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Original Article

Validation of the Emory Risk Score in the Transcatheter Aortic Valve Implantation Population: A Canadian Perspective

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ABSTRACT

Background: Permanent pacemaker (PPM) implantation may be indicated post-transcatheter aortic valve implantation (TAVI). The Emory Risk Score (ERS) is a validated predictive risk score of the need for a PPM post-TAVI using a balloon-expandable valve. Our objectives were to determine the validity of the ERS in our local TAVI population with both balloon-expandable and self-expanding valves and to identify additional electrocardiographic (ECG) parameters predictive of the need for a PPM post-TAVI.

Methods: Retrospective chart and electronic database reviews were performed to collect demographic and procedural information. Two expert readers reviewed all ECGs. Independent factors associated with PPM implantation were examined with multivariable logistic regression via a stepwise selection process with calculation of the area under the receiver operating characteristic curve to assess model discrimination.

RÉSUMÉ

Introduction : L'implantation d'un stimulateur cardiaque permanent (SCP) peut être indiquée après l'implantation valvulaire aortique par cathéter (post-IVAC). L'Emory Risk Score (ERS) est un score de prédiction du risque validé de la nécessité d'un SCP post-IVAC au moyen d'une valve expansible par ballonnet. Nous avions pour objectif de déterminer la validité de l'ERS auprès de notre population ayant eu une IVAC soit par valve expansible par ballonnet ou valve auto-expansible, et de déterminer d'autres paramètres électrocardiographiques (ECG) prédictifs de la nécessité d'un SCP post-IVAC.

Méthodes : Nous avons réalisé des revues rétrospectives de dossiers et de bases de données électroniques pour collecter les données démographiques et interventionnelles. Deux experts ont lu et interprété tous les ECG. Les facteurs indépendants associés à l'implantation du SCP ont été examinés en effectuant la régression logistique

Transcatheter aortic valve implantation (TAVI) is the treatment of choice for patients with symptomatic severe aortic stenosis who are considered to be inoperable or at high operative risk, and it can be a reasonable alternative to surgical aortic valve replacement (SAVR) in certain patients with intermediate or low surgical risk.[1] Complications arising from TAVI are limited; however, the need for permanent pacemaker (PPM) implantation has been reported to occur twice as frequently in TAVI patients, compared to SAVR patients,[2] regardless of valve type, generation of valve, or vascular access approach used.[2] Rather than immediately implant a PPM, current recommendations are to maintain a temporary pacing wire for 24 hours post-TAVI if conduction issues are noted.[3] Temporary pacing requires that a patient be monitored in a high-dependency or intensive care unit (ICU) environment,

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Ethics Statement: Following research ethics board (HS23991/H2020:272) and site approval, data collection was performed using retrospective chart and electronic database reviews.

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Results: The overall PPM implantation rate was 11.7%; rates were 9% for the Sapien 3 valves, 10% for the Evolut Pro valves, and 17% for the Evolut R valves. The ERS was found to not be predictive of need for PPM post-TAVI for the entire cohort. Right bundle branch block was the only ERS parameter independently associated with new PPM implant (8.5% vs 25%, odds ratio = 3.59, $P = 0.01$). No additional ECG parameters met the criteria for statistical significance.

Conclusions: The poor predictive value of the ERS in determining the need for a PPM post-TAVI in our patient population suggests that further refinement of a formula (or risk-calculator) is warranted. Identification of a precise risk-calculator is likely to facilitate patient mobilization and reduce inpatient healthcare resource utilization.

multivariée par processus de sélection pas-à-pas au moyen du calcul de la surface sous la courbe caractéristique d'efficacité du récepteur afin d'évaluer la discrimination du modèle.

Résultats : Le taux global d'implantation d'un SCP était de 11,7 % ; les taux étaient de 9 % pour les valves Sapien 3, de 10 % pour les valves Evolut Pro et de 17 % pour les valves Evolut R. Nous avons observé que l'ERS ne permettait pas de prédire si l'implantation d'un SCP post-IVAC était nécessaire pour la cohorte entière. Le bloc de branche droit était le seul paramètre de l'ERS indépendamment associé à la nouvelle implantation d'un SCP (8,5 % *vs* 25 %, rapport de cotes = 3,59, $P = 0{,}01$). Aucun autre paramètre ECG ne satisfaisait au critère de signification statistique.

