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Original Article

Clinical application of double-capsule fecal catheter device in ICU patients with fecal incontinence

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Abstract: Objective: To explore and analyze the clinical effect and potential value of a double-capsule fecal catheter device in patients with fecal incontinence in the intensive care unit (ICU). Methods: A total of 107 patients with fecal incontinence who were admitted to the ICU of the First Affiliated Hospital of Gannan Medical University from May 2017 to April 2023 were selected and randomly divided into the observation group and the control group, with 68 cases in the observation group and 39 cases in the control group. The observation group was given a double-capsule fecal catheter device, and the control group was given an ordinary fecal catheter device for drainage. The clinical baseline data, adverse events, skin conditions, changes of patients' quality of life (QoL), indicators from laboratory test, working pressure and burden of nursing, average length of stay (ALOS) and prognosis of patients were compared between the two groups. Results: There was no significant difference in age, gender, body mass index (BMI), hypertension history, diabetes mellitus history and smoking history between the observation group and the control group (all $P>0.05$). The occurrence probability of the number of catheter obstructions, perianal leakage, catheter prolapse and the incidence of discomfort reactions in the observation group were significantly lower than those in the control group, and the difference was statistically significant ($P<0.01$). After the use of the double-capsule fecal catheter device, the skin condition of the patient's perineum and perianal area was significantly improved and remained dry and comfortable for a long time, and the recovery of the primary disease in patients with fecal incontinence was also more optimistic. After application of the double-capsule fecal catheter device, the scores of QoL significantly increased in patients from the observation group ($P<0.05$). After using the double-capsule fecal catheter device, the levels of WBC, neutrophils count, PCT and IL-6 in the observation group were significantly lower than those in the control group after nursing ($P<0.05$). However, there was no significant difference in levels of CRP, TNF-α, albumin and prealbumin between the two groups ($P>0.05$). The responsible nurses of the patients in the control group expressed significantly higher nursing work burden than the observation group ($P<0.05$). Patients in the observation group had shorter ALOS and lower mortality than those in the control group ($P<0.01$). Conclusion: The application of the novel double-capsule fecal catheter device can reduce the adverse events and working pressure and burden of nursing, it also improved skin condition and patients' QoL. Correspondingly, it improved relevant prognostic indicators during the patient's hospitalization. It has beneficial clinical practicability and popularity for fecal incontinence in patients, and it is worthy of use and promotion.

Keywords: Double-capsule fecal catheter device, fecal incontinence, ICU, prognosis, clinical application

Introduction

As the population structure changes and the population continues to age in China, the number of patients with fecal incontinence increases with the age of the patients [1, 2]. The lower the cognitive level of patients, such as in cases of dementia, disturbance of consciousness and even coma, the incidence of fecal incontinence can be as high as 96.0% [3]. Fecal incontinence can easily cause great irritation to the skin. If it is not cleaned up in time, it will easily lead to local redness, rash, blisters, tissue infection, ulceration and other adverse conditions on the patients' skin. Perineal or coccygeal dermatitis and pressure ulcers are particularly common among the above adverse health events [4]. Therefore, how to prevent fecal

incontinence has become a hot topic of clinical and nursing research in recent years [5, 6]. Based on this, research on the anatomical characteristics and defecation physiological characteristics of the human anus and rectum, and combined with clinical nursing practice, we have developed a double-capsule fecal catheter device based on annular double-capsule membrane material. The utility model realizes that the loose stool or the formed stool of the patient can be exported and stored in the fecal storage device, and the double-capsule fecal catheter device can also maintain the normal physiological function of the patients' anus, and the clinical application is convenient and safe. This article is explores the effect of double-capsule fecal catheter device in patients with fecal incontinence in the intensive care unit (ICU), in order to promote its application and promotion value.

Methods and materials

Baseline data

A total of 107 patients with fecal incontinence from the ICU of the First Affiliated Hospital of Gannan Medical University from May 2017 to April 2023 were selected and randomly divided into the observation group and the control group, with 68 cases in the observation group and 39 cases in the control group. This study was approved by the hospital ethics committee of the First Affiliated Hospital of Gannan Medical University, and the patients' family signed the informed consent.

