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RESEARCH

Development and validation of a predictive model for failure of ureteral access sheath placement in patients with ureteral calculi

Di Luo[1†], Jingdong Zhang[1†], Linguo Xie[1†], Rui Wang[1], Haotian Ren[1], Zhiqun Shang[1], Chunpeng Li[1] and Chunyu Liu[1*]

Abstract

Objective The Ureteral Access Sheath (UAS) has notable benefits but may fail to traverse the ureter in some cases. Our objective was to develop and validate a dynamic online nomogram for patients with ureteral stones who experienced UAS placement failure during retrograde intrarenal surgery (RIRS).

Methods This study is a retrospective cohort analysis using medical records from the Second Hospital of Tianjin Medical University. We reviewed the records of patients with ureteral stones who underwent RIRS in 2022 to identify risk factors associated with UAS placement failure. Lasso combined logistic regression was utilized to identify independent risk factors associated with unsuccessful UAS placement in individuals with ureteral stones. Subsequently, a nomogram model was developed to predict the likelihood of failed UAS placement in this patient cohort. The model's performance was assessed through Receiver Operating Characteristic Curve (ROC) analysis, calibration curve assessment, and Decision Curve Analysis (DCA).

Results Significant independent risk factors for unsuccessful UAS placement in patients with ureteral stones included age (OR = 0.95, $P < 0.001$), male gender (OR = 2.15, $P = 0.017$), body mass index (BMI) (OR = 1.12, $P < 0.001$), history of stone evacuation (OR = 0.35, $P = 0.014$), and ureteral stone diameter (OR = 0.23, $P < 0.001$). A nomogram was constructed based on these variables. Model validation demonstrated an area under the ROC curve of 0.789, indicating good discrimination. The calibration curve exhibited strong agreement, and the decision curve analysis revealed a favorable net clinical benefit for the model.

Conclusions Young age, male sex, high BMI, no history of stone evacuation, and small diameter of ureteral stones were independent risk factors for failure of UAS placement in patients with ureteral stones, and the dynamic nomogram established with these 5 factors was clinically effective in predicting the outcome of UAS placement.

Keywords Ureteral access sheath, Dynamic nomogram, Risk factors, Retrograde intrarenal surgery, LASSO regression

† Di Luo, Jingdong Zhang and Linguo Xie contributed equally to this work.

*Correspondence:
Chunyu Liu
liuchunyu@tmu.edu.cn
[1] Department of urology, Tianjin institute of urology, The Second Hospital of Tianjin Medical University, 23 Pingjiang Road, Hexi District, Tianjin 300000, People's Republic of China

Introduction

Retrograde intrarenal surgery (RIRS) is currently one of the first-line options for the treatment of kidney stones and/or ureteral stones up to 2 cm in diameter [1]. The ureteral access sheath (UAS) is an important adjunct in RIRS [2]. The intervention of the UAS facilitates repeated access to the ureter during the procedure and therefore reduces operative time, improves stone clearance and reduces postoperative complications [2, 3]. In addition, UAS improves the visibility of the surgical operation and maintains relatively low intrarenal pressure [4].

Despite the advantages of UAS, a small number of patients fail to undergo RIRS due to ureteral stricture or other reasons for failure of UAS placement and are left with a ureteral stent for 2–4 weeks awaiting a second-stage procedure. Studies have shown that placing a ureteral stent before RIRS can greatly improve the success rate of RIRS [5], Intraoperative damage to the ureter is also reduced [6], it has also been found that placing the ureter a week earlier in an animal model can greatly increase the circumference of the ureteral lumen [7]. However, the European Association of Urology (EAU) guidelines do not recommend routine preoperative indwelling ureteral stents [8]. Hence, it is essential to identify preoperative factors associated with the failure of initial ureteral access sheath (UAS) treatment. Although previous studies have identified one or more clinical factors to predict the outcome of UAS placement, joint analyses incorporating multiple clinical factors into multivariate predictive models have not been performed [9–14].

In the era of personalized medicine, nomograms, statistical tools, empower patients to visualize disease risk, considering multiple factors. They offer personalized assessment, ease of use, and simple interpretation. Dynamic online nomograms, fusing web interactivity with classic models, bolster clinical decision-making, exhibiting robust predictive power for disease & cancer prognosis.

