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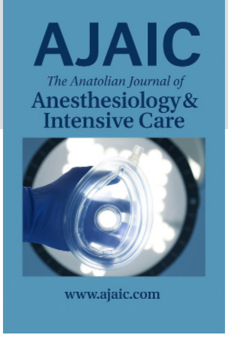

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Perioperative Complications Related to Patient Positioning in Neurosurgical Procedures: A Prospective Observational Study

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Abstract

Background: Although patient positioning in neurosurgical procedures is essential for optimal surgical exposure, it may adversely affect venous drainage, airway management, hemodynamic stability, and peripheral neurovascular structures. The aim of this study was to prospectively evaluate perioperative complications related to surgical positioning and head fixation methods in neurosurgical procedures.

Materials and Methods: This prospective, single-center observational study included 61 adult patients scheduled for neurosurgical procedures under general anesthesia. Patients were divided into two groups according to the occurrence of position-related perioperative complications. The primary outcome was the development of position-related perioperative complications, while secondary outcomes included hemodynamic changes and perioperative time variables.

Results: During the perioperative period, a total of 12 position-related complications were identified in 10 patients (16.4%). The most frequently observed complications were bilateral orbital edema and diffuse facial edema. Anesthesia duration was significantly longer in the complication group compared with the uncomplicated group ($p = 0.021$). No significant differences were observed between the groups with respect to surgical duration, intraoperative fluid administration, or blood product transfusion. There was no statistically significant association between surgical position and the development of complications. Mean arterial pressure and heart rate values measured at different perioperative time points were comparable between the groups (all $p>0.05$). Position-related complications were most commonly observed in the prone position and predominantly involved the facial and upper airway soft tissues.

Conclusion: Position-related perioperative complications occur at a non-negligible frequency in neurosurgical procedures. Appropriate patient positioning, standardized padding, and meticulous intraoperative management are of critical importance in ensuring patient safety.

Keywords: Neurosurgery; Patient positioning; Perioperative complications; Anesthesia; Patient safety

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Introduction

Patient positioning is essential in neurosurgical practice to optimize the surgical field and ensure operative safety; however, particularly in certain surgical positions, it may lead to a variety of complications through its effects on cerebral hemodynamics, venous return, airway management, cardiopulmonary stability, and mechanical stress on peripheral neurovascular structures [1,2]. The incidence of position-related complications is influenced by multiple factors, including the type and duration of the applied position, patient-specific physiological characteristics, and anesthetic management. Previous studies have reported that such complications constitute a substantial proportion of complications observed in the postoperative period [3,4].

Improper head and neck positioning may result in serious consequences such as reduced blood flow in the vertebral and carotid arteries, stretching of the cervicomedullary junction, and subsequent neural ischemia [2,5]. The most commonly reported intraoperative complications include nerve injuries and pressure-related injuries caused by excessive stretching, compression, or ischemia; notably, these complications may occur in all major patient positions used in neurosurgery [6].

Pins used in cranial fixation systems are associated with specific complications, including scalp injuries, bleeding, skin necrosis, and venous air embolism (VAE) [7].

The aim of this study was to prospectively evaluate the incidence of perioperative complications related to patient positioning and head fixation methods in neurosurgical procedures and to compare perioperative hemodynamic changes between patients with and without complications, thereby contributing to clinical awareness regarding patient safety.

Materials and Methods

Study Design and Ethical Approval

This study was designed as a prospective, single-center, observational study. It was conducted between September 10, 2022, and March 10, 2023, at Bursa Yüksek İhtisas Training and Research Hospital, Health Sciences University. Ethical approval was obtained from the Institutional Clinical Research Ethics Committee (Approval No: 2011-KAEK-25 2022/09-17). Written informed consent was obtained from all participants in accordance with the principles of the Declaration of Helsinki.

Study Population and Group Definition

Adult patients scheduled for neurosurgical procedures under general anesthesia were evaluated in this study. The study population was established based on predefined inclusion and exclusion criteria. Patients aged between 18 and 75 years with an American Society of Anesthesiologists (ASA) physical status classification of ASA I–II were eligible for inclusion. Patients with advanced or clinically significant cardiovascular or chronic respiratory disease, those diagnosed with cervical myelopathy or significant cervical spine pathology, and patients with incomplete clinical data were excluded from the study.

