Prognosis of Patients on Extracorporeal Membrane Oxygenation plus Continuous Arteriovenous Hemofiltration

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Background: Extracorporeal membrane oxygenation (ECMO) has been utilized for critically ill patients such as those with life-threatening respiratory failure or post-cardiotomy cardiogenic shock. Patients on ECMO with acute renal failure have high mortality rates. This study identifies specific predictors of hospital mortality for patients receiving ECMO and continuous arteriovenous hemofiltration (CAVH).

Methods: This study reviewed the medical records of 123 critically ill patients on ECMO plus CAVH at a cardiovascular surgical intensive care unit (CVSICU) at a tertiary care university hospital between March 2003 and August 2010. Patient baseline, clinical, and laboratory data were collected retrospectively as survival predicators.

Results: The overall mortality rate was 85.4%. The most common conditions requiring ECMO plus CAVH were cardiogenic shock and oliguria. The Acute Physiology and Chronic Health Evaluation II (APACHE II) score and organ system failure (OSF) score both indicated good discriminative power (area under the receiver operating characteristic curve [AUROC] 0.812 $\pm$ 0.048 and 0.758 $\pm$ 0.057, respectively). Multiple logistic regression analysis indicated that age, mean arterial pressure, and OSF score on day 1 of ECMO plus CAVH were independent risk factors for hospital mortality. Cumulative survival rates at the 6-month follow-up differed significantly ($p < 0.001$) between those with an OSF score ≤ 4 vs. those with an OSF score > 4.

Conclusions: During ECMO plus CAVH support, both the OSF and APACHE II scores showed good discriminative power in predicting hospital mortality for these patients.

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Key words: extracorporeal membrane oxygenation, acute kidney injury, continuous arteriovenous hemofiltration, organ system failure, advanced heart failure

Extracorporeal membrane oxygenation (ECMO) is effective in treating severe, reversible myocardial dysfunction (*e.g.*, myocarditis, cardiomyopathy, postoperative cardiogenic shock) and as a bridge to

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another treatment modality. Acute kidney injury (AKI) developing during ECMO is associated with a very poor outcome;[1-3] patients who develop AKI have high mortality rates and resource utilization. Most studies demonstrate that patients exhibiting signs of renal failure typically respond poorly to ECMO. In a study by Morris *et al.,* all 13 children managed with ECMO and slow continuous ultrafiltration died. In these cases, a fatal outcome was often associated with progression of conduction disturbance to electromechanical dissociation and asystole.[4] Balasubramanian *et al.,* reported high hospital mortality in a study of 30 pediatric surgical cardiac patients requiring renal replacement therapy while on ECMO.[5] Kolovos *et al*. also demonstrated that children who underwent post-cardiotomy ECMO requiring hemofiltration had a mortality rate five times that of patients without AKI.[6]

In a previous study by our study group, 21 AKI patients treated with ECMO and continuous arteriovenous hemofiltration (CAVH) died during hospitalization.[2] In a subsequent study, two patients with myocardial dysfunction survived following ECMO and CAVH treatment.[7] Early diagnosis and aggressive treatment of patients with fewer than three failed organs achieved favorable outcomes. Timely administration of ECMO and CAVH is effective in supporting circulation and renal function for myocardial dysfunction refractory to conservative treatment and will likely become standard treatments. These studies indicate that advanced cardiac failure may require very early initiation of ECMO support before AKI develops. However, the prognostic factors for ECMO plus CAVH are unclear. Given the promising new treatment methods now available and limited medical resources, investigators and physicians require reliable tools for monitoring and stratifying risk for critically ill patients in clinical practice and clinical trials. This study investigated short-term mortality predictors in patients receiving ECMO and CAVH.

