306†
7 hours	75.6±8.325	72.5±10.786	0.711* (U-statistic-8.00)
Before extubation	71.725±4.552	71.475±7.2	0.617* (U-statistic-748.50)
After extubation	75.05±7.524	74.025±6.083	0.594* (U-statistic-744.50)

Values are mean ±SD
*Mann-Whitney U test; †t-test

Table 4. Mean Intraoperative Propofol and Fentanyl Consumption in Groups B and P

Parameter	Group B	Group P	*P* value
Propofol; 1%	19.35±7.62	21.38±7.89	0.2423* (U-statistic-678.00)
Fentanyl; 10 µg kg^{-1}	10.69±2.57	9.22±1.64	0.0599* (U-statistic-604.00)

Values are mean ± SD and rate of infusion is in mL hr^{-1}
*Mann-Whitney U test

Two of the most commonly used EEG-based monitoring systems are the BIS and the PSI. While BIS monitors EEG in one hemisphere only, PSI measures EEG in both hemispheres.[7] A previous study concluded that using PSI to titrate propofol administration resulted in a significantly reduced usage of propofol and improved early recovery profile.[8] However, in our study, the mean dosage of propofol required for induction was higher with the PSI monitor (139.28±17.86) compared to BIS (130.45±26.579), but the difference was statistically insignificant. In another study, the use of BIS, compared with PSI, showed a decrease in the dosage of propofol required for induction; however, in our study, it was found to be statistically insignificant (P=0.085).[9]

The Modified Observer's Assessment of Alertness and Sedation (mOASS score) is a validated 6-point scale that assesses the responsiveness of individuals and correlates with the ASA continuum of sedation. A previous study compared the correlation of BIS and PSI with mOASS and showed that BIS had a stronger association.[10] However, in our study, the mOASS score was comparable between the monitors at various time points. No significant hemodynamic changes were noted while using both monitors, which is consistent with a previous study.[11] A previous study concluded that BIS and PSI are comparable to each other in terms of differentiating consciousness and unconsciousness, during the induction of anaesthesia and emergence, and during any episode of awareness, in patients undergoing surgery, which is consistent with our study.[12]

The mean dose of fentanyl was found to be comparable between the groups in our study. The depth of anaesthesia is also influenced by the level of analgesia. The nociception level index using tetanic stimulation was previously used to titrate remifentanil, but its utility in a surgical setting has not been established.[13] Therefore, most anaesthesiologists use clinical parameters to titrate opioids.

In our study, there was no significant difference between the two groups in the total intraoperative consumption of propofol. In a study, authors reported that processed EEG values may help clinically evaluate the depth of anaesthesia but do not correlate well with clinical parameters during the period of awakening or deep anaesthesia planes.[14] Thus, a clinician's decision to alter an anaesthetic agent may not always correlate well with real-time brain function monitoring. Moreover, processed EEG in many instances may take more time to reflect changes than cardiovascular indices. Further studies are required to establish the time delay between the change in conscious level and the change in processed EEG signals. From our study, we can conclude that both BIS and PSI are equally effective in titrating anaesthetic agents and provide an extra edge over the traditional way of using only clinical parameters like heart rate, blood pressure, and movement to noxious stimuli in response to surgical stimuli as a guide to anaesthesia depth monitoring.

The time of recovery from anaesthesia (time to eye-opening) was similar in both groups in our study. Similar findings were reported by a study,[7] which found that BIS and PSI values after neuromuscular block reversal were similar in patients undergoing surgery under total intravenous anaesthesia. EEG-based monitors have been successfully used in select patient groups to avoid delayed recovery.[15] A recent meta-analysis has shown that the use of BIS-guided anaesthesia results in reduced recovery times, reduced anaesthesia agent dose, and reduced risk of adverse events.[16] According to another meta-analysis, the use of BIS in elderly patients resulted in an improved recovery profile but did not reduce the incidence of postoperative delirium.[17]

In our study, no patient had intraoperative awareness in any group when the BIS and PSI values were in the recommended range. A randomized control trial[18] similarly found that the use of BIS resulted in decreased awareness in at-risk patients undergoing surgery under general anaesthesia with muscle relaxants. In an extensive systematic review,[19] the authors concluded that the use of the BIS might reduce the incidence of awareness, but because of the low incidence of incidence, the evidence of the effectiveness of the BIS is not precise.

