COMPARISON OF HEMODYNAMIC VARIABLES DURING CONTINUOUS SPINAL ANESTHESIA AND GENERAL ANESTHESIA IN HIGH RISK CARDIAC PATIENTS: A RANDOMIZED STUDY

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Abstract

Background and aim: Surgical patients may be exposed to stress response that may be presented with hypertension, tachycardia, arrhythmia and myocardial ischemia. Stress response may expose the patients for serious outcome, especially patients with cardiovascular disease. The purpose of the current study was to evaluate the effect of general anesthesia and continuous spinal anesthesia on the perioperative hemodynamic stability in high risk cardiac patients undergoing major surgery.

Methods: The study included 146 cardiac patients classified randomly into two groups: Group GA (n = 73) (general anesthesia). and Group CSA (continuous spinal anesthesia) (n = 73). The primary outcome was hemodynamic stability as assessed by changes in the heart rate, blood pressure, cardiac output, systemic vascular resistance, electrocardiography changes and troponin I level.

Results: There were increases in heart rate, arterial blood pressure, cardiac output, and systemic vascular resistance in group GA and minimal changes in group CSA and the comparison between the two groups was significant ($p < 0.05$). The incidence of tachycardia, hypertension and hypotension was higher in group GA than CSA ($p < 0.05$). The postoperative troponin I level was higher in group GA than CSA ($p < 0.05$). The requirement for pharmacological support was higher in group GA than group CSA ($p < 0.05$).

Conclusions: Continuous spinal anesthesia induced minimal changes in hemodynamic variables compared to general anesthesia in high risk cardiac patients undergoing elective surgery.

Key words: Continuous spinal anesthesia, General anesthesia, High risk cardiac patients, Tachycardia, Hypertension, Hypotension.

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Introduction

General anesthesia is routinely used for major abdominal surgery. The incidence of morbidity and mortality increases if the patient is elderly and suffers from multiple and severe systemic diseases (American Society of Anesthesiologists classification ≥III).[1]

Continuous spinal anesthesia has several advantages, such as its usefulness in high risk patients undergoing surgeries, its slow and gradual onset of action, its good sensory and motor block, and its initial dose can be minimized so that hemodynamic variables are maintained and anesthesia can also be prolonged,[2] with reduced cardiovascular and respiratory complications.[3]

Recently, a continuous noninvasive hemodynamic (CNAP) monitoring is available to measure the heart rate, arterial blood pressure, systemic vascular resistance and cardiac output during spinal[4] and general anesthesia.[5]

The aim of the present study was to evaluate the effect of general and continuous spinal anesthesia on the perioperative hemodynamic stability using of CNAP monitoring in high risk cardiac patients undergoing major surgery.

