ORIGINAL ARTICLE

Three point transfusion risk score in hepatectomy: an external validation using the American College of Surgeons – National Surgical Quality Improvement Program (ACS-NSQIP)

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Abstract

Background: Risk of red blood cell transfusion (RBCT) in partial hepatectomy is 17–27%; strategies to reduce transfusions can be targeted in patients at increased risk. A Three Point Transfusion Risk Score (TRS) was previously developed to predict patients' risk of transfusion during and following hepatectomy. Here, it was subject to external validation using the ACS-NSQIP database.

Methods: TRIPOD guidelines were followed. A validation cohort was created with the ACS-NSQIP dataset. Risk groups for RBCT were created using the TRS: anemia (hematocrit $\leq$36%), major liver resection ($\geq$4 segments) and primary liver malignancy. Concordance index was used to assess the discrimination. The Hosmer–Lemeshow test for goodness of fit and calibration curves were used to assess calibration.

Results: Of 2854 hepatectomies, 18.9% received RBCT. The TRS stratified patients from low (8.5% risk of RBCT) to very high risk (40.6%) of RBCT. The concordance was 0.68 (95% CI 0.66–0.70). Hosmer–Lemeshow test and calibration curves supported good predictive performance of the model.

Conclusion: The TRS adequately discriminated risk of RBCT in an external sample of patients undergoing hepatectomy. It provides a simple method to identify patients at high transfusion risk. It can be used to tailor patient blood management initiatives and reduce the use of RBCT.

Received 14 November 2017; accepted 7 January 2018

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Introduction

Blood loss and peri-operative red blood cell transfusions (RBCTs) remain a significant issue in hepatectomy, with RBCTs administered in 17–27% of cases.[1–4] Use of RBCTs is potentially detrimental, with increased risk of post-operative morbidity, and compromised oncologic outcomes.[5,6] Further, RBCTs are a costly, limited resource, and have been recognized has overused.[7–11] Comprehensive patient blood management (PBM) programs can effectively reduce surgical patients' risk of transfusion and improve outcomes, and are now part of the World Health Organization's standards of practice.[12–15] Interventions designed to manage pre-operative anemia, minimize blood loss, and ensure appropriate indications for ordering RBCTs are part of PBM programs. These include pre-operative iron supplementation, intra-operative cell-salvage, hemostatic medication (e.g. tranexamic acid), anesthetic management specific to hepatectomy (e.g. low central venous pressure, phlebotomy with controlled hypovolemia), and liver inflow occlusion.[12,16–20] Incorporating such strategies into clinical practice relies on predicting patient risk of transfusion pre-operatively to direct appropriate strategies at patients likely to benefit while optimizing use of resources.

Part of this work has been presented at the American Hepato-Pancreato-Biliary Association held in Miami, Florida, in April 2017 and the Canadian Surgery Forum held in Victoria, British Columbia in September 2017.

Complex transfusion risk scores pertaining to hepatectomy had been developed.[2–4] However, their usefulness in clinical practice is limited due to complexity of the scoring process, inclusion of intra-operative variables, and low performance in an independent external validation.[1] A more recent simplified score was developed using a contemporary multi-institutional cohort of patients undergoing hepatectomy.

The Three Point Transfusion Risk Score (TRS) was developed using three factors associated with peri-operative RBCTs for hepatectomy: pre-operative anemia (hemoglobin $\leq$12.5 g/dL), primary liver malignancy, and major resection ($\geq$4 liver segments removed).[1–4] Each of these factors are assigned one point and summed to produce the TRS. Patients are separated into four risk categories: low risk (TRS = 0), moderate risk (TRS = 1), high risk (TRS = 2) and very high risk (TRS = 3). This simplified method showed comparable performance to more complex scores.[1] Details of the TRS development and performance in the development cohort have been previously reported.[1]

In order for a predictive score to hold value and be integrated in practice, it must be validated in a different sets of patients.[21] Without such assessment, the performance of the model in alternate patient populations remains unknown. Assessment of external validity is a central component of Transparent Reporting of a Multivariable Prediction Model for individual Prognosis or Diagnosis (TRIPOD) recommendations.[22] In this study, the TRS was subjected to an external validation using the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) targeted hepatectomy database.

