e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(11); 514-522

Original Research Article

Efficacy of Ultrasonographic Inferior Venacaval Collapsibility Index and Caval-Aorta Index for Averting Spinal Anaesthesia Induced Hypotension: A Randomised Controlled Trial

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Received: 25-08-2024 / Revised: 23-09-2024 / Accepted: 26-10-2024
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Conflict of interest: Nil

Abstract:

Background: USG hydration status assessment by Inferior venacava collapsibility index (IVCCI) & caval aorta index detects the early phase of hypovolemia caused by spinal anaesthesia.

Objectives: To evaluate IVCCI & Caval Aorta index guided preoperative volume optimization in reducing the incidence of spinal induced hypotension (SIH), requirement of vasopressors, total fluid requirement & to correlate the utility of these indices in predicting SIH.

Design: Randomized controlled trial.

Setting: Operating room Single centric study during the period December 2020 to May 2022.

Patients: Overall, 120 patients of 18-65 years, ASA I or II, scheduled for infraumbilical surgeries were randomly divided into Group A, Group B with IVCCI guided and caval aorta index guided volume correction respectively. Patients' refusal for consent, need for IBP, Mean arterial pressure (MAP<70mmHg), contraindications for SAB and BMI>30kgm^{-2} were excluded.

Interventions: USG guided hydration status optimization in preoperative period incorporating IVCCI & caval aorta index measurements before the commencement of Spinal anesthesia. Main outcome measures: The primary aim of this study was to compare the incidence of SIH between the groups.

Results: Statistical Analysis was done in 158 patients with SPSS version19. After fluid correction Group A showed higher SIH 55.17% (32/58) than Group B 37.93% (22/58) P<0.0001 thus suggesting a significant reduction of hypotension in Group B (62%) than Group A (44.82%) P<0.0001. Dose of Vasopressors given intraoperatively were higher in Group A 34.48% (20/58) than Group B 17.24% (10/58) P<0.001. The total fluids given were approximately similar in both the groups (P>0.005) ROC analysis showed that Caval-Aorta index was a better predictor of SIH with 94.4% sensitivity,96.9% specificity & 74% accuracy with area under the curve (AUC) 0.956 when compared to IVCCI which showed 94.4% sensitivity, 65.6% specificity and 60% accuracy in predicting SIH with AUC of 0.793.

Conclusion: Prespinal USG guided Caval aorta index directed fluid optimization reduces the incidence of SIH and vasopressor requirements and is found to be a superior predictor of SIH than IVC collapsibility index.

Trial registration: Clinical trials.gov (CTRI/2020/10/028612).

Keywords: Inferior Venacava, Aorta, Hypotension, Fluid Optimization, Receiver Operating Characteristics.

Introduction

Hypotension is the most common side effect of Sub arachnoid block (SAB). The causes of Spinal Induced Hypotension (SIH) include block above T5 level, age above 40yrs, sympathetic blockade, decreased cardiac output, low preoperative volume status, comorbidities, preoperative fasting and medications. [1] Hydration status of the patients is a major predictor of SIH. In patients with pre-existing intravascular fluid deficit, the effects of hypotension are pronounced, leading to untoward side effects like nausea, vomiting, aspiration, dizziness, syncope, cardiac arrhythmias and

ischemic effects. Preloading or co-loading of fluids although routinely performed to prevent and treat SIH; [2] carries the risk of volume overload leading to pulmonary edema, congestive cardiac failure, and renal dysfunction which may prove deleterious in high-risk patients. [3] Assessing preoperative volume status of patients undergoing spinal anesthesia and optimizing it may to a greater extent reduce the intensity of SIH. There are several methods for assessing intravascular volume preoperatively however most of them are either invasive or burdened with erroneous measurements due to complex calculations. USG guided measurement of Inferior vena cava diameter (IVCD) during respiration is a quick and non-invasive dynamic parameter for assessment of status of intravascular volume. IVC Collapsibility index is determined by maximum diameter of the IVC (IVCDmax) at end expiration, minimum diameter (IVCDmin). Utility of Inferior venacaval collapsibility index (IVCCI) for prevention of SIH is established in several studies. [4] IVCCI is reliable, easy and non-invasive nevertheless it has certain limitations like the need to compare it with body surface area (BSA), and variation with respiration.

