

Predictive nomogram for deep brain stimulation–related infections

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OBJECTIVE Infection is one of the important and frequent complications following implantable pulse generator and deep brain stimulation (DBS) electrode insertion. The goal of this study was to retrospectively evaluate and identify potential risk factors for DBS infections.

METHODS From January 2015 to January 2021 in Qingdao municipal hospital (training cohort) and The First Affiliated Hospital of the University of Science and Technology of China (validation cohort), the authors enrolled patients with Parkinson disease who had undergone primary DBS placement or implantable pulse generator replacement. The cases were divided into infection or no-infection groups according to the 6-month follow-up. The authors used the logistic regression models to determine the association between the variables and DBS infection. Depending on the results of logistic regression, the authors established a nomogram. The calibration curves, receiver operating characteristic curve analysis, and decision curves were used to evaluate the reliability of the nomogram.

RESULTS There were 191 cases enrolled in the no-infection group and 20 cases in the infection group in the training cohort. The univariate logistic regression showed that BMI, blood glucose, and albumin were all significant predictors of infection after DBS surgery (OR 0.832 [$p = 0.009$], OR 1.735 [$p < 0.001$], and OR 0.823 [$p = 0.001$], respectively). In the crude, adjust I, and adjust II models, the three variables stated above were all considered to be significant predictors of infection after DBS surgery. The calibration curves in both training and validation cohorts showed that the predicted outcome fitted well to the observed outcome ($p > 0.05$). The decision curves showed that the nomogram had more benefits than the “All or None” scheme. The areas under the curve were 0.93 and 0.83 in the training and validation cohorts, respectively.

CONCLUSIONS The nomogram included BMI, blood glucose, and albumin, which were significant predictors of infection in patients with DBS surgery. The nomogram was reliable for clinical application.

<https://thejns.org/doi/abs/10.3171/2022.9.FOCUS21558>

KEYWORDS deep brain stimulation; Parkinson disease; infection; nomogram; logistic regression

DEEP brain stimulation (DBS) has been accepted as an effective treatment for Parkinson disease. However, given the implantation of pulse generator devices, concerns about postoperative complications will continue to arise among patients who are going to undergo DBS. As one of the most common adverse events, DBS-related infection is frequently associated with explanting or reimplanting the hardware, which inevitably leads to

high cost for such patients. The rates of DBS-related infection vary between 1% and 8%,^{1–3} and previous reports have shown that the implantable pulse generator (IPG) and DBS electrode were most susceptible, given that postoperative infection risk factors related to postoperative infection including premorbid device infection, seasonal variation, diabetes, hypertension, and body habitus have been investigated in several studies.^{4–6}

ABBREVIATIONS ASA = American Society of Anesthesiologists; AUC = area under the curve; DBS = deep brain stimulation; IPG = implantable pulse generator; ROC = receiver operating characteristic; VIF = variance inflation factor.

SUBMITTED September 17, 2021. **ACCEPTED** September 21, 2022.

INCLUDE WHEN CITING DOI: 10.3171/2022.9.FOCUS21558.

In this case, identifying risk factors during the preoperative phase may guide clinicians to adopt correct therapeutic strategies to prevent DBS-related infections. Previous studies found that preoperative skin washing with 70% ethyl alcohol antiseptic, application of prophylactic antibiotics, and intrawound topical vancomycin powder could diminish the incidence of infection after DBS.^{7,8} Moreover, several previous studies found that several other factors such as diabetes or smoking history may increase the rate of infection.^{9,10} Although no study focused on the role of patients' nutritional status on infection following DBS, nevertheless, consensus on infection prevention was mostly dependent on clinical experience in practice, and to date, no clinically useful tool has been created to predict the incidence of DBS-related infection before surgery. The goal of this study was to retrospectively evaluate and identify potential risk factors for DBS infections. A nomogram incorporating independent predictors was established to help determine the risk of infection onset.

