ORIGINAL RESEARCH

Application of fecal collection device in Intensive Care Unit Patients with fecal incontinence Receiving Extracorporeal Membrane Oxygenation: A Comparison Cohort Study

Xingliang Zhou, BM; Qingyun Wang, BM; Zhi He, BM; Sufei Xiao, BM, RN; Weiqing Ruan, MM

ABSTRACT

Objective • The objective of this study was to assess the effectiveness of fecal collection devices in preventing incontinence-associated dermatitis (IAD) and reducing skin care time in ICU patients with fecal incontinence undergoing Extracorporeal Membrane Oxygenation (ECMO).

Methods • A nonrandomized comparison cohort (quasi-experimental) study with pre-post comparison was carried out in a general intensive care unit. 85 bedridden patients receiving ECMO with fecal incontinence (FI) in a general intensive care unit between June 2017 and May 2022 participated in the study and separated into two groups according to the fecal collection device they received. 40 were assigned to the Control group (structured IAD preventive care protocol alone) and 45 to the Intervention group (structured IAD preventive care protocol plus application of fecal collection device). The status of IAD was assessed using the Incontinence Associated Dermatitis Intervention Tool (IAD-IT). Fecal consistency was evaluated via the Bristol Stool Scale. Outcome measures included the nursing time for skin care and the incidence of IAD, and bleeding complications between the two groups during the period.

Results • Participants in the Intervention group had fewer IAD occurrences than participants in the Control group (13.33% vs. 52.50%, $P < .05$). The patients in the Intervention group significantly reduced skincare time (63.30±14.09 min in the Control group versus 28.44±2.04 min in the Intervention group, $P < .01$). There was 3 turning complications for bleeding in the Intervention group and 11 in the Control group and had a significant reduction in urning complications(3 vs.11, $P = .022$).

Conclusions • Applying a fecal collection device may reduce skincare time and reduce occurrences of IAD and bleeding related to turning position for skin care in ICU patients with FI associated with diarrhea receiving ECMO Support.This study offers a more efficient way to use the fecal collection device in ECMO patients.Future research needs to focus on the perianal skin in ECMO patients regarding fecal collection devices connected to continuous low-negative-pressure suction devices. (*Altern Ther Health Med.* 2024;30(10):244-249).

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INTRODUCTION

Incontinence-associated dermatitis (IAD) is irritant contact dermatitis and skin damage associated with prolonged skin contact with urine and/or feces.[1] IAD resulting from fecal incontinence (FI) associated with diarrhea is a common problem in intensive care, occurring in up to 50% of critically ill patients.[2,3] In addition, there was a study indicating that IAD develops in 36% of patients, and the median time to onset of IAD was 4 days in critically ill patients with FI and does not resolve in most patients (81%) before their discharge from the ICU.[4] However, FI is usually a symptom, and the cause of FI in hospitalized patients, particularly in the ICU, is often unknown.[5] As IAD is skin damage mainly caused by exposure to stool or urine. Therefore, early monitoring and protection the skin from exposure to urine or stool is supposed to be a priority for preventing IAD, especially patients with critical disease and diminished cognition with sedation have frequent leakage of loose or liquid feces at the same time.[6]

Extracorporeal membrane oxygenation (ECMO) is a modified form of cardiopulmonary bypass used to support critically ill adults with respiratory or circulatory failure refractory to conventional management strategies.[7,8] As patients are wholly dependent on the ECMO circuit for survival, which makes the nursing care for ECMO patients unique and poses a major challenge for nurses for IAD protection.[9] Adult ECMO treatment requires placing two large bore peripheral catheters in

