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Evaluation of the effectiveness of Pleth Variability Index (PVI) and Internal Jugular Vein Collapsibility Index (IJV-CI) measurement methods in predicting hypotension following spinal anesthesia

Gül Özlem Akgül, Zeynep Nur Akçaboy, Feryal Akçay, Gülay Yalçın Yılmaz*

Department of Anesthesiology and Reanimation, Ankara Bilkent City Hospital, University of Health Sciences, Ankara, Turkiye

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***Corresponding Author:** Gülay Yalçın Yılmaz, drgulayalcinyilmaz@gmail.com

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ABSTRACT

Aims: Hypotension following spinal anesthesia is a significant issue in clinical practice. The aim of this study is to evaluate the efficacy of Pleth Variability Index (PVI) and Internal Jugular Vein Collapsibility Index (IJV-CI) in predicting the risk of hypotension that may develop in patients undergoing spinal anesthesia while breathing spontaneously.

Methods: After ethics committee approval, 116 patients scheduled for elective orthopedic surgery in the supine position under spinal anesthesia were included. Hypotension was defined as a drop in mean arterial pressure (MAP) below 60 mmHg or more than 20% below the baseline value. Patients who developed hypotension were designated as Group A, and those who remained normotensive as Group B. Preoperative and intraoperative PVI and IJV-CI values were measured for all patients and effectiveness of these values in predicting the risk of hypotension compared.

Results: Hypotension was observed in 69 (59.5%) patients. No statistically significant differences were observed between the groups in the comparison of PVI, and IJV-CI values at any time interval. No correlation between MAP values and PVI, and IJV-CI values at baseline (T0) and post-spinal block (T1) time points was identified.

Conclusion: Our findings demonstrated that neither pleth PVI nor IJV-CI exhibited significant efficacy in predicting hypotension among spontaneously breathing patients.

Keywords: Post-spinal hypotension, Pleth Variability Index, Internal Jugular Vein Collapsibility Index, spontaneous breathing

INTRODUCTION

Spinal anesthesia is commonly used in surgical operations to be performed in the pelvis, lower abdomen, and lower extremities. Hypotension is observed in approximately 15.3% to 33% after spinal anesthesia and can lead to decreased perfusion in organs and ischemic conditions.[1] This hypotension results from a decrease in systemic vascular resistance due to sympathetic blockade[2] and has been associated with increased mortality. To prevent hypotension and mitigate its adverse effects, recommended measures include fluid loading, patient repositioning, and the use of positive inotropic agents.[3,4] In patients with low cardiac reserve or in those who cannot tolerate hypotension or would be adversely affected by it, the ability to predict post-spinal anesthesia hypotension is crucial. Early appropriate intervention in such patients can reduce intraoperative and postoperative complications.[5]

Continuous monitoring of physiological parameters with basic hemodynamic monitoring is mandatory during anesthesia. However, these methods alone are not sufficient to predict the risk of hypotension and cannot directly assess oxygen delivery or cardiac output (CO). Proper fluid management is very important when ensuring intraoperative stability, and it is faster and easier to use non-invasive methods during fluid management. Pulse oximetry plethysmographic waveform variables and ultrasonography (USG) can be used for this purpose.

The Perfusion Index (PI) generated from pulse oximetry is used to interpret peripheral perfusion dynamics due to changes in peripheral vascular tone. It is calculated as the ratio of pulsatile blood flow to non-pulsatile blood flow in peripheral tissue. Many studies have found that a higher baseline PI is associated with a greater decrease in blood pressure and the need for higher doses of positive inotropes.[6]

The Perfusion Index (PVI) is the automated measurement of dynamic changes in the PI, particularly those influenced by respiration. Numerous studies have suggested that PVI can be used as a dynamic parameter for goal-directed fluid therapy in mechanically ventilated patients. While many studies have focused on mechanically ventilated patients, research on spontaneously breathing patients is limited. Since spinal anesthesia-induced hypotension can be related to the patient's volume status, pre-spinal anesthesia measurement of PVI may be used to predict patients at risk for hypotension.[7]

