

ORIGINAL RESEARCH

INTENSIVE CARE

Fluid management using cardiometry versus simplified 'Fluid and Catheter Treatment Trial' protocol in acute respiratory distress syndrome

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ABSTRACT

Background & Objective: Fluid management is a complicated subject and an important part of medical care. Fluid balance has been shown to improve respiratory physiology in patients with acute respiratory distress syndrome (ARDS). We compared fluid management in ARDS guided by electrical cardiometry (EC) versus guided with conservative fluid protocol, simplified Fluid and Catheter Treatment Trial ('FACTT Lite').

Methodology: This prospective randomized study was conducted on 70 patients, who were 18 y or older and who fulfilled the Berlin definition of ARDS. Enrolled patients were randomly allocated into two equal groups; Group A: fluid management was guided by 'FACTT Lite' and Group B, in which fluid management was guided by EC.

Results: Mortality at 28th day was lower in Group B than in Group A; the hazardous ratio of mortality in Group A was 2.55 times than Group B. Duration of survival was higher in Group B than in Group A. Intensive care unit (ICU) stay and duration of mechanical ventilation (MV) were significantly lower in Group B than in Group A. Weaning was better in Group B than Group A. Lung Injury Score (LIS) was significantly decreased in Group B than Group A at 4, 5, 6, 7 and 14 days. Intravenous fluid intake and urine output were significantly decreased in Group B than Group A at all time measurements.

Conclusions: Electrical cardiometry was superior to 'FACTT Lite' in the fluid management in ARDS in terms of decreased 28-day mortality, Lung Injury Score, fluid intake, duration of mechanical ventilation and ICU stay.

Abbreviations: ARDS - acute respiratory distress syndrome; EC - electrical cardiometry; 'FACTT Lite'- Simplified conservative fluid protocol, Fluid and Catheter Treatment Trial; MV - mechanical ventilation

Key words: Electrical Cardiometry; FACTT Lite; Fluid management; Mechanical ventilation; Acute Respiratory Distress Syndrome.

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1. INTRODUCTION

Acute respiratory distress syndrome (ARDS) is a common complication of mechanical ventilation that affects up to 23% of intensive care patients. It has been established that protective lung ventilation together with the application of an appropriate (optimal) level of positive end-expiratory pressure (PEEP) are the

Box 1: Berlin Criteria of Mild to Moderate ARDS

- (1) Onset within one week,
- (2) Arterial oxygen tension (PaO₂)/fraction of inspired oxygen (FiO₂) between 100 and 300 mmHg with a minimum PEEP of 5 cmH₂O,
- (3) Bilateral lung opacities consistent with pulmonary edema on chest radiograph or lung ultrasound,
- (4) Exclusion of cardiac failure and fluid overload, and ARDS due to a pulmonary cause.

standards of ARDS management.¹ Fluid management is a complicated subject and one of the most difficult aspects of medical care. An optimal fluid balance has been demonstrated to benefit respiratory physiology in ARDS patients.² However, numerous investigations have demonstrated that the current indices are incapable of correctly predicting fluid responsiveness.³ Instead, while time-varying indicators such as pulse pressure variation, systolic blood pressure fluctuation, stroke volume variation (SVV), and Pleth Variability Index (PVI) have been acknowledged as efficient predictors of fluid responsiveness for ventilated patients, dynamic indicators like these have been previously overlooked. SVV has been demonstrated to be the most trustworthy of these indicators for determining volume status in chronic patients.⁴

Fluid management is a complicated subject and one of the most difficult aspects of medical care. An optimal fluid balance has been demonstrated to benefit respiratory physiology in ARDS patients.² However, numerous investigations have demonstrated that the current indices are incapable of correctly predicting fluid responsiveness.³ Instead, while time-varying indicators such as pulse pressure variation, systolic blood pressure fluctuation, stroke volume variation (SVV), and Pleth Variability Index (PVI) have been acknowledged as efficient predictors of fluid responsiveness for ventilated patients, dynamic indicators like these have been previously overlooked. SVV has been demonstrated to be the most trustworthy of these indicators for determining volume status in chronic patients.⁴

Thoracic bioreactance is a unique non-invasive approach for monitoring cardiac output (CO). Electrical cardiometry (EC) is a technique used to determine the stroke volume (SV), CO, and other hemodynamic parameters in adults, children, and newborns.⁵

As an attempt to reduce lung edema, to shorten the time of mechanical ventilation (MV), and improve the survival, the simplified Fluid and Catheter Treatment Trial ('FACTT Lite') protocol restricts fluid intake and increases urine output. This technique may result in a decrease in CO levels and poor organ performance.⁶ There are not many studies comparing the fluid management in ARDS patients guided by EC and the guidance with 'FACTT Lite'.

