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Prediction of hypertensive responses associated with interscalene block, a prospective cohort study

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Abstract

Background The aim was the effects of interscalene block (ISB) on blood pressure, focusing on identifying anatomical and clinical predictors of hypertensive responses. The aim is to improve the safety and effectiveness of ISB, especially in patients at increased risk of adverse hemodynamic events.

Methods We conducted a prospective cohort study including patients undergoing ISB. Key measurements included carotid intima-media thickness (CIMT), neck length, anterior scalene muscle thickness, BMI, age, history of diabetes mellitus, and hypertension. Blood pressure was monitored at multiple intervals, and logistic regression was used to identify independent systolic blood pressure elevation predictors.

Results A total of 110 patients were included in the study. Reduced anterior scalene muscle thickness (OR = 0.620, 95% CI = 0.462–0.833; $p = 0.002$), increased CIMT (OR = 1.006, 95% CI = 1.002–1.009; $p = 0.001$), and history of hypertension hypertension (OR = 4.31, 95% CI = 1.173–15.85; $p = 0.028$), were independent predictors of blood pressure elevation during ISB ($p = 0.028$, $p = 0.001$, $p = 0.002$). CIMT ≥ 750 µm and anterior scalene muscle thickness ≤ 12.75 mm were identified as critical cut-off values ($p < 0.001$ for both).

Conclusions Preoperative evaluation of anatomical and clinical predictors, such as CIMT and anterior scalene muscle thickness, may improve patient safety, particularly for high-risk individuals during ISB. However, the moderate predictive ability of these factors suggests that they should be considered part of a comprehensive preoperative risk assessment.

Trial registration NCT06394960, date: January 25, 2024, first patient registration date: May 2, 2024.

Keywords Anterior scalene muscle thickness, Blood pressure regulation, Carotid intima-media thickness, Interscalene block, Hypertensive response

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Background

The interscalene block (ISB) is a cornerstone anesthetic technique for shoulder surgeries, offering effective analgesia and reducing reliance on opioids. However, its proximity to the carotid sinus baroreceptors poses risks of hemodynamic instability, particularly hypertensive responses [1–3]. While ISB-induced hypertension is not universally observed, emerging evidence highlights its clinical significance in specific patient subgroups. For instance, Hernandez et al. reported a 16% incidence of hypertensive crises within 5–10 min post-ISB in normotensive patients, with half requiring pharmacological intervention [4]. Similarly, Tutar & Kozanhan demonstrated that 62.5% of medically controlled hypertensive patients experienced a ≥ 20% systolic blood pressure (SBP) elevation after ISB, with 12.5% progressing to hypertensive crises [3]. These findings underscore the need for risk stratification, particularly in patients with pre-existing hypertension or anatomical vulnerabilities [3–6].

Hypertensive responses are mechanistically linked to local anesthetic (LA) spread affecting carotid baroreceptors, which regulate blood pressure via the glossopharyngeal nerve [3]. Structural factors, such as increased carotid intima-media thickness (CIMT), amplify this risk by impairing vascular compliance and baroreceptor sensitivity [7, 8]. Furthermore, anatomical laterality plays a role: Yurtlu et al. observed significantly higher blood pressure elevations in right-sided ISB, likely due to right-dominant sympathetic cardiovascular outflow [9]. These insights emphasize the importance of preoperative evaluation to mitigate risks in susceptible populations.

Anatomical factors, including neck circumference, neck length, and the thickness of the anterior scalene muscle, may play a critical role in the distribution of local anesthetic, potentially influencing the likelihood of such complications. Understanding these anatomical variations is vital for anticipating and mitigating risks during ISB. Additionally, conditions like diabetes mellitus, which can lead to autonomic dysfunction and impaired vascular response, might further compromise cardiovascular stability, particularly in hypertensive individuals [10].

Despite the potential importance of these patient-specific factors, comprehensive studies still need to examine their impact on blood pressure changes during ISB. The primary aim of this study is to identify anatomical features and patient characteristics—such as age, gender, BMI, comorbidities, and anxiety scores—that may predict changes in systolic blood pressure during ISB. A ≥ 20% increase in SBP from T2 at any interval was defined as a disruption in blood pressure regulation. By exploring these factors, this study seeks to improve the safety and effectiveness of ISB, particularly for patients at higher risk of adverse hemodynamic events.

Methods

Ethics approval and registration

This prospective observational study was approved by the Hamidiye Scientific Research Ethics Committee of the University of Health Sciences (decision no = 19/15, dated November 03, 2023). Written informed consent was obtained from all participants prior to their inclusion in the study. The cover page of the questionnaire provided detailed information about the study, and participants were required to sign the consent form before enrollment. The clinical trial was registered prior to patient enrollment in the ClinicalTrials.gov database (registration number: NCT06394960, principal investigator: Mahmut Sami TUTAR, registration date: January 25, 2024, with the first patient enrolled on May 2, 2024). All procedures followed the Helsinki Declaration and the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [11, 12].

