CLINICAL RESEARCH

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Prevalence and associated risk factors for pressure ulcers (PU) vary in different body areas and diseases. Few studies have focused on PU in patients with enterocutaneous fistula (ECF). The aim of the present study was to investigate the prevalence and risk factors for PU in patients with ECF.			
From January 2016 to June 2016, medical records of 140 patients with ECF who were transferred to the Enterocutaneous Fistula Treatment Center, Jinling Hospital, were reviewed and analyzed. The prevalence of PU was investigated. To evaluate the risk factors for PU in patients with ECF, 5 patients with PU before admission were excluded, and the remaining 135 patients were divided into 2 groups: the PU group and the non-PU group. The risk factors for PU were confirmed by multivariate logistic regression analysis of characteristics on admission			
There were 42 cases with PU (5 cases with PU before admission, 37 cases with PU in the treatment after admission), and the prevalence of PU in patients with ECF was 30%. In addition, Braden risk score <19 (OR=9.33, Cl: 2.80-31.08, p<0.001); underweight (BMI<18.5) (OR=5.21, Cl: 1.65-16.39, p=0.005); onset of duodenal fistula (OR=4.86, Cl: 1.33–17.78, p=0.017); diabetes (OR=4.95, Cl: 1.03–23.85, p=0.046); and APACHE II score (OR=1.34,			
The PU prevalence was 30% in patients with ECF. Braden risk score <19, underweight, onset of duodenal fis- tula, diabetes, and APACHE II score were risk factors for PU in patients with ECF.			
Pressure Ulcer • Prevalence • Risk Factors • Fistula			
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Background

The National Pressure Ulcer Advisory Panel (NPUAP) defines pressure ulcers (PU) as a localized injury to the skin and/or underlying tissue [1]. It contributes to rising health care costs, consumes nursing resources, increases hospitalization, worsens patient health, and increases morbidity and mortality rates [2-5]. The prevalence of pressure ulcers varies in different body areas and different diseases. Prevalence rates have been reported at 3-26% in North America [6,7], and 8.1-49% in Europe [8,9]. There are many factors associated with the onset of PU, such as Braden score, elderly patients, patients with diabetes, and nutritional or general health status [10–12]. The Braden score is widely used as a risk assessment tool in clinical work [13]. However, risk factors for diseases are not identical, and in a recent study, risk appropriateness of assessment tools - including Braden score - were questioned for assessing elderly patients [14]. It is suggested that it is not appropriate to assess the risk for PU using one assessment tool alone [1]. Enterocutaneous fistula (ECF) is an abnormal communication between the small intestine or colon and the skin, which allows the intestinal juice to leak to the skin from the digestive tract. ECF occurs following surgical procedures, trauma, necrotizing pancreatitis, and inflammatory bowel diseases [15-18]. Malnutrition, dampness of the skin caused by the inadequate drainage of the intestine juice, and infrequent repositioning because of the many drainage tubes might complicate the causes of PU in patients with ECF. However, few studies have been carried out in patients with ECF to assess the risk of pressure ulcer development. The present study assessed the prevalence of PU in patients with ECF and explored the associations between PU and risk factors for patents with ECF.

Material and Methods

Study design

This was a retrospective study performed at the Enterocutaneous Fistula Treatment Center, Department of General Surgery, Jinling



Hospital, a tertiary referral hospital. From January 2016 to June 2016, medical records of patients with ECF during a 6-month period were investigated. The study was approved by Jinling Hospital Institutional Review Board (NO.2016NJZY-001-29). Each patient was transferred into our unit for the treatment of ECF. To investigate the prevalence, patients younger than 18 years old, and with a length of stay (LOS) less than 5 days were excluded (Figure 1). The formula for calculating the prevalence rate in the present study was: (Number of patients with PU before admission + Number of patients with PU during the treatment of hospitalization)/Total number of patients enrolled.

To investigate the risk factors for PU, patients with a PU before admission were also excluded (Figure 1). Depending on if the PU occurred or not, eligible patients were divided into the PU group and the non-PU group. Further, univariate and multivariate regression analyses were performed on the clinical data of the 2 groups. Risk factors for PU in patients with ECF were evaluated.

Data collection and measurements

Clinical data including sex, age, body mass index (BMI), Braden score, number of drainage tubes, co-morbidities (such as diabetes, hypertension, and coronary disease), and Acute Physiology and Chronic Health Evaluation II (APACHE II) score were collected from the clinical records of each patient within the first 24 h after admission. Before PU occurred, patients were turned over every 2 h. In addition, medical records of the whole course of disease were reviewed, and patients were grouped according to whether PU occurred in the course of the treatment. PU was classified as stages I-IV according to the EPUAP classification system: I, non-blanchable erythema; II, partial-thickness skin loss; III, full-thickness skin loss; and IV, full-thickness tissue loss [19]. In this study, underweight was defined as BMI \leq 18.5 kg/m² and obesity was defined as BMI \geq 30 kg/m², and the 2 values were regarded as cut-off points. Data on weight loss were not collected because the data were collected on admission, and the general situation before admission was not

Figure 1. Patient selection and grouping.

