SciencePG
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Constructing ECMO Care Quality Evaluation Index System Based on "Structure-Process-Outcome" Three-Dimensional Theoretical Model

Yunhong Lei[1], Jinglan Liu[1, *], Qing Tang[2], Liu Qiong[1], Zuyang Xi[2], ChaXiang Li[2], Yakong Liu[2], Minmin Chen[1], Fei Tian[1], Zhaohui Zhang[1], Zifeng Li[2], Luhuan Yang[1]

[1]Department of Intensive Care Unit, The First College of Clinical Medical Science, Three Gorges University/Yichang Central People's Hospital, Yichang, China

[2]The First College of Clinical Medical Science, Three Gorges University/Yichang Central People's Hospital, Yichang, China

Email address:

yichanghospital@163.com (Jinglan Liu)

[*]Corresponding author

To cite this article:

Abstract: Objective: To construct a set of objective, relatively perfect and clinically applicable ECMO nursing quality evaluation index system, and to provide practical basis and reference for clinical nurses to implement ECMO nursing. Methods: The literature was analyzed and semi-structured interviews were used, through systematic references and searching keywords. Based on the "Structrue-Process-Outcome" three-dimensional theoretical model, the prototype of the ECMO nursing quality evaluation index system was constructed. 28 experts were selected and 2-round Delphi study on ECMO nursing quality evaluation indicators was performed, to evaluate the enthusiasm, authoritativeness, concentration and coordination of opinion of the experts, and to test the reliability and validity of the evaluation index system. The AHP method was used to determine the mean importance ratings, the standard variation of importance ratings, the coefficient of variation (CV) and full-score frequency K (%) of indicators at all levels in the evaluation index system. Results: Through literature review and searching keywords, an questionnaire including 3 first-level indicators, 15 second-level indicators and 62 third-level indicators was initially formed. The positive coefficient of the experts was 100% (20/20) and 96.42% (19/20) respectively, and the authoritative coefficient was 0.926 and 0.934 respectively in the first and second round of expert consultation. The weights of the three first-level indicators were 0.34, 0.52, and 0.31, respectively. The ECMO nursing quality evaluation index system including three first-level indicators, 15 second-level indicators, and 66 third-level indicators was determined. The effective recycling rates of the two rounds of Delphi surveys were 80% and 90%, respectively. The authoritative coefficients of experts in the two rounds were 0.889 and 0.88, respectively. The Kendall coordination coefficients of the two rounds of surveys were 0.259 and 0.161, respectively (P<0.05). Finally, an ECMO nursing quality evaluation index system including three first-level indicators, 15 second-level indicators and 66 third-level indicators was constructed, based on the "Structrue-Process-Outcome" three-dimensional model. Conclusion:The ECMO nursing quality evaluation index system is constructed based on the "Structrue-Process-Outcome" three-dimensional theoretical model, which is provided as a practical and operational assessment tool for clinical nurses in the implementation of ECMO care.

Keywords: ECMO, Theoretical Model, Nursing Quality, Evaluation Index System

1. Introduction

Extracorporeal membrane oxygenation (ECMO), also known as extracorporeal life support system (ECLS), is an established treatment in the management of patients with refractory cardiogenic shock (CS) or acute respiratory failure (ARF) [1, 2]. Extracorporeal membrane oxygenation (ECMO) was established in the 1970s and first used clinically by Hill.

Emory University Hospital (EUH) offered emergent extracorporeal membrane oxygenation (ECMO) support on the necessary basis. Outcomes during this time were not tracked, but perception was that survival rate was below observed at a large number of centers with established extracorporeal membrane oxygenation (ECMO) programs and protocols. In recent years, the number of cases and centers offering adult extracorporeal membrane oxygenation (ECMO) has increased [3-6]. The basic principle of ECMO is to drain venous blood to the outside of the body, exchange the gas, and then back to the artery or vein in patients to replace or partially replace the function of heart and lung. It can maintain the patient's life for a period of time, in order to give the opportunity to the heart, lung disease and functional recovery. The venoarterial (VA) or venovenous (VV) ECMO can be used to stable patients with refractory cardiogenic shock (CS) or acute respiratory failure (ARF), respectively, until definitive therapy can be offered. Recent publications show that the ECMO outcomes are related to the case load at respective centers. Experienced centers have proven that patients can safely be transported on ECMO to specialized centers for further care. ECMO system mainly includes vascular access catheters, connecting tube, blood pump, oxygenator, heat exchanger, water tank and some monitoring devices. Once the ECMO adjuvant therapy is activated, blood circulation and gas exchange can be provided to the body and the patient's heart and lungs take a short break, and the ventilator and vasoactive drugs can be reduced to safe levels. Continuous heparin anticoagulation is used during extracorporeal circulation and is monitored with activated clotting time (ACT). Platelet dysfunction, thrombocytopenia and some other body and mechanical complications may be occurred due to the interaction of blood with artificial surfaces [7-10]. Therefore, the monitoring of the patient's vital signs and quality of care is very important during ECMO adjuvant therapy. The standardized monitoring methods or monitoring indicators are urgently needed during ECMO adjuvant therapy. Through literature review, the current literature on the ECMO care quality evaluation criteria during adjuvant therapy has not been found. The main purpose of this study is to build ECMO care quality evaluation index system based on "Structrue-Process-Outcome" three-dimensional theoretical model, and to provide a practical and operational assessment tool for the clinical nurses in ECMO care.

