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The Effect of Cardiometry Guided Fluid Management on Outcome of Patients Presented for Intracranial Surgeries: Randomized Controlled Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Background: Fluid management in neurosurgical patients is critical and important during the perioperative period. Electrical cardiometry (EC) is a new noninvasive technique for measuring cardiac output (COP). EC works based on the application of a high frequency transthoracic current and the analysis of variations of voltage in each heartbeat. The aim of this work is to compare the fluid management of intracranial surgeries using EC routine parameters.
Methods: This is a prospective randomized, double-blinded controlled study was carried out on 70 patients of both genders aged > 21 years old, ASA physical status II or III, GCS 15 scheduled for elective craniotomy. Patients were divided into two equal groups at random; group A: standard management, group B: EC guided management. The primary outcome was the duration of intensive care unit (ICU) stay.
Results: The ICU and hospital stay duration were significantly decreased in group B compared to group A. The mean total amount of infused volume of crystalloid solutions was significantly decreased in group B compared to group A. Hemodynamics, and number of patients received colloid, blood, vasopressor, and inotropes were insignificantly different between both groups. There

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was a significant increase in optic nerve sheath diameter in group A compared to group B at PACU and 24 h. Adverse events were comparable between both groups except encephalodema, which was significantly higher in group A.
Conclusions: EC is an effective tool in COP measurement and a novel guide for fluid therapy as EC guided fluid therapy group was significantly decreased in ICU and hospital stay duration and the total amount of crystalloid with fewer adverse events.

Keywords: Electrical cardiometry; fluid management; outcome; intracranial surgery.

1. INTRODUCTION

Fluid management in neurosurgical patients in most critical and important during the perioperative period [1]. Neuro-anesthesiologists usually deal with complications in neurosurgery patients including hypovolemia or edema or cerebral ischemia. Therefore, they need appropriate timing and quantifications and adequate composition of fluid [2,3].

In the literature, there has been much argument on the most appropriate intraoperative fluid algorithm especially in major surgeries and whether a more liberal dealing with fluids can be beneficial for the outcome of the patients or goal directed one [4].

Goal directed fluid therapy (GDFT) aims to keep (zero fluid balance) to reduce fluid administration, that is associated complications, by depending on real time continuous measurements [5]. GDFT in high risk surgeries can be monitored by Cardiac output (COP) to reach better post-operative results and less complications of surgery [6] .

Fluid responsiveness is accepted when there is ten to fifteen percent increase in stroke volume (SV) or COP in response to a fluid Challenge. [7] In order to evaluate volume of hydration of patients under anesthesia we use Static Indicators like central venous pressure (CVP) and pulmonary capillary wedge pressure (PCWP) [8]. For detecting fluid responsiveness, we use systolic pressure variation (SPV), stroke volume variation (SVV), pulse pressure variation (PPV) and pleth variability index (PVI) [9,10].

A novel noninvasive technique to measure COP is electrical cardiometry (EC). It is based on passing electromagnetic current of high frequency through the thorax and then it analyze the microvoltage changes with cardiac pulsations [11].

The aim of this work is to compare the fluid management of intracranial surgeries using EC routine parameters.

2. PATIENTS AND METHODS

This prospective randomized double blinded controlled study was carried out from September 2018 to July 2019 in Neurosurgery Department, after it had obtained Local Ethical Committee approval (approval code: 32482/07/18). It was registered on the Pan African Clinical Trial registry with its identification no PACTR201902530245620. Written informed consent was obtained from the patients.

Patients of both genders aged more than 21 years old with ASA physical status II or III with GCS 15 (fully conscious) and scheduled for elective brain surgery for tumor resection, aneurysm or brain abscess removal through craniotomy were enrolled in the study.

2.1 Exclusion Criteria

Exclusion criteria of the study included patients with arrhythmia which leads to limitation to use SVV as an indicator of fluid responsiveness, significant renal dysfunction (serum creatinine >1.5 mg/dL) and severe heart failure (New York Heart Association classification 3or 4).

2.2 Randomization and Blinding

The 70 patients were randomly allocated in a parallel way into two equal groups (group A: standard management, group B: EC guided management) following the order of computer-generated software introduced into closed sealed envelopes to make the patients blinded to their own group. The patients and the surgeon were blinded to each patient's randomization number. The randomization and allocation were done by an anesthetist who didn't participate in the study.