We compared the fluid management in ARDS patients guided by EC and the guidance with 'FACTT Lite'.

2. METHODOLOGY

This prospective randomized open-labeled parallel study was carried out at surgical intensive care unit (SICU) of Tanta University Hospital, Egypt, from January 2020 to December 2020. The study was done after approval from the institutional ethics committee [code number 32721/11/18 and registration on clinicaltrials.gov with number "NCT04219150"]. Written informed consent was obtained from the patients' relatives.

Patients included in this study were 18 y of age or older and met the Berlin criteria of mild to moderate ARDS (Box 1).

Patients with hemodynamic instability, vasopressor usage, barotrauma, or organ dysfunction at presentation or throughout pregnancy were excluded.

All patients were ventilated according to basal ventilator strategy of ARDS-network protocol⁷ using volume assist-control mode, with tidal volume 4 to 8 mL/kg predicted body weight, an inspiratory plateau pressure < 30 cmH₂O. The ventilator rate was adjusted to achieve a pH >7.25 to 7.44, maximum respiratory rate 35 cycle/min. FiO₂ levels were manipulated to maintain peripheral oxygen saturation 90–95% or PaO₂ between 60–80 mmHg. Titration of PEEP according to FiO₂ as recommended by ARDS-network.

Weaning from MV was by the protocol of our unit: e.g., the cause of ARDS is cured or under control, PEEP is < 6 cmH₂O, FiO₂/PaO₂ > 200 mmHg, and hemodynamic parameters are stable. All patients received spontaneous breathing trials daily with a modest level of pressure support 6-8 cmH₂O, when they were legible for weaning.

The enrolled patients were randomly allocated into two equal groups according to plan for fluid management of ARDS through the aid of computer-generated software of randomization introduced into sealed opaque envelopes. Group A (n = 35) patients received fluid

Box 2: Simplified fluid and catheter treatment trial 'FACTT Lite' protocol ⁸		
Central venous pressure (mmHg)	Mean arterial pressure \geq 60 mmHg and off vasopressors \geq 12 h	
	Urine output < 0.5 mL/kg/h	Urine output \geq 0.5 mL/kg/h
> 8	Furosemide ^{A, B}	Furosemide ^{A, C}
4–8	Fluid bolus ^B	Furosemide ^{A, C}
< 4	Fluid bolus ^B	No intervention ^C
^A : Recommended furosemide dosing = begin with 20 mg bolus or 3 mg/h infusion or last known effective dose. Double each subsequent dose until goal achieved (oliguria reversal or intravascular pressure target) or maximum infusion rate of 24 mg/h or 160 mg bolus reached. Do not exceed 620 mg/d. Also, if a patient has heart failure, consider treatment with dobutamine. ^B : Reassess in 1 h, ^C : Reassess in 4 h		

management according to 'FACTT Lite' and in Group B (n = 35) fluid management was guided by EC.

Group A: Simplified conservative fluid protocol - 'FACTT Lite'.

According to CVP and urine output, the FACTT Lite gave three treatment options: furosemide administration, fluid bolus, or no intervention. FACTT Lite contained recommendations to discontinue furosemide for at least 12 h once the patient's mean arterial pressure exceeded 60 mmHg without the use of vasopressors (Box 2). This protocol was initiated within 4 h of randomization in enrolled patients and continued until study day 7.