2. Methods

2.1. Establishing Development Team of ECMO Nursing Quality Indicators

The ECMO nursing quality evaluation index construction working group consisted of 15 members, including 3 directors, 1 attending physician, 1 resident physician, 3 head nurses, 2 academic nursing leaders and 4 nurses with master's degree of the intensive care unit (ICU), 1 director of respiratory intensive care unit (RICU),1 director of nursing department, and 1 nurse of emergency department. Among them, there were 6 people with senior professional titles and 5 with intermediate professional titles.

The main tasks of the group were as follows : Responsible for reviewing the literature, collecting data, and determining research topics and research plans; Formulating prototypes of ECMO nursing quality index system and preparing expert consultation forms; Determining the consulting experts; Organizing and coordinating expert consultation activities; Statistical analysis of the results of the study.

2.2. Drafting of ECMO Nursing Quality Indicators Evaluation System

The domestic and international literature related to ECMO nursing was searched, and a total of 1200 articles were retrieved. After deduplication, irrelevance, and inability to obtain full-text articles, 20 articles were obtained finally. Key words, phrases, and sentences for key monitored indicators of basic care and specialist care in the treatment of ECMO patients were screened and summarized, by further analyzing and collecting these documents. Based on the "Structrue-Process-Outcome" three-dimensional theoretical model, a preliminary draft of ECMO nursing quality evaluation index system was initially established, which included 3 first-level indicators, 16 second-level indicators and 73 third-level indicators.

One director, one attending physician, one nurse head nurse and one academic nursing leader were selected in the intensive care unit (ICU), to conduct a semi-structured interview. The interviews mainly included the preparation of ECMO adjuvant treatment (structure quality), process quality control, terminal quality feedback, and the quality monitoring of ECMO nursing basic and specialist nursing. The template analysis method was used to analyze the interview data, and the concept of the main axis was refined. Combined with the experience of the ICU patient's ECMO nursing, the related indicators were perfected after repeatedly summarizing, analyzing and collating. One second-level indicator and twelve third-level indicators were deleted and one third-level indicators was added. The preliminary draft of ECMO nursing quality evaluation index system was formed, including 3 first-level indicators, 15 second-level indicators, 81 third-level indicators, with a total of 99 indicators in the first round.

2.3. Delphi Method

2.3.1. Selection of Correspondence Experts

(i) Expert Inclusion Criteria
According to the purpose of study, the inclusion criteria of determining the experts were as follows: Engaging in ECMO adjunctive treatment or nursing care for more than one patient with a duration of at least 72 hours; Those who had a intermediate title or above or a master's degree with ICU clinical work experience for not less than 1 year, or those who had a junior title and worked in the ICU for not less than 10 years; Obtaining ECMO training certification and engaging in ECMO adjunctive treatment or nursing care for more than one patient; Volunteer participants who had a certain

understanding of this study.

(ii) Determination of the Number of Experts

There is no clear provision for the number of consulting experts at present. The number of consulting experts depends on the research objective. The determination of expert number should be able to ensure that the consultation results have a high degree of authority and credibility, and also should control the number and reduce the amount of statistical workload. According to the theory of mathematical statistics, under the condition of random sampling, the relationship between the ratio of sample standard deviation to the overall standard deviation and the sample content m meets $\frac{\overline{\sigma_s}}{\sigma_s} = \frac{1}{\sqrt{m}}$.

As m gradually increases, the ratio of sample standard deviation to the overall standard deviation ($\frac{\overline{\sigma_s}}{\sigma_s}$) gradually decreases and tends to be flat. In practice, due to limitations in human and material resources, the sample content cannot be infinite, and the sample content can only be reasonably determined in combination with specific conditions. According to the authoritative and representative principles of expert selection, the number of experts participating in the consultation is controlled between 15-50.

20 consulting experts in the ICU (including comprehensive ICU and specialist ICU) from Yichang, Enshi, Wuhan, Beijing, Tianjin, Shanghai, Shenzhen and other regions in China were selected, of whom 2 had doctor's degree, 6 had senior professional title, 4 had associate professional title, 3 had intermediate professional title, 2 experts were ICU academic nursing leaders, and 3 had master's degree. The average age of consulting experts was (39.3±3.5) years. Their length of employment in ICU was 5 to 30 years, with the average of (12.6±7.4) years.

2.3.2. Expert Reliability Analysis

(i) Expert's Enthusiasm

The enthusiasm coefficient of an expert is generally expressed as the effective recovery rate of the questionnaire, that is, the ratio of experts participating with effective feedback in the consultation to the total number of consultants. A total of 2 rounds of expert consultation were conducted in this study, and 20 questionnaires were distributed in each round. According to the ratio of the number of returned questionnaires to the total number of consulting experts in each round, the effective recovery rate was calculated. The effective recovery rate of 100% meant that the enthusiasm of experts was high.

(ii) Expert Familiarity (Cs)

The self-evaluation standard of expert familiarity was to assign values to each entry and finally calculate the arithmetic mean, based on the assignment method of Cs=0.9 (very familiar), Cs=0.7 (familiar), Cs=0.5 (generally familiar), Cs=0.3 (less familiar), Cs= 0.1 (very unfamiliar).

