

Strategic comparison of fluid management in pre-eclampsia before cesarean section between 1 ml/kg BW/hour of colloid plus 5 mg/hour of furosemide and 80 ml/hour of crystalloid: Hemodynamic optimization and plasma albumin level improvements

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Abstract

Objective: Pre-eclampsia is a major cause of mortality and morbidity in pregnant women and complicates 7-10% of pregnancies. The specific protocol for fluids administration in pre-eclampsia has not been used globally with potential generating pulmonary edema. The process of fluid shifting that occurs in the interstitial can be assessed objectively with a non-invasive monitor. The objective of this study was to determine the impact of colloid 1 ml/kg body weight (BW)/hour and furosemide 5 mg/hour administration compared with crystalloid 80 ml/hour administration as fluid therapy in pre-eclamptic patients related to hemodynamic profile and plasma albumin levels.

Design: An analytical experimental study with a randomized controlled clinical trial design.

Setting: A single tertiary care center in Tangerang, Indonesia.

Patients and participants: Forty patients diagnosed with pre-eclampsia who underwent elective or emergency cesarean section during August-December 2020.

Interventions: Patients were randomly divided into two groups and were given different pre-operative fluids. Group F received 1 ml/kg BW/hour of hydroxyethyl starch (HES) 6% with

5 mg/hour of furosemide and Group K received 80 ml/hour of crystalloid.

Measurements and results: Demographics, clinical characteristics, albumin level, and hemodynamic profile were evaluated. The reduction of albumin levels in Group F was significantly lower than in Group K. A significant difference was found in 24th-hour mean arterial pressure (MAP) ($p=0.024$), 15th-minute pulse rate ($p=0.033$), 24th-hour corrected flow time (FTc) ($p=0.018$), 15th-minute to 24th-hour thoracic fluid content (TFC) ($p<0.05$), and 24th-hour pleth variability index (PVI) ($p=0.01$). Giving 1 ml/kg BW of colloids and 5 mg/hour of furosemide could improve better hemodynamic profiles compared to 80 ml/hour of crystalloid based on evaluation of blood pressure, pulse rate, FTc, TFC, and PVI from non-invasive monitoring and also showed a slower reduction in plasma albumin level. This result might be due to the mechanism of fluid shifting from interstitial to plasma. However, the adverse events of hypotension still need to be cautiously monitored.

Conclusion: Colloid and furosemide administration affect improvements of hemodynamic profile parameters and plasma albumin levels in parturients with pre-eclampsia.

Key words: Pre-eclampsia, colloid, diuretic, crystalloid, hemodynamic profile, albumin level.

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Introduction

Pre-eclampsia complicates 7-10% of pregnancies and has become a major cause of mortality and morbidity in pregnant women in the world. (1) In addition, pre-eclampsia-related postpartum pulmonary edema occurred in 70-80% of the cases. (2) Postpartum mobilization of interstitial fluid contributes to pulmonary edema due to increased pulmonary capillary wedge pressure (PCWP). Furthermore, decreased colloid oncotic pressure and increased vas-

cular permeability resulting from endothelial damage contribute to the increased risk of pulmonary edema. (3-5)

To date, there is still no particular guideline for fluid management in pre-eclampsia, which might be the underlying causes of the high incidence of pulmonary edema. However, in recent years, FIGO (International Federation of Gynaecology and Obstetrics) has recommended limiting fluid with crystalloids to 80 ml per hour as fluid management in pre-eclamptic patients. Despite that, the maximum total amount of crystalloid fluid before termination was not stated in detail. (6)

Pre-eclampsia might damage the glycocalyx and the underlying system. The damage to the glycocalyx then leads to a decrease in its thickness, an increase in microvascular permeability, a decrease in mechano-transduction signaling, and an increase in the interaction of blood cells with the vessel wall. This damage triggers extravascular conditions into hypervolemia and intravascular conditions into hypovolemia. (7)

Furosemide, a loop-active diuretic, has been a standard treatment in heart failure for the past few decades. Apart from its primary activity as a diuretic, furosemide can also affect the vascular wall on the cardiovascular system due to the regulation reflex of the vascular system. Furosemide increases the drawing of extravascular fluid into intravascular, which is directly related to albumin levels so that oncotic pressure increases. (4) Therefore, we hypothesized that the use of furosemide in pre-eclamptic patients would improve the hemodynamic profile in pre-eclamptic patients.

