Clinical prediction model for red cell blood transfusion in elective primary posterior lumbar spine fusion

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Informed Consent: A comprehensive agreement for academic use of information acquired during their treatments was obtained from the patients by the hospital at the time of their hospitalization, and no identifiable information of the participants is included in this manuscript.

Data availability: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request

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Abstract:

Overestimated the cross-match of preoperative PRC preparation for elective primary lumbar spinal fusion needs revision for cost-effectiveness. We aimed to develop a novel preoperative predictive model for appropriate PRC preparation. This clinical prediction model in a retrospective cohort was studied between January 2015 and September 2022. Multivariate logistic regression models were used to assess predictive variables. The logistic coefficient of each predictor generated scores to establish a predictive model. The area under the receiver operating characteristic curve (AuROC) was used to evaluate the model. The predictive performance was validated using bootstrapping techniques and externally validated in 102 independent cases. Among 416 patients, 178 (43%) required transfusion. Four final predictors: preoperative hematocrit level, laminectomy level, transforaminal lumbar interbody fusion level, and sacral fusion. When categorized into two risk groups, the positive predictive values for the low-risk score (≤4) were 18.4 (95% Cl 13.9, 23.6) and 83.9 (95% CI 77.1, 89.3) for the high-risk score (>4). AuROC was 0.90. Internal validation (bootstrap shrinkage = 0.993) and external validation (AuROC:0.91).

A new model demonstrated exemplary performance and discrimination in predicting the appropriate preparation for PRC. This study should be corroborated by rigorous external validation in other hospitals and by prospective assessments.

Introduction

Elective primary lumbar spine fusion is a major surgery with a high risk of perioperative blood loss associated with increased blood component transfusion requirements. Significant blood loss[1] requires a packed red cell (PRC) transfusion of approximately 50%–81%.[2] A systematic review[2] revealed significant postoperative cardiac and noncardiac complications, such as surgical site infection, deep vein thrombosis, pulmonary embolism, myocardial infarction, transient ischemic attack, stroke, respiratory tract infection, and sepsis, in allogeneic transfusion. A prospective randomized controlled trial revealed that preoperative autologous blood donation reduces the risk of allogeneic blood transfusion in patients who undergo elective lumbar spine surgery.[3] The preoperative cross-matched transfusion ratio (C: T ratio) was overestimated. The high C: T ratio results in the loss of global costs in the management chain of blood processes, such as blood bank resources, time, finances, and human resources.[4–6] As recommended, cross-match PRC by the maximum surgical blood-order schedule (MSBOS) was indicated for general preparation of PRC in lumbar spine surgery.[7]

Previous potential predictors associated with the risk of PRC transfusion may guide the general adjustment for the cross-match order, such as female sex[8–10], older age[8,9], high body mass index (BMI)[1], pulmonary disease or dyspnea[8,9,11], bleeding disorders[8], anticoagulant/antiplatelet therapy [8], high American Society of Anesthesiologist (ASA) classification[1,9,12], low preoperative hemoglobin (Hb) levels[11], hematocrit (Hct)[8,9], multilevel surgery (laminectomy and fusion)[8,9,11–13], long surgical time[8,9,11–13], transforaminal lumbar interbody fusion (TLIF)[1,12], and sacrum fusion.[12] Recent limited studies[14] revealed that a nanogram for PRC transfusion was not simplified for application, reported only preoperative predictors[15], and did not define the type of fusion[3]. Intraoperative procedures were strong predictors that affected the accuracy of the prediction model[1,3,8,9,11–14,16], but they were inappropriate in the preoperative prediction model. Lumbar spine magnetic resonance imaging stimulated preoperative procedure planning in a previous cohort[17], similar to actual surgery. This study used preoperative procedural planning in this model.

They overestimated the cross-match PRC, which resulted in a blood reservation shortage, especially during the coronavirus disease 2019 pandemic.[18] The MSBOS recommends a general cross-match PRC of two units for lumbar spine surgery.[19] PRC transfusions in this spine referral center demonstrated a 43% prevalence. To date, limited data is available regarding the influencing factors in determining an appropriate PRC transfusion for elective primary lumbar spine fusion in developing countries, where healthcare resources are relatively limited. Additionally, the

parameters for predicting the probability of PRC transfusion have no practical use in surgical planning. Geographic variations in healthcare resources, socioeconomic status, and ethnicity may affect predictive PRC preparation. This study aimed to develop a preoperative predictive model for appropriate PRC transfusion in elective primary lumbar spine fusion.

