Original Article

Nomogram for preoperative estimation of prognosis after retropubic tension free vaginal tape in female patients with stress urinary incontinence

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Background: To identify risk factors by developing a nomogram for predicting surgical outcomes for female patients who underwent tension free vaginal tape (TVT) for stress urinary incontinence (SUI).

Methods: Data on 365 patients with pure SUI who underwent TVT at the Shanghai General Hospital between February, 2017 and July, 2018, were retrospectively collected. Within this group, symptoms of patients who were found to have disappeared or have been improved (subjective success group) were compared with symptoms of those patients who were found to have no change or recurrence (subjective failure group). We evaluated the effect of treatment after TVT surgery on SUI patients based upon patient prognosis.

Results: During the study period, 327 women underwent TVT surgery and met the qualifications for inclusion in six-month follow-up consultations and 38 patients were lost. Multivariable logistic regression analysis of risk factors that were important in relation to the failure of surgery indicated two independent predictors: total cholesterol (TC) (P=0.005) and maximal urethral closure pressure (MUCP) (P=0.028). We developed a nomogram to predict prognosis after TVT in female patients with SUI using these parameters.

Conclusions: We developed a predictive model for preoperative estimation of prognosis in female patients who underwent TVT based treatment for SUI. This model could select patients who were found to have successful postoperative outcomes, which can lead to a rational therapeutic choice.

Keywords: Nomogram; prognosis; stress urinary incontinence (SUI); tension-free vaginal tape (TVT)

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Introduction

Urinary incontinence is one of the most common of chronic diseases that impact women, and stress urinary incontinence (SUI) is the most common type of this affliction. The incidence of SUI in women is dependent upon age and ranges from around 29–75%, with an average of 48% (1,2). Although SUI is a relatively common affliction, it can seriously impact private and public aspects of quality of life, including such as work, sleep, psychological health, physical health, and sexual functions.

There are many treatment options for patients afflicted by SUI. Pelvic floor exercise is the preferred and most used first-line treatment for SUI. If conservative measures such as this type of approach have failed, there are several surgical options for the treatment of SUI which are available. According to the update of the International Consultation on incontinence guidelines from 2013, surgically based treatments for SUI include bulking agents, midurethral slings, and colpo suspension. Tension-free midurethral sling is a sometimes-preferred approach as it has the advantages of stable efficacy, less damage, and fewer potential complications (3,4). Currently, the common treatment approach for SUI in China is to use tension free vaginal tape (TVT) and tension-TVT-obturator (TVT-O) (5-7), and in our hospital, TVT has been the most used approach to treat SUI for nearly the last 20 years.

Little research has closely examined factors affecting the prognosis of patients with SUI undergoing TVT surgery. Patients who were predicted to have failure postoperative outcomes are suitable candidates for studies on a carefully adjusted sling tension during TVT surgery or giving up surgery directly. Predicting the outcome of TVT is important for the appropriate counselling of the patient about to undergo surgery (8). The treatment of SUI aims an improvement of the patient's quality of life, therefore, one of the most important issues of the therapy is to meet the patient's expectations. Considering what is usually a relatively normal life after a patient undergoes surgery to treat SUI, we decided to explore this issue further. In our research, we sought to collect and examine indicators for patients undergoing treatment that could be used to perform regression analyses in order to attempt to determine which factors may have had the important influence upon patient prognosis for treatment of SUI using TVT-based surgery. We explored these risk factors by developing a nomogram for predicting surgical outcomes for female patients who underwent TVT for SUI. We even expected that we would be able to target a guided approach for patients intended to improve postoperative recovery and improve operational efficiencies. We present the following article in accordance with the TRIPOD reporting checklist (available at http://dx.doi.org/10.21037/apm-20-2316).