Materials and methods

This study was a prospective, randomized controlled clinical trial that compared the use between 1 ml/kg body weight (BW)/hour of colloid plus 5 mg/hour of furosemide with 80 ml/hour crystalloid in patients with pre-eclampsia who underwent cesarean section at a single tertiary care center. The study protocol was approved by the institutional review board and all participants provided written informed consent. The primary objective of this study was to evaluate the impact of the fluid management given with hemodynamic optimization and plasma albumin level improvements.

Patient population

Pregnant women who underwent elective or emergency cesarean section from August to December 2020 and had a diagnosis of pre-eclampsia and were enrolled in this study. Inclusion criteria were pregnant women aged 18 to 40 years old with a singleton

pregnancy, ASA (American Society of Anaesthesiologists) physical status classification 2-3, body height 145-175 cm, body mass index 18.5-35 kg/m², and agreed to become a participant in the study. Exclusion criteria were patients who had absolute or relative contraindications for spinal/intrathecal anesthesia (such as local infection, sepsis, thrombocytopenia [less than 75,000/mm³], coagulopathy, and spinal deformities), chronic hypertension, eclampsia, history of cardiovascular or cerebral vascular disease, history of pregestational and gestational diabetes mellitus with blood glucose level more than 200 mg/dl, placental abruption/placenta previa/placenta accrete, umbilical cord prolapse, gestational age less than 34 weeks, active labor, patients confirmed positive for Covid-19, and non-cooperative patients.

The sample size calculation was based on the previous study reporting the hemodynamic profile and albumin levels in pre-eclamptic patients. Using an alpha (two sides) of 0.05 and beta of 0.2, the sample size calculated was 18 patients in each group. Considering the possible loss of follow-up and a dropout rate of 10%. The total sample size required was 40 patients.

Definitions

Pre-eclampsia is defined as a syndrome characterized by hypertension and positive proteinuria at the gestational age of more than 20 weeks, without severe symptoms. It may occur at early-onset (gestational age 21-33 weeks) or late-onset (gestational age >34 weeks) of gestation. Improvement in the hemodynamic profile is defined as improvement in at least 3 from 4 parameters evaluated (corrected flow time [FTc], thoracic fluid content [TFC], pleth variability index [PVI], and systemic vascular resistance index [SVRI]).

Methods

This study recruited 40 patients with pre-eclampsia who underwent cesarean section and met the study criteria. We randomly assigned the participants into two groups using permuted block random sampling with computer-generated assignment through the independent party from www.randomizer.org. Group K was given 80 ml/hour crystalloid as fluid management, and Group F was given 1 ml/kg BW/hour colloid plus 5 mg/hour furosemide. The patients, treating physicians, and research personnel were all blinded to the study fluid allocation.

All participants were given oxygen supplementation with a flow of 2-3 liters per minute with a nasal cannula and monitored with a non-invasive blood pressure (NIBP) measuring device, electrocardiogram

(ECG), pulse oximeter (SpO₂), and electric velocimetry. NIBP measurements were set at 5 minutes intervals. Intravenous way using 20 G cannula and Foley catheter to monitor urine output were inserted.

Spinal anesthesia was performed and researchers conducted baseline and intraoperative monitoring of ECG, pulse, NIBP, SpO₂, and electrical velocimetry assessment, namely FTc, TFC, PVI, and SVRI continuously every 5 minutes, and the results were recorded until the cesarean section was completed.

The electrical velocimetry used in the study was ICON[®] Osypka Medical, Berlin, Germany. The measurement was performed by using four electrodes, the first position was 5 cm above the base of the left neck along the internal carotid artery, the second was at the base of the left neck, the third was below the left thorax parallel to the xiphoid, and the fourth was 10-15 cm below the xiphoid in the anterior axillary line. MASIMO[®] was used on the fingertip of the patient's left hand. After the electrodes were connected, ICON[®] was turned on; then, the researchers entered the setup menu, entered patient data, pressed measure, and recorded the data. TFC and SVRI were recorded on the study sheet. Next, MASIMO[®] was turned on, then recorded data of FTc and PVI.

