中国临床研究 Chin J Clin Res, February 2026, Vol.39, No.2

Cite as: Guan Z, Zuo XY, Zhang YS. Construction of prediction model for perforation risk in endoscopic submucosal dissection of early gastric cancer [J]. Chin J Clin Res, 2026, 39(2):183-187.
DOI: 10.13429/j.cnki.cjcr.2026.02.004

Construction of prediction model for perforation risk in endoscopic submucosal dissection of early gastric cancer

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Abstract: **Objective** To construct a risk prediction model for perforation during endoscopic submucosal dissection (ESD) in early gastric cancer, and to provide a scientific basis for clinicians to assess surgical risks and formulate reasonable treatment plans. **Methods** Clinical data of 102 patients with early gastric cancer who underwent ESD treatment in the Third Affiliated Hospital of Soochow University from January to December 2024 were collected, including general information, tumor-related characteristics, and operation-related indicators. Univariate analysis and multivariate logistic regression analysis were used to identify related factors and independent risk factors, and a perforation risk prediction model was constructed. The predictive efficacy of the model was evaluated by receiver operating characteristic (ROC) curve. **Results** Among the 102 patients, there were 20 cases in the perforation group and 82 cases in the non-perforation group. Multivariate logistic regression analysis showed that tumor diameter >3 cm, tumor located in the upper part of the gastric body, and operation time >120 min were independent risk factors for ESD-related perforation in early gastric cancer (*OR*=3.557, 95%*CI*: 1.777-7.120, *P*<0.01; *OR*=2.892, 95%*CI*: 1.406-5.949, *P*=0.004; *OR*=4.276, 95%*CI*: 2.253-8.117, *P*<0.01). Hosmer-Lemeshow goodness of fit test results showed that the regression model had a good fitting effect on the data (χ^2=6.328, *P*=0.612). The area under the ROC curve (AUC) for the combined factors in predicting the risk of ESD perforation was 0.86 (95%*CI*: 0.80-0.92), indicating good predictive accuracy. **Conclusion** The successfully constructed risk prediction model for ESD-related perforation in early gastric cancer incorporates independent risk factors such as tumor diameter, tumor location, and operation time. It can predict the perforation risk relatively accurately.

Keywords: Gastric cancer, early stage; Endoscopic submucosal dissection; Perforation risk; Prediction model

Early gastric cancer refers to cancer tissue confined to the gastric mucosa or submucosa, regardless of lymph node metastasis [1]. In recent years, with the development of endoscopic technology, endoscopic submucosal dissection (ESD) has become an important method for treating early gastric cancer and precancerous lesions [2-3]. Compared with traditional surgery, ESD has advantages such as minimal trauma, rapid recovery, and complete lesion resection, which can effectively improve patients' quality of life and survival rate [4]. However, as an invasive procedure, ESD also carries certain complication risks, among which perforation is a relatively serious complication that not only increases patient suffering and medical costs but may also affect patient prognosis [5]. The occurrence of perforation is associated with multiple factors, including patients' individual characteristics, biological tumor behavior, and complexity of surgical procedures [6].

Currently, clinical assessment of ESD perforation risk mainly relies on physicians' experience and subjective judgment, lacking scientific and accurate prediction models. This makes it difficult to accurately assess patients' perforation risk before surgery, increasing surgical uncertainty and risk [7]. Therefore, constructing a scientific and accurate ESD perforation risk prediction model has significant clinical implications. Through this model, clinicians can quantitatively assess patients' perforation risk before surgery, identify high-risk patients in advance, and take targeted preventive measures, such as adjusting surgical plans and strengthening intraoperative monitoring, thereby reducing the incidence of surgical perforation, improving the safety and effectiveness of ESD treatment, and enhancing patient prognosis. Therefore, this study aims to construct a prediction model for early gastric cancer ESD perforation risk to provide strong support for clinical practice and promote the development of ESD treatment of early gastric cancer toward standardization and precision.

1 Subjects and Methods

1.1 Study Subjects

A total of 102 patients with early gastric cancer who underwent ESD treatment at the Third Affiliated Hospital of Soochow University from January 2024 to December 2024 were retrospectively selected as study subjects. This study was approved by the Ethics Committee of the Third Affiliated Hospital of Soochow University [Ethics Approval Number: (CZYY-LL-25021)].

1.2 Inclusion Criteria

(1) Diagnosed with early gastric cancer through gastroscopy and histopathological biopsy, defined as cancer tissue confined to the gastric mucosa or submucosa, regardless of lymph node metastasis; (2) Met the surgical indications for ESD treatment, including but not limited to

relatively small lesion diameter, absence of obvious ulcers, and relatively clear lesion boundaries, and ESD treatment was adopted after evaluation through multidisciplinary consultation (including experts from gastroenterology, surgery, pathology, and other departments); (3) Patients or their family members fully understood relevant information about ESD treatment, including the surgical procedure, possible complications, and prognosis, and signed informed consent forms.