Evaluation of the inferior vena cava (IVC) and internal jugular vein (IJV) using USG is among the recently preferred predictive methods for assessing patients' volume status due to its non-invasive, rapid, and complication-free nature. During spontaneous breathing, inspiration causes negative intrathoracic pressure, increasing venous return and right ventricular filling. There are a limited number of studies examining the efficacy of IJV USG in predicting post-spinal hypotension.[4]

The aim of this study is to evaluate the efficacy of PVI and Internal Jugular Vein Collapsibility Index (IJV-CI), which are non-invasive and dynamic measurement methods, in predicting the risk of hypotension that may develop in patients undergoing spinal anesthesia with spontaneous respiration.

METHODS

The study was conducted with the approval of the Ankara City Hospital No. 2 Clinical Researches Ethics Committee (Date: 29.09.2021, Decision No: E2-21-874). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. 116 patients, aged 18-65 years (ASA class I-II) who were scheduled for elective orthopedic surgery under spinal anesthesia in the supine position were included and written informed consent was obtained from all participants. Patients with an ASA score of 3 or higher, a body mass index of 40 or higher, history of cardiac arrhythmia, peripheral vascular disease, severe heart failure, pregnancy, emergency surgery, a position other than supine, sedation requirement and unsuccessful spinal block were excluded from the study.

The patients were taken to the operating table and rested in the supine position for 5 minutes. Standard monitoring with a GE Healthcare Carescape B 450® monitor was applied including non-invasive arterial blood pressure measurement, five-lead electrocardiogram. Oxygen saturation measurement was done with Masimo Radical-7 Pulse CO-Oximeter®, and probe placed on the index finger of the dominant hand. Time intervals for measurements were determined as follows: baseline values (T0), after spinal anesthesia in supine position (T1), at the 5th (T5), 10th (T10), 15th (T15), 30th (T30), 60th (T60) minutes. After the resting period, baseline heart rate, non-invasive systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP), peripheral oxygen saturation (SpO_2), PI and PVI were measured and recorded.

All ultrasonographic measurements were performed by the same anesthesiologist using the same ultrasound device (Sonosite S-Nerve®), while patients were breathing spontaneously in the supine position. Using a linear probe, the right IJV was visualized at the level of the cricoid cartilage, using B mode in a transverse plane perpendicular to the skin, without applying pressure to the jugular vein as much as possible. The IJV was verified using compression and color Doppler sampling. Dynamic diameter changes were measured using M-mode over a 20-second period of spontaneous respiration, recording maximum (end-expiration) and minimum (end-inspiration) dimensions. The right IJV-CI was calculated using the formula:

Collapsibility Index (%)=

$$[(\text{max IJV diameter} - \text{min IJV diameter})/\text{max IJV diameter}] \times 100$$

Venous access was established through a 20-gauge intravenous catheter on the non-dominant hand, but no pre-spinal fluid loading was performed. Immediately following spinal block administration, intravenous infusion of 0.9% NaCl at 10 ml/kg/hr was initiated. Spinal anesthesia was performed in the sitting position, after disinfection and sterile draping, at the L3-4 or L4-5 intervertebral space using a 25-Gauge spinal needle (Braun®), administering 12.5 mg of 0.5% hyperbaric bupivacaine. The patient was then positioned supine and remained in the supine position throughout the procedure. The level of sensory block was assessed using the pinprick test up to T6-T8 level. Motor block was evaluated using the Bromage Scale. Measurements were conducted at predetermined intervals and recorded throughout the operation.

Hypotension was defined as a decrease in MAP below 60 mmHg or a reduction of more than 20% from baseline. Patients who developed hypotension were classified as Group A, while those who did not were classified as Group B. When MAP fell below 60 mmHg, 5 mg ephedrine was administered, and when heart rate dropped below 50 bpm, 0.5 mg atropine was given.

