Comparative Study between Continuous Spinal Anesthesia versus General Anesthesia in Patients with Sepsis

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Abstract

Background: Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Hemodynamic instability due to high block largely limits the use of conventional dose spinal anesthesia in high-risk septic patients.

Objectives: This work aimed to evaluate the efficacy and safety of continuous spinal anesthesia (CSA) and compareit with general anesthesia (GA) technique in sepsis-diagnosed patients.

Patients and methods: This prospective randomized single-blind comparative clinical study was carried out on 110 patients aged above 21 years old of both sexes, American Society of Anesthesiologist I, II and III diagnosed with sepsis, SOFA score up to 7, hemodynamically stable and not on vasopressorsupport. Patients were randomly allocated into two equal groups. Group I: received CSA via conventional epidural catheter and Group II: received GA.

Results: Compared to the GA group, the CSA group achieved significant hemodynamic stability during and after surgery with notably lower reported vasopressor dosages ($p \leq 0.05$). In GA group, there were 6 patients not extubated from mechanical ventilation (MV), while in the CSA group, no patients needed MV during the surgery ($p=0.027$). Over 72h postoperatively, more patients needed MV in GA group (14.5%) versus (3.6%) in CSA ($p=0.047$). Additionally, at various research time intervals, the CSA group statistically outperformed the GA group in terms of maintained urine output, acid-base status, and lower mortality incidence.

Conclusions: With superior hemodynamic stability, better acid-base balance, less need for vasopressors, postoperative mechanical ventilation, and a reduced mortality rate, CSA is safer than GA in patients with sepsis during the perioperative phase.

Keywords: Continuous spinal anesthesia; General anesthesia; Sepsis; Mechanical ventilation.

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Introduction

A dysregulated host response to infection results in sepsis, a potentially fatal organ failure. The 2016 Conesus standards state that organ dysfunction is defined as an increase in the rapid sequential organ failure assessment (qSOFA) score of two or more **(Sinha and Ray, 2018).**

Both hospital-acquired and community-acquired infections may be the cause of sepsis, which is linked to morbidity and mortality. Despite helpful therapies and potent antibiotics, the mortality rate for afflicted patients ranges from 30% to 70% **(Neubeiser et al., 2020).** Surgery often has to wait until the first supportive treatment is initiated; nevertheless, in certain instances, surgery is essential to remove the source and cannot be postponed. For example, the removal of an infected prosthetic device, necrotic tissue debridement, or investigation for septic peritonitis on top of intestinal rupture cannot be delayed **(Talapko et al., 2021)**.

Speculating on a mistaken sepsis diagnosis, which is often caused by an infection or the rapid progression of sepsis leading to septic shock, delays effective initial treatment, thus surgery is undertaken without any special plans or considerations **(Ursin Rein et al., 2018)**.

Anesthetic medications often reduce myocardial contractility and act directly on the heart and blood vessels, causing vasodilation. All induction agents cause a dose-dependent reduction in cardiac work. Thus, maintaining hemodynamic stability during anesthesia induction is critical, as is selecting a suitable anesthetic **(Yancey, 2018)**.

No single anesthetic approach or medication appears to provide universal benefits for septic surgery patients' survival. Regional anesthesia provides various advantages over general anesthesia (GA) in lower limb surgery. In lower abdomen and limb surgery, spinal anesthesia is a preferred anesthetic technique due to its rapid onset, limited impact on mental status, and less blood loss. Spinal anesthesia is a widely utilized anesthetic technique in lower limb surgery because of its quick onset, minimal influence on mental status, and reduction in blood loss **(Mancel et al., 2021)**.

In high-risk septic patients, the application of typical dose spinal anesthetic is severely restricted by hemodynamic instability brought on by high block. Because septic patients may have a lower physiological reserve and a reduced blood flow to several essential organs, hypotension is more prevalent and dangerous in these individuals. A reduced dose of local anesthetic lowers the severity and incidence of hypotension during spinal anesthesia (**Massoth et al., 2020**). Continuous spinal anesthesia (CSA) is the technique of creating and sustaining spinal anesthesia using modest doses of local anesthetic that are titrated intermittently into the subarachnoid space via an indwelling catheter (**Kader et al., 2018)**.