(iii) Expert Authority

Expert authority was expressed as an authority degree coefficient (Cr). Experts' judgment basis was that they divided the influence degree of factors that affected problem judgment

(theoretical analysis, practical experience, understanding of domestic and foreign counterparts, and intuition) into large-, medium- and small-level. Then they assigned value to the different influence degree as follows: theoretical analysis (0.3, 0.2, 0.1), practical experience (0.5, 0.4, 0.3), understanding of domestic and foreign counterparts (0.1, 0.1, 0.1), intuition (0.1, 0.1, 0.1). And finally they calculated the arithmetic mean. The authority degree coefficient (Cr) was determined by the expert's judgment basis (Ca) and familiarity with the research problem (Cs), with the specific calculation formula Cr=(Ca+Cs)/2. Some studies showed that the expert authority coefficient above 0.7 indicated a good authority degree.

(iv) The Coordination Degree of Expert Opinions

The degree of coordination of expert opinions is measured by indicators including the score of importance of the indexes, the ratio of full-score, and coefficient of variation. The Likert 5-point scale (5 points meaning vey important, 4 points meaning important, 3 points indicating generally important, 2 points implying unimportant, 1 point indicating very unimportant) was used for assignment in this study. Experts scored the points and made judgment. The score of importance of the indexes reflected the importance degree of the indicator considered by the expert. The higher the score, the more important the indicator in the eyes of the experts.

The coefficient of variation (CV) aimed to measure the degree of variability among the indicators at each level and to judge the fluctuation of each expert in evaluating indicator's importance. The smaller the coefficient of variation, the higher coordination degree of expert opinions. Studies showed that the coefficient of variation (CV) value <0.3 was in an acceptable range. The ratio of full-score K referred to the percentage of indexes importance score of 4 or 5 points or more in the total indicators. Each indicator was judged and the average score of importance (X), the standard deviation of score of importance (S), coefficient of variation (CV), the ratio of full-score K (%) were calculated.

2.3.3. Expert Consultation

Two rounds of expert consultation were conducted. In the first round, experts were invited to evaluate the importance of 3 first-level indicators, 15 second-level indicators and 62 third-level indicators, to judge whether the indicators were correct and agreed to be included. Then the arithmetic mean of the score of importance (Mj), full-score ratio (Kj), coefficient of variation (CV), and Kandall coordination coefficient (W) of each index item were analyzed. In the second round, the ineligible indicators were removed and the indicators recommended by experts were added. At the same time, an expert review form was prepared to judge the importance of the indicators at all levels. By doing above, it could be determined that whether the indicators were correct, feasible and agreed to be included, and the weight of each indicator was set. And then the arithmetic mean of the score of importance (Mj), the ratio of full-score (Kj), coefficient of variation (CV), and Kandall coordination coefficient (W) of each index item were analyzed again. In order to prevent some experts from having an impression on the previous round of

evaluation and affect the results of the study, each round was separated by 3 weeks to ensure the scientificity and authenticity of the data.

2.3.4. Processing of the Results of Expert Consultation

Index screening criteria was that the reserved index must meet the following three conditions: the average score of importance (X)> 3.5 points; the standard deviation of the importance score (S) ≤ 0.30 and the full-score ratio (K)> 10%. The coordination degree of expert opinion was measured using the coefficient of variation and the Kendall Coefficient of Coordination (W). Kendall coordination coefficient (W) fluctuated at about 0.5, indicating the coordination of views was good.

The analysis was performed in this study, according to the amendments proposed by experts for setting, naming and index weight assignment of the evaluation index of ECMO care quality indicators. If expert's approval rate of the index was < 95%, the indicator would be revised, based on the expert opinion, the comprehensive consideration of the actual clinical conditions and further analysis. Whether another round of expert consultation was determined, based on the degree of disagreement in the opinions of the previous round of expert consultation.

2.4. Statistical Analysis

SPSS20.0 was used for data entry and statistical analysis. The enthusiasm of experts, expert authority degree coefficient and the degree of concentration of expert advice were calculated by descriptive statistics including mean, standard deviation, coefficient of variation, and full-score ratio. The Kendall Coefficient was calculated by using SPSS20.0. $P<0.05$ indicated that the difference was statistically significant.

3. Results

3.1. The Enthusiasm of the Experts

In the first round of expert consultation, 20 questionnaires were sent out and 20 questionnaires were effectively recovered. The effective recovery rate of the expert consultation form was 100.0%. Among them, 16 experts put forward some suggestions on the evaluation index of ECMO care quality indicators, accounting for 80%. In the second round of expert consultation, 20 expert consultation forms were issued, and 18 expert questionnaires were effectively recovered, and the effective recovery rate was 90%. Among them, 4 experts put forward relevant suggestions on the evaluation index of ECMO nursing quality indicators, accounting for 22.22%. It is generally believed that effective recovery rate of the questionnaire more than 70%, indicating that the experts in this study have high enthusiasm and great interest in this field.

3.2. Expert Authority

The results of two rounds of expert consultation showed that the judgment coefficient was 0.915 (Ca=0.915), familiarity coefficient was 0.864 (Cs=0.864), and authority coefficient was 0.889 (Cr=0.889) in round 1; and the judgment coefficient was 0.924 (Ca=0.924), familiarity coefficient was 0.851 (Cs=0.851), and authority coefficient was 0.887 (Cr=0.887) in round 2. The authority coefficients Cr in two rounds were 0.889 and 0.887, respectively, indicating that the degree of expert authority was high (usually Cr> 0.70 were considered acceptable).

3.3. Concentration Degree of Expert Opinions

The concentration degree of expert opinions on this study was mainly represented by the average score of importance (X), the standard deviation of score of importance (S) and the ratio of full-score K (%). In the first survey, the X of the 99 indicators was 3.51 to 5.00, the S was 0.12 to 0.84, and the K was 11.56% to 100.0%. In the second survey, the X of the 92 indicators was 3.57 to 5.01, S was 0.18 to 0.76, and K was 22.05% to 97.68%. These data showed that the concentration degree of expert opinions was highly concentrated.