Patient enrollment

This study included patients scheduled for elective shoulder surgery with an ISB at the Department of Anesthesiology and Reanimation, Health Sciences University Konya City Hospital, between April 2024 and July 2024. All participants provided informed written consent to participate. Eligible patients were between 18 and 80 and classified within ASA I-III risk groups. Exclusion criteria included renal insufficiency (eGFR < 30 mL/min/1.73 m^2 or chronic kidney disease stage 4–5), hepatic insufficiency (chronic liver disease, cirrhosis, or liver enzymes > 2x upper limit), severe respiratory disease (COPD GOLD III/IV, FVC < 50%, or long-term oxygen therapy), cardiovascular disease (NYHA III/IV heart failure, unstable angina, or recent myocardial infarction),, a history of chronic opioid or benzodiazepine use (> 3 months), allergies to local anesthetic drugs, any contraindications to ISB, and patients scoring ten or higher on the anxiety subscale and seven or higher on the depression subscale of the Hospital Anxiety and Depression Scale (HADS) [13, 14].

Anthropometric measurements

Anthropometric measurements were performed and recorded prior to the procedure to ensure that the anesthesiologist performing the block was blinded to the data. Neck circumference was measured at the level of the thyroid cartilage [15]. Neck length was determined as the distance from the mid-clavicular notch to the angle of the mandible [16]. The anterior scalene muscle thickness was assessed at its thickest point using a linear ultrasound probe positioned perpendicular to the muscle. CIMT was measured at three points on the main carotid artery on the side where the ISB was applied, and the average of these measurements was calculated as the CIMT value

[17]. All measurements were conducted by Ahmet Polat prior to the intervention.

ISB preparation

Patients adhering to the standard preoperative fasting period underwent routine monitoring, including ECG, pulse oximetry, heart rate (HR), and non-invasive blood pressure (systolic blood pressure [SBP], diastolic blood pressure [DBP], mean arterial pressure [MAP]), as well as oxygen saturation (SpO2) in the preoperative room. Before the block procedure, peripheral venous access was established using a 20-gauge intravenous (IV) cannula, and a sodium chloride solution infusion was initiated at a rate of 8–10 ml/kg/hour. For premedication, 1–3 mg of midazolam IV was administered to achieve a Ramsey sedation level of 2.

Ultrasound-guided ISB

For the ISB procedure, patients were positioned at a 45-degree angle on the stretcher, and a linear USG probe was placed in the supraclavicular fossa to visualize the sternocleidomastoid muscle, medial carotid artery, and internal jugular vein. The brachial plexus was visualized as hyperechoic structures adjacent to the subclavian artery, and the probe was moved cephalad to the interscalene groove. Nerve structures were visualized as round hypoechoic circles between the anterior and medial scalene muscles. The cervical nerve roots were traced until they disappeared into the vertebrae. A peripheral nerve block needle was advanced into the interscalene space using an in-plane approach, and nerve root stimulation confirmed the correct placement. A total of 20 ml of a local anesthetic mixture consisting of 15 ml of 0.5% bupivacaine (Bustesin 0.5%, Verm İlaç) and 5 ml of 2% lidocaine was administered around the C5 and C6 nerve roots with intermittent aspiration, without the addition of epinephrine. Successful motor block was assessed using the loss of shoulder abduction, while the sensory block was evaluated using a pinprick test in the C5 and C6 dermatomes. The ISB was performed by an anesthesiologist with at least five years of experience, who had no prior knowledge of the anthropometric measurements.

Outcome measures

Blood pressure and HR were recorded at 5-minute intervals for 30 min at the following time points = baseline (T1), post-premedication and pre-ISB (T2), post-ISB (T3), 5 min (T4), 10 min (T5), 15 min (T6), 20 min (T7), 25 min (T8), and 30 min (T9). The primary aim of this study is to identify potential anthropometric and patient characteristics (age, gender, BMI, comorbidities, anxiety scores) that may predict changes in systolic blood pressure associated with ISB. A ≥ 20% increase in SBP from T2 at any interval was defined as a disruption in blood pressure regulation [18]. The hypertensive crisis was defined as SBP ≥ 180 mmHg or DBP ≥ 110 mmHg at any time. Nitroglycerin infusion was administered for hypertensive crises [19].