Statistical Analysis

G Power 3.1.9.2 Package program was used for sample size calculation before starting the study. Based on a previous study,[8] it was calculated that a total of 112 patients should be included in the study with an effect size of d=0.26, 80% power and 0.05 error level, assuming that a 2.3 point difference between the preoperative PVI values of patients who developed and did not develop hypotension would be considered significant.

IBM SPSS Statistics 20 software was used for statistical analysis. Mean±standard deviation and median values were presented for continuous data while frequencies and percentages were presented for categorical data. The Shapiro-Wilk test was used to evaluate the normality of continuous variables. For comparison of continuous variables between two groups, the t-test was used for normally distributed data, while the Mann-Whitney U test was used for non-normally distributed data. For comparisons across three groups, the Kruskal-Wallis test was employed, and the source of any detected differences was explored using Kruskal-Wallis multiple comparison test. Friedman test was used to compare the repeated values measured during the operation (at T0, T1, T5, T10, T15, T30, T60 times) and followed by a post-hoc analysis via Friedman multiple comparison test. Factors affecting the decrease in MAP were analyzed using Multivariate Logistic Regression analysis. A value of $p<0.05$ was accepted as statistically significant.

RESULTS

A total of 116 patients who underwent elective orthopedic surgery in the supine position under spinal anesthesia were included in the study, and all patients were analyzed properly. Hypotension was observed in 69 patients. Patients were divided into two groups as those who developed hypotension (Group A, n=69) and those who did not (Group B, n=47). No statistical difference was observed in comparisons of age, gender, body weight, height, BMI, surgical duration, and fasting duration between the groups. Only ASA scores were found to be higher in Group A, which resulted in a statistically significant difference (p=0.025). Evaluation of patients' comorbidities revealed a significant difference between the groups only in terms of diabetes mellitus (p=0.011), whereas no significant differences were observed for hypertension or coronary artery disease. (Table 1).

Table 1. Comparison of demographic data, surgical duration, fasting duration, asa scores, and comorbidities between groups

		Group A (n=69)	Group B (n=47)	p
Age (years)		48.39±15.33	43.91±14.84	0.095
Weight (kg)		75.42±14.01	78.36±16.17	0.300
Height (m)		1.66±0.08	1.67±0.10	0.342
BMI (kg/m^2)		27.87±5.17	28.40±4.99	0.580
Duration of surgery minute		88.41±18.99	88.19±15.65	0.989
Fasting duration (hr)		8.10±0.38	8.17±0.43	0.704
Gender	Female	45 (65.2%)	25 (53.2%)	0.194
	Male	24 (34.8%)	22 (46.8%)	
ASA	I	28 (40.6%)	29 (61.7%)	0.025
	II	41 (59.4%)	18 (38.3)	
HT	No	38 (55.1%)	30 (63.8)	0.347
	Yes	31 (44.9)	17 (36.2)	
DM	No	52 (75.4)	44 (93.6)	0.011
	Yes	17 (24.6)	3 (6.4)	
CAD	No	67 (97.1)	46 (97.9)	1.000
	Yes	2 (2.9)	1 (2.1)	

Data are shown as mean±SD or number (percentages) of patients. BMI: Body-mass index, hr: Heart rate, ASA: American Society of Anesthesiologists, HT: Hypertension, DM: Diabetes mellitus, CAD: Coronary artery disease

No statistically significant differences were observed between the groups in terms of block level (p=0.776) and the level of spinal anesthesia administration (p=0.342).

In Group A, who developed hypotension and bradycardia, ephedrine was administered to 20 patients, while atropine was administered to 5 patients.

Comparisons of baseline (T0) MAP values between the groups were statistically significant (p=0.001), with MAP values being higher in Group A patients. However, when comparing baseline (T0) PI, PVI, and IJV-CI values between the groups, no statistical difference was observed, despite the values being higher in Group A patients (Table 2).