Along with IVC, measurement of abdominal aortic diameter (Ao) in systole has also been recommended for volume status assessment of the patients. USG determination of diameters of abdominal Aorta and correlating it with maximum IVC diameter; known as Caval Aorta index (IVCmax: Ao index) is a newer diagnostic tool, easy to perform and relevant to assess volume status in body. [5] USG guided Caval Aorta index is found superior in comparison to Mean Arterial Pressure (MAP), heart rate variability (HRV), and Central Venous Pressure (CVP). Several authors have studied USG guided IVCCI and Caval Aorta index in volume assessment and prediction of hypotension individually. However very few studies have been conducted on USG guided identifying and optimizing fluid status utilizing these parameters before spinal anesthesia to curtail as well as predict hypotension, hence we aimed to compare the effectiveness of IVC collapsibility index and Caval Aorta index in reducing the incidence of Spinal induced hypotension (SIH). Although IVC and Aorta both are sensitive to changes in the intravascular volume, but aorta is relatively less affected by position or respiration unlike IVC hence we hypothesized that optimizing fluid status utilizing ultrasonographic Caval Aorta index may be a more reliable in assessing and optimizing peri-operative volume status of patients and prove to be better predictor of SIH than IVCCI.

The primary objective of our study was to assess the reduction in the incidence of hypotension in IVC collapsibility index group and Caval Aorta index group. Secondary objectives were to assess intraoperative fluid requirement, requirement of vasopressors in both the groups and to correlate the utility of both IVCCI and Caval-Aorta Index for predicting SIH.

Methods

The study was registered with Clinical Trial Registry India (CTRI/2020/10/028612). Written informed consent was taken from of all participants.

Ethics: Ethical approval for this study (SNMC/IECHSR/2019-20/A-78/1.1) was provided by institutional ethics committee (IEC) on human subject research of S. Nijalingappa Medical College and HSK hospital and Research Centre Bagalkot Karnataka (Chairperson-Dr. S. L. Hoti Scientist-Director grade scientist ICMR-NITN, Belgaum) on 24th June 2020.

Overall, 120 patients of age group18-65 years, ASA I or II, posted for infra umbilical surgeries under SAB were included in the study. The study period was from December 2020 to May 2022. Patients who refused to give consent, patients with need for invasive blood pressure monitoring (IBP), pre-existing hypotension (Systolic blood pressure [SBP]<90mmHg or MAP<70mmHg), absolute or relative contraindications to undergo SAB, BMI> 30kgm^{-2}, patients sensitive to anesthetic drugs and patients posted for unilateral spinal anesthesia were excluded from this study. Participants were randomly divided into 2 groups of 60 patients each using computer generated random number tables. Concealment of group allocation was done using sealed opaque envelopes. We named the groups as Group A (IVCCI group where IVC guided volume optimization was done) & Group B (Caval Aorta index group where IVC and Aorta ratio guided fluid optimization was done). Preoperative fasting of 6 hours was ensured. Once the patient was shifted to theatre 18G cannula was secured and monitors like heart rate (HR), pulse oximetry (SPO2), Electrocardiogram (ECG) and non-invasive blood pressure (NIBP) were attached and baseline parameters noted. The ultrasound assessments were then carried out in both the groups utilizing Logic E GE portable USG machine (GE healthcare, CALIFORNIA USA) by an anesthesiologist with level 1 experience of USG. In Group A, patients USG examination of IVC was carried out in supine position using a curvilinear probe of 1-8 Hz. The probe was positioned on subxiphoid region longitudinally & Inferior venacava diameter was assessed just distal to IVC hepatic vein juncture, almost 2 cm distance from heart. [6] IVC was identified by Doppler compressibility and collapse with spontaneous respiration. The largest & smallest anteroposterior (AP) diameter of IVC were measured during

expiration & inspiration respectively. IVCCI was estimated using the equation (IVCDMAX - IVCDMIN)/IVCDMAX ×100 [7] (Figure 1).