Albumin levels were measured before being given treatment and 24 hours after treatment. In addition, blood pressure, pulse rate, TFC, FTc, PVI, and SVRI were measured before treatment (baseline), 5 minutes (I), 10 minutes (II), 15 minutes (III), 20 minutes (IV), 30 minutes (V), 45 minutes (VI), 60 minutes (VII), and 24 hours (VIII) after treatment. Baseline characteristics, including age, body height, body weight, body mass index, baby birth weight, Apgar score, operating time, and previous history of cesarean section were also recorded.

Statistical analysis

SPSS software (version 21.0; IBM) was used for statistical analysis. Patients' demographic and clinical characteristics were reported using mean (standard deviation [SD]) or median (interquartile range [IQR]) or number (percent). The comparison of data between two groups was analyzed using chi-square or Fisher's exact test for categorical data. The independent t-test was used for numeric data with normal distribution and the Mann-Whitney test for numeric data without normal distribution. Friedman test and general linear model (GLM) analysis test were performed to measure the association between clinical variables. A p-value of less than 0.05 was considered statistically significant.

Results

Forty parturients were randomized into Group K (n=20) and Group F (n=20). There was a significant difference in the mean age between the two groups, with the mean age of Group K being higher than that of Group F, namely 34.3±4.1 years and 29.6±5.9 years (p<0.05). The previous history of cesarean section was significantly more common in Group F, i.e., ten subjects (50%), while in Group K were three subjects (15%) (p<0.05). Other characteristics were equivalent between the two groups (p>0.05) (**Table 1**).

A significant difference in post-operative albumin levels between the two groups (p<0.001) was reported, with median postoperative albumin levels in Group F higher than in Group K, which was 2.9 mg/dl and 2.6 mg/dl, respectively. The decrease in plasma albumin levels in Group F was significantly lower than in Group K (p=0.002) (**Table 2**).

There was a significant difference in mean arterial pressure (MAP) at 24 hours (p=0.024), with the median MAP of Group F being 93.5 mmHg, lower than Group K, which was 99.0 mmHg. The median pulse rate at 15 minutes (p=0.033) in Group F was significantly lower than Group K, 88 bpm, and 92 bpm, respectively. There was a significant difference in TFC at the time of measurement from 15 minutes to 24 hours (p=0.033; p=0.009; p=0.005; p=0.011; p=0.018; p<0.001), with the median TFC of Group F lower than Group K at the time of measurement from 15 minutes to 24 hours. A significant difference in FTc at 24 hours was reported (p=0.018), with the median FTc of Group F being 352.0 ms, higher than Group K, which was 316.0 ms. There was a significant difference in PVI at 24 hours (p=0.01), with the median PVI of Group F being 11.0% lower than that of Group K, which was 19.5%. However, there was no significant difference in those parameters between the two groups at other measurement times. Furthermore, there was no significant difference in SVRI between the two groups at all times of measurement.

Friedman analysis test was performed to analyze the difference between the time of measurement in both groups. We found a significant difference in MAP (p<0.001), pulse rate (p<0.001), and SVRI between measurement times in Group K. Meanwhile in Group F, we found a significant difference in MAP (p<0.001), pulse rate (p<0.001), TFC (p<0.001), FTc (p<0.001), and PVI (p<0.001) between measurement times. The median MAP trend in Group F was lower than Group K from the 15-minute to the 24-hour measurement times (**Figure 1**). The median pulse rate trend in both groups tends to decrease from the baseline measurement time to 24 hours

(**Figure 2**). The median trend of TFC in Group F has decreased from baseline to 24 hours, meanwhile in Group K tends to be stable (**Figure 3**). The median trend of FTc in Group F became higher from the 15-minute to the 24-hour measurement, with a decline at 60-minute of measurement (**Figure 4**). The median PVI trend in Group F was initially higher at the time of the baseline measurement but then became lower from the 5-minute to 24-hour measurement (**Figure 5**). The median SVRI trend in Group F increased at the time of the baseline to 24-hour measurement (**Figure 6**).