2.3 Intervention

Medical and surgical history of all patients was evaluated, clinical examination was performed, and routine laboratory investigation was done.

The five ASA monitors were applied in the form of a 5-lead ECG monitor, pulse oximetry, an automated non-invasive arterial blood pressure, capnogram (before induction of anesthesia) and temperature probe (applied after induction of anesthesia). In addition to the five ASA monitors, an arterial radial line was inserted in all patients for invasive blood pressure monitoring and a BIS sensor was used to estimate deepness of anesthesia.

Ultrasound machine (Philips CX50 Extreme edition) equipped with high frequency probe used to insert the central line and assess optic nerve sheath diameter.

Patients were preoxygenated for 3 minutes using 80 % oxygen. Propofol (1 mg/kg), fentanyl (2 mcg/kg) and cis-atracurium (0.15 mg/kg) were used to induce anaesthesia and endotracheal tube was inserted. Ventilator parameters were adjusted to maintain the end tidal CO_2 between 30– 35 mmHg. Propofol (1 mg/kg) and fentanyl (1 mcg/kg) were used to maintain depth of anesthesia in addition to top up doses of cis-atracurium. Incremental doses of propofol (0.5 mg/kg) and fentanyl (0.5 mcg/kg) were used to maintain BIS in the range 40– 60 if needed. Warmed solutions and insulation blankets were used to maintain body temperature at normal range.

Patient were distributed into two groups at random following the order of computer-generated software introduced into closed sealed envelopes to make the patients blinded to their own group:

Group (A) (n=35): The fluid management of patients in this group followed the routine management through 5 mL/kg/h of lactated ringer. Fluid management depended on the routine parameters as heart rate, mean arterial blood pressure, urine output and central venous pressure. Additional fluid bolus was given in case of blood loss or mean arterial blood pressure less than 20% of baseline and CVP less than 12 mmHg in form of crystalloid 4 mL/kg. The bolus of crystalloid fluids can be repeated until CVP equal to 12 mmHg considering that the total dose didn't exceed 20 mL/kg. Colloid (hydroxyl n styl starch: 5 ml / kg and maximum dose 30 ml/kg) was administered if MAP was less than 20% of baseline and CVP was <12mmHg and crystalloid reached the maximum dose. Vasopressor (norepinephrine 0.1 mcg/kg/min) was administered if still MAP less than 20% of baseline and CVP > 12mmHg or bolus of crystalloid fluids exceeded 20 ml/kg , colloid fluis reach 30 ml/kg and patient still MAP was less than 20% of baseline and CVP was <12mmHg. Dobutamine was added at dose of 0.05 mcg/kg/min in case of MAP was less than 20% of baseline and CVP was <12mmHg mmHg despite maximal dose of norepinephrine was reached. Blood components were given when the blood loss had exceeded the allowable blood loss.

Group (B) (n=35): The EC monitor (Electrical Cardiometry monitor, ICON Cardiotronics, Germany, model C3, serial number 1725303) was mounted to the patients.

The height, weight, sex, blood pressure were input to the EC monitor and for less than thirty seconds to measure Corrected flow time (FTC) and stroke volume (SV) were measured continuously in less than 30 seconds after placing the sensors.

An electronic infusion pump was used to maintain fluids at 3 mL/kg/h of lactated ringer solution, and fluid boluses (200 mL) were allowed according to an FTc-based fluids algorithm protocol and the type of bolus fluids was determined according to transthoracic fluid content (TFC). Vasopressors (norepinephrine 0.1-0.5 mcg/kg/min) and inotropes (dobutamine 2-20 mcg/kg/min IV) were given according to reading of EC reading of systemic vascular resistance (SVR) and index of contractility (I CON).

At the end of the operation, the propofol and fentanyl infusions were stopped and deep extubation was done. After that, patients were transferred to PACU and optic nerve sheath diameter (ONSD) was measured guided by ultrasound. Bedside, ONSD measurements were obtained. The ultrasonography was tuned as low as possible to avoid any damage to the retina and the lens while performing ultrasound imaging to the orbit.

While the subject in recumbent position, with head of bed elevated 30 degrees and with using a high-resolution linear array probe. The eyes of the patient are closed and ultrasound gel is applied probe, we used the probe very gently with minimal reasonable pressure, we could obtain clear images for the optic nerve entry to the eye globe.