3.4. The Coordination Degree of Expert Opinions

The coordination degree of expert opinions was measured using the coefficient of variation and the Kendall Coordination Coefficient (W). The coefficient of variation of indicators in round 1 was 0.04 to 5.13, and there were 4 indicators more than 0.3. The coefficient of variation of indicators in round 2 was 0.04 to 0.38, and there were 2 indicators more than 0.3. The Kendall coordination coefficients of 2 Delphi surveys were 0.259 and 0.161, respectively (P<0.05). The Kendall Coordination Coefficient (W) was generally 0.4 to 0.5, indicating that the degree of expert coordination was good.

3.5. Indicator Revision

According to the results of relevant statistics analysis and recommendations of the experts, and after the discussion of ECMO care quality indicators evaluation team, 1 second-level indicator was modified, 6 third-level indicators were deleted, 13 third-level indicators were increased and 11 third-level indicators were modified in the first round. And 1 second-level indicator was modified, 8 third-level indicators were deleted, 3 third-level indicators were modified in the second round. Finally, the ECMO nursing quality evaluation index system was obtained including 3 first-level indicators, 15 second-level indicators and 66 third-level indicators, based on the "Structrue-Process-Outcome" three-dimensional theoretical model. See Table 1 for details.

Table 1. *ECMO Nursing Quality Indicators.*

Indicators	The average score of importance (X)	The standard deviation of score of importance	Coefficient of variation (CV)	The ratio of full-score K (%)
1. Structure quality	4.79	0.30	0.18	96.00
1.1ECMO Nursing Team	4.83	0.43	0.07	98.00
1.1.1 Keeping goods	3.84	0.47	0.01	62.36
1.1.2 Pipe pre-filled personnel	3.19	0.07	0.03	77.67
1.1.3 Basic Support Drug Group	4.74	0.45	0.18	88.74
1.1.4 Tube Fitting Group	3.25	0.77	0.20	65.71
1.1.5 Record Group	3.12	0.72	0.14	35.23
1.1.6 Mobile Group	4.58	0.87	0.01	28.44
1.2 Material Preparation	3.43	0.11	0.05	84.38
1.2.1 One ECMO Instrument Car	4.23	0.09	0.13	57.81
1.2.2 A Set of ECMO circulation device	4.32	0.41	0.14	55.89
1.2.3 One Material cabinet	4.76	0.93	0.08	29.91
2. Process quality	4.89	0.70	0.20	99.00
2.1 Pipeline pre-filling	3.81	0.02	0.01	89.51
2.1.1 Preparations for pipeline pre- filling	3.70	0.52	0.06	69.81
2.1.2 Preparations for pre-filled liquid and drug	3.01	0.14	0.06	51.22
2.2 ECMO Basic Care	4.48	0.98	0.17	63.82
2.2.1 Keeping patient's comfortable position and rest, quiet environment, relieving pain and anxiety of the patient and preventing the restlessness	3.72	0.29	0.13	38.80
2.2.2 Emotional support and psychological care for patients and their families	4.71	0.20	0.18	49.62
2.2.3Periodical removal of respiratory secretions	4.63	0.77	0.14	79.66
2.2.4 Preventing the tube from bending or the patient from pulling off the pipe due to agitation	4.01	0.57	0.16	96.82
2.2.5 The cooperation of 2 nursing staff or more is needed when great movements such as changes in posture, scrubbing the body, changing clothes and slapping on the back happened to ECMO patients	4.03	0.95	0.01	55.76
2.2.6 Oral care, maintenance of respiratory safety	4.36	0.97	0.10	25.92
2.3 ECMO Pipeline Care	3.21	0.97	0.01	82.82
2.3.1 Fixing the location of ECMO pipeline, close observation and protection of arteriovenous cannula and pipeline	4.28	0.67	0.14	70.98
2.3.2 Full-time or cross-management of ECMO pipeline	3.98	0.68	0.08	59.35
2.3.3 Attention to intubation (puncture) position bleeding	4.29	0.78	0.08	87.72
2.3.4 Do not drag along the ground when the pipeline is too long	4.65	0.27	0.11	82.49
2.3.5 Do not inject drugs or draw blood in ECMO System	4.14	0.99	0.06	39.94
2.4 ECMO Anticoagulation Care	4.49	0.46	0.13	56.66
2.4.1 Systemic heparin must be maintained during ECMO adjunctive treatment	3.26	0.82	0.16	95.80
2.4.2 Monitoring of ACT and blood anticoagulation index	4.64	0.96	0.20	98.73
2.4.3 The effect of intravenous drugs or intravenous fluids on ACT	4.13	0.51	0.19	93.46
2.5 ECMO Skin Care	4.25	0.87	0.06	45.55
2.5.1 Protection of the skin on the back of the head, heel and sacrococcygeal when changing the patient position (3-4 hours/time)	3.99	0.52	0.19	63.67
2.5.2 Keeping vein puncture dressing clean	3.83	0.72	0.17	29.47
2.5.3 Regular inspection and sterilization of the surface of the arteriovenous catheterization site	3.91	0.28	0.16	40.22
2.5.4 Avoiding new vein access	4.68	0.44	0.18	69.49
2.6 ECMO Monitoring Care	4.86	0.71	0.06	76.74
2.6.1 Monitoring of respiratory function	4.51	0.34	0.09	98.98
2.6.2 Monitoring of circulation function	4.02	0.96	0.02	96.35
2.6.3 Monitoring of heart rate	4.52	0.95	0.03	96.67
2.6.4 Monitoring of oxygen metabolism	4.50	0.29	0.12	85.49
2.6.5 Perfusion flow monitoring	4.31	0.52	0.03	87.88
2.6.6 Body temperature monitoring	3.01	0.62	0.01	87.25
2.6.7 Urine monitoring	3.13	0.55	0.11	84.42
2.7 ECMO body temperature management	4.57	0.98	0.14	81.45
2.7.1 24-hour monitoring of patient temperature and maintaining body temperature between 35 and 37°C	3.56	0.22	0.17	35.92
2.7.2 Normal operation of membrane lung variable temperature tank	3.94	0.05	0.17	77.36
2.8 ECMO blood flow management	3.75	0.15	0.12	72.55
2.8.1 Observation on ECMO flow balance	3.92	0.80	0.03	40.59
2.8.2 normal reference index indicating sufficient blood flow	4.80	0.77	0.11	38.95
2.9 ECMO blood gas management	4.91	0.18	0.02	89.75
2.9.1 Membrane-lung gas management and normal centrifugal pump	3.67	0.75	0.05	91.00