Although CSA with big needles and catheters was associated with a significant incidence of post-dural puncture headache (PDPH), it is now widely understood that PDPH is caused by cerebrospinal fluid leakage through dural puncture as well as the size of the needle used (**Elfeky et al., 2019)**.

An improved catheter-over-needle design has been developed to lessen the challenges and complications of CSA with microcatheters, which include problematic catheter insertion, breakage, poor anesthetic, PDPH, and, seldom, the development of cauda equina syndrome **(McKenzie et al., 2016)**.

This work aimed to evaluate the anesthetic efficacy and safety of CSA and compare it with GA technique in sepsis-diagnosed patients.

Patients and methods

This prospective randomized single-blind comparative clinical study was carried out on 110 patients aged above 21 years old of both sexes, American Society of Anesthesiologist (ASA) Ⅰ, Ⅱ and Ⅲ

diagnosed with sepsis (according to sepsis 3 criteria) **(Singer et al.,2016)**. SOFA score up to 7,hemodynamically stable and not on vasopressor support due to lower abdomen and limb pathology and candidate for spinal anesthesia to drain source of infection. The study was conducted from November2022 to August 2023 after approval from the Ethical Committee of our institution, (approval code: 35987/10/22) and registration of clinicaltrials.gov (ID: NCT05897151). Informed written consent was obtained from the patients or their legal representatives in case of cognition impairment.

Excluded from this study, were patients who had preexisting neurological disease (either upper or lower motor neuron lesions), coagulation disorder, and/or on thromboprophylaxis or presence of infection at the site of spinal anesthesia.

Randomization

According to the anesthetic technique, patients were randomly allocated into two equal groups. Group I: received CSA via conventional epidural catheter and Group II: received GA. For both groups, the standard ASA monitoring was placed, including electrocardiogram (ECG), pulse oximetry, and non-invasive blood pressure. After Allen's test, insertion of the arterial cannula for invasive blood pressure, lactate, and ABG monitoring. Intravenous (IV) line (20G cannula) was inserted and secured. Preloading 3-5 ml\kg crystalloid over 30 min before induction of anesthesia either general or CSA. Fluids were administrated later according to fluid responsiveness and intraoperative needs and vasopressor was considered if patients were fluid nonresponsive.

Group I (CSA): All patients were monitored by standard ASA monitoring (a 5-lead electrocardiogram, non-invasive blood pressure, pulse oximetry, and temperature surface probe) and had intravenous access in situ with an infusion of lactated ringer solution at a volume of 3-5 ml/kg as a preload. A radial artery cannula was inserted (after -ve Allen's test) for invasive blood pressure monitoring. A 20-gauge epidural catheter (B-Braun) through an 18-gauge Tuohy needle **(Hay and Gupta, 2022)** was used for CSA, which was primarily conducted at the level of the L3-L4 or L4-L5 interspace in the sitting position using the median approach. However, some patients were placed in the lateral position because they were unable to sit down due to lower limb pathology. Under perfect aseptic conditions, the skin was disinfected with povidine iodine before the L3-L4 or L4-L5 interspace was palpated and 2ml of 2% lidocaine was infiltrated subcutaneously (skin wheal). An 18G Tuohy needle was utilized to penetrate the skin and then proceed forward. The needle was pushed (with its point orientated laterally) a few millimetres forward, until the dura was pierced. This was confirmed by the presence of spinal fluid at the needle's hub, after which the needle's tip was rotated cephaled to orient the catheter cephaled. The plastic catheter director was employed to reduce CSF leakage. The catheter was put into the needle as quickly as possible to minimize cerebrospinal fluid (CSF) loss. It was advanced without resistance 2 to 3 cm into the subarachnoid space, and the epidural needle was carefully withdrawn over the catheter. The continual and steady trickle of CSF should exit through the catheter. The catheter was clearly marked as intrathecal and secured. It was then closed with a stopcock and a bacterial filter. Injections were made with a strict aseptic method. The patient was turned on his/her back and 5 mg (1 ml) of 0.5% hyperbaric bupivacaine+25mcg fentanyl was injected intrathecally as the initial loading dose **(Hay and Gupta, 2022)**. Regarding the catheter and bacterial filter capacity (the volume of local anesthetic required to fill the catheter and bacterial filter, which was previously found to be approximately 0.8 ml), we flushed the catheter with 0.8 ml of local anesthetic prior to the first injection. If no motor or sensory

block occurred within 10 minutes of the initial hyperbaric bupivacaine injection, or if the sensory level did not reach at least T 10 dermatome, a second dose was considered. If no motor or sensory block occurred, or if the sensory level did not reach at least T 10 dermatome, the procedure was deemed to have failed, and failed instances were excluded. Injections were given every 45 to 60 minutes to keep the block level stable. Each injection was closely monitored hemodynamically. At the end of the surgery, the catheter was carefully removed.