Therefore, we analyzed a consecutive cohort of patients to identify the variables that provided the highest discriminatory power. We hypothesized that this approach would lead to the development of a dynamic online nomogram that could accurately predict the risk of failure of UAS placement by a number of preoperative clinical indicators, thus pre-positioning the ureteral stenting tube and avoiding direct one-stage general anesthesia procedures.

Materials and methods

Informed consent

was not required for this study because this study is retrospective research. All protocols received approval from the Ethics Committee of the Second Hospital of Tianjin Medical University and were conducted in accordance with its regulations and guidelines (KY2024K004).

We retrospectively analyzed the medical records and stone characteristics of 1078 patients with ureteral stones who underwent RIRS between January 2022 and December 2022 at our center. Patients underwent screening based on specified inclusion and exclusion criteria. Inclusion Criteria: (1) CT confirmed diagnosis of urinary stones requiring RIRS treatment. (2) 11/13F UAS was used to perform the procedure. (3) Participants aged over 18 years were included, with exclusion criteria based on absence of physiological or anatomical abnormalities such as isolated kidneys, horseshoe kidneys, or giant ureter disease. Exclusion criteria: (1) Preoperative ureteral stenting. (2) Patients with simple kidney and bladder stones or without ureteral stones. (3) Patients who had undergone previous surgery in the ureteral region. A total of 794 patients were included in the study after screening.

Collection of patient information and stone characteristics

This study was divided into success and failure groups based on 11/13F UAS placement results. Clinical factors included in the analysis included: age, gender, BMI, underlying disease (diabetes, hypertension, coronary artery disease, cerebral infarction), symptoms (low back pain, hematuria, fever), extracorporeal lithotripsy treatment, history of lithotripsy, stone-related characteristics (size, side, upper and lower segments), degree of hydronephrosis, and results of urine culture. Definition of UAS placement failure in stage I RIRS: (1) Difficulty with guidewire-guided F8 ureteroscopy, with a pronounced sense of holding the mirror and a high risk of ureteral injury. (2) Failure to insert the UAS in 11/13F after predilatation with a flexible core in the sheath.

Statistical methodology

The study population was divided into success and failure groups based on the success or failure of UAS placement. For numerical variables, the student t-test was used if the data distribution conformed to normal distribution, described by mean and standard deviation, and the Mann-Whitney U test was used if the data distribution did not conform to normal distribution, described by median and interquartile spacing. Categorical variables were assessed using either the chi-square test or Fisher's exact test and presented as frequencies and percentages.

For the construction of the predictive model, Lasso regression was used for the initial screening of study variables, and all resulting study variables with non-zero coefficients were included in a multifactorial Logistic regression and independent risk factors for failure of UAS placement were identified. An interactive web-based dynamic nomogram application for visualizing and subsequently validating and evaluating predictive model results via R software was built with Shiny version 0.13.2.26. The discriminatory power of the predictive model was assessed by plotting the Receiver Operator Characteristic Curve (ROC) and calculating the Area Under the Curve (AUC); the calibration of the model was evaluated by plotting the Calibration curve; and the clinical usefulness of the predictive model was analyzed by plotting the clinical usefulness of the prediction model was analyzed by drawing the Decision Curve Analysis (DCA). Statistical significance was defined as $P<0.05$ by two-sided test. Data were analyzed using IBM SPSS Statistics Version 25.0 (IBM Corp., Armonk, NK, USA) and R version 4.2.3 (http://www.r-project.org).