Indicators	The average score of importance (X)	The standard deviation of score of importance	Coefficient of variation (CV)	The ratio of full-score K (%)
operation				
2.9.2 normal operation of blood gas continuous monitoring system	4.33	0.82	0.02	80.99
2.9.3 Monitoring and regulation of oxygen concentration and air flow	4.93	0.74	0.19	89.99
2.9.4 Proportional adjustment of air flow and oxygen concentration according to blood flow into the membrane	3.76	0.94	0.12	82.59
2.9.5 Use of dry gas consist of air and oxygen mixture	4.83	0.89	0.02	94.63
2.9.6 Normal oxygen-gas-blood ratio	3.28	0.28	0.03	97.93
2.10 Monitoring of complications	4.95	0.78	0.02	81.47
2.10.1 Ischemia or hemorrhage	4.71	0.22	0.02	87.29
2.10.2 Vascular embolization	4.89	0.82	0.17	66.26
2.10.3 Hemolysis	4.93	0.01	0.18	51.40
2.10.4 Renal insufficiency	3.88	0.60	0.17	41.60
2.10.5 Infection	3.23	0.30	0.07	56.21
2.10.6 Neurological disorders	3.48	0.27	0.09	33.21
3. Result quality	4.08	0.81	0.01	70.37
3.1 Basic nursing results	4.16	0.62	0.19	62.30
3.1.1 Patients are satisfied with the care	4.87	0.02	0.09	46.43
3.1.2 Patients are satisfied with the service	4.74	0.41	0.14	48.45
3.1.3 Patients are satisfied with the working environment	4.42	0.93	0.13	46.41
3.1.4 There is no abnormality in the pipeline of patients	4.66	0.11	0.17	75.32
3.1.5 The patients' nutrition are normal	4.06	0.70	0.06	47.29
3.2 Circulation monitoring results	4.68	0.37	0.05	85.75
3.2.1 Normal hemodynamic parameters	4.12	0.52	0.04	79.94
3.2.2 No dizziness, headache, giddiness, fatigue symptoms	4.75	0.04	0.08	72.90
3.3 Respiratory monitoring results	3.78	0.99	0.19	64.75
3.3.1 Normal oxygen metabolism indicators	3.33	0.82	0.05	86.25
3.3.2 No chest tightness or shortness of breath	4.69	0.86	0.06	95.27
3.3.2 Unlimited light activities	4.98	0.80	0.15	62.71
3.4 Complication monitoring results	3.24	0.36	0.13	86.96
3.4.1 No bleeding, ischemia, hemolysis, or vascular embolism	4.06	0.73	0.21	76.90
3.4.2 No infection	2.54	0.91	0.19	85.78
3.4.3 No renal insufficiency and abnormal neurological function	1.69	0.41	0.15	71.91

4. Discussion

4.1. The Significance of Constructing ECMO Nursing Quality Evaluation Index System [11]

Quality Assessment and Monitoring completed by Avedis Donabedian (the founder of American medical quality management) after 20 years of hard work is considered as the "Bible" in the field of medical quality research. The "structure-process-result" three-dimensional theory is the main theoretical basis for the establishment of hospital quality evaluation standards in various countries of the world, which has a great influence on the quality standards and evaluation of nursing in countries around the world [12-16]. The theory puts forward that the quality of nursing can be evaluated from the aspects of quality of nursing structure, quality of nursing process and quality of care outcome. And the connotations of quality of nursing structure, quality of nursing process and quality of care outcome are elaborated. Extracorporeal Membrane Oxygenation (ECMO) uses a centrifugal pump to drain part of the venous blood from the patient's body to the outside of the body, and then enter the body after exhausting the CO2 through the membrane oxygen, thus improving oxygenation and increasing oxygen supply to the organs. ECMO adjuvant therapy is generally used in critically ill patients [17-19]. This requires a close cooperation between the high-quality ECMO treatment team and the ECMO care team to achieve the best results for the patient's adjuvant treatment. It is especially important to ensure the quality of ECMO-assisted care and the safety of patients. Objective and effective ECMO-assisted nursing care quality evaluation index is not only an urgently needed standard in the clinical nursing process, but also an important reference tool for the evaluation of clinical nursing quality. The construction of the ECMO nursing quality evaluation index system based on the general "Structrue-Process-Outcome" three-dimensional theoretical model in this study has important practical value and reference value.