Conclusions : La faible valeur prédictive de l'ERS à déterminer la nécessité d'un SCP post-IVAC au sein de notre population de patients montre que des améliorations de la formule (ou calculateur de risques) sont justifiées. L'identification d'un calculateur de risques précis devrait favoriser l'adhésion des patients et réduire l'utilisation des ressources en soins de santé en milieu hospitalier.

with the need for advanced assessment utilizing higher skill or critical care nurse resources. With recent evidence of an increasing utilization of TAVI in the setting of the current pandemic,[4] the national critical care nursing shortage,[5] and the lack of ICU bed availability, new rhythm disturbances following a TAVI procedure have the potential to significantly impact healthcare resources and patient-reported outcomes. Temporary pacing requires bed rest to avoid movement of the pacing wire and loss of capture,[3] which removes the ability to implement early mobility and the Vancouver 3M (multidisciplinary, multimodality, but minimalist) clinical pathway.[6] This approach also increases procedural costs related to prolonged hospital length of stay.[7]

PPM Risk Score

Although many independent risk factors for PPM implantation post-TAVI are recognized, until recently, no validated risk score to predict the need for PPM post-TAVI has been available.[2,8-11] The Emory Risk Score (ERS) was developed as a predictive risk score for the need for new PPM implantation post-TAVI in patients implanted with a balloon-expandable valve.[12] The ERS assigns 2 points for preexisting right bundle branch block (RBBB), and 1 point each for a history of syncope, QRS duration $\geq$ 140 ms, and valve oversizing $\geq$ 16%[12] (Table 1). A higher ERS was found to be significantly correlated with the implantation of a PPM.[12] Furthermore, increasing scores were highly associated with PPM implantation, compared to a risk score of zero, with an odds ratio (OR) of 2.2 per point increase.[12] The ERS was shown to have a sensitivity of 72.9% in the derivation cohort (778 patients) and 77.8% in the validation cohort (367 patients).[12] A recent study noted that the ERS demonstrated similar predictability in self-expandable valves and balloon-expandable valves (area under the receiver operating characteristic [AUROC] curve 0.657 and 0.645, respectively).[13]

Table 1. Overview of the Emory Risk Score

Characteristic	Points
History of syncope	1
Right bundle branch block	2
QRS duration $\geq$ 140 ms	1
Valve oversizing $\geq$ 16%	1

The validity of the ERS in our local patient population is unknown. Assessment of frailty is recommended in Canada as part of the preprocedural assessment for TAVI.[1] Frailty was not considered in the development of the ERS, and details on the frailty of the patients included in the derivation and validation cohorts are unknown.

Purpose

Whether the ERS can be extrapolated and applied to our centre is not known. At our centre, TAVI is currently performed for mostly high and intermediate surgical risk aortic stenosis patients, and the number of procedures has steadily increased each year, with continued anticipated growth with the aging population and expanded indications. Our objectives were to determine the validity of the ERS in our local TAVI population with both balloon-expandable (Sapien 3, Edwards Life Sciences, Irvine, CA) and self-expanding valves (Evolut-R and Evolut-Pro, Medtronic, Minneapolis, MN) and identify additional electrocardiographic (ECG) parameters that predict the need for a PPM post-TAVI. We hypothesize that the ERS is not predictive of the need for a PPM post-TAVI with either balloon-expandable or self-expandable valves. We further hypothesize that no additional ECG characteristics are predictive of the need for a PPM post-TAVI.

Methods

Following Research Ethics Board (HS23991/H2020:272) and site approval, data collection was performed using retrospective chart and electronic database reviews. All patients undergoing TAVI at St Boniface Hospital in Winnipeg, Manitoba, from September 2015 to August 2020, were included. Patients who received a Sapien XT valve (Edwards Life Sciences, Irvine, CA) were excluded from our analysis, as this valve is no longer implanted. We also excluded patients

Table 2. Baseline characteristics of transcatheter aortic valve implantation patient population