Table 2. Comparison of baseline (T0) MAP, PI, PVI and IJV-CI values of patients between groups

	Group A (n=69)	Group B (n=47)	p
T0-MAP	108.46±11.42	100.06±13.33	0.001
T0 PI	2.36±1.83	2.33±1.42	0.636
T0 PVI	16.96±6.52	15.62±5.81	0.299
T0 IJV-CI	22.48±9.81	19.87±10.11	0.187

Data are shown as mean±SD (standard derivation), MAP: Mean arterial pressure, PI: Perfusion Index, PVI: Pleth Variability Index, IJV-CI: Internal Jugular Vein Collapsibility Index

The time intervals during which patients' MAP decreased by more than 20% and/or remained below 60 mmHg are given in Figure 1. It was observed that 65.2% of the patients experienced a decrease after spinal block (T1) compared to T0.

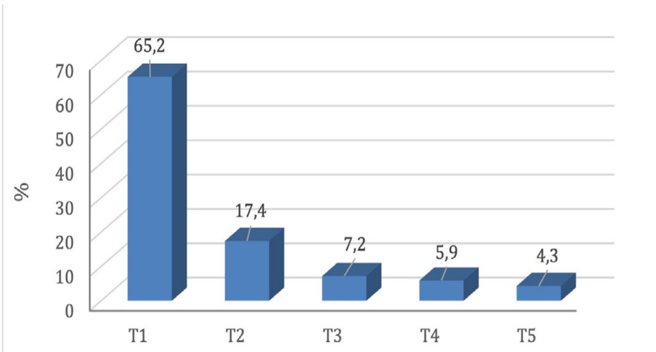

Figure 1. Distribution of hypotension onset times

No statistically significant differences were observed between the groups in the comparison of PI, PVI, and IJV-CI values at any time interval throughout the procedure (Figure 2).

Based on studies[9] that found a higher incidence of hypotension in patients with PVI values >15, we re-evaluated the T0- PVI values in our study patients, categorizing them as those with PVI values of 15 and above, and those below 15. No difference was found in the rate of hypotension between groups. In a study[10] where IJV-CI was used to evaluate fluid responsiveness, a cutoff point of 36% was calculated for IJV-CI. When we re-evaluated our study patients as those with a T0- IJV-CI value equal or greater than 36 and those with T0-IJV-CI<36, no statistically significant difference was found between the groups in terms of hypotension rates (Table 3).

In patients categorized as hypotensive (Group A), an investigation was conducted to determine the presence of a correlation between MAP values and PI, PVI, and IJV-CI values at baseline (T0) and post-spinal block (T1) time points (which is the most common time for hypotension). No statistically significant correlation was identified (Table 4).

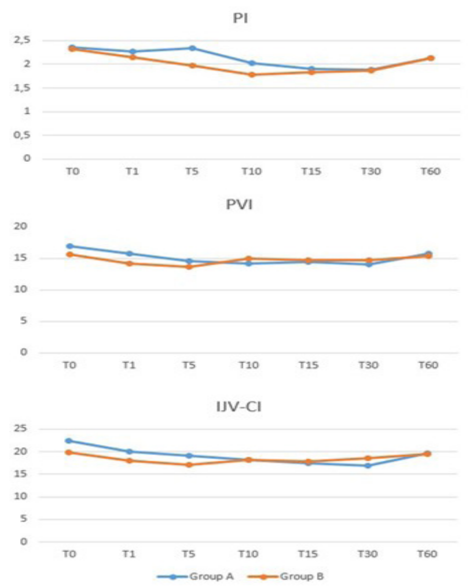

Figure 2. PI, PVI and IJV-CI values in groups
PI: Perfusion Index, PVI: Pleth Variability Index, IJV-CI: Internal Jugular Vein Collapsibility Index

Table 3. Comparison of hypotension rates according to the determined cut-off values of T0-PVI (<15/≥15) and initial IJV-CI (<36%/≥36%)

	Group A (n=69)		Group B (n=47)		p
	n	%	n	%	
T0-PVI <15	30	56.6	23	43.4	0.562
T0-PVI ≥15	39	61.9	24	38.1	
T0-IJV-CI <36%	64	59.3	44	40.7	0.486
T0-IJV-CI ≥36%	5	62.5	3	37.5	