METHODS

Patient information and data collection

The local Institutional Review Board approved the study and waived the need for informed consent. Medical records of 123 patients on ECMO plus CAVH in a 20-bed cardiovascular surgical intensive care unit (CVSICU) between March 2003 and August 2010 were examined. Patients on ECMO plus CAVH who died within 24 hours (5 patients), uremic patients undergoing renal replacement therapy (6 patients), and 2 patients who transferred from other hospitals and were on ECMO and CAVH before admission were excluded.

The following retrospective data were obtained: patient characteristics, primary diagnosis for ECMO, primary indication for CAVH, whether the patient was currently being withdrawn from ECMO support, Acute Physiology and Chronic Health Evaluation (APACHE) II scores,[8] Sequential Organ Failure Assessment (SOFA) scores,[9] organ system failure (OSF) scores on day 1 of ECMO plus CAVH support,[10] length of hospitalization; and outcome. The principal study outcome was hospital mortality. Follow-up at 6 months after hospital discharge was performed via chart records or telephone interviews when necessary.

Definitions

Illness severity was assessed using APACHE II and SOFA scores. Physiological calculations utilized the worst physiological values on day 1 of CAVH support instead of day 1 of ECMO support to reflect the real condition when patients on ECMO received renal replacement therapy. Organ function was assessed using the OSF score. The most anomalous value for each organ system on day 1 of CAVH support was recorded. Organ failure was defined according to the consensus committee of the American College of Chest Physicians and Society of Critical Care Medicine with one point given for each system failure as follows: respiratory failure, need for mechanical ventilation; cardiovascular failure, systolic blood pressure ≤ 90 mmHg or mean arterial pressure (MAP) ≤ 60 mmHg for 1 h despite a fluid bolus; renal failure, low urine output (*e.g.,* < 0.5 mL kg^{-1} h^{-1}); increased creatinine level (≥ 50% increase from baseline) or need for acute dialysis; hematological failure, low platelet count (< 100,000 mm^{-3}) or prothrombin time/activated partial thromboplastin time exceeding the upper limit of normal; metabolic failure, low pH with high lactate (*e.g.,* pH < 7.30 and plasma lactate greater than the upper limit of normal); hepatic failure, liver enzymes exceeding two times the upper limit of normal; central nervous system failure, altered consciousness; and reduced Glasgow Coma Scale score.[10]

Clinical management

The ECMO device (Medtronic, Inc., Anaheim, CA, U.S.A) consisted of a centrifugal pump and a hollow-fiber microporous membrane oxygenator with an integrated heater. All ECMO circuits had a heparin-bound Carmeda bioactive surface. All patients were treated with CAVH therapy during ICU hospitalization (1) when their fluid overloads were inadequately controlled by diuretic therapy, (2) when they had severe metabolic acidosis or hyperkalemia with a poor response to medical therapy, (3) when they needed hyperalimentation and had insufficient urinary output, or (4) when they had a sign or symptom of encephalopathy, for which uremia could not be ruled out as a precipitating cause. The CAVH was performed with a hemofilter (AV60S; Gambro, Hechingen, Germany) and connected to the pre- and post-oxygenator circuits of the ECMO with a blood flow of roughly 350 ml/min, depending on the intervening pressure gradient, and a hemofiltration flow of 35 ml/kg/h controlled by a pump. Replacement fluid was bicarbonate-buffered and was administered post-dilution at a dynamically adjusted rate to achieve the desired fluid therapy. CAVH support was applied to regulate intravascular volume and overall fluid balance, enable rapid administration of blood products without inducing volume overload, and correct azotemia, and acid-base and electrolyte imbalances.

Statistical analysis

Descriptive statistics are expressed as means ± SE. Variables in hospital survivors and non-survivors were compared in the primary analysis. All variables were tested for normal distributions using the Kolmogorov-Smirnov test. The Student *t*-test was applied to compare means of continuous variables and normally distributed data; otherwise, the Mann-Whitney U test was employed. Categorical data were tested using the χ^2 test. Correlations between paired variables within groups were assessed by linear regression using Pearson analysis. Finally, risk factors were assessed by univariate analysis, and variables statistically significant ($p < 0.05$) in univariate analysis were subjected to multivariate analysis by multiple logistic regression applied based on forward data elimination.