Methods

After approval from the local ethics committee (03/10/2015. 197/2015), and obtaining written informed consent from all patients, a randomized study included 146 patients (22/10/2015-05/08/2018) undergoing elective surgery (abdominal surgery, urological, vascular or orthopedic surgery) with expected surgery time more than two hours. The inclusion criteria were cardiac patient with ASA physical status (II, III, IV), patients with hypertension, coronary artery disease [patients with ischemic heart disease or percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass grafting (CABG)], low ventricular function (ejection fraction 30-45%), dilated cardiomyopathy, valvular disease (except severe aortic or mitral stenosis), or atrial fibrillation. Exclusion criteria included patients with congestive heart failure, acute myocardial infarction, obese patients (BMI >30 kg/cm^2), emergency, coagulation disorders, neurological deficits or psychiatric diseases. The patients were assessed using New York Heart Association (NYHA) and American Society of Anesthesiologists Physical Status Score (ASA). All patients were evaluated preoperatively by cardiologists and anesthesiologists. Investigations such as electrocardiography (ECG) and transthoracic echocardiography were done for all patients to evaluate the function of the myocardium and cardiac valves and for diagnosis and treatment of ischemic heart diseases. The patients who received preoperative anticoagulants were managed by cardiologists. All patients received their medications for hypertension, ischemic heart disease, or arrhythmia approximately two hours prior to anesthesia induction. For all patients, no premedication was given before anesthesia (to avoid the effect of the premedication such as benzodiazepine on the hemodynamics). For all patients and under local anesthesia, a radial arterial cannula and central venous line were inserted before anesthesia induction for administration of fluids, inotropic drugs and vasodilators if needed. The concealment of allocation was done by using random numbers generated through excel. Group GA (General Anesthesia group, n=73): Anesthesia induction was started by preoxygenation (100% oxygen), intravenous fentanyl (1-2µg/kg), etomidate (0.3mg/kg), and cisatracurium (0.2mg/kg). After tracheal intubation, anesthesia was maintained with sevoflurane (1-3%), fentanyl infusion (1-3µg/kg/hr), cisatracurium (1-2µg/kg/min) and oxygen:air (50:50%). Group CSA (Continuous Spinal anesthesia group, n = 73): an intravenous crystalloid infusion (500-1000 ml) was started and under full aseptic precautions, the skin was cleaned with an antiseptic solution, and the subcutaneous tissues was infiltrated with 3 ml of lidocaine 2%. An epidural set (Perican®needle G18, catheter G 27, B. Braun Melsungen AG Germany) was used. The epidural needle was introduced into the subarachnoid space at L4-5 or L3-4 interspace under aseptic conditions. After the free flow of cerebrospinal fluid was obtained, a 27-gauge catheter was inserted 3-4 cm beyond the tip of the needle. Correct positioning of the catheter within the subarachnoid space was confirmed by the establishment of free flow of cerebrospinal fluid. Once inserted, the catheter was secured and covered with a sterile, transparent dressing from the insertion site to the shoulder and the catheter was connected to a bacterial microfilter. After obtaining baseline vital signs, and applying face oxygen mask at 3-4 L/min, a dose of 5 mg of 0.5% heavy bupivacaine and 25 µg of fentanyl were given first, followed by a slowly incremental injection of 5 mg of 0.5% heavy bupivacaine every 5 minutes until the level of the block reached T6-7. Incremental doses of 5 mg of 0.5% heavy bupivacaine were given during surgery when necessary. The sensory block was assessed by pin prick and cold application every 5 minutes until the onset of sensory block using a 3-point scale. The motor block was assessed by modified Bromage three point score for the lower extremity.[6] The pain relief was assessed by the pain verbal scale.[7] The level of sedation was assessed by a modified Wilson sedation scale from one to four.[8] The catheters were removed at the end of surgery in the most of the patients, but after vascular surgery, it was removed after 12 hours of the last dose of heparin.

For all patients in both groups, intraoperative fluids were given cautiously according to the hemodynamics readings by CNAP, central venous pressure and the clinical situation of the patients. Intraoperative tachycardia (heart rate ≥100 bpm), and systemic hypertension (systolic arterial blood pressure ≥20% above baseline) were managed by bolus doses of fentanyl (1-2µg/kg), morphine (1-2 mg bolus dose), and if there was no response, sevoflurane concentration was increased to 3% in GA group, and if hypertension persisted for five minutes, nitroglycerine infusion 0.5-1µg/kg/min was started. Intraoperative hypotension (systolic arterial blood pressure ≤20% below baseline) was managed by bolus doses of ephedrine 5-10 mg and fluid administration and if persisted for five minutes, dopamine infusion, epinephrine, or norepinephrine was started. Bradycardia (heart rate <60 bpm) was managed by a bolus dose of atropine (0.05 mg/kg).

At the end of the procedure (general or continuous spinal anesthesia), the patients were transferred to the intensive care unit with closed monitoring and observation for 3 to 4 days.