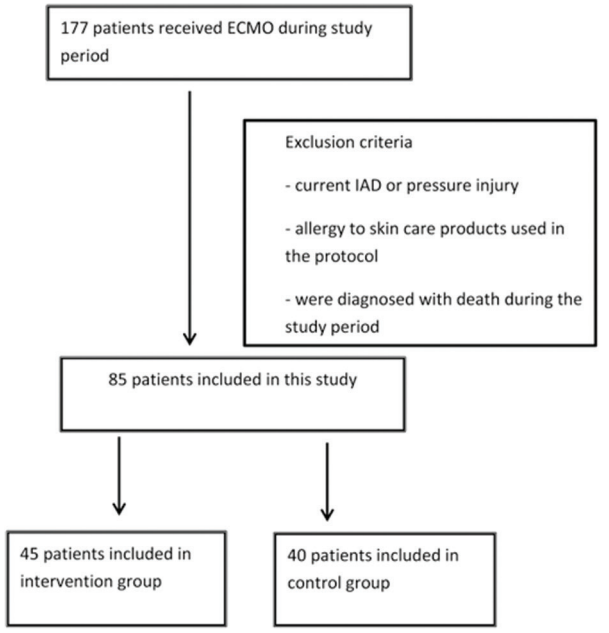
the femoral artery and vein and delivering continuous cardiopulmonary support. Major bleeding are a great concern of critical care nurses and has been a common and serious complication largely due to the requirement of systematic anticoagulation and severely affected the effects of ECMO support.[10] Researchers found major bleeding was reported in 31.4% of patients and was associated with higher in-hospital mortality and poor outcome.[11] Bleeding may occur from the cannula site, especially when the patient's position is changed for clean-up stools. Besides, most of these ECMO patients have limited mobility and many are deeply sedated and unable to inform staff when an FI episode occurs, which prevents the frequent position changes and timing cleaning that are common nursing practices in the prevention of IAD.[2] In one study, researchers found that 34% of bedside nurses worry about the dislodgement of tubes and potential injury to patients during turning.[3] Therefore, the fear of the dislodgement of patient tubes and catheters and bleeding during positioning is a major concern of critical care nurses and can be a deterrent to mobilize and turn received ECMO patients which are at a greater risk of developing IAD.

Research has found that Using the developed structured skin care protocol for IAD in critically ill patients lowered the incidence and severity of IAD and delayed IAD development.[12] However, there was little effect on the use of preventive care measures once IAD had already developed because of persistent skin irritation with stool present. Currently, the most widely used management method for FI associated with diarrhea for critically ill patients is the application of fecal collection products for collecting feces in the area around the anus. It is used to collect liquid fecal material away from the skin, minimize odor, track output accurately, decrease exposure to stool, reduce nursing workload, and limit or prevent environmental contamination.[14,15] Rachel Binks[16] reported that the use of fecal collection devices was associated with substantially higher satisfaction in managing FI compared with traditional management methods, particularly for long-lasting FI. Managing FI episodes using traditional management methods required approximately 0.7 nursing hours per day.In the FIRSTTM Survey, it was found that patients experiencing each FI episode need approximately 10-20 min and three nursing staff ,thus consuming 3.75 h of nursing time for one patient experiencing five episodes of FI in a 24-h period.[17]

Despite these reported advantages, the fear of the dislodgement of ECMO patients tubes and related complications such as bleeding during repositioning are a major concern of critical care nurses and can be a deterrent to mobilizing ECMO patients for skin care. The fecal collection device still has not been used for ECMO patients yet, and several disadvantages have impeded its adoption. The anal pouch requires intact sacral skin to apply the adhesive and is prone to dislodgement and leak; emptying was difficult if patients passed formed or hard stool. In addition, the pouch needed to be changed frequently due to its limited capacity.[15]

As the effect of the fecal collection device on patients with ECMO is not clearly, The purpose of this study is to assess the effectiveness of fecal collection devices in preventing IAD and reducing skin care time in Intensive Care Unit Patients with FI and diarrhea Receiving ECMO.

Figure 1. Flow chart for the study procedure



METHODS

Design and setting

A quasi-experimental study with pre-post comparison carried out in a general intenstive care unit located in the Shunde Hospital, Southern Medical University between June 2017 and May 2022 participated in the study.

Participants

Patients over 18 admitted to ICU with ECMO support for longer than 24 hours were studied. Because the study aimed to evaluate the effect of Because the study aimed to evaluate the effect of fecal collection devices on the incidence of IAD in patients with FI, all patients had indwelling urethral catheters. Inclusion criteria were (1) bedridden, (2) at least 3 FI episodes during 24 hours with Bristol Stool Scale form types 5, 6, and 7, (3) intact skin of the perineal, perianal, and buttocks areas. Exclusion criteria were current IAD or pressure injury and allergy to skin care products used in the protocol. They were diagnosed with death during the study period, and was not possible to evaluate the skin.