Sample size and statistical analyses

Using G*Power software and the “Linear multiple regression = Fixed model, R^2 deviation from zero” test, a power analysis was performed for seven potential predictive factors = neck length, history of diabetes mellitus, anterior scalene muscle thickness, CIMT, BMI, age, and history of hypertension. With an effect size F^2 of 0.150, $\alpha = 0.05$, and 80% power, the sample size was calculated as 103 patients. Considering the dropout rate, 110 patients were included.

Data were analyzed using IBM-SPSS version 26.0. The Kolmogorov-Smirnov test was used to assess normal distribution. Continuous variables were expressed as mean ± standard deviation or median (25th-75th percentile) depending on distribution, and categorical variables as numbers and percentages. The Independent Samples T-test was used for continuous variables when parametric assumptions were met; otherwise, the Mann-Whitney U test was used. The Chi-Square test was used for categorical variables. Logistic regression analysis identified potential independent risk factors for ISB-induced SBP elevation and blood pressure regulation disruption providing odds ratios (ORs) and their corresponding confidence intervals for each significant predictor. Variables included in the logistic regression model were selected based on their clinical relevance and univariate analysis results, using a p-value threshold of < 0.20 to ensure potentially relevant predictors were considered. The model was constructed using the enter method, where all selected variables were entered into the model simultaneously to assess their independent effects. Model fit was evaluated using the Hosmer-Lemeshow goodness-of-fit test, which indicated no significant lack of fit ($p > 0.05$), confirming the model's adequacy. Blood pressure (systolic, diastolic, and mean arterial pressure) and heart rate changes were analyzed using a two-way repeated measures ANOVA within a multilevel linear model framework. This approach was used to evaluate time effects, group effects, and their interaction (time × group). Assumptions of sphericity were tested using Mauchly's test, and, if violated, the Greenhouse-Geisser correction was applied. Post-hoc analyses with Bonferroni correction were performed to identify significant differences at specific time points. To determine the cut-off values of the numerical variables for predicting hypertensive response, Receiver Operating Characteristic (ROC) analysis was employed. The coordinates obtained from the ROC analysis were transferred to Microsoft Excel 2010, and the point with the highest sum of sensitivity and specificity was identified as the 'optimal cut-off value.' Different cut-off values were systematically evaluated to ensure the selection of the most appropriate threshold. Youden's Index was used as the statistical criterion to identify the optimal cut-off point, further ensuring a robust and evidence-based determination. A p-value of < 0.05 was considered statistically significant.

Results

In this study, 115 cases were initially considered. However, 5 cases declined to participate, leaving 110 cases for evaluation (Fig. 1). Patients with hypertensive responses were classified as Group H ($n = 43$). In contrast, the remaining patients were classified as Group N ($n = 67$). Upon evaluation, patients with a hypertensive response were observed to be older, with a higher BMI, thicker CIMT, and thinner anterior scalene muscle thickness. Among these factors, age, CIMT, and anterior scalene muscle thickness were statistically significant ($p = 0.001$, $p < 0.001$, and $p < 0.001$, respectively). The prevalence of hypertension, diabetes mellitus, and both conditions was significantly higher in Group H ($p < 0.001$, $p = 0.023$, and $p = 0.036$, respectively). Although not statistically significant, females were more common in Group H (60.5% vs. 43.3%, $p = 0.079$). Neck circumference, neck length, smoking status, and history of pulmonary disease were similar between groups ($p > 0.05$ for each). Anxiety and depression scores showed no significant difference ($p = 0.404$ and $p = 0.395$, respectively) (Table 1).

A multivariate logistic regression analysis identified significant variables associated with ISB-induced systolic blood pressure elevation. History of hypertension (OR = 4.31, 95% CI = 1.173–15.85; $p = 0.028$), CIMT (μm) (OR = 1.006, 95% CI = 1.002–1.009; $p = 0.001$), and anterior scalene muscle thickness (mm) (OR = 0.620, 95% CI = 0.462–0.833; $p = 0.002$) were found to be