Materials and Methods

Study design and population

A retrospective observational cohort design and prognostic prediction model were developed using data from a spine referral center hospital. The Institutional Ethics Committee approved the study protocol, which was conducted in accordance with the Declaration of Helsinki.

Selection of participants

This study included patients aged ≥50 years who underwent elective primary posterior lumbar spine fusion. The inclusion criteria were: 1.) Lumbar disc herniation 2.) Lumbar spinal stenosis 3.) Lumbar spondylolisthesis, and 4.) Lumbar disc herniation with spinal stenosis at a tertiary spine referral center. The electronic medical records between January 2015 and September 2022 were retrospectively analyzed.

Data collection

Potential clinical predictors include baseline characteristics, such as female sex [8–10], age[8,9], and BMI[1]; comorbidities, such as type II diabetes mellitus[8,11], hypertension[11], pulmonary disease[3,8,9], anticoagulant or antiplatelet [8], ASA classification[1,9,12]; preoperative laboratory parameters, such as preoperative Hct[8,9] and platelets[14]; operative data, such as operative time[8,9,11–13], decompression level and fusion method[1,8,9,11–13], sacral fusion[12], number of pedicular screw fixations [3], use of tranexamic acid[20], and estimated blood loss (EBL)[14].

This study categorized the intraoperative transfusion of PRC into the transfusion and nontransfusion groups.

Sample size calculation

No standard recommended approach has been used for sample size calculations in the development of clinical prediction models. A database was used for score derivation to maximize statistical power and generalizability. The minimum sample size required to develop a multivariable prediction based on the rule of thumb to estimate the sample size used for a prediction model in the 1990s included ≥10 events per predictor.[21]

Statistical Methods

Statistical analysis

Continuous data are presented as the mean and standard deviation (SD), and categorical data are presented as frequencies and percentages. Comparisons of categorical data were performed using the chi-square test or Fisher's exact probability test, and unpaired t-tests were used for continuous data. Variables significant in the univariate logistic regression were subsequently included in the multivariable logistic regression analyses using STATA version 15.1 (Stata et al. Station, TX, USA). Statistical significance was set at $P < 0.05$.

Model development

Eliminating each of the 19 candidate predictors depends on the magnitude of association (odds ratio), statistical significance (*P*-value), AuROC, or significant clinical-related predictors. Logistic regression analysis was used to identify predictors of PRC transfusion. First, univariate analysis was used to analyze the baseline characteristics, comorbidities, preoperative laboratory findings, and operative data. This model avoided bias; significance predictors from univariate analysis were only determined once they were considered in the multivariable model.[22] Significant variables($P < 0.05$) were then included in a multiple logistic regression model with backward selection. The reduced multivariable model retained its predictive performance in terms of discrimination and calibration, and clinical AuROC was used to evaluate the discriminative ability of the derived score. Calibration using the calibration curve and Hosmer–Lemeshow goodness-of-fit test, where a nonsignificant $\chi 2$ value indicates a good fit model. The decision curve analysis determined the potential clinical use, which calculates the net benefit of using the model in practice to classify patients across a range of clinically relevant threshold probabilities compared with transfusion and non transfusion of PRC in patients with elective primary posterior lumbar spine fusion. Each model's performance included sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

The final predictors were assigned the logistic regression coefficients. After model reduction, the regression coefficients, in log-odds form, of the remaining predictors were determined and used to generate a weighted score. The model's lowest coefficient was categorized by dividing each predictor's logistic coefficient and then rounded to the nearest nondecimal integer for applicability. Classification of the sum score indicated a lower or higher risk. The calculated PPV was assigned to each score group to indicate the average patient predictor. Measures of calibration and discrimination were also performed using regression with the PRC transfusion on the model. A calibration plot comparing the model-predicted risk with the observed risk indicated predictive performance. Internally validated by

nonparametric receiver operating characteristic (ROC) regression with 1,000 bootstrapped replicates and externally validated in 102 independent cases. Statistical significance was set at $p < 0.05$.