Methods

Subjects

Data were extracted from the electronic database of Qingdao Municipal Hospital, and this study was approved by the hospital's institutional review board. Because the study was retrospective and observational, the board waived the patients' informed consent. We included the cases of patients who had undergone primary DBS placement or IPG replacement between January 2015 and January 2021. We excluded the cases of patients who met the following criteria: 1) cases with infection before surgery; 2) cases with missing data; and 3) cases followed up less than 6 months (Fig. 1). The clinical data of 144 patients, as external validation data, were extracted from the Department of Neurosurgery, The First Affiliated Hospital of the University of Science and Technology of China.

According to the National Surgical Quality Improvement Program, DBS-related infection was defined as occurring within 6 months postsurgery, and the following indications for infection were considered eligible: 1) purulent drainage surrounding the surgical site; 2) organisms isolated from the site of interest; and 3) at least one of the following signs: pain, localized swelling or heat, or fever ($> 38^{\circ}\text{C}$). No matter where the infection occurred—at any level, including the IPG, connecting cable, and cranial region—we defined it as a DBS-related infection.

Clinical Evaluations

Demographic data (age, sex, course of disease, BMI, and smoking history); surgical information (operation time, operation type, operation season, and American Society of Anesthesiologists [ASA] score); premorbid chronic diseases (diabetes, hypertension, and hyperlipidemia); and laboratory parameters (blood glucose, albumin, and hemoglobin) were collected. The ASA scores were used to assess the physical condition of patients before surgery. In accordance with Hardaway's study, the seasons were defined as winter (January–March), spring (April–June), summer (July–September), and fall (October–December).⁴

Surgical Procedures and Therapeutic Strategies for DBS-Related Infection

The DBS surgeries were performed as described in previous studies.^{11–13} For all patients with Parkinson disease in our study, we selected the subthalamic nucleus as the target nucleus. We placed the IPG in an ipsilateral subcutaneous, subclavicular pouch. Before making the skin incision, we administered the antibiotics (cefazolin; Pfizer, Inc.) for all patients. Once infection was diagnosed, we removed the IPG and extensions at the infection site. The patients with infection were treated with antibiotics for at least 6–8 weeks by intravenous injection based on intraoperative cultures as well as antimicrobial sensitivity tests. The IPG and extensions were reimplanted after resolution of the infections.

Statistical Analysis

The categorical and continuous data were expressed as number (percentage) and mean \pm SD, respectively. For categorical variables we conducted the t-test or Mann-Whitney U-test to make comparisons between the groups, whereas for continuous variables, the chi-square test or Fisher's exact tests were used. In order to check multicollinearity between clinical variables, we used the variance inflation factor (VIF) and tolerance. A logistic regression was conducted to determine the independent predictors for DBS-related infection. Depending on the results of logistic regression, we established a nomogram. In order to evaluate the reliability and the net benefit of the nomogram, we applied a receiver operating characteristic (ROC) curve analysis and plotted decision curves. We used the Hosmer-Lemeshow test to analyze the degree of fitting, and if the p value was > 0.05 , it indicated that the Hosmer-Lemeshow test was passed. For other variables, we considered them statistically significant if the p value was < 0.05 . We used the statistical packages R (version 3.4.3; The R Foundation, <http://www.r-project.org>) and Empower (X&Y Solutions, Inc., www.empowerstats.com) to analyze the data.

Results

Demographic Characteristics

In our study, we enrolled 211 cases in the training cohort and 144 cases in the validation cohort. There was no difference in various indicators between the 2 cohorts ($p > 0.05$) (Table 1). A total of 191 cases were enrolled in the no-infection group and 20 cases were in the infection group in the training cohort (Fig. 1). No significant differences were observed in aspects of age, sex, course of disease, smoking history, diabetes, hypertension, systolic pressure, diastolic pressure, hyperlipidemia, hemoglobin, operation time, ASA score, operation type, and operation season between the two groups (Table 2).