Characteristic	Missing, N	No new pacemaker (N = 212)	New pacemaker (N = 28)	*P*	Area under ROC curve
Demographics					
Age, y	2	82 (78−87)	84 (78−87)	0.873	0.509
Sex (female)	1	109 (51.4%)	13 (48.2%)	0.749	0.516
BMI, kg/m^2	4	28.4 (25.1−33.2)	29.3 (27.0−33.8)	0.193	0.577
Comorbidities/patient history					
Myocardial Infarction	1	39 (18.5)	6 (21.4)	0.708	0.515
Previous PCI	2	61 (29.1)	9 (32.1)	0.736	0.515
Previous CABG	1	39 (18.5)	7 (25.0)	0.411	0.533
Cerebrovascular accident	3	24 (11.5)	2 (7.1)	0.748	0.522
Transient ischemic attack	2	22 (10.5)	1 (3.6)	0.491	0.535
Malignancy	2	48 (22.9)	6 (21.4)	0.865	0.507
Chronic lung disease	2	45 (21.4)	5 (17.9)	0.663	0.518
Diabetes	1	69 (32.7)	9 (32.1)	0.953	0.503
Dialysis	1	3 (1.4)	0 (0.0)	1.000	0.507
Hypertension	0	176 (83.0)	22 (78.6)	0.561	0.522
Dyslipidemia	1	137 (65.0)	20 (71.4)	0.496	0.532
Home oxygen	3	7 (3.3)	0 (0.0)	1.000	0.517
Former smoker	12	95 (47.5)	8 (28.6)	0.059	0.595
Current smoker	12	5 (2.5)	0 (0.0)	1.000	0.513
Endocarditis	1	5 (2.4)	1 (3.6)	0.531	0.506
Peripheral arterial disease	3	21 (10.1)	2 (7.1)	1.000	0.515
Renal Insufficiency	13	94 (47)	14 (51.9)	0.636	0.524
Creatinine, mmol/L	11	95 (77−115)	93 (77−118)	0.931	0.505
NYHA class III or IV	2	130 (61.9)	19 (67.9)	0.541	0.530
CCS class III or IV	6	27 (13.0)	6 (22.2)	0.236	0.546
Atrial fibrillation	4	59 (28.4)	8 (28.6)	0.982	0.501
Heart failure	5	76 (36.7)	12 (42.9)	0.529	0.531
Syncope	5	54 (26.1)	7 (25.0)	0.902	0.505
Porcelain aorta	7	17 (8.3)	0 (0.0)	0.232	0.541
Risk scores					
STS risk score, %	94	3.4 (2.4−5.1)	3.1 (2.2−4.1)	0.350	0.568
EuroSCORE, %	140	2.5 (1.3−4.0)	2.3 (0.1−6.7)	0.735	0.532
Year of procedure					
2016	0	17 (8.0)	3 (10.7)	0.628	0.541
2017	0	34 (16.0)	7 (25.0)	0.283	
2018	0	54 (25.5)	4 (14.3)	0.194	
2019	0	59 (27.8)	9 (32.1)	0.634	
2020	0	48 (22.6)	5 (17.9)	0.566	
Medications					
ASA	3	107 (51.2)	15 (53.6)	0.813	0.512
Clopidogrel	3	42 (20.1)	4 (14.3)	0.465	0.529
Ticagrelor	3	6 (2.9)	0 (0.0)	1.000	0.514
Warfarin	3	19 (9.1)	2 (7.1)	1.000	0.510
Digoxin	3	14 (6.7)	0 (0.0)	0.383	0.533
Statin	3	126 (60.3)	15 (53.6)	0.497	0.534
Bronchodilators/steroids	3	33 (15.8)	2 (7.1)	0.392	0.543
NOAC	3	30 (14.4)	6 (21.4)	0.327	0.535
Beta blockers	3	94 (45.0)	15 (53.6)	0.392	0.543
ACE/ARB Inhibitors	3	85 (40.7)	11 (39.3)	0.889	0.507
Diuretic	3	88 (42.1)	10 (35.7)	0.519	0.532
Nitrates	4	27 (13.0)	6 (21.4)	0.226	0.542
CCB	7	85 (41.3)	11 (40.7)	0.959	0.503
Status					
Urgent	13	32 (16.0)	3 (11.1)	0.776	0.524
Procedural characteristics					
Valve-in-valve	6	11 (5.3)	1 (3.7)	1.000	0.508
Evolute Pro valve (Medtronic)	0	19 (9.0)	2 (7.1)	1.000	0.509
Evolute valve (Medtronic)	0	64 (30.2)	13 (46.4)	0.084	0.581
Sapien 3 valve	0	129 (60.9)	13 (46.4)	0.145	0.572
Oversized, %	4	13.4 (1.5−20.7)	13.7 (6.6−20.5)	0.433	0.546
Valve oversizing > 15.6%	4	90 (43.3)	12 (42.9)	0.967	0.502
Echo characteristics					
LVEF, %	2	60 (60−60)	60 (60−60)	0.204	0.562
AV mean gradient, mm Hg	3	42 (34−52)	41 (28−56)	0.457	0.543
AV peak gradient, mm Hg	6	69 (56−85)	65 (48−80)	0.296	0.520
AVA, cm^2	1	0.74 (0.60−0.88)	0.83 (0.62−0.90)	0.252	0.567
EKG characteristics					
PR Interval, ms	52	176 (160−202)	198 (165−235)	0.047	0.626
QRS, ms	2	100 (88−116)	109 (87−138)	0.309	0.559
QRS ≥ 138	2	30 (14.3)	7 (25.0)	0.164	0.554