We separated our patients into two groups according to the fecal collection device they received: the Control group (structured IAD preventive care protocol alone between June 2017 and February 2021) and the Intervention group (structured IAD preventive care protocol plus application of fecal collection device between March 2021 and May 2022).

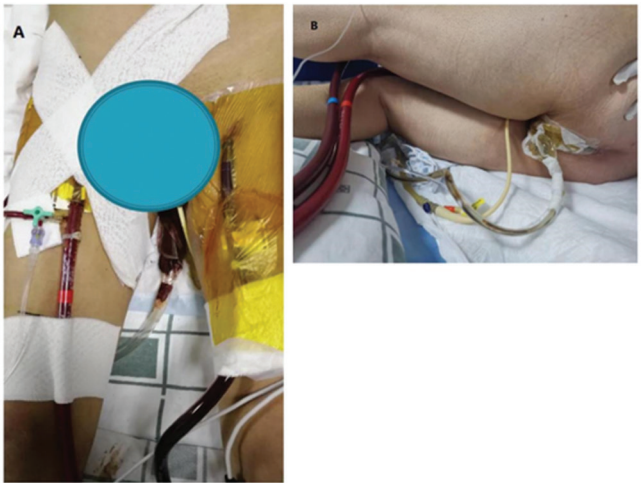
Instruments

We used the Incontinence-Associated Dermatitis Intervention Tool (IAD-IT) to assess patient's IAD status.[18] This

instrument has been widely used in our hospital and we obtained permission for use from the designers of the IAD-IT. The IAD-IT has three columns to classify IAD. The far left column contained the classification of IAD along with a picture to aid the nurse in determining the appropriate category to illustrate the five categories (high risk, early IAD, moderate IAD, severe IAD, and fungal-appearing rash). The definitions for each category were in the middle column. The far right column summarizes Interventions for each of the categories. It was simple to use the IAD-IT without any supervision of the clinicians and extensive training, which made it appropriate for nursing staff.

Stool consistency was evaluated and classified using the Bristol Stool Scale.[19] The Bristol stool scale consists of 7 types: types 1 to 4 are solid stool, type 5 is semisolid, and types 6 and 7 are liquid stool. Type 5, 6, and 7 indicate liquid stool with or without smaller formed or semi-formed fecal content which is the main cause of IAD. Nurses were educated on assessing stool consistency and accurately identifying diarrhea with the Bristol Stool Scale and provided skincare to ECMO patients after the patients had a stool.

Figure 2. The pouch connected to fecal collection device which comprised a 1-piece drainable pouch, a disposable drainage tube, and an infusion tube attached to a saline bottle that is used to diluent solid fecal materials specifically designed for containment of FI for ECMO patients. (A) The pouch was full of stool. (B) The pouch was clean after continuous suctioning and flushing several times.



Study Procedures

Before ECMO cannulation, the access vessels are evaluated with ultrasound. The vessels were accessed using the Seldinger technique under ultrasound. All cannulation was performed by ICU doctors who were trained in ECMO cannulation. All eligible patients with Peripheral percutaneous cannulation were attempted at our hospital in all patients were connected to the PLS System (Maquet, Getinge Group, Goteborg, Sweden), composed by a centrifugal pump (Rotaflow Centrifugal Pump, Maquet) and an external oxygenator (PLS-i, Maquet). Every ECMO cannula is secured using suture and elastic bandage in three points for (venous or arterial) femoral cannulae. The cannula and the tubing are maintained along the leg axis. When a cannula is placed in the internal jugular vein, it's fixed to the patient's head with a bandage.In addition, the ECMO tubing is fixed with two pliers on the bed sheet. Nurses are routinely examine at cannulation sites to rule out any signs of bleeding or dislodgement of tubes. The ICU nurse records the distance between the insertion site and the end of the wire-wound every morning to recognize any cannula movement.