Group II (GA): On arrival at the operating room, monitoring of the patient was started through the attachment of a monitor device consisting of a 5-lead electrocardiogram, non-invasive blood pressure, pulse oximetry, temperature probe, and capnography (after intubation). Intravascular access was established by introducing an 18-gauge peripheral venous cannula with injection of midazolam 0.02 mg/kg as a premedication and intravenous infusion of lactated ringer solution at a volume of 3-5 ml/kg as a preload. A radial artery cannula was inserted (after -ve Allen's test) for invasive blood pressure monitoring. Induction of anesthesia was performed after 3 minutes of pre-oxygenation with 100% oxygen by fentanyl 2 ug/kg (Sunny Pharmaceutical), titrating dose of propofol 1-2 mg/kg (Fresenius, Kabi), and cis-atracurium 0.15-0.2 mg/kg to facilitate endotracheal intubation through a suitable sized cuffed endotracheal tube. Patients were connected to a mechanical ventilator, and the ventilators' settings were adjusted to maintain the end-tidal carbon dioxide ($ETCO_2$) between 35 and 38 mmHg then nasopharyngeal temperature probe was inserted. Anesthesia was maintained with isoflurane at 1 MAC (minimum alveolar concentration) in a mixture of oxygen: air (1:1) at a flow rate of 1 L/min. Cisatracurium, 0.04 mg/kg, was given when needed to maintain muscle relaxation. A Bispectral Index Monitor (BIS) was attached to each patient, and its value was kept between 40 and 60. At the end of the surgery, the isoflurane was switched off and extubation was done after reversal of muscle relaxant with neostigmine 0.05 mg/kg. Intraoperative bradycardia (a reduction in heart rate < 45 beats/min) was treated with an intravenous infusion of atropine (0.5-1 mg), which could be repeated if necessary. IV Dexamethasone, 4mg, was administered following anesthesia induction, and IV ondansetron 4 mg was administered at the end of the surgery as prophylactic against postoperative nausea and vomiting. When the modified Aldrete score exceeded nine, the patients were moved to the post-anesthesia care unit (PACU) for intensive observation and monitoring.

For both groups, Surgery time was recorded (from skin incision to surgery completion). Norepinephrine (levophrine 4mg/4mL EGYPHARM ampule) with a starting dose of 0.01 µg/kg/min was available for both groups if necessary (MAP < 65 or MAP lowered more than 20% from preoperative value). The infusion was administered through a wide-bore intravenous line. The dose was adjusted up or down based on the patient's hemodynamics.

In cases of severe hemodynamic disruption, severe hypoxemia, and/or disturbed consciousness level (GCS<8), the choice to use mechanical ventilation was taken into consideration. Noninvasive ventilation [Nasal Cannula, Simple mask, non-rebreather, continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BPAP)] could be used in certain selected cases of mild respiratory failure with preserved or relatively stable hemodynamic status. The therapeutic effect of NIV was frequently reassessed to limit delay in reintubation and mechanical ventilation.

Measurements

All patients in both groups were evaluated for invasive mean blood pressure (mmHg) and heart rate (beats per minute) before

induction (baseline), immediately following induction, and then at 1, 5, 10, 15, and 30 minutes, as well as one hour after induction, the end of the surgery, and two hours postoperatively. Urine Output (ml/kg/h): in the last 24h preoperatively, during the surgery, and over 24h postoperatively. GCS: preoperative and 2 hours postoperative. ABG: 24h preoperatively, one hour after induction, at the end of surgery, and 2 hours postoperative. The total dose of norepinephrine infusion (mcg/kg/min) and number of patients needed it. Need for post-operative invasive mechanical ventilation within 72h. Patients' mortality during the first 28 days after surgery.

