

Observational Study

Risk factors and risk prediction model for mucocutaneous separation in enterostomy patients: A single center experience

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Abstract

BACKGROUND

Mucocutaneous separation (MCS) is a common postoperative complication in enterostomy patients, potentially leading to significant morbidity. Early identification of risk factors is crucial for preventing this condition. However, predictive models for MCS remain underdeveloped.

AIM

To construct a risk prediction model for MCS in enterostomy patients and assess its clinical predictive accuracy.

METHODS

A total of 492 patients who underwent enterostomy from January 2019 to March 2023 were included in the study. Patients were divided into two groups, the MCS group ($n = 110$), and the non-MCS ($n = 382$) based on the occurrence of MCS within the first 3 weeks after surgery. Univariate and multivariate analyses were used to identify the independent predictive factors of MCS and the model constructed. Receiver operating characteristic curve analysis was used to assess the model's performance.

RESULTS

The postoperative MCS incidence rate was 22.4%. Suture dislodgement ($P < 0.0001$), serum albumin level ($P < 0.0001$), body mass index (BMI) ($P = 0.0006$), hemoglobin level ($P = 0.0409$), intestinal rupture ($P = 0.0043$), incision infection ($P < 0.0001$), neoadjuvant therapy ($P = 0.0432$), stoma site ($P = 0.0028$) and elevated intra-abdominal pressure ($P = 0.0395$) were potential predictive factors of MCS. Suture dislodgement [$P < 0.0001$, OR: 28.0075 95%CI: (11.0901-82.1751)], serum

albumin level ($P = 0.0008$, OR: 0.3504, 95%CI: [0.1902-0.6485]), BMI [$P = 0.0045$, OR: 2.1361, 95%CI: (1.2660-3.6235)], hemoglobin level [$P = 0.0269$, OR: 0.5164, 95%CI: (0.2881-0.9324)], intestinal rapture [$P = 0.0351$, OR: 3.0694, 95%CI: (1.0482-8.5558)], incision infection [$P = 0.0179$, OR: 0.2885, 95%CI: (0.0950-0.7624)] and neoadjuvant therapy [$P = 0.0112$, OR: 1.9769, 95%CI: (1.1718-3.3690)] were independent predictive factors and included in the model. The model had an area under the curve of 0.827 and good clinical utility on decision curve analysis.

CONCLUSION

The mucocutaneous separation prediction model constructed in this study has good predictive performance and can provide a reference for early warning of mucocutaneous separation in enterostomy patients.

Key Words: Enterostomy; Mucocutaneous separation; Risk assessment model; Performance validation

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Core Tip: In this study a risk prediction model for mucocutaneous separation in enterostomy patients was developed, identifying key predictive factors such as suture dislodgement, serum albumin levels, and body mass index. The model demonstrated strong predictive accuracy with an area under the curve of 0.827, offering a valuable tool for early intervention and improved patient outcomes in clinical practice.

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INTRODUCTION

Enterostomy is one of the most commonly performed surgeries by gastrointestinal surgeons. It involves temporary or permanent diversion of the patient's intestinal tract to an artificial opening (stoma) in the abdominal wall as a means of excreting intestinal contents[1]. According to statistics, hundreds of thousands of people worldwide undergo enterostomy surgery each year due to conditions such as inflammation, trauma, or intestinal cancer, with the number of patients undergoing ostomy surgery in China exceeding one hundred thousand annually, and the total number currently exceeding one million[2]. However, enterostomy also imposes varying degrees of physiological and psychological burdens on patients, severely affecting their quality of life and imposing significant economic burdens on families and society[3,4]. Leakage of intestinal contents after enterostomy surgery can lead to serious complications, with reported complication rates ranging from 10% to 50%[5,6]. Mucocutaneous separation (MCS) of enterostomy is one of the common early complications following enterostomy surgery, with its occurrence frequency accounting for 4% to 24% of enterostomy surgery complications[7].