Discussion

Pulmonary edema is the most common cardiopulmonary complication in pre-eclamptic patients, with a prevalence of about 3%. Pulmonary edema often occurs in the peripartum or post-partum phase. (8) Patients with pre-eclampsia have a lower oncotic pressure than in normal pregnancy due to protein loss through urinary excretion. Blood volume expansion fails to occur in severe pre-eclampsia due to decreased intravascular volume, generalized vasoconstriction, and haemoconcentration, resulting in pulmonary edema. (9,10) Patients with pre-eclampsia generally experience hemodynamic changes characterized by high systemic vascular resistance, low right and left ventricular filling pressures, increased cardiac index (CI), hyperdynamic left ventricular function, and normal or high PCWP. There is an increase in capillary permeability and right ventricular diastolic pressure, resulting in acute pulmonary edema in severe pre-eclampsia. (9) Excessive intravenous fluid therapy accompanied by other pathological mechanisms will increase the hydrostatic pressure in the pulmonary vasculature. Therefore, a maximum fluid restriction of 80 ml/hour is used in pre-eclamptic patients. (10,11)

We found that the median albumin levels in Group F were significantly higher than in Group K and the decrease in albumin levels in Group F was significantly lower than in Group K. The results of this study can illustrate that administration of colloids and diuretics can inhibit more progressive albumin loss in pre-eclamptic patients as well as increasing colloid osmotic pressure (COP). No previous study examined the comparison of albumin levels in pre-eclamptic patients who received crystalloid fluid restriction and received colloids and furosemide in preventing the incidence of pulmonary edema. It was also mentioned that no studies were using other colloids as fluid therapy in pulmonary edema patients. (12,13) Previous research by van der Heijden et al mentioned that colloids in critically ill patients with hypovolemia have increased plasma volume,

cardiac index, and central venous pressure more than crystalloids. In addition, COP increased with colloid administration. In contrast, crystalloid administration decreased COP, but pulmonary edema was not affected by the type of fluid, which was probably caused by pulmonary protective factors such as changes in interstitial pressure and lymph flow, thereby preventing pulmonary edema. (14) However, Wahjoeningsih said that the administration of crystalloids or colloids in pre-eclamptic patients was still controversial as some cases showed varying conditions from low COP and leaky capillaries to cause non-cardiogenic pulmonary edema. (15) In this study, the administration of diuretics combined with colloids could overcome fluid overload due to fluid mobilization, extravascular and hydrostatic-oncotic changes. The pathology of capillary permeability in pulmonary edema is still unclear but may be caused by endothelial damage. van der Heijden et al (14) reported that administering hydroxyethyl starch (HES) to patients with acute lung injury (ALI) could improve pulmonary permeability and reduced pulmonary leakage index (PLI). In this study, the trend of mean MAP in Group F was lower from 15-minute to 24-hour. The results of this study were in line with previous meta-analyses, which stated that administration of colloid expansion in pre-eclamptic patients was significantly associated with lower systolic and diastolic pressure, but not significantly on the cardiac index (CI). (16)

There was no statistically significant difference between the time of measurement and the treatment groups in our study. However, the median pulse rate in group F was lower from the baseline measurement time to 24 hours. These results were consistent with several previous prospective studies that there was no significant change in pulse rate and CI after administration of fluid expansion with colloids. Pulse wave analysis studies showed significant variability in the stroke volume responsiveness of patients with severe pre-eclampsia after administration of colloid bolus before spinal anesthesia. This variability indicates that fluid restriction is safer to use if there is no modality to monitor stroke volume. There is a negative correlation between changes in pulse rate and stroke volume after administration of colloids, which means that if the pulse rate increases drastically, it is necessary to limit further fluid administration. (16)

The trend of the median TFC in Group F was initially higher at the baseline measurement time but then became lower from the 5-minute to 24-hour of measurement. In parturients with pre-eclampsia, TFC is a good tool for detecting pulmonary edema.

The high negative predictive value of the test makes it a useful screening test to exclude pulmonary edema. (17) The patient population treated empirically with diuretics showed significantly lower TFCs than patients treated with other antihypertensive drugs, untreated patients, and control subjects. (18)

There was a significant difference in FTc at 24-hour measurement in our study. A randomized controlled study by Tamilselvan et al (19) reported that FTc increased significantly compared to baseline in all groups, both crystalloid and colloid administration after fluid loading. However, after spinal anesthesia, FTc remained significantly higher than baseline only in the colloid group. Another study by McDonald et al (20) showed that FTc increased significantly above baseline in both the colloid (HES) and crystalloid groups, with a lasting effect in the colloid group for 20 minutes but only up to 10 minutes in the crystalloid group. The FTc was significantly higher than baseline in the colloid group but not in the crystalloid group, and this might be due to the ability to maintain adequate intravascular expansion. Therefore, it is important to recognize conditions in which a patient may be volume overloaded but have a low FTc due to pathological limitations in LV preload (pulmonary embolism, mitral stenosis, tamponade). (21)