Meta-rules for the protocol: Discontinue maintenance fluids; maintain medicines and nutrition. Maintain electrolytes and blood products in accordance with standard procedures. For shock, any combination of fluid boluses (15 mL/kg crystalloid [rounded to the nearest 250 mL] or 1 unit packed red cells or 25 g albumin) and vasopressor(s) should be used to quickly achieve a mean arterial pressure of 60 mmHg. Withhold diuretic therapy in patients with renal failure (defined as dialysis dependence, oliguria, and serum creatinine > 3 mg/dL) and for 12 h after the last fluid bolus or vasopressor given.

Group B: Electrical cardiometry group.

The four sensors used on the patient were located at the base of the neck, just below the third electrode at the anterior axillary line, one on the lower thorax 5 cm below the xiphoid, and another at the base of the neck. The ECG monitor (EC monitor) was attached to the sensor cable and patient data were sent into it (ICON Cardiometrics, Inc., La Jolla, CA 92307; Osyka Medical GmbH, Berlin, and Germany, model C3, serial number 1725303). In less than 30 seconds after the sensors were installed and the height and weight were input, the corrected flow time (FTc) and SV were continuously monitored. Fluids were allowed using the FTc algorithm, and the kind of bolus fluids was decided by the transthoracic fluid content (TFC). Vasopressors and inotropes were given in line with the EC, SVR, and contractility index readings (ICON).

2.1 Measurements

Parameters of oxygenation by Lung Injury Score (LIS), total intravenous fluid intake, and urine output were recorded at the beginning of the study, at 12 h post-inclusion, and then on days 1, 2, 3, 4, 5, 6, 7, 14, 21, and 28. LIS consists of 4 items (**Error! Reference source not found.**)⁹ The score was calculated by adding the sum of each component and dividing the number of components used. Interpretation

Table 1: Lung Injury Score		
1- Chest radiograph score		
No alveolar consolidation		0
Alveolar consolidation confined to 1 quadrant		1
Alveolar consolidation confined to 2 quadrants		2
Alveolar consolidation confined to 3 quadrants		3
Alveolar consolidation in all 4 quadrants		4
2- Hypoxemia score		
PaO ₂ /FiO ₂	\geq 300	0
	225–299	1
	175–224	2
	100–174	3
	< 100	4
3- PEEP score		
PEEP	\leq 5 cmH ₂ O	0
	6–8 cmH ₂ O	1
	9–11 cmH ₂ O	2
	12–14 cmH ₂ O	3
	\geq 15 cmH ₂ O	4
4- Respiratory system static compliance score		
Compliance	\geq 80 ml/cmH ₂ O	0
	60–79 ml/cmH ₂ O	1
	40–59 ml/cmH ₂ O	2
	20–39 ml/cmH ₂ O	3
	\leq 19 ml/cmH ₂ O	4

Table 1: Comparative patients' characteristics in both groups

Variable		Group A (n = 35)	Group B (n = 35)	P-value
Age (y)		37.8 ± 13.15	41.69 ± 12.03	0.208
BMI (kg/m²)		26.52 ± 3.6	27.64 ± 3.67	0.208
Sex	Male	15 (42.9)	19 (54.3)	0.339
	Female	20 (57.1)	16 (45.7)	
Cause of ARDS	Pneumonia	26 (74.29)	28 (80.0)	0.569
	Aspiration	9 (25.71)	7 (20)	
Severity of ARDS	Mild	11 (31.43)	13 (37.14)	0.615
	Moderate	24 (68.57)	22 (62.86)	

Data presented as mean ± SD or n (%). BMI: body mass index, ARDS: acute respiratory distress syndrome

Table 3: ICU stay, duration of MV, MV free days, and weaning of both groups.

Clinical parameters		Group A (n = 35)	Group B (n = 35)	P value
ICU stay (days)		16.66 ± 7.14	13.46 ± 4.11	0.027
Duration of MV (days)		13.09 ± 6.03	9.31 ± 3.85	0.003
MV free days (days)		5 (0–6)	5 (4–5)	0.809
Successful weaning		21 (60%)	29 (82.86%)	0.034
Weaning categories	Simple	4 (11.43%)	8 (22.86%)	0.003
	Difficult	3 (8.57%)	14 (40.0%)	
	Prolonged	14 (40.0%)	7 (20.0%)	

Data presented as mean ± SD, median (IQR) or frequency (%). ICU intensive care unit, MV mechanical ventilation.

of score was (No lung injury = 0, mild to moderate lung injury = 0.1–2.5, and severe lung injury > 2.5).