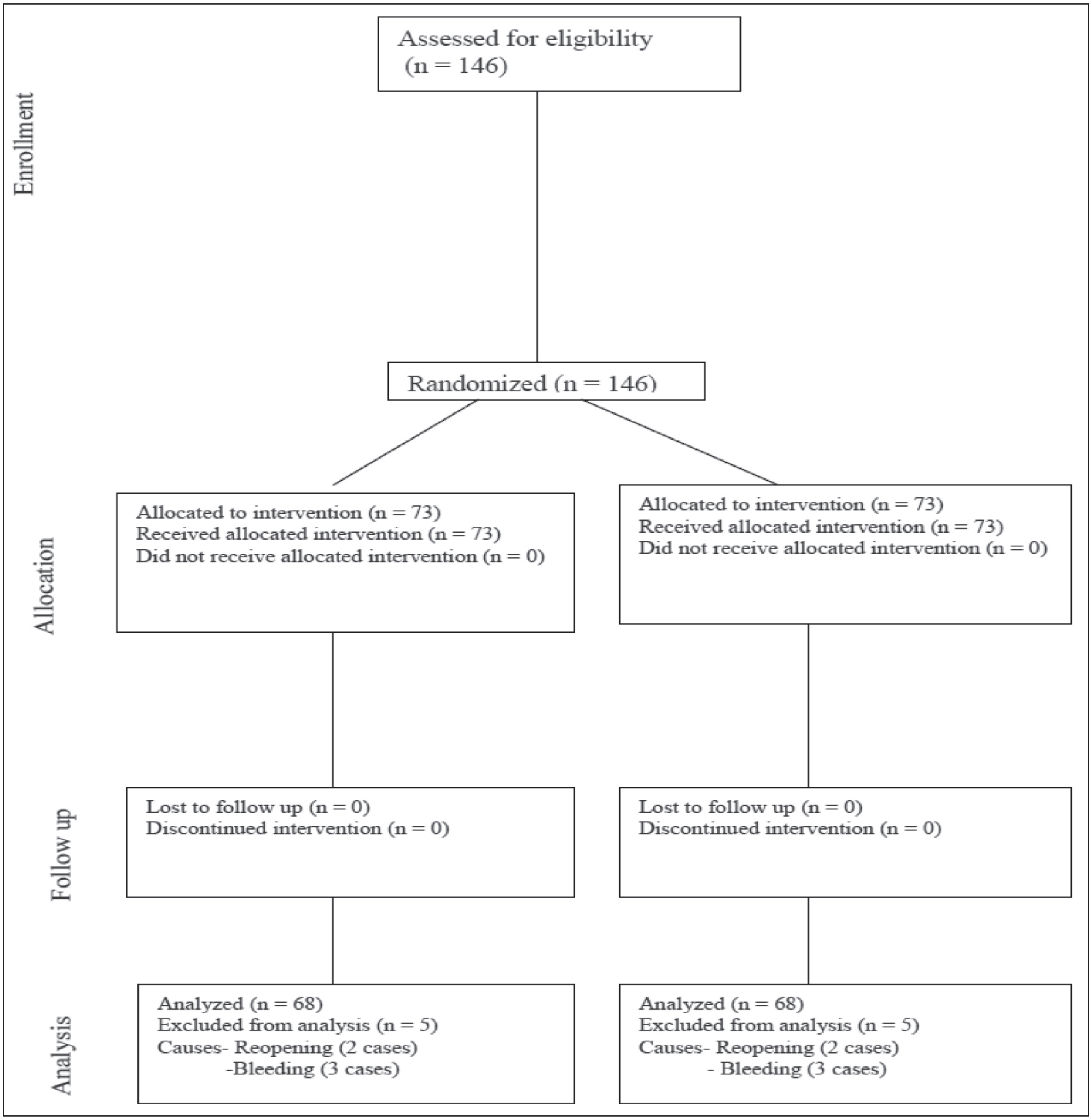
The CNAP™500 (Continuous non-invasive arterial pressure CNSystems Medizintechnik, Graz, Austria) monitoring system was used to monitor the arterial blood pressure, cardiac output, and systemic vascular resistance. A continuous ECG with automatic ST-segment analysis (leads II and V) was used to monitor the heart rate, arrhythmia and ST-segment changes. Also, the measurements included the hematocrit value, arterial oxygen saturation, the total dose of fentanyl, arterial blood gasses, temperature, and urine output.