The mean value of BMI was $21.68 \pm 2.28 \text{ kg/m}^2$ for those who suffered from DBS-related infection, which was significantly lower than that in the no-infection group ($24.46 \pm 3.73 \text{ kg/m}^2$). In the infection group, the mean value of blood glucose was $9.63 \pm 3.94 \text{ mmol/L}$, which was significantly higher than that in the no-infection group ($5.32 \pm 1.53 \text{ mmol/L}$). In the infection group, the mean

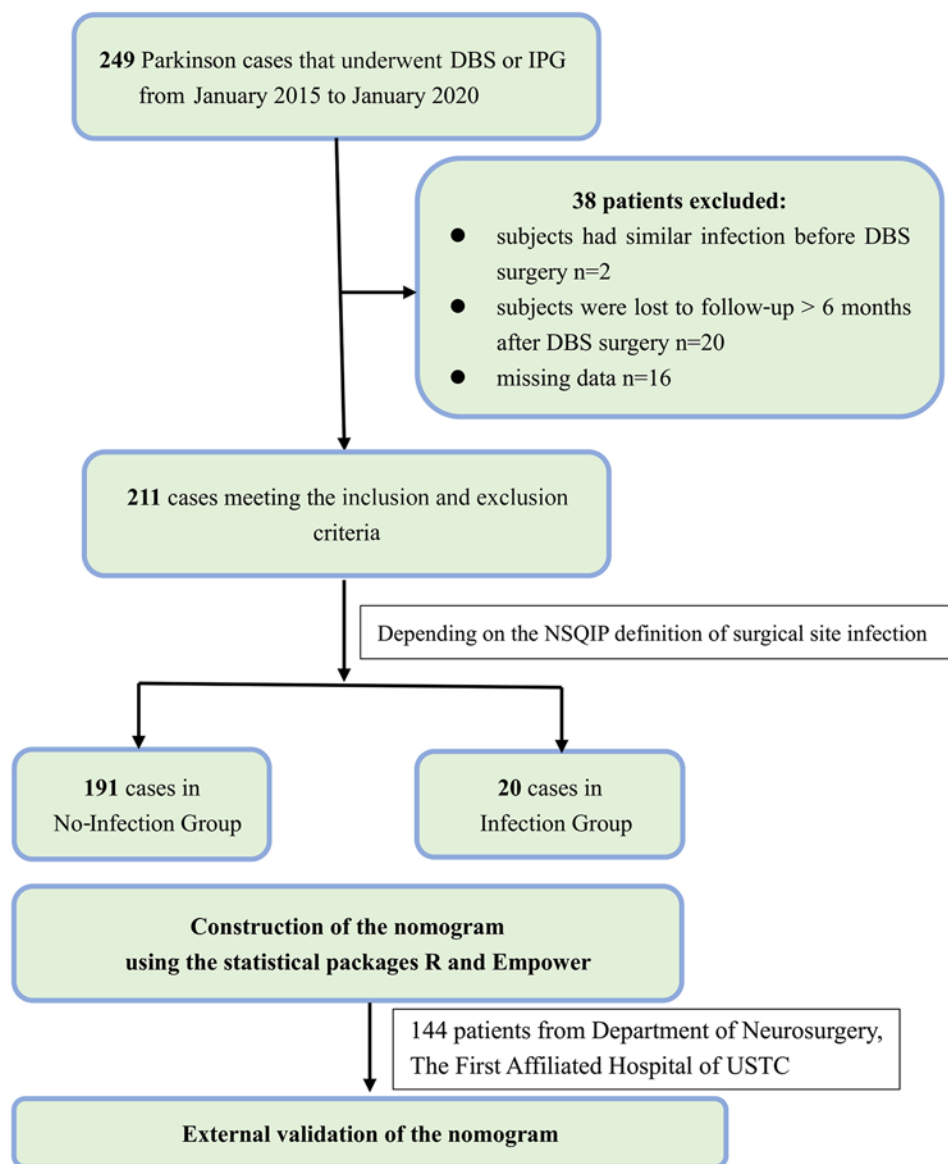


FIG. 1. Flowchart outlining inclusion and exclusion criteria. NSQIP = National Surgical Quality Improvement Program; USTC = University of Science and Technology of China.

value of albumin was 36.95 ± 4.68 g/L, which was significantly lower than that in the no-infection group (40.11 ± 3.89 g/L) (Table 2).