MCS, the separation of the edge of the intestinal stoma mucosa from the sutured area of the abdominal wall skin, commonly occurs within 1 to 3 weeks after surgery. Incomplete tissue healing at the suture site results in an open wound between the mucosa and the skin[7]. The overall incidence rate of MCS outside China ranges from 3.7% to 9.7%[8,9], while in China, it is reported to be 16.33%[10]. MCS often leads to a series of adverse reactions of varying degrees, including acute peritonitis, incision infection, and stoma retraction. Additionally, scarring produced after the healing of MCS can cause stoma stenosis or retraction[11]. When MCS occurs, the reduced adhesion effect at the separation site impairs the healing process, not only slowing down wound healing but also increasing damage to the skin around the stoma. The occurrence of MCS after enterostomy prolongs the patient's hospital stay, causing physical and psychological distress to patients while dramatically increasing the difficulty, satisfaction, and workload of nursing care. Therefore, early detection and management of MCS post-enterostomy are of paramount importance for patients, their families, and healthcare providers.

Previous studies on MCS vary in terms of included variables and sample sizes, with most being retrospective studies and controversial in their conclusions. To date, there have been no reports on the establishment of a risk assessment model for MCS. This study aims to explore risk factors for MCS, establish a risk prediction assessment model, and assess the accuracy of the model.

MATERIALS AND METHODS

Participants

A prospective cohort was established, including patients who underwent enterostomy at our center from January 2019 to March 2023. Participants were included based on the following inclusion criteria: Patients determined to need

enterostomy after admission; Aged 18 years and above; Patients without mental disorders, capable of normal communication and interaction; Able to maintain regular contact for follow-up. Participants were excluded based on the following exclusion criteria: Had prior abdominal surgery; Occurrence of severe complications such as pulmonary embolism, myocardial infarction, or stroke after surgery; critically ill or deceased patients; Were lost to follow-up. This study was approved by the ethics committee of our hospital. All participants provided informed consent.

Mucocutaneous separation assessment

An expert team consisting of ten experienced gastroenterologists was set up to evaluate participants' clinical presentation to determine whether MCS had occurred or not. All members of the team were blinded by the research objectives and details.

Determination of MCS was based on expert consensus[12] and relevant guidelines[13]. The criteria for defining MCS, its clinical manifestations, and predisposing factors were summarized in the assessment criteria for MCS. Predisposing factors were defined as poor peristomal tissue healing resulting in an open wound between the skin and mucosa. A normal stoma exhibits glossiness, redness, and slight convexity, with tight adhesion between the peristomal mucosa and skin. The surrounding skin color is normal and intact. Clinical symptoms of MCS include varying degrees of separation depth ranging from 1 to 1.4 cm within the subcutaneous abdominal wall layers. White or yellowish odorless fluid may exude from the separation site.

Statistical analysis

Statistical analysis was conducted using R version 4.1.1. Continuous data are presented as mean \pm SD and were compared between groups using the independent sample *t*-test. Categorical data are reported as absolute numbers and percentages. Categorical variables were compared using the χ^2 test. Univariable logistic regression was used to identify potential predictive factors of MCS and multivariate logistic regression was then used to identify independent predictors of MCS. The independent predictors were then used to construct a binomial logistic predictive model. Receiver operating characteristic (ROC) curve analysis was also used to evaluate the model's performance. Decision curve analysis (DCA) was used to assess the utility of the model. The model was expressed as a nomogram. *P* values < 0.05 were considered statistically significant.

RESULTS

Baseline characteristics

A total of 548 participants were initially included, however, 56 were excluded due to being critically ill ($n = 6$), deceased ($n = 12$), or having prior abdominal surgery ($n = 38$). In total, 492 participants were included. The mean age was 62.0 \pm 13.56 years. One hundred and eighty-seven (38%) of the participants were female and 305 (62%) were male. The most common indication for enterostomy in the cohort was colorectal tumors, accounting for 412 (75.2%) of all cases. The main sites of enterostomy were ileostomy (63.2%) and colostomy (36.8%). Participants in the study group were assigned to the MCS Group ($n = 110$) and the non-MCS Group ($n = 382$). The median occurrence of MCS was 16.1 (7-25) days after surgery. Body mass index (BMI) ($P = 0.007$), enterostomy site ($P = 0.003$), suture dislodgement ($P < 0.001$), elevated intra-abdominal pressure ($P = 0.001$), and incision infection ($P < 0.001$) were significantly different between the two groups. There were significant differences between the two groups with respect to other variables. The baseline characteristics of the participants are summarized in [Table 1](#).