Calibration was assessed using the Hosmer-Lemeshow goodness-of-fit test to compare the number of observed and predicted deaths in risk groups for the entire range of death probabilities. Discrimination was assessed using the area under the receiver operating characteristic curve (AUROC). The AUROCs were compared using a nonparametric approach. AUROC analysis was also utilized to calculate cutoff values, sensitivity, specificity, and overall correctness. Finally, cutoff points were calculated by acquiring the best Youden index (sensitivity + specificity – 1). Cumulative survival curves as a function of time were generated utilizing the Kaplan-Meier approach and compared using the log rank test. All statistical tests were two-tailed; a value of $p < 0.05$ was considered statistically significant. Data were analyzed using SPSS 12.0 for Windows (SPSS, Inc., Chicago, IL, U.S.A).

RESULTS

Subject characteristics

Between March 2003 and August 2010, 123 patients on ECMO and CAVH support in the ICU were enrolled. The average patient age was 47 years; 72 were male (59%) and 51 were female (41%). In total, 101 patients were adults (82%) and 22 were children or neonates (18%). Overall, in-hospital mortality for the entire group was 85.4% (105/123). Table 1 presents patient baseline and clinical characteristics of both survivors and non-survivors. Table 2 describes the reasons for ICU admission and indications for ECMO and CAVH. The most frequent indications for ECMO and CAVH in this patient subset were cardiogenic shock and oliguria, respectively.

Hospital mortality and short-term prognosis

Univariate analysis identified 12 (Table 3) of 26 variables (Table 1) as prognostically valuable. Multivariate analysis identified age, MAP, and, OSF score as having independent prognostic significance (Table 3). Regression coefficients of these variables were utilized to calculate a logit of death for each patient as follows:

The logarithm of death odds = –6.529 + 0.057 x Age – 0.068 x MAP + 2.193 x OSF score.

Table 4 lists goodness-of-fit measured by the Hosmer-Lemeshow chi-square statistic of predicted mortality risk, and the predictive accuracy of the APACHE II, SOFA, and OSF scores. Table 4 also

Table 1. Patient Baseline and Clinical Characteristics

	Survivors (n = 18)	Non-survivors (n = 105)	*p*
Age (years)	33 ± 25	49 ± 23	0.007
Gender (M/F)	12/6	60/45	NS (0.449)
Adult/Child	11/7	90/15	0.012
Duration of CAVH support (day)	5 ± 4	5 ± 5	NS (0.585)
Duration of ECMO support (hour)	244 ± 254	187 ± 146	NS (0.174)
Weaning from ECMO support (Yes/No)	18/0	15/90	< 0.001
GCS, on CAVH first day (points)	12 ± 3	7 ± 4	< 0.001
MAP, on CAVH first day (mmHg)	55 ± 15	46 ± 16	0.035
UO, the day before CAVH (ml/day)	315 ± 322	434 ± 473	NS (0.352)
SCr, baseline (mg/dL)	1.3 ± 1.0	1.2 ± 1.0	NS (0.628)
SCr, at pre-CAVH (mg/dL)	3.8 ± 2.4	3.2 ± 1.9	NS (0.171)
WBC count (mL) x 1000	17 ± 11	14 ± 9	NS (0.173)
Hemoglobin, on CAVH first day (g/dL)	9.3 ± 2.2	8.3 ± 1.9	0.045
Platelets, on CAVH first day (x10^9/l)	77 ± 51	58 ± 33	0.038
Sodium, on CAVH first day (mmol/l)	142 ± 9	149 ± 12	0.034
Glucose, on CAVH first day (mg/dl)	191 ± 99	185 ± 131	NS (0.866)
Albumin, on CAVH first day (g/l)	2.7 ± 0.7	2.5 ± 0.5	NS (0.201)
Bilirubin (total), on CAVH first day (mg/dl)	3.8 ± 10.2	4.0 ± 6.5	NS (0.914)
Troponin I, on CAVH first day (ng/ml)	31 ± 42	89 ± 192	0.011
Lactate, on CAVH first day (mmol/L)	70 ± 78	116 ± 79	0.048
PaO2/FiO2	282 ± 237	232 ± 244	NS (0.421)
AaDO2	257 ± 206	384 ± 200	0.014
APACHE II score	21 ± 6	30 ± 8	< 0.001
SOFA score	14 ± 3	17 ± 3	0.005
OSF score	4 ± 1	5 ± 1	< 0.001
AKIN category (Stage 1/2/3)	0/4/14	2/13/90	NS (0.706)*