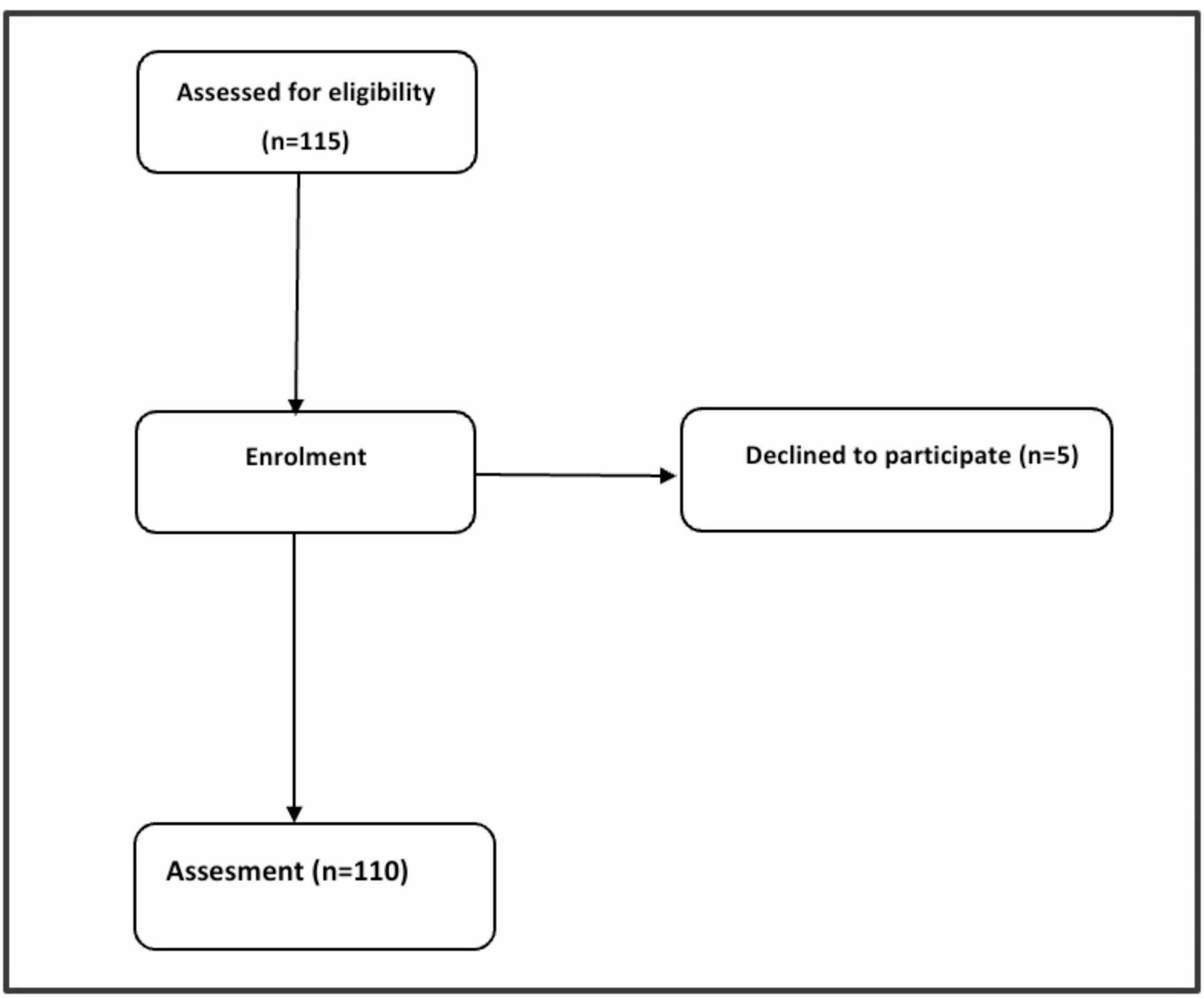

Fig. 1 Study flowchart

Table 1 Evaluation of patient parameters in relation to systolic blood pressure elevation induced by interscalene block

Factor	Group H ($n=43$)	Group N ($n=67$)	P value
Age (yr)	60.7 ± 9.2	53.2 ± 12.4	0.001
Height (cm)	163.1 ± 8	166 ± 8.3	0.067
Weight (kg)	80.44 ± 16.37	79.15 ± 11.73	0.655
BMI(kgm^{-2})	30.22 ± 5.71	28.79 ± 4.33	0.139
Neck circumference (cm)	40(37–43)	40(38–42)	0.985
Neck length (cm)	13(11–14)	13(12–15)	0.104
Anterior scaleneus muscle tightnes (mm)	11.62 ± 2.32	13.2 ± 1.99	< 0.001
CIMT (µm)	850 ± 240	660 ± 150	< 0.001
Gender (Female)	26(60.5%)	29(43.3%)	0.079
ASA physical status			
1	6(13.9%)	6(8.9%)	0.183
2	22(51.2%)	46(68.7%)	
3	15(34.9%)	15(22.4%)	
Side (Right)	26(60.5%)	42(62.7%)	0.815
Smoking	9(20.9%)	22(32.8%)	0.176
Pulmoner disase	8(18.6%)	9(13.4%)	0.464
Additional disase	35(81.4%)	36(53.7%)	0.003
Hypertension	25 (58.1%)	17 (25.4%)	< 0.001
Diabetes mellitus	16(37.2%)	12(17.9%)	0.023
Both diabetes mellitus and hypertension	11(25.6%)	7(10.4%)	0.036
Other disase	3(7%)	10(14.9%)	0.208
HADS anxiety score	6.26 ± 1.33	6.03 ± 1.41	0.404
HADS depression score	4.01 ± 1.1	5 ± 1.13	0.395