Table 2. Continued.

Characteristic	Missing, N	No new pacemaker (N = 212)	New pacemaker (N = 28)	*P*	Area under ROC curve
QTc, ms	2	442 (424 - 464)	460 (435 - 482)	0.083	0.601
LBBB	0	0 (0.0)	0 (0.0)	1.000	-
Incomplete LBBB	0	8 (3.8)	0 (0.0)	0.601	0.519
RBBB	0	18 (8.5)	7 (25.0)	0.007	0.583
Incomplete RBBB	0	4 (1.9)	0 (0.0)	1.000	0.509
NSICD	0	7 (3.3)	1 (3.6)	1.000	0.501
LAFB	0	29 (13.7)	5 (17.9)	0.565	0.521
LPFB	0	3 (1.4)	1 (3.6)	0.393	0.511
1st-degree AVB	0	38 (17.9)	10 (35.7)	0.027	0.589
NSR	0	67 (31.6)	9 (32.1)	0.954	0.503
Sinus bradycardia	0	20 (9.4)	1 (3.6)	0.483	0.529
Sinus tachycardia	0	2 (0.9)	1 (3.6)	0.312	0.513
Sinus pauses/arrest	0	0 (0.0)	0 (0.0)	1.000	-
Atrial fibrillation	0	40 (18.9)	4 (14.3)	0.556	0.558
Atrial flutter	0	3 (1.4)	1 (3.6)	0.393	0.511
Atrial tachycardia	0	1 (0.5)	0 (0.0)	1.000	0.502
LVH	0	72 (34.0)	4 (14.3)	0.035	0.598

Continuous characteristics are expressed as median (quartile 1−quartile 3), and were compared using the Mann-Whitney test.

Categorical variables are expressed using N (%), and were compared using the χ^2 or Fisher's exact test. Exclusion criteria are as follows: in-hospital mortality; Sapien XT device (Edwards Life Sciences); previous permanent pacemaker implanted, concurrent.

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ASA, acetylesalicylic acid; AV, aortic valve; AVA, aortic valve area; AVB, atrioventricular block; BMI, body mass index; CABG, coronary artery bypass grafting; CCB, calcium channel blocker; CCS, Canadian Cardiovascular Society; EKG, electrocardiogram; LAFB, left anterior fascicular block; LBBB, left bundle branch block; LPFB, left posterior fascicular block; LVEF, left ventricular ejection fraction; LVH, left ventricular hypertrophy; NOAC, non-vitamin K oral anticoagulant; NSICD, nonspecific intraventricular conduction delay; NSR, normal sinus rhythm; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBBB, right bundle branch block ROC, receiver operating characteristic; STS, Society of Thoracic Surgeons; EuroSCORE, European System for Cardiac Operative Risk Evaluation.

with a preexisting PPM. Demographics and procedural information were collected. Two expert readers reviewed all ECGs, and parameters including QRS measurements, RBBB, left bundle branch block, bi-fascicular block, and first-degree atrioventricular (AV) block were collected. The need for PPM implantation post-TAVI was defined as having a PPM implanted during the same hospitalization as the TAVI procedure or within 30 days following the TAVI procedure. The need for PPM implantation was determined through consultation with the arrhythmia service following usual procedures. Reporting of this work was guided by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines[14] for reporting observational studies (Appendix 1).