Abbreviations: M: male; F: female; NS: not significant; CAVH: continuous arteriovenous hemofiltration; ECMO: extracorporeal membrane oxygenation; GCS: Glasgow coma scale; MAP: mean arterial pressure; UO: urine output; SCr: serum creatitine; WBC: white blood cells; PaO2: partial pressure of oxygen; FiO2: fraction of inspired oxygen; AaDO2: alveolar-arterial oxygen tension difference; APACHE II: acute physiology and chronic health evaluation II; SOFA: sequential organ failure assessment; OSF: organ system failure; AKIN: acute kidney injury network; *: χ^2 test for trend.

compares the discriminatory value of the three scoring systems. AUROC analysis verified that APACHE II had the best discriminatory power.

To assess the predictive value of each measure for hospital mortality, the sensitivity, specificity, and overall correctness of prediction were determined. The APACHE II had the best Youden index and highest overall prediction accuracy (Table 5).

At the 6-month follow-up, cumulative survival rates differed significantly ($p < 0.001$) between patients with an OSF score ≤ 4 and those with an OSF score ≥ 5 (Figure) on day 1 of ECMO plus CAVH.

Table 2. Primary Diagnosis for ICU Admission, ECMO Support and CAVH Indication

	Survivors (n = 18) n (%)	Non-survivors (n = 105) n (%)	*p*
Primary diagnosis for ICU admission			
Postcardiotomy cardiogenic shock	3 (17)	38 (36)	NS (0.174)
Myocarditis	4 (23)	4 (4)	0.016
ARDS	3 (17)	23 (21)	NS (0.762)
Post-lung transplantation	0 (0)	2 (2)	NS (1.000)
Post-CABG cardiogenic shock	2 (11)	10 (10)0	NS (0.688)
Acute myocardial infarction	1 (5)	12 (11)	NS (0.690)
Desaturation under unstable hemodynamics	3 (17)	8 (8)	NS (0.203)
Decompensated heart failure	1 (5)	2 (2)	NS (0.381)
Sudden collapse status post CPCR	1 (5)	6 (6)	NS (1.000)
Primary reason for ECMO support			
Cardiogenic shock	13 (72)	77 (73)	NS (1.000)
ARDS	5 (28)	28 (27)	NS (1.000)
Primary reason for CAVH support			
Anuria (> 12 hours)	4 (22)	32 (30)	NS (0.583)
Oliguria (> 12 hours)	6 (34)	32 (30)	NS (0.789)
AKI in progression	2 (11)	16 (15)	NS (1.000)
Oliguria/AKI with metabolic acidosis	2 (11)	10 (10)	NS (0.688)
Oliguria/AKI with hyperkalemia	3 (17)	7 (7)	NS (0.163)
Oliguria/AKI with pulmonary edema	1 (5)	8 (8)	NS (1.000)

Abbreviations: ICU: intensive care unit; ECMO: extracorporeal membrane oxygenation; CAVH: continuous arteriovenous hemofiltration; NS: not significant; ARDS: acute adult distress syndrome; CABG: coronary artery bypass graft; CPCR: cardiopulmonary cerebral resuscitation; AKI: acute kidney injury.