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) All patients with fecal incontinence in the ICU; (2) Patients with involuntary bowel movements more than five times a day, with watery or mushy stools; (3) Patients with detailed clinical data; (4) Patients who had not received surgical treatment; (5) After clinical intervention, the patient still had fecal incontinence. There were no significant differences in gender, age and other baseline clinical data between the observation group and control group ($P>0.05$), which were comparable.

The exclusion criteria were as follows: (1) Patients with perianal infection, anal stenosis, anal injury, and severe hemorrhoids; (2) Patients with severe heart, liver, and renal system diseases; (3) Patients in a stage of acute cardiocerebrovascular adverse events; (4) Patients with allergy to the treatment; (5) Patients with incomplete clinical data; (6) Patients' whose family did not agree to enroll due to privacy concerns.

Research methods

The observation group was treated with a new type of double-capsule fecal catheter device (Haohong Medical Technology Co., Ltd., Xinyu, China), and the control group was treated with an inner diameter of 8 mm of ordinary fecal catheter device for drainage, and routine digital rectal examination was performed before nursing practice. The schematic diagram of the patented design and physical photos of the double-capsule fecal catheter device can be seen in **Figure 1A** and **1B**, respectively.

(1) The patients in both groups were placed on the right side of the bed, lying on the left side with their legs flexed to expose the anus. In the observation group, paraffin oil was smeared before the balloon was placed, and the inner ring of double-capsule fecal catheter device entered the anus laterally. The nurses pulled on the of double-capsule fecal catheter device slightly to make it straight, revealing the outer air bag, and then inflated the outer air bag with 8 ml, the pressure is 30 cm H_2O, the double-capsule fecal catheter device is fixed to the anus, and the fecal storage bag is connected. In the control group, the front end of the catheter was smeared with paraffin oil, the catheter was placed 15 cm into the anus, the balloon was inflated with about 10 ml, the pressure was 30 cm H_2O, the catheter was slightly pulled, and the closed drainage bottle was connected. (2) The air bag pressure was measured every six hours in both groups to prevent air bag leakage. If the air bag pressure was stable, the air bag pressure was measured once a day. (3) Perianal care occurred twice a day to keep the perineum dry, and nurses changed the contaminated dressing in time. (4) Nurses replaced the catheter once a week. When replacing, nurses took a lateral position, emptied the airbag, and directly pulled it out. The fecal storage bag was replaced according to the filling condition. (5) Nursed paid attention to the excretion of stool, whether there is pipeline prolapse, leakage, obstruction, and so on.

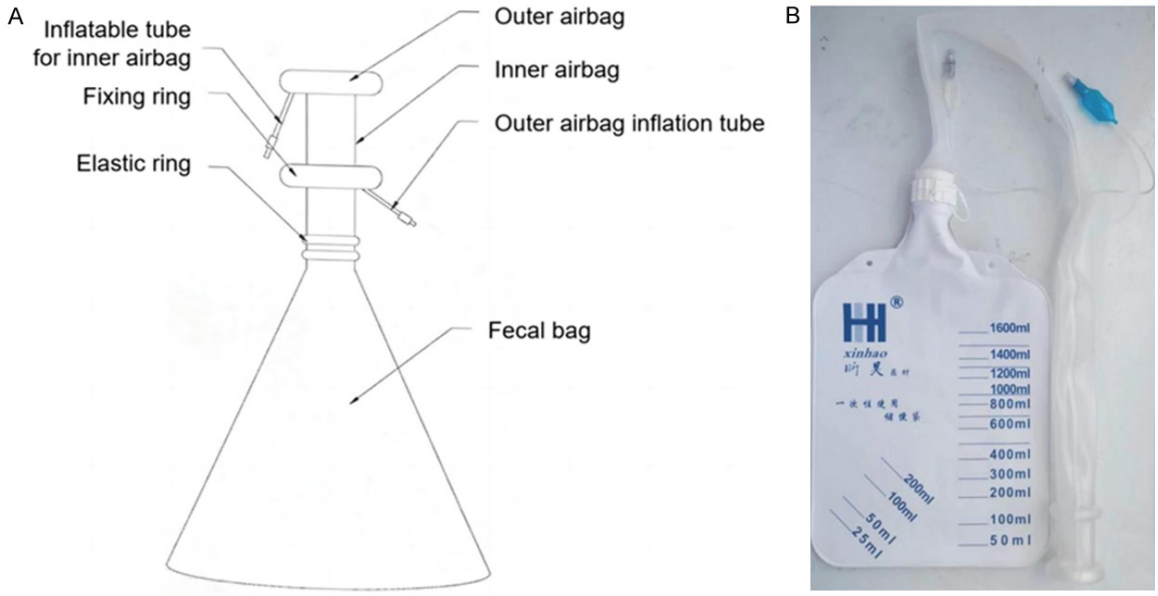

Figure 1. The new type of double-capsule fecal catheter device. A. The schematic diagram of the patented design. B. The physical photos of the double-capsule fecal catheter device.