Our study showed that the trend of the median PVI in Group F was initially higher at the time of the baseline measurement but then became lower from the 5-minute to 24-hour measurement. Greater PVI is associated with hypotension after spinal anesthesia for a cesarean section but may not be a clinical helpful predictor. (22) The PVI value can be influenced by factors such as ambient temperature, patient stress, and anxiety. (23) Meanwhile, according to the study of Kuwata et al, PVI after spinal anesthesia was a good predictor of spinal anesthesia-induced hypotension in patients undergoing cesarean delivery. (24)

Regional anesthesia can decrease SVRI and cause hypotension. Colloid infusion as a preload has been shown to be more effective than crystalloid in reducing the incidence of hypotension and increasing cardiac output. (25,26) Meanwhile, in this study, there was no significant difference in SVRI between

the two groups at all times of measurement. However, the median SVRI in Group F was higher at the time of the baseline measurement compared to the 24-hour one. This result was different from the study of Pretorius et al (16), which showed a significant reduction in systemic vascular resistance after volume expansion with colloids.

Study limitations

This study has a limitation as we only used the modern non-invasive hemodynamic profile assessment method. However, the hemodynamic changes associated with pulmonary edema in pregnant women with severe pre-eclampsia are complex and involve multiple factors. In addition, this research was only carried out at one research center to affect the significance of the research results. The distribution of characteristics in each equal treatment group is expected to represent the general population's actual results. Further studies with larger samples and research centers are still needed to analyze fluid therapy in pre-eclamptic patients further and monitor hemodynamic profiles to obtain more optimal maternal and neonatal outcomes.

Conclusion

There was an improvement in the hemodynamic profile of blood pressure, TFC, FTc, and a lower decrease in plasma albumin value in pre-eclamptic patients undergoing cesarean section who received colloid administration of 1 ml/kg BW/hour and furosemide 5 mg/hour. However, there was no improvement in the hemodynamic profile of pulse rate, PVI, and SVRI. Therefore, administration of colloid 1 ml/kg BW/hour and furosemide 5 mg/hour can be used as an alternative to preoperative fluids in spinal anesthesia for cesarean section with pre-eclampsia because it can prevent a decrease in albumin levels and improve FTc and TFC after spinal anesthesia.

Conflict of interest

All authors declare that there is no conflict of interest.

Source of funding

None.

Table 1. Patients' characteristics

	Group K (n=20)	Group F (n=20)	p-value
Age, mean±SD (years)	34.3±4.1	29.6±5.9	0.006*
Height, mean±SD (cm)	155.4±4.9	154.4±5.1	0.513*
Weight, mean±SD (kg)	76.8±10.3	72.2±10.4	0.166*
BMI, median (min-max) (kg/m ²)	31.3 (25.8-43.0)	30.0 (22.9-36.8)	0.192**
Baby birth weight, mean±SD (g)	2491.0±386.0	2561.5±600.7	0.662*
Apgar score, 1st-minute, median (min-max)	7 (6-8)	7 (6-8)	0.841**
Apgar score, 5th-minute, median (min-max)	8 (7-9)	8 (7-9)	0.620**
Operating time, median (min-max) (minutes)	60 (60-90)	60 (60-70)	0.779**
History of cesarean section (yes), n (%)	3 (15.0%)	10 (50.0%)	0.018***
Albumin pre-operatif, median (min-max) (g/dl)	3.1 (2.1-3.4)	3.1 (2.8-3.5)	0.096**
Baseline MAP, median (min-max) (mmHg)	110.5 (94.0-130.0)	108.0 (98.0-139.0)	0.620**
Baseline HR, median (min-max) (bpm)	101.5 (88.0-125.0)	99.5 (80.0-130.0)	0.583**
Baseline FTc, median (min-max) (ms)	315.5 (241.0-413.0)	313.5 (272.0-365.0)	0.883**
Baseline TFC, median (min-max) (kOhm-1)	36.0 (20.0-48.0)	36.5 (26.0-50.0)	0.659**
Baseline PVI, median (min-max) (%)	18.0 (3.0-28.0)	19.0 (13.0-26.0)	0.383**
Baseline SVRI, median (min-max) (dynes • sec/cm ⁵ /m ²)	1930.5 (1450.0-3142.0)	2300.5 (1010.0-2867.0)	0.301**

Legend: SD=standard deviation; BMI=body mass index; MAP=mean arterial pressure; HR=heart rate; FTc=corrected flow time; TFC=thoracic fluid content; PVI=pleth variability index; SVRI=systemic vascular resistance index.