Predictive factors of MCS and the nomogram

Based on the univariate logistic regression analysis, suture dislodgement ($P < 0.0001$), serum albumin level ($P < 0.0001$), BMI ($P = 0.0006$), hemoglobin level ($P = 0.0409$), intestinal rapture ($P = 0.0043$), incision infection ($P < 0.0001$), neoadjuvant therapy ($P = 0.0432$), stoma site ($P = 0.0028$) and elevated intra-abdominal pressure ($P = 0.0395$) were determined to be potential predictive factors of MCS. These were included in the multivariate logistic regression analysis. Following multivariate logistic regression analysis, suture dislodgement [$P < 0.0001$, OR: 28.0075 95%CI: (11.0901-82.1751)], serum albumin level [$P = 0.0008$, OR: 0.3504, 95%CI: (0.1902-0.6485)], BMI [$P = 0.0045$, OR: 2.1361, 95%CI: (1.2660-3.6235)], hemoglobin level [$P = 0.0269$, OR: 0.5164, 95%CI: (0.2881-0.9324)], intestinal rapture [$P = 0.0351$, OR: 3.0694, 95%CI: (1.0482-8.5558)], incision infection [$P = 0.0179$, OR: 0.2885, 95%CI: (0.0950-0.7624)] and neoadjuvant therapy [$P = 0.0112$, OR: 1.9769, 95%CI: (1.1718-3.3690)] were determined to be independent predictive factors of MCS. The results of univariate and multivariate logistic regression analysis are presented in [Table 2](#).

Based on the factors identified above, we constructed first a logistic model including only the independent predictive factors (suture dislodgement, serum albumin level, BMI, hemoglobin level, intestinal rapture, incision infection and neoadjuvant therapy) to predict MCS (MCS model). The nomogram had an area under the curve (AUC) of 0.827. For comparison, we also constructed a simplified predictive model including only suture dislodgement, albumin level and BMI (MCS Basic) and an extended model that included all the predictive factors identified from univariate analysis (MCS Extended). These two models had an AUC: 0.790 and AUC: 0.833, respectively. There was no significant difference in performance between the MCS model and the MCS extended models ($P = 0.266$). Both the MCS model and MCS Extended were significantly better than MCS Basic ($P = 0.005$ and $P = 0.004$, respectively). ROC curves for the models are shown in [Figure 1](#). The MCS model was expressed as a nomogram ([Figure 2](#)). Nomograms of MCS Extended and models are shown in [Supplementary Figures 1 and 2](#). Clinical utility of the models was compared using DCA. Overall, the MCS

Table 1 Clinicopathological characteristics, *n* (%)

Variable	Non-MCS (<i>n</i> = 382)	MCS (<i>n</i> = 110)	<i>P</i> value
Sex			0.4106
Male	241 (63.1)	64 (58.2)	
Female	141 (36.9)	46 (41.8)	
Age (years)			0.8209
< 60	115 (30.1)	35 (31.8)	
≥ 60	267 (69.9)	75 (68.25)	
Intestinal rapture	14 (3.7)	12 (10.95)	0.0059
Diabetic	89 (23.3)	26 (23.6)	1.0000
Immunotherapy	153 (40.0)	45 (40.9)	0.9592
Neoadjuvant therapy	153 (40.0)	56 (50.9)	0.0548
Suture dislodgement	42 (11.0)	63 (57.3)	< 0.0001
Incision infection	49 (12.8)	42 (38.2)	< 0.0001
BMI (kg/m ²)			0.0007
< 24	257 (67.3)	54 (49.1)	
≥ 24	125 (32.7)	56 (50.9)	
Stoma site			0.0036
Ileum	228 (59.7)	83 (75.4)	
Colon	154 (40.3)	27 (24.6)	
Elevated intra-abdominal pressure	183 (47.9)	65 (59.1)	0.0501
Hemoglobin level			0.0501
≤ 90	82 (21.5)	34 (30.9)	
> 90	300 (78.5)	76 (69.1)	
Albumin level			< 0.0001
≤ 28	54 (14.1)	34 (30.9)	
> 28	328 (85.9)	76 (69.1)	

