


## ORIGINAL RESEARCH

## External validation of the Canadian Syncope Risk Score for patients presenting with undifferentiated syncope to the emergency department

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## Abstract

**Objective:** To validate the accuracy and safety of the Canadian Syncope Risk Score (CSRS) for patients presenting with syncope.

**Methods:** Single centre prospective observational study in Brisbane, Australia. Adults presenting to the ED with syncope within the last 24 h were recruited after applying exclusion criteria. Study was conducted over 1 year, from March 2018 to March 2019. Thirty-day serious adverse events (SAE) were reported based on the original derivation study and standardised outcome reporting for syncope. Individual patient CSRS was calculated and correlated with 30-day SAE and disposition status from ED.

**Results:** Two hundred and eighty-three patients were recruited to the study. Average age was 55.6 years (SD 22.7 years), 37.1% being male with a 39.9% admission rate. Thirty-day SAE occurred in seven patients (2.5%) and no recorded deaths. The CSRS performed with a sensitivity of 71.4% (95% confidence interval [CI] 30.3–94.9%), specificity 72.8% (95% CI 67.1–77.9%) for a threshold score of 1 or higher.

**Conclusion:** Syncope patients in our study were predominantly very low to low risk (72%). The prevalence of 30-day SAE was low, majority occurring following hospital discharge. Sensitivity estimates for CSRS was lower than the derivation study but lacked robustness with wide CIs because of a small sample size and number of events observed. However, the CSRS did not miss any clinically relevant outcomes in low risk patients making it potentially useful in aiding their disposition. Larger validation studies in Australia are encouraged to further test the diagnostic accuracy of the CSRS.

**Key words:** clinical decision rule, emergency department, risk stratification, syncope, validation.

## Introduction

Syncope is defined as a transient loss of consciousness because of global cerebral hypoperfusion, followed by spontaneous and complete recovery.<sup>1</sup> It is a common ED presentation accounting for up to 3% of ED visits.<sup>2–4</sup> Underlying causes for

## Key findings

- Admission rate for undifferentiated syncope patients was high (39.9%) despite majority being very low to low risk (72%) according to the CSRS.
- The rate of SAE was low (2.5%) with most events occurring outside the hospital setting and were not prevented by initial hospitalisation even in non low risk patients.
- Despite a modest rule out sensitivity of 71.4% for a threshold score of 1, the CSRS did not miss any clinically relevant SAE in low risk patients and may be useful in aiding their disposition from