Table 1. Characteristics of 140 patients with ECF.

Clinical variables Patients			
Age, (years; mean ±SD)	42.74	±13.19	
Female, n (%)	71	(50.71)	
Anatomy of fistula, n(%)			
Duodenum	42	(30)	
Jejunum/ileum	52	(38.57)	
Colon	46	(32.85)	
BMI <18.5 kg/m², n (%)	42	(30)	
BMI >30 kg/m², n (%)	19	(13.57)	
Number of drainage tubes, (median (IQR))) 3	(3–4)	
Braden score <19, n (%)	38	(27.14)	
With enteroatmospheric fistula, n	19	(13.57)	
High output, n (%)	39	(27.86)	
Co-morbidities, n (%)			
Hypertensio	12	(8.57)	
Diabetes mellitus	21	(15)	
Coronary disease	12	(8.57)	
APACHE II score (mean ±SD)	14.16	±2.48	
LOS (day, mean ±SD)	124.12	2±68.94	

APECHE II – acute physiology and chronic health evaluation II; LOS – length of stay.

thoroughly investigated. A Braden score ranges from 6 (highest risk) to 23 (lowest risk), as shown in the Supplementary Table 1. Total scores below 19 indicate a risk for pressure ulcers [14], and a cut-off of 19 was used to dichotomize the total Braden score (<19=mild to very high PU risk, 19–23=no pressure ulcer risk). According to the American Society for Parenteral and Enteral Nutrition (ASPEN) [20], high-output ECF is defined as output exceeding 500 mL/24 h. Enterocutaneous fistula can be defined as abnormal communications between the gastrointestinal tract and the skin or the abdomen [21]. Enteroatmospheric fistula, which is a type of enterocutaneous fistula, is nonepithelialized and drains the enteric contents directly into the abdominal wound in patients with the open abdomen type [22].

Statistical analysis

All statistical analyses were performed using SPSS version 20.0 for Windows (IBM Analytics, Armonk, NY). The Kolmogorov Smirnov test was performed to determine whether the continuous variables conformed to normal distribution. We used the t test for normally distributed data and the Mann-Whitney U test for non-normally distributed data to compare continuous



Figure 2. Categories of pressure ulcer stage.

Table 2. Prevalence of pressure ulcer (N=140).

PU classification	Prevalence (n, (%))		95% CI
Stage I	17	(12.1)	6.7–17.6%
Stage II	15	(10.7)	5.5-15.9%
Stage III	8	(5.7)	1.8–9.6%
Stage IV	2	(1.4)	0.6-3.4%
Total	42	(30)	22.3–37.7%

variables. Fisher's exact test was used to compare categorical variables. Multiple logistic regression analysis was performed to evaluate the risk factors for PU. Odds ratios (ORs) are expressed as 95% confidence intervals (CIs). A P value of <0.05 was considered to indicate statistical significance.

Results

Population and Prevalence

A total of 157 medical records of patients were reviewed. There were 13 patients younger than 18 years old, and 4 patients died within the first 5 days after admission. To investigate the prevalence of PU in patients with ECF, 140 patients were enrolled in the present study.

The characteristics of the 140 cases are presented in Table 1. Of the 140 patients, there were 69 males and 71 females. The average age was 42.74 ± 13.19 years. There were 42 cases with a BMI <18.5 kg/m², and 38 cases with a Braden score <19. A total of 42 patients had PU (5 cases with PU before admission and 37 cases with PU in the treatment after admission), and the prevalence was 30% (95%CI: 22.3–37.7%). The early stages of pressure ulcers (stages I and II) accounted for 78.57% of all PU, with a prevalence of 23.57% (17 in stage I and 15 in stage II, respectively). Stage III PU accounted for 19.05% (n=8) of all PU, with a prevalence of 5.72%. Stage IV PU accounted for



Figure 3. Categories of pressure ulcer location.

4.76%, with a prevalence of 1.43% (Figure 2, Table 2). Among patients with PU, the majority had skin abnormalities on their sacrum (64.29%, n=27) or back (16.67%, n=7, Figure 3).

Risk factors for PU in patients with ECF

To make the results more accurate, we excluded 5 patients with a PU before admission; 135 patients were enrolled to investigate the risk factors for PU. According to whether PU occurred, the 135 patients were divided into the PU group (n=37) or the non-PU group (n=98). The characteristics of the 2 groups are displayed in Table 3. After univariate analysis for risk factors of PU, Braden risk score <19, diabetes, onset of duodenal fistula, higher APACHE II score, more drainage tubes, high-output fistula, with enteroatmospheric fistula, and being underweight (BMI<18.5) were associated with PU.