1.3 Exclusion Criteria

(1) Presence of severe cardiopulmonary dysfunction, such as severe coronary atherosclerotic heart disease (coronary heart disease), acute exacerbation of chronic obstructive pulmonary disease, etc., making them unable to tolerate ESD surgery, or severe hepatic or renal insufficiency that may affect surgical safety and postoperative recovery; (2) Presence of coagulation dysfunction, such as thrombocytopenic purpura, hemophilia, etc., or currently receiving anticoagulant or antiplatelet therapy that cannot be adjusted to a safe range before surgery, increasing the risk of intraoperative bleeding and perforation; (3) Inconsistent lesion characteristics: extensive tumor invasion exceeding the resectable range of ESD, or special lesion location, such as proximity to important blood vessels, nerves, and other structures, making surgical operation extremely difficult with very high perforation risk, as well as patients with distant metastasis; (4) Pregnant or lactating women; (5) History of mental illness and inability to cooperate with surgery and related examinations; (6) Incomplete clinical data, unable to obtain sufficient information for analysis.

1.4 Data Collection

1.4.1 General Information

(1) Baseline data: age, gender, height, weight, body mass index (BMI), and other basic information. (2) Medical history: whether the patient had a history of gastric surgery, peptic ulcer disease, cardiovascular disease, diabetes, and other underlying conditions. (3) Family history: whether there is a family history of gastric cancer or other malignant tumors.

1.4.2 Tumor-Related Information

(1) Tumor size: accurate measurement of the maximum tumor diameter through preoperative endoscopic ultrasound, abdominal CT, and other imaging examinations. (2) Tumor location: specific location of the tumor within the stomach, such as gastric fundus, gastric body, gastric antrum, cardia, etc., and whether it is close to important anatomical structures of the stomach, such as pylorus, cardiac sphincter, etc. (3) Pathological type: determination of the tumor's pathological type based on postoperative pathological examination results, such as well-differentiated adenocarcinoma, moderately differentiated adenocarcinoma, poorly differentiated adenocarcinoma, mucinous adenocarcinoma, etc. (4) Histological grade: assessment of the tumor's histological grade to determine the degree of tumor cell differentiation.

1.4.3 Surgery-Related Information

Through the hospital electronic medical record system (including surgical records, anesthesia records, intraoperative nursing records), endoscopic operation image archiving system, and pathological examination reports, the following information was extracted and verified. (1) Surgical duration: total time from the start of endoscopic insertion into the digestive tract to the completion of surgery. (2) Operative difficulty: assessed by the surgeon based on actual conditions during surgery, such as lesion boundary clarity, degree of adhesion to surrounding tissues, and complexity of the procedure, classified into three levels: high, moderate, and low. (3) Intraoperative conditions: whether complications such as bleeding and perforation occurred during surgery, as well as management measures and outcomes. (4) Anesthesia method: the anesthesia method used for surgery.

1.5 Statistical Methods

SPSS 26.0 and R software were used for data analysis and plotting. For measurement data conforming to normal distribution, they were expressed as $\bar{x}\pm s$, and comparisons were performed using independent sample t-test; count data were expressed as cases (%), and χ^2 test was used. Multivariate logistic regression was used to analyze independent influencing factors of perforation, and a prediction model was constructed based on the influencing factors. The predictive performance of the model was analyzed using receiver operating characteristic (ROC) curve. $P<0.05$ was considered statistically significant.

2 Results

2.1 Baseline Data Analysis

Among 102 patients, 20 cases developed perforation (perforation group), and 82 cases did not develop perforation (non-perforation group). Patients in the perforation group had higher age, larger tumor diameter, higher proportion of tumors located in the upper gastric body, higher proportion of poorly differentiated adenocarcinoma, longer surgical duration, and higher proportion of high operative difficulty compared to the non-perforation group, with statistically significant differences ($P<0.05$). [**Table 1]**

2.2 Multivariate Logistic Regression Analysis

Univariate analysis showed that age ≥60 years, tumor diameter >3 cm, tumor located in the upper gastric body, poorly differentiated adenocarcinoma, surgical duration >120 min, and high operative difficulty were significantly associated with ESD perforation risk ($P<0.05$). Multivariate logistic regression analysis indicated that tumor diameter >3 cm, tumor located in the upper gastric

body, and surgical duration >120 min were independent risk factors for early gastric cancer ESD perforation (P<0.05), while age ≥60 years and poorly differentiated adenocarcinoma were not independent risk factors (P>0.05). [**Table 2]** The model goodness-of-fit test used the Hosmer-Lemeshow test, showing χ^2=6.328, P= 0.612>0.05, indicating that the regression model had good fit to the data and the model specification was reasonable.

2.3 Model Construction

The prediction model constructed based on these factors had an area under the curve (AUC) of 0.86 (95% CI: 0.80-0.92), demonstrating good predictive accuracy. Through ROC curve analysis, the optimal cutoff value for the combined prediction model was determined to be 0.423. At this point, the model's sensitivity was 80.0%, specificity was 79.3%, and Youden index was 0.593. [**Table 3 & Figure 1]**

2.4 Decision Curve Analysis (DCA)

To evaluate the clinical utility of the model, DCA was performed on the combined prediction model. The results showed that when the threshold probability ranged from 0.10 to 0.85, the net benefit rate of the combined prediction model was higher than the two extreme strategies of "treat all" and "treat none," suggesting that this model can provide valuable reference for clinicians in making treatment decisions in clinical practice, effectively identifying high-risk patients and avoiding excessive intervention. [**Figure 2]**