Patients in both study groups were treated with the structured IAD preventive care protocol following each incontinence episode.[12,20] Skin integrity was assessed every shift (8 h) to determine the existence of IAD. Clean the perineal skin after each incontinence episode with warm fresh water and dry it with disposable wet tissue. The skin protection included the use of moisturizers (Shi Squibb skin care powder, Coloplast, Humlebaek, Denmark) and skin protectants (3M skin protective film, 3M, MN, USA). The skin care powder was applied to transiently absorb moisture from the skin and promote adherence of the adhesive faceplate to the perianal skin. Skin care powder and skin protectant were simultaneous used for three times respectively. Skin care was performed whenever the skin was soiled. At least 5 nurses are required to prevent tubes and catheters from dislodging during turning while cleaning skin for ECMO patients in turning around following an episode of FI. They are responsible for holding ECMO tubes and puncture points, the head, the legs, and turning and cleaning up the stool, respectively. The structured IAD preventive care should be done as soon as possible following an episode of FI to reduce the skin contact with stool during each turning or repositioning and protect the fragile skin.

Patients in the intervention group between March 2021 and May 2022 were provided with structured IAD preventive care plus the application of a fecal collection device. The fecal collection device comprised a 1-piece drainable pouch (Assura One-Piece Drainable Pouch, Coloplast, Coloplast, Humlebaek, Denmark), two disposable drainage tubes for suction, and an infusion tube and a disposable collection bag specifically designed for containment of stool. Assura One-Piece Drainable Pouch had a 500-mL capacity and a self-adhering skin barrier that could be fixed to the perianal area, which was available with flat or convex barriers.

The procedure for applying the fecal collection device as follows. (1) after the structured IAD was performed, the area around the anus needed to be thoroughly dry. (2) the buttock was opened with the other hand to widen the perianal space, and the central hole of the pouch was cut according to the patient anal size before removing the protective paper. (3) we used a blower with hot air for two minutes to softer self-adhering adhesive disc such that the pouch adhered tightly to the skin. (4) the pouch was placed over the anus, and the adhesive disc was pressed tightly with hand to the perianal skin for more than 60 seconds. (5) once the pouch was in place tightly, the lower opening of the pouch was connected to an infusion tube and the first disposable drainage tube. The other side of the first disposable drainage tube was connected to a disposable collection bag for containment of stool. The other side of the other disposable drainage tube was

connected to a disposable collection bag and the central suction device, respectively, with continuously negative pressure of 20 to 40 kPa (150-300 mm Hg) in order to facilitate removal of liquid fecal materials from the pouch (Figure 2A). The infusion tube is attached to a saline bottle that is used to diluent solid fecal materials that are not cleared by negative pressure suction and clean the remaining stool from the pouch to reduce stool skin irritation. The solid stool is usually diluted with 100ml of saline to irrigate the pouch. This procedure was repeated several times until stool was cleared from the pouch (Figure 2B). The pouch was changed when stool leakage was found.

Demographic and patient clinical data were extracted from participants' medical records, including age, gender, ICU length of stay (h), ECMO support time (h), ECMO model, the bore size of the ECMO cannula, ICU length of stay, and average frequency of FI, Bristol Stool Scale, the nursing time for skin care and complications related to turning between the two groups during the period. Stool consistency was evaluated using the Bristol Stool Scale. Assessment of the skin of the perineal, perianal and buttock areas was performed daily by 5 nurses holding ECMO tubes to prevent tubes and catheters from dislodging during skin care using the IAD-IT for a maximum of 5 days. Perianal's skin status in the intervention group was evaluated immediately after the fecal collection device was removed. If a patient had more than 1 type of IAD during the study period, the worst one was used for data analysis. Bleeding is defined as the appearance of visible blood related to puncture after changing body position and the need for a dressing change.

Statistical Analysis

All statistical analyses were performed using Statistic Package for Social Science (SPSS) version 25.0 (Statistical Package for the Social Sciences, Chicago, IL, USA). Descriptive statistics were performed with means(standard deviation), frequencies, and proportions according to the type of variables in each period. The comparability between both groups was analysed. Patient characteristics between the Intervention and Control groups were compared using the independent *t* test and chi-square test. The chi-square test and the Fisher exact test were used to detect any significant differences in IAD occurrences and a number of complications related to turning positions between the 2 groups, 95% confidence intervals were provided for the estimated parameters. $P < .05$ suggested statistical significance.