Methods

The TRS was validated according to the TRIPOD recommendations.[1,22] This study was exempted from ethics approval by the Sunnybrook Health Sciences Centre Research Ethics Board.

External validation cohort

An external validation cohort was assembled using the ACS-NSQIP targeted hepatectomy database. The ACS-NSQIP is a multicenter prospective registry designed for quality improvement purposes. The ACS-NSQIP targeted hepatectomy module collects hepatectomy-specific data at 92 participating sites since 2014. Included hospitals represent academic and community settings in various regions of North America. Over 275 variables are collected, including demographics, pre-operative risk factors, procedural indication and details, and 30-day post-operative morbidity and mortality. Data are collected by trained data abstractors and audited for accuracy.[23] The methods of ACS-NSQIP abstractors training, data collection process, and reliability audits have previously been reported.[23–26]

All patients in the ACS-NSQIP targeted hepatectomy database from January 1 to December 31 2014 were identified. Patients were excluded in case of missing data on the following key variables necessary for analysis: perioperative RBCT, pre-operative hematocrit, final pathology, or extent of liver resection. Missing data were encountered in 0% for RBCT, 2.0% for pre-operative hematocrit, 4.9% for pathology, and 0% for extent of liver resection.

Outcome measure

The outcome of interest was perioperative RBCT defined as the receipt of RBCT within 72 h from the start of surgery, as captured in the ACS-NSQIP registry.[27] This definition relies on a shorter time window than that used in the original development of the TRS which considered RBCT over patients' entire hospital stay.

Patient demographics and components of the TRS

Data on patients' baseline demographics, clinical and treatment characteristics were available from the ACS-NSQIP registry.[27] Pre-operative anemia was defined as a pre-operative hematocrit $\leq$36%.[28] Major liver resection was defined as a resection of four or more segments, including left hepatectomy, right hepatectomy, and trisegmentectomy.[29] Primary liver malignancy was defined as hepatocellular carcinoma or cholangiocarcinoma.

The TRS was computed for each patient. Patients were grouped in four risk categories according to the TRS, as previously described.

Statistical analysis

Continuous variables were reported as median with interquartile range (IQR), and categorical data as absolute number (n) with proportion (%). Characteristics of the development and the validation cohorts were compared using Kruskal–Wallis test or Chi square test, as appropriate. Characteristics of patients excluded from the validation cohort were reported separately to inform on any potential selection bias resulting from the decision to exclude based on missing data.

Patients were assigned a TRS with one point assigned to each factor: pre-operative anemia (hematocrit $\leq$36%), major liver resection ($\geq$4 segments) and primary liver malignancy. The distribution of patients among each TRS were reported. Transfusion rates were compared between the development and the validation cohorts in each risk category using Chi Square test.

The external validation was evaluated using discrimination (the predictive ability of the TRS) and calibration (the degree of agreement between the predicted and observed probabilities). Discrimination was evaluated using the concordance index between the probability of transfusion predicted by the TRS and the incidence of transfusion within the cohort. Calibration was evaluated using the Hosmer–Lemeshow test for goodness of fit and calibration plots compared the probabilities predicted by the TRS and the actual probabilities. Predicted probabilities were defined as those generated from the TRS.[30] Actual probabilities were smoothed using locally weighted least squares regression to allow the binary outcome (receipt/no receipt of a peri-operative RBCT within the first 72 h of surgery) to be evaluated over a range of probabilities.[31–33]

Statistical significance was set at $p \leq 0.05$. All analyses were performed using SAS Version 9.4 (SAS Institute Inc., Cary NC).

Results

A total of 3064 hepatectomy cases were identified from the ACS-NSQIP targeted hepatectomy database, of which 2854 were included in the validation cohort. Exclusion due to missing data occurred in 7.3% (n = 210) of the cohort: 60 missing pre-operative hematocrit, 148 missing diagnosis, and 2 missing both pre-operative hematocrit and diagnosis (online only Table 1).