Clinical data collection

Age, sex, smoking status, medical history and complications of the patients were collected from the electronic medical record system. Data were observed and compared between two groups, including white blood cell (WBC), neutrophils count, C-reactive protein (CRP), procalcitonin (PCT), interleukin 6 (IL-6), tumor necrosis factor-α (TNF-α), albumin prealbumin and average length of stay (ALOS). The above clinical data were collected, the differences between the observation group and the control group were compared, and the influence of the use of novel double-capsule fecal catheter device on the numerical changes of the above clinical laboratory examination indicators and the prognosis of patients was analyzed and discussed.

Observation indicators

Patency: The fecal drainage status of the patients was registered daily. For those patients with bowel obstruction, abdominal distension, and obvious perianal leakage, which are regarded as high-risk groups of catheter obstruction, the double-capsule fecal catheter device was removed, and the ordinary fecal catheter device was reinserted as appropriate.

Perianal leakage situation: We performed perianal care for patients with fecal incontinence twice a day, and recorded whether the patient had perianal leakage. Patients with stool leakage were given perianal scrub care, and the number of cases and times was recorded. Patients with severe perianal leakage were given increased scrubbing and even removal of the catheter.

Recording of the dislodgement of the catheter: To observe whether the catheter is prolapsed, re-insert the catheter if necessary, and register the number of dislocations.

Outcome measures

Primary outcome measures: The two groups were compared in terms of catheter obstruction, the number of perianal leakage cases, and the number of catheter prolapse cases. Quality of life (QoL) was compared between observation group and control group, and the QoL-brief (QOL-BREF) covered physiological factors, psychological factors, social relations and environmental factors. QOL-BREF has a total score of 100 points, and 80 is usually used as critical value in China, with a score of ≥90 points for excellence, a score of 80-89 points for medium, and a score ≤79 for poor. A higher score suggests better QoL.

Secondary outcome measures: The clinical data and the changes in the results of laboratory tests were compared between the two

Table 1. The clinical baseline data

Variable	Observation Group (*n*=68)	Control Group (*n*=39)	χ^2 value	*P* value
Age			0.814	0.367
≥60 years old	46	23		
<60 years old	22	16		
Gender			0.152	0.697
Male	41	25		
Female	27	14		
BMI			0.005	0.941
≥23 kg/m^2	17	10		
<23 kg/m^2	51	29		
Hypertension			0.484	0.487
Yes	25	17		
No	43	22		
Diabetes ellitus			0.409	0.523
Yes	22	15		
No	46	24		
Smoking history			0.124	0.725
Yes	29	18		
No	39	21		

Note: BMI, Body Mass Index.

groups. In addition, the self-made nursing work burden scale was used to evaluate the clinical workload and degree of fatigue of nurses, and the scale was conducted among 30 nurses in each group, the score of 8-10 was classified as high-load work with severe burden, the score of 6-8 was classified as moderate work load with certain burden, and the score of less than 6 was classified as certain work but no burden.

Statistical analysis

SPSS 15.0 software was used for data processing and statistical analysis. Normality test was performed by Shapiro Wilk method, and measured data in accordance with a normal distribution were expressed as mean ± standard deviation ($\bar{x}\pm s$), and independent sample *t* test was used for comparison between the two groups. Data with non-normal distribution was represented by M (IQR), and comparison between the two groups was performed by Mann-Whitney U test. Paired samples *t* test was used when the paired samples fit the normal distribution. The Wilcoxon Signed Ranks Test was used for non-normal distribution. Statistical data were expressed as frequency (%), and χ^2 test was used for comparison between groups. *P*<0.05 was considered statistically significant.

Results

Comparison of baseline data

According to analysis of clinical data between the two groups, there was no significant difference between the two groups in age, gender, body mass index (BMI), hypertension history, diabetes mellitus history and smoking history (all *P*>0.05, **Table 1**).