PVI: Pleth Variability Index, IJV-CI: Internal Jugular Vein Collapsibility Index

Table 4. Correlation analysis between MAP and PI, PVI, and IJV-CI values in hypotensive patients (Group A)

		T0 PI	T0 PVI	T0 IJV-CI
T0 MAP	r	0.027	0.063	-0.024
	p	0.828	0.605	0.846
		T1 PI	T1 PVI	T1 SIJV-CI
T1 MAP	r	-0.025	0.152	-0.195
	p	0.841	0.213	0.107

MAP: Mean arterial pressure, PI: Perfusion Index, PVI: Pleth Variability Index, IJV-CI: Internal Jugular Vein Collapsibility Index

In order to examine the risk factors affecting the decrease in MAP, the independent variables age, gender, ASA score, presence of DM, and T0 IJV-CI values, which were found to be significant in the univariate analysis (variables with p<0.20), were included in the multivariate logistic regression analysis and the final model was obtained. The effect of these variables on the decrease in MAP was not found to be significant (Table 5).

Table 5. Multivariate logistic regression analysis of factors associated with decrease in mean arterial pressure

Factors	Regression coefficient (SE)	OR	95 % CI		p
Age (>50)	-0.010 (0.019)	1.010	0.829	1.058	0.576
Gender (female)	0.394 (0.445)	1.482	0.608	3.615	0.378
ASA II	0.888 (0.605)	2.429	0.742	7.959	0.143
DM	1.227 (0.730)	3.411	0.815	14.273	0.093
T0 IJV-CI	0.038 (0.021)	1.039	0.996	1.083	0.073

SE: Standard error, OR: Odds ratio, CI: Confidence interval, ASA: American Society of Anesthesiologists, DM: DM: Diabetes mellitus, IJV-CI: Internal Jugular Vein Collapsibility Index

DISCUSSION

In this study, we aimed to evaluate the predictive capacity of noninvasive measurements PI, PVI and IJV-CI, in the prediction of hypotension, which is an important complication in spinal anesthesia. Our findings revealed that these parameters were not effective in predicting hypotension in spontaneously breathing patients.

In recent years, many studies have been conducted on parameters that would allow predicting post-spinal hypotension in order to prevent hypotension, which is one of the most common and serious complications of spinal anesthesia. It should be kept in mind that if fluid deficit is present which is not uncommon, considering the long fasting periods in the preoperative period for many patients, then post-spinal hypotension frequently occurs. While attempting to correct the fluid deficit, it is necessary to avoid excessive volume overload especially in patients with heart failure. Therefore, it is important to assess the intravascular volume status accurately, quickly, and without complications before administering anesthesia. Many measurement methods can be used for hemodynamic monitoring. Information about CO can be obtained with invasive methods such as arterial catheter, central venous catheter, and pulmonary artery catheter, but the application of these invasive methods takes time and has risks of infection and complications. In addition, PVI and IJV-CI measurement methods can also be used for non-invasive evaluation of the patient's intravascular volume status. Due to its high accessibility and the limited number of studies available in the current literature, this study aimed to evaluate the effectiveness of IJV-CI measurements by comparing them with PVI measurements.

In studies, the incidence of hypotension after spinal anesthesia administration has been reported to be between 15.3% and 33%.[1] This variation is attributable to the different definitions of hypotension, different local anesthetics and their doses chosen, and differences in the level of intervention. In our study, similar to Kılıç et al.,[4] hypotension was defined as a decrease of 20% or more in MAP compared to the baseline value and/or a decrease in MAP below 60 mmHg. As in the study of Kılıç et al.,[4] the incidence of post-spinal hypotension was observed at a high rate of 59.5% in our study, and we believe this is due to our definition of hypotension.