Demographic and clinical characteristics of patients in the development and validation cohorts are presented in Table 1. The development and validation cohorts had different rates of pre-operative anemia and primary liver malignancy. There were also significant differences in transfusion risk scores between the groups. Perioperative RBCT was administered in 539 (18.9%) patients in the validation cohort compared to 341 (26.5%) in the development cohort ($p < 0.001$).

Transfusion risk scores were assigned, with the majority of patients in the moderate risk group (TRS = 1, 40.5% n = 1157) and the minority in the very high risk group (TRS = 3, 3.4% n = 96) (Fig. 1). Comparison of transfusion rates between the development and validation cohorts is depicted in Fig. 2. Transfusion rates differed across low, moderate, and high risk categories, with higher rates in the development cohort. No difference was detected in the very high risk category.

The concordance index of the TRS was 0.68 (95% CI 0.66–0.70), close to the concordance index reported in the development of the score 0.66 (0.63–0.69).[1] The Hosmer–Lemeshow test for goodness of fit did not detect a poor fit on the model ($p = 0.107$). The calibration curve showed the TRS underestimated the transfusion rate, most severely in the highest risk group (Fig. 3).

Discussion

In this study, the previously developed TRS was subjected to external validation using the ACS-NSQIP targeted hepatectomy database.[1] Despite having a lower transfusion rate (18.9%) than the development cohort (26.5%), the model showed comparable performance (concordance index 0.68; 95% CI 0.66–0.70) to the development cohort (concordance index 0.66; 95% CI

Table 1 Characteristics of the development and validation cohorts

	Development cohort[1] (n = 1287)	Validation cohort (n = 2854)	p-value
Age (years)	62 (53–70)	60 (50–69)	<0.001
Male gender	56.1 (722)	47.6 (1460)	<0.001
Body mass index	26.9 (23.7–30.2)	27.3 (24.0–31.4)	0.005
Pre-operative anemia[a]	28.2 (362)	25.3 (723)	<0.001
Pre-operative platelets ($\times 10^9$/L)	225 (182–278)	223 (175–277)	0.371
Pre-operative INR	1.00 (0.94–1.05)	1.00 (0.99–1.10)	<0.001
Pre-operative bilirubin (μmol/L)	7.4 (5.1–11.0)	8.6 (6.8–12.0)	<0.001
Pre-operative creatinine (μmol/L)	72.0 (61.0–85.0)	72.5 (61.9–88.4)	<0.001
Diagnosis			
Primary liver	19.9 (256)	29.5 (841)	<0.001
Metastases	69.1 (889)	49.8 (1422)	
Benign	11.0 (142)	20.7 (591)	
Major liver resection[b]	35.9 (462)	38.4 (1097)	0.100
Inflow occlusion	23.7 (301)	26.5 (757)	0.178
Procedure time (minutes)	227 (167–309)	227 (164–314)	0.405
Transfusion risk score category			
Low risk (TRS = 0)	36.5 (469)	34.8 (993)	<0.001
Moderate risk (TRS = 1)	44.7 (575)	40.5 (1157)	
High risk (TRS = 2)	17.2 (221)	21.3 (608)	
Very high risk (TRS = 3)	1.6 (21)	3.4 (96)	
Receipt of peri-operative RBCT	26.5 (341)	18.9 (539)	<0.001

Values are median (inter-quartile range) or % (n).
RBCT: red blood cell transfusion; TRS: transfusion risk score.
[a] Anemia: hemoglobin ≤12.5 g/dL (development cohort) or hematocrit ≤36% (validation cohort).
[b] Major liver resection: resection of 4 or more liver segments.