Data presented as mean ± standart deviation, median (Q1-Q3), or n (%).cm, centimeter; mm, millimeter; µm, micrometer; kg, kilogram; ASA, American Society of Anesthesiologists physical status; CIMT, Carotis intima-media thicness; HADS, Hospital Anxiety and Depression Scale

Table 2 Multivariate regression analysis of variables associated with interscalene block-induced systolic blood pressure elevation

Variable	Reference group	OR (95% CI)	P value
Age (per year)	-	1.002(0.951–1.055)	0.947
Anterior scaleneus muscle tightnes (mm)	-	0.620(0.462–0.833)	0.002
CIMT (µm)	-	1.006(1.002–1.009)	0.001
Diabetes mellitus	no diabetes mellitus	2.82(0.56–14.34)	0.210
Hypertension	no hypertension	4.31 (1.173–15.85)	0.028
Both diabetes mellitus and hypertension	no diabetes mellitus or no hypertension	0.361(0.041–3.199)	0.360

mm, millimeter; µm, micrometer; OR, Odd's ratio; CI, confidence interval; CIMT, Carotis intima-media thicness

independently associated with this condition (Table 2). ROC analysis identified cut-off points for predicting systolic blood pressure elevation= "CIMT ≥ 750 µm" and "anterior scalene muscle thickness ≤ 12.75 mm."

Table 3 Test values regarding independent risk factors for predicting clinically significant blood pressure elevation induced by interscalene block

Factor	Cut off	Specificity (%)	Sensitivity (%)	AUC (95% CI)	P value
CIMT (µm)	750	70.1	58.1	0.743 (0.651–0.835)	< 0.001
Anterior scalene muscle thicness (mm)	12.75	65.1	62.7	0.687 (0.586–0.788)	< 0.001

mm, millimeter; µm, micrometer; AUC, Area under curve; CI, confidence interval; CIMT, Carotis intima-media thicness

Sensitivity, specificity, and ROC curve areas for these values are presented in Table 3; Fig. 3a and b.

Regarding changes in blood pressure and heart rate over time, significant differences were observed in the time*group interactions for systolic, diastolic, and mean arterial blood pressures (SABP, DABP, and MABP) between the groups, while heart rate changes remained similar ($p < 0.001$, $p < 0.001$, $p < 0.001$, and $p = 0.298$, respectively) (Fig. 3). Hypertensive crises occurred in three individuals (7%) in Group H, compared to none in Group N ($p = 0.057$). Horner's syndrome was observed in four individuals (9.3%) in Group H and five individuals (7.5%) in Group N, with no statistically significant difference between the groups ($p = 0.735$). No significant differences in Ramsey scores were observed between the groups ($p = 1$), indicating consistent sedation levels across all participants.

Discussion

This study investigated the relationship between anthropometric measurements and patient variables in predicting hypertensive responses during ISB. Our findings indicate that increased CIMT, reduced anterior scalene muscle thickness, and a history of hypertension are significant independent predictors of blood pressure elevation during ISB.

The significant role of CIMT as a predictive factor in this study aligns with existing literature, which links increased CIMT to a heightened risk of cardiovascular complications due to underlying atherosclerosis. However, this study emphasizes the critical importance of CIMT in the specific context of ISB-induced hypertensive responses, providing new insights into cardiovascular risk factors during anesthesia. The significant role of CIMT as a predictive factor in this study aligns with existing literature, which links increased CIMT to a heightened risk of cardiovascular complications due to underlying atherosclerosis [20–22]. However, our study further emphasizes the importance of CIMT by demonstrating its independent predictive value, specifically in the context of ISB-induced hypertensive responses. This