After multi-logistic regression analysis, it was confirmed that Braden risk score <19 (OR=9.33, Cl: 2.80–31.08, p<0.001); underweight (BMI<18.5) (OR=5.21, Cl: 1.65–16.39, p=0.005); onset of duodenal fistula (OR=4.86, Cl: 1.33–17.78, p=0.017); diabetes (OR=4.95, Cl: 1.03–23.85, p=0.046); and APACHE II score (OR=1.34, Cl: 1.04–1.72, p=0.019) were the risk factors for PU in patients with ECF (Table 4).

Clinical variables	PU group (n=37)	Non-PU group (n=98)	р
Age, (years; mean ±SD)	45.81±13.76	41.40±12.04	0.070
Female, n (%)	17 (45.95)	51 (52.04)	0.528
Anatomy of fistula, n (%)			
Duodenum	19 (51.35)	20 (20.41)	<0.001
Jejunum/ileum	10 (27.03)	41 (41.86)	0.113
Colon	8 (21.62)	37 (37.11)	0.076
BMI <18.5 kg/m², n (%)	22 (59.46)	18 (18.37)	<0.001
BMI >30 kg/m², n (%)	6 (16.22)	13 (13.27)	0.660
Number of drainage tubes,(median (IQR))	3 (3–4)	3 (2–4)	0.017
Braden score <19, n (%)	18 (48.65)	17 (17.35)	<0.001
With enteroatmospheric fistula, n (%)	10 (27.03)	7 (7.14)	0.002
High output, n (%)	14 (37.84)	23 (23.47)	0.004
Co-morbidities,n.(%)			
Hypertensio	4 (10.81)	8 (8.16)	0.630
Diabetes mellitus	14 (37.84)	6 (6.12)	<0.001
Coronary disease	5 (13.51)	6 (6.12)	0.161
APACHE II score (mean ±SD)	14.97±1.75	13.69±2.55	0.006
LOS (day, mean ±SD)	132.19±50.98	118.76±98.11	0.430

Table 3. Univariate analysis of factors associated with mortality.

APECHE II – acute physiology and chronic health evaluation II; LOS – length of stay.

Clinical variables	OR	95%CI	р
Braden risk score <19	9.33	2.80-31.08	<0.001
Underweight (BMI<18.5)	5.21	1.65–16.39	0.005
Onset of duodenal fistula	4.86	1.33–17.78	0.017
Diabetes	4.95	1.03–23.85	0.046
APACHE II score	1.34	1.04–1.72	0.019
Number of drainage tubes	1.490	0.743–2.94	0.261
Receiving the treatment of open abdomen technique	1.77	0.46-11.02	0.201
High output	2.07	0.96–7.01	0.114

Table 4. The result of the multivariate logistic regression analysis.

Discussion

ECF is a complicated disease, and the mortality of those affected by it varies from 10% to 37% [23–25]. The literature on nursing care for patients with ECF is scant [26]. Patients with ECF can be exposed to corrosion by digestive juices [26,27], contributing to skin damage. In addition, ECF can lead to malnutrition, electrolyte disturbance, septic shock, organ failure, and bleeding [21,28], leading emaciation, length of longer stay in the ICU, and infrequent repositioning [21,28]. As a result, the study of PU with ECF should be given special attention.

It has been reported that the prevalence of PU varies from 3% to 51% [6,29]. In the present study, the overall prevalence of PU was 30%, which is within the range reported in the literature. Of the PU identified in this study, 40.74% were stage I and 35.71% were stage II. The early stages of pressure ulcers (stages I and II) accounted for more than 75% of all PU in the present study. This is consistent with findings from previous research [30]. The most common anatomical areas for PU development in the present study were the sacrum and back. The back did not seem to be a high-risk area for PU in previous studies (the sacrum and heel were the areas most commonly reported in previous studies). However, in patients with ECF, most patients were positioned in supine position. For adequate drainage, more complex and additional tubes were applied. This led to infrequent truncal repositioning, while the extremities and the head were free to move. Long-term pressure on the back and sacrum caused the PU to appear.