Figure 1: USG image of IVC and calculation of collapsibility index

Based on previous studies patients with IVCCI cutoff value of ≥36% were considered as fluid responders [8]. Fluid bolus dose of 500ml crystalloids (Ringer Lactate) was given over 15 mins to all the fluid responders.

IVC was then reassessed similarly and fluids continued until IVCCI value of <36% was observed on USG thereby suggesting fluid optimization. Once the fluid optimization using IVCCI was complete spinal anesthesia was administered and episodes of hypotension noted.

Similarly in Group B patients USG guided Abdominal Aorta was visualized 10mm above the celiac trunk and then the largest internal AP diameter of Aorta was measured during systole, along with it maximum IVC diameter was taken during expiration; then Caval Aorta index was then estimated by taking the ratio of both. [9] (Figure 2)

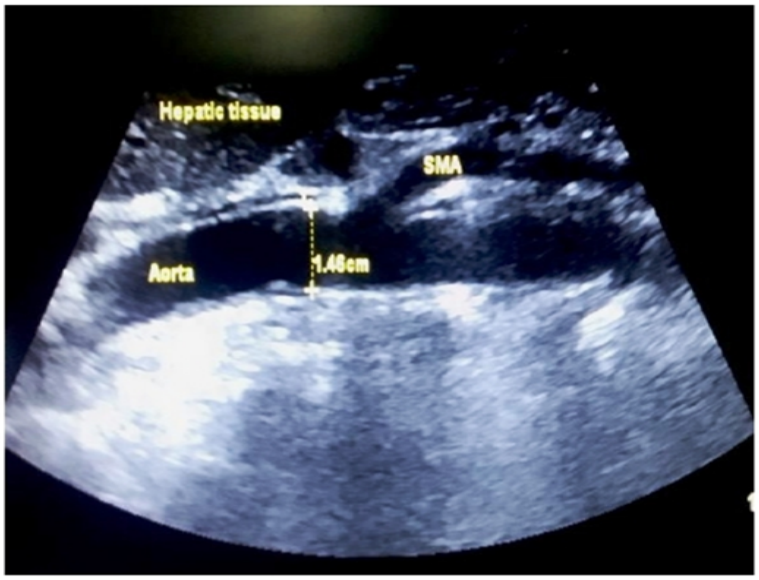

Figure 2: USG image of abdominal aorta and calculation of maximum diameter during systole (SMA-superior mesenteric artery)

Based on recent studies patients with a cut off value of caval aorta index of 1.2±2sd were considered as fluid responders. [10] Similar fluid bolus of 500ml was given over 15mins to all responders as done in Group A and fluids were continued until Caval Aorta index value of ≥1.2±2sd suggesting volume correction was observed on ultrasound.

Since the application of IVCCI in prevention of SIH is already established in several independent studies we considered group A as control group and Caval aorta index group as case group. The attending anaesthetist registered the time from placing the probe on the patient and localizing the IVC and aorta. If the measurement time exceeded ≥ 15 minutes or the vessels could not be located due to any reason (like excess fat/bowel gas shadows), the case was excluded from the study. In order to minimize errors in measurements, all readings were taken 3 times and an average of them was chosen for final estimation. Fluid optimization was continued until the indices value normalized in both the groups. Total amount of fluid given preoperatively to optimize body volume status was noted. The optimization process was carried out only preoperatively and not carried over after spinal injection due to surgical refrains.

Thereafter SAB was performed at L3-L4 space with the patient in lateral decubitus posture, the spinal anesthesia procedure was standardized for both the groups. A standard dose of 0.5% hyperbaric bupivacaine (15mg) was administered slowly through a 25G Quincke's needle (B Braun Medical SA Melsungen Germany) to achieve spinal blockade of T8-T10 level. Patients were then placed supine and vitals were monitored throughout the surgery. All the surgeries included in our study had been performed in supine position. Episodes of hypotension after SAB were recorded. Significant hypotension after SAB was explained by fall in Systolic BP to 25% of the baseline value or MAP less than 60mmHg. Episodes of hypotension were noted and treated with ephedrine 5mg in both the groups. If required, incremental doses of ephedrine mg were given. The total amount of vasopressors needed in each group was recorded. Bradycardia (HR<60bpm) was treated with atropine 0.6mg. Fluids administered in the intraoperative period were noted and standardized in both the groups. Complications like nausea, vomiting, shivering, and discomfort were noted & managed.