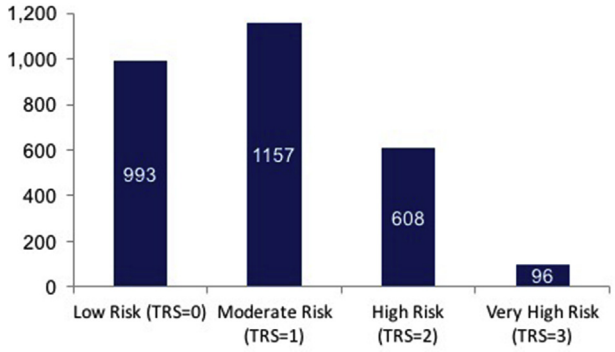
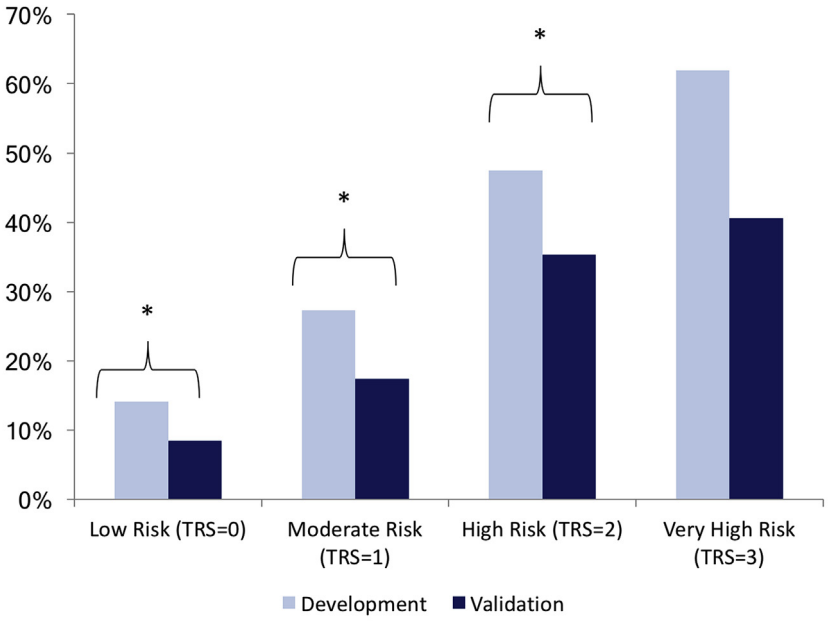


Figure 1 Distribution of patients in each TRS category. TRS: Transfusion Risk Score

0.63–0.69).[1] Transfusion rates across each score were 8.5% for low risk, 17.4% for moderate risk 1, 35.4% for high risk, and 40.6% for very high risk.

Predicting peri-operative risk of transfusion in hepatectomy is critical to direct efforts in PBM.[2–4,12] The advantage of the TRS is its ease of use, requiring very little information and ability to be computed quickly in clinic to predict transfusion risk in the pre-operative setting. While the factors considered in this score are intuitive, together they provide an effective method for assessing risk of transfusion. When other more complicated existing scores were subject to validation on a multi-institutional contemporary external dataset, they did not outperform the simplified TRS, suggesting the increased complexity does not result in an improved score.[1]

The ability to accurately predict patient risk of transfusion is important to direct resources appropriately. PBM include a wide array of interventions to be tailored to individual patients.[12] Such interventions include pre-operative iron supplementation, acute normovolemic hemodilution, whole blood phlebotomy, intra-operative hemostatic medications, and intra-operative cell salvage.[12,20] Some interventions are associated with improved outcomes, but can also be wasteful and potentially harmful when used in patients unlikely to benefit.[34–36] For instance, use of intra-operative cell salvage has been shown both to be oncologically safe and reduce transfusions by 38%.[17,37] It is however associated with elevated costs, and may not be beneficial or cost-minimizing if used in hepatectomy patients with a low to moderate transfusion risk.[16] Therefore, a validated simple TRS can have direct applications in tailoring and improving peri-



	Low Risk (TRS=0)	Moderate Risk (TRS=1)	High Risk (TRS=2)	Very High Risk (TRS=3)
Development, % (n)	14.1% (66)	27.3% (157)	47.5% (105)	61.9% (13)
Validation, % (n)	8.5% (84)	17.4% (201)	35.4% (215)	40.6% (39)
P-value	<0.001	<0.001	<0.001	0.058

Figure 2 Comparison of transfusion rates between the development and validation cohorts by TRS Risk categories. *Indicates statistical significance. TRS: Transfusion Risk Score