Ethical considerations

The hospital ethics committees of the Shunde Hospital, Southern Medical University reviewed the research procedures and waived informed consent for anonymous analyses of routinely collected clinical data as it was an evidence-based intervention that sought to improve patient care (Ethical aproval number: KYLS20230901).

RESULTS

177 patients were analyzed, and 85 bedridden patients were allocated to 2 groups: 45 were assigned to the Intervention group (structured IAD preventive care protocol plus application of fecal collection device), and the remaining 40 to the Control group (structured IAD preventive care protocol alone). Figure. 1 shows the flow chart for the study procedure. The patient characteristics are summarized in Table 1. The total mean age of patients was 51.06±15.98 years; 30.5% were females. There were no statistically significant differences in the baseline patient characteristics of the two groups.

IAD incidence and severity is summarized in Table 2. IAD occurred in 6 and 21 patients in the two groups, respectively.The patients in the Intervention group showed a significantly lower occurrence of IAD than those in the Control group (13.3% vs 52.50%, $P = .000$). A comparison of Skin care time between the two groups within a day is shown in Table 3. The patients in the Intervention group significantly reduced skincare time (63.30±14.09 min in the Control group versus 28.44±2.04 min in the Intervention group, $P = .000$). During the study, a number of complications related to turning positions in Patients in the two groups is summarized in Table 4. There were 3 bleeding complications for in the Intervention group and 11 bleeding in the Control group(6.67% vs 27.50%, $P = .022$).

Table 1. Characteristics of Enrolled Patients

Variables	Control(n = 40) M±SD or n (%)	Intervention(n = 45) M±SD or n (%)	*P* value
Gender n(%)			.285
Male	25(62)	34(76)	
Female	15(38)	11(24)	
Age(year)	50.12±15.71	51.89±16.35	.614
ECMO support time (h)	171.60±18.76	214.20±25.09	.41
ICU length of stay (h)	287.40±27.45	430.22±51.72	.187
Bristol Stool Scale n(%)			.777
Type5	18(45)	20(44)	
Type6	17(42)	17(38)	
Type7	5(12)	8(18)	
Average frequency of FI (per day) n(%)			.648
≥ 6 times	1(2)	41(91)	
3 times ---5 times	39(98)	4(9)	
ECMO Mode n(%)			.207
VV	17(42)	15(33)	
VA	23(57)	30(67)	

Table 2. Incidence of IAD and Severity in the Intervention group and Control group

Group	Intervention group (n = 45)	Control group (n = 40)	*P* value
Early IAD	4	9	.15
Moderate IAD	1	5	.09
Severe IAD	0	3	.10
Fungal Appearing Rash	1	4	.18
Total Incidence n(%)	6(13.33)	21(52.50)	.00

Table 3. Comparison of Skin care time between the two groups within a day

Group	Intervention group (n = 45)	Control group (n = 40)	Crude OR (95%CI)	*P* value
Skin care time, min	28.44±2.04	63.30±14.09	(30.33-38.77)	.000

Table 4. Number of complications related to turnning position in Patients in the two groups

	Intervention group (n = 45)	Control group (n = 40)	*P* value
Group complications related to turnning position, n (%)	3(6.67)	11(27.50)	.022