Tab.1 Comparison of baseline data between two groups

Variable	Perforation group (n=20)	Non-perforation group (n=82)	t/χ^2 value	P value
Age (years, $\bar{x}\pm s$)	65.3±7.2	58.6±6.5	3.987	<0.001
Age ≥60 years [n(%)]	14(70.0)	28(34.2)	8.533	0.004
Gender (male/female, n)	12/8	49/33	0.012	0.984
Underlying diseases [n(%)]	9(45.0)	22(26.8)	2.509	0.113
Tumor diameter (cm, $\bar{x}\pm s$)	3.8±1.1	2.5±0.9	5.538	<0.001
Tumor diameter >3 cm [n(%)]	15(75.0)	20(24.4)	18.271	<0.001
Tumor location [n(%)]				
Upper gastric body	13(65.0)	25(30.5)	8.193	0.004
Other	7(35.0)	57(69.5)		
Pathological type [n(%)]				
Poorly differentiated adenocarcinoma	8(40.0)	10(12.2)	6.747	0.010
Other	12(60.0)	72(87.8)		
Surgical duration (min, $\bar{x}\pm s$)	135.6±25.8	98.5±18.3	7.459	<0.001
Surgical duration >120 min [n(%)]	16(80.0)	24(29.3)	17.360	<0.001
Operative difficulty (high/medium/low, n)	10/10	18/64	6.352	0.012

Tab.2 Multivariate logistic analysis of ESD perforation in early gastric cancer

Variable	β	SE	Wald	OR value	95%CI	P value
Tumor diameter >3 cm	1.269	0.354	12.850	3.557	1.777-7.120	<0.001
Tumor located in upper gastric body	1.062	0.368	8.328	2.892	1.406-5.949	0.004
Surgical duration >120 min	1.453	0.327	19.744	4.276	2.253-8.117	<0.001
Age ≥60 years	0.421	0.385	1.198	1.524	0.716-3.240	0.274
Poorly differentiated adenocarcinoma	0.513	0.412	1.551	1.670	0.745-3.744	0.212

Tab.3 Analysis of the diagnostic efficacy of the model

Variable	AUC	95%CI	Optimal cutoff value	Sensitivity (%)	Specificity (%)	Youden Index
Tumor diameter >3 cm	0.65	0.61-0.69	0.350	75.0	58.5	0.335
Tumor located in upper gastric body	0.60	0.56-0.64	0.320	65.0	59.8	0.248
Surgical duration >120 min	0.63	0.59-0.67	0.380	80.0	54.9	0.349
Combined model	0.86	0.80-0.92	0.423[a]	80.0	79.3	0.593

Note: [a] segmentation threshold of risk probability

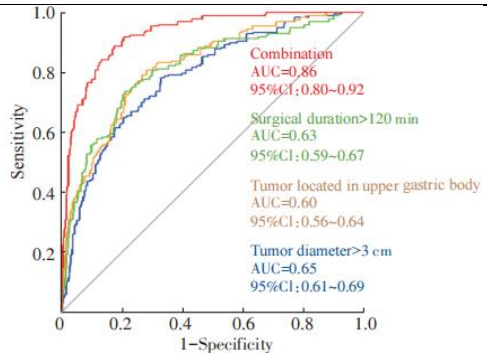

Fig.1 The ROC curves for the diagnostic efficacy of the model

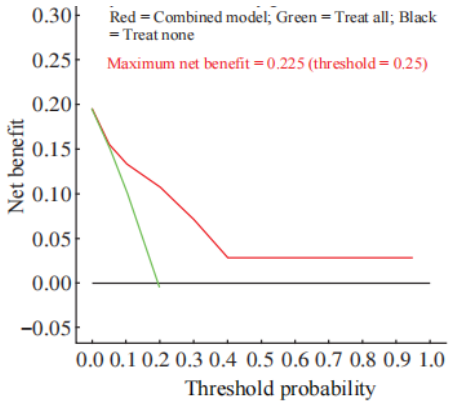

Fig.2 Clinical DCA of the joint prediction model

3 Discussion

ESD, as an important therapeutic approach for early gastric cancer, offers numerous advantages; however, perforation remains a critical complication affecting its safety and efficacy [8]. Univariate analysis in this study demonstrated that age ≥60 years, tumor diameter >3 cm, tumor location in the upper gastric body, pathological type of poorly differentiated adenocarcinoma, operative time >120 min, and high practical difficulty were significantly associated with the risk of ESD perforation. Age represents one of the important factors influencing surgical risk. Regarding patient characteristics, physiological function gradually declines with advancing age, accompanied by decreased tissue elasticity and repair capacity [9]. In patients ≥60 years, tissue of stomach wall may be more vulnerable, rendering it more susceptible to perforation during ESD procedures. This finding aligns with previous research, as multiple studies have demonstrated that elderly patients face higher complication risks when undergoing endoscopic surgery [10]. Tumor diameter is also a critical factor affecting perforation risk [11]. When tumor diameter > 3 cm, the surgical field expands, requiring more extensive tissue manipulation, thereby increasing the likelihood of perforation [12]. Larger tumors may exhibit tighter adhesion to surrounding tissues, and the separation process may damage the full thickness of the stomach wall, leading to perforation. Tumor location in the upper gastric body is associated with increased perforation risk. The upper gastric body has complex anatomical structures with important blood vessels and nerves distributed in close proximity, and the relatively confined operative space increases surgical difficulty and perforation risk [13]. Furthermore, the stomach wall at this location is relatively thin, making it more susceptible to perforation during manipulation. Poorly differentiated adenocarcinoma exhibits stronger invasiveness and metastatic potential. Its histological features result in unclear boundaries between the tumor and surrounding tissues, making accurate assessment of resection margins difficult during surgical excision, thus predisposing to perforation [14]. Additionally, poorly differentiated adenocarcinoma is characterized by active cellular proliferation and firm consistency, which may more easily cause stomach wall injury during separation. Operative time > 120 min is one of the risk factors for perforation. Prolonged surgical procedures may lead to operator fatigue, decreased attention, and reduced procedural precision, thereby increasing perforation risk [15]. Simultaneously, prolonged operative time may exacerbate patients' stress responses, affecting tissue blood supply and repair capacity, further increasing the probability of perforation.