In recent studies, pulse oximetry, a dynamic method for hemodynamic monitoring of peripheral perfusion, has been increasingly used. In particular, the parameters PI and PVI have been monitored to predict fluid responsiveness.[11] It has been reported that by monitoring peripheral perfusion trends with PI and PVI measurements, postoperative hypotension can be predicted and prevented.[12-15] Based on these studies, we aimed to evaluate the baseline PI and PVI values of patients to predict preoperative residual volume status, which is one of the significant causes of post-spinal hypotension.

In their study using pulse oximetry to predict post-spinal hypotension, Yokose et al.[16] found that PVI and PI values of hypotensive patients were higher than those of non-hypotensive patients, similar to our study's findings, but noted that this difference was not statistically significant.

Sun et al.[17] investigated the PI and PVI parameters to predict post-spinal anesthesia hypotension and found that the baseline PVI values of patients who developed hypotension were higher, but did not observe a significant difference in baseline PI. Additionally similar to the findings of our study, they concluded that PVI had poor diagnostic accuracy, stating that it was not a useful predictor of hypotension.

In a study conducted by Küpeli et al.[8] on the geriatric patient population, the incidence of post-spinal hypotension was observed at a high rate of 56.4%, similar to our findings. Similarly, it was found that baseline PVI values were higher in patients who developed post-spinal hypotension, but it was reported that this finding did not reach statistical significance.[8]

In their study investigating whether preoperative volume status assessment could predict the risk of hypotension, Kuwata et al.[18] found that 64% of patients undergoing spinal anesthesia for cesarean section developed hypotension. To predict hypotension, they determined a PVI threshold value of 18, after spinal anesthesia rather than at baseline. Consequently, the researchers reported that PVI after spinal anesthesia was a good predictor of post-spinal hypotension in patients undergoing caesarean delivery.

Yüksek et al.[9] evaluated the ability of PVI values in the geriatric patient population to predict hypotension that may develop after general anesthesia and found a higher incidence of hypotension in patients with a baseline PVI value >15.45%. In their study to predict hypotension that may occur after general anesthesia induction, Tsuchiya et al.[7] emphasized that patients with a preoperative PVI value of 15 or higher had a >25 mmHg decrease in MAP, suggesting that PVI could predict hypotension. Based on these studies, when we re-evaluated the patients in our study by grouping them as those with T0-PVI values of 15 and above and those below 15, we could not find a significant difference in the incidence of hypotension between the groups.

The use of USG in assessing intravascular volume status has increased in recent years due to its non-invasive nature, bedside applicability, and low cost. In particular, the ultrasonographic evaluation of the IVC for this purpose, using collapsibility and distensibility index values calculated from respiratory variations in diameter, has been shown to be beneficial in the management of critically ill patients by guiding selected intravascular hydration strategies.[19]

Ceruti et al.[20] performed IVC-CI measurements to determine the amount of volume replacement before spinal anesthesia and thus prevent hypotension. They determined the fluid replacement cut-off point as 36%, based on the results in the literature. In patients with IVC-CI greater than 36%, they found a slight correlation between the increase in post-spinal IVC-CI and the decrease in MAP, despite adequate fluid administration before spinal anesthesia.

In their study, Jaremko et al.[21] performed IVC-ex, IVC-in, and IVC-CI measurements before spinal anesthesia and after administering 500 ml of isotonic saline infusion to predict post-spinal hypotension, and divided the patients into two groups as hypotensive and non-hypotensive. They reported that, no statistically significant differences were detected between changes in IVCex, IVCin, and IVC-CI comparing hypotensive and non-hypotensive patients at the baseline and after the interventions. Additionally according to ROC analysis, IVC-CI is found not effective in the prediction of severe hypotension during spinal anesthesia in spontaneously breathing patients. In our study, instead of IVC measurements, we aimed to investigate whether IJV-max, IJV-min, and IJV-CI parameters could be used to predict post-spinal hypotension, based on the premise that extrathoracic veins can provide information about intrathoracic pressure and volume changes, and therefore performed measurements on the right IJV. Similar to Jaremko's study, there was no statistically significant difference in baseline measurements between the hypotensive and non-hypotensive groups. This could be because intravascular volume status is not the sole determinant of blood pressure; changes in systemic vascular resistance, which are closely related to sympathetic activity, are also major determinants of hypotension. Additionally, in both studies, the effects of respiratory variations on vascular diameter may not have been evaluated as effectively as in mechanical ventilation due to the patients' spontaneous breathing.