The patients hemodynamic data were collected at the following time points; T0: Baseline reading; T1: 15 minutes after induction; T2: 30 minutes after induction; T3: one hour after induction; T4: two hours after induction; T5: at the end of surgery; T6: on admission in ICU; T7: one hour after admission in ICU; T8: 6 hours after admission in ICU; T9: 12 hours after admission in ICU; T10: 24 hours after admission in ICU. The cardiac enzyme troponin I was measured before administration of study medication, at 12th, 24th, and 48th hours postoperatively. The transthoracic echocardiography was done in cases with ischemic changes in the ECG and elevated troponin I.

The primary outcome was the stability of the hemodynamic status of the patients assessed by changes in the heart rate, blood pressure, cardiac output, systemic vascular resistance or ECG changes (arrhythmia or ST-segment analysis leads II and V). A secondary outcome was the safety of the anesthetic technique, which was assessed by the occurrence of any adverse events and the requirements for pharmacological support.

Power analysis was performed using the Chi square test for independent samples on frequency of intraoperative hemodynamic instability (heart rate ≥100 bpm or ≤60 bpm, hypertension (systolic arterial blood pressure ≥20% above baseline), hypotension (systolic arterial blood pressure ≤20% below baseline), cardiac output ≤2 L/min, and ST-segment changes in the ECG), because it was the main outcome variable in the present study. A pilot study was done before starting this study using the CNAP monitoring in high risk cardiac patients undergoing major surgery and anesthetized either by general anesthesia or continuous spinal anesthesia. The results of the pilot study [14 cases in each group] showed the incidence of hemodynamic instability to be 42.85% in the general anesthesia group and 21.42% in continuous spinal anesthesia. Considering a power of 0.8, alpha error 0.05, and beta 0.2, a minimum sample size of 73

Fig. 1
CONSORT diagram for the flow of participants through each stage of the present study



patients was calculated for each group.

Data were statistically described in terms of mean ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate. Comparison of numerical variables between the study groups was done using Student t test for independent samples. Repeated measure ANOVA was used to see the effect of continuous spinal anesthesia and general anesthesia on heart rate, mean arterial pressure and cardiac output at different follow up intervals. For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5. P values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the

Table 1
Preoperative data of patients (mean±standard deviation, number, percentage)

Variables		Group GA (n=68)	Group CSA (n=68)	P-value
Age (year)		60.17±9.09	59.70±9.17	0.816
Weight (kg)		76.92±12.01	77.45±12.92	0.662
Gender	Male:Female	38:30	35:33	0.605
Hypertension		49 (72%)	41 (60%)	0.147
Diabetes mellitus		46 (68%)	52 (76%)	0.251
Ejection fraction (%) (30-45%)		39.01±3.33	38.14±3.46	0.137
Atrial fibrillation		13 (19%)	16 (24%)	0.530
Ischaemic heart disease		39 (57%)	35 (51%)	0.491
PTCA		25 (37%)	29 (43%)	0.483
CABG		14 (21%)	12 (18%)	0.662
Pacemaker		5 (7%)	8 (12%)	0.381
Valvular disease		11 (16%)	14 (21%)	0.506
Dilated cardiomyopathy		2 (3%)	5 (7%)	0.244
Angiotensin-converting-enzyme inhibitors		38 (56%)	45 (66%)	0.218
Beta-blockers		50 (74%)	41 (60%)	0.101
Calcium channels-blockers		20 (29%)	26 (38%)	0.276
Aspirin		35 (51%)	39 (57%)	0.491
Stroke		2 (3%)	4 (6%)	0.403
Smoking		25 (37%)	29(43%)	0.483
ASA II		7 (10%)	9 (13%)	0.791
ASA III		51 (75%)	45 (66%)	0.346
ASA IV		10 (15%)	14 (21%)	0.500

PTCA: Percutaneous transluminal coronary angioplasty, CABG: Coronary artery bypass grafting, ASA: American Society of Anesthesiologists Physical Status Score.

Social Science; SPSS Inc., Chicago, IL, USA) release 15 for Microsoft Windows (2006).