Statistical analysis

Baseline characteristics of the full cohort were compared between those who did vs did not require a PPM implantation. Continuous variables were expressed as median (quartile 1- quartile 3) and were compared using the Mann-Whitney test. Categorical variables were expressed as N (%) and were compared using the χ^2 or Fisher's exact test, as appropriate. The AUROC curve was evaluated for each individual variable examined. A final multivariable logistic regression model was developed using a stepwise selection process with $P < 0.05$ for entry and $P > 0.05$ for removal. The AUROC curve and corresponding 95% confidence interval was calculated for this model to assess model discrimination. The ROC curve for this model was visualized with the ROC curves of both the user-friendly ERS (QRS duration of $\geq$ 140 ms and valve oversizing of $\geq$ 16%[12]) and the final ERS (QRS duration of $\geq$ 138 ms and valve oversizing of $\geq$ 15.6%[12]), based on model coefficients for the final patient population (including both balloon-expandable and self-expandable valves). The Hosmer-Lemeshow test was performed to assess model goodness-of-fit. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

During the study period, 323 patients underwent TAVI. A total of 83 patients were excluded from analysis—54 who received a Sapien XT valve and 29 with a preexisting PPM, leaving 240 patients included in the analysis. Of these patients, 142 patients received a Sapien 3 valve, 77 with an Evolut R valve, and 21 with an Evolut Pro valve. Baseline patient characteristics between the 2 groups were very similar (Table 2). The PPM implantation rate was 8% for the Sapien 3 valve, 17% for the Evolut R, and 8% for the Evolut Pro. An overall PPM implantation rate was found to be 10.8%.

Of the ERS parameters, only RBBB was independently associated with the need for PPM implantation (OR = 3.59; $P = 0.010$). An RBBB was noted in the preprocedural ECGs in 18 of 212 patients (8.5%) who did not receive a PPM post-TAVI and 7 of 28 patients (26.9%) who did receive a PPM post-TAVI. The other components of the ERS, history of syncope, QRS duration $\geq$ 138 ms, and valve oversizing $\geq$ 15.6% were not predictive of PPM implantation in our local patient population. The difference in history of syncope was statistically significant between patients who did not vs who did require a PPM post-TAVI (54 of 212 [26.1%] vs 7 of 28 [25%], $P = 0.902$). The median QRS duration for patients who did not require a PPM post-TAVI was 100 ms (88-116 ms), and it was 105 ms (86-140 ms) for patients who did require a PPM post-TAVI ($P = 0.503$). A QRS duration $\geq$ 138 ms was noted in 30 of 212 patients (14.3%) who did not

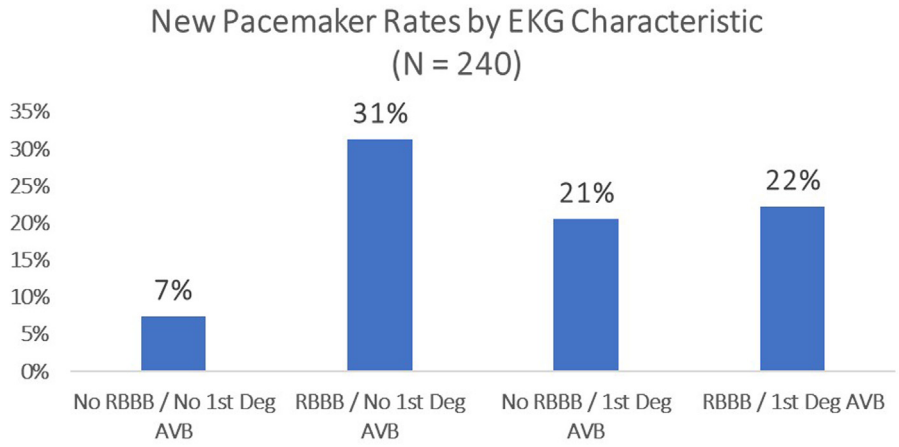

Figure 1. New pacemaker rates by electrocardiogram characteristic (N = 240). AVB, atrioventricular block; Deg, degree; RBBB, right bundle branch block.

require a PPM post-TAVI and 7 of 28 patients (25%) who did require a PPM post-TAVI ($P = 0.164$). Valve oversizing $\geq$ 15.6% was found in 90 of 212 patients (43.3%) who did not require a PPM post-TAVI and in 12 of 28 patients (42.9%) who did require a PPM post-TAVI ($P = 0.967$).