Table 1 Characteristics of included patients

Variable	Total (*n*=794)	Success to insert UAS (*n*=709)	Failed to insert UAS (*n*=85)	*P* value
Age, Mean ± SD	54.21 ± 12.69	55.22 ± 12.23	45.82 ± 13.40	< 0.001[t]
BMI, Mean ± SD	26.49 ± 4.05	26.22 ± 3.90	28.68 ± 4.59	< 0.001[t]
Gender, n (%)				0.010[x]
Female	236 (29.72)	221 (31.17)	15 (17.65)	
Male	558 (70.28)	488 (68.83)	70 (82.35)	
DM, n (%)	193 (24.31)	172 (24.26)	21 (24.71)	0.928[x]
HT, n (%)	365 (45.97)	327 (46.12)	38 (44.71)	0.805[x]
CHD, n (%)	84 (10.58)	77 (10.86)	7 (8.24)	0.457[x]
CI, n (%)	38 (4.79)	33 (4.65)	5 (5.88)	0.816[x]
History of lithotripsy, n (%)	136 (17.13)	129 (18.19)	7 (8.24)	0.021[x]
No	658 (82.87)	580 (81.81)	78 (91.76)	
Yes	136 (17.13)	129 (18.19)	7 (8.24)	
ESWL, n (%)				0.113[x]
No	588 (74.06)	519 (73.20)	69 (81.18)	
Yes	206 (25.94)	190 (26.80)	16 (18.82)	
Lumbago, n (%)	466 (58.69)	412 (58.11)	54 (63.53)	0.338[x]
Hematuria, n (%)	257 (32.37)	227 (32.02)	30 (35.29)	0.542[x]
Fever, n (%)	167 (21.03)	147 (20.73)	20 (23.53)	0.550[x]
Location of ureteral stones, n (%)				0.748[x]
Upper segment	619 (78.65)	551 (78.49)	68 (80.00)	
Lower segment	168 (21.35)	151 (21.51)	17 (20.00)	
Lateral				0.858[x]
Left	432(50.59)	371(52.33)	45(52.94)	
Right	392(49.41)	338(47.67)	40(47.06)	
Diameter of ureteral stone, Mean ± SD	14.7 ± 0.50	15.1 ± 0.49	12.6 ± 0.49	< 0.001[t]
Degree of n (%) (hydronephrosis)				0.825[x]
None	59 (7.43)	53 (7.48)	6 (7.06)	
Mildly	454 (57.18)	404 (56.98)	50 (58.82)	
Moderately	247 (31.11)	220 (31.03)	27 (31.76)	
Seriously	34 (4.28)	32 (4.51)	2 (2.35)	
UC, n (%)				0.786[x]
Negative	674 (84.89)	601 (84.77)	73 (85.88)	
Positive	120 (15.11)	108 (15.23)	12 (14.12)	

Continuous variables with a normal distribution are reported as the mean ± standard deviation (SD); categorical variables are reported as the number (percentage). Student's t-test was used to compare the means of two continuous normally distributed variables. A chi-squared test or Fisher's exact test were used for categorical variables. [t] Student t test; [m] Mann-Whitney U test; [x] Chi-square test. BMI, body mass index; CAD, coronary artery disease; CI, Cerebral infarction; DM, diabetes mellitus; HT, hypertension; ESWL, Extra-Corporeal Shock Wave Lithotripsy; UC, urine culture

Results

Comparison of patient data and stone characteristics

Out of 1078 inpatients requiring RIRS for ureteral calculi, 794 patients were enrolled in this study and UAS placement failed in 85 (10.71%) patients. Among them, the proportion of males (82.35% versus 68.83%, $P=0.010$) and mean BMI (28.68 versus 26.22 kg/m2, $P<0.001$) were significantly higher in the failure group than in the success group. The mean age (45.82 versus 55.22 years, $P<0.001$), mean ureteral stone size (12.6 mm versus 15.1 mm, $P<0.001$), and history of lithotripsy (7.24% versus 18.19%, $P=0.021$) in the failure group were significantly lower than those in the success group (Table 1).

Predictive modelling and evaluation

Lasso regression was used for the initial screening of the results of the one-way analyses, and the coefficient of contraction of the variables was plotted (Fig. 1A) and cross-validated graphs (Fig. 1B). According to the results obtained from the cross-validation, the Lambda value (Lambda.min) corresponding to the smallest model error is 0.002064728, all five variables have non-zero coefficients in the Lasso regression analysis (Fig. 1C) and the correlation heatmap shows that there is no multicollinearity among the five factors (Fig. 1D).

Variables screened by Lasso regression were subsequently included in a multifactorial logistic regression to determine independent risk factors. The results showed that older age ($P<0.001$, OR: 0.95, 95% CI: 0.93–0.97) and history of lithotripsy ($P=0.014$, OR: 0.35, 95% CI: 0.15–0.81) were the protective factors for the success of UAS placement; whereas, men ($P=0.017$, OR: 2.15, 95% CI: 1.15–3.02), high BMI ($P<0.001$, OR: 1.12, 95% CI: 1.06–1.18) and small diameter of ureteral stone ($P<0.001$, OR: 0.23, 95% CI: 0.12–0.43) were the risk factors for failure of UAS placement (Table 2). We then visualized the influence of each factor on the outcome (Fig. 2).