Univariate Analysis for Infection

We used univariate logistic regression to analyze the association between BMI, blood glucose, albumin, and infection. We found that BMI, blood glucose, and albumin were all significant predictors of infection after DBS surgery (OR 0.832 [$p = 0.009$], OR 1.735 [$p < 0.001$], and OR 0.823 [$p = 0.001$], respectively) (Table 3). In addition, we found that the tolerance was > 0.1 and the VIF was < 10 for the predictors, suggesting no collinearity among these independent variables (Supplementary Table 1).

Association Between Variables and Infection in Different Models

Multivariate logistic regression was used to analyze the association between BMI, blood glucose, albumin, and infection after DBS surgery (Table 4). In the crude model, BMI, blood glucose, and albumin were all considered to be significant predictors of infection after DBS surgery (OR 0.8, 1.9, and 0.8, respectively).

In the adjust I (adjusting for age and sex) and adjust II (adjusting for sex, age, smoking, diabetes, hypertension, systolic pressure, diastolic pressure, hyperlipidemia, hemoglobin, ASA score, operation type, operation time, operation season, and course of disease) models, the three variables stated above (BMI, blood glucose, and albumin) were all considered to be significant predictors of infection.

TABLE 1. Characteristics of patients in the training and validation cohorts

Characteristic	Training Cohort, n = 211	Validation Cohort, n = 144	p Value
Age (yrs)	63.31 ± 9.30	65.41 ± 10.46	0.427
Sex			0.062
Male	108 (51.2%)	89 (61.8%)	
Female	103 (48.8%)	55 (38.2%)	
Course of disease (mos)	11.03 ± 5.21	10.50 ± 6.34	0.389
BMI (kg/m ²)	24.19 ± 3.71	24.43 ± 3.90	0.958
Smoking	9 (4.3%)	12 (8.3%)	0.111
Diabetes	47 (22.3%)	39 (27.1%)	0.299
Blood glucose (mmol/L)	5.73 ± 2.26	5.88 ± 2.64	0.168
Hypertension	62 (29.4%)	50 (34.7%)	0.288
Systolic pressure (mm Hg)	130.10 ± 17.89	132.18 ± 17.03	0.570
Diastolic pressure (mm Hg)	77.35 ± 10.32	79.97 ± 10.14	0.373
Hyperlipidemia	68 (32.2%)	58 (40.3%)	0.120
Albumin (g/L)	39.81 ± 4.07	40.21 ± 4.00	0.960
Hemoglobin (g/dl)	135.24 ± 15.12	137.17 ± 14.46	0.247
Op time (mins)	150.55 ± 97.05	160.70 ± 96.12	0.814
ASA score			0.649
I	9 (4.3%)	5 (3.5%)	
II	49 (23.2%)	27 (18.8%)	
III	101 (47.9%)	78 (54.2%)	
IV	52 (24.6%)	34 (23.6%)	
Op type			0.160
DBS	91 (43.1%)	73 (50.7%)	
IPG	120 (56.9%)	71 (49.3%)	
Op season			0.511
Jan–Mar	50 (23.7%)	34 (23.6%)	
Apr–Jun	48 (22.7%)	40 (27.8%)	
Jul–Sep	49 (23.2%)	25 (17.4%)	
Oct–Dec	64 (30.3%)	45 (31.3%)	
Infection	20 (9.5%)	18 (12.5%)	0.366

Data are expressed as the mean ± SD or number of patients (%) unless otherwise indicated.

tion after DBS surgery (adjust I: OR 0.8, 1.9, and 0.8 respectively; adjust II: OR 0.6, 9.2, and 0.6, respectively).