Table 3. Variables Showing Prognostic Significance

Parameter	Beta coefficient	Standard error	Odds ratios (95% CI)	*p*
Univariate logistic regression				
Age	0.026	0.010	1.027 (1.006-1.047)	0.009
GCS, on CAVH first day	–0.295	0.077	0.744 (0.640-0.866)	< 0.001
MAP, on CAVH first day	–0.034	0.016	0.967 (0.936-0.998)	0.039
Hemoglobin, on CAVH first day	–0.264	0.134	0.768 (0.590-0.998)	0.049
Sodium, on CAVH first day	0.058	0.027	1.060 (1.004-1.118)	0.034
Platelets, on CAVH first day	0.000	0.000	1.000 (1.000-1.000)	0.047
Lactate, on CAVH first day	0.009	0.005	1.009 (1.000-1.019)	0.057
Troponin I, on CAVH first day	0.004	0.004	1.004 (0.997-1.012)	0.251
APACHE II	0.168	0.045	1.183 (1.083-1.293)	< 0.001
SOFA score	0.239	0.089	1.270 (1.068-1.512)	0.007
OSF score	1.103	0.336	3.013 (1.559-5.824)	< 0.001
AaDO2, on CAVH first day	0.003	0.001	1.003 (1.001-1.006)	0.018
Multivariate logistic regression				
Age	0.057	0.019	1.059 (1.020-1.099)	0.003
OSF score	2.193	0.670	8.961 (2.411-33.307)	0.001
MAP, on CAVH first day	–0.068	0.029	0.935 (0.883-0.989)	0.020
Constant	–6.529	3.111	0.001	0.036

Abbreviations: GCS: Glasgow coma scale; CAVH: continuous arteriovenous hemofiltration; MAP: mean arterial pressure; APACHE II: acute physiology and chronic health evaluation II; SOFA: sequential organ failure assessment; OSF: organ system failure; AaDO2: alveolar-arterial oxygen tension difference.

Table 4. Comparison of Calibration and Discrimination of the Scoring Methods in Predicting Hospital Mortality

	Calibration			Discrimination		
	Hosmer-Lemeshow χ^2	df	*p*	AUROC ± SE	95% CI	*p*
OSF score	1.180	3	0.758	0.758 ± 0.057	0.646-0.869	0.001
Age	11.582	8	0.171	0.693 ± 0.066	0.564-0.822	0.009
MAP	5.322	8	0.723	0.665 ± 0.067	0.533-0.796	0.027
APACHE II score	4.450	8	0.814	0.812 ± 0.048	0.717-0.907	< 0.001
SOFA score	5.465	6	0.486	0.707 ± 0.062	0.585-0.828	0.005

Abbreviations: df: degrees of freedom; AUROC: area under the receiver operating characteristic curve; SE: standard error; CI: confidence intervals; OSF: organ system failure; MAP: mean arterial pressure; APACHE II: acute physiology and chronic health evaluation II; SOFA: sequential organ failure assessment.

Table 5. Subsequent Hospital Mortality Predicted on the First Day of CAVH Support

Predictive factors	Cutoff point	Youden index	Sensitivity (%) (95% CI) (%)	Specificity (%) (95% CI) (%)	Overall correctness (%)
Age	50*	0.37	59 (49-68)	78 (52-93)	68
OSF score	4*	0.46	69 (59-77)	78 (52-93)	73
MAP, pre-CAVH	40*	0.33	61 (51-70)	6 (3-29)	33
APACHE II score	24*	0.55	76 (67-84)	78 (52-93)	77
SOFA score	16*	0.36	53 (42-63)	83 (58-96)	68

Abbreviations: CAVH: continuous arteriovenous hemofiltration; OSF: organ system failure; MAP: mean arterial pressure; APACHE II: acute physiology and chronic health evaluation II; SOFA: sequential organ failure assessment; *: Value giving the best Youden index.