We then used R software to fit the independent risk factors into a nomogram to quantitatively assess the probability of UAS placement failure (Fig. 3A), and then built up a dynamic web-based online nomogram (Fig. 3B), which can be accessed at https://ydeyjs.shinyapps.io/dynnomapp by using this prediction program. By plotting the ROC curve, the AUC was 0.789 (95% CI 0.736), indicating that the model was well discriminated (Fig. 4A). By plotting the ROC curve, the AUC was 0.789 (95% CI:

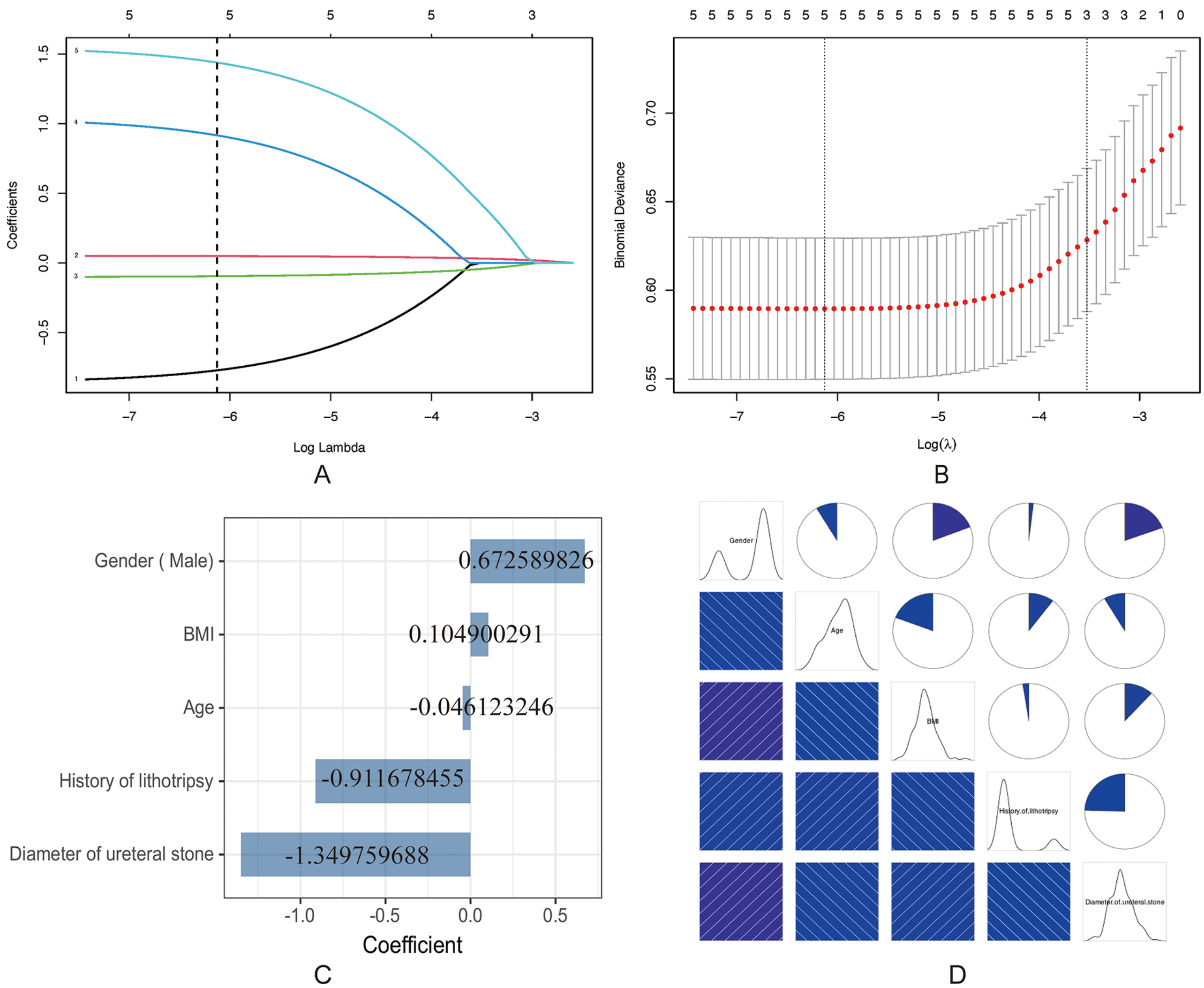

Fig. 1 Variable selection using LASSO regression models. **(A)** The adjustment parameter (λ) in the LASSO model was selected using 10-fold cross-validation via the minimum criterion. The lower horizontal coordinate indicates the logarithmic value of λ, and the upper horizontal coordinate indicates the number of variables with non-zero regression coefficients that entered the model. **(B)** LASSO coefficient curves for the five potential predictors. **(C)** Coefficient coefficients for each of the LASSO regression terms. (D) Visualization of the correlation between all variables in the LASSO model, with the area of the sector representing the magnitude of the correlation