The primary outcome was a postoperative 28-day mortality rate, while the secondary outcome was intraoperative hemodynamic stability.

Sample size calculation

The sample size and power analysis were determined using the Epi-Info software statistical package, which was developed by the World Health Organization and the Centers for Disease Control and Prevention in Atlanta, Georgia, USA in 2002. The sample size was calculated using the following criteria: [The study has 80% power and a 95% confidence limit]. The predicted postoperative twenty-eight-day mortality rate is 5% in the best treatment group (CSA) as compared to 25% in the least favorable treatment group (GA). The previously indicated criteria resulted in a sample size of N=51 in each category. We extended the sample size to 55 to account for the incomplete results.

Statistical analysis

Data was uploaded into the computer and analyzed with the IBM SPSS software program version 20.0. (Armonk, NY: IBM Corporation) The qualitative data was described using numbers and percentages. The Kolmogorov-Smirnov test was employed to ensure that the distribution was normal. Parametric data were described using the range (minimum and maximum), mean, and standard deviation. Nonparametric data were reported as medians and interquartile ranges (IQR). The significance of the results obtained was judged at the 5% level.

Results

In this trial, 140 patients were evaluated for eligibility; 27 did not match the requirements. The remaining patients were randomly divided into two groups of 55 each. All allocated patients were monitored and statistically assessed **(Fig.1).**