Scores were classified into two risk groups for clinical utility: low and high-risk. In the low-risk group, lower cut-off points minimized the magnitude of the PPV, while higher cut-off points maximized the magnitude of the PPV in the high-risk group. The model's discriminative ability used 95% CIs to avoid overlapping with the specific PPV. The potential clinical use of the model was identified by decision curve analysis, which calculates the net benefit of applying the model to classify patients across a range of clinically relevant threshold probabilities compared to the two groups of outcomes (transfusion or non transfusion of PRC) in patients with elective primary posterior lumbar spine fusion.

Results

Among the 785 patients identified, a total of 518 patients met the criteria, including 416 patients (transfusion group, n = 178, 43% classified by 1–2 units was 34 % and at least three units was 9%); nontransfusion group, n = 238, 57%) included in the analysis for developing the model, and the remaining 102 patients were included in the independent case in external validation. Of these, 267 patients were excluded because they underwent (1) trauma and emergencies(n = 82), (2) minimally invasive or endoscopic techniques(n=9), (3) tumors(n = 26), (4) infection(n = 21), (5) revision spine surgery(n = 79), and (6) thoracic and cervical levels (thoracic and cervical spine fusion at the same time of lumbar spine fusion) (n = 50) (Fig. 1).

Baseline characteristics, preoperative laboratory results, and operative modality findings are shown in Table 1. Prognostic factors with a high predictive performance showing a statistically significant *P*-value of < 0.05, AuROC of >0.60 (select from Diagnostic Accuracy as the minor sufficient level)[23], and clinically meaningful correlation were chosen. The univariable logistic regression analysis, which included the preoperative Hct cut-off of 38% (level suitable for blood donation)[24], laminectomy, TLIF, and sacral fusion, were identified as critical clinical predictors.

The authors analyzed four potential clinical predictors using multivariable logistic regression (Table 2). The PRC transfusion sum score was calculated by adding the scores of each variable (sum score = preoperative Hct [score] + laminectomy [level] [score] + TLIF [level] [score] + sacral fusion [score]). This study transformed the model predictor (β) regression coefficients into simple scores. Subsequently, the authors developed a simplified model that incorporated clinically relevant factors that can be easily used in clinical practice. The model could predict the use of PRC transfusion with good discriminative ability (AuROC: 0.90 (95%CI 0.87, 0.93)) (Fig. 2. A). The model

correctly classified with sensitivity, specificity, PPV, and negative predictive values of 79.78%,86.13%, 81.14%, and 85.06%, respectively.

Measures of calibration: The calibration plot showed that the model-predicted risk and observed risk of PRC transfusion concomitantly increased (C-statistic = 0.895, slope = 0.993) (Fig. 2. B). Internal validation performance of the model via nonparametric receiver operating characteristics (ROC) with 1,000 bootstrap sampling techniques (bootstrap shrinkage = 0.993) and external validation in 102 independent cases (AuROC: 0.91, 95% CI 0.86, 0.97).

A model performance with a high-risk score (>4) predicted PRC transfusion (Fig. 3. A). The clinical predictions were categorized into two risk groups. The PPVs in the low-risk (≤4) and high-risk (>4) groups were 18.4 (95% CI 13.9, 23.6) and 83.9 (95% CI 77.1, 89.3) respectively (Table 3).

Model performance regarding clinical usefulness and curve analysis can explain the prediction model's net benefit (NB) (PRC transfusion). A cut-off probability threshold of 0.43 (the prevalence point) indicated that our predicted model showed an NB of 2.8 times compared with that without the predictive model. (Fig. 3. B)

Discussion

Preoperative PRC preparation is required for lumbar spinal fusion because the probability of PRC transfusion increases during surgery and in the postoperative period. The problem with this spine referral center is that the hospital needs to be more appropriate for cost-effectiveness in preoperative PRC preparation, especially hospital blood reserve shortages. Early and accurate prediction of PRC transfusion risk is necessary to use blood resources and reduce the risk of allogeneic blood transfusion.[12] This study aimed to develop a new prediction model to reduce the cross-match-to-transfusion ratio in the preoperative preparation of PRC and inform patients of the amount of preoperative autologous PRC donation. Elective lumbar spine fusion provides time to prepare the appropriate blood, especially for autologous blood donation. Autologous blood transfusion reduces complications associated with allogeneic blood transfusions. Each surgery has a separate scoring system because the weight of factors affecting total PRC transfusion varies in different diseases.