Table 2 Multivariate logistic regression analysis of risk factors

Variables	Beta	SE	Z	*P*	OR (95%CI)
Age	-0.05	0.01	-4.83	< 0.001	0.95 (0.93–0.97)
BMI	0.11	0.03	3.81	< 0.001	1.12 (1.06–1.18)
Diameter of ureteral stone	-1.47	0.32	-4.61	< 0.001	0.23 (0.12–0.43)
Gender					
Female					1.00 (Reference)
Male	0.76	0.32	2.39	0.017	2.15 (1.15–3.02)
History of lithotripsy					
No					1.00 (Reference)
Yes	-1.04	0.42	-2.45	0.014	0.35 (0.15–0.81)

0.736–0.842), which indicated that the model had good discriminatory power (Fig. 4A), and the calibration curve (Fig. 4B) demonstrated that the predicted probabilities were sufficiently consistent with the actual observations. In addition, the results of the decision curve analysis (Fig. 4C) showed sufficient net clinical benefit, indicating that the model has good application value.

Discussion

Previous studies have shown that the incidence of experiencing difficulty with UAS placement during an initial ureteroscopy is 8–10% [15], the incidence of failure of 11/13F UAS placement in patients with ureteral stones in our center was 10.71%. We efficiently screened five independent risk predictors by Lasso combined Logistic regression. These predictors included age, gender, BMI, history of stone evacuation, and ureteral stone diameter. A nomogram based on these factors showed good

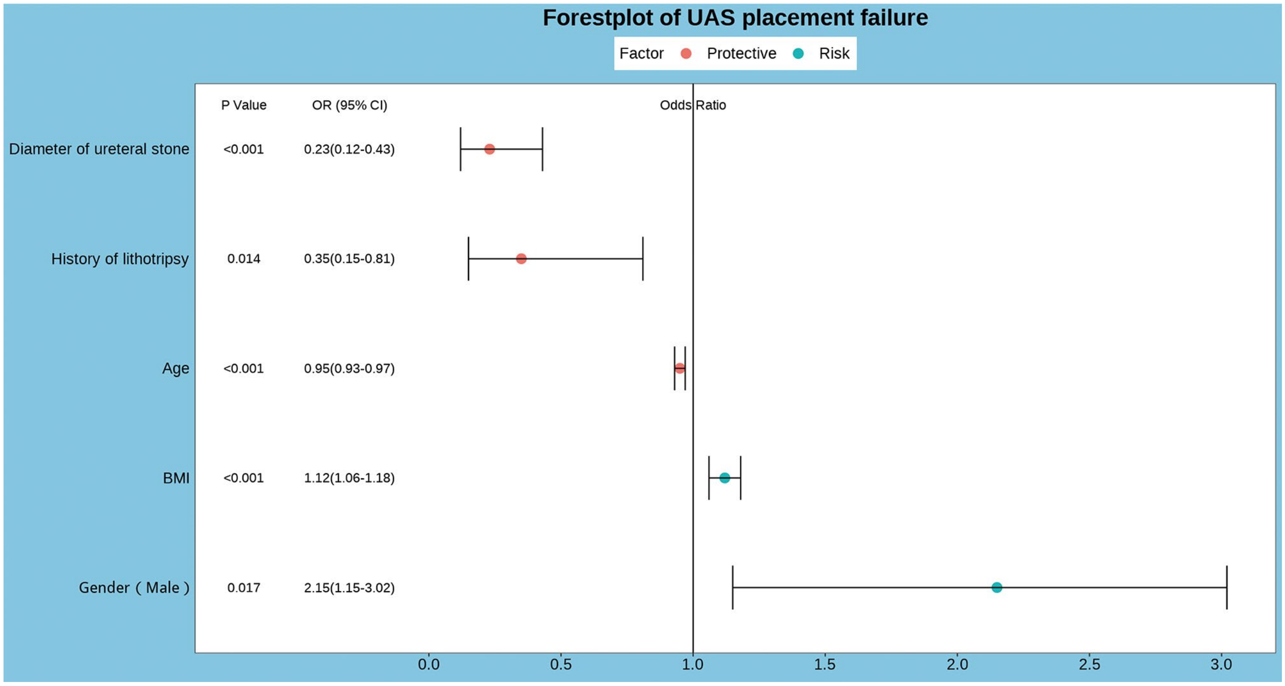

Fig. 2 Forest plot of UAS placement failure

predictive power and can be used as a tool to quantitatively assess the failure rate of UAS placement.