The incidence of mortality at 28th day, duration of MV, duration of ICU stay, weaning categories (simple, difficult, and prolonged weaning), and adverse effects (such as hemodynamic instability, or organ/s failure) were recorded.

The primary outcome was 28th-day mortality. The secondary outcomes were LIS, duration of MV and ICU stay, and weaning categories.

2.2. Sample size calculation

The sample size was estimated using the Epi-Info statistical tool to be 58. The criteria used for sample size calculation were: 95% confidence limit, 80% power of the study, the ratio between both groups is 1:1, the mortality in mild to moderate in ARDS is 45% according to a previous study,¹⁰ and expected to be 12% with EC. Six cases were added in each group to overcome drop-outs. Therefore, we recruited 35 patients in each group.

2.3. Statistical analysis

The statistical analysis was performed using IBM SPSS v25 (Chicago, IL, USA). The Shapiro-Wilks test and histograms were used to determine the normality of data distributions. On quantitative parametric data, the mean, standard deviation (SD), and range were utilized to conduct an unpaired student's t-test. To analyze non-parametric quantitative data, the Mann-Whitney test was utilized. The median and interquartile ranges were used to describe the data (IQR). Qualitative data were presented as numbers and percentages and compared using the chi-square (X²) or Fisher's Exact test, if necessary. Using two-tailed tests, statistical significance was determined as a P = 0.05.

3. RESULTS

The comparison shows insignificant differences between both groups as regards the age, body mass index, sex, cause of ARDS, and severity of ARDS. (Table 1)

There was a significant increase in ICU stays and duration of MV in Group A than Group B. There was an insignificant difference in MV free days between both

groups. Weaning categories and percentage of patients successfully weaned were significantly better in Group B than in Group A. (Table 1).

We assessed 103 patients for eligibility, 24 patients did not meet the criteria and 9 patients' relatives refused to participate in the study. The remaining 70 patients were randomly allocated into two equal groups. All patients were followed-up and analyzed statistically (**Error! Reference source not found.1**).

Mortality at 28 d was higher in Group A than Group B; 14 (40%) vs. 6 (17.1%); $P = 0.043$. Duration of survival was higher in Group B than Group A ($P = 0.021$). The hazardous ratio of mortality in Group A was 2.55 times (95% CI: 1.18 - 5.52) than Group B (Figure 2).

There was an insignificant difference between both groups in LIS at baseline, 12 h, 1, 2, and 3 days while at 4, 5, 6, 7, and 14 days and a significant decrease in Group B compared to Group A (Figure 3). There was a significant decrease in IV fluid intake in Group B compared to Group A at all-time measurements (Figure 4).

There was a significant increase in urine output in Group A compared to Group B at all-time measurements (Figure 5).

There was insignificantly different in hemodynamic instability, renal failure, heart failure, sepsis, and arrhythmia in both groups. (Figure 6)

4. DISCUSSION

To our knowledge, this is the first study to examine the function of EC in ARDS patients and to compare it to a modified conservative fluid regimen called "FACTT Lite."