The present study identified PRC preparation factors that predicted the risk of PRC transfusions in developing countries. The prevalence of PRC transfusion (43%) during the study period at this spine referral center hospital was similar to some studies (40%–81%)[2,13,15] but in contrast with other previous studies (5%–32%)[9,12,14].

The model predicted the risk of PRC transfusion with a good discriminative ability AuROC of 0.90 (95%CI 0.87, 0.93) and an excellent discriminative ability AuROC of 0.91(95% CI 0.86, 0.97) for external validation in independent cases.

In recent studies reporting individual prediction models, Wang et al. 2021[14] proposed a prediction nanogram model using predictors such as fusion level, intraoperative EBL, time to surgery, preoperative Hb level, and operative time. The AuROC of this study was 0.898, which is the use of learning efforts for daily clinical practice. This study requires using parameters intraoperatively (intraoperative EBL and operative time), making it impossible to predict preoperative PRC preparation.

Nie et al. 2021[15] revealed that age, BMI, abnormal coagulation, preoperative Hb level, multiple lesions, and revision surgery were discriminatory (AuROC = 0.73), with a smaller sample size and only preoperative predictors. Previous studies indicated the substantial effect of intraoperative predictors.[1,3,8,9,11–14,16]

Another previous study[3] revealed the association of PRC transfusion with age, low BMI, number of fusion and fixation segments, spine deformity, and preoperative Hb level. Further, the type of lumbar spine fusion is associated with variations in intraoperative blood loss, which should be defined. Furthermore, the present study demonstrated a better discrimination performance.

The present model was determined using four predictors: 1) a high preoperative Hct level is a preventive predictor of a significantly low risk of transfusion[11,13], as a recent systematic review revealed that high preoperative Hct or Hb levels were associated with a lower blood transfusion rate, better outcomes, and lower complication rates[25], 2). laminectomy at multiple levels generates muscles, soft tissues, and bones that detach from the vertebrae, causing bleeding from raw surfaces[8,9,11–13], 3). TLIF at more than one level [1,12] produces more bleeding in the intervertebral end plate, and 4). sacral fusion[12] due to a more complex procedure, longer operative time, and extensive muscle and soft tissue detachment.

This study has limitations: (1) The prediction model must be validated in a more extensive prospective study before use. (2) The study retrospectively analyzed the collected data; some data did not include all types of posterior spinal fusion (small number of PLIF (12 cases) due to this type of fusion more risk of nerve root injury than TLIF), patient bleeding disorder, experience of an orthopedist, and preoperative blood predictors (active partial thromboplastin time (APTT), prothrombin time (PT), and other clotting factors were not routine preoperative laboratory). (3) The model was also based on a single center, which requires external validation for good predictive

performance, particularly in other public health hospitals. (4) In case of missed predictions, discussing and setting a safety protocol with a blood bank before using this model is recommended.

This study had several strengths. 1.) This study predicts appropriate PRC transfusion in elective lumbar spine fusion with good discriminative ability (AuROC: 0.90) and good external validation in independent cases (AuROC: 0.91). 2.) The calibration slope for the predictive model was close to 1 (calibration slope = 0.993). The present model informs clinical decision-making with a better-expected benefit. Thus, the model may be cost-effective and use preoperative planning procedure predictors for a more accurate and reliable preoperative plan. 3.) Our model was more accurate than the previous model[3,14,15] for preparing blood resources before elective spinal surgery, with the cost-effectiveness of the blood reserves in limited healthcare systems. 4.) Clinical application safely discussed to patients that preoperative blood preparation by a low score category is not an essential cross-match of PRC, and cross-match should be performed in 1–2 units of PRC following the suggestion from the MSBOS for a high-risk category[19]. This is consistent with the data of this study (transfusion group, n = 178, 43% classified by 1–2 units was 34%, and at least three units was 9%) and informs patients about autologous blood donation. However, if a physician still needs to book more PRC than recommended, the preparation type and screening method for PRC should be identified because they are less expensive.

In conclusion the present study developed a model for predicting the preoperative preparation for PRC and may be used to inform patients about the necessity of autologous PRC donation. This model has high discriminative ability, simplicity, and cost-effectiveness. Further research is necessary for external validation in other spine referral center hospitals and a prospective study cohort with a large sample size before application.