As with some of the previous studies, we found a higher failure rate of UAS placement in male, younger such patients. This may be related to the mechanical characteristics of the ureter itself [16]. It has been found that with age, the ureter undergoes remodeling secondary to histomorphometry changes, mainly consisting of an increase in ureteral circumference, wall thickness, length and Cross-Sectional Area (CSA) [17, 18]. At the same time, it was found that UAS insertion force (UASIF) increased with increasing dilator or access sheath size, and some variations could be observed according to age and gender; for example, a decrease in median maximal UASIF at the PUJ and VUJ was observed in patients aged>70 years, and lower median maximal UASIF at the PUJ in women than in men was reported [19, 20]. In our center's study, a significant difference in the history of stone removal between the two groups could be seen, with patients in the failed UAS placement group having a much lower rate of previous stone removal than those in the successful UAS placement group. This result is consistent with the conclusions obtained by Kevin Morgan et al. in predicting failure of ureteroscopy without stent placement, who concluded that previous stone evacuation and distal ureteral stone location correlate with successful microscopy, whereas proximal ureteral stone location correlates with failure of microscopy [13]. However, in our study, the size of the ureteral stone was more predictive than the location of the ureteral stone, and the proportion of such patients with smaller ureteral stones combined with failure to evacuate was much higher in the failure group than in the success group, which is consistent with the results of the study of Taguchi et al., who also concluded that male sex and smaller stone diameter were important predictors of ureteral stricture [12]. Our study found a mean BMI of 28.68 kg/m2 in the failure group, which definitely indicates a higher rate of obesity in patients in the failure group. Studies have shown that obesity leads to changes in the diameter of the ureter and that excess body fat exerts pressure on the kidneys, leading to an increase in their size, and this increase leads to pressure on neighboring structures, including the ureter [21]. In their assessment of the incidence of intraoperative challenges faced by overweight patients with ureteral and renal stones during retrograde ureteroscopy, Abdolsalam Ahmadi et al. found that the percentage of unsuccessful ureteroscopies due to ureteral orifice stenosis was significantly higher in the overweight group than in the normal body group, while the stone clearance rate was slightly lower in the overweight group than in the normal body group [14].

Although the probability of UAS placement failure is around 10%, given the large and growing number of patients requiring RIRS, it is necessary to develop a model that quantitatively evaluates ureteral placement failures to identify those patients who are prone to UAS placement failures, so that they can avoid direct one-stage general anesthesia procedures and reduce the cost and discomfort of treatment for patients. Dynamic online