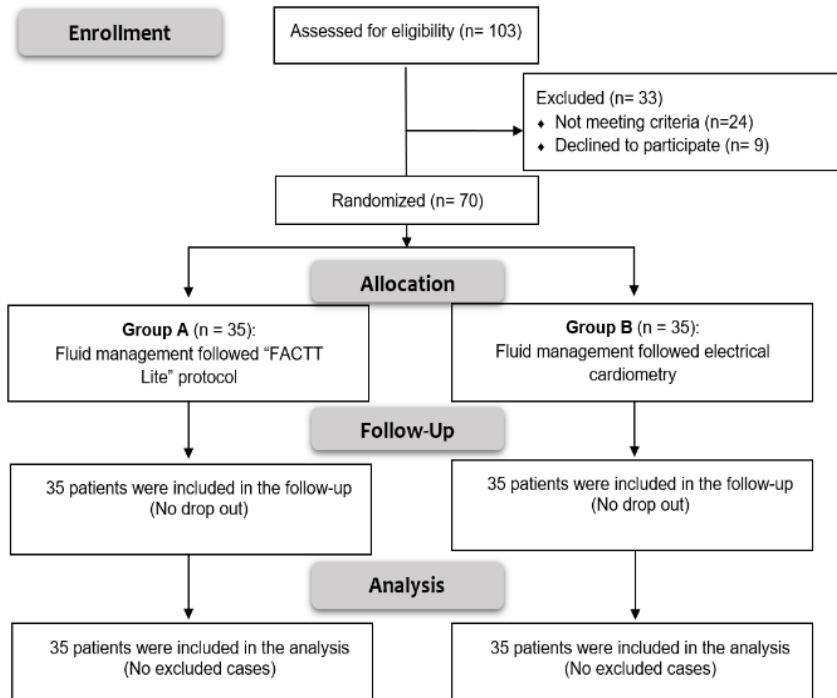


Figure 1: CONSORT patient flowchart

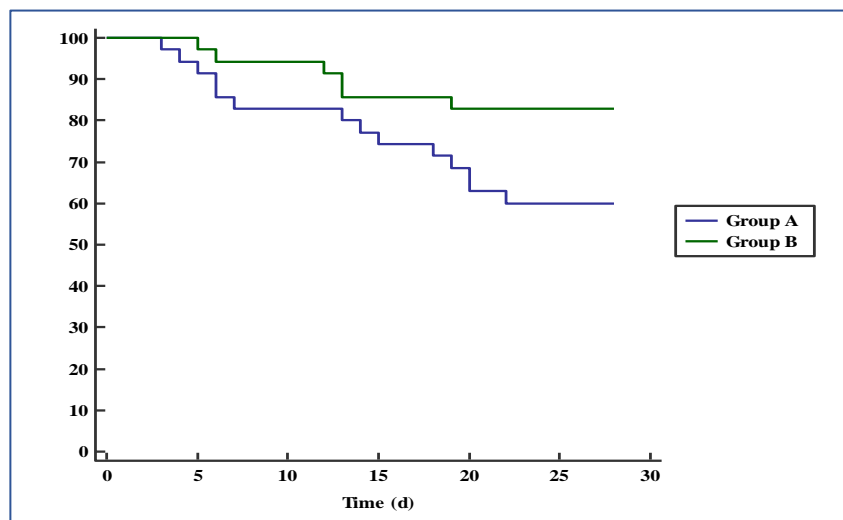


Figure 2: Kaplan Meier curve of survival probability of both groups

In 2007, Wiedemann and colleagues, through The Fluids and Catheters Treatment Trial (FACTT), demonstrated that a conservative fluid management approach improved outcomes in terms of oxygenation and ventilator usage in patients with ARDS.² The experiment's objective was to boost diuretic use while reducing the use of intravenous crystalloids. The

protocol guidelines established what are considered to be the optimal fluid management methods for individuals with ARDS.¹¹⁻¹³ Additionally, a less strict follow-up approach (FACTT Lite) was related to improved results.⁸

Seitz et al. in a retrospective cohort research conducted in nine ICUs; 234 adult patients with ARDS were included who were admitted to the ICU at least three days after meeting the criteria for moderate-severe ARDS (PaO₂:FiO₂ 150).¹⁴ They found that patients taking diuretics had a lower incidence of in-hospital mortality than those getting placebos (14% vs 25%; P = 0.025). Early diuretic use has been linked to a decreased in-hospital mortality (odds ratio 0.46, 95 percent CI 0.22–0.96).

Both the CVP line and the pulmonary artery catheter present with a variety of complications. While the CVP has been used to guide fluid management, it is an unreliable predictor of fluid responsiveness and may not accurately reflect preload: due to changes in venous tone, intrathoracic pressures, left ventricle (LV), and right ventricle (RV) compliance that occur in critically ill patients, the CVP has a poor relationship with RV end-diastolic volume.¹⁵ Additionally, individuals treated with early diuretics have a higher risk of hypokalemia and metabolic alkalosis. Despite ICU-level monitoring and likely potassium replacement by ICU personnel, these effects were seen. FACTT demonstrated an increased risk of hypokalemia and metabolic alkalosis.¹⁶ These may explain the higher mortality in 'FACTT lite' as it depended on the use of CVP.