Methods

Subjects

In this study, all patients with urodynamically proven pure SUI afflictions and whom also underwent retropubic TVT procedures from the period of February, 2017 to July, 2018 were included for assessment in our study. Evaluation of all patients included accounts and assessments of age, body mass index (BMI), menopausal status, mode of delivery for childbirth, >4,000 g birth weight event histories, hysterectomy, dysuria, nycturia (≥3), and total cholesterol (TC). Patients also underwent complete urodynamic testing consisting of determinations of maximal urethral closure pressure (MUCP), Valsalva leak point pressure (VLPP), and urethral functional length. Before surgery patients were investigated for the presence of urinary tract infections (UTIs). Physical examinations included cough stress tests with a full bladder (urinary volume in bladder greater than 400 mL) and the pelvic organ prolapse quantification (POP-Q) test which was described during a maximal Valsalva maneuver and which was performed with the patient holding in the lithotomy position during urodynamic testing. All patients also completed the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), the Urogenital Distress Inventory-Short Form (UDI-6), and the Incontinence Impact Questionnaire-Short Form (IIQ-7). We removed the catheter on the first day post-operation. Foley catheters were left *in situ* if patients were characterized as having voiding difficulty or urinary retention after removing the main catheter. Symptoms were assessed at the six-month follow-up, as well as were measures for UDI-6 Score, IIQ-7 Score, and ICIQ-SF. Subjective success was defined as when SUI disappeared or had improved. A reduction in the frequency and volume of SUI per day was defined as improvement. Symptoms of patients who were found to have disappeared or have been improved (subjective success group) were compared with symptoms of those patients who were found to have no change or recurrence (subjective failure group). Repeated urodynamic evaluations were not routinely performed. Postoperative cough stress tests were also performed in the lithotomy and upright positions as part of measures of objective outcomes of the surgery (9). We followed up with all patients to measure outcomes in terms of efficacies and complications resultant from treatment.

Inclusion criteria were urodynamically proven to be pure cases of SUI and subsequently underwent retropubic TVT treatment procedures. Exclusion criteria were as follows: women with urges of incontinence, overactive bladder, mixed incontinence, concomitant vaginal prolapse greater than stage 1 according to the POP-Q system, post void residual urine volume >100 mL, any systematic disease,

urinary infection, previous incontinence surgery, and current smokers. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Medical Ethics Committee of the Shanghai General Hospital, China (No. 2020KY228) and individual consent for this retrospective analysis was waived.

Surgical procedures

All TVT procedures were performed by a fixed-term and highly experienced surgeon according to the technique which originally employs the use of the inside-out approach. General anesthesia was used for all patients. The operation was performed by making a small incision in the anterior wall of the vagina approximately 1 cm below the urethra. Along the incision, we removed the urethra-vaginal space to both sides until reaching the margin at the pelvic fascia. The sling was employed to pass through the upper edge of the pubic joint through the pubic bone from the urethra-vaginal space. Then, we adjusted the tension below the middle of the urethra based upon the preoperative individual conditions for each patient. The wound was sutured with a 3-0 absorbable thread intermittently. Cystoscopy and vaginal examinations were performed at the conclusion of procedures in order to rule out potential bladder and vaginal perforations.

Statistical analysis

Continuous variables of the normal distribution were expressed as the mean ± standard deviation (SD), which values were compared by using *t*-tests, and of the non-normal distribution were expressed as median and quartile, which values were compared by using the Mann-Whitney U tests. Categorical data were expressed as frequency and percentage, the disordered categorical data were analysed by using chi-square test, and the rank categorical data were analysed by using Mann-Whitney U tests. The results were considered statistically significant when P values were <0.05. All tests were bilateral. All statistical analyses and data plots had been performed and generated with R version 3.6.1. In order to make the result repeatable, we set the seed number 123. Lasso regression model was constructed by glmnet package and the variable whose regression coefficient was nonzero was filtered by Lambda min. When the selected variables were incorporated into the multivariable logistic regression model, P values <0.05 was considered to be an independent predictor of SUI surgical outcome. Nomogram was constructed based on independent predictive variables using rms package. The ROC curve was constructed with ROCR package, in which the area under the curve represented the differentiation of the model. The calibration curve was drawn and the goodness of fit of the model was assessed by Hosmer-Lemeshow test.

Results

Preoperative demographic data for patients of the two groups including age, BMI, menopausal status, mode of delivery, >4,000 g birth weight history, hysterectomy, dysuria, nycturia, TC, preoperative UDI-6 Score, IIQ-7 Score, ICIQ-SF, and urodynamic evaluations which included MUCP, VLPP and urethral functional length are shown in *Table 1*. During the study period, 365 women underwent TVT and met the qualifications for inclusion. Among all the 365 women, 327 women had completed six-month follow-up consultations including 290 patients in subjective success group and 37 patients in subjective failure group, and 38 patients were lost. MUCP and TC between the two groups were statistically different (P=0.012 and P=0.018, respectively).