The sample size was evaluated using Open Epi software version 2.3.1 Based on the pilot study we conducted on 40 patients overall 20 patients out of 40 developed hypotension; among IVCCI group 60% and caval aorta index group 30% with 95% confidence level and alpha error 0.05 the sample size was calculated to be 90 which was approximated to 120 to allow for possible drop outs.

Statistical analysis was carried out with SPSS (Statistical Package for the Social Sciences IBM, SPSS statistics USA) version19.0. Data obtained was tabulated in Excel sheet for analysis. Continuous data was represented in the form of Mean ±SD, categorical values were entered as numbers or percent, and continuous data was calculated by independent student's t test. All categorical data was analyzed by x2test.The association between these indices and SIH was assessed by Receiving Operator Characteristics (ROC) model. P value was considered statistically significant < 0.05(95% confidence interval).

Results

Overall, 120 participants were enrolled in our study starting from 20/10/2020. However, due to reasons like failure of SAB, spinal converted to general anaesthesia, IVC/Aorta not clearly visible in USG or surgery got postponed; 4 patients dropped out of our study and 116 patients completed the study [Figure 3]

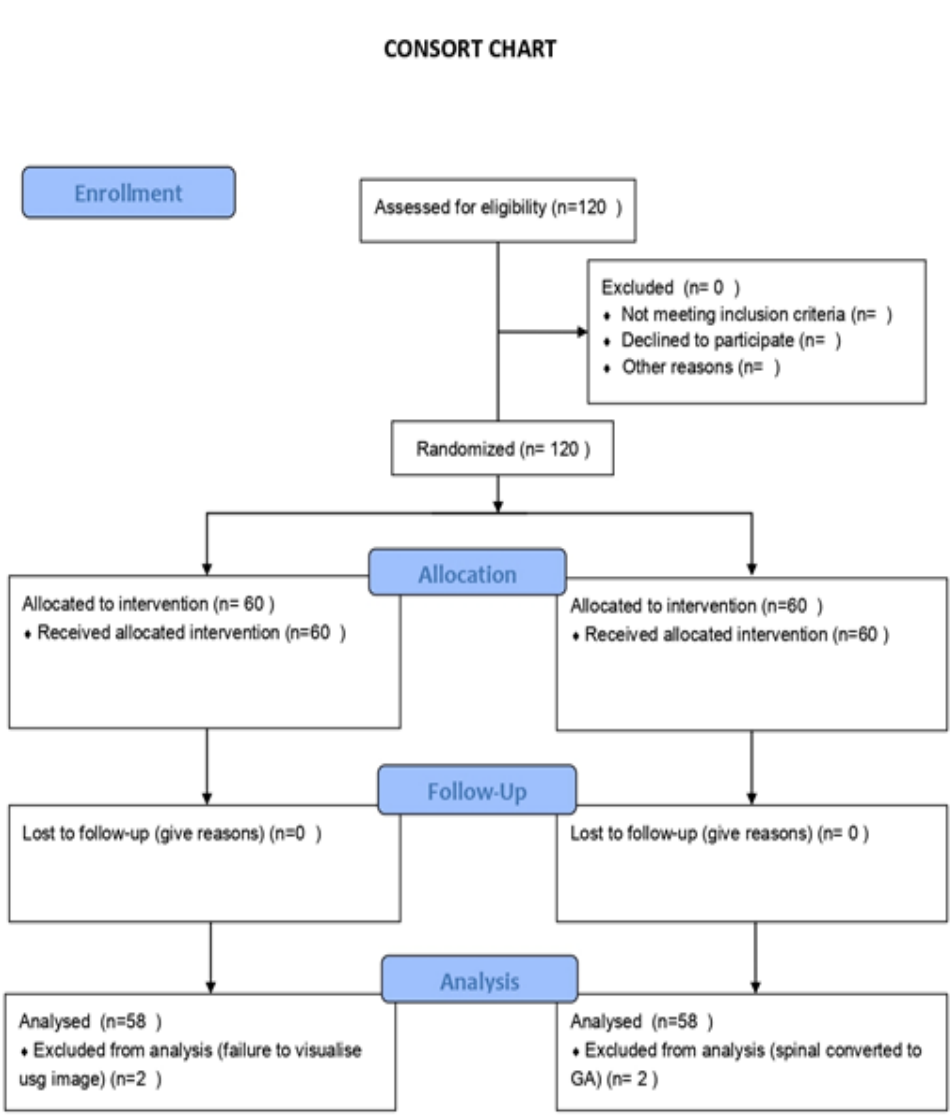

Figure 3: Consort chart

Demographic profiles like age, height, weight, gender and the type of the surgery were similar in both the groups (Table 1).