EC has been validated to monitor CO and other hemodynamic parameters non-invasively compared to different techniques such as thermodilution

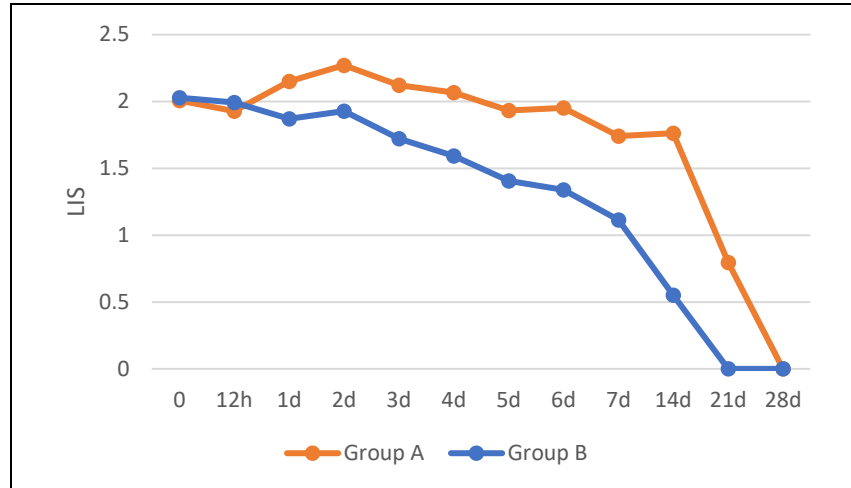


Figure 3: Lung injury score (LIS) of both groups

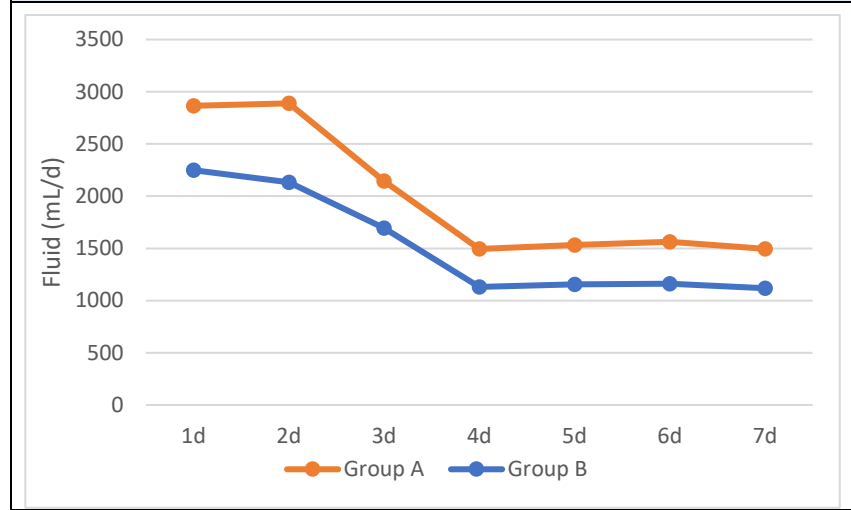


Figure 4: Intravenous fluid intake (ml) in both groups

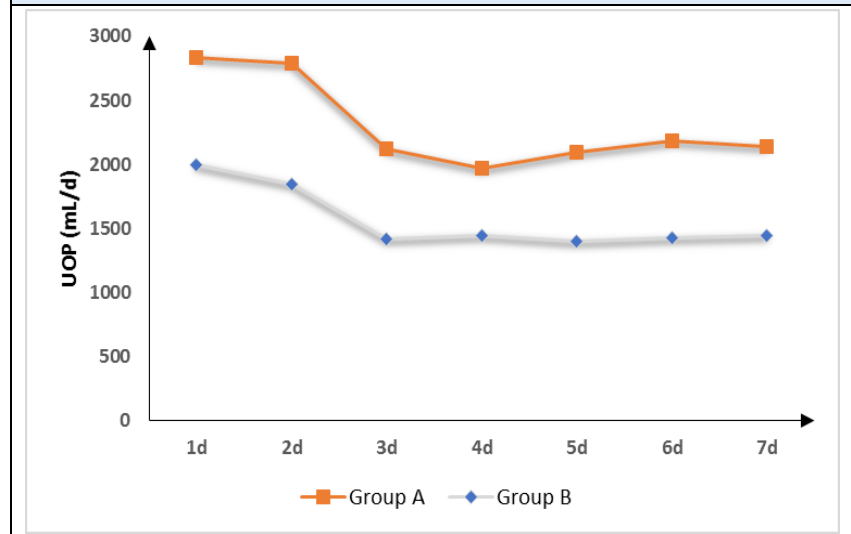
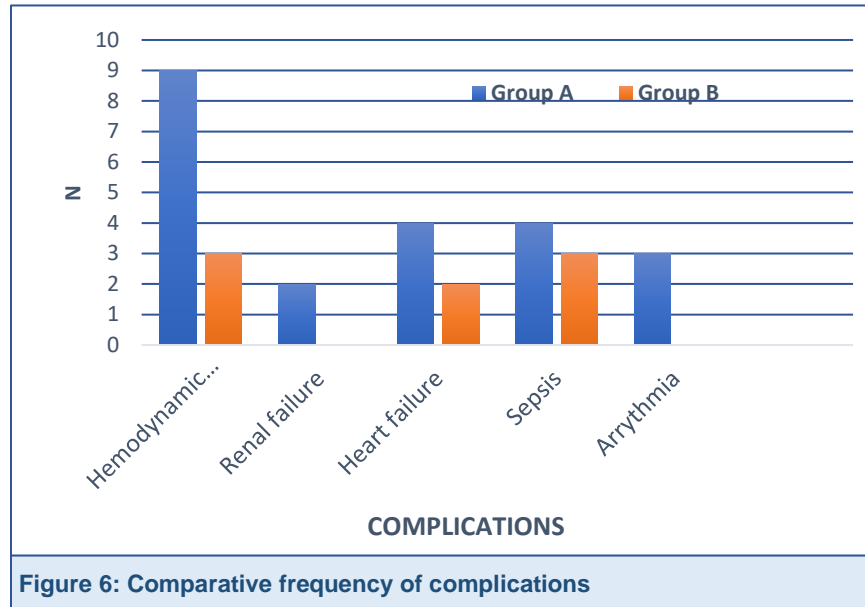


Figure 5: Urine output (ml/d) of both groups



technique,^{17,18} transesophageal Doppler (TED), echocardiography and cardiac catheterization including critically ill patients,^{18,19} intra-operative settings, in pregnant women, in children with congenital heart diseases, even in obese children.²⁰ For noninvasive continuous CO monitoring after lobectomy or pneumonectomy, EC is compared to transthoracic echocardiography (TTE). In contrast to the TTE, the EC provided accurate and reliable CO, SV, and HR measurements before and after lung surgery.²⁰

Our results were in line with Rajput et al. who conducted a study to compare the cardiac output by using EC, a noninvasive method of continuous cardiac output monitoring during cardiac surgery with pulmonary artery catheter (PAC) derived cardiac output on 25 patients undergoing coronary artery bypass surgery with cardiopulmonary bypass.¹⁷ Their study indicated that the electric cardiometry device yielded numerically comparable results to cardiac outputs derived from the PAC during the cardiac surgery.

Also, Zoremba et al. compared EC with invasive thermodilution methods on 50 critically ill patients.¹⁸ The values of cardiac output were statistically comparable between the groups. Therefore, they concluded that electrical velocimetry is a suitable method to evaluate hemodynamic variables with clinically acceptable accuracy.

However, in disagreement with the accuracy of EC, Cox, et al. demonstrated that cardiac index (CI) obtained by continuous pulmonary artery thermodilution catheter and CI obtained by EC are not interchangeable in cardiac surgical patients.²¹ This difference may be related to the skin incision done in cardiac surgeries. Moreover, a

recent meta-analysis done by Sanders et al. indicated that the mean percentage error was more than what was considered clinically acceptable.²² The meta-analysis found that EC cannot be used in place of thermodilution and transthoracic TTE for the determination of absolute CO levels and advised that further research be conducted to determine its clinical use and applications.