Conflict of interests

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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306 **Tables**

307 **Table 1.** Comparison of the baseline characteristics of the PRC transfusion and non-transfusion groups.

	Elective primary posterior lumbar spinal fusion				
PRC	PRC transfusion (n = 178)	PRC non-transfusion (n = 238)	OR	*P*-value	AuROC (95% CI)
Female (%)	71.9	64.3	1.42	0.101	0.54 (0.49, 0.58)
Age (y) (mean ± SD)	62.4± 7.8	61.7± 7.8	1.01	0.378	0.53 (0.47, 0.58)
Body mass index (kg/m^2) (mean ± SD)	26.0± 4.1	25.3± 3.8	1.05	0.058	0.55 (0.50, 0.61)
Diabetes mellitus type II (%)	20.8	14.7	1.52	0.106	0.53 (0.49, 0.57)
Anticoagulant/antiplatelet use (%)	9.0	5.0	1.86	0.117	0.52 (0.49, 0.54)
Hypertension (%)	53.4	51.3	1.09	0.670	0.51 (0.46, 0.56)
Pulmonary disease (%)	1.7	3.8	0.44	0.218	0.51 (0.47, 0.50)
ASA classification (%)	1.4± 0.5	1.2 ± 0.5	1.97	0.001	0.59 (0.54, 0.63)
Preoperative Hct level (mean ± SD)	37.3 ± 3.8	39.0± 3.4	0.87	<0.001	0.64 (0.31, 0.42)
Preoperative platelet count ($\times 10^3$/mL) (mean ± SD)	273.9± 66.3	285.9± 76.8	1.00	0.097	0.54 (0.40, 0.52)
Operative time (min) (mean ± SD)	254.7± 60.8	183.6± 53.3	1.02	<0.001	0.81 (0.77, 0.85)
Laminectomy (level) ± SD	3.2 ± 0.8	1.9 ± 0.8	5.87	<0.001	0.85 (0.82, 0.89)
Fusion method (level)					

(mean ± SD)					
PL fusion	3.5 ± 1.0	2.2 ± 1.0	3.51	<0.001	0.81 (0.77, 0.85)
TLIF	0.7 ± 0.8	0.3 ± 0.5	2.60	<0.001	0.64 (0.59, 0.69)
PLIF	0.0 ± 0.2	0.1 ± 0.3	0.44	0.153	0.52 (0.47, 0.49)
Sacrum fusion (%)	81.5	26.5	12.20	<0.001	0.78 (0.73, 0.82)
Pedicular screw (level) (mean ± SD)	3.6 ± 0.9	2.2 ± 1.1	3.51	<0.001	0.81 (0.78, 0.85)
Tranexamic acid (%)	75.3	57.6	2.25	<0.001	0.59 (0.54, 0.63)
Estimate blood loss (mL) (EBL mean ± SD)	1281.8 ± 996.5	476.7 ± 254.9	1.00	<0.001	0.87 (0.83, 0.90)

Abbreviations: ASA, American Society of Anesthesiologists; AuROC, area under the receiver operating characteristic; EBL, estimate blood loss; Hct, hematocrit; PL fusion, posterolateral fusion; TLIF, transforaminal lumbar interbody fusion; OR, odds ratio; PLIF, posterior lumbar interbody fusion; PRC, packed red cells; $P < 0.05$, significant difference; 95% CI, 95% confidence interval.

Table 2. Best multivariable clinical predictors.

Predictors	OR	95% CI	*P*-value	Beta coefficient	Adjusted βeta coefficient	Score
Preoperative hematocrit level						
≥38	1.00	reference	-	-	-	0
<38	2.06	1.19, 3.59	0.010	0.73	1.00	1
Laminectomy (level)						
≤2	1.00	reference	-	-	-	0
>2	10.41	5.91, 18.34	<0.001	2.34	3.23	3
TLIF (level)						
≤1	1.00	reference	-		-	0
>1	8.41	2.53, 27.92	0.001	2.13	2.93	3
Sacral fusion						
no	1.00	reference	-		-	0
yes	5.31	2.96, 9.51	<0.001	1.67	2.30	2.5

OR, odds ratio; 95% CI, 95% confidence interval; β, logistic regression beta coefficient.