We estimated ONSD while using the ultrasound probe in horizontal and vertical positions to get two measurements for every optic nerve. The ONSD was measured bilaterally at 3 mm before entrance of the optic nerve to the globe. The mean ONSD measurements from each eye were averaged to create a binocular ONSD measurement.

Lastly, patients were transferred to ICU where the both two groups received maintenance fluid (Ringer lactate) by infusion pump set at a rate of 0.5 mL/kg/h (with a minimum of 40 mL/h).

2.4 Outcome Assessment and Follow-Up

Demographic data of the patients including age, gender, BMI, ASA physical status, type and duration of operation were recorded. The length of ICU stay was our primary outcome variable. The secondary outcome variables were assessment of morbidity depending on lactates level at the end of surgery, assessment of changes in intracranial tension by measurement of ONSD, postoperative complications, postoperative morbidity (the proportion of patients who developed one or more complications), and mortality.

2.5 Statistical Analysis

The sample size was calculated using Epi-Info software statistical package version 2002. The criteria used were: 95% confidence limit, 80% power of the study, expected outcome (length of ICU stay) in treatment group 90% decrease compared to 60% decrease for control group and two cases were added to overcome drop-out. Therefore, we decided to include 35 patients per group.

SPSS version 24 (IBM Corporation, Armonk, NY) was used for data processing and statistical analysis. Categorical variables were presented as absolute numbers and percentages. Continuous variables were presented as mean values with standard deviation or medians with an interquartile range. To compare data between groups, the chi-square test was used to assess categorical variables, and the Student t test or the Mann–Whitney U test was used to analyze continuous variables as appropriate. A two-tailed P value of < 0.05 was considered to indicate a statistically significant difference.

3. RESULTS

Eighty-eight patients were examined to be included in the study. Eighteen patients were excluded; eight patients did not meet the inclusion criteria and ten patients refused to participate in this study. The remaining 70 patients were allocated in the two studied groups. Fig. 1.

Demographic data (age, gender, BMI and ASA physical status) and type and duration of operation were comparable between the 2 groups (Table 1).

The length of ICU stay, and hospital stay were significantly decreased in group B compared to group A (p value = 0.007 and 0.017 respectively). The mean total amount of infused volume of crystalloid solutions was significantly decreased in group B compared to group A (3582.9 ± 471.8 vs 1908 ± 284.2, p value <0.001). Patients received colloid, blood, vasopressor and inotropes were insignificantly different between both groups (Table 2).

There were statistically insignificant changes in HR and MAP between both groups at all times of measurement (p value > 0.05) (Fig. 2 and Fig. 3).

There was statistically insignificant change in venous lactate in group A compared to group B at all times of measurement (Fig. 4).

There was a significant increase in ONSD in group A compared to group B at PACU and 24 h (Fig. 5).

The incidence of encephalodema was significantly increased in group A than group B (p value =0.025). On the other hand, the incidence of post-operative ARDS, pneumonia, sepsis, skin infection, AKI, skin infection, arrythmia and need of mechanical ventilation were insignificantly different between both groups (Table 3).

4. DISCUSSION

Our results revealed that EC guided fluid therapy as compared to traditional fluid therapy led to significant decrease in length of ICU stay, and length of hospital stay. Also, we found that there was statistically significant decrease in total amount of infused volume of crystalloid solutions and ONSD in EC guided fluid therapy as compared to traditional fluid therapy. There was a statistically insignificant change in total amount of infused volume of colloid solutions and the number of patients who needed colloid solutions, blood component, vasopressors administration and inotropes in both groups. Moreover, there

were statistically insignificant changes in H, MAP between both groups at all times of measurement. Also, there was statistically insignificant change in venous lactate between both groups at all times of measurement. The incidence of encephalodema was significantly increased in group A than group B. The incidence of post-operative ARDS, sepsis, pneumonia, acute kidney injury, renal failure, arrhythmia and skin infection were insignificant among the two groups. Moreover, 5 patients in group needed post-operative mechanical ventilation while only 1 patient in group B needed mechanical ventilation.