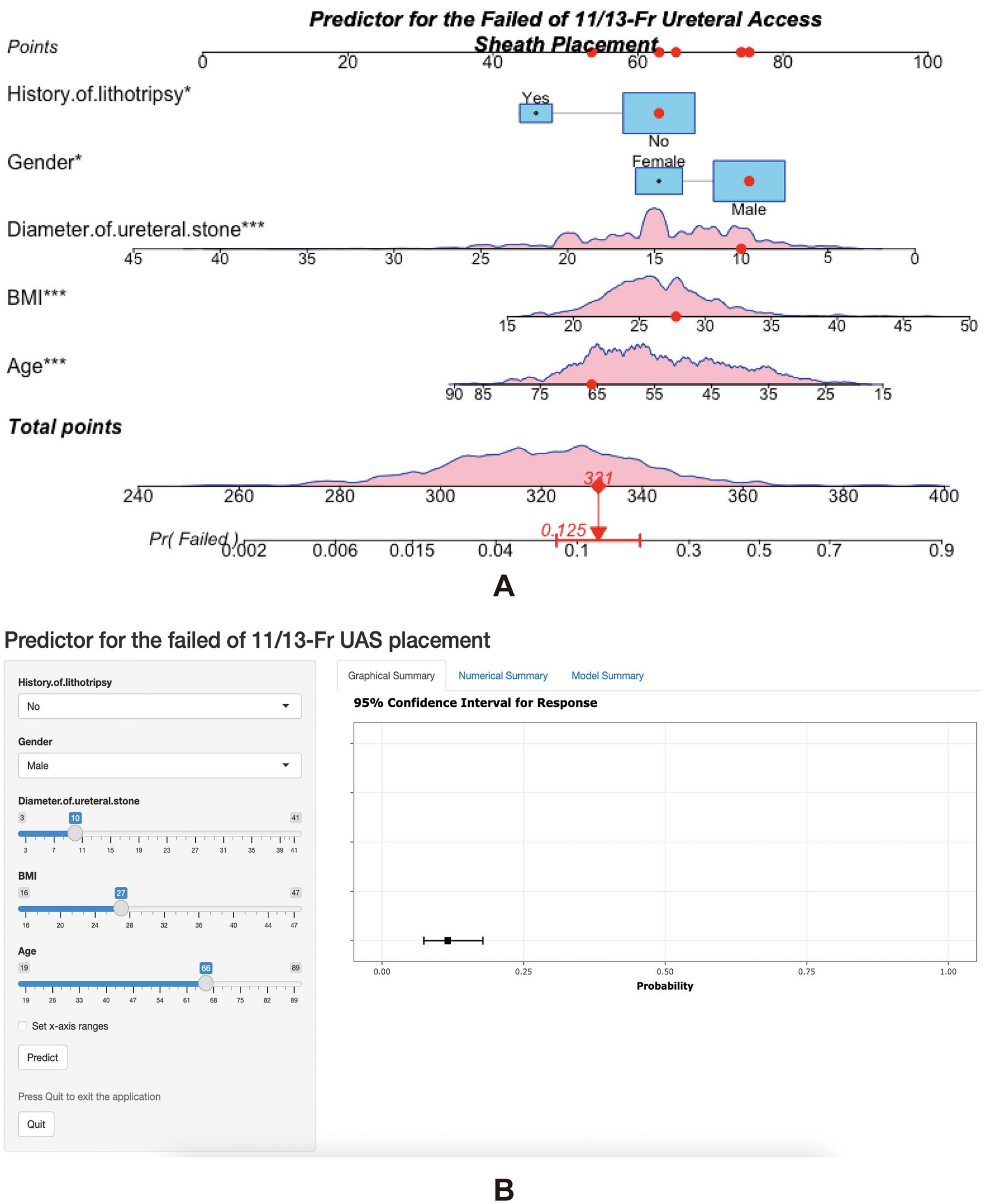

Fig. 3 **(A)** Nomograms are used to predict the probability of UAS placement failure. Each variable has matching points assigned to a given variable size, and after calculating the total score, a score for the risk of UAS placement failure can be found. **(B)** The probability of UAS placement failure can be found at https://ydeyjs.shinyapps.io/dynnomapp, the programmer can automatically give specific predicted probabilities