4.2. The Scientificity of Constructing ECMO Nursing Quality Evaluation Index System

In this study, experts in related fields were focused by the Delphi method to evaluate indicators [20, 21]. A total of 20 experts from ICUs (including comprehensive ICUs and specialist ICUs) from Yichang, Enshi, Wuhan, Beijing, Tianjin, Shanghai, Shenzhen, etc. were selected to analyze and screen the ECMO nursing quality evaluation indicators. The experts' enthusiasm for index evaluation, expert authority, the concentration degree of the expert opinions, and The coordination degree of expert opinions were evaluated. The results of this study showed that the recovery rates of the first and second round were 80% and 90%, both more than 70%,

indicating that the experts showed high enthusiasm for evaluation of the indicators and great interest in this area. The authority coefficients in two rounds were 0.889 and 0.887, respectively, indicating that the degree of expert authority was high (usually Cr> 0.70 were considered acceptable). And it showed that the concentration degree of expert opinions was highly concentrated in two surveys. The Kendall coordination coefficients in 2 rounds of Delphi surveys were 0.259 and 0.161 respectively (P<0.05), indicating that the degree of expert coordination was good [22]. A scientific method is used in the construction and index screening of the ECMO nursing quality evaluation index system, making the use efficiency of the ECMO nursing quality evaluation index system more accurate and scientific.

4.3. Connotations of Structural Quality Index in ECMO Nursing Quality Evaluation Index System

"Structure" is the structural aspect, that is, the attributes of the care environment, including material properties, organizational structure, and human resource allocation. The evaluation indicators mainly include the patient's care environment， caregivers related information, including nurse-patient ratio, professional level, psychological skills and application, etc.， patient characteristics, including general patient information, basic disease status, etc., and other indicators such as social support staff related to care activities. The structural quality indicators in the ECMO nursing quality evaluation index system finally determined in this study include ECMO nursing team (item storage, pipe pre-filled personnel, basic support medication group, tube fitting group, record group, mobile group), material preparation (ECMO One instrument car, one set of ECMO circulation device, and one material cabinet). The purpose of the structural quality assessment is to analyze the preparation of personnel, environment, and articles before the ECMO adjuvant treatment to ensure the smooth progress of the ECMO adjuvant treatment. The importance score of the ECMO nursing team was 4.79, and the importance of material preparation was 4.58, which shows that the ECMO nursing team and material preparation have important role in process quality control.

4.4. Connotations of Process Quality Index in ECMO Nursing Quality Evaluation Index System

Process quality refers to the quality and efficiency in the dynamic operation of medical institutions. How process quality assessment applies structural attributes to clinical nursing practices allows patients to receive medical care and other activities directly or indirectly. The contents of the evaluation include the progress of care activities, the changes of the roles and relationships of caregivers and patients in the course of care activities; and the identification of problems in the course of care activities and providing solutions [23-25]. The main evaluation indicators are caregivers' intervention techniques, the communication level of caregivers and their ability to find and solve problems, the range of interventional

strengths that patients can accept. The second-level indicators of process quality in the ECMO Nursing Quality Evaluation Index System include pipeline pre-filling, ECMO basic nursing, ECMO pipeline nursing, ECMO anticoagulation nursing, ECMO skin care, ECMO monitoring nursing, ECMO body temperature management, ECMO blood flow management and ECMO blood gas management. The process quality indicators mainly consist of pre-filling the pipeline to ensure smooth flow, regular basic care to prevent the pipe from being discounted, distorted, and slipping, systemic anticoagulant heparinization, skin nursing to avoid pressure sores, as well as monitoring the body temperature, the blood flow and blood gas status of the patient.

4.5. Connotations of Outcome Quality Index in ECMO Nursing Quality Evaluation Index System

Outcome is a measure of the final quality of the structure and operation of a medical institution. Outcome quality refers to the change in the outcomes of the nursing process, aiming to evaluate the effectiveness of nursing activities. And it includes both subjective and objective evaluation indicators. The subjective indicators mainly include the degree of satisfaction of the nurse and the patient, health-related life quality, and the improvement of the patient's bad mood such as anxiety or depression. The objective indicators mainly consist of the improvement of patient's health status, with or without presence of complications; readmission rate; clinical endpoints, such as mortality; social benefits, such as costs incurred by patients themselves and their health care activities. The second-level indicators of process quality in the ECMO nursing quality evaluation index system in this study include basic care results, circulation monitoring results, respiratory monitoring results, and complications monitoring results, the purpose of which is to provide feedback on the final results of the quality of care after ECMO adjunctive treatment.

5. Conclusions

"Structure-Process-Outcome" is used as theoretical framework in this study. A set of relatively systematic and scientific ECMO nursing quality evaluation index system is established by using a literature review method, semi-structured interviews and Delphi method, combined with the experience and status quo in clinical ECMO nursing operations, which includes 3 first-level indicators, 15 second-level indicators and 65 third-level indicators. However, the empirical research has not been conducted for the applicability of this study in clinical nursing practice. It is necessary to further evaluate indicators in ICU departments across the country, to explore the applicability and scientificity of ECMO nursing quality indicators.

Acknowledgements

Conflicts of Interest

None of the authors has any conflict of interest to declare.

References

[1] Fong K M, Au S Y, Wu H, et al. A potential source of cerebral emboli in patients supported with peripheral VA-ECMO [J]. Intensive Care Med, 2018.