Results

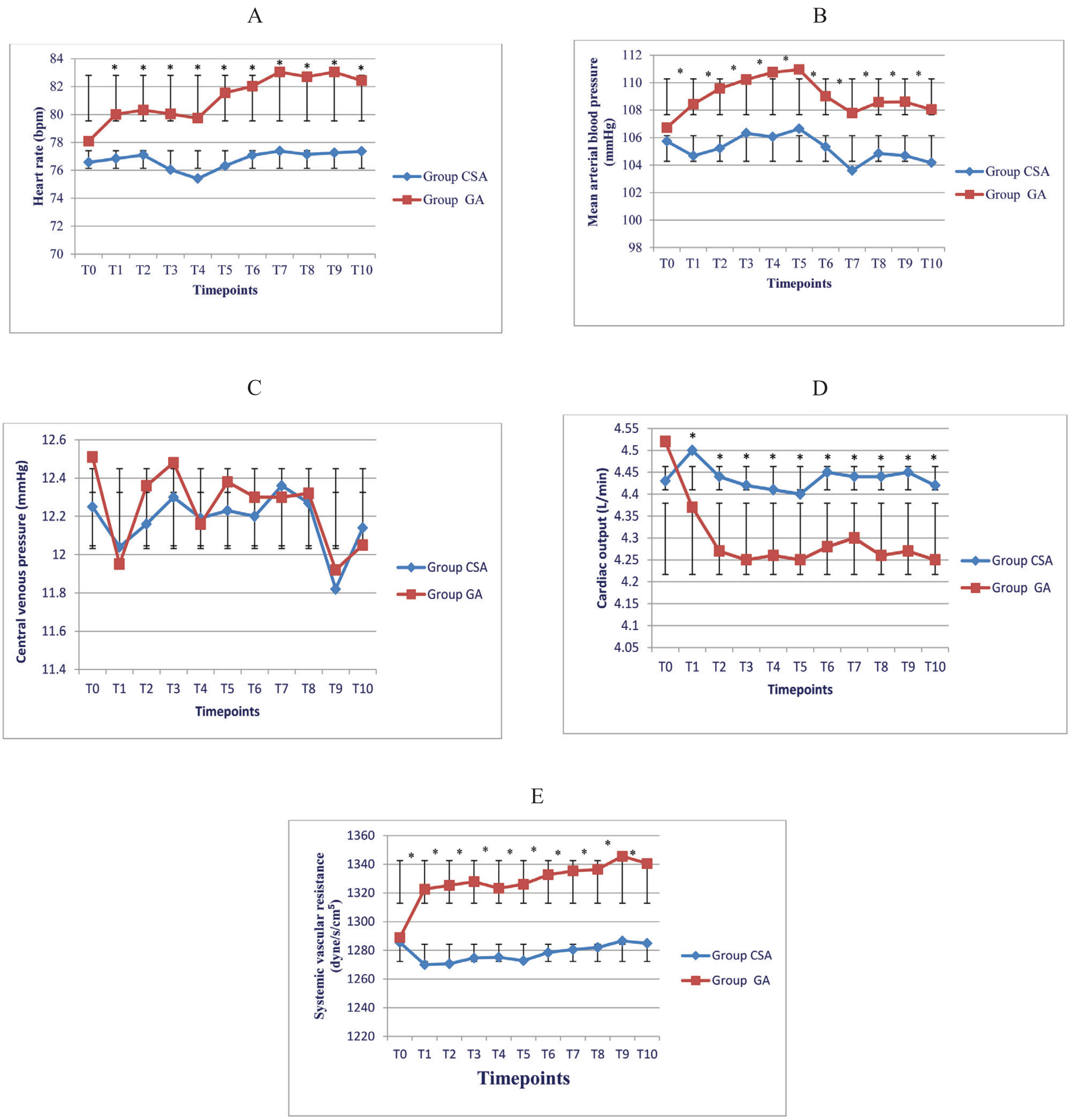
Figure 1 shows the CONSORT diagram for the flow of participants through each stage of the study. Five patients in each group did not complete the study (because of reopening and bleeding) and the remaining 68 patients from each group completed the study and were included in the data analysis.

Table 1 shows no significant differences regarding the demographic data, co-morbidities, preoperative medications and ASA physical status score between the two groups.