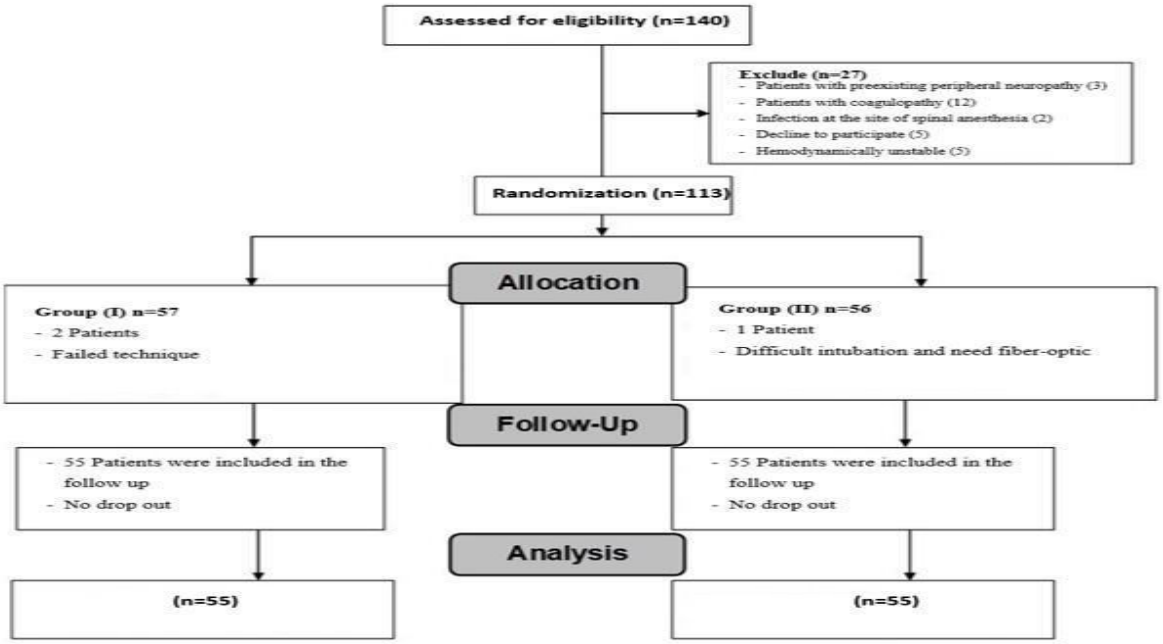


Fig. 1. Flowchart of the enrolled patients

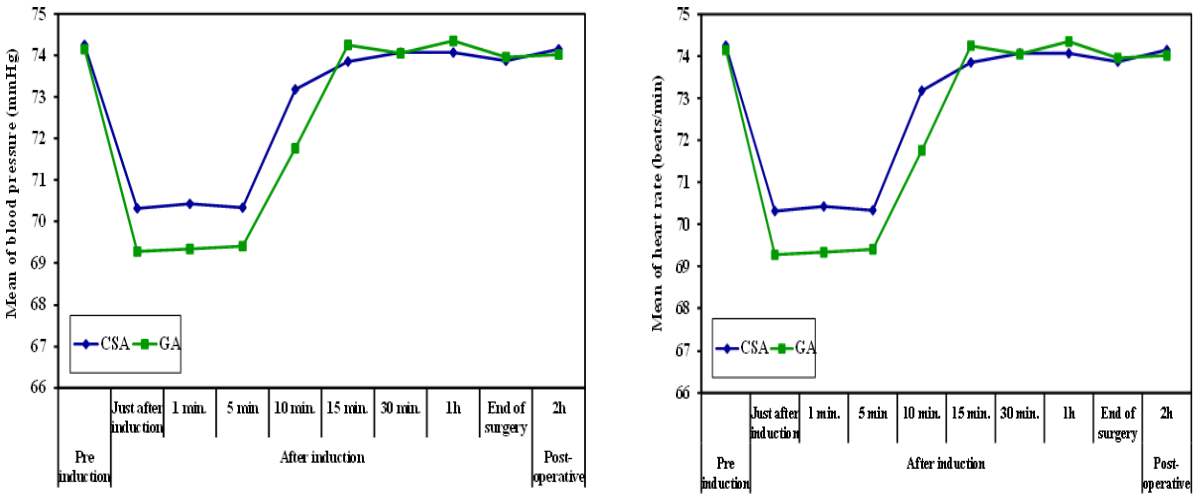
Sex, age, weight, ASA, time of operation, and type of surgery were insignificantly differentbetween the two groups, (**Table.1).**

Table 1. Comparison between the two studied groups according to demographic data

Variables		CSA (n=55)	GA (n=55)	P
Age (years)		55.71±6.27	55.07±5.36	0.568
Sex	Male	30(54.5%)	27(49.1%)	0.567
	Female	25(45.5%)	28(50.9%)	
Weight (kg)		88.67±11.75	89.02±14.88	0.893
ASA	III	24(43.6%)	28(50.9%)	0.444
	IV	31(56.3%)	27(49.1%)	
Type of operation	Diabetic foot for debridement	20(36.4%)	20(36.4%)	0.912
	Amputation LL ischemia	14(25.5%)	17(30.9%)	
	Gluteal Abscess debridement	12(21.8%)	10(18.2%)	
	Removal of infected plate and screw	9(16.4%)	8(14.5%)	
Time of surgery per min.		151.84±31.63	150.18±29.66	0.778

Data are presented as mean ± SD or frequency (%). CSA: continuous spinal anesthesia, GA: general anesthesia.

When comparing the two groups, MABP was significantly lower in the GA group than the CSA group at (just after induction, 1min, 5min, and 10min) (p<0.05). There was more increase in HR in the GA group than CSA group at the time of (just after induction, 1min, 5min, and10min) with significant difference (P<0.05). (**Fig. 2).**



(A) **(B)**

Fig.2. Comparison between the two studied groups according to (A) mean blood pressure (mmHg), (B) heart rate (beats/min)

At 1 hour after induction and end of the surgery, PH values were significantly lower in the GA group compared with the CSA group, while insignificant difference at preoperative and 2h post-operative (P<0.05). At one hour after induction, at the end of surgery, and 2h postoperative, PCo2 was insignificantly different between the two groups (P<0.05). At one hour after induction, end of surgery, and 2h post-operative, HCo3 values were significantly lower in the GA group compared with the CSA group (P<0.05), **(Table.2).**

Table 2.Comparison between the two studied groups according to PH, Co2, and HCo3

Variables		CSA (n=55)	GA (n=55)	p
PH	**Pre-operative**	7.36 ± 0.04	7.35 ± 0.04	0.161
	1h after induction	7.34 ± 0.02	7.31 ± 0.07	**0.005***
	End of surgery	7.37 ± 0.03	7.29 ± 0.13	**<0.001***
	2h post-operative	7.37 ± 0.02	7.37 ± 0.02	0.445
PCo2	**Pre-operative**	33.16 ± 2.97	33.27 ± 2.97	0.848
	1h after induction	34.58 ± 2.09	33.80 ± 2.32	0.066
	End of surgery	35.16 ± 3.59	34.02 ± 2.97	0.071
	2h post-operative	33.95 ± 2.66	34.16 ± 2.81	0.677
HCo3	**Pre-operative**	19.58 ± 1.51	19.09 ± 1.28	0.069
	1h after induction	20.4 ± 1.1	19.89 ± 1.27	**0.025***
	End of surgery	21.62 ± 1.11	20.95 ± 0.87	**0.001***
	2h post-operative	21.91 ± 1.51	20.58 ± 1.01	**<0.001***