Comparison of the adverse events

The comparison of the occurrence probability of the number of catheter obstructions, perianal leakage, catheter prolapse and the incidence of discomfort reactions between the two groups is shown in **Table 2**.

Comparison of the skin conditions

Before the use of the double-capsule fecal catheter device, the perineal skin of fecal incontinence patients in the ICU was red, swollen, ulcerated, and infected due to excrement such as feces discharged from the anus (**Figure 2A**). After the use of the double-capsule fecal catheter device, the skin condition of the patient's perineum and perianal area was significantly improved and remained dry and comfortable for a long time, and the recovery of the primary disease in patients with fecal incontinence was also more optimistic (**Figure 2B**, **2C**).

Changes of patients' QoL

The control group received conventional nursing means, the observation group received nursing care and treatment with the novel double-capsule fecal catheter device. Before application of the double-capsule fecal catheter device, there was no significant difference in scores of physiological factors, psychological factors, social relations and environmental factors between the two groups (*P*>0.05, **Figure 3**). After nursing, the scores significantly increased in patients of both groups (*P*<0.05). Further comparison showed that after application of the double-capsule fecal catheter device, the scores of the observation group were higher than those in the control group (*P*<0.05).

Table 2. The comparison of the multiple adverse events

Group	Duct obstruction *n* (%)	Perianal leakage *n* (%)	Catheter prolapse *n* (%)	Discomfort reactions *n* (%)
Observation Group (*n*=68)	3 (4.41)	4 (5.88)	3 (4.41)	5 (7.35)
Control Group (*n*=39)	10 (25.64)	12 (30.77)	13 (33.33)	14 (35.90)
χ^2 value	8.571	12.071	16.302	13.828
P	0.003	0.001	0.000	0.000

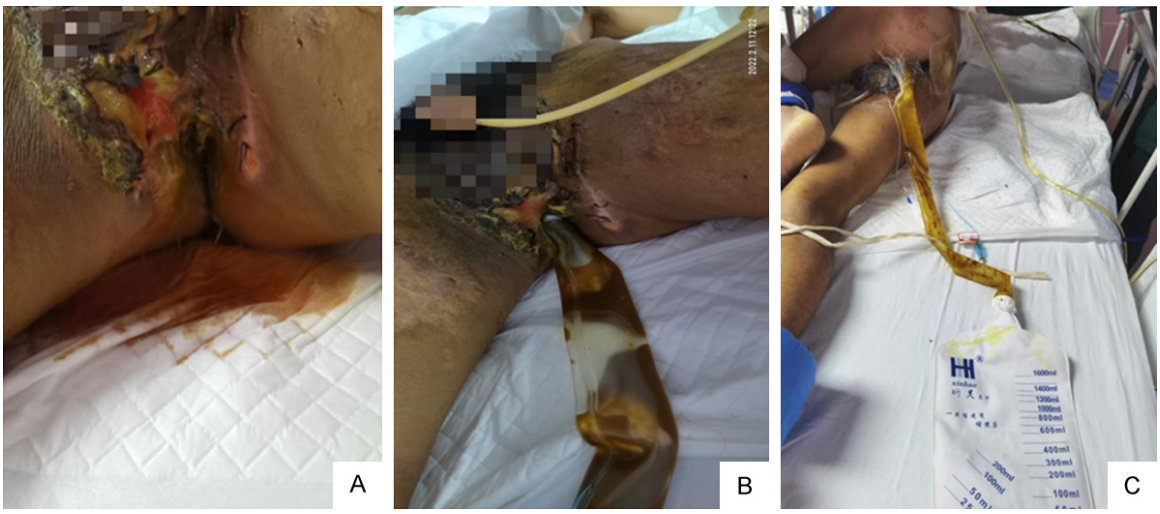

Figure 2. The skin conditions of the patients with fecal incontinence before and after the use of the double-capsule fecal catheter device. A. Perianal injury with infection (before application). B, C. Drying of perianal skin and injured infected tissue was nearly healed (after application).