Development of Nomogram and Clinical Validation

We developed a nomogram (Fig. 2) to generate the probability of infection after DBS surgery based on the following logistic model: $\text{logit}(\text{infection}) = 4.74655 - 0.18104 * \text{BMI} + 0.62279 * \text{glucose} - 0.18068 * \text{albumin}$.

The calibration curves showed that the predicted outcome fitted well to the observed outcome ($p = 0.53$) (Fig. 3B). The decision curves showed that the nomogram had more benefits than the “All or None” scheme if the threshold probability was $> 10\%$ and $< 75\%$ (Fig. 3C). The area under the curve (AUC), accuracy, specificity, sensitivity, positive likelihood ratio, negative likelihood ratio, and diagnostic odds ratio were 0.93 (95% CI 0.83–

TABLE 2. Clinical characteristics of 211 patients in the training group

Characteristic	No-Infection Group, n = 191	Infection Group, n = 20	p Value
Age (yrs)	63.69 ± 9.26	59.70 ± 9.18	0.068
Sex			0.484
Male	96 (50.3%)	12 (60.0%)	
Female	95 (49.7%)	8 (40.0%)	
Course of disease (mos)	10.77 ± 6.46	11.50 ± 5.42	0.629
BMI (kg/m ²)	24.46 ± 3.73	21.68 ± 2.28	0.001
Smoking	9 (4.7%)	1 (5.0%)	0.954
Diabetes	41 (21.5%)	6 (30.0%)	0.383
Blood glucose (mmol/L)	5.32 ± 1.53	9.63 ± 3.94	<0.001
Hypertension	58 (30.4%)	4 (20.0%)	0.443
Systolic pressure (mm Hg)	130.31 ± 18.16	128.05 ± 15.40	0.592
Diastolic pressure (mm Hg)	77.69 ± 10.28	74.10 ± 10.38	0.139
Hyperlipidemia	60 (31.4%)	8 (40.0%)	0.457
Albumin (g/L)	40.11 ± 3.89	36.95 ± 4.68	0.001
Hemoglobin (g/dl)	135.45 ± 15.32	133.20 ± 13.29	0.528
Op time (mins)	152.29 ± 100.18	133.85 ± 58.44	0.420
Days from surgery	NA	15.63 ± 12.91	NA
ASA score			0.124
I	9 (4.7%)	0	
II	48 (25.1%)	1 (5.0%)	
III	88 (46.1%)	13 (65.0%)	
IV	46 (24.1%)	6 (30.0%)	
Op type			0.636
DBS	82 (42.9%)	7 (35.0%)	
IPG	109 (57.1%)	13 (65.0%)	
Op season			0.496
Jan–Mar	47 (24.6%)	3 (15.0%)	
Apr–Jun	41 (21.5%)	7 (35.0%)	
Jul–Sep	44 (23.0%)	5 (25.0%)	
Oct–Dec	59 (30.9%)	5 (25.0%)	

NA = not applicable.

Data are expressed as the mean ± SD or number of patients (%) unless otherwise indicated.

0.98), 0.86, 0.85, 0.90, 6.14, 0.12, and 52.39, respectively (Fig. 3A).

The AUC of the external validation cohort was 0.83 (Fig. 3D), which indicated favorable discrimination. The

TABLE 3. Univariate logistic regression analysis for infection

Variable	OR (95% CI)	p Value
BMI in kg/m ²	0.832 (0.725, 0.955)	0.009
Blood glucose in mmol/L	1.735 (1.415, 2.128)	<0.001
Albumin in g/L	0.823 (0.730, 0.927)	0.001