Data are presented as mean ± SD. * significant p value <0.05. CSA: continuous spinal anesthesia, GA: general anesthesia.

Urine output was significantly lower in the GA group at the end of surgery and for 24h postoperative when compared with the CSA group (P<0.05), (**Table.3).**

Table 3. Comparison between the two studied groups according to urine output

Variables		CSA (n=55)	GA (n=55)	P
Urine output (ml/kg/h)	**Last 24h Pre-operative**	0.56±0.11	0.53±0.13	0.265
	At the end of surgery	0.54±0.13	0.46±0.17	**0.017***
	24h post-operative	0.53±0.12	0.45±0.19	**0.048***

Data are presented as mean ± SD. * significant p value <0.05. CSA: continuous spinal anesthesia, GA: general anesthesia.

According to the time of postoperative mechanical ventilation, in the GA group there were 6 patients not extubated and from MV, while in the CSA group, there was no patient needed MV duringthe surgery with a statistically significant difference between the two groups (p=0.027). 72h after surgery, there were more patients needed MV in GA group 8 patients (14.5%) when compared with CSA group 2 patients (3.6%) with a significant difference between the two groups (p=0.047). Incidence of mortality within 48 hrs after surgery was statistically insignificant however mortality within the first week after surgery was statistically higher in the GA group (P value=0.026). Mortality incidence from 1 week to 28 days post-operative was insignificantly different between both groups, **(Table. 4).**

Table 4. Comparison between the two studied groups according to postoperativemechanical ventilation and incidence of mortality

Variables		CSA (n=55)	GA (n=55)	p
Not extubated	No	55(100.0%)	49(89.1%)	**0.027***
	Yes	0(0.0%)	6(10.9%)	
Intubated	Within 72hrs after surgery	2(3.6%)	8(14.5%)	**0.047***
Incidence of mortality	Within 48hrs. after surgery	1(1.8%)	8(9.1%)	0.206
	From 48 hrs. after surgery to1 week after surgery	2(3.6%)	9(16%).	**0.026***
	From 1 week to 28-day post-operative	4(7.3%)	2(3.6%)	0.679

Discussion

The body's systemic immune response to an infectious process from a community or hospital-acquired infection can result in end-stage organ malfunction and mortality, which is known as sepsis, a medical emergency. Around 30 million individuals globally are thought to have sepsis each year, which could lead to 6 million fatalities. Sepsis-related mortality accounts for approximately one-fifth (11 million) of all fatalities worldwide, making it a prominent cause of death (**Carsetti et al., 2023).**

According to our results, in the CSA group, MABP was lower at (just after induction, 1min and 5 min) when compared with pre-induction values with a statistically significant difference. While at the remaining points of time, it returned close to the pre-induction values without significant difference. In the GA group, lower MABP values were observed up to ten minutes after induction with a statistically significant difference when compared with pre-induction values. While at the remaining points of time, it returned close to the pre-induction values with no statistically significant difference. When comparing the two groups in our study, MABP was lower in the GA group than CSA group at (just after induction, 1min, 5 min, and 10min) with statistically significant difference. Confirming our results, Nasr and Elsayed (**Nasr and Elsayed., 2020)** revealed that MAP was lower after GA induction when compared with pre-induction values then at the remaining points of time returned close to the pre-induction value.

However, Abd Alla et al. **(Abd Alla et al., 2019)** found that the mean blood pressure was 93.83±8 mmHg which is higher than that in our results (60.33 ± 1.62). Including critically ill patients in our study may explain this difference.