Multivariate logistic regression analysis indicated that tumor diameter >3 cm, tumor location in the upper gastric body, and operative time >120 min were independent risk factors for perforation during ESD for early gastric cancer. The odds ratio for tumor diameter >3 cm was relatively high, indicating its significant impact on perforation risk. This suggests that clinicians should pay attention to tumor size during preoperative assessment. For tumors with larger diameters, perforation risk should be fully considered, and appropriate preventive measures should be formulated. More detailed preoperative imaging examinations can be performed to evaluate the relationship between the tumor and surrounding tissues, facilitating the development of more rational surgical plans. Tumor location in the upper gastric body is also an important independent risk factor. For such patients, surgeons should possess extensive experience and refined technical skills, exercising greater caution during procedures. Adjunctive techniques such as endoscopic ultrasound-guided manipulation may be employed to enhance surgical safety [16]. Operative time > 120 min also substantially impacts perforation risk. To reduce operative time, surgeons can ensure thorough preoperative preparation and familiarize themselves with patients' conditions and anatomical structures. During surgery, procedural steps should be rationally organized to improve efficiency. Additionally, team collaboration may be considered to reduce operator fatigue and enhance procedural precision [17].

The prediction model constructed based on the above independent risk factors demonstrated a combined prediction AUC of 0.86, with an optimal cutoff value of 0.423, sensitivity of 80.0%, specificity of 79.3%, and Youden index of 0.593. Hosmer-Lemeshow test indicated good model fit, suggesting that the model not only possesses good predictive accuracy but also ideal fitting performance, enabling relatively accurate prediction of perforation risk during ESD for early gastric cancer.

This prediction model has important application value. Preoperatively, clinicians can utilize this model to assess

patients' perforation risk based on tumor diameter, tumor location, and operative time. For high-risk patients, targeted preventive measures can be implemented, such as adjusting surgical plans and strengthening intraoperative monitoring to reduce perforation incidence [18]. For low-risk patients, surgical indications may be appropriately relaxed to improve the accessibility of ESD treatment. This model can also provide a basis for rational allocation of medical resources. High-risk patients can be assigned to experienced surgeons or operated in better-equipped operating rooms to enhance surgical safety. Simultaneously, unnecessary waste of medical resources can be reduced, improving healthcare efficiency [19-20]. DCA confirmed that the model demonstrated significant net benefit within the threshold probability range of 0.10-0.85, suggesting its high practical utility in clinical practice. Preoperatively, clinicians can calculate perforation risk probability through the model based on patients' baseline characteristics such as tumor diameter and tumor location, combined with estimated operative time. When the risk probability is ≥0.423, patients are classified as high-risk, and targeted preventive measures can be adopted, such as optimizing surgery, increasing intraoperative monitoring intensity, and arranging experienced operators to reduce perforation incidence. For low-risk patients with risk probability <0.423, ESD treatment can be routinely performed, avoiding excessive consumption of medical resources.

This study also has certain limitations. First, the sample size was relatively small, including only 102 patients, which may introduce some sampling error. Future studies could expand sample size and conduct multicenter research to improve the accuracy and reliability of the model. Second, this study only considered some factors that may affect perforation risk, and other unincorporated factors may influence perforation risk, such as patients' psychological status and intraoperative bleeding [21-22]. In subsequent studies, additional influencing factors could be further explored to refine the prediction model. The prediction model constructed in this study requires validation and optimization in broader clinical practice. The model can be applied to patients in different regions and hospitals to observe the stability and generalizability of its predictive performance. Simultaneously, based on feedback from practical applications, the model can be continuously adjusted and improved.

In conclusion, this study successfully constructed a perforation risk prediction model for ESD in early gastric cancer. The model incorporated independent risk factors including tumor diameter, tumor location, and operative time, demonstrating good predictive accuracy. This model provides a scientific basis for clinicians to assess surgical risk and formulate rational treatment plans, helping to reduce surgical perforation incidence and improve the safety and efficacy of ESD treatment.