Table 1: Demographic Characteristic features of patients in both groups

Variables	Group A (Mean±SD)	GROUP B (Mean±SD)	P Value
Age(YEARS)	43.5±14.50	44.92±15.17	0.4994
Weight(kgs)	56.7±7.52	58.88±11.20	0.4774
BMI(kg/m^2)	20.86±3.68	21.9±4.22	0.0647
Height(cms)	165.25±24.10	163.52±23.16	0.6053
Duration of surgery	60.30±18.50	62.25±19.30	0.5796
ASA(I/II)	13:37	23:27	
Gender (M: F)	20:30	24:26	
Types of surgery			
Hip/knee surgery	20	18	
Lower abdominal surgery	16	35	
Gynecology surgery	5	5	

***ASA-American Society of Anesthesiologists, *BMI-Body Mass Index, *SD-Standard Deviation**

The overall incidence of hypotension after spinal anesthesia was 46% (54/116) in all the patients. Group A showed higher hypotension 55.17% (32/58) when compared with Group B 37.93% (22/58) P<0.001 (Figure 4)

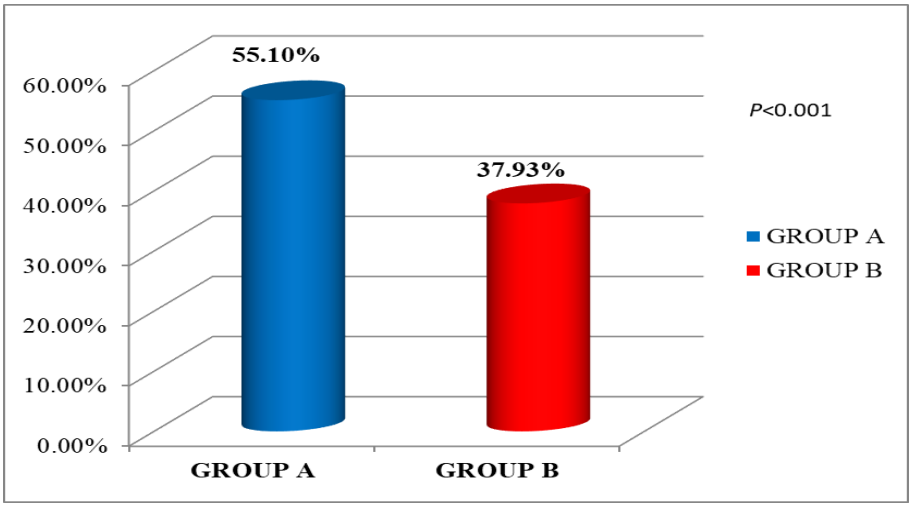

Figure 4: Incidence of hypotension in both the groups

The relative reduction in the incidence of hypotension was higher in Group B 62% (36/58) than Group A 44.82% (26/58) P<0.001. The total number of patients requiring first dose of vasopressors was more in Group A 34.48% (20/58) when compared to Group B 17.24% (10/58) (P<0.001). However, in Group A 5 patients needed a second dose whereas in Group B no patients required second dose (Table2).

Table 2: Requirement of vasopressors and total fluid requirement in both the groups

Variables	IVCCI Group (n=50)	IVC:AO index Group (n=50)	p value
Vasopressors required	20/58(34.48%)	10/58(17.24%)	<0.001
Prespinal iv fluids	525±150.40	480-180.30	0.1471
Total amount of fluids	1300.4.309	1200±332	0.1222

The total amount of Prespinal fluid was relatively higher in Group A than Group B however the total amount of intravenous fluids was approximately similar in both the groups(P>0.005) Receiver operating characteristic curve analysis of IVCCI and Caval Aorta index showed that (Figure 5) caval aorta index was 94.4% sensitive 96.9% specific and 74% accurate to predict SIH at cut off point of 1.2with area under the curve 0.956 and IVCCI was 94%sensitive and 65.6% specific & 60% accurate at a cut-off point more than>36% with area under the curve0.793.