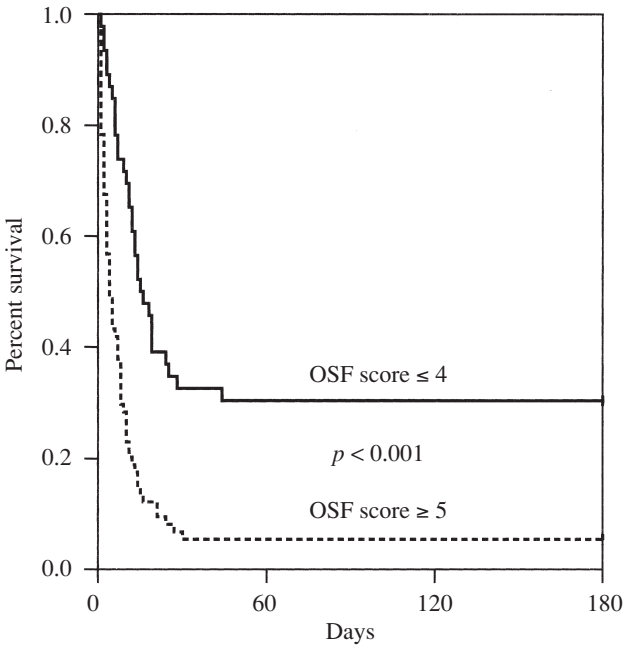

Figure Cumulative survival rates at the 6-month follow-up for 123 critically ill patients based on their organ system failure (OSF) score on the first day of extracorporeal membrane oxygenation plus continuous arteriovenous hemodialysis.

DISCUSSION

Several studies have identified mortality rates of 48–76% for patients on ECMO.[1-3,11,12] The hospital mortality rate of 85.4% in this study extends these observations by demonstrating the poor prognosis of this patient subgroup treated with ECMO and CAVH. This investigation demonstrated that age, MAP, and OSF score on day 1 of ECMO plus CAVH were strongly correlated with in-hospital mortality (Table 3). The APACHE II score had better discriminatory power than the SOFA and OSF scores (Table 4). The APACHE II score also had the best Youden index and highest overall prediction accuracy (Table 5).

Survival on ECMO generally decreases as patient age increases. Nehra and colleagues reported a bimodal distribution of survival with respect to patient age, with the highest survival in groups 0–9 years and 30–39 years old.[13] This distribution was noted previously and has been confirmed by data from the Extracorporeal Life Support Organization database.[14] For patients treated with ECMO and CAVH, this study adopted the best Youden index and established a cut-off value of 50 years of age (Table 5). Hospital mortality rates differed significantly according to the best Youden index for patients below and above the cutoff of 50 years of age (75.4% vs. 93.9%, $p = 0.005$) in this investigation.

Hypotension is related to worsening renal function for patients on ECMO. Damaged cardiac function, creating a situation with low cardiac output and, therefore, hypoperfusion, may precipitate pre-renal AKI, which, if not promptly corrected, can evolve into intrinsic AKI and even cortical necrosis, which results in an irreversible loss of renal function.[15,16] Our analysis demonstrated that the pre-CAVH MAP is an independent risk factor for patients on ECMO. This study applied the best Youden index and a recognized MAP cut-off value of 40 mmHg (Table 5). The hospital mortality rates below and above the cut-off value of 40 MAP (in mmHg) were 97.6% (40/41) and 79.3% (65/82) ($p = 0.006$), respectively.