It is widely recognized that PU development is multifactorial. There are many factors associated with PU. In the present study, the Braden risk score <19, being underweight (BMI<18.5), the onset of duodenal fistula, diabetes, and APACHE II score were confirmed to be associated with PU in patients with ECF. Although a few studies questioned the appropriateness of risk assessment tools such as the Braden score [14], it was confirmed that the Braden risk score is associated with PU [13], and this conclusion was supported in the present study. Many studies have reported that lower BMI is associated with PU [31]. Our study indicated that patients with BMI<18.5 kg/m² were at greater risk of PU, which is consistent with the findings of Børsting et al. [30]. In addition, Kottner et al. [32] found that thin patients were at higher risk for pressure ulcers on the sacrum. Interestingly, in addition to underweight patients; Tschannen et al. [33] reported that patients with low BMI were also at risk of PU. However, it should be noted that many patients with PU in their study were still considered overweight (average BMI was 27.6±7.5 kg/m²). The relationship between being overweight and the development of pressure ulcers is complicated, and BMI is even related to the position of the PU [32]. Based on the contradictory and complicated results in the literature, additional studies are warranted. Duodenal fistulas are reported to account for 3-14% of all enterocutaneous fistulas [34]. Duodenal juice is the mixture of gastric juice, bile, and pancreatic juice, which is more corrosive than that found within the small intestine and colon [35]. In addition, the output of duodenal fistulas is always high [20,28,34], and the drainage is more difficult. The additional drainage tubes and higher volume of corrosive digestive juice are more difficult to manage, causing prolonged bed rest and infrequent repositioning, leading to PU [36]. Diabetes was recognized as a risk factor for pressure ulcers in several prior studies [37], and this association was also evident in the present study.

Cox [12] and Theaker et al. [38] showed that APACHE II score was associated with PU. The APACHE II score in patients with PU in the present study was 14.97 \pm 1.75, consistent with the study by Theaker et al. [38] that reported an APACHE II score of \geq 13 was predictive of PU.

In contrast, the present study did not find an association between PU development and other factors previously identified, such as older age [39] and LOS [30]. The patients in our study were not old, and the average age of the patients with PU was 45.81 ± 13.76 years. There was little difference between the average ages of the 2 groups (45.81 ± 13.76 vs. 41.40 ± 12.04), although the difference was statistically significant (p=0.070). LOS was regarded as a risk factor for PU in previous studies [30]. However, for patients with ECF, the LOS was too long [21,26]. In the present study, LOS in the 2 groups did not show an obvious difference, leading to the conclusion that there was no association between LOS and PU.

Conclusions

The PU prevalence was 30% in patients with ECF. In addition to Braden risk score <19, being underweight, diabetes, and APACHE II score – similar to other diseases – the present research showed that onset of duodenal fistula was also a risk factor for PU in patients with ECF. Therefore, patients with duodenal fistula need careful attention.

Conflicts of interest

None.

Supplementary Table

Supplementary Table 1. Braden score.

	1 point	2 point	3 point	4 point
Sensory perception Ability to respond meaningfully to pressure-related discomforts	Completely limited Unresponsive(dose not moan,flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation OR Limited ability to feel pain over most of body surface	Very limited Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR Has sensory impairment that limits the ability to feel pain or discomfort over half the body	Slightly limited Responds to verbal commands, but cannot always communicate discomfort or need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities	No impairment Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort
Moisture Degree in which skin is exposed to moisture	Constantly moist Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned	Very moist Skin is often, but not always moist.Linen must be changed at least once a shift	Occasionally moist Skin is occasionally moist, requiring an extra linen change approximately once a day	Rarely moist Skin is usually dry. Linen only requires changing at routine intervals.
Activity Degree of activity	Bedfast Conflined to bed. Completely immobile. Does not make an even slight change in body or extremity position without assistance	Chairfast Ability to walk severely limited or non-existent. Cannot bear own weight and /or must be assisted into chair or wheelchair	Walks occasionally Walks occasionally during day, but for very short distances, with or without ssistance. Spends majority of each shift in bed or chair	Walks frequently Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours
Mobility Ability to change and control body position	Completely immobile Does not even make slight changes in body or extremity position without assistance	Very limited Make occasional slight changes in body or extremity position but significant changes independently	Slightly limited Makes frequent though slight changes in body or extremity position independently	No limitations Makes major and frequent changes in position without assistance

	1 point	2 point	3 point	4 point
Nutrition Usual food intake pattern	Very poor Never eats a complete meal.Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein(meat or diary products)per day. Takes fluids poorly supplement, OR is NPO and /or maintained on clear liquids or IV's for more than 5 days	Probably inadequate Rarely eats a complete meal.only about 1/2 of any food offered. Protein intake includes only 3servings or dairy products per day. Occasionally will take dietary supplement OR receive less than optimum amount of liquid diet or tube feeding	Adequate Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally will refuse a meal, but will usually take a supplement if offered. OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs	Excellent Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation
Friction and shear	Problem Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation lead to almost constant friction	Potential problem Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against the sheets chair restraints, or other devices.Maintains relatively good position in chair or bed most of the time but occasionally slides down	No apparent problem Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times	

The main evaluation items of Braden Score include: Sensory perception, Moisture, Activity, Mobility, Nutrition, and Friction and Shear. According to different situations, the score of each item was assessed. The scores of these items are added up to calculate the Braden score.

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