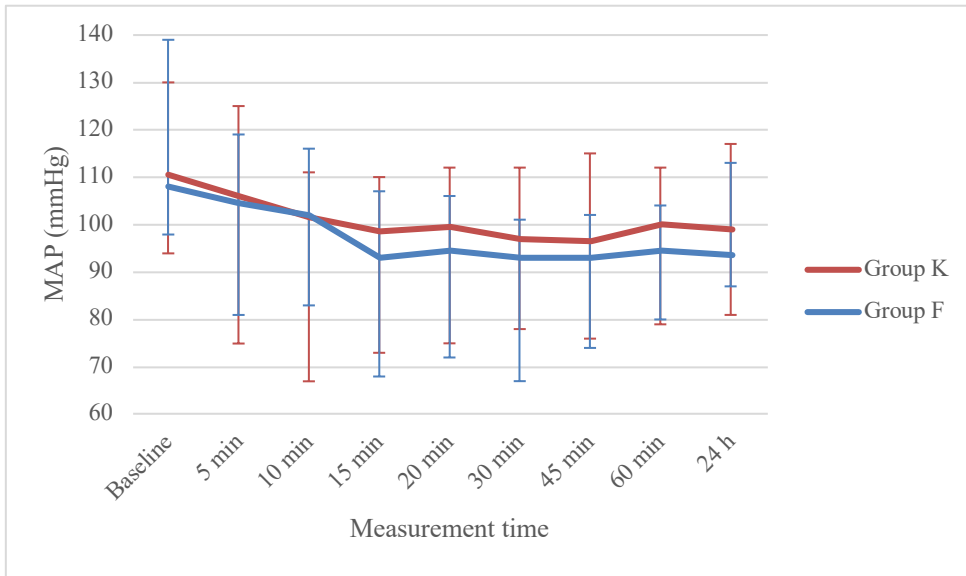
*independent t-test, **Mann-Whitney test, ***chi-square test

Table 2. Comparison of pre- and post-operative plasma albumin level

Plasma albumin level, median (min-max) (mg/dl)	Group K (n=20)	Group F (n=20)	p-value
Pre-operative	3.1 (2.1-3.4)	3.1 (2.8-3.5)	0.096*
Post-operative	2.6 (2.0-3.0)	2.9 (2.5-3.4)	<0.001*
Delta	-0.4 (-0.6-(-0.1))	-0.2 (-0.6-(-0.1))	0.002*

Legend: *Mann-Whitney test.

Figure 1. MAP trend in Group K and Group F



Legend: MAP=mean arterial pressure.