All the fifteen variables were included in the Lasso regression model, and the most predictive variables were screened by Lambda min in Figure S1. Among the variables whose regression coefficient was nonzero were MUCP, dysuria, preoperative IIQ-7, and TC, which were thought to be associated with SUI surgical outcome. The four variables were incorporated into the stepwise logistic regression model, P values <0.05 was considered to be an independent predictor of SUI surgical outcome. Multivariable logistic regression analysis of risk factors that were important in relation to the failure of surgery indicated two independent predictors: TC (P=0.005) and MUCP (P=0.028) (*Table 2*).

We developed a nomogram to predict prognosis after TVT in female patients with SUI using the two preoperative characteristics of TC and MUCP (*Figure 1*). The total score of the nomogram (with a maximum score of 160 points) was derived from the sum of each predictive variable (TC, ranged 0–100 points; MUCP, ranged 0–60 points). A high total score was predictive of subjective success after TVT in female patients with SUI. The mean value of the area under the receiver-operating characteristic curve (ROC) for our nomogram predictions was 0.685 (95% CI, 0.593–0.776) (*Figure 2*). In addition, calibration curve graphically showed good agreement on the prognosis

Table 1 Demographic data of SUI subjective success group and subjective failure group

Items	Subjective failure group (n=37)		Subjective success group (n=290)		P value
	N	% or SD	N	% or SD	
Age	61.35	9.77	60.90	10.13	0.798
Menopausal status					0.802
No	7	18.9	60	20.7	
Yes	30	81.1	230	79.3	
Mode of delivery					0.676
Vaginal	30	81.1	243	83.8	
Instrumental	7	18.9	47	16.2	
>4,000 g birth weight history					0.637
No	32	86.5	242	83.4	
Yes	5	13.5	48	16.6	
Hysterectomy					1.000
No	34	91.9	268	92.4	
Yes	3	8.1	22	7.6	
Dysuria					0.605
No	37	100	281	96.9	
Yes	0	0	9	3.1	
Nycturia					1.000
No	34	91.9	264	91.0	
Yes	3	8.1	26	9.0	
UDI6	5.08	1.30	5.19	1.33	0.650
IIQ7	10.24	2.92	11.07	3.55	0.178
ICIQSF	13.70	3.50	13.69	3.71	0.980
MUCP	54.35	17.76	61.33	15.51	0.012*
VLPP	91.49	25.55	99.50	25.72	0.075
Urethral functional length	26.54	4.86	27.16	5.37	0.508
BMI	25.77	3.89	25.24	3.25	0.428
TC	6.40	2.31	5.43	1.61	0.018*

Data were presented as mean value ± standard deviation or count (percentage). Using Student's *t*-test to analysis the continuous variables and the Pearson Chi-square test or the exact Fisher test were used to assess the categorical variables. *, P<0.05 was considered statistically significant. SUI, stress urinary incontinence; TC, total cholesterol; MUCP, maximal urethral closure pressure; BMI, body mass index; VLPP, Valsalva leak point pressure.

Table 2 Multivariate logistic regression analysis of selected variables

Variables	β	Odds ratio	95% CI	P value
TC	–0.242	0.785	0.663–0.932	0.005
MUCP	0.024	1.025	1.003–1.047	0.028

β is the regression coefficient. CI, confidence interval.

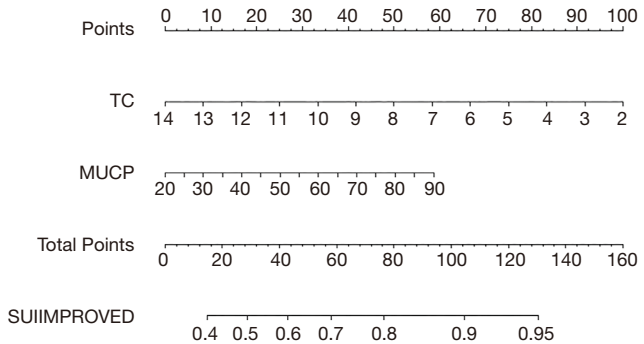

Figure 1 Nomogram predicting the SUI surgical outcomes after TVT. SUI, stress urinary incontinence; TVT, tension free vaginal tape; TC, total cholesterol; MUCP, maximal urethral closure pressure.