Patients included in the study were divided into two groups according to the presence or absence of position-related perioperative complications. Patients in whom no position-related complications were observed during the perioperative period were classified as the Uncomplicated group, whereas patients who developed at least one position-related complication were categorized as the Complication group. Group allocation was based on intraoperative findings and clinical assessments performed during the early postoperative follow-up period.

Anesthesia and Intraoperative Management

General anesthesia was administered to all patients in accordance with the institutional standard anesthesia protocols. Anesthetic management was planned by the attending anesthesiologists based on the type and extent of the surgical procedure.

In patients requiring head fixation, local infiltration with 2 mL of 0.5% bupivacaine was administered at the planned pin insertion sites as part of a scalp block to attenuate the hemodynamic response associated with pin placement. Additionally, intravenous fentanyl at a dose of 1–2 µg/kg was administered to provide supplementary analgesia.

During the intraoperative period, position-appropriate support pads were placed at anatomical pressure points to prevent pressure-related injuries and neurovascular complications. To reduce the risk of hypothermia, active temperature management strategies were applied in all patients, including the use of warming blankets and warmed intravenous fluids. Elastic compression stockings were used for deep vein thrombosis prophylaxis.

Patient Positioning and Head Fixation

The surgical positions of the patients were determined based on the type of planned neurosurgical procedure and specific surgical requirements. The recorded surgical positions included prone, supine, sitting, and lateral–park bench positions. Selection of the surgical position and patient positioning was performed according to the clinical judgment of the surgical team.

In patients requiring head fixation, a pin-type head fixation system (Mayfield 2000) was used to ensure optimal exposure of the surgical field and maintain head stability. The decision to apply a pin-based head holder was made considering the localization of the surgical procedure and the need for intraoperative stabilization. In patients who did not require head fixation, surgical positioning was achieved using standard support and stabilization devices.

Hemodynamic Monitoring and Time Points

In all patients, mean arterial pressure (MAP) and heart rate (HR) were monitored and recorded intraoperatively using standard monitoring techniques. Hemodynamic measurements were obtained at predefined time points selected to represent clinically relevant phases of the perioperative period. These time points included before anesthesia induction (T0), after induction (T1), during patient positioning (T2), after completion of positioning (T3), and after extubation or, in patients who remained intubated, immediately before leaving the operating room (T4).

In patients who underwent head fixation, MAP and HR measurements were additionally recorded before, during, and after pin application to evaluate hemodynamic changes associated with the head fixation procedure.

Outcome Measures

The primary outcome of this study was the development of position-related perioperative complications. Secondary outcomes included perioperative hemodynamic changes (MAP and HR) as well as anesthesia and surgical durations.

Definition of Perioperative Complications

Perioperative complications were defined based on clinical findings occurring during surgery or in the early postoperative period that were considered to be related to surgical positioning or head fixation. These complications included neurological symptoms, sensory and/or motor deficits, abnormal cranial nerve function, peripheral neuropathy, spinal cord symptoms, venous air embolism, upper airway pain and/or edema, macroglossia, pneumocephalus, and ocular complications such as hyperemia, chemosis, conjunctival edema, and optic neuropathy.

Postoperatively, clinically stable patients were transferred to the surgical ward, while patients deemed necessary by the attending anesthesiologist were monitored in the post-anesthesia care unit for postoperative care and management. The presence of perioperative complications was recorded based on clinical assessments performed during the intraoperative period and early postoperative follow-up.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for macOS, version 30.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was assessed using the Kolmogorov–Smirnov test. Continuous variables with a normal distribution were presented as mean ± standard deviation, whereas non-normally distributed continuous variables were expressed as median (interquartile range, IQR). Categorical variables were presented as number and percentage [n (%)].

For comparisons between groups, Student's *t*-test was used for normally distributed continuous variables, and Welch's *t*-test was applied when variance homogeneity was not met. The Mann–Whitney U test was used for non-normally distributed continuous variables. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate.

Hemodynamic parameters were comparatively analyzed between groups at predefined time points. Changes over time were evaluated descriptively. A *p* value <0.05 was considered statistically significant for all analyses.

Results

During the study period, a total of 100 patients scheduled for neurosurgical procedures under general anesthesia were assessed for eligibility. Patient selection, exclusion reasons, and the final analysis process are illustrated in Figure 1. Twenty-six patients with severe cardiovascular or chronic respiratory comorbidities, nine patients diagnosed with cervical myelopathy, and four patients with incomplete clinical data were excluded from the study. Data from a total of 61 patients who met the inclusion criteria were included in the final analysis.