[2] Park Y G, Ha C W, Han C D, et al. A prospective, randomized, double-blind, multicenter comparative study on the safety and efficacy of Celecoxib and GCSB-5, dried extracts of six herbs, for the treatment of osteoarthritis of knee joint [J]. J Ethnopharmacol, 2013,149(3):816-824.

[3] Hayes K, Holland A E, Pellegrino V A, et al. Acute skeletal muscle wasting and relation to physical function in patients requiring extracorporeal membrane oxygenation (ECMO) [J]. J Crit Care, 2018,48:1-8.

[4] Mazzeffi M A, Tanaka K, Roberts A, et al. Bleeding, Thrombosis, and Transfusion With Two Heparin Anticoagulation Protocols in Venoarterial ECMO Patients [J]. J Cardiothorac Vasc Anesth, 2018.

[5] Schilcher G, Valentin T, Eisner F, et al. Candida infection of membrane oxygenator during ECMO therapy [J]. J Infect, 2018.

[6] Brizmohun A M, Sidhu H S, Dikaios N, et al. Characterizing indeterminate (Likert-score 3/5) peripheral zone prostate lesions with PSA density, PI-RADS scoring and qualitative descriptors on multiparametric MRI [J]. Br J Radiol, 2018,91(1083):20170645.

[7] Ben-Horin S, Andrews J M, Katsanos K H, et al. Combination of corticosteroids and 5-aminosalicylates or corticosteroids alone for patients with moderate-severe active ulcerative colitis: A global survey of physicians' practice [J]. World J Gastroenterol, 2017,23(16):2995-3002.

[8] Barrigon M L, Rico-Romano A M, Ruiz-Gomez M, et al. Comparative study of pencil-and-paper and electronic formats of GHQ-12, WHO-5 and PHQ-9 questionnaires [J]. Rev Psiquiatr Salud Ment, 2017,10(3):160-167.

[9] Herborn C U, Watkins D M, Baumann S, et al. Contrast-enhanced magnetic resonance angiography: P792 blood pool agent versus Gd-DOTA in rabbits at 3.0 T versus 1.5 T [J]. Invest Radiol, 2007,42(9):622-628.

[10] Cairo S B, Arbuthnot M, Boomer L A, et al. Controversies in extracorporeal membrane oxygenation (ECMO) utilization and congenital diaphragmatic hernia (CDH) repair using a Delphi approach: from the American Pediatric Surgical Association Critical Care Committee (APSA-CCC) [J]. Pediatr Surg Int, 2018.

[11] Liu S W, Singer S J, Sun B C, et al. A conceptual model for assessing quality of care for patients boarding in the emergency department: structure-process-outcome [J]. Acad Emerg Med, 2011,18(4):430-435.

[12] Levine A D, Boulet S L, Berry R M, et al. Assessing the use of assisted reproductive technology in the United States by non-United States residents [J]. Fertil Steril, 2017,108(5):815-821.

[13] Levine R B, Levy A P, Lubin R, et al. Evaluation of a course to prepare international students for the United States Medical Licensing Examination step 2 clinical skills exam [J]. J Educ Eval Health Prof, 2017,14:25.

[14] Witzig T E, Johnston P B, LaPlant B R, et al. Long-term follow-up of chemoimmunotherapy with rituximab, oxaliplatin, cytosine arabinoside, dexamethasone (ROAD) in patients with relapsed CD20+ B-cell non-Hodgkin lymphoma: Results of a study of the Mayo Clinic Cancer Center Research Consortium (MCCRC) MC0485 now known as academic and community cancer research united (ACCRU) [J]. Am J Hematol, 2017,92(10):1004-1010.

[15] Stys T, Stys A, Raizada A, et al. Rural United States Experience of Incorporation of a Technologically Advanced and Procedurally Complex Cardiovascular Program - the Sanford Trans-Catheter Aortic Valve Replacement Experience [J]. S D Med, 2016,69(8):351-357.

[16] Hatamleh M M, Alnazzawi A A, Abbariki M, et al. Survey of Ocular Prosthetics Rehabilitation in the United Kingdom, Part 2: Anophthalmic Patients' Satisfaction and Acceptance [J]. J Craniofac Surg, 2017, 28(5):1297-1301.

[17] Fuehner T, Kuehn C, Welte T, et al. ICU Care Before and After Lung Transplantation [J]. Chest, 2016,150(2):442-450.

[18] Yen C C, Kao C H, Tsai C S, et al. Identifying the Risk Factor and Prevention of Limb Ischemia in Extracorporeal Membrane Oxygenation with Femoral Artery Cannulation [J]. Heart Surg Forum, 2018,21(1):E18-E22.

[19] Greathouse K C, Sakellaris K T, Tumin D, et al. Impact of Early Initiation of Enteral Nutrition on Survival During Pediatric Extracorporeal Membrane Oxygenation [J]. JPEN J Parenter Enteral Nutr, 2018,42(1):205-211.

[20] Knight S, Aggarwal R, Agostini A, et al. Development of an objective assessment tool for total laparoscopic hysterectomy: A Delphi method among experts and evaluation on a virtual reality simulator [J]. PLoS One, 2018,13(1):e190580.

[21] Conchin S, Carey S. The expert's guide to mealtime interventions - A Delphi method survey [J]. Clin Nutr, 2017.

[22] Van den Bulcke B, Piers R, Jensen H I, et al. Ethical decision-making climate in the ICU: theoretical framework and validation of a self-assessment tool [J]. BMJ Qual Saf, 2018.