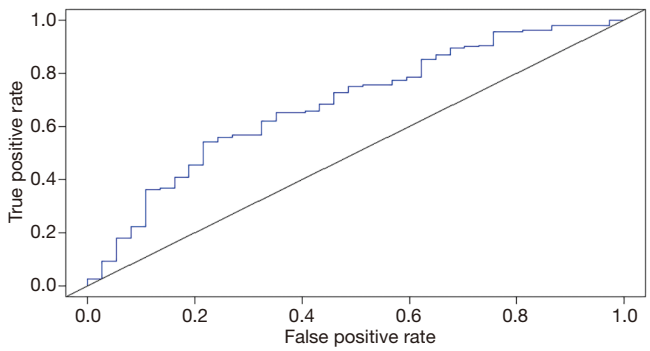

Figure 2 ROC curve analyses were generated to test the discrimination of the nomogram. ROC, receiver-operating characteristic curve.

after TVT in female patients with SUI by the nomogram (P=0.8424) in Figure S2.

Discussion

In our study, postoperative efficacy of SUI patients undergoing TVT surgery was retrospectively examined. The use of the approach of middle urethral suspension (MUS) is considered to be the gold-standard procedure for the treatment of female patients afflicted by SUI. A recent systematic review and meta-analysis had results that indicated that retropubic MUS and transobturator MUS have objectively similar cure rates for long- and medium-term assessments, however, transobturator tapes have a subjectively lower cure rate than has been observed for TVT based treatments (10-12). In the results for our study, TVT based surgery has been found to have a cure rate of nearly 90% for SUI patients and has been found to have had a low incidence of complications for all two treatment groups. Its efficacy and relative lower risk revealed that TVT should also be considered as a classic procedure for treating SUI patients. Although TVT has a higher cure rate for cases of SUI, there is still a certain failure rate of patients who have undergone this type of surgery, experiencing persistent SUI postoperatively. Predicting the outcome of TVT is important for the appropriate counselling of the patient about to undergo surgery. Patients who were predicted to have failure postoperative outcomes are suitable candidates for studies on a carefully adjusted sling tension during TVT surgery or giving up surgery directly. Different studies have shown that failure of urinary incontinence surgery may be associated with increased length of stay, BMI <25, reduced postoperative peak urinary flow rate, decreased bladder outlet resistance after surgery or low serum albumin (<3.5 ng/dL) (13-16). Our study suggests that preoperative factors, including TC, and MUCP, are significantly associated with postoperative outcomes. Our nomogram enables us to select patients who were found to have successful postoperative outcomes undergoing TVT surgery. Nomograms are easy to use and can facilitate management-related decision making, so that surgical treatment will better meet patients' expectations.

Urodynamics, defined by the International Continence Society (ICS), represents the study of the function and dysfunction of the urinary tract by an appropriate method (17). Urodynamics is widely used nowadays before continence surgery, particularly in the presence of mixed symptoms or after previous failed continence

procedures. Although the role of urodynamics in the preoperative evaluation of patient with SUI symptoms was questioned by the National Institute for Health and Clinical Excellence (NICE) (18), most of the urogynecologists and urologists in UK are however using mandatory urodynamic testing before surgery for SUI (19). Preoperative urodynamic examination provides a precision diagnosis and enable surgeons to modify the surgical technique and sling tension. The combination of medications used after the suburethral sling procedure may be considered for patients with concomitant vesicourethral dysfunction (20). In our study, all patients also had a mandatory preoperative urodynamic examination to verify they were pure SUI. The nomogram indicated that low preoperative MUCP correlate with higher risk of failure of surgical treatment for SUI undergoing TVT. A recent review that evaluated the predictive value of urodynamic parameters regarding the outcome of mid-urethral sling surgery indicated increased rates of success were generally found for both transobturator and retropubic approaches in patients with higher preoperative urodynamic parameters, namely MUCP (21). These studies support our clinical findings that MUCP is an important factor associated with postoperative outcomes. However, some studies had found no association between MUCP and postoperative outcomes. Therefore, the influence of MUCP was controversial and should be assessed by more detailed examinations in randomized-controlled trials.