Figure 2. Heart rate trend in Group K and Group F

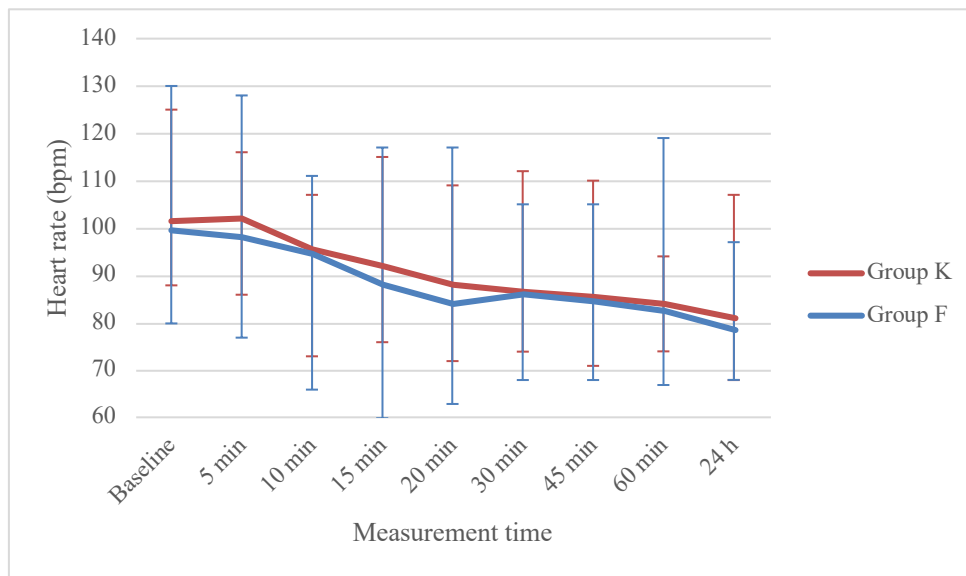
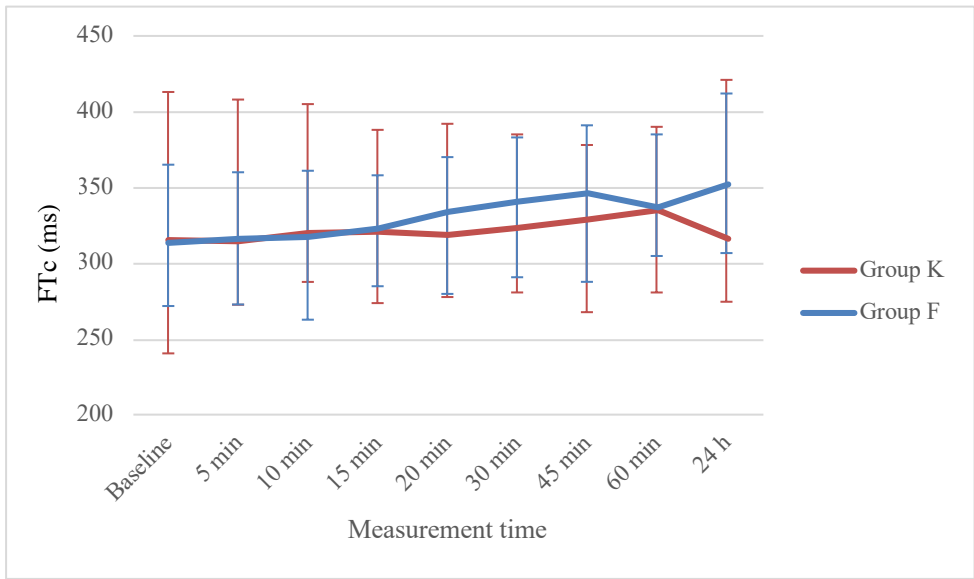
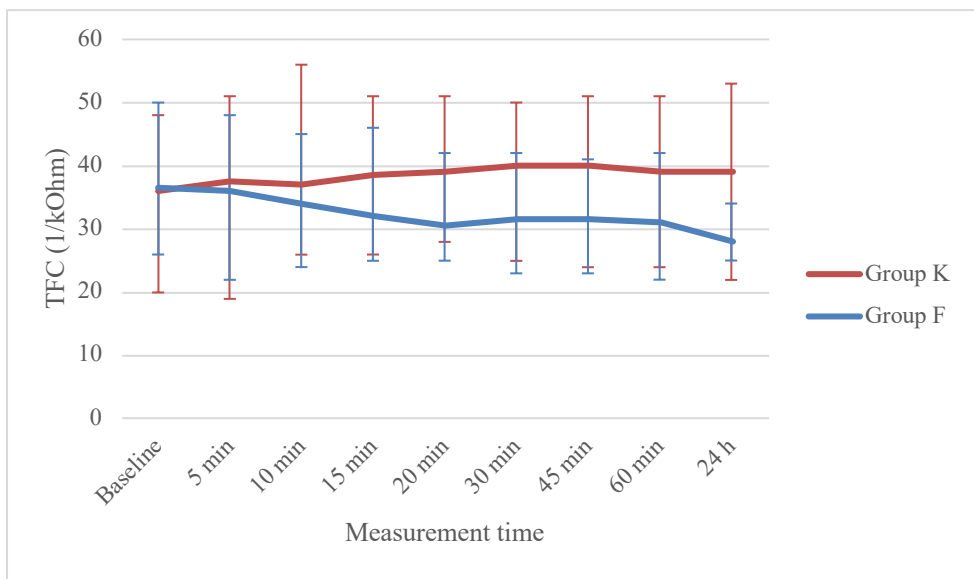