A total of 12 position-related complications were observed in 10 patients (16.4%) during the perioperative period. The most frequently observed complications were bilateral orbital edema (n = 3) and diffuse facial edema (n = 3). Among patients who underwent pin-type head fixation, pain at the pin insertion sites accompanied by facial edema was observed in two patients. Other position-related complications included left orbital ecchymosis (n = 1), venous air embolism (n = 1), erythema at joint pressure areas (n = 1), and uvular edema (n = 1). The distribution of position-related perioperative complications by type is presented in Figure 2.

A comparison of demographic characteristics, clinical variables, and perioperative findings between patients with and without complications is presented in Table 1. No statistically significant differences were observed between the groups with respect to age, sex, body mass index, ASA physical status, or the presence of comorbidities.

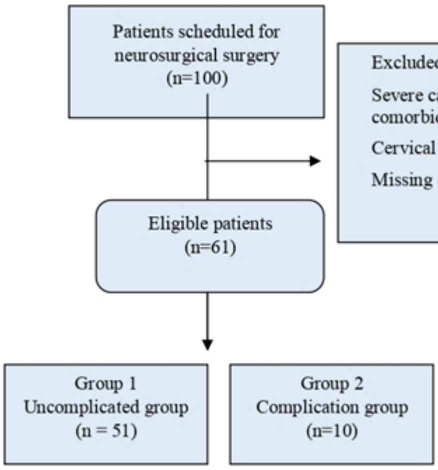

Figure 1. Flow diagram of patient selection and study inclusion

The study population was divided into two groups according to the presence or absence of position-related perioperative complications. Patients without any perioperative complications were classified as the Uncomplicated group (n = 51), whereas patients who developed at least one position-related perioperative complication were classified as the Complication group (n = 10).

When perioperative durations were evaluated, anesthesia duration was found to be significantly longer in the Complication group compared with the Uncomplicated group (p = 0.021). In contrast, no significant difference was observed between the groups regarding surgical duration (p = 0.214). Similarly, no statistically significant differences were found between the groups in terms of total intraoperative fluid administration or blood product transfusion requirements (Table 2).

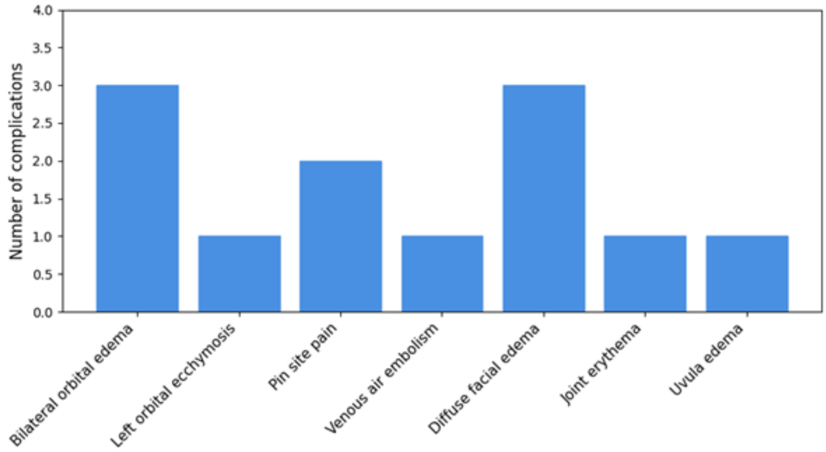

Figure 2. Distribution of perioperative position-related complications

Table 1. Demographic characteristics and comorbidities of the study groups

Variables	Uncomplicated group (n = 51)	Complication group (n=10)	P*
Gender			
Female, n (%)	17 (33,3)	4 (40)	0,725
Male, n (%)	34 (66,7)	6 (60)	
Age, mean ± SD, years	61±11	55±18	0,338
Body mass index, mean ± SD, kg/m2	27,3±4,4	29,5±5,8	0,167
ASA			
ASA-I, n (%)	3 (5,89)	0 (0)	0,326
ASA-II, n (%)	48 (94,11)	10 (100)	
Comorbidities			
Hypertension, n (%)	17 (51,5)	5 (71,4)	0,427
Diabetes mellitus, n (%)	7 (21,2)	4 (57,1)	**0,075**
Cardiovascular disease, n (%)	2 (6,1)	1 (14,3)	0,448
Chronic respiratory disease, n (%)	2 (6,1)	1 (14,3)	0,448
Obesity, n (%)	10 (30,3)	5 (71,4)	0,081
Malignancy, n (%)	4 (12,1)	0 (0)	1,000
Thyroid disease, n (%)	4 (12,1)	0 (0)	1,000
Rheumatologic disease, n (%)	1 (3)	1 (14,3)	0,323