Figure 2 shows the changes in heart rate, mean arterial blood pressure, central venous pressure, cardiac output and systemic vascular resistance of patients from the two groups. The heart rate of patients was significantly higher in GA group compared to CSA group (Figure 2A). Significant increases and decreases were seen in heart rates of patients undergoing both types of anesthesia at different follow up time intervals (Figure 2A). Interaction between heart rate and type of anesthesia failed to reach statistical significance (p = 0.208). The mean arterial pressure was significantly higher in patients of GA group compared to CSA group (Figure 2 B). However, during follow up time intervals, significant increases and decreases were observed in the mean arterial pressure (p = 0.001). Interaction between mean arterial pressure and type of anesthesia did not show statistically significant association (p = 0.778) [Figure 2 B]. Cardiac output of patients was significantly lower in patients under

Figure 2

A: Heart rate of patients; B: Mean arterial blood pressure of patients; C: Central venous pressure of patients, D: Cardiac output of patients; E: Systemic vascular resistance of patients.



Group GA: General anesthesia group.

Group CSA: Continuous spinal anesthesia group.

*p<0.05, significant comparison between the two groups.

T0: Baseline reading; T1: Reading 15 minutes after induction; T2: Reading 30 minutes after induction; T3: Reading one hour after induction; T4: Reading two hours after induction; T5: Reading at the end of surgery; T6: Reading on admission in ICU; T7: Reading one hour after admission in ICU; T8: Reading 6 hours after admission in ICU; T9: Reading 12 hours after admission in ICU; T10: Reading 24 hours after admission in ICU.

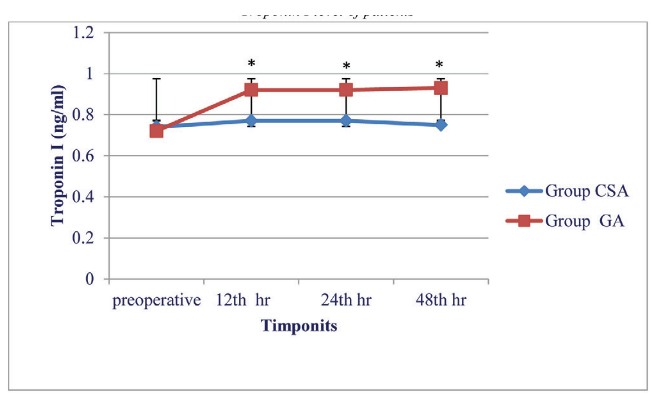
Table 2

Intraoperative data and outcome of patients (mean±standard deviation, number, percentage)

Variables			Group GA (n=68)	Group CSA (n=68)	P-value
Type of surgery	Abdominal surgery		18 (26%)	23 (33%)	0.350
	Vascular		6 (9%)	9 (13%)	0.411
	Orthopedic hip surgeries		26 (38%)	21 (31%)	0.367
	Hysterectomy		10 (15%)	6 (9%)	0.287
	TURP		8 (12%)	9 (13%)	0.795
Duration of anesthesia (minutes)			224.92±30.64	225.58±28.10	0.895
Duration of surgery (minutes)			197.42±32.18	194.48±28.74	0.575
Hypertension (SAP≥20% above baseline)			24 (35%)	11 (16%)	0.011
Hypotension (SAP≤20% below baseline)			9 (13%)	3 (4%)	0.047
Tachycardia (HR>100bpm)			13 (19%)	5 (7%)	0.042
Bradycardia (HR<60bpm)			3 (4%)	7 (10%)	0.205
PaCO2 (mmHg)			35.79±3.58	36.72±3.15	0.110
SPO2 (%)			99.19±017	99.12±0.22	0.973
Hematocrit (%)			37.37±2.74	36.71±2.53	0.146
Total dose of fentanyl (µg)			197.20±40.98	25.00±0.00	0.001
Morphine (mg)			8.74±2.60	2.45±1.38	0.001
Ephedrine			9 (13%)	3 (4%)	0.046
Dopamine			9 (13%)	3 (4%)	0.047
Epinephrine			8 (12%)	2 (3%)	0.048
Norepinephrine			7 (10%)	1 (1.4%)	0.028
Nitroglycerin			17 (25%)	8 (12%)	0.046
Fluids transfusion	Crystalloids (ml)		1885.60±270.10	2050.45±318.20	0.005
	Hesteril 6 %		270.27±76.10	305.14±85.40	0.013
P-RBC (unit)			1.80±1.33	1.35±1.15	0.036
Intraoperative urine output (ml)			645.40±210.35	670.27±220.10	0.5017
Postoperative mechanical ventilation			7 (10%)	1 (1.4%)	0.028
Troponin I increase	Preoperative (ng/ml)		0.72±0.16	0.74±0.15	0.495
	12 hr	Number	5 (7%)	2 (3%)	0.244
		Mean	0.92±0.50	0.77±0.36	0.046
	24 hr	Number	5 (7%)	2 (3%)	0.244
		Mean	0.92±0.46	0.77±0.36	0.042
	48 hr	Number	5 (7%)	2 (3%)	0.244
		Mean	0.93±0.48	0.75±0.36	0.012
Postoperative ECG changes			3 (4%)	1 (1.4%)	0.310
Acute MI			5 (7%)	2 (3%)	0.244
Congestive heart failure			6 (9%)	1 (1.4%)	0.052
Pulmonary edema			6 (9%)	1 (1.4%)	0.052
Post dural puncture headache.			-	-	
New neurological complications			-	-	
Thromboembolism			-	-	
ICU length of stay (days)			3.29±1.03	2.80±1.24	0.015
Hospital length of stay (days)			8.73±3.62	7.41±2.91	0.020
Mortality			3 (4%)	1 (1.4%)	0.310