Conflict of Interest None

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Submission Received 2025-04-30/**Revised** 2025-08-28

·消化道肿瘤专题·论著·

早期胃癌内镜黏膜下剥离术穿孔风险预测模型构建

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摘要：目的　构建早期胃癌内镜黏膜下剥离术（ESD）穿孔风险预测模型，为临床医生评估手术风险、制定合理治疗方案提供科学依据。**方法**　回顾性收集2024年1月至12月苏州大学附属第三医院接受ESD治疗的102例早期胃癌患者的临床资料，包括一般信息、肿瘤相关特征，以及手术相关指标。运用单因素分析筛选出与穿孔风险相关的因素，多因素logistic回归分析ESD穿孔的独立危险因素，并构建穿孔风险预测模型，通过受试者工作特征（ROC）曲线评估模型的预测效能。**结果**　102例患者中，穿孔组20例，非穿孔组82例。多因素logistic回归分析表明，肿瘤直径>3 cm、肿瘤位于胃体上部、手术时间>120 min是早期胃癌ESD穿孔的独立危险因素（*OR*=3.557，95%*CI*：1.777～7.120，*P*<0.01；*OR*=2.892，95%*CI*：1.406～5.949，*P*=0.004；*OR*=4.276，95%*CI*：2.253～8.117，*P*<0.01）。Hosmer-Lemeshow拟合优度检验结果显示该回归模型对数据的拟合效果良好（χ^2=6.328，*P*=0.612）。该模型联合因素对ESD穿孔风险预测的ROC曲线下面积（AUC）为0.86（95%*CI*：0.80~0.92），该模型具有良好的预测准确性。**结论**　本研究构建的早期胃癌ESD穿孔风险预测模型，纳入了肿瘤直径、肿瘤位置和手术时间等因素，能够较准确地预测ESD穿孔风险。

关键词：胃癌，早期；内镜黏膜下剥离术；穿孔风险；预测模型

中图分类号：R735.7　**文献标识码：**A　**文章编号：**1674-8182（2026）02-0183-05

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Abstract: Objective　To construct a risk prediction model for perforation during endoscopic submucosal dissection (ESD) in early gastric cancer, and to provide a scientific basis for clinicians to assess surgical risks and formulate reasonable treatment plans. **Methods**　Clinical data of 102 patients with early gastric cancer who underwent ESD treatment in the Third Affiliated Hospital of Soochow University from January to December 2024 were collected, including general information, tumor-related characteristics, and operation-related indicators. Univariate analysis and multivariate logistic regression analysis were used to identify related factors and independent risk factors, and a perforation risk prediction model was constructed. The predictive efficacy of the model was evaluated by receiver operating characteristic (ROC) curve. **Results**　Among the 102 patients, there were 20 cases in the perforation group and 82 cases in the non-perforation group. Multivariate logistic regression analysis showed that tumor diameter >3 cm, tumor located in the upper part of the gastric body, and operation time >120 min were independent risk factors for ESD-related perforation in early gastric cancer (*OR*=3.557, 95%*CI*: 1.777-7.120, *P*<0.01; *OR*=2.892, 95%*CI*: 1.406-5.949, *P*=0.004; *OR*=4.276, 95%*CI*: 2.253-8.117, *P*<0.01). Hosmer-Lemeshow goodness of fit test results showed that the regression model had a good fitting effect on the data (χ^2=6.328, *P*=0.612). The area under the ROC curve (AUC) for

DOI：10.13429/j.cnki.cjcr.2026.02.004

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出版日期：2026-02-20

QR code for English version

the combined factors in predicting the risk of ESD perforation was 0.86 (95%*CI*: 0.80-0.92), indicating good predictive accuracy. **Conclusion** The successfully constructed risk prediction model for ESD-related perforation in early gastric cancer incorporates independent risk factors such as tumor diameter, tumor location, and operation time. It can predict the perforation risk relatively accurately.

Keywords: Gastric cancer, early stage; Endoscopic submucosal dissection; Perforation risk; Prediction model

早期胃癌是指癌组织局限于胃黏膜层或黏膜下层，不论有无淋巴结转移[1]。近年来，随着内镜技术的发展，内镜黏膜下剥离术（endoscopic submucosal dissection，ESD）已成为治疗早期胃癌及癌前病变的重要手段[2-3]。与传统手术相比，ESD具有创伤小、恢复快、能完整切除病变等优点，可有效提高患者的生活质量和生存率[4]。然而，ESD作为一种侵入性操作，也存在一定的并发症风险，其中穿孔是较为严重的并发症，不仅增加患者的痛苦和医疗费用，甚至可能影响患者的预后[5]。穿孔的发生与多种因素相关，包括患者的个体特征、肿瘤的生物学行为以及手术操作的复杂性等[6]。

目前，临床上对于ESD穿孔风险的评估主要依赖医生的经验和主观判断，缺乏科学、准确的预测模型，手术前难以准确评估患者的穿孔风险，增加了手术的不确定性和风险[7]。因此，构建一个科学、准确的ESD穿孔风险预测模型具有重要的临床意义。通过该模型，临床医生可以在手术前对患者的穿孔风险进行量化评估，提前识别高风险患者，并采取针对性的预防措施，如调整手术方案、加强术中监测等，从而降低手术穿孔的发生率，提高ESD治疗的安全性和有效性，改善患者的预后。因此，本研究构建早期胃癌ESD穿孔风险预测模型，以期为临床实践提供有力的支持，推动早期胃癌ESD治疗向规范化和精准化方向发展。