Multivariable regression analysis of risk factors for examination of which were important to the failure of surgery indicated that TC played an important role in the prognosis of patients post-surgery. The nomogram manifested that high TC correlate with higher risk of failure of surgical treatment for SUI undergoing TVT. It is well known that hypercholesterolemia may lead to a series of cardiovascular problems including such as atherosclerosis, and studies have shown that hypercholesterolemia is associated with microcirculatory dysfunction. When hypercholesterolemia exists, the microcirculatory system is activated by oxidative stress leading to atherosclerotic plaques (22-24). The presence of atherosclerosis affects blood supplies to wounds and affects the tissue at the healing site. Hypercholesterolemia impairs endothelium-derived nitric oxide (EDNO) release while EDNO plays an important role in the regulation of angiogenesis (25). A reduction in blood supply caused by atherosclerosis or angiogenesis decreases wound healing rates and limits reaching desired goals for treatment. Also, from the perspective of general surgery, TC seems to have been associated with the risk of nosocomial infection in surgical patients (26). The occurrence of postoperative infection also can seriously affect postoperative tissue growth and wound healing. The application of the TVT sling should be affixed by using the surrounding connective tissue, but hypercholesterolemia can cause poor healing of connective tissue, thus resulting in potentially unsatisfactory fixation of the TVT sling, ultimately leading to an unsatisfactory prognosis. Hypercholesterolemia affects TVT postoperative outcomes, and because of atherosclerosis, angiogenesis, infections, or other reasons, there is also a need for further basic experimental verification.

The present study had some limitations. For example, we had to exclude subjects that did not meet inclusion criteria, including for cases such as mixed urinary incontinence and so forth. And, our study approach was to use patients from only a single treatment center. The small sample size also likely limited the power of our study. Limited to the retrospective study, the number of patients between the two groups were big differences. The mean value of the area under the ROC for our nomogram predictions was 0.685, which was not very high. In the future, if we include more variables, maybe the results will be better. Another limitation was the short postoperative follow-up period and a lack of follow-up data derived from assessments of long-term postoperative outcomes and complications.

Conclusions

We developed a predictive model for preoperative estimation of prognosis in female patients who underwent TVT based treatment for SUI. This model could select patients who were found to have successful postoperative outcomes, which can lead to a rational therapeutic choice but still requires more basic experiments and data to elucidate the most important dynamics and mechanistics.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/apm-20-2316). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Medical Ethics Committee of the Shanghai General Hospital, China (No. 2020KY228) and individual consent for this retrospective analysis was waived.