***** ***P <0.05, Significance level,; SD, Standard Deviation; ASA, American Society of Anesthesiologists.***

The most frequently applied surgical position in the study population was the prone position, accounting for 60.7% of procedures (n = 37), followed by the supine position in 31.1% (n = 19), the sitting position in 4.9% (n = 3), and the lateral–park bench position in 3.3% (n = 2). Although a numerically higher number of complications was observed in patients positioned prone, there was no statistically significant difference between surgical positions with respect to the number of patients developing complications (p = 0.431) (Table 2**).** The distribution of specific position-related complications according to surgical position is shown in Figure 3.

Pin-type head fixation (Mayfield 2000) was used for head stabilization in 29 patients (47.5%) of the study population. Among patients who underwent pin-type head fixation, the mean MAP was 60.1 mmHg before head fixation, 67.2 mmHg during head fixation, and 57.4 mmHg after head fixation. At the same time points, mean HR values were 77.8 beats/min, 83.2 beats/min, and 77.7 beats/min, respectively. The temporal distribution of MAP and HR values before, during, and after head fixation is presented in Figure 4.

The distribution of MAP and HR values over time in the Uncomplicated and Complication groups is shown in Table 3. At baseline (before anesthesia induction, T0),

Table 2. Intraoperative and surgical characteristics of the study groups

Variables	Uncomplicated group (n = 51)	Complication group (n=10)	P*
Anesthesia duration, mean ± SD, minute	232,3±80,4	299,5±90,2	**0,021**
Surgical duration, mean ± SD, minute	185,7±71,9	216,5±64,9	0,214
Total fluid volume administered, mean ± SD, ml	3675,8±1738,2	4255,6±1557,3	0,371
Blood product transfusion, n (%)	9 (17,6)	2 (20)	1,000
Surgical procedure			
Spine surgery, n (%)	31 (60,78)	5 (50)	0,153
Intracranial mass surgery, n (%)	15 (29,4)	4 (40)	
Aneurysm surgery, n (%)	5 (9,8)	0 (0)	
Chiari decompression surgery, n (%)	0 (0)	1 (10)	
Patient positioning			
Supine position, n (%)	17 (33,3)	2 (20)	0,431
Prone position, n (%)	31 (60,8)	6 (60)	
Sitting position, n (%)	2 (3,9)	1 (10)	
Lateral / park-bench position, n (%)	1 (2)	1 (10)	

**** P <0.05, Significance level,; SD, Standard Deviation.***

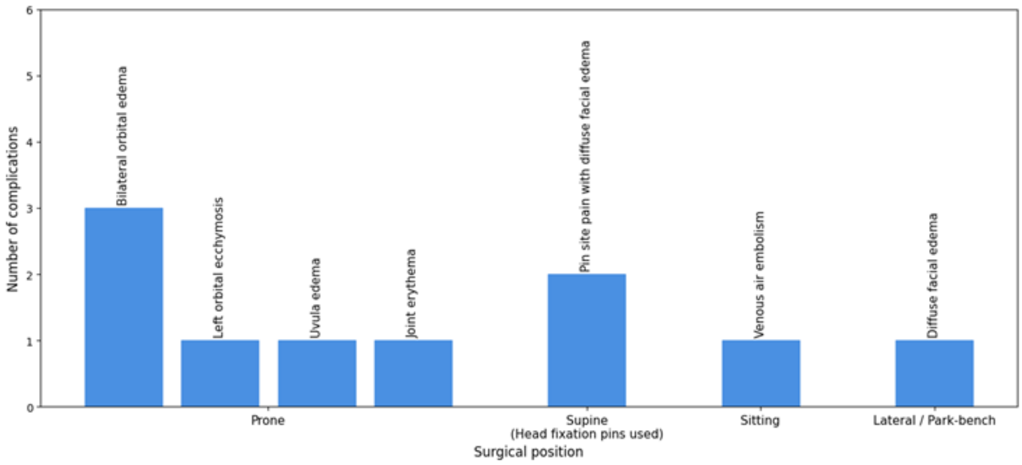

Figure 3. Distribution of position-related perioperative complications according to surgical position

no statistically significant differences were observed between the groups in terms of MAP or HR (p>0.05). Similarly, MAP and HR values were comparable between the Uncomplicated and Complication groups at all subsequent time points, including after anesthesia induction, during patient positioning, after completion of positioning, and in the post-extubation period (all p>0.05) (Table 3).