TABLE 4. Relationship between variables and infection in different models

Variable	Crude Model		Adjust I Model		Adjust II Model	
	OR (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
BMI in kg/m ²	0.8 (0.7, 1.0)	0.043	0.8 (0.7, 1.0)	0.034	0.6 (0.4, 0.9)	0.017
Blood glucose in mmol/L	1.9 (1.4, 2.4)	<0.001	1.9 (1.4, 2.4)	<0.001	9.2 (2.2, 37.8)	0.002
Albumin in g/L	0.8 (0.7, 1.0)	0.020	0.8 (0.7, 1.0)	0.014	0.6 (0.4, 1.0)	0.038

Crude model not adjusted; no variables. Adjust I model adjusted for sex and age. Adjust II model adjusted for sex, age, smoking, diabetes, hypertension, systolic pressure, diastolic pressure, hyperlipidemia, hemoglobin, ASA score, operation type, operation time, operation season, and course of disease.

calibration curves showed that the predicted outcome fitted well to the observed outcome in the external validation cohort ($p = 0.65$) (Fig. 3E). The decision curves showed the nomogram had more benefits than the All or None scheme if the threshold probability was $> 20\%$ and $< 100\%$ in the external validation cohort (Fig. 3F).

Discussion

This study revealed that BMI, blood glucose, and albumin levels were significant predictors of infection in patients with DBS surgery. We developed a nomogram based on the risk factors for predicting the probability of infection with DBS surgery, and the ROC curve analysis, calibration curve, and decision curves showed the relatively good performance in terms of clinical application. Other factors thought to be associated with infection were not statistically significant in this study, including age, smoking history, operation season, and ASA score.^{2,3}

Previous studies showed that the infection rates ranged from 2% to 15% and that it was the most frequent postoperative complication following DBS.^{1,4,6} In our study, we found that the infection rate was 9.5% within 6 months. The difference of infection rates in different studies may be due to the variability of the time window and the definition of infection. The emphasis in this study was on

the risk factors for postsurgical DBS infection. Previous studies showed that several factors, such as age, medical comorbidities, disease duration, and scalp thickness, may be associated with infection after DBS surgery. Recently, Farrokhi et al. investigated clinical risk factors for postoperative infection by using machine learning algorithms, and found that patients with a history of smoking were more likely to experience postoperative infection (OR 4.20).³ However, in our study there was no significant difference in the history of smoking between the infection and no-infection groups. Atchley et al. retrospectively reviewed patients with DBS surgery and found that a lower patient BMI was a risk factor for erosion (OR 3.1), which was similar to our study.² In our study we found that the albumin level, from which we inferred nutritional status, was a significant predictor of infection in patients who underwent DBS surgery. Maimaiti et al. demonstrated that serum albumin may be an effective biomarker to assess nutritional status and predict acute joint infection after revision total joint arthroplasty.¹⁴ Previous studies showed that hypoalbuminemia may increase the risks of primary and secondary infections.^{15,16} In our study, we found that blood glucose was a significant predictor of infection in patients with DBS surgery. Li et al. showed that a high blood glucose level ($p < 0.001$) was a risk factor for surgical site infection.¹⁷ Edwards et al. also found