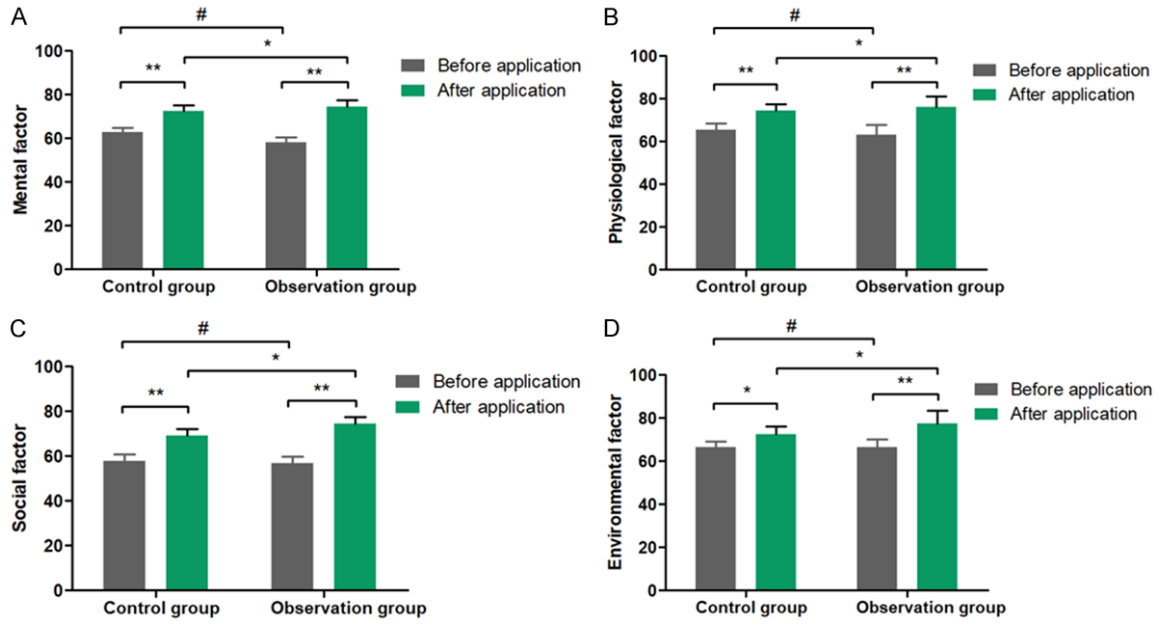

Figure 3. Changes in QOL-BREF score of patients before and after application of the double-capsule fecal catheter device. A. Changes of physiological factor score before and after treatment. B. Changes of psychological factor score before and after treatment. C. Changes of social relation score before and after treatment. D. Changes of environmental factor score before and after treatment. Note: QOL-BREF, Quality of life-brief; **P*<0.05, ***P*<0.01, #*P*>0.05.

Table 3. Comparison of indicators from laboratory test before using the double-capsule fecal catheter device in observation group

Clinical laboratory indicators	Before application		*Z*/*t* value	*P* value
	Observation Group (*n*=68)	Control Group (*n*=39)		
WBC (×10^9/L)	16.63 (11.99~18.90)	17.87 (11.52~21.23)	*Z*=-0.762	0.446
Neutrophils count (×10^9/L)	15.30 (10.53~16.92)	15.19 (10.57~18.96)	*Z*=0.293	0.770
CRP (mg/L)	71.41 (46.66~177.21)	69.43 (48.31~171.64)	*Z*=0.459	0.646
PCT (ng/ml)	1.50 (0.29~8.01)	2.67 (0.73~15.47)	*Z*=-1.457	0.145
IL-6 (pg/ml)	45.43 (28.33~196.79)	33.22 (10.56~133.66)	*Z*=0.516	0.606
TNF-α (pg/ml)	0.81 (0.08~2.31)	0.90 (0.42~2.22)	*Z*=-1.276	0.202
Albumin (g/L)	30.92±6.09	31.92±5.19	*t*=-0.861	0.391
Prealbumin (mg/L)	132.92±59.94	138.20±75.55	*t*=-0.374	0.710

Table 4. Comparison of indicators from laboratory test after using the double-capsule fecal catheter device