Discussion

In this prospective observational study, the incidence of position-related perioperative complications in patients undergoing neurosurgical procedures under general anesthesia was found to be 16.4%. As illustrated in Figure 1, the patient selection process, exclusion criteria, and the number of patients included in the final analysis consistently reflect the target study population, providing an appropriate framework for evaluating complications specifically related to patient positioning.

The absence of statistically significant differences between the Uncomplicated and Complication groups with respect to demographic characteristics and baseline clinical variables (Table 1) suggests that position-related complications may arise through multifactorial perioperative mechanisms rather than patient-related factors alone. Nevertheless, the higher prevalence of

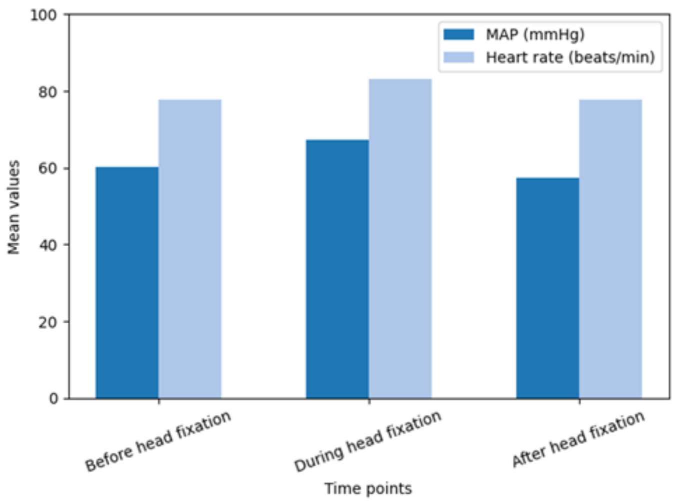

Figure 4. Changes in mean arterial pressure and heart rate associated with pin-type head fixation (n=.29)

Table 3. Changes in mean arterial pressure and heart rate at predefined time points

Variables	Uncomplicated group (n = 51)	Complication group (n=10)	P*
T0: Baseline, before anesthesia induction			
MAP, mean ± SD, mmHg	101,3±15,5	102,4±9,5	0,826
Heart rate, mean ± SD, beats/min	81,6±17,4	84,7±10,9	0,597
T1: After anesthesia induction			
MAP, mean ± SD, mmHg	83,9±16	88,2±13,9	0,437
Heart rate, mean ± SD, beats/min	78,2±13,6	77,1±10	0,813
T2: During position change			
MAP, Median (IQR), mmHg	77,7 (68,7-84,7)	82,5 (73,7-87,7)	0,209
Heart rate, mean ± SD, beats/min	75,4±11,6	76,3±16,9	0,840
T3: After positioning			
MAP, Median (IQR), mmHg	73 (66-76,7)	76,2 (71-84,3)	0,325
Heart rate, mean ± SD, beats/min	71,6±10,6	73,8±15,7	0,582
T4: After extubation / final operating room value if intubated			
MAP, Median (IQR), mmHg	85,7 (71,7-95)	92,2 (85,3-100)	0,209
Heart rate, mean ± SD, beats/min	75,1±9,8	78,6±9,9	0,306

***** *P <0.05, Significance level,; SD, Standard Deviation; IQR, Interquartile range; T, Time point; MAP, Mean arterial pressure. Normally distributed data are presented as mean ± SD, and non-normally distributed data as median (IQR).*

diabetes mellitus in the Complication group, showing a trend toward statistical significance is a clinically noteworthy finding, even though it could not be identified as an independent risk factor. Increased capillary permeability and a predisposition to soft tissue edema in diabetic patients may create a vulnerable background for the development of position-related edema when combined with prolonged surgical or anesthetic duration and mechanical pressure. Indeed, previous studies have reported that diabetes may predispose patients to pressure- and soft tissue–related complications, particularly in the prone position [8].