Study Limitations

Our study has limitations because it was performed in a specific population of patients who were undergoing spine surgery under total intravenous anaesthesia. Therefore, these findings may not be applicable to patients undergoing other types of surgery under different anaesthetic techniques. Second, the effect site concentrations of propofol and fentanyl were not estimated in our study because the monitors for the same concentrations were not available in our institute at the time of conducting this study. Third, our study did not evaluate the effect of coadministration of other agents like dexmetatomidine. Thus, further studies are needed to determine whether BIS and PSI perform comparatively with different anaesthetic agents and different types of surgeries.

Conclusion

In conclusion, the intraoperative PSI and BIS had similar clinical efficacy in terms of the dose of propofol required for induction, time of induction, maintenance dose of propofol and fentanyl, time of eye opening, and recovery profile in patients undergoing elective spine surgery under neuromonitoring. Thus, both BIS and PSI can be used in patients with similar outcomes.

Ethics

Ethics Committee Approval: The study approved by the Institutional Ethical Committee of All India Institute of Medical Sciences,

Rishikesh (Uttarakhand) (decision no.: AIIMS/IEC/19/749, date: 12.04.2019) and registered in the clinical trial registry (CRTI) of India (CTRI/2021/12/038503).

Informed Consent: Written consent was obtained from all patients prior to their inclusion in the study.

Author Contributions: Concept - D.S., S.A.; Design - D.S., S.A.; Data Collection and/or Processing - D.S., P.T., A.B.A.; Analysis and/or/ Interpretation - D.S.; Writing - D.S., M.M.

Declaration of Interests: The authors declare no conflicts of interest.

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Improvement of the Resuscitation Environment with the Modified Toyota Kaizen Approach Via *In Situ* Anaesthesia Simulation Training

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In situ anesthesia simulation is performed by a multidisciplinary team (anaesthesiologists and nurses) with good team dynamics and clinical and resource management skills.[1] However, in current *in situ* simulations, opportunities to discuss the environmental aspects of resuscitation during anaesthetic emergencies is limited. Optimizing the resuscitation environment (optimal allocation or amount of prepared resuscitation equipment in operating rooms and routes for effective resuscitation) can reduce the stress levels of resuscitation team members and ensure smooth resuscitation during anaesthetic emergencies. However, current resuscitation guidelines lack detailed guidance on how to effectively optimize equipment preparation.

Kaizen, meaning "continuous improvement" or "change for the better," is based on the idea that small incremental changes and improvements can lead to significant advancements over time. Toyota Motor Corporation (Tokyo) incorporates Kaizen principles into its production and operations processes. Kaizen has recently been adopted in various healthcare fields worldwide for process improvement, error reduction, patient safety, and staff training and education.[2,3] It reduces stress and increases worker satisfaction by creating a pleasant working environment.[4] During resuscitation in operating suites, stressful situations, such as the unavailability of necessary medications and equipment or blocked access to patients, are encountered due to a lack of streamlined routes for team members. Solving these issues can improve the quality of resuscitation during chaotic anaesthesia emergencies in operating suites.

The "3As" key components of Kaizen were selected from five standardizations ("Access," "Amount," "Allocation," "Naming," and "Coloring") based on the original Toyota Kaizen method for resuscitation in operating suites. First, "Access" focuses on optimal routes for smoothly channeling necessary medications and equipment. Second, "Amount" ensures appropriate numbers of medications and equipment for efficient resuscitation. Finally, "Allocation" standardizes the location of medications and equipment in each operating suite.

Our institution incorporated the Kaizen method into *in situ* simulation debriefing to improve the environment for efficient resuscitation and reduce the stress levels of the resuscitation team members. Simulation educators can set up an *in situ* simulation that intentionally modifies the "3 As" of medical equipment and medications in operating rooms. These situational changes can provide learners with critical learning experiences regarding the importance of the "3 As" and offer them opportunities to explore potential improvements in current emergency equipment preparation within their institutions. A Kaizen consultant identified issues and provided feedback to change the resuscitation environment and improve resuscitation quality.

Changes to the resuscitation environment included: 1) access to team members during resuscitation, 2) optimal amount of resuscitation equipment in the emergency cart and operating suite, and 3) allocation of resuscitation

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equipment (airway securing equipment, medications). Moreover, the facilitator encouraged the resuscitation team members to discuss potential environmental issues during the debrief. Additionally, the facilitators should educate learners on the Kaizen method and clearly explain the role of the Kaizen consultant during the debriefing session.

In conclusion, there is a lack of focus on resuscitation-related environmental aspects in simulation training, despite their potential influence on the quality of resuscitation and team stress levels. This limitation can be addressed using the Kaizen approach.

Ethics

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