Clinical laboratory indicators	After application		*Z*/*t* value	*P* value
	Observation Group (*n*=68)	Control Group (*n*=39)		
WBC (×10^9/L)	5.37 (2.96~7.36)	9.13 (6.81~11.94)	*Z=-2.324*	0.020
Neutrophils count (×10^9/L)	2.93 (1.56~5.07)	6.88 (4.52~10.64)	*Z=-2.435*	0.015
CRP (mg/L)	25.48 (22.78~59.96)	29.96 (8.17~129.81)	*Z=-1.030*	0.303
PCT (ng/ml)	0.15 (0.06~1.60)	0.53 (0.14~2.55)	*Z=-2.235*	0.026
IL-6 (pg/ml)	4.20 (2.41~12.54)	16.27 (8.65~56.50)	*Z=-2.532*	0.013
TNF-α (pg/ml)	0.66 (0.53~1.08)	0.78 (0.10~2.22)	*Z*=-0.292	0.771
Albumin (g/L)	35.50±7.96	33.88±5.25	*t=1.266*	0.209
Prealbumin (mg/L)	175.11±85.01	170.99±78.75	*t=0.248*	0.805

Table 5. Comparison of working pressure and burden of nursing

Nursing group	Severe burden *n* (%)	Certain burden *n* (%)	No burden *n* (%)
Nurses from the observation group (*n*=30)	0 (0.00)	7 (23.33)	23 (76.67)
Nurses from the control group (*n*=30)	14 (46.67)	11 (36.67)	5 (16.66)
χ^2 value	18.261	1.270	21.696
P	0.000	0.260	0.000

Comparison of indicators from laboratory test

The control group received conventional nursing means, the observation group received nursing care and treatment with the double-capsule fecal catheter device. Before using the double-capsule fecal catheter device, there was no significant difference in WBC, neutrophils count, CRP, PCT, IL-6, TNF-α, albumin and prealbumin between the two groups (all *P*>0.05, **Table 3**). While after using the double-capsule fecal catheter device, the levels of WBC, neutrophils count, PCT and IL-6 in the observation group were significantly lower than those in the control group after nursing (*P*<0.05). However, there was no significant difference in levels of CRP, TNF-α, albumin and prealbumin between the two groups (*P*>0.05, **Table 4**).

Comparison of working pressure and burden of nursing

According to comparison of nursing work burden between the two groups, the responsible nurses of the patients in the control group expressed significantly higher nursing work burden than the nurses in the observation group (*P*<0.01, **Table 5**).

Comparison of ALOS and prognosis of patients

By comparing the ALOS (average length of stay) in the ICU and the outcomes of patients in the

Table 6. The comparison of ALOS and prognosis of patients in two groups

Group	ALOS (days)	Acceptable prognosis (improved discharge rate, %)	Poor prognosis (mortality rate, %)
Observation Group (*n*=68)	13 (7~23)	41 (60.29)	27 (39.71)
Control Group (*n*=39)	26 (16~50)	9 (23.08)	30 (76.92)
χ^2/*Z* value	*Z*=-2.770	χ^2=13.791	χ^2=13.791
P	0.006	0.000	0.000

two groups, we were surprised to find that patients in the observation group had shorter ALOS and lower mortality than those in the control group (*P*<0.01, **Table 6**), suggesting that the application of the double-capsule fecal catheter device could also improve the outcomes and shorten ALOS of patients with fecal incontinence from the ICU.

Discussion

Fecal incontinence refers to the loss of the anal sphincter's ability to control the excretion of feces and gas, which is a type of defecation disorder [7]. A serious consequence of fecal incontinence is the "uncontrollable" discharge of intestinal waste from the anus, patients have irregular bowel movements every day, up to dozens of times a day, and the skin or tissue around the anus is contaminated with feces, which then causes perianal dampness, resulting in perianal skin redness, itching, ulceration, and even festering, necrosis and other frustrating outcomes.

Nowadays, nursing staff in ICU have a large workload for taking care of patients with fecal incontinence, but the nursing measures for patients with fecal incontinence are relatively simple. Although some researchers have made a lot of explorations on this, such as indwelling tubes, sticking fecal storage bags, and so on, the nursing results are not satisfactory [8, 9]. To this end, our team designed and developed a high-quality, delicate and practical double-capsule fecal catheter device. The designed and developed double-capsule fecal catheter device was successfully declared in 2015 and was approved by the State Patent Office of China for application (Patent grant number CN 204971786U) and promotion in mainland China, and the application in ICU patients with fecal incontinence, which has important practical significance.