1　对象与方法

1.1　研究对象　回顾性选取2024年1月至2024年12月苏州大学附属第三医院接受ESD治疗的102例早期胃癌患者作为研究对象。本研究经医院伦理委员会批准（伦理批号：CZYY-LL-25021）。

1.2　纳入标准　（1）经胃镜检查及病理组织学活检，确诊为早期胃癌，即癌组织局限于胃黏膜层或黏膜下层，不论有无淋巴结转移；（2）符合ESD治疗的手术适应证，包括但不限于病变直径较小、无明显溃疡、病变边界相对清晰等情况，且经过多学科会诊（包括消化内科、外科、病理科等专家）评估后采用ESD治疗；（3）患者或其家属充分了解ESD治疗的相关信息，包括手术过程、可能的并发症及预后等情况，并签署知情同意书。

1.3　排除标准　（1）存在严重的心肺功能障碍，如严重冠状动脉粥样硬化性心脏病（冠心病）、慢性阻塞性肺疾病急性发作期等，无法耐受ESD手术，或患有严重的肝肾功能不全，可能影响手术安全性及术后恢复；（2）存在凝血功能障碍，如血小板减少性紫癜、血友病等，或正在接受抗凝、抗血小板治疗且无法在手术前调整至安全范围，增加手术中出血及穿孔风险；（3）病变特征不符，肿瘤侵犯范围广泛，超出ESD可切除范围，或病变部位特殊，如靠近重要血管、神经等结构，手术操作难度极大且穿孔风险极高，以及存在远处转移的患者；（4）妊娠或哺乳期女性；（5）有精神疾病史，无法配合手术及相关检查；（6）临床资料不完整，无法获取足够信息用于分析。

1.4　资料收集

1.4.1　一般信息　（1）基本情况：年龄、性别、身高、体质量、身体质量指数（body mass index，BMI）等基本信息。（2）既往史：患者既往是否有胃部手术史、消化性溃疡病史、心血管疾病史、糖尿病史等基础疾病情况。（3）家族史：了解患者家族中是否有胃癌或其他恶性肿瘤的遗传病史。

1.4.2　肿瘤相关信息　（1）肿瘤大小：通过术前内镜超声、腹部CT等影像学检查，准确测量肿瘤的最大直径。（2）肿瘤部位：明确肿瘤在胃内的具体位置，如胃底、胃体、胃窦、贲门等部位，以及是否靠近胃的重要解剖结构，如幽门、贲门括约肌等。（3）病理类型：依据术后病理检查结果，确定肿瘤的病理类型。（4）组织学分级：评估肿瘤的组织学分级，判断肿瘤细胞的分化程度。

1.4.3　手术相关信息　通过医院电子病历系统（含手术记录单、麻醉记录单、术中护理记录）、内镜操作影像存档系统及病理检查报告，提取并核实以下信息。（1）手术时间：从内镜进入消化道开始操作至手术结束的总时间。（2）操作难度：由手术医生根据手术过程中的实际情况进行评估，如病变的边界清晰度、与周围组织的粘连程度、操作的复杂性等，分为高、中、低三个等级。（3）术中情况：术中是否出现出血、穿孔

等并发症，以及处理措施和效果。(4) 麻醉方式：手术所采用的麻醉方式。

1.5　统计学方法　采用SPSS 26.0和R语言软件分析数据和作图。符合正态分布的计量资料以 $\bar{x}\pm s$ 表示，比较采用独立样本 t 检验；计数资料以例(%)表示，采用 χ^2 检验。采用多因素 logistic 回归分析穿孔的独立影响因素，根据影响因素构建预测模型，采用受试者工作特征(receiver operating characteristic，ROC)曲线分析模型的预测效能。P<0.05 为差异有统计学意义。

2　结　果

2.1　基线数据分析　102 例患者中发生穿孔 20 例(穿孔组)，未发生穿孔 82 例(非穿孔组)。穿孔组患者年龄、肿瘤直径、胃体上部肿瘤占比、低分化腺癌占比、手术时间以及操作难度高比例高于非穿孔组，差异有统计学意义(P<0.05)。见表 1。

2.2　多因素 logistic 回归分析　单因素分析显示，年龄≥60 岁、肿瘤直径>3 cm、肿瘤位于胃体上部、低分化腺癌、手术时间>120 min、操作难度高与 ESD 穿孔风险显著相关(P<0.05)。多因素 logistic 回归分析表明，肿瘤直径>3 cm、肿瘤位于胃体上部、手术时间>120 min 是早期胃癌 ESD 穿孔的独立危险因素(P<0.05)，而年龄≥60 岁，病理类型-低分化腺癌等因素不是独立危险因素(P>0.05)。见表 2。模型拟合优度检验采用 Hosmer-Lemeshow 检验，结果显示 χ^2=6.328，P=0.612>0.05，提示该回归模型对数据的拟合效果良好，模型设定合理。

2.3　构建模型　基于这些因素构建的预测模型，曲线下面积(area under the curve，AUC)为 0.86(95%*CI*：0.80~0.92)，具有良好的预测准确性。通过 ROC 曲线分析确定联合预测模型的最佳临界值为 0.423，此时，模型的灵敏度为 80.0%，特异度为 79.3%，约登指数为 0.593。见表 3 和图 1。