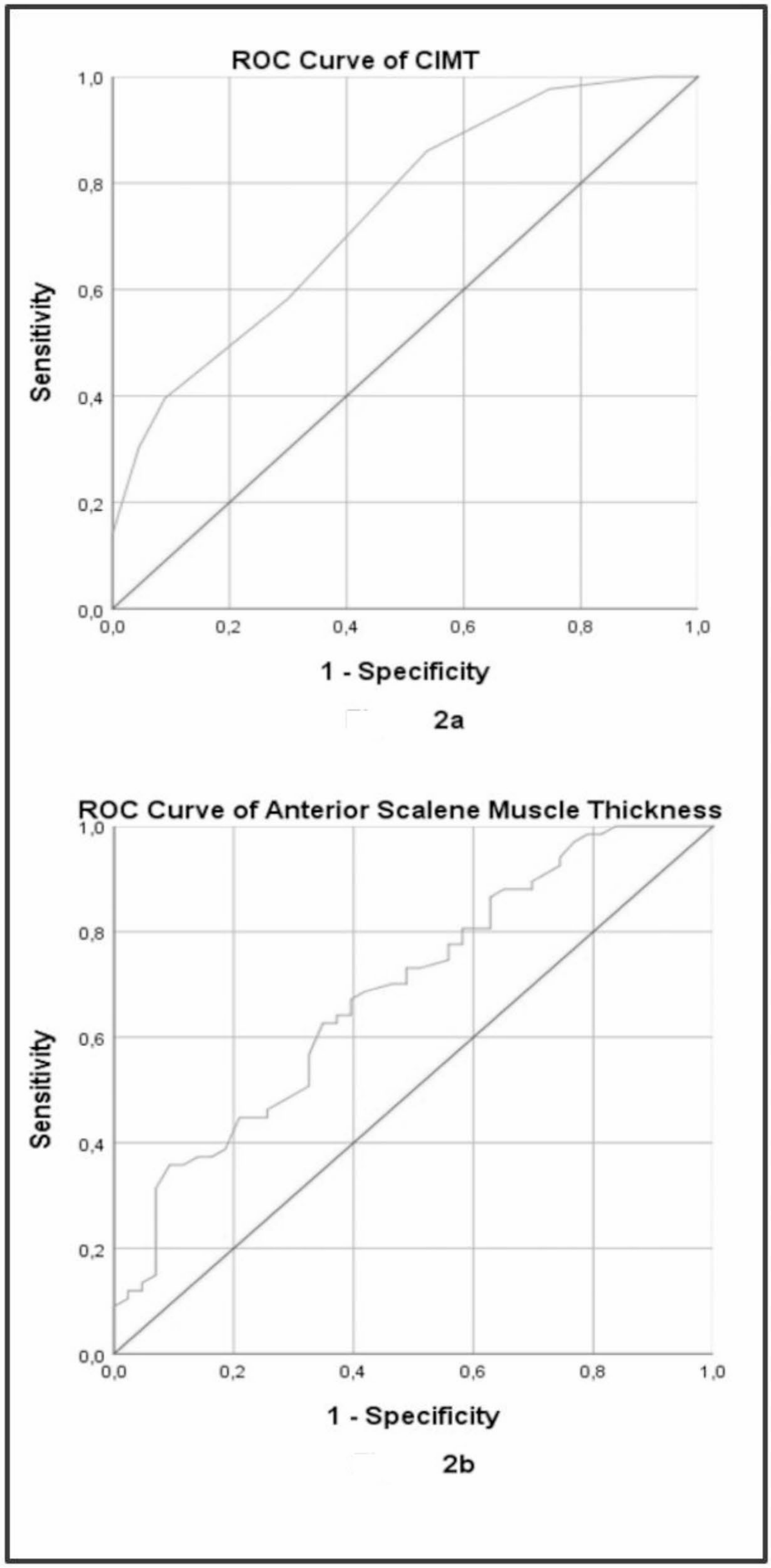

Fig. 2 (**a**) ROC Curve Analysis of CIMT for predicting clinically significant systolic blood pressure elevation induced by interscalene block. (**b**) ROC Curve Analysis of anterior scalene muscle thickness for predicting clinically significant systolic blood pressure elevation induced by interscalene block