BMI: Body mass index; MCS: Mucocutaneous separation.

Table 2 Univariate and multivariate analysis

Variable	Univariate, <i>P</i> value	Multivariate, <i>P</i> value	OR	95%CI	
				Lower	Upper
Suture dislodgement	< 0.0001	< 0.0001	28.0075	11.0901	82.1751
Serum albumin	< 0.0001	0.0008	0.3504	0.1902	0.6485
BMI	0.0006	0.0045	2.1361	1.2660	3.6235
Hemoglobin	0.0409	0.0269	0.5164	0.2881	0.9324
Intestinal rapture	0.0043	0.0351	3.0694	1.0482	8.5558
Incision infection	< 0.0001	0.0179	0.2885	0.0950	0.7624
Neoadjuvant therapy	0.0432	0.0112	1.9769	1.1718	3.3690
Stoma site	0.0028	0.1996	0.6908	0.3881	1.2071
Elevated intra-abdominal pressure	0.0395	0.1194	1.5162	0.2881	0.9324

Diabetic	0.9412	-	-	-
Age	0.7309	-	-	-
Immunotherapy	0.8717	-	-	-
Sex	0.3506	-	-	-

BMI: Body mass index.

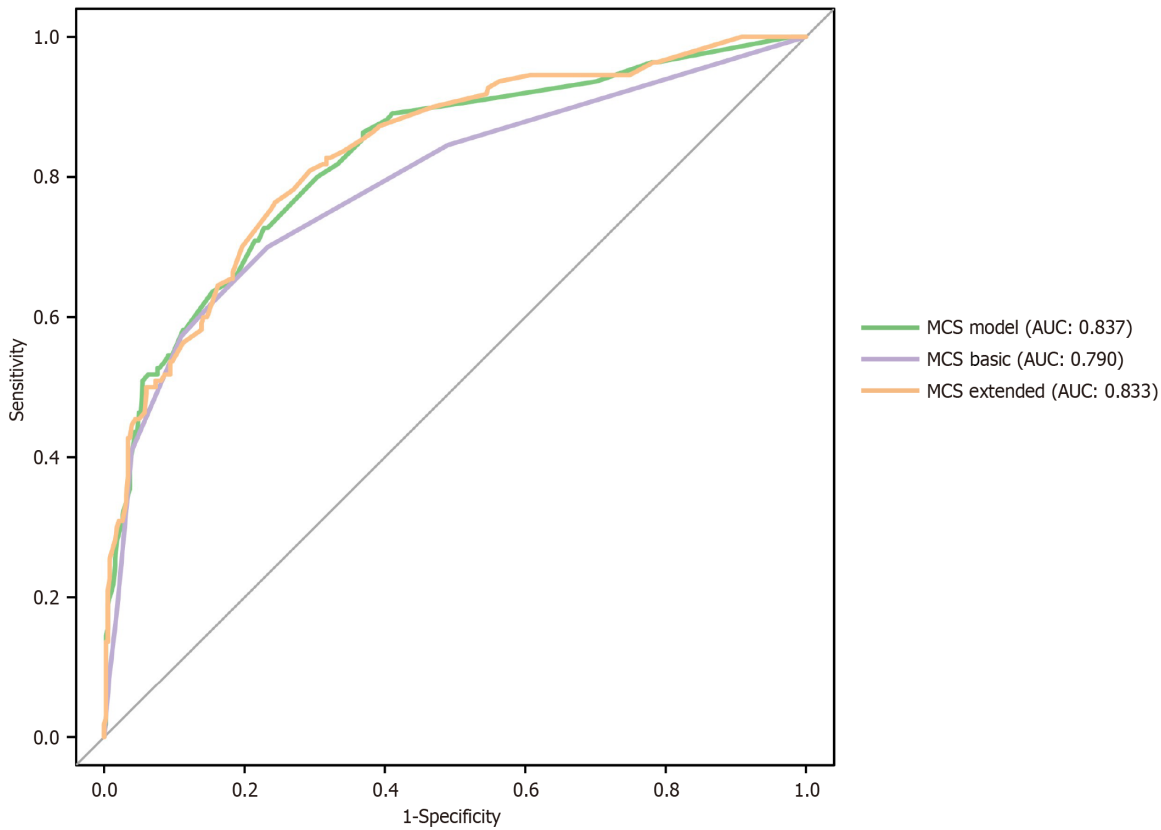


Figure 1 Receiver operating characteristic analysis curves. Mucocutaneous separation (MCS) model is the primary model incorporating all 7 independent predictive factors [suture dislodgment, albumin level, body mass index (BMI), hemoglobin level, intestinal rupture, incision infection and neoadjuvant therapy]. MCS Basic is the stripped-down model using only suture dislodgment, albumin level and BMI. MCS Extended incorporates all the potential predictive factors. MCS: Mucocutaneous separation; AUC: Area under the curve.

model had the best clinical utility compared to the other two models. However, the clinical utility at risk threshold between 0.4 and 0.8 was better in the extended model. Below the risk threshold of 0.4, MSC model and MSC Extended were comparable. Above the 0.8 risk threshold the MCS model was better. DCA analysis results are shown in [Figure 3](#).

DISCUSSION

Enterostomy surgery is commonly used in the treatment of inflammatory bowel disease, intestinal rupture, intestinal obstruction, rectal and anal tumors, and other diseases. Recent studies have shown that high Duke stage, preoperative neoadjuvant chemoradiotherapy, diabetes, inflammatory bowel disease, immunosuppressants, steroids, BMI, albumin levels, and regular follow-up visits by patients are high-risk factors for complications in enterostomy skin. Previous studies have shown that compared to colostomy, patients with ileostomy have higher daily stool output, which is often pasty or watery, carrying various digestive enzymes, making it easy to damage the skin[14].

The results of this study indicate that the risk of MCS in patients with ileostomy is significantly higher than in patients with colostomy. Therefore, for patients with ileostomy who have a large amount of stool output and rapid dissolution of the adhesive base, an enhanced adhesive base should be used, and the ostomy support rod should be removed promptly within one month after surgery. Surgical reasons causing ischemic necrosis of the intestinal mucosa, intraoperative use of electro-surgical devices, and obesity leading to incisional fat liquefaction can all cause skin and mucosal separation[15]. Peristomal fat liquefaction, peristomal abscesses, and infection at the site of enterostomy skin and mucosal sutures