Of the additional ECG parameters (Table 2), a first-degree AV block had a statistically significant association with new PPM implant, with 38 of 212 patients (17.9%) who did not require a PPM post-TAVI and 10 of 28 patients (35.7%) who did require a PPM post-TAVI ($P = 0.027$) in univariable analysis. This difference was not found to be statistically significant in the multivariable regression model. The median baseline PR interval for patients that did not have a PPM was 176 ms (160-202 ms), compared to 198 ms (165-235 ms; $P = 0.047$) in those who required a PPM post-TAVI. No other values reached statistical significance. New PPM implant rates by ECG characteristics can be seen in Figure 1.

Following adjustment in the generated multivariable model (Table 3), only RBBB (OR 3.46, 95% confidence interval [CI] 1.23-9.56) was independently associated with having a new PPM implant. As described in Figure 2, the AUROC curve of the RBBB only (95% CI) is 0.583 (0.499-0.666) compared to 0.577 (0.460-0.695) for the ERS as described in the paper and 0.581 (0.462-0.700) for the user-friendly version shared in the central illustration of the ERS paper.

Table 3. Results of permanent pacemaker univariate and multivariable logistic regression models: right bundle branch block (RBBB)

Characteristic	Odds ratio	95% CI	*P*
Univariate analysis			
EKG characteristics			
1st-degree AVB	3.45	1.45−8.24	0.027
RBBB	3.59	1.35−9.60	0.007
Multivariate analysis			
EKG characteristics			
RBBB	3.59	1.35−9.60	0.010

Final logistic regression model was generated using a stepwise selection process (entry $P < 0.05$; removal $P > 0.05$). Area under the receiver operating characteristic curve (95% confidence interval [CI]): 0.583 (0.499−0.666).

AVB, atrioventricular block; EKG, electrocardiogram.

Due to the small sample size, which would lead to large CIs, the AUROC curve of the ERS was not calculated for self-expandable and balloon-expandable valves separately.

Discussion

The findings of this study confirm our hypothesis of a poor predictive value of the ERS in the local patient population undergoing a TAVI procedure using conventional valve prostheses, with both self-expanding and balloon-expanding valves within our local clinical context (older patients with unknown differences in frailty). This finding is in accordance with a previous report that showed that the ERS did not offer better discriminatory utility other than pre-operative RBBB.[13] The predictive value found in our study is much poorer than the predictive value previously reported by Kiani et al.[12] Of the additional ECG parameters reviewed, only first-degree AV block demonstrated a numerical, but statistically nonsignificant predictability of PPM implantation. The PPM implantation rate with a balloon-expandable valve was consistent with that of Kiani et al.,[12] but it was much lower than that found in other studies of the same generation of balloon-expandable valve.[9,13] The PPM implantation rate with self-expanding valves was again lower than that in previous reports.[13,15,16] This difference may be related to the small sample size of the current study. Our findings support findings in previous reports that rates of PPM implantation are higher with the use of the self-expanding valves[2,10] and that the newer generation Evolut-Pro valve has a lower rate of PPM implantation compared to the Evolut-R valve.[16]

The original article determining and validating the ERS included only patients implanted with balloon-expandable valves. The current study includes all patients implanted with balloon-expandable and self-expanding valves at one site. To the best of our knowledge, this study is one of the first to apply the ERS to evaluate patients undergoing TAVI in a Canadian centre and to investigate additional ECG parameters not included in the ERS. This study is the second to apply the ERS to balloon-expandable valves.[13]

The presence of RBBB continues to be predictive of PPM implantation. This finding is consistent with findings in the literature.[9,10,12,13] This finding supports the suggestion by the