Adjusted βeta coefficient = βeta coefficient in that Raw/lowest βeta coefficient (*)

Preoperative planning procedure: laminectomy (level), TLIF (level), Sacral fusion

sum score = preoperative hematocrit (score) + laminectomy (level) (score) + TLIF (level) (score) + sacral fusion (score).

Table 3. Distribution of prediction scores into low- and high-probability categories.

Score categories	Score	PRC transfusion (n = 178)		PRC nontransfusion (n = 238)		PPV (%)	95% CI	*P*-value
		n	(%)	n	(%)			
Low	≤4	48	(18)	213	(82)	18.4	(13.9, 23.6)	<0.001
High	>4	130	(84)	25	(16)	83.9	(77.1, 89.3)	<0.001

PPV, positive predictive value; PRC, packed red cells; 95% CI, 95% confidence interval.

Figure legends

Figure 1 Flow diagram of patient enrollment.

Figure 2

Figure 2A Receiver operating characteristics (ROC) curves of the clinical prediction model for PRC transfusion. PRC, packed red cells.

Figure 2B Calibration plot of the model-predicted risk vs. the observed risk of using a PRC transfusion in primary elective lumbar spinal fusion. PRC, packed red cells.

Figure 3

Figure 3A Evaluation of the model performance in terms of clinical predictive ability. Observed risk (circle) vs. model-predicted risk (solid line) of PRC transfusion. The circle size represents the frequency of PRC transfusions in each score. PRC, packed red cells; prc1umore: use of PRC transfusion ≥1 unit.

Figure 3B Evaluation of the model performance in terms of clinical usefulness based on the score calibration curve and decision curve analysis. PRC, packed red cells; prc1umore, use of PRC transfusion ≥1 unit.