Regarding our results, in the GA group, the HR increased at times of (just after induction, 1min, 5 min, and 10min) when compared with pre-induction values with a statistically significant difference while at the remained points of time returned close to the pre-induction values with no statistically significant difference. In the CSA group, the heart rate increased at the time of (just after induction) (mean ± SD 107.91± 3.3) when compared with pre-induction values (mean ±SD 97.7± 1.8) with a statistically significant difference while at the remaining points of timereturned close to the pre-induction values with no statistically significant difference. When comparing the two groups, there was more increase in HR in the GA group than CSA group at the time of (just after induction, 1min, 5 min, and 10min) with statistically significant difference. However, Nasr and Elsayed (**Nasr and Elsayed., 2020)** documented that heart rate decreased after induction. The different age and ASA clinical status of the patients in their study may explain this difference from our findings. In disagreement with our results, Amin and Sadek (**Amin and Sadek., 2016)** found that heart rate decreased after induction than at baseline. The younger patients with a high vagal tone may explain this difference from our results.

Regarding our results, according to the number of patients who needed Nor-Epinephrine, in the GA group, there was an increased number of patients who needed NA as there were 12 patients (21.8%)while 4 patients (7.27%) in the CSA group with a statistically significant difference. According to the dose of nor-epinephrine, it ranged from (0.06 – 0.1) in the CSA group with Mean ± SD of 0.08± 0.02 (mcg/kg/min) while ranged from (0.1 – 0.3 mcg/kg/min) in GA group with mean ±SD of 0.22± 0.07 (mcg/kg/min) with a statistically significant increase of total NA dose in the GA group. However, Amin and Sadek **(Amin and Sadek, 2016)** illustrated that the dose of noradrenaline was 100.25 ± 35.25 µg for total dose in a dose of 4–8 µg/min.In the current study, pH ranged in the CSA group from (7.30 – 7.38) at 1 hour after induction and from

(7.32 – 7.41) at the end of surgery, while in GA group ranged from (7.08 – 7.38) at 1 hour after induction and from (7.01 - 7.41) at the end of surgery with statistically significant decrease in GA group as compared with CSA group (1 hour after induction, end of surgery). According to PCO_2, there was an insignificant difference between the two groups at 1 hour after induction, at the end of surgery, and 2h postoperative. HCO_3 was ranged in the CSA group from (19 – 22) at 1 hour after induction from (19 – 23) at the end of surgery and from (19 - 24) at 2h post- operative while in the GA group ranged from (18 – 22) at 1hour after induction and from (19 -22) at the end of surgery and from (18 -22) at 2h post-operative with a statistically significant decrease in GA group at compared with CSA group (1 hour after induction, end of the surgery, 2h post-operative). In agreement with our results, Madkour et al. **(Madkour et al., 2019)** showed that urine output at the first postoperative hour was significantly higher in the spinal group than GAgroup.

Regarding our results, there were more patients needed invasive MV in the GA group N= 14 patients (25.45%) when compared with the CSA group N= 2 patients (3.6%) with a statistically significant difference between the two groups. According to the time of postoperative MV, in the GA group there were 6 patients not extubated from MV while in the CSA group, there was no patient needed MV during the surgery with a statistically significant difference between the two groups. Post-operatively: within 72h after surgery, there were more patients needed MV in the GAgroup (N= 8 patients) when compared with the CSA group (N= 2) patients with a statistically significant difference between the two groups. Supporting our results, Nasr and Elsayed **(Nasr and Elsayed., 2020)** found thatrespiratory depression didn't happen in any patient of the CSA group postoperatively.

In the present study, according to overall mortality, more patients died in the GA group (N=16) patients (29.1%) when compared with the CSA group (N=7) patients (12.7%) with a statistically significant difference between the two groups. That came in line with Perlas et al. **(Perlas et al., 2016)** who documented that the 30-day mortality rate was significantly lower in the spinal anesthesia group than in the GA group. Supporting our results, Soliman (**Soliman, 2013)** illustrated that spinal anesthesia was associated with low mortality indices.

Limitations of this study included that the sample size was relatively small. The study was in asingle center. The study lacked comparison with other regional anesthetic techniques.

Conclusions

In sepsis-diagnosed patients, CSA is safer than GA during the perioperative period with better hemodynamic stability, better acid-base balance, lower need for nor epinephrine, less need for mechanical ventilation, and lower mortality rate.

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Conflict of Interest: Nil

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