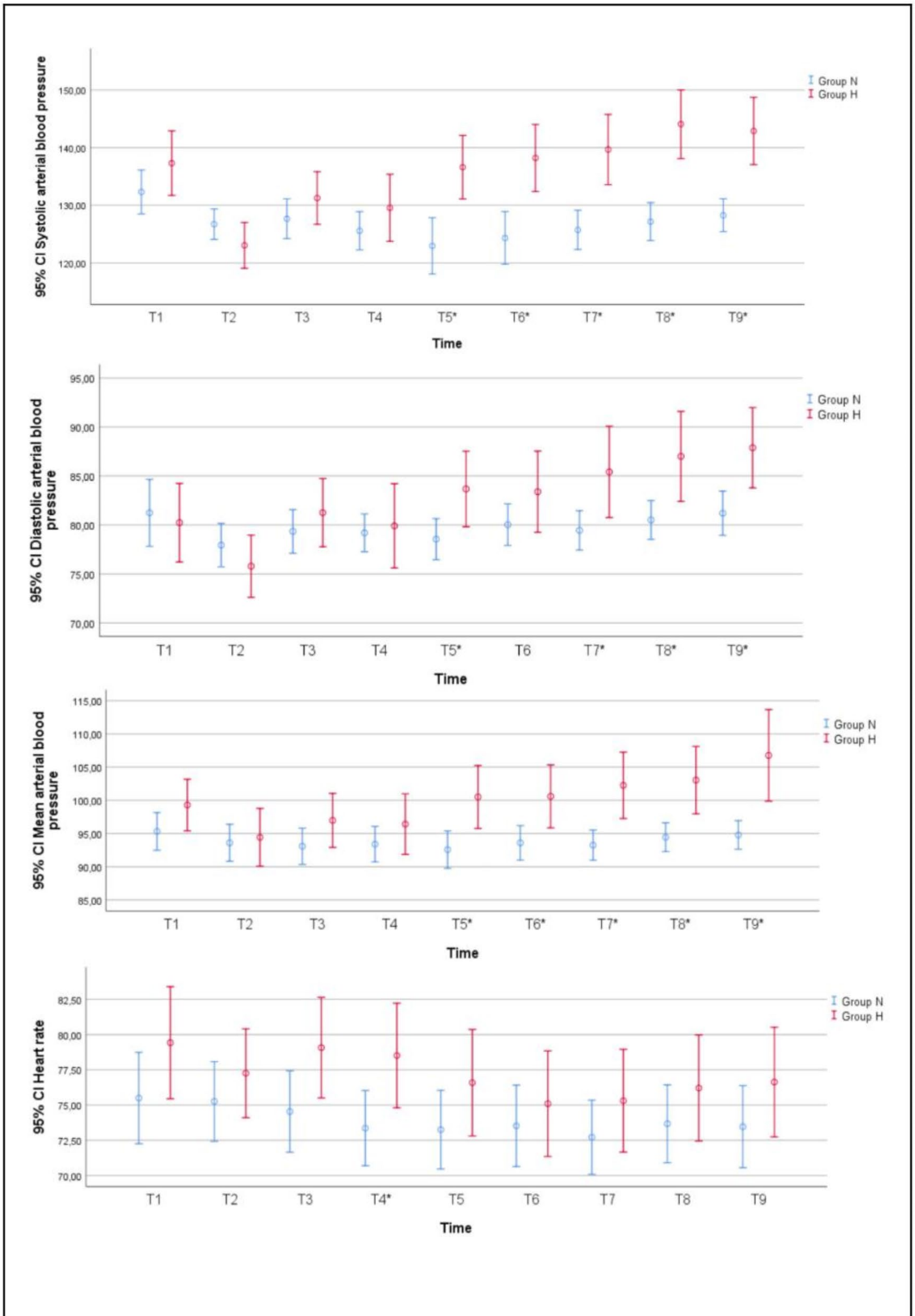

Fig. 3 Patient hemodynamic parameters, * $p < 0,05$

adds a new dimension to understanding cardiovascular risk factors during anesthesia, underlining the need for more targeted preoperative assessments. CIMT, a well-established marker of atherosclerosis, correlates with cardiovascular risk, particularly in hypertensive patients where increased arterial stiffness and impaired baroreceptor sensitivity can exacerbate hypertensive episodes during anesthesia [20, 23]. By confirming the role of CIMT in this specific clinical scenario, our findings not only reinforce the established knowledge but also suggest that the integration of CIMT measurement into routine preoperative evaluations could enhance patient safety during ISB. In light of these findings, we recommend that CIMT be considered a routine part of the preoperative evaluation in patients undergoing ISB, particularly those with known cardiovascular risk factors, to better predict and manage potential hypertensive responses. Our study reinforces this by identifying CIMT as a critical, independent predictor of blood pressure elevation during ISB, with a cut-off value of 750 μm providing strong sensitivity and specificity. These findings suggest that measuring CIMT can be instrumental in assessing cardiovascular risk and predicting hypertensive responses to ISB, making it an essential consideration in clinical practice.

The inverse relationship between anterior scalene muscle thickness and hypertensive response is a novel finding that highlights the importance of anatomical considerations in ISB. A thinner anterior scalene muscle may allow for a more extensive spread of the local anesthetic, increasing the risk of affecting adjacent structures like the carotid sinus. This finding aligns with previous reports indicating that the anatomical spread of the anesthetic is a crucial determinant of hemodynamic outcomes during ISB [2, 24]. Given the novelty of this finding, it opens up new avenues for future research to explore how anatomical variations can influence the safety and efficacy of ISB, potentially leading to more personalized approaches in anesthesia. Based on these results, we propose that the anterior scalene muscle thickness measurement should be included in the preoperative assessment protocol for ISB, as it may help predict and mitigate hypertensive responses by tailoring the anesthetic approach to the patient's specific anatomy.