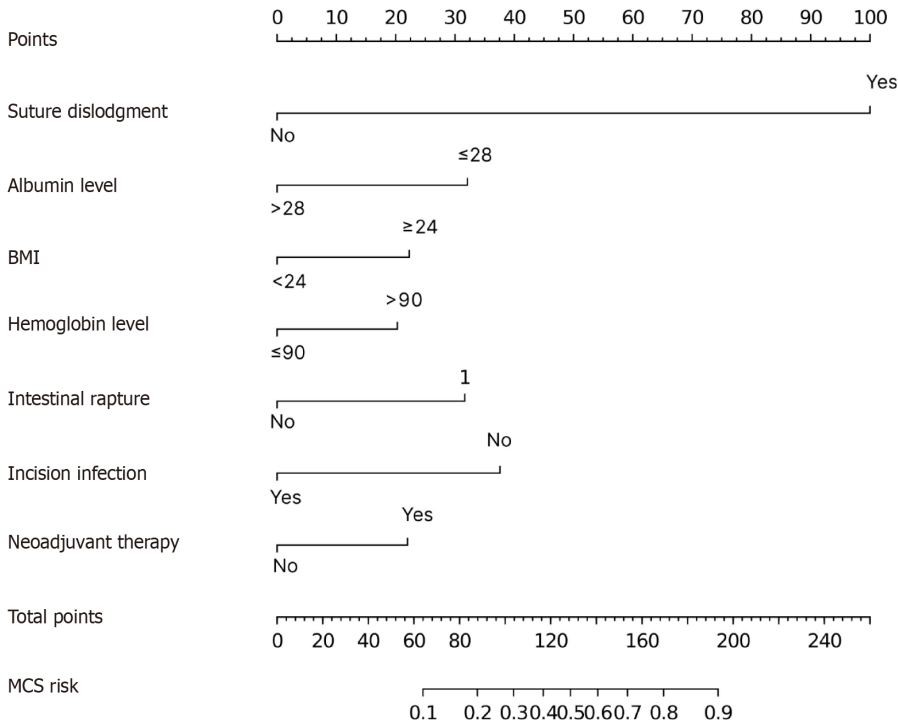


Figure 2 Mucocutaneous separation model nomogram. Visualization of the mucocutaneous separation (MCS) model via a nomogram. The risk of MCS is determined based on the total points based on the seven independent predictive variables. MCS: Mucocutaneous separation.

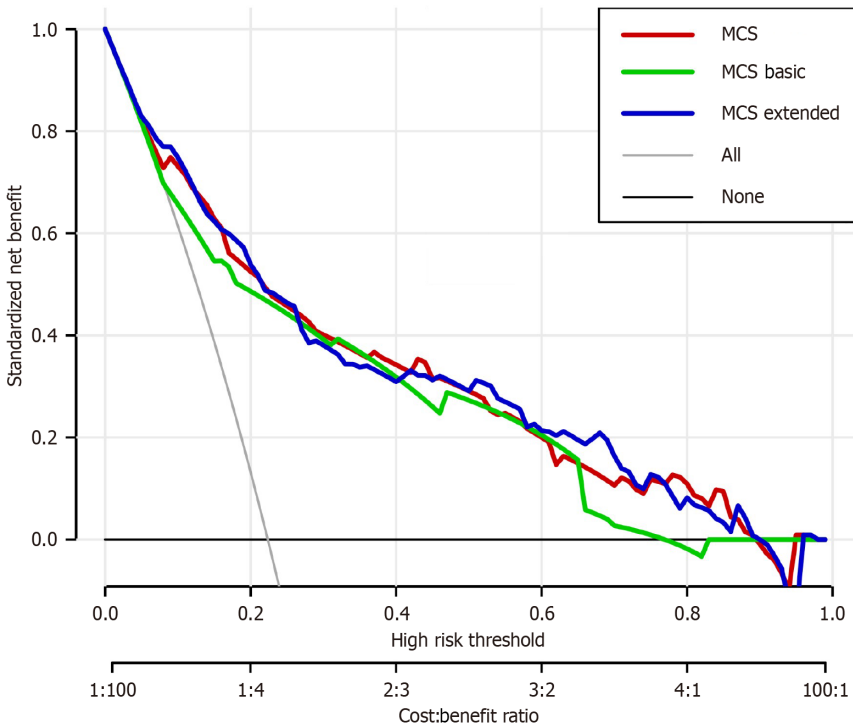


Figure 3 Decision curve analysis. The clinical utility of the three models is generally comparable, however, at higher risk profiles, the mucocutaneous separation model is generally better. MCS: Mucocutaneous separation.

significantly increase the probability of MCS[16]. The results of this study show that partial necrosis of the enterostomy intestinal mucosa, detachment of enterostomy mucosal sutures, subcutaneous fluid infection around the enterostomy, liquefaction of local tissue around the enterostomy, and incision infection all increase the risk of MCS. It is recommended that when patients have symptoms of infection, secretions from the wound should be collected for bacterial culture, and antibiotic treatment should be administered according to the doctor’s orders. With good intestinal function, solid food intake should be increased to prevent fecal contamination of the wound. Physicians should remove ineffective sutures at

the site of MCS, and clean and remove necrotic tissue from the wound.