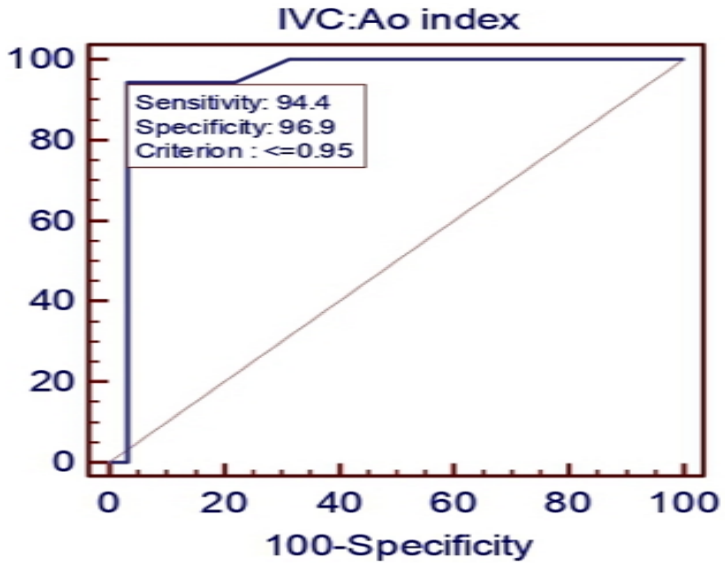

Figure 5: ROC curve showing the ability of Caval Aorta index in predicting SIH

Discussion

Identifying hypovolemia at an early phase and initiating definitive management can reduce the morbidity associated with SIH particularly in body fluid deprived conditions. The application of sonographic hydration status assessment has been previously confirmed both in pediatric and adult patients in several independent studies. It is very well established that IVC is a highly compliant vessel with good sensitivity to changes in intravascular volume and that IVC volume changes, before there are any detectable changes in vital signs. The correlation of IVC diameter, body height, and BSA has already been proven. With critically ill or emergency patients, accessing BSA is difficult and time consuming. Moreover, IVC variations during respiration make accurate measurements often difficult. The usefulness of this method would significantly increase if IVC diameter was compared with a parameter independent of BSA. Therefore, comparing IVC diameter with Aorta diameter could be a promising method of estimating fluid status without having to look for reference values for each age group or calculating BSA

In the study conducted by Eman Ramadan Salama and Mohamed Elkashlan [11] the overall incidence of hypotension developed was 45% as in our study. They concluded that both IVCCI and Caval Aorta index are predictive of the occurrence of SIH. The ROC derived analysis showed that caval aorta index was 96% sensitive and 88% specific alike our study. However, they got IVCCI 84% sensitive whereas it was much higher in our study (94%). Such variability in our results could be explained by 1) subjective differences in the USG measurements 2) different cut off points, their IVCCI cut off was 44% while ours was 36%.

Our results clearly demonstrated a greater reduction in the incidence of hypotension with caval aorta index and caval aorta index guided volume optimization had a higher sensitivity, specificity and accuracy in predicting SIH in accordance with Jauregui et al [12] who inferred that caval aorta index is significant in identifying decreased hydration status. Our outcomes in favour of caval aorta index could be explained by the fact that Caval Aorta index estimation is easy and reproducible whereas IVCCI varies with age, BSA, Body mass index [13] thoracic and abdominal pressures making room for erroneous measurements leading to under or over correction of fluid status. Hisamuddin NA Rahman, Rashidi Ahmad Meera Mohaideen Kareem et al [14] conducted a study on assessment of inferior vena cava and abdominal aorta diameter index as a new approach of assessing hypovolemic shock class 1 and concluded that the use of caval aorta index in diagnosing hypovolemia is a promising noninvasive technique to predict hypovolemia in correspondence with our study. They standardized based on their derivations that index value below 1.14 should be considered as fluid deprived and shows the early phase of hypovolemic shock. Menon LP, Balakrishnan JM Wilson Thomas MK [15] also studied caval aorta index in obstetric emergencies and concluded that caval aorta index is a useful tool to assess volume status similar to our study however they studied the utility of the caval aorta index in pregnant women