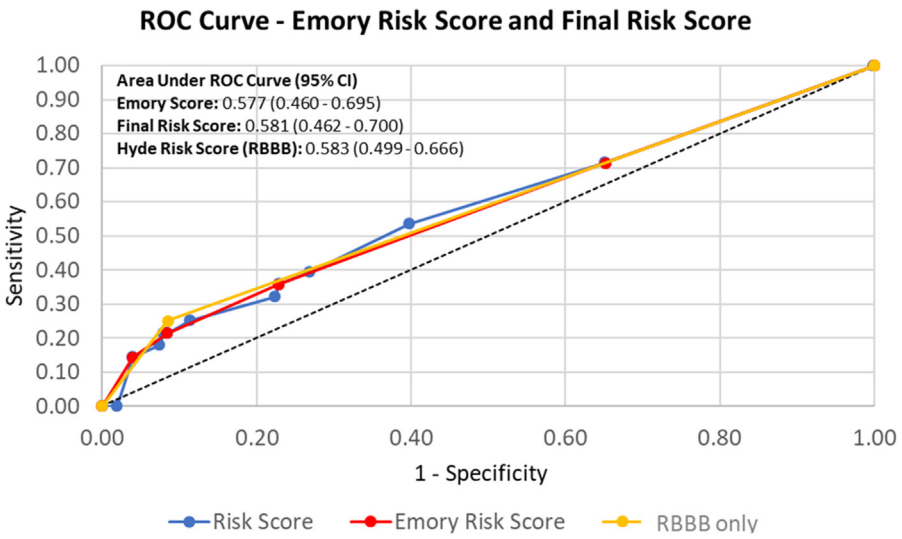

Figure 2. Area under the receiver operating characteristic (ROC) curves—Emory Risk Score, final risk score, right bundle branch block (RBBB) only. CI, confidence interval.

Canadian Cardiovascular Society that SAVR be considered in patients with RBBB.[1] The PPM implantation rate after SAVR has been reported to be between 2.7%[17] and 3.4%.[18] A consensus document related to management of conduction disturbances post-TAVI uses pre-existing RBBB as a parameter that should warrant consideration for maintaining a transvenous wire overnight for up to 24 hours.[3] The reporting of preexisting RBBB should be taken into consideration by an interdisciplinary heart team and for consideration of peri-procedure PPM.

We noted no difference in syncope in those that did, vs those that did not, require PPM. The reported history of syncope in the entire cohort is higher than that reported by Kiani et al.[12] and Spring et al.[13] Such variability in the reported incidence rate of syncope could be due to inherent patient population differences, alternative aetiologies other than underlying conduction anomalies, and how providers enquire about syncope.

The QRS durations in the current study in all patients are narrower compared to those in previous reports.[12,13] The proportion of patients with a QRS duration $\geq$ 138 ms who did not require a PPM post-TAVI is larger than that in previous reports.[12,13] The study by Spring et al.[13] also found that, after multivariate analysis, QRS duration $\geq$ 138 ms is not strongly associated with PPM post-TAVI. The consensus document related to management of conduction disturbances post-TAVI uses prolongation of QRS duration $\geq$ 20 ms to maintain the temporary pacing wire overnight for up to 24 hours.[3] Future studies into the utility of the impact of a change in QRS duration on PPM implantation post-TAVI are warranted.

Valve oversizing is, in part, reflective of operator variability, which occurs between institutions and within institutions as operators gain more experience or new operators are brought in. The original ERS study reported significantly less valve oversizing, at 7.4% for patients not requiring a PPM post-TAVI and 12.0% for patients requiring a PPM post-TAVI, with a P value of 0.028,[12] whereas Spring et al. reported more valve oversizing (56.6% vs 53.5%, $P = 0.586$)[13]. Nazif et al. found that the ratio of prosthesis diameter to left ventricular outflow tract diameter was greater in patients requiring a PPM post-TAVI, and this difference remained significant after multivariate analysis.[10] These findings suggest that including parameters that can be influenced by operator experience without adjusting for this experience may overstate or understate the actual risk of requiring a PPM post-TAVI.

Our findings of first-degree AV block approaching predictability of PPM post-TAVI are consistent with the pre-procedural ECG measurements made by Kiani et al. (27.9% vs 44.2%, $P = 0.035$).[12] The presence of a first-degree AV block neared statistical significance in our study after multivariate logistic regression, which is consistent with the original ERS report.[12] Preexisting first-degree AV block and new first-degree AV block post-TAVI are suggested as indications to maintain the temporary pacing wire overnight and up to 24 hours post-TAVI, by the consensus document,[19] and our findings support the inclusion of the PR interval in determining the risk of PPM post-TAVI.