2.4　决策曲线分析(decision curve analysis，DCA)　为评估模型的临床实用性，对联合预测模型进行 DCA。结果显示，当阈值概率在 0.10~0.85 范围内时，联合预测模型的净获益率高于“全部治疗”和“全部不治疗”两种极端策略，提示该模型在临床实践中能够为医生制定治疗决策提供有价值的参考，可有效识别高风险患者并避免过度干预。见图 2。

表 1　两组基线资料比较

Tab.1　Comparison of baseline data between two groups

项目	穿孔组(n=20)	非穿孔组(n=82)	t/χ^2值	P值
年龄(岁，$\bar{x}\pm s$)	65.3±7.2	58.6±6.5	3.987	<0.001
年龄≥60岁[例(%)]	14(70.0)	28(34.2)	8.533	0.004
性别(男/女，例)	12/8	49/33	0.012	0.984
基础疾病[例(%)]	9(45.0)	22(26.8)	2.509	0.113
肿瘤直径(cm，$\bar{x}\pm s$)	3.8±1.1	2.5±0.9	5.538	<0.001
肿瘤直径>3 cm[例(%)]	15(75.0)	20(24.4)	18.271	<0.001
肿瘤部位[例(%)]				
胃体上部	13(65.0)	25(30.5)	8.193	0.004
其他	7(35.0)	57(69.5)		
病理类型[例(%)]				
低分化腺癌	8(40.0)	10(12.2)	6.747	0.010
其他	12(60.0)	72(87.8)		
手术时间(min，$\bar{x}\pm s$)	135.6±25.8	98.5±18.3	7.892	<0.001
手术时间>120 min[例(%)]	16(80.0)	24(29.3)	17.360	<0.001
操作难度(高/中/低，例)	10/6/4	18/32/32	6.352	0.012

表 2　早期胃癌ESD穿孔的多因素logistic分析

Tab.2　Multivariate logistic analysis of ESD perforation in early gastric cancer

因素	β	SE	Wald	OR值	95%CI	P值
肿瘤直径>3 cm	1.269	0.354	12.850	3.557	1.777~7.120	<0.001
肿瘤位于胃体上部	1.062	0.368	8.328	2.892	1.406~5.949	0.004
手术时间>120 min	1.453	0.327	19.744	4.276	2.253~8.117	<0.001
年龄≥60 岁	0.421	0.385	1.198	1.524	0.716~3.240	0.274
病理类型-低分化腺癌	0.513	0.412	1.551	1.670	0.745~3.744	0.212

表 3　模型诊断效能分析

Tab.3　Analysis of the diagnostic efficacy of the model

因素	AUC	95%CI	最佳临界值	灵敏度(%)	特异度(%)	约登指数
肿瘤直径>3 cm	0.65	0.61~0.69	0.350	75.0	58.5	0.335
肿瘤位于胃体上部	0.60	0.56~0.64	0.320	65.0	59.8	0.248
手术时间>120 min	0.63	0.59~0.67	0.380	80.0	54.9	0.349
联合因素	0.86	0.80~0.92	0.423[a]	80.0	79.3	0.593