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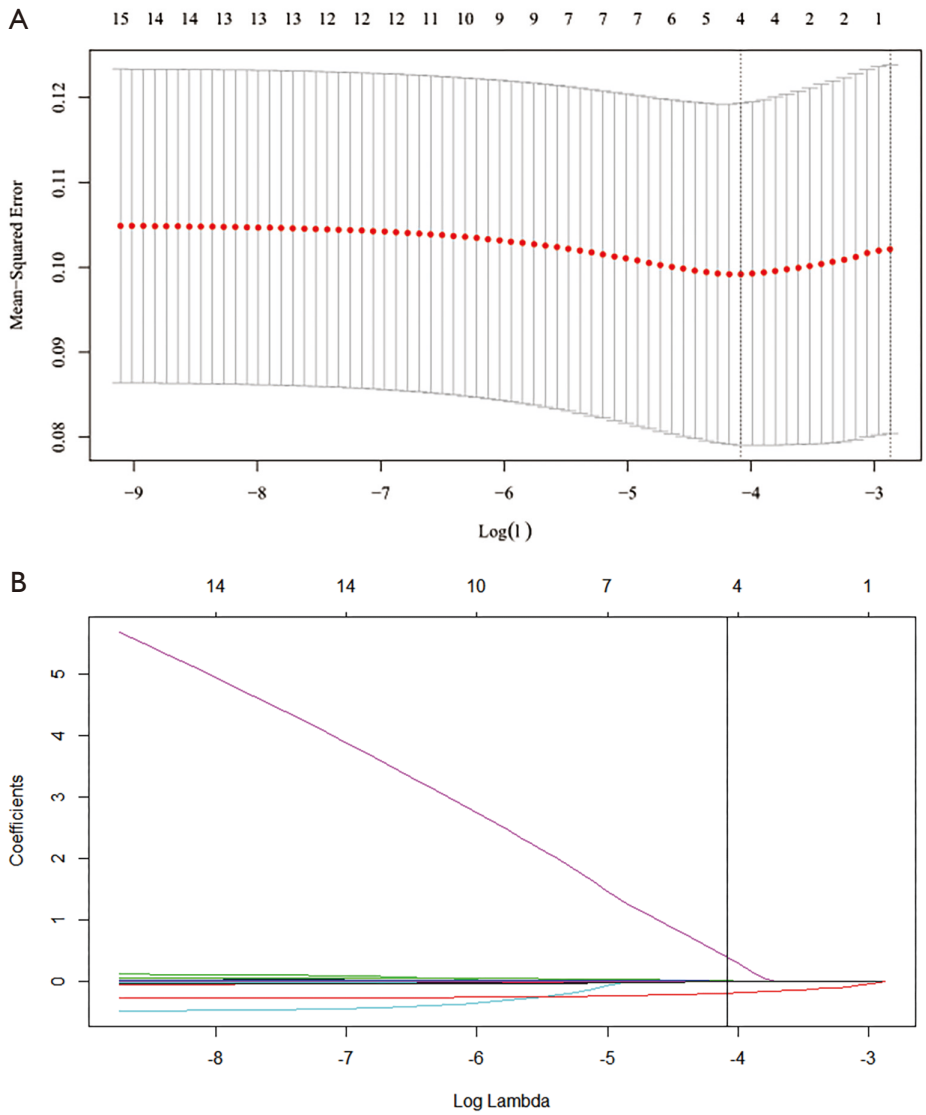

Figure S1 Demographic and clinical feature selection using the Lasso binary logistic regression model. (A) Optimal parameter(lambda) selection in the Lasso model used fivefold cross-validation via minimum criteria. (B) Lasso coefficient profiles of the 15 features. A coefficient profile plot was produced against the log(lambda) sequence. Vertical line was drawn at the value selected using fivefold cross-validation, where optimal lambda resulted in five features with nonzero coefficients.

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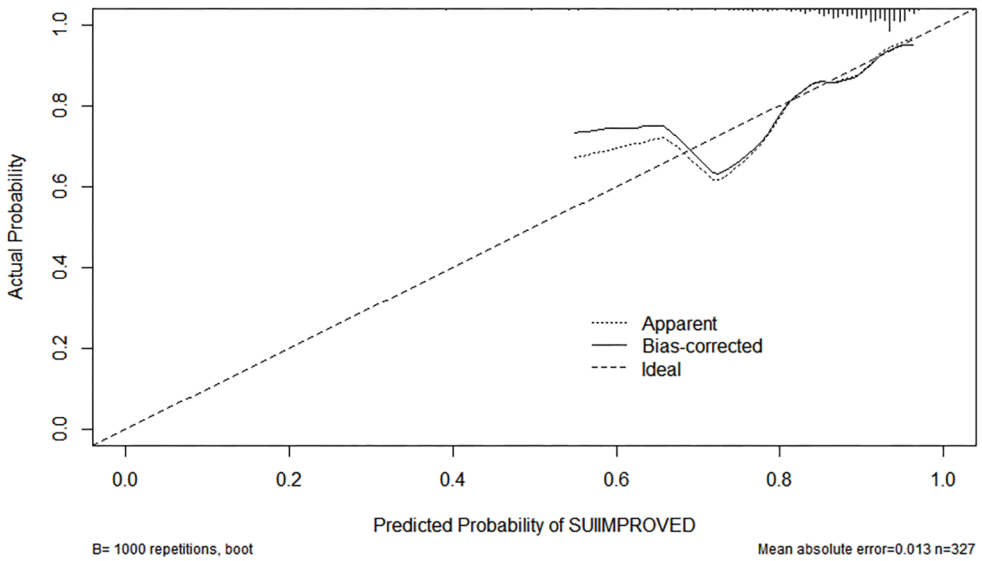

Figure S2 Calibration curve calibration curve depicts the calibration of the nomogram model in terms of the agreement between the predicted probabilities and observed outcomes.

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