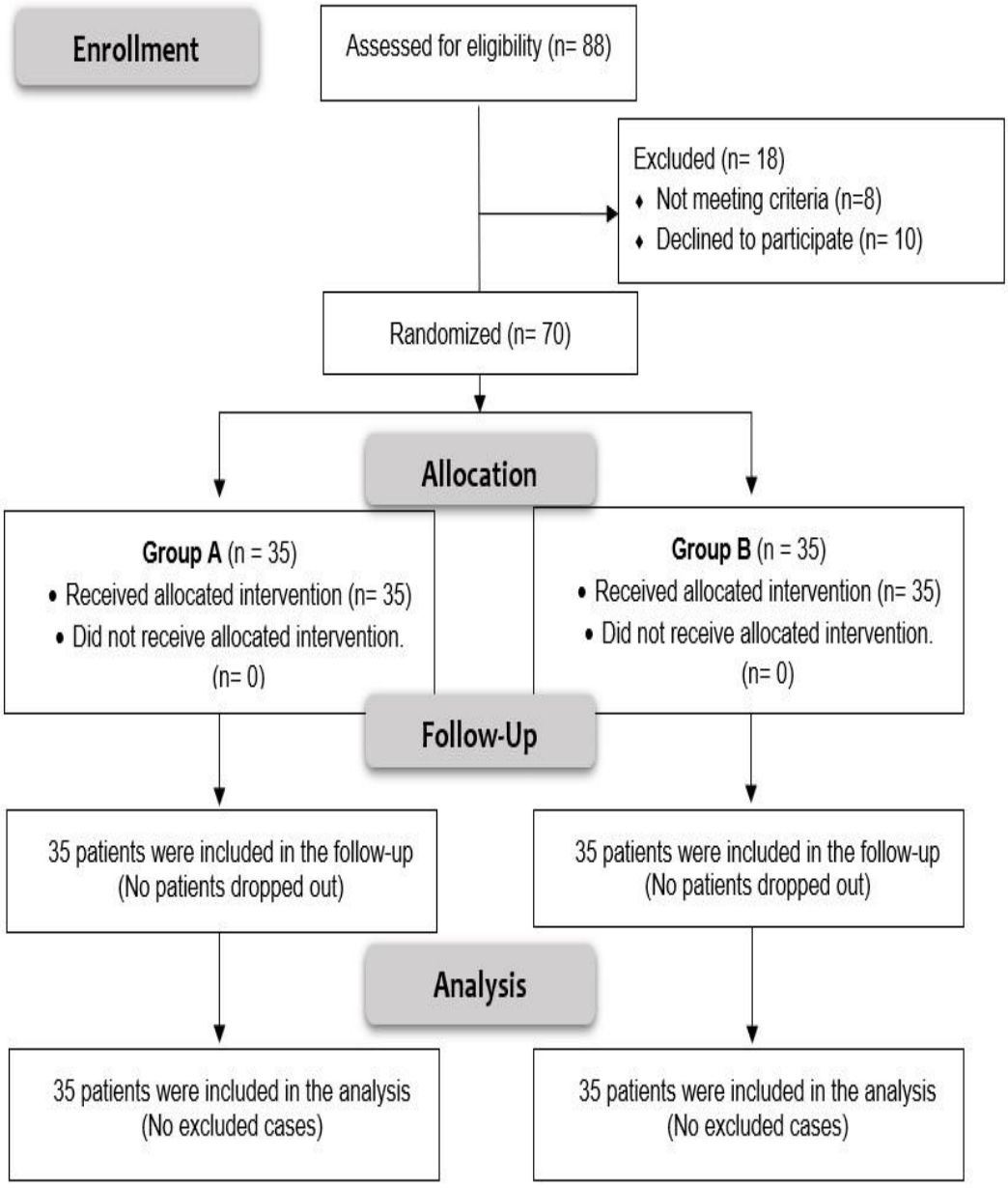

Fig. 1. CONSORT flow diagram of the participants

Table 1. Comparison of demographic data between groups

		Group A (n = 35)	Group B (n = 35)	p. value
Age (years)		40.26± 7.87	36.46± 9.23	0.072
BMI (Kg/m^2)		30.27± 3.26	30.01± 2.87	0.731
Sex	Male	14 (40%)	18 (51.43%)	0.337
	female	21 (60%)	17 (48.57%)	
ASA	ASA II	24 (68.57%)	22 (62.86%)	0.615
physical status	ASA III	11 (31.43%)	13 (37.14%)	
Duration of surgery (h)		7.642 ± 0.88	7.28 ± 1.04	0.125
Type of surgery	Glioma	16 (45.71%)	18 (51.43%)	0.666
	Meningioma	9 (25.71%)	6 (17.14%)	
	Medulloblastoma	7 (20%)	7 (20%)	
	Craniopharyngioma	2 (5.71%)	4 (11.43%)	
	Cerebral aneurysm	1 (2.86%)	0	