A study was conducted by Omar et al [16] to know the accuracy of IVC collapsibility index and caval aorta index for prediction of hypotension after General anesthesia. They found that both the parameters are reliable predictors of hypotension however IVC/Ao is a more reliable and accurate indicator than IVCCI

Serkan Bilgin et al [17] studied the effect of changes in the intravascular volume on IVC and Aorta diameters and caval aorta index in healthy volunteers. They observed that the IVCD and IVCD/AAD index and shock index (SI) were all significantly successful in assessing class 1 Hypovolemic Shock .We also found that both IVCCI and IVC/Ao are both reliable in assessing volume status and can better predict the occurrence of hypotension.

Jatin Lal et al [18] conducted a similar study to assess the correlation of the IVCCI and the caval aorta index with SAIH. They demonstrated that preoperative ultrasonographic assessment of IVC collapsibility index is predictable of SAIH whereas caval aorta index was found to have poor diagnostic performance in predicting SAIH. However, their results do not correspond to our findings. This discrepancy could be explained by the fact that unlike us they did not optimize the preoperative volume status they only measured preoperative indices and tried to corelate with hypotension.

Ayyanagouda B, Ajay BC [19] et al did a similar study on USG guided inferior venacava assessment in averting SIH. They found that fluid optimization before SAB decreases hypotension & vasopressor requirement similar to our results. However, our study differs with Ayyanagouda study by the fact that we both compared IVCCI against different parameters. Nonetheless we obtained more reduction in vasopressor requirement with caval aorta index guided volume optimization.

Ting Tian et al [20] evaluated the efficacy of IVCCI in predicting the incidence of hypotension following spinal anesthesia. Their ROC analysis revealed that IVCCI had a sensitivity of 83.9%, specificity of 76.3% at a cut off value of 42% for predicting SIH however we found IVCCI was 94%sensitive and 65.6% specific in predicting SIH

at a cut off value of 36%. In spite of volume optimization before administering SAB our patients in both the groups developed hypotension which can be attributed to the fact that SIH is multifactorial and hypotension cannot be fully prevented by preoperative volume optimization alone. We believe that caval aorta index is a quick effective and promising method for the evaluation of intravascular volume. Therefore, preoperative USG assessment of caval aorta index can be recommended for patients planned for spinal anaesthesia and to screen those at risk of developing subsequent hypotension. The simplicity of the examination technique with quite constant measurement points makes caval aorta index assessment applicable in every situation where body fluid status affects further treatment and prognosis.

There are few limitations in our study. A relatively small number of patients were included although the estimated power of the study was sufficient to detect reliable results. Measurements of IVC collapsibility index could be compromised by the craniocaudal movement of diaphragm, thus leading to under or overestimation of IVC. In assessing intra-abdominal structure with ultrasound, the main limitation is the bowel gas variability in anatomical position which could compromise the measurements. As it was a single-center study, a multicenter study is required to evaluate the optimal cut-off point of such predictors. Blood pressure measurement for noting the incidence of SIH was done with NIBP, Invasive BP monitoring might be better for providing more accurate continuous readings. Despite of these limitations our study provides new insight of the utility of caval aorta index. Inferior vena cava to aorta diameter index (IVC/Ao) hasn't been studied before as a predictor for PSAH. The study findings open up a new horizon of options in clinical practice where caval aorta index can be utilized in estimation and monitoring of volume status thereby aiding goal directed fluid therapy specially in high-risk patients.

Conclusion

Both IVC collapsibility index and Caval aorta index are good predictors of SIH however Caval aorta index guided fluid optimization leads to a greater reduction in the incidence of spinal induced hypotension as well as the vasopressor requirements.

Acknowledgement pertaining to this study-The authors would like to thank Dr.S.Y. Hulakund professor and head of department of Anesthesiology for his assistance in performing the study.

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