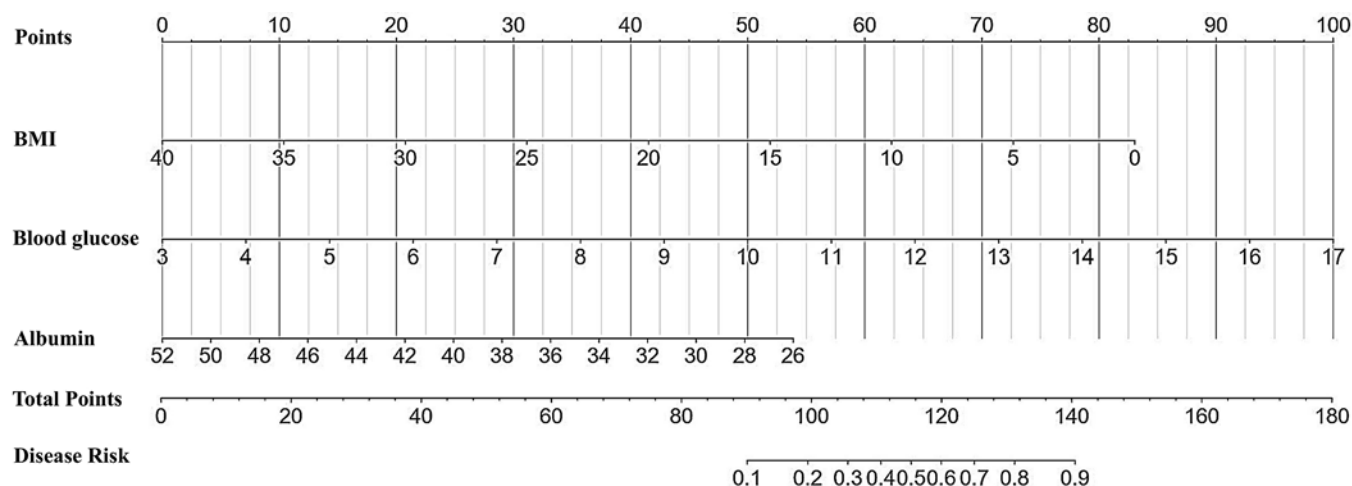


FIG. 2. The nomogram used to predict the probability of infection in patients with DBS surgery. Based on the independent risk factors selected, we developed a nomogram to predict the probability of infection after DBS surgery based on the following logistic model: $\text{logit (infection)} = 4.74655 - 0.18104 \times \text{BMI} + 0.62279 \times \text{glucose} - 0.18068 \times \text{albumin}$.