Major abdominal surgery: Strangulated umbilical or inguinal hernia- Subtotal colectomy.

Fig. 3
Troponin I level of patients



*p<0.05, significant comparison between the two groups.
Group GA: General anesthesia group.
Group CSA: Continuous spinal anesthesia group.
12^{th} hr: 12 hours after surgery; 24^{th} hr:24 hours after surgery; 48^{th} hr:48 hours after surgery.

general anesthesia. Interaction between cardiac output and type of anesthesia did not show statistically significant association (p = 0.056) [Figure 2 C]. There were no significant differences in the central venous pressure between the two groups [Figure 2 D]. There were no significant differences in the systemic vascular resistance before surgery, but the systemic vascular resistance increased significantly after anesthesia in the patients of groups GA with minimal changes in patients of group CSA (p <0.05) [Figure 2 E].

Table 2 shows the intraoperative data and outcome in both groups. The incidence of hypertension was 24 (35%) patients in group GA and 11 patients (16%) in group CSA (p = 0.011). The incidence of hypotension was 9 (13%) patients in group GA and 3 patients (4%) in group CSA (p = 0.047). The incidence of tachycardia was significantly higher in group GA. A higher number of patients received nitroglycerine and other pharmacological support in the GA group compared to the CSA group. The required dose of fentanyl and morphine was higher in patients of group GA than patients of group CSA (p <0.001). Patients in group GA required less transfusion of fluids and packed red blood cells. More patients in the GA group required postoperative mechanical ventilation. The serum level troponin I increased significantly at 12, 24, and 48 hours in five patients in group GA and two patients in group CSA (p = 0.244), but the increase was significantly higher in group GA than group CSA (p = 0.046, p = 0.042, p = 0.012 respectively) [Figure 3]. The incidence of acute myocardial infarction was five patients in group GA and two patients in group CSA (p = 0.244). The duration of ICU length of stay and hospital length of stay were longer in patients of group GA than patients of group CSA (p = 0.015, p = 0.020 respectively). There was no difference in mortality between the two groups.

Urological: TURP: [Transurethral resection of prostate]- radical cystectomy-radical cystectomy- Percutaneous nephrolithotomy.
Vascular: Aortobifemoral bypass - Femoropopliteal bypass.
Orthopedic surgery: total hip replacement- total knee replacement (unilateral or bilateral).
SAP: Systolic blood pressure; HR: Heart rate; PaCO2: Partial pressure of carbon dioxide; SPO2: Arterial oxygen saturation; P-RBC: Packed- red blood cells; Acute MI: Acute myocardial infarction; ICU: Intensive care unit.