注：[a]风险概率的分割阈值。

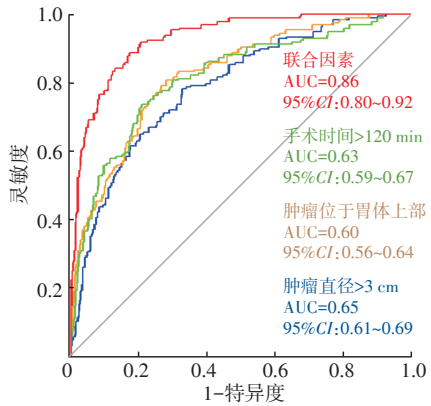

图 1　模型诊断效能的ROC曲线

Fig.1　The ROC curves for the diagnostic efficacy of the model

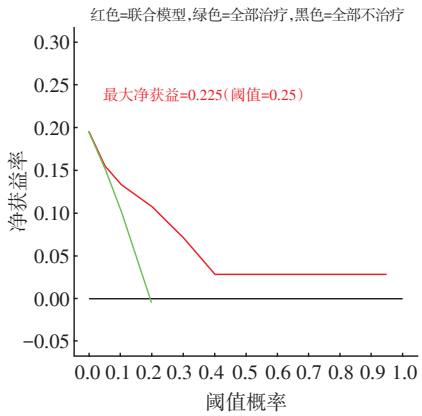

图2　联合预测模型的临床DCA

Fig.2　Clinical DCA of the joint prediction model

3　讨　论

ESD作为治疗早期胃癌的重要手段，虽具有诸多优势，但穿孔并发症仍是影响其安全性和有效性的关键问题[8]。本研究单因素分析显示，年龄≥60岁、肿瘤直径>3 cm、肿瘤位于胃体上部、病理类型为低分化腺癌、手术时间>120 min、操作难度高等因素与ESD穿孔风险显著相关。其中，年龄是影响手术风险的重要因素之一。在患者个体特征方面，随着年龄的增长，患者的身体机能逐渐衰退，组织弹性和修复能力下降[9]。60岁以上的患者，其胃壁组织可能更为脆弱，在ESD操作过程中更容易发生穿孔。这与以往的研究结果一致，多项研究表明高龄患者在接受内镜手术时面临更高的并发症风险[10]。肿瘤直径也是影响穿孔风险的关键因素[11]。肿瘤直径>3 cm时，手术操作范围增大，需要处理的组织更多，增加了穿孔的可能性[12]。较大的肿瘤可能与周围组织的粘连更为紧密，分离过程中容易损伤胃壁全层，导致穿孔。肿瘤位于胃体上部与穿孔风险增加相关。胃体上部的解剖结构较为复杂，周围有重要的血管和神经分布，手术操作空间相对狭小，增加了手术的难度和穿孔的风险[13]。此外，该部位的胃壁相对较薄，在操作过程中更容易发生穿孔。病理类型为低分化腺癌的肿瘤具有更强的侵袭性和转移潜能，其组织学特征使得肿瘤与周围组织的界限不清晰，手术切除时难以准确判断切除范围，容易导致穿孔[14]。低分化腺癌的细胞增殖活跃，质地较硬，在分离过程中也更容易引起胃壁的损伤。手术时间>120 min是穿孔的危险因素之一。长时间的手术操作会使医生疲劳，注意力下降，操作的精准度降低，从而增加穿孔的风险[15]。同时，手术时间过长也会增加患者的应激反应，影响组织的血供和修复能力，进一步增加穿孔的可能性。

多因素logistic回归分析表明，肿瘤直径>3 cm、肿瘤位于胃体上部、手术时间>120 min是早期胃癌ESD穿孔的独立危险因素。肿瘤直径>3 cm的优势比较高，说明其对穿孔风险的影响较为显著。这提示临床医生在术前评估时，应特别关注肿瘤的大小，对于直径较大的肿瘤，需充分考虑穿孔的风险，并制定相应的预防措施。可以在术前进行更详细的影像学检查，评估肿瘤与周围组织的关系，制定更合理的手术方案。肿瘤位于胃体上部也是重要的独立危险因素。针对此类患者，手术医生应具备更丰富的经验和精湛的技术，在操作过程中要更加谨慎。可以采用一些辅助技术，如超声内镜引导下操作，以提高手术的安全性[16]。手术时间>120 min同样对穿孔风险有较大影响。为了缩短手术时间，医生可以在术前做好充分的准备工作，熟悉患者的病情和解剖结构。在手术过程中，合理安排操作步骤，提高操作效率。同时，也可以考虑采用团队协作的方式，减少医生的疲劳，提高手术的精准度[17]。

基于上述独立危险因素构建的预测模型，联合预测的AUC为0.86，最佳临界值为0.423，灵敏度80.0%，特异度79.3%，约登指数0.593，且Hosmer-Lemeshow检验显示模型拟合良好，表明该模型不仅具有良好的预测准确性，且拟合效果理想，能够较为准确地预测早期胃癌ESD穿孔的风险。在临床实践中，该预测模型具有重要的应用价值。术前，临床医生可以根据患者的肿瘤直径、肿瘤位置和手术时间等因素，利用该模型评估患者的穿孔风险。对于高风险患者，可以采取针对性的预防措施，如调整手术方案、加强术中监测等，以降低穿孔的发生率[18]。对于低风险患者，可以适当放宽手术指征，提高ESD治疗的可及性。该模型还可以为医疗资源的合理分配提供依据。对于高风险患者，可以安排经验丰富的医生进行手术，或者在设备更齐全的手术室进行操作，以提高手术的安全性。同时，也可以减少不必要的医疗资源浪费，提高医疗效率[19-20]。DCA进一步证实，该模型在0.10~0.85的阈值概率范围内具有显著的净获益，提示其在临床实践中具有较高的实用性。术前，临床医生可根据患者的肿瘤直径、肿瘤位置等基线特征，结合预估手术时间，通过模型计算穿孔风险概率。当风险概率≥0.423时，判定为高风险患者，可采取针对性的预防措施，如优化手术方案、增加术中监测强度、安排经验丰富的术者操作等，以降低穿孔发生率；对于风险概率<0.423的低风险患

者，可常规实施 ESD 治疗，避免过度医疗资源消耗。

本研究也存在一定的局限性。首先，研究样本量相对较小，仅纳入了 102 例患者，可能存在一定的抽样误差。未来可以扩大样本量，进行多中心的研究，以提高模型的准确性和可靠性。其次，本研究仅考虑了部分可能影响穿孔风险的因素，可能还有其他未被纳入的因素对穿孔风险有影响。例如，患者的心理状态、术中的出血情况等[21-22]。在后续的研究中，可以进一步探索更多的影响因素，完善预测模型。本研究构建的预测模型还需要在更多的临床实践中进行验证和优化。可以将模型应用于不同地区、不同医院的患者，观察其预测效能的稳定性和普遍性。同时，根据实际应用中的反馈，对模型进行不断的调整和改进。

综上所述，本研究成功构建了早期胃癌 ESD 穿孔风险预测模型，该模型纳入了肿瘤直径、肿瘤位置和手术时间等独立危险因素，具有良好的预测准确性。该模型为临床医生评估手术风险、制定合理治疗方案提供了科学依据，有助于降低手术穿孔发生率，提高 ESD 治疗的安全性和有效性。

利益冲突　无

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收稿日期：2025-04-30　**修回日期**：2025-08-28　**编辑**：王宇