The improvement in outcome seen in our study with the EC-guided fluid management group may be a result of the more restricted fluid intake. Fluid overload has been linked to organ failure and is well recognized as a

major predictor of poor outcomes. Consistent evidence indicates that fluid restriction may be associated with better outcomes, especially in critical illness and ARDS.²³⁻²⁵

Afandy et al. compared echocardiography derived indices to indicators generated from EC in the therapy of septic patients.²⁶ The EC-guided treatment group had a substantially lower mortality rate than the Early Goal-Directed Therapy (EGDT) group. The EC group, on the other hand, required a longer period to wean off vasopressors and MV, as well as a lengthier stay in the ICU and hospital.

Zhao et al. showed that the hospitalization days after surgery and the crystalloid quantity infused were much shorter than in the EC group than the control group (routine fluid infusion) in elderly gastrointestinal cancer patients.²⁷

Habicher et al. evaluated the EC protocol that was based on continuous monitoring and optimization of stroke volume during the hip revision arthroplasty.²⁸ Hemodynamic optimization in EC group was done as follows: SV was monitored using a pulse contour method and a special pressure transducer. Patients were treated according to the EC protocol (EC group). These patients were compared to historical matched patients (control group). Patients from the control group stayed significantly longer at PACU/ICU than patients from the EC group. Patients from the EC group received less crystalloids during surgery. They concluded that the EC was successful and associated with reduced postsurgical complications, most importantly a reduction in postoperative bleeding as well as hospital and ICU stay.

Muñoz et al. found that for morbidly obese patients undergoing laparoscopic sleeve gastrectomy, the duration of hospital stay and IV fluid received were substantially less in the EC group than in the standard treatment group.²⁹ Similar results were observed in patients having open right hepatectomy as compared to conventional therapy.³⁰

Lotfy et al. compared EC to TED for hemodynamic monitoring and fluid management in patients undergoing hepatopertoenterostomy operation.³¹ Electrical Cardiometry (EC) group and TED group. A good degree of reliability was found between TED CO and EC CO at all measuring points. Both methods were able to monitor the trend changes of CO and equally guide fluid management, with a good degree of reliability. Both FTc (Flow Time Corrected) TED and Stroke Volume Variation (SVV) of EC were monitored during mechanical ventilation under surgery and were used to provide data about the intravascular fluid status (preload) in each group to help guide fluid managements.

In disagreement with our results, Gerent et al. assessed EC on patients receiving high-risk surgery for cancer treatment that lasted longer than 90 min and required ICU stay.³² The EC group used more dobutamine than the standard care group. But there were no significant changes in mortality or any of the secondary outcomes. In their research, there was no significant difference in ICU or hospital stay, which may be explained by controlling preload through fluid loading until pressure pulse variation (PPV) was 10% in both groups. Apart from standard care, the multimodal hemodynamic care group received optimization of hemodynamic parameters and tissue perfusion indicators, which may be sufficient to maintain an adequate oxygen supply throughout the postoperative period. Secondly, patients were monitored under general anesthesia through central venous and arterial lines, and hemodynamic parameters such as PPV, central venous oxygen saturation (ScvO₂), and arterial lactate were evaluated according to protocolized therapy (not like our usual care that depends on CVP only).

4. LIMITATION

Our study trail has a small sample size. More randomized trials need to be conducted to verify the study's findings. The relatively small sample size was to prove the secondary outcomes of the present study. Further, the follow-up period (just 28 days) so a long follow-up period should be considered in the coming studies.

5. CONCLUSIONS

EC was superior to 'FACTT Lite' in the fluid management in ARDS as regards decreasing 28th-day

mortality, LIS, fluid intake, duration of MV and ICU stay.

6. Data availability

Numerical data generated during this study is available with the authors.

7. Financial support

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

8. Conflict of Interest

The authors declare no conflict of interest.

9. Author contribution

All authors contributed equally in concept, conduct of study, data analysis, literature search and manuscript writing and editing.

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