[23] Olchanski N, Dziadzko M A, Tiong I C, et al. Can a Novel ICU Data Display Positively Affect Patient Outcomes and Save Lives? [J]. J Med Syst, 2017,41(11):171.

[24] Heyland D K, Davidson J, Skrobik Y, et al. Improving partnerships with family members of ICU patients: study protocol for a randomized controlled trial [J]. Trials, 2018,19(1):3.

[25] Oczkowski S, Centofanti J E, Durepos P, et al. Organ donation in the ICU: A document analysis of institutional policies, protocols, and order sets [J]. Intensive Crit Care Nurs, 2018.

[26] Robinson J R, Conroy P C, Hardison D, et al. Rapid resolution of hyperammonemia in neonates using extracorporeal membrane oxygenation as a platform to drive hemodialysis [J]. J Perinatol, 2018.

[27] Muszynski J A, Reeder R W, Hall M W, et al. RBC Transfusion Practice in Pediatric Extracorporeal Membrane Oxygenation Support [J]. Crit Care Med, 2018.

[28] Patel S M, Lipinski J, Al-Kindi S G, et al. Simultaneous Venoarterial Extracorporeal Membrane Oxygenation and Percutaneous Left Ventricular Decompression Therapy with Impella Is Associated with Improved Outcomes in Refractory Cardiogenic Shock [J]. ASAIO J, 2018.

[29] Sivam S, Dentice R, Reddy N, et al. Use of extracorporeal membrane oxygenation in cystic fibrosis in an Australian cystic fibrosis centre [J]. Intern Med J, 2018,48(3):340-343.

[30] Ling L, Chan K M. Weaning adult patients with cardiogenic shock on veno-arterial extracorporeal membrane oxygenation by pump-controlled retrograde trial off [J]. Perfusion, 2018:1051836464.

[31] Rubino A, Costanzo D, Stanszus D, et al. Central Veno-Arterial Extracorporeal Membrane Oxygenation (C-VA-ECMO) After Cardiothoracic Surgery: A Single-Center Experience [J]. J Cardiothorac Vasc Anesth, 2017.

[32] Liu C, Sun W, Wang C, et al. Delivery during extracorporeal membrane oxygenation (ECMO) support of pregnant woman with severe respiratory distress syndrome caused by influenza: a case report and review of the literature [J]. J Matern Fetal Neonatal Med, 2018:1-5.

[33] Diedrich D A, Brown D R. Analytic reviews: propofol infusion syndrome in the ICU [J]. J Intensive Care Med, 2011,26(2):59-72.

[34] Schwartz S P, Bonadonna D, Hartwig M G, et al. Bedside Tracheostomy on Pediatric ICU Subjects Supported by Extracorporeal Membrane Oxygenation [J]. Respir Care, 2017,62(11):1447-1455.

[35] Huygh J, Clotman K, Malarvannan G, et al. Considerable exposure to the endocrine disrupting chemicals phthalates and bisphenol-A in intensive care unit (ICU) patients [J]. Environ Int, 2015,81:64-72.

[36] Darocha T, Kosinski S, Podsiadlo P, et al. EMS, HEMS, ECMO Center, ICU Team: Are You Ready for Hypothermic Patients?: Extracorporeal Membrane Oxygenation in Severe Accidental Hypothermia [J]. JACC Heart Fail, 2016,4(10):829-830.

[37] Fukuhara S, Takeda K, Kurlansky P A, et al. Extracorporeal membrane oxygenation as a direct bridge to heart transplantation in adults [J]. J Thorac Cardiovasc Surg, 2017.

[38] Ebrahim S, Singh S, Hutchison J S, et al. Adaptive behavior, functional outcomes, and quality of life outcomes of children requiring urgent ICU admission [J]. Pediatr Crit Care Med, 2013,14(1):10-18.

[39] MacGowan L, Smith E, Elliott-Hammond C, et al. Adequacy of nutrition support during extracorporeal membrane oxygenation [J]. Clin Nutr, 2018.

[40] Barbaro R P, Xu Y, Borasino S, et al. Does Extracorporeal Membrane Oxygenation Improve Survival in Pediatric Acute Respiratory Failure? [J]. Am J Respir Crit Care Med, 2018.

[41] Distelmaier K, Wiedemann D, Binder C, et al. Duration of extracorporeal membrane oxygenation support and survival in cardiovascular surgery patients [J]. J Thorac Cardiovasc Surg, 2017.

[42] Sinnah F, Dalloz M A, Magalhaes E, et al. Early Electroencephalography Findings in Cardiogenic Shock Patients Treated by Venoarterial Extracorporeal Membrane Oxygenation [J]. Crit Care Med, 2018.

[43] Kai M C, Koon N L. Endogenous carbon monoxide production in extracorporeal membrane oxygenation-related hemolysis: potential use of point-of-care CO-oximetry carboxyhemoglobin to detect hemolysis [J]. Clin Case Rep, 2018,6(2):346-349.

[44] Keller D, Lotz C, Kippnich M, et al. [Venoarterial extracorporeal membrane oxygenation in an awake patient : Use of the mobile ECMO team for fulminant pulmonary embolism] [J]. Anaesthesist, 2015,64(5):385-389.

[45] Gutsche J T, Vernick W J. Cardiac and Critical Care Anesthesiologists May Be Ideal Members of the Mobile ECMO Team [J]. J Cardiothorac Vasc Anesth, 2016, 30(6):1439-1440.