When the enterostomy roll edge leaks or becomes pale, it should be replaced promptly to prevent fecal leakage and delay wound healing. When serum albumin levels are < 35 g/L, the risk of postoperative site infection will increase by 2.5-fold[17]. Another study found that preoperative low albumin levels are independent risk factors for deep skin and mucosal separation[18]. Multiple studies have shown that patients in a malnourished state have low immune function and should receive enteral or parenteral nutrition support before and after surgery to improve immune function and effectively prevent skin and mucosal separation[19,20]. The results of this study indicate that when serum albumin levels are low, indicating malnutrition, the probability of MCS occurrence significantly increases. Poor nutritional status in patients is a high-risk factor for MCS occurrence. It is recommended to strengthen patient health education, provide dietary guidance to patients, and enhance patient awareness of nutritional supplementation and dietary balance.

This study was based on a prospective design, employing uniform criteria to identify the occurrence of MCS, and to avoid subjective bias, outcome assessment was conducted blindly. Additionally, predictive variables were rigorously selected by an expert team following relevant guidelines[21]. Through extensive literature review, expert consultations, and preliminary investigations, predictive factor variables were selected. Single-factor analysis and multi-factor analysis were conducted to obtain the strongest combination of variables for joint prediction. Furthermore, the measurement methods for the included predictive variables were simple, data acquisition was relatively convenient, and the model exhibited good reproducibility and operability. In addition to these findings, the potential of Negative Pressure Wound Therapy (NPWT) as a treatment for complicated cases of MCS is noteworthy. A recent case series by Ding *et al*[22] demonstrated the effectiveness of NPWT in managing moderate to severe MCS following ileal conduit urinary diversion. Their study showed that NPWT not only prevented infection but also facilitated the healing process in patients with significant MCS. This suggests that NPWT could be considered a therapeutic option in severe cases of MCS, particularly where conventional treatments may be insufficient. Future studies should explore the broader applicability of NPWT in MCS management following enterostomy surgery.

While this study offers valuable insights into the risk factors and predictive model for MCS in enterostomy patients, several limitations should be acknowledged. Firstly, as a single-center study, the findings may not be generalizable to other populations or settings, where different surgical techniques, postoperative care protocols, and patient demographics may influence the incidence and risk factors of MCS. Additionally, although the study employed a prospective design and rigorous criteria for identifying MCS, the potential for selection bias remains, as patients who were critically ill, deceased, or lost to follow-up were excluded from the analysis. Moreover, the reliance on expert assessment for determining MCS may introduce some level of subjectivity, despite the blinding procedures used. Lastly, while the model demonstrated good predictive accuracy, external validation in diverse clinical settings is necessary to confirm its broader applicability. Future studies should also explore the inclusion of additional variables, such as genetic predispositions and long-term patient outcomes, to enhance the robustness of the model.

CONCLUSION

MCS often occurs within 1 to 3 weeks after enterostomy surgery. If MCS is not promptly addressed, it can lead to complications such as irritant dermatitis, stoma retraction, stoma stenosis, and even stoma reconstruction, which can significantly increase the psychological and economic burden on patients and their families, causing immense suffering. The MCS risk prediction model developed in this study demonstrates good predictive performance, providing a scientific basis for early warning and precise prevention of MCS complications. It can guide the development of MCS prevention and intervention strategies. However, this study has certain limitations. It only underwent temporal validation, and the number of modeling samples needs to be further increased. The external validity of this model needs to be verified in different hospitals.

FOOTNOTES

Author contributions: Liu Y and Ye JH contributed to conceptualization; Liu Y contributed to methodology; Li H contributed to writing—original draft preparation; Wu JJ and Ye JH contributed to writing—review and editing; contributed to supervision; All authors have read and agreed to the published version of the manuscript.

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