DISCUSSION

This study's findings suggest that applying a fecal collection device significantly reduced the incidence of IAD compared with the structured IAD preventive care protocol alone in ICU patients with FI associated with diarrhea receiving ECMO Support. This finding was consistent with previous studies that reported that applying a perianal pouch reduced the incidence of IAD and protected perianal skin integrity.[21,22] The fecal collection device could reduce the incidence of IAD for the following reasons. Since the main causative agent for IAD is stool, protecting the skin from exposure to stool becomes a priority. Timely cleaning and applying a skin protectant are especially important following an episode of FI. However, ECMO patients often have limited mobility, and many are sedated and unable to inform staff when an FI episode occurs. We have found that stool is usually present during every episode of turning and repositioning for pressure injury prevention, which is performed at least every 2 hours. As a result, it is particularly difficult to time cleaning and protecting the skin from exposure to stool. This study provided a more effective way to use fecal collection devices for ECMO patients. The lower opening of the pouch was connected to the infusion device and a disposable drainage tube and the other side of the tube to the central suction device and saline. The continuous suction pressure was generally around 20–40 kPa, which facilitated the suction of watery stool or even formed or hard stool. The pouch was emptied by shutting down the central suction device, putting saline into the pouch for diluting the stool, and opening the central pressure suction device several times (Figure 2B). As IAD is skin damage mainly caused by exposure to stool. therefore,timely cleansing, moisturizing, and applying a skin protectant are especially important following an episode of FI. The stool did not stay in the pouch and cann`t cause further damage to the perianal skin at any time, thereby minimizing stool leakage. Water with neutral pH in the pouch can help clean perianal skin, thereby avoiding scrubbing to minimize friction damage and maintain normal functioning of the perianal skin. Based on the aforementioned analysis, the present findings indicate that the use of a fecal collection device may reduce IAD risk by diverting and collecting the stool in a pouch, thereby avoiding exposure of the vulnerable skin surfaces to stool even if stool has not been found or the FI has not been controlled.

The patients in the Intervention group significantly reduced skin care time (63.30±14.09 min in the Intervention group versus 28.44±2.04 min in the Control group). ECMO is a modified form of cardiopulmonary bypass used to provide support to critically ill adults with respiratory or circulatory failure refractory. The dislodgement of these catheters would place the ECMO patient at high risk.[23] Ensuring vascular access is fundamentalto ECMO management and is essential to prevent two large bore peripheral catheters in the femoral artery and vein from dislodging during turning.[24,25] It is suggested that repositioning be planned and adequate resources (respiratory therapists, perfusionist, and extra nurses to hold tubes and drains) be available at the bedside.[26,27] In the Control group, 5 nurses are responsible for holding ECMO tubes and puncture points, the head, and the legs, turning and cleaning up the stool to prevent tubes from dislodging while cleaning skin for ECMO patients at our hospital in Control group. It takes longer (63.30±14.09 min) to clean stool. This greatly increases the workload of nurses and the risk of bleeding in ECMO patients. We observed 13 turning complications for bleeding in the control group. After we applied the fecal collection device in Intervention group, The nurse did not need to pay special attention to whether the patient had a stool as the stool did not stay in the fecal collection device. And most important, the nurses could easily keep the skin clean for ECMO patients and don't need to turn the patient to wash the skin and clean the stool while significantly greatly reducing skincare time and reduced turning complications for bleeding.

This study offers a more efficient way to use the fecal collection device. Applying a fecal collection device could reduce skin care time and keep skin clean. Due to the availability of materials for making the fecal collection device, this method can be easily adopted more widely in ICU setting and does not cost much money.However, it is a challenge to take the pouch adhered tightly to the anus skin and keep it longer. Further high-quality research with large sample sizes is still needed regarding fecal collection devices connected to continuous low-negative-pressure suction devices.

CONCLUSIONS

Applying a fecal collection device may reduce skincare time and reduce occurrences of IAD and bleeding related to turning position for skin care in ICU patients with FI associated with diarrhea receiving ECMO Support.This study offers a more efficient way to use the fecal collection device in ECMO patients.

Limitations

This study had certain limitations..The patients were not randomized and may have been biased. The frequency of assessment of skin status differed in the 2 groups because the skin could only be assessed during pouch changes in the Intervention group, while the skin could only be easily assessed in the Control group. In addition, the sample size is small and data were collected from a single site, which should be treated cautiously.

ETHICAL COMPLIANCE

This study was approved by the ethics committee of ethics committees of the Shunde Hospital, Southern Medical University.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest related to this article.

AUTHOR CONTRIBUTIONS

XZ and WR designed the study and performed the experiments, QW and ZH collected the data, QW, ZH and SX analyzed the data, XZ and WR prepared the manuscript. All authors read and approved the final manuscript.

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