In the present study, no statistically significant differences were observed between the groups regarding the distribution of surgical procedures or surgical positions (Table 2). However, the significantly longer anesthesia duration in patients who developed complications suggests that prolonged anesthetic exposure may be an important contributing factor in the development of position-related perioperative complications. When the distribution of complications was analyzed, bilateral orbital edema and diffuse facial edema were the most frequently observed findings (Figure 2). This observation is consistent with previous reports indicating that gravitational effects, partial impairment of venous drainage, and prolonged mechanical pressure during neurosurgical procedures performed in the supine, prone, and lateral park-bench positions may result in edema of the face, periorbital region, and upper airway soft tissues [1,9].

In our study, position-related complications were most frequently observed in the prone position, predominantly affecting the periorbital region and upper airway soft tissues (Figure 3). Although the prone position optimizes surgical exposure in spinal and posterior fossa surgeries, it creates a predisposition to edema formation due to partial impairment of venous return associated with the head and face being positioned below the level of the heart, as well as prolonged mechanical pressure [2,9]. The literature emphasizes that facial, periorbital, and upper airway edema are common during prone positioning and that the risk increases with prolonged surgical and anesthetic duration [2,9]. The cases of bilateral periorbital edema and uvular edema observed in our study are consistent with these pathophysiological mechanisms.

Postoperative visual loss (POVL) is a rare but severe complication associated with prone positioning, particularly during prolonged spinal surgery, with a reported incidence of approximately 2–3 per 10,000 cases [10,11]. No cases of POVL were observed in our study. This finding may reflect the effective use of appropriate supports to protect the head and face from excessive pressure. Furthermore, the absence of significant perioperative fluctuations in MAP and HR (Table 3) supports the importance placed on maintaining intraoperative hemodynamic stability.

Perioperative nerve injuries and pressure-related injuries are clinically significant complications that have been reported across all major surgical positions, including the prone position. According to data from the American Society of Anesthesiologists Closed Claims Project, nerve injuries account for approximately 15–16% of anesthesia-related closed claims [12]. The most commonly affected structures include the ulnar nerve, brachial plexus, and lumbosacral nerve roots [4]. Compression, excessive stretching, and ischemia have been identified as the primary mechanisms underlying these injuries [12]. In the prone position, excessive abduction of the upper extremities and shoulder girdle stretching due to head and neck rotation are considered critical risk factors for brachial plexus injury, emphasizing the importance of limiting head rotation and supporting the arms in a neutral position [13]. No nerve injuries or pressure ulcers were observed in our prone-positioned patients, which may be attributable to experienced personnel, standardized padding practices, and regular intraoperative position checks.

Uvular edema observed in the prone position is associated with mechanical trauma or prolonged pressure exerted by the endotracheal tube on oropharyngeal structures. During prolonged surgeries, increased contact between the endotracheal tube and the uvula due to head and neck positioning may impair venous drainage and lead to mucosal edema [14]. The uvular edema observed in our study aligns with this mechanism and highlights the vulnerability of upper airway soft tissues to positional and mechanical factors in the prone position.

The supine position is one of the most commonly used surgical positions in neurosurgery and is applied across a wide range of procedures, with or without head fixation. In this position, the head may be placed in flexion, extension, or rotation depending on surgical requirements, and such alterations in head and neck positioning can significantly affect cervical vascular structures and venous drainage [1,15]. Excessive flexion or rotation of the head and neck has been reported to impair jugular venous drainage, potentially leading to increased intracranial pressure, cerebral congestion, brain swelling, and an increased risk of cerebral ischemia or infarction [1]. To mitigate these adverse effects, maintaining a thyromental distance of at least 2–3 finger breadths and avoiding excessive cervical strain are recommended during head and neck positioning in the supine position [1]. In our study, as shown in Figure 3, complications such as headache and facial edema were observed in patients who developed complications in the supine position, findings that may be attributed to impaired venous drainage and mechanical pressure related to head and neck positioning.