Data are presented as mean ± SD or frequency (%)

Table 2. Length of ICU and hospital stay, total amount of crystalloid solutions and patients received colloid, blood, vasopressor and inotrope

	Group A (n = 35)	Group B (n = 35)	p. value
Length of ICU stay (days)	(1-2) 2	(1-1) 1	0.007
Length of hospital stay (days)	(5 - 3.5) 5	(4 - 3) 4	0.017
Total amount of crystalloid (solutions (mL	471.8 ± 3582.9	284.2 ± 1908.6	<0.001
Patients received colloid	(11.45%)4	(8.57%)3	1
Patients received blood	(8.57%)3	(2.86%)1	0.614
Patients received vasopressor	(8.57%)3	(11.45%)4	1
Patients received inotrope	(0.00%)0	(2.86%)1	1

Data are presented as mean ± SD, median (IQR: Interquartile range) or frequency (%)

Table 3. Adverse events in both groups

	Group A (n = 35)	Group B (n = 35)	P value.
Encephalodema	6 (17.1%)	0 (0%)	0.025
ARDS	5 (14.3%)	1 (2.9%)	0.314
Pneumonia	4 (11.4%)	0 (0%)	0.114
Sepsis	5 (14.3%)	1 (2.9%)	0.314
AKI	3 (8.6%)	0 (0%)	0.239
Skin infection	4 (11.4%)	3 (8.6%)	1
Arrythmia	3 (8.6%)	0 (0%)	0.239
Need of mechanical ventilation	5 (14.3%)	1 (2.9%)	0.314