Wu *et al*. proved that independent predictors for hospital mortality among ECMO patients on dialysis were high central venous pressure, a high APACHE IV score when initializing dialysis, and latency from hospital admission to dialysis.[17] Because of the difficulty in calculating an APACHE IV score on day 1 of ECMO plus CAVH, this study determined that the APACHE II score had the best Youden index and highest overall accuracy for predicting in-hospital mortality (Table 5). The SOFA and OSF scores ignore diagnosis, age, and co-morbid conditions. However, age is a known risk factor for mortality.[13,14] Failure to consider age may account for the inferiority of the SOFA and OSF scores relative to the discriminative capability of the APACHE II score (Table 3).

Despite the promising study results, several important limitations must be recognized. First, this is a retrospective study performed at a single tertiary-care medical center, thereby limiting generalization of findings. Second, difficulties were produced by this retrospective study because some data were not available for all patients, such as the delivered dose of vasoactive/inotropic agents, and serum albumin, total bilirubin, and lactate levels. Third, this study examined scoring systems for only day 1 of ECMO plus CAVH support, even though these models were developed and calculated on day 1 of ICU admis-

sion. Finally, sequential measurement of these scoring systems (*e.g.,* daily or weekly) may reflect the dynamic aspects of clinical diseases, thus providing superior information for mortality risk.

In conclusion, this study shows that the prognosis for critically ill patients on ECMO and CAVH is very poor. Our analysis showed the risk of mortality increased with increased age, a low MAP, and a high OSF score at initiation of CAVH. Experimental data also demonstrated good discriminative power of the OSF and APACHE II scores in predicting hospital mortality of critically ill patients treated with ECMO plus CAVH. Considering the limitations in healthcare funding and ease of implementation, we conclude that the OSF and APACHE II scores can improve the accuracy of short-term prognosis in this homogeneous subset of patients. Because of excess mortality and the relatively small sample size, the predictive roles of the OSF and APACHE II scores warrant further external validation.

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接受葉克膜和連續性動靜脈透析治療病人的預後評估

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背 景： 葉克膜 (Extracorporeal membrane oxygenation, ECMO) 通常被用在病危的病人身上，像是有生命危險的呼吸衰竭或是心切開術後的心因性休克等等。而接受葉克膜治療的病人一旦合併有急性腎衰竭的話其死亡率都很高。本研究主要想找出對於同時接受葉克膜和連續性動靜脈透析治療 (continuous arteriovenous hemofiltration, CAVH) 的病人其死亡率的特定預測因子。

方 法： 本研究瀏覽了自 2003 年三月到 2010 年八月在本院心臟外科加護病房共 123 位接受葉克膜和連續性動靜脈透析治療之臨床危急病人的病歷紀錄。有關統計學、臨床和實驗室數據都以回溯性的方式收集來找出存活預測指標。

結 果： 整體的死亡率爲百分之八十五點四。其中最常見需要同時接受葉克膜和連續性動靜脈透析治療的情況爲心因性休克和寡尿。藉由比較 ROC 曲線下面積 (areas under the receiver operating characteristic curve, AUROC)，發現 APACHE II (Acute Physiology and Chronic Health Evaluation II) 分數和器官系統衰竭 (Organ System Failure, OSF) 數目都有很好的辨別能力 (AUROC 分別爲 0.812 ± 0.048 和 0.758 ± 0.057)。進一步作多重邏輯迴歸分析找出了接受葉克膜和連續性動靜脈透析治療第一天時的年齡、平均動脈血壓和器官系統衰竭數目爲預測住院死亡率的獨立危險因子。最後，經過六個月的追蹤，器官系統衰竭數目小或等於四的病人和大於四的病人兩者的累積存活率在統計上有顯著的差異 ($p < 0.001$)。

結 論： 在葉克膜和連續性動靜脈透析支持下，器官系統衰竭數目和 APACHE II 分數顯示出在預測這群病人住院死亡率上有很好的辨別能力。

(長庚醫誌 2011;34:636-43)

關鍵詞： 葉克膜，急性腎衰竭，連續性動靜脈透析，器官系統衰竭，後期心衰竭

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