In their study, Mačiulienė et al.[22] measured IVC-in and IVC-ex before and after spinal anesthesia administration in patients undergoing elective knee arthroplasty, and divided the patients into hypotensive and non-hypotensive groups. No statistically significant changes were shown in IVC-in, IVC-ex, and IVC-CI measurements between these groups, compared to baseline and other time points. However, similar to our study, they found a higher collapsibility index in the hypotensive group. Consistent with our study, they concluded that measuring venous diameters before spinal anesthesia was not a predictor of hypotension.

In their study evaluating fluid responsiveness in 34 mechanically ventilated patients, Iizuka et al.[23] measured IJV, SCV, and IVC diameters and collapsibility values. Subsequently, they performed a passive leg-raising test on the patients. An 8% increase in stroke volume, calculated by arterial pulse contour analysis, was considered indicative of fluid responsiveness, and the patients were divided into two groups to examine the role of venous measurements in predicting fluid responsiveness. They showed that right IJV collapsibility was higher in the fluid-responsive group and found a threshold value of 11.4%. In our study, which was conducted on patients with equal fasting periods and the same fluid strategy, patients in the post-spinal hypotension group had a higher collapsibility index, as Iizuka also reported. Although this difference was not statistically significant, we believe that administering fluid before the procedure to patients with a high collapsibility index before spinal anesthesia could reduce the incidence of hypotension.

Haliloğlu et al.[10] demonstrated that in spontaneously breathing septic patients exhibiting fluid responsiveness, both the IVC and internal jugular vein collapsibility index (IJV-CI) values were significantly elevated. They also reported that IJV-CI could be used to assess volume responsiveness in non-mechanically ventilated patients. Furthermore, a cutoff value of 36% was calculated for IJV-CI. In our current study, we re-evaluated whether the proportion of patients with IJV-CI

>36% differed between groups. However, we did not find a statistically significant difference.

Similar to our study, Kılıç et al.,[4] in their investigation evaluating the efficacy of IJV in predicting post-spinal hypotension in spontaneously breathing patients, reported a 46.8% incidence of hypotension. In contrast to other studies in literature[10,23] and also to our findings, this study demonstrated lower collapsibility index values in hypotensive patients compared to non-hypotensive patients.

Limitations

This single-center study was limited to patients undergoing orthopedic surgical procedures, which may restrict the generalizability of the results. Furthermore, intraoperative blood loss was not considered as a variable, and this factor could have affected the incidence of intraoperative hypotension.

CONCLUSION

This study aimed to evaluate the predictive accuracy of the PVI, derived from plethysmographic waveforms, and the IJV-CI, measured via non-invasive USG, for the incidence of hypotension following spinal anesthesia. While prior investigations have indicated potential utility in mechanically ventilated or specific surgical populations, our findings demonstrate that neither PVI nor IJV-CI may reliably predict hypotension in spontaneously breathing patients. Consequently, large-scale, prospective studies are needed to validate these observations and explore the integration of other hemodynamic and clinical variables to refine preoperative risk stratification.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was conducted with the approval of the Ankara City Hospital No. 2 Clinical Researches Ethics Committee (Date: 29.09.2021, Decision No: E2-21-874).

Informed Consent

Written informed consent was obtained from all individual participants prior to their inclusion in the study. Participants were fully informed about the study's aims, procedures, potential risks and benefits, and their rights-including the right to withdraw at any time without consequence. All participants voluntarily signed a written informed consent form.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

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

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Author Contributions

Concept: GÖA; Design: ZNA; Control: GÖA; Data Collection and/or Processing: GÖA, GYY; Analysis and/or Interpretation: ZNA; Literature Review: GYY; Article Writing: ; Critical Review: All Authors.

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