Data are presented as frequency (%) *AKI: acute kidney injury*

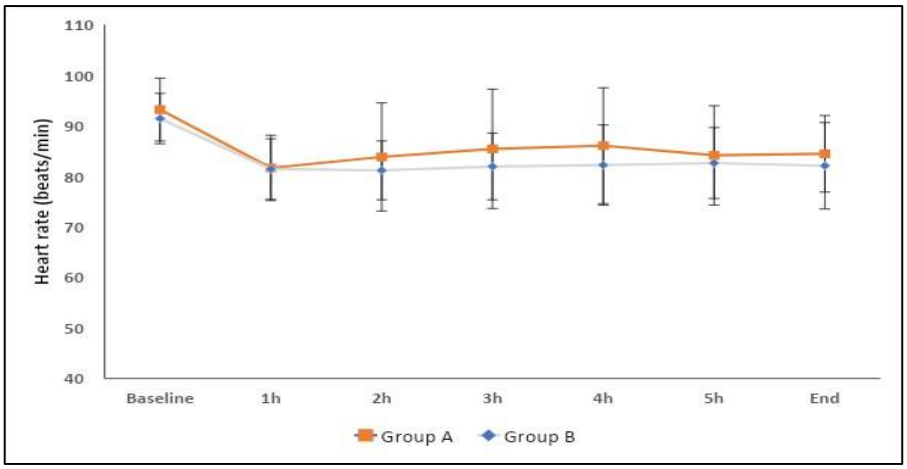

Fig. 2. Comparison of heart rate changes between both groups

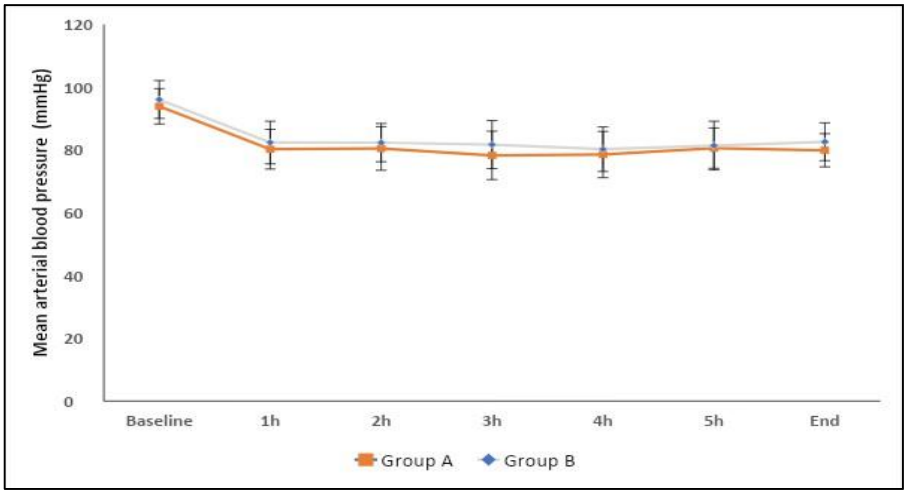

Fig. 3. Comparison of mean arterial blood pressure changes between both groups

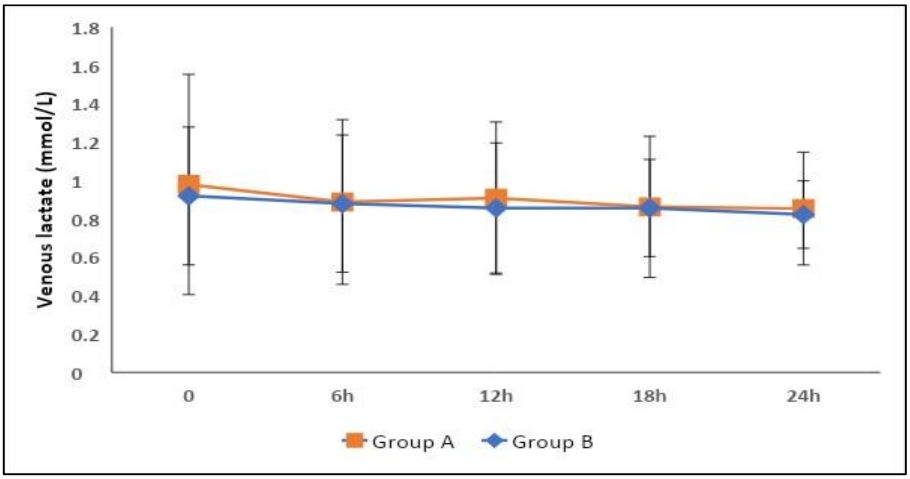

Fig. 4. Comparison of venous lactate changes (mmol/l) between the two groups

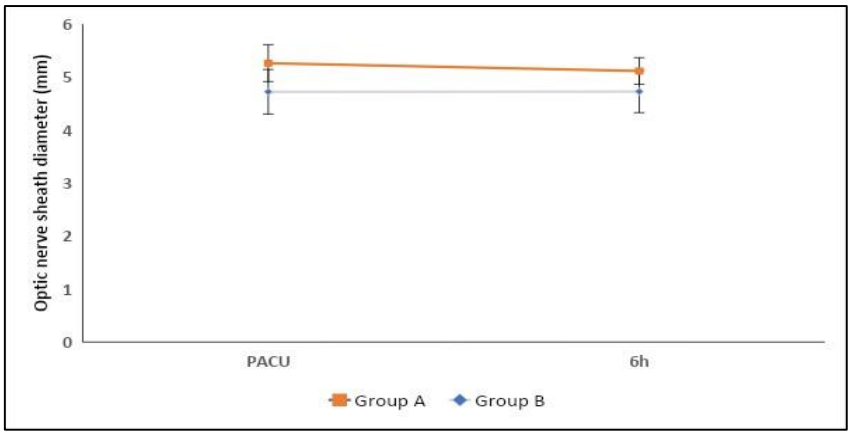

Fig. 5. Comparison of optic nerve sheath diameter changes between both groups

In agreement with our study, Zhao et al. [12] who studied (GDFT) in the perioperative period for plateau-elderly gastrointestinal cancer patients. They were randomly allocated into two equal groups: GDFT and routine fluid infusion group (control group). FloTrac/Vigileo system was employed to obtain blood flow dynamic indices including SVV in GDFT group and fluid management depend on SVV values. The hospitalization days after surgery in GDFT group were much shorter than that in control group and the crystalloid quantity infused in GDFT group was markedly less than that in control group. They concluded that GDFT used in the perioperative period could improve the prognosis of old patients undergoing radical correction of gastrointestinal cancers and reduce the incidence of postoperative complications in addition to cost savings.