While CIMT and anterior scalene muscle thickness were identified as significant predictors in this study, these parameters' moderate AUC values and sensitivity-specificity indicate limited predictive ability. For example, the AUC for CIMT was 0.743 (0.651–0.835), and for anterior scalene muscle thickness was 0.687 (0.586–0.788), suggesting that although these factors are statistically significant, their clinical utility as standalone predictors is restricted. This emphasizes the need to incorporate these predictors into a broader preoperative risk assessment framework, alongside other clinical and anatomical variables, to enhance the accuracy of risk stratification for hypertensive responses during ISB.

Our study corroborates previous findings that patients with a history of hypertension are particularly vulnerable to blood pressure fluctuations during ISB [3–6]. Our findings align with the literature, showing that a history of hypertension was an independent predictive factor, leading to a hypertensive response approximately 3.3 times more frequently compared to those without a history of hypertension. This vulnerability is likely due to compromised vascular compliance and altered autonomic regulation commonly seen in hypertensive individuals [25]. The observed hypertensive crises in a subset of patients, although limited, underscore the importance of careful monitoring and the reassurance of potential preemptive management strategies in high-risk populations.

Our study's findings, particularly the lack of significant correlation between factors such as neck circumference and length with hypertensive responses, highlight the potential for future research to enhance our understanding of ISB. This suggests that while these factors may influence other aspects of ISB, they are not primary determinants of blood pressure changes in this context. This finding challenges existing literature and indicates the potential for further research to clarify these relationships [26]. These results also highlight the need for future studies to identify other anatomical or physiological parameters that might better predict hypertensive responses, allowing for improved risk stratification and personalized anesthetic care.

However, our study has certain limitations. Firstly, in this research, the hemodynamic parameters of patients were monitored for 30 min following the ISB, and due to the nature of the study, long-term follow-up of the patients was not conducted. Our study only examined specific anthropometric and patient characteristics, while other potential factors were disregarded. Another feature of this study is that, due to the lack of similar studies, we had a sample size encompassing many potential factors. Therefore, future studies should explore this topic with a more optimal sample size or different parameters. In the future, studies that include a broader range of patient parameters and more extended follow-up periods are needed to validate these findings and investigate other possible risk factors.

Conclusions

In conclusion, our study identifies critical anthropometric and clinical factors, such as CIMT and anterior scalene muscle thickness, that contribute to hypertensive responses during ISB. While these factors were found to be significant predictors, their moderate AUC values and sensitivity-specificity indicate a limited predictive ability. These parameters should be considered part of a comprehensive preoperative risk assessment rather than standalone predictors. By integrating these findings with the existing literature, we can better understand the risks associated with ISB and develop strategies to enhance its safety, particularly for patients with pre-existing cardiovascular conditions. Future research should focus on refining anesthetic techniques and incorporating additional predictors to minimize the risk of adverse hemodynamic events.

Abbreviations

ISB	Interscalene block
CIMT	Carotid intima-media thickness
HADS	Hospital Anxiety and Depression Scale
HR	Heart rate
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
MAP	Mean arterial pressure
SpO2	Oxygen saturation
IV	Intravenous
ROC	Receiver Operating Characteristic

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Author contributions
M.S.T: Conception and design, data acquisition, analysis, interpretation, drafting, revising, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, roles/writing-original draft, writing-review. A.P: Conception and design, data acquisition, analysis, interpretation, drafting, revising, funding acquisition, visualization. R.K: Conception and design, data acquisition, analysis, interpretation, drafting, revising, resources, roles/writing-original draft, writing-review B.K: Conception and design, data acquisition, analysis, interpretation, drafting, revising, methodology, writing review. I.A: Conception and design, data acquisition, analysis, interpretation, drafting, revising, validation. F.D: Conception and design, data acquisition, analysis, interpretation, drafting, revising, project administration, validation. A.Y: Conception and design, data acquisition, analysis, interpretation, drafting, revising, investigation, software. M.H.S: Conception and design, data acquisition, analysis, interpretation, drafting, revising, supervision, roles/writing-original draft, writing-review. M.Y: Conception and design, data acquisition, analysis, interpretation, drafting, revising, supervision, roles/writing-original draft. B.K: Conception and design, data acquisition, analysis, interpretation, drafting, revising, investigation, supervision, roles/writing-original draft, writing-review.

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Data availability
The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This prospective observational study was approved by the Hamidiye Scientific Research Ethics Committee of the University of Health Sciences (decision no = 19/15, dated November 03, 2023). We obtained written and verbal consent from patients.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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