The results of the previous unpublished research within our team confirms that: (1) Rectal volume responsiveness: After deflating the spherical air bag, nurses put it into the rectal orifice and inflate it. When the diameter of the spherical air bag is more than 5.0-5.5 cm, the human body begins to have the urge to defecate; (2) Rectal responsiveness to stress: Nurses placed the large-volume balloon (the balloon with an inflated diameter of less than 8 cm is generally used without tension), fully deflate the large-volume balloon and place it in the rectum, and then inflate it. Under the condition that the balloon is restricted by the rectal wall, the balloon is pressed (at this time, it is equal to the pressure on the inner wall of the rectum) when the pressure is above 35-40 cm H_2O, the human body has a feeling of wanting to defecate.

According to the research results of the above points from our team, we have developed a double-capsule fecal catheter device, in which the inner and outer two airbags can fix the catheter device to the anus, the maximum inflation diameter of the inner airbag is 5 cm, and the diameter is generally close to 3 cm when the inflation is small. The balloon pressure is 25-35 cm H_2O, which is lower than the capillary pressure perfusion pressure. In this air pressure range, there is no discomfort to the human body, and the air bag will not cause pressure damage to the local mucous membrane; the inner diameter of the catheter device is 3 cm, and the stool can be discharged smoothly.

At present, the ordinary fecal catheter device used by public or private hospitals in mainland China for patients with fecal incontinence have always been the early design of the inner air bag without an elastic inner ring, and part of the airbag will be deformed and discharged during use of this ordinary fecal catheter device, which should be avoided by increasing the pressure of the airbag, but the high pressure poses a risk to the patient [10]. While our new-designed double-capsule fecal catheter device has been improved to add an elastic inner ring to the inner airbag, reducing the

deformation of the inner airbag, and increasing the stability of the inner airbag without increasing the pressure of the airbag. It solves the problem of airbag deformation and discharge very well. Accordingly, our research team also noticed that after the use of the new-designed double-capsule fecal catheter device, the workload of the nursing team was reduced, and the nurses were more focused on caring for the patients' other physical and mental conditions, rather than cleaning up the patients' excrement multiple times a day. This improved the rate of job burnout of the nursing team and provided better nursing services, which is also an important embodiment of humanistic care.

Admittedly, we have also noted that some studies suggest that pelvic floor muscle exercises may be an effective treatment for patients with fecal incontinence, reducing symptoms and improving rectal function and mental health [11, 12]. At the same time, Tibial nerve electrical stimulation (TNS) therapy can reduce the clinical symptoms of patients with fecal incontinence and improve the anal physiological function, with potential overall safety and efficacy [13]. In addition, some scholars even believe that biofeedback therapy has a positive effect on the treatment of patients with fecal incontinence after treatment of anorectal malformation, and the study found that symptom duration and anal sphincter integrity are the main factors affecting the effect of biofeedback therapy [14]. However, we have reflected that due to the particularity of ICU, fecal incontinence patients admitted to ICU are usually troubled by serious underlying diseases, which may not be realistic for some rehabilitation physiotherapy or pelvic floor muscle exercise, and the improvement effect on the symptoms and prognosis of patients with fecal incontinence in ICU is almost negligible.

In our study, the results of this study showed that the occurrence probability of the number of catheter obstructions, perianal leakage, catheter prolapse and the incidence of discomfort reactions in the observation group were significantly lower than those in the control group which was treated with conventional nursing means. After the use of the double-capsule fecal catheter device, the skin condition of the patient's perineum and perianal area was significantly improved and remained dry and comfortable for a long time, and the recovery of the primary disease in patients with fecal incontinence was also more optimistic. After application of the double-capsule fecal catheter device, the scores of QoL significantly increased in patients from the observation group and the levels of WBC, neutrophils count, PCT and IL-6 in the observation group were significantly lower than those in the control group after nursing. The responsible nurses of the patients in the observation group expressed lower nursing work burden than the control group; while patients in the observation group had shorter ALOS and lower mortality than those in the control group. To sum up, the application of the novel double-capsule fecal catheter device can reduce the adverse events and working pressure and burden of nursing, it also improved skin conditions and patients' QoL. Correspondingly, it improved relevant prognostic indicators during the patient's hospitalization.

It is worth mentioning that compared with ordinary fecal catheter device of conventional nursing means, our new-designed double-capsule fecal catheter device is more safe, hygienic, and convenient to use in daily nursing care work. Besides, this novel dual-capsule fecal catheter device reduces incontinence dermatitis, and reduces nursing workload. It is commendable that it can improve the prognosis of patients and is worthy of clinical promotion.

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Disclosure of conflict of interest

None.

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