336 **Figure 1**

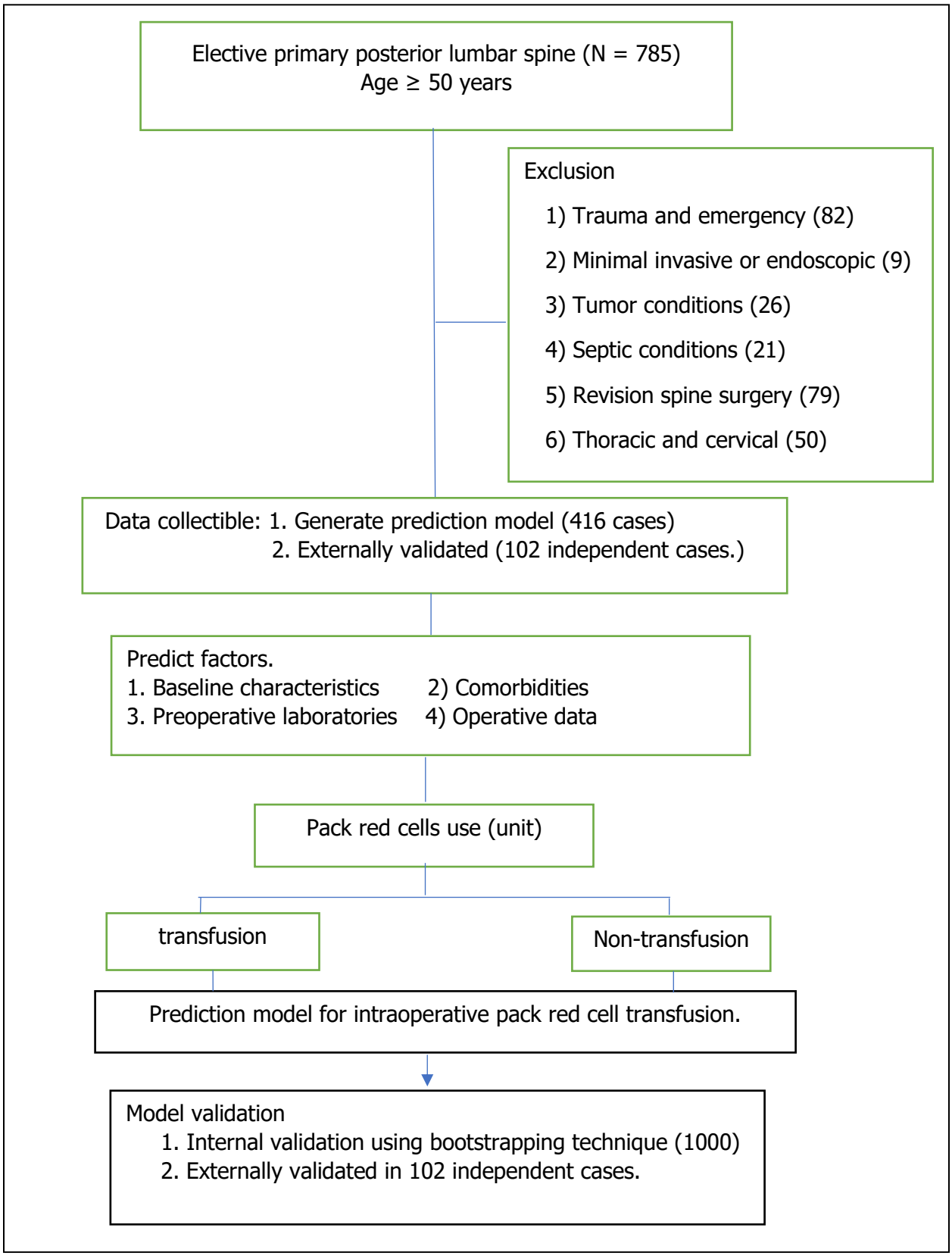

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Figure 2

Figure 2.A

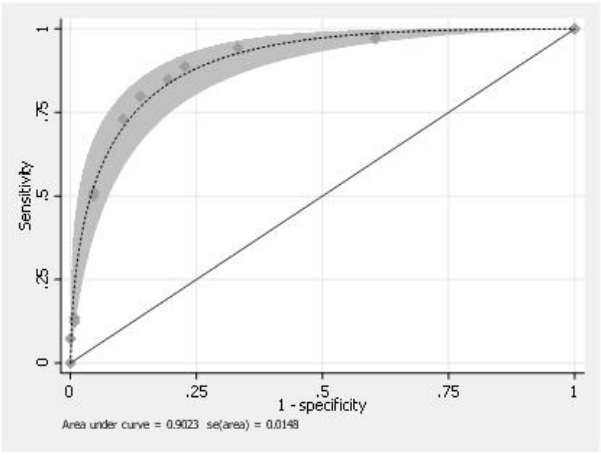

Figure 2.B

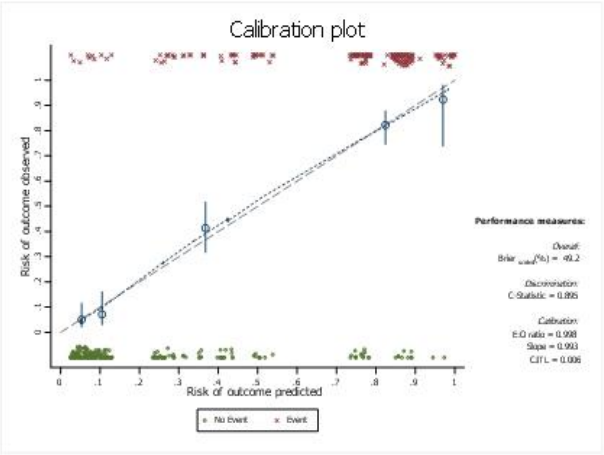

Figure 3

Figure 3.A

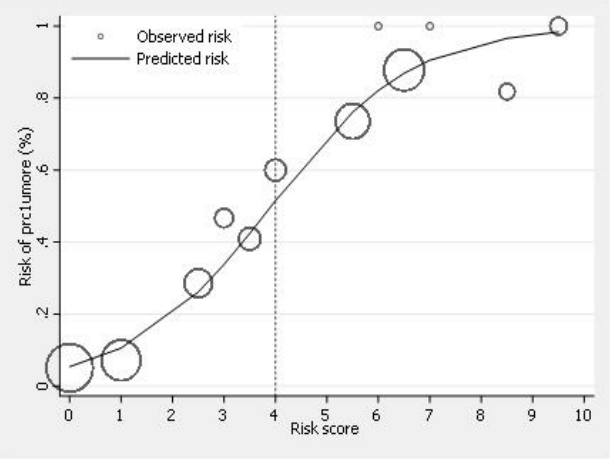

Figure 3.B