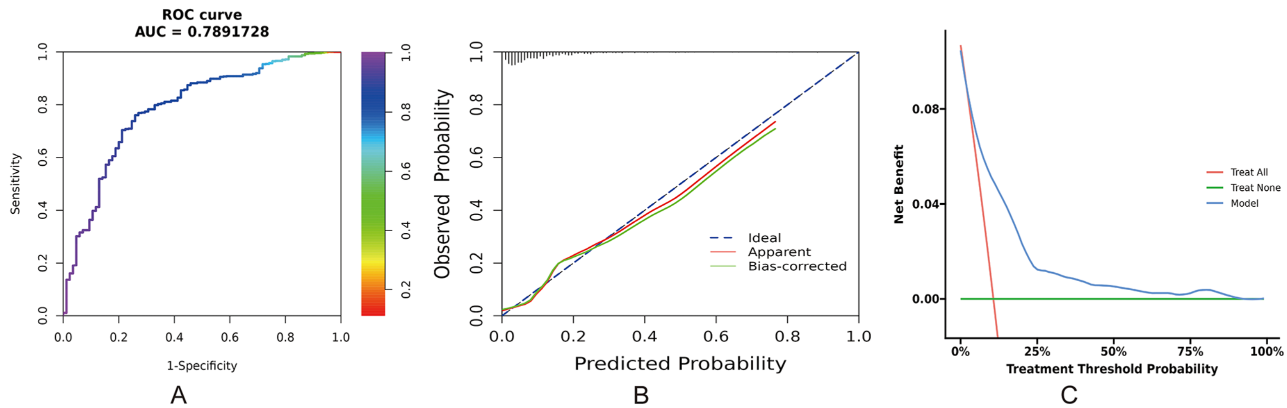

Fig. 4 **(A)** Subject operating characteristic curve for evaluating the column-line graph. the area under the ROC curve is 0.789, which indicates that the model has good discriminatory power. **(B)** Calibration curves for predicting nomograms. x-axis and y-axis indicate the predicted and actual probability of delayed bleeding after polypectomy, respectively. **(C)** Decision curve analysis of the predicted nomogram. x-axis and y-axis represent the net benefit and high-risk threshold, respectively

nomograms have demonstrated significant utility in predicting disease onset and cancer prognosis. For instance, Xueyi Miao et al. utilized dynamic online nomograms to forecast the trajectory of frailty in elderly gastric cancer patients one-year post-operation [22]. Xue Zhang et al. developed a personalized treatment approach through a dynamic columnar plot to predict severe mycoplasma pneumonia risk in children [23]. Dongzhou Zhuang et al. conducted a retrospective analysis of 937 patients who underwent traumatic decompressive craniotomy, employing various machine learning models to compare with logistic regression models and assess factor importance. They subsequently developed a dynamic nomogram for predicting IOBB, available online as a simple calculator [24]. Additionally, Lingqian Zhao et al. employed dynamic online nomograms to stratify preoperative risk in patients with papillary thyroid cancer≤1 cm based on preoperative blood inflammatory markers [25]. This underscores the broad clinical applicability of dynamic online nomograms in disease diagnosis, preoperative assessment, and treatment prognosis. To our knowledge, this study represents the first effort to construct a predictive model using dynamic online nomograms for the failure of ureteral access sheath placement in patients with ureteral stones.

Our model has several advantages: (1) The parameters needed for the model are simple and easy to obtain, and clinicians can easily obtain them from the healthcare system. (2) The stability of the parameters in the model is good, with high consistency of values between different measurers, and no significant changes in a short period of time to affect the judgement of the results. (3) The model is simple and involves only 5 parameters, which can be obtained through consultation and imaging data. (4) This dynamic prediction procedure is more clinically useful than the traditional nomogram.

Despite all the advantages of the model, it is not without its limitations. Firstly, this is a retrospective study, which cannot avoid the inherent flaws of retrospective studies. Secondly some of the patients' history taking, such as the patient's past history of stone removal and alcohol consumption, based on the patient's recollection, may have some deviation from the facts. At the same time, studies have shown that drug administration affects ureteral relaxation, which has been documented in clinical phenomena and basic experiments [20, 26, 27], it has also been shown that ureteral stenosis can be accurately predicted by CT measurement of the corresponding ureteral parameters [28, 29]. We did not statistically analyze drug administration and did not introduce ureter-related parameters. This may affect the results of our experiment. Next, we will introduce all the factors that may affect and expand the amount of data to make our model more effective in predicting the results.

Conclusions

Young age, male sex, high BMI, no history of stone evacuation, and small diameter of ureteral stones were independent risk factors for failure of UAS placement in patients with ureteral stones, and the nomogram established with these 5 factors was clinically effective in predicting the outcome of UAS placement.

Abbreviations

UAS	Ureteral access sheath
RIRS	Retrograde intrarenal surgery
BMI	Body mass index
CAD	Coronary artery disease
CI	Cerebral infarction
DM	Diabetes mellitus
HT	Hypertension
ROC	Receiver Operating Characteristic Curve
DCA	Decision Curve Analysis
CAS	Cross-Sectional Area

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Author contributions
LD, ZJD and XLG collected the patients' information. LD and WR wrote the manuscript and participated in the design of the study, RHT, LCP and SZQ performed the statistical analysis. LCY conceived of the study and participated in its design and coordination. All authors read and approved the final manuscript.

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Data availability
Dataset generated and/or analyzed during the current study is included in this published article. Remaining data is available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Informed consent was not required for this study because this study is retrospective research. All protocols received approval from the Ethics Committee of the Second Hospital of Tianjin Medical University and were conducted in accordance with its regulations and guidelines (KY2024K004).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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