While head fixation with a pin-type head holder in the supine position provides surgical stability, pin insertion may elicit a pronounced sympathetic response with associated hemodynamic fluctuations. Previous studies have demonstrated that scalp block performed before pin insertion significantly attenuates this hemodynamic response; Pinosky et al. reported that bupivacaine scalp block effectively suppressed increases in blood pressure and heart rate during craniotomy [16]. In our study, the use of scalp block and supplemental opioid analgesia before pin insertion resulted in no clinically significant fluctuations in MAP or HR before, during, or after pin placement (Figure 4). These findings suggest that skull block, when combined with appropriate analgesic strategies, may effectively control hemodynamic responses associated with pin-type head fixation.

Overall, although the supine position is widely regarded as safe in neurosurgical practice, failure to individualize head and neck positioning may predispose patients to position-related complications. Our findings underscore the importance of meticulous positioning and close intraoperative monitoring to ensure patient safety in the supine position.

The sitting position is preferred in certain posterior fossa procedures due to improved surgical exposure and enhanced venous drainage [17]. However, elevation of the head above the level of the heart creates a significant negative venous pressure gradient, rendering this position one of the most anesthetically challenging. Physiological and clinical consequences of the sitting position include VAE, hypotension, pneumocephalus, facial edema, and position-related neurological complications [18]. VAE is the most frequently reported and potentially serious complication in the sitting position, with reported incidence rates ranging from 16% to 86% depending on the monitoring modality used, although most cases are subclinical [19]. Dural opening and tumor resection have been identified as the surgical stages most commonly associated with VAE [19]. Clinical severity is related to the volume of entrained air and the accompanying cardiovascular response [20]. Management strategies include cessation of air entry, surgical field flooding, head-down positioning, appropriate positioning maneuvers, and aspiration of air via a central venous catheter [21].

In our study, three patients underwent surgery in the sitting position, and one developed a position-related complication (Table 2). The complication was VAE (Figure 3), diagnosed based on hemodynamic instability, hypoxemia, and a decrease in end-tidal CO_2. Early recognition and prompt intervention, consistent with recommendations in the literature, resulted in no residual sequelae [21]. This finding aligns with previous reports indicating that most VAE cases have limited clinical impact when detected early and managed appropriately [19].

The lateral park-bench position is widely used in posterior fossa surgeries, particularly for cerebellopontine angle tumors, cerebellar hemispheric lesions, and selected vascular pathologies. Although positioning the patient with the lesion side up facilitates surgical exposure, gravitational effects and mechanical pressure on the head and neck may partially compromise venous drainage. Position-related complications such as facial and neck soft tissue edema have been reported in association with the park-bench position, particularly with prolonged surgical duration and suboptimal head and neck alignment [22,23].

In our study, two patients underwent surgery in the lateral park-bench position (Table 2), and one developed diffuse facial edema as a position-related complication (Figure 3). This finding supports the clinical importance of preserving venous drainage and ensuring meticulous head and neck positioning in the park-bench position [22,23].

Limitations

This study has several limitations. First, its single-center design and relatively small sample size, particularly the limited number of patients in the sitting and lateral park-bench positions, restricted the ability to perform detailed statistical analyses specific to these positions. Second, the effects of patient positioning on pulmonary ventilation parameters were not evaluated. Finally, hemodynamic changes were assessed at predefined time points, and continuous invasive monitoring data were not included in the analysis, representing another limitation of the study. Despite these limitations, the prospective design and systematic data collection approach contribute valuable clinical insight into position-related perioperative complications in neurosurgical procedures.

Conclusion

This prospective observational study demonstrates that surgical positions and head fixation techniques used in neurosurgical procedures may be associated with clinically meaningful perioperative complications affecting patient safety. Position-related complications appeared to be more closely associated with perioperative factors such as anesthesia and surgical duration, positioning technique, and intraoperative management rather than patient-related characteristics.

Appropriate patient positioning, standardized padding practices, careful head and neck alignment, and effective intraoperative hemodynamic control play a crucial role in preventing position-related complications. These findings emphasize that patient positioning in neurosurgery should be approached with a multidisciplinary and meticulous strategy, not only to optimize surgical exposure but also to enhance patient safety.

Ethics / Informed Consent

This study was conducted with approval from the Institutional Clinical Research Ethics Committee (Approval No: 2011-KAEK-25 2022/09-17), and written informed consent was obtained from all participants in accordance with the Declaration of Helsinki.

Data Availability Statement

The data used in this study are available from the corresponding author upon reasonable request.

Disclosure

The authors declare that there are no conflicts of interest related to this study.

Financial Disclosure

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