Discussion

The present study showed that continuous spinal anesthesia minimized the changes in the heart rate, blood pressure, systemic vascular resistance, and cardiac output. The incidence of fluctuations in the hemodynamic variables was higher in group GA compared to group CSA. Fluctuations in the hemodynamic variables during general anesthesia may cause disturbance in the oxygen supply/demand ratio of the myocardium and expose the myocardium to ischemia and infarction. The number of patients requiring for pharmacological support to manage the hypotension was higher in patients of group GA compared to the group CSA and these medications can cause tachycardia and hypertension thus increasing the oxygen requirement of the myocardium. These findings are similar to those of the study that assessed the incidence of hypotension and myocardial ischemia in patients undergoing surgery for fractured hip.[9] The incidence of fluctuations in the hemodynamic variables was more higher with general anesthesia than spinal anesthesia in patients underwent transurethral resection of the prostate.[10] One study showed that the incidence and severity of hypotension increased significantly with general anesthesia compared to the spinal anesthesia.[11] Another study documented that small dose bupivacaine provides a successful anesthesia and better hemodynamic stability, and the required ephedrine and fluid infusion to manage the hypotension increased significantly with general anesthesia compared to spinal anesthesia ($p<0.01$, $p<0.05$ respectively),[12] and the same findings were documented by other studies.[13,14] A study evaluated the effect of continuous spinal anesthesia in elderly patients with cardiomyopathy (EF ≤45%) undergoing lower abdominal surgeries and showed no significant changes in the hemodynamics or postoperative ECG changes and the postoperative troponin was negative in patients with cardiomyopathy anaesthetized by a continuous spinal anesthesia,[15] and other studies showed similar findings.[16-20]

The present study showed that the number of patients suffered from congestive heart failure and pulmonary edema was higher in group GA compared to the group CSA, and these findings correlate with another study showed that the pulmonary complication was higher with general anesthesia compared to the spinal anesthesia ($p=0.020$) and the incidence of myocardial infarction and cardiac arrest was higher with general anesthesia compared to the spinal anesthesia.[21]

Contrary to the results of the present study, one study showed that the regional anesthesia (epidural or spinal) was associated high incidence of myocardial infarction compared with general anesthesia and this was explained by the significant decrease in myocardial oxygen consumption,[22] and the protective effects of inhalational anaesthetics[23], and also the incidence of mortality was higher with regional anesthesia compared to the general anesthesia, but not significant. The number of patients required for postoperative mechanical ventilation was higher in the group GA than the group CSA and also, the duration of ICU and hospital length of stay prolonged with general anesthesia and these findings correlate with the results of other studies.[15,21,24]

The laryngoscopy, intubation and surgical trauma cause a stress response associated with an increase in the heart rate and blood pressure, therefore increasing the oxygen demand to the myocardial which already may suffer from oxygen supply, and this expose the myocardial to more ischaemia and infarction.[25] Also, the general anesthesia causes fluctuation in the hemodynamics for the 24 postoperative hours and this can increase the oxygen requirement or disturb the oxygen supply/demand ratio of the myocardium, which already suffer from ischaemia in high risk patients.[26,27] While patients with continuous spinal anesthesia; (1) There is no stress response due to intubation, laryngoscopy or surgery;[2,15] (2) The incremental doses allow titrating effect of local anaesthetics[28] that provides slow, gradual onset block of the sympathetic system, and allows the cardiovascular system to adapt more easily without fluctuation in the hemodynamics,[2,16] therefore maintaining the relation of oxygen supply/demand ratio of the myocardium and provide a protection to the myocardium from the exposure to ischaemia or infarction; (3) The continuous spinal anesthesia provides a good analgesia in comparison to general anesthesia;[29] (4) The sympathovagal balance was more stable during spinal anesthesia than during general anesthesia in patients with a high risk of ischaemic heart disease.[30]

The present study recognizes some limitations such as a being single center study and small number of patients.

Conclusion

Continuous spinal anesthesia induced minimal changes in hemodynamic variables compared to general anesthesia in high risk cardiac patients undergoing elective surgery. Continuous spinal anesthesia decreased the requirement for pharmacological support in high risk cardiac patients.

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