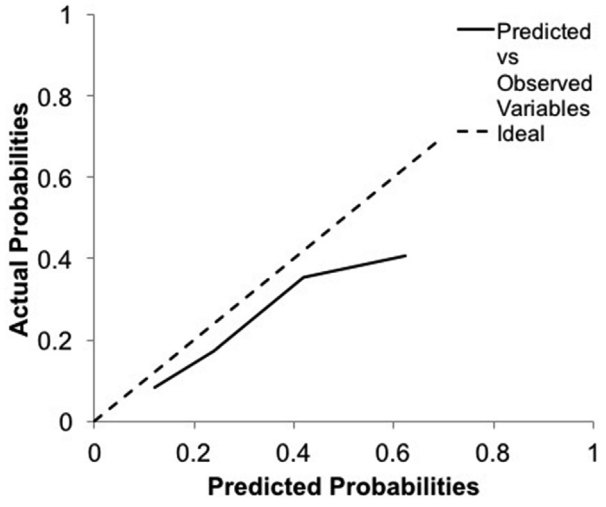


Figure 3 Comparison of predicted and observed probabilities of perioperative RBCT using the TRS

operative care for hepatectomy. Assessing the impact of the TRS on resource allocation and to reduce use of RBCT falls beyond the scope of this study.

The usefulness of clinical scores is often limited by the lack of demonstrated generalizability to other populations. External validation is a critical part of predictive models' development and application, and thus is emphasized in the TRIPOD recommendations.[22,38] While external validation frequently shows reduced performance, it provides a more realistic assessment of the performance of the model in a wider population.[1,39] This highlights the importance of external validation prior to uptake of predictive scores to understand the limitations of the model before applying it in clinical practice. The current study provides evidence of the accuracy and validity of the TRS in an external population necessary to support its use in practice to direct perioperative hepatectomy care.

The differences in transfusion rates can be in part attributed to the different definitions of perioperative RBCT. In the development cohort, RBCT was defined as a transfusion occurring from the start of the procedure until discharge from hospital.[1] In this study, only RBCTs occurring within 72 h of the start of the procedure were included, as available in the ACS-NSQIP. This difference did not impact the overall performance of the model. However, it resulted in lower transfusion rates in the validation cohort overall and within each transfusion risk group. When considering only transfusions within 72 h in the development cohort, the transfusion rate is reduced to 294 patients (23.0%) but remains different from the validation cohort with statistical significance ($p = 0.001$). With transfusion rates continuing to lower over time in hepatectomy, reevaluating the transfusion risk associated with the score may be beneficial.[40] However, the fact that the TRS performed well in an independent population with different transfusions practices further strengthens its usefulness: it can be used accurately in various populations.

While the validation may not be independent, it relies on rigorous methods and data from an alternate, representative dataset of a North American population. This study is limited by the information available in the ACS-NSQIP. Implications of different definitions of perioperative RBCT have previously been discussed. Patients who may be misdiagnosed or have a change in surgical plan could not be accounted for, where the TRS would change from the pre-operative assessment. Nevertheless, a major strength of this study is the breadth and quality of the ACS-NSQIP database used for this analysis. It provides multi-institutional clinical data from institutions with various volumes of hepatectomy and in both academic and community settings. The data is captured by rigorously trained data abstractors and subjected to frequent audits to ensure accuracy; information bias is limited.[23–26] Therefore, the ACS-NSQIP targeted hepatectomy database provides very robust data in a widespread contemporary (2014) group of patients. With such large datasets, missing data can present an issue.[41] Previous studies have concluded that here is no significant change between various strategies to handle missing data in the ACS-NSQIP. Therefore, the few patients with missing data were excluded.[41] The amount of missing data was limited and the characteristics of excluded patients did not differ substantially from those of included patients.

Conclusion

The TRS accurately predicts risk of perioperative RBCT for hepatectomy in an external multi-institutional contemporary validation cohort. Only three factors are required to calculate the score: pre-operative anemia, primary liver malignancy, and major resection, allowing for easy use in a busy clinical environment. This score appropriately discriminates between four risk categories, from low (8.5% RBCT) to very high (40.6% RBCT) in independent populations. It can be used pre-operatively to accurately define the transfusion risk and tailor PBM interventions for patients undergoing hepatectomy.

Funding/support

No funding was provided for this project.

Conflicts of interest

None declared.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.hpb.2018.01.010.