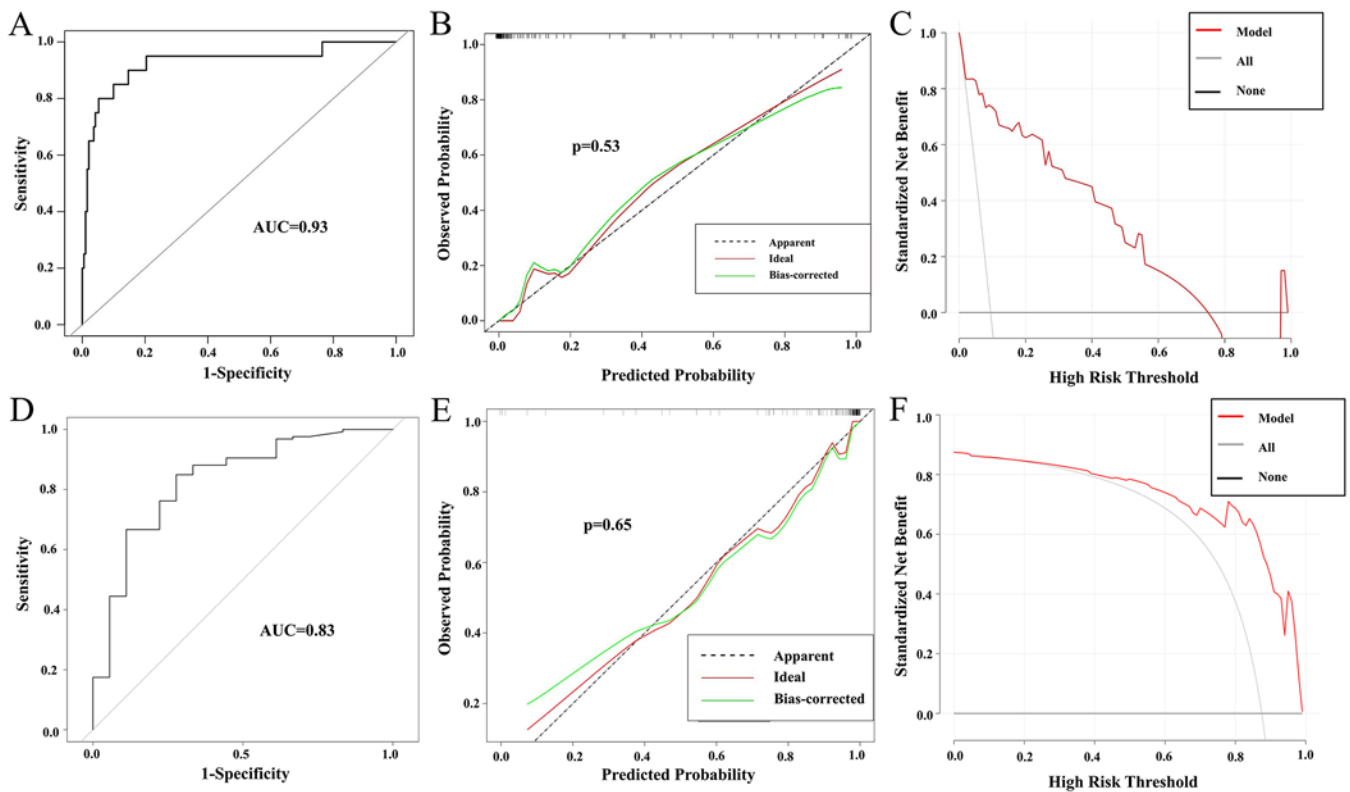


FIG. 3. Graphs showing procedures used to establish and assess nomogram. The calibration curves showed that the predicted outcome fitted well to the observed outcome in both the training (B) and external validation (E) cohorts. The decision curves showed that the nomogram had more benefits than the All or None scheme if the threshold probability was > 10% and < 75% (C). The AUCs of the training and external validation cohorts were 0.93 (A) and 0.83 (D), respectively. The decision curves showed that the nomogram had more benefits than the All or None scheme if the threshold probability was > 20% and < 100% in the external validation cohort (F).

that patients with postoperative infections had higher mean perioperative blood glucose.¹⁸ All in all, patients with lower BMI and albumin, which implies a worse state of nutrition, may experience poor healing of the surgical site. Moreover, a higher blood glucose level may result in poor wound healing and more microbial reproduction. Consequently, the BMI, blood glucose, and albumin levels were significant predictors of infection in patients with DBS surgery.

In most cases, postoperative surgical site infection may lead to a complete system removal and a substantial increase in financial costs. In our study we managed infections by removing the IPG and the extension wire. However, the latent colonization of residual hardware may inoculate the newly implanted system. Fenoy and Simpson described the management of IPG-related infections in detail.^{19,20} According to their reports, 5 patients (0.7%) had hardware infections within 12 months of IPG revision. Two (0.2%) were managed with antibiotics alone, and 3 (0.4%) required further surgery. Pepper et al. implemented a strategy similar to the one used at our institution in that all hardware infections were treated with antibiotics and partial or total removal.¹⁰ Consequently, removal of implantation materials and an adequate course of effective intravenous antibiotics are needed if infections have occurred.

Conclusions

The nomogram included BMI, blood glucose, and albumin, which were significant predictors of infection in patients with DBS surgery. The calibration curves, ROC curve analysis, and decision curves showed that the nomogram was reliable for clinical application. The predictive effect was susceptible to bias because the sample size was small. Other factors not included in the nomogram may also lead to infection in patients with DBS surgery. Consequently, we need more research with validation in multiple, external, independent patient populations.

Acknowledgments

This work was supported by the government of China under grants from the National Natural Science Foundation (grant nos. 82001184 and 82001253).

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Liu, Chen. Acquisition of data: Meng, T Li, Chang. Analysis and interpretation of data: T Li, S Li, Zhou, Hou. Drafting the article: Tan, Mei. Critically revising the article: Tan, Mei. Reviewed submitted version of manuscript: Xu. Statistical analysis: Xu, L Li. Administrative/technical/material support: L Li, Wang. Study supervision: Chen, Wang.

Supplemental Information

Online-Only Content

Supplemental material is available online.

Supplementary Table 1. <https://thejns.org/doi/suppl/10.3171/2022.9.FOCUS21558>.

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