The lack of a validated risk score for PPM implantation post-TAVI, the changing indications for TAVI, and the introduction of new TAVI valves require healthcare providers to explore options for providing safe patient care while reducing the need for ICU-level care. Rather than relying on temporary pacing wires, the use of temporary PPMs for TAVI patients with post-procedure conduction issues should be explored. Temporary permanent pacing involves placing a pacing lead threaded through a tear-away introducer that is attached to a PPM pulse generator secured externally to the neck.[20] This option would liberate patients from an ICU stay and allow for nurse-led mobilization of patients after 4 hours of bed rest, a key aspects of the Vancouver 3M clinical pathway that promotes next-day discharge post-TAVI.[6]

Equally important is consideration of the inclusion of an electrophysiologist as a core team member of the TAVI heart team to screen and identify those patients who have an indication for pacing. The indication for considering pacing

could be expanded to include the data indicating that RBBB and first-degree AV block are associated with PPM post-TAVI. Because TAVI is preferentially performed currently in older adult patients, and age is a risk factor for needing a pacemaker,[21] screening for expanded pacing criteria may allow for PPM implantation immediately pre- or post-TAVI and reduce the need for an ICU bed. The heart team can also assist with ensuring the availability of PPM implantation resources for days when TAVIs are being performed. to allow for implantation of a permanent device if the patient meets criteria, rather than maintaining a temporary pacing wire and implanting later.

Our study has several limitations. The difference in predictive value may be related to the differences in patient population (frailty, degree of calcium in left ventricular outflow tract, depth of deployed valve, degree of valve oversizing, and impact of post-dilatation) between our 2 studies. These variables were not explored in our study, however, and may be confounding variables that alter the predictability of the ERS in the local population. Also, the small number of patients requiring a PPM is a limitation, as we were not able to explore the differences in predictability of the ERS between self-expandable and balloon-expandable valves or the relationship between RBBB and first-degree atrioventricular block and RBBB with no first-degree atrioventricular block. As well, included in the analysis are only limited computed tomography-derived data that have been indicative of PPM implantation in other studies.[22] Finally, this work does not look at downstream communication considerations, such as the need to share concerns about pacing risks after the patient is discharged from the hospital.

Conclusions

The findings of this study suggest that the ERS has poor predictive value for determining TAVI patients at risk of need for post-procedure PPM implantation (for both balloon-expandable and self-expanding valves). An additional finding is that the rate of PPM implantation post-TAVI is relatively low. The presence of pre-TAVI RBBB was predictive of PPM implantation post-TAVI. Approaches to providing TAVI that reduce the burden or potential burden on ICU resources while maintaining the ability to provide the procedure and achieve early discharge from the hospital, such as the use of temporary permanent pacemakers, are imperative to explore. Equally important is ensuring that the appropriate experts are reviewing criteria together for screening for pacing indications preprocedure and facilitating timely PPM implantation either pre- or post-TAVI as needed. A reliable scoring system that predictably identifies patients who may need a PPM post-TAVI is warranted, as such identification is likely to facilitate reduced healthcare resource utilization and better patient management.

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Disclosures

The authors have no conflicts of interest to disclose.

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Appendix 1. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement—checklist of items that should be included in reports of cohort studies

	Item No.	Recommendation	Page No.
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract.	4
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found.	4
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported.	6–7
Objectives	3	State specific objectives, including any prespecified hypotheses.	7–8
Methods			
Study design	4	Present key elements of study design early in the paper.	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.	8
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	8
		(b) For matched studies, give matching criteria and number of exposed and unexposed.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group.	8
Bias	9	Describe any efforts to address potential sources of bias.	
Study size	10	Explain how the study size was arrived at.	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why.	8–9
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding.	8–9
		(b) Describe any methods used to examine subgroups and interactions.	8–9
		(c) Explain how missing data were addressed.	
		(d) If applicable, explain how loss to follow-up was addressed.	
		(e) Describe any sensitivity analyses.	8–9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed.	9
		(b) Give reasons for non-participation at each stage.	
		(c) Consider use of a flow diagram.	
Descriptive data	14*	(a) Give characteristics of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders.	9
		(b) Indicate number of participants with missing data for each variable of interest.	Table
		(c) Summarise follow-up time (eg, average and total amount).	
Outcome data	15*	Report numbers of outcome events or summary measures over time.	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included.	9–10
		(b) Report category boundaries when continuous variables were categorized.	Table
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.	
Other analyses	17	Report other analyses done—eg, analyses of subgroups and interactions, and sensitivity analyses.	9–10
Discussion			
Key results	18	Summarize key results with reference to study objectives.	10, 11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	14
Generalizability	21	Discuss the generalizability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.	15

An "Explanation and Elaboration" article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the following Web sites: PLoS Medicine at http://www.plosmedicine.org/; Annals of Internal Medicine at http://www.annals.org/; and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

* Give information separately for exposed and unexposed groups.