In accordance with our results, Habicher et al. [13] evaluated The GDFT protocol that based on continuous monitoring and optimization of SV during the hip revision arthroplasty. These patients were compared to historical matched patients (control group). Patients from the GDFT group received less crystalloids during surgery and with significantly shorter period of hospitalization postoperative than the control.

Also, our results were supported by Muñoz et al. [14] who studied the efficacy of GDFT protocol on patients having sleeve gastrostomy. He found that GDFT patients had less fluid intervention and shorter period of postoperative hospitalization.

Furthermore, Weinberg et al. [15] were in agreement with our results as they studied the of GDFT in patients having open right hepatectomy. He found that GDFT patients had less fluid intervention and shorter period of postoperative hospitalization.

Also, Lotfy et al. [16] compared EC to transesophageal Doppler (TED) for COP monitoring and fluids intervention in patients undergoing hepatoportoenterostomy. Patients undergoing surgical hepatoportoenterostomy were divided into two equal groups for guided fluid intraoperative management: (EC) group and (TED) group. Both methods were proved to be effective and reliable in monitoring changes of COP with equally guided fluid management. Both methods could provide accurate data about intravascular fluid status for mechanically ventilated patients using FTc (Flow Time Corrected) of TED and SVV (Stroke Volume Variation) of EC.

Moreover, Liu et al. [17] reported their experience in monitoring cardiac output with EC for patients having regional caudal anaesthesia and their response of COP changes to epinephrine. They demonstrated the clinical benefit of noninvasive EC monitoring of COP in rapid detection of COP change and response to medical intervention. The study concluded that EC could be an additional important hemodynamic monitor that can track changes as a result of intraoperative hemodynamic interventions among children of all sizes.

The previous two studies are in agreement with us that EC is able to monitor the trend changes of COP without exposing them to the risks of invasive procedures and effectively guide fluid management.

In disagreement to our results, Gómez-Izquierdo et al. [18] conducted a trial on adult patients having laparoscope-guided colorectal surgery within an Enhanced Recovery after Surgery program. Patients were assigned randomly to esophageal Doppler monitor-guided GDFT and usual care group. They found that duration of hospital stay and postoperative morbidity and mortality were not significantly different. The hospital stay duration wasn't different and that can be explained by different type of patients and different type of surgery as the methodology of control group depend on The cardiovascular response obtained 30 s after positioning the patient in steep trendelenburg (change of position) and before starting the pneumoperitoneum was measured and recorded. Not like us depend on CVP monitoring. However, they were agreeing with us that patients in the goal-directed fluid therapy group received less intravenous fluids.

Furthermore, Gerent et al. [19] assessed GDFT. Patients having major surgery for cancer treatment. Hemodynamic parameters and perfusion indexes were similar among studied (H, MAP, $ScvO_2$, lactate levels, base excess and PCO_2 gap. The GDFT group reported higher use of dobutamine more than other groups. Mortality rate was similar in both groups. They was no difference between GDFT and usual care groups: septic shock, ICU readmission, ICU stay and hospital period of stay. There was no statistically significant change in this study in length of ICU and hospital stay which can explained by Preload was optimized by fluid loading until pressure pulse variation (PPV) was < 10% in both groups.

Also, in disagreement with our results, Phan et al. [20] compared the standard fluid therapy to GDFT in elective major colorectal surgery. Patients were randomized to either Doppler-guided GDFT or restrictive fluid therapy. The duration of hospital stay and incidence of complications were similar. We think GDFT not affect the hospital length-of-stay in their study as GDFT used within an ERAS (early recovery after surgery) pathway and ERAS pathway already reduce the length of hospital stay, besides they compared the GDFT with restrictive fluid therapy.

A limitation of our study, that it was a single center study. We recommend further studies on a larger sample size for generalization of these results.

5. CONCLUSIONS

EC is an effective tool in COP measurement and a novel guide for fluid therapy as EC guided fluid therapy group was significantly decreased in duration of ICU stay, hospital duration of stay and total amount of fluids with less adverse events.

CONSENT AND ETHICAL APPROVAL

This prospective randomized double blinded controlled study was carried out from September 2018 to July 2019 in Neurosurgery Department, after it had obtained Local Ethical Committee approval (approval code: 32482/07/18). It was registered on the Pan African Clinical Trial registry with its identification no PACTR201902530245620. Written informed consent was obtained from the patients.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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