Figure 3. FTc trend in Group K and Group F



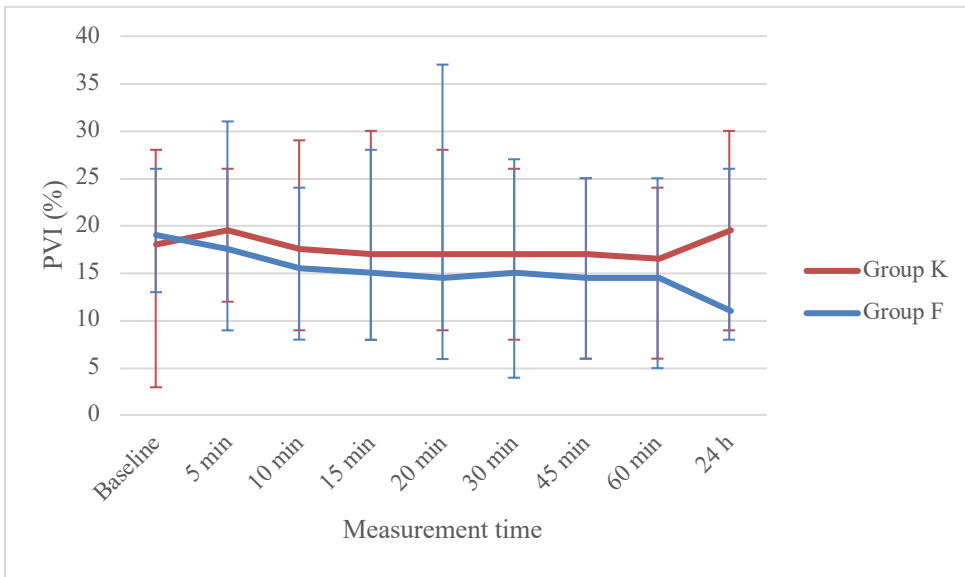
Legend: FTc=corrected flow time.

Figure 4. TFC trend in Group K and Group F



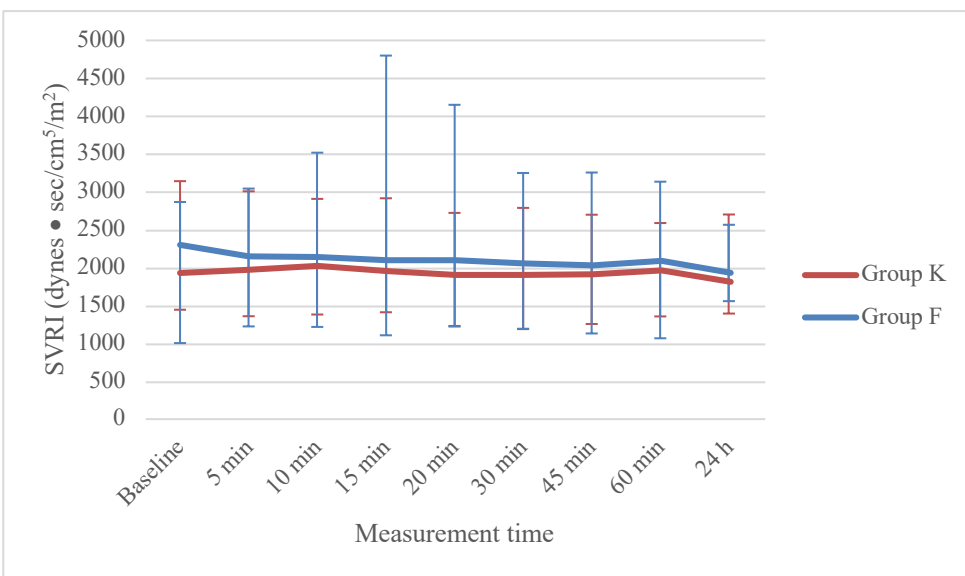
Legend: TFC=thoracic fluid content.

Figure 5. PVI trend in Group K and Group F



Legend: PVI=pleth variability index.

Figure 6. SVRI trend in Group K and Group F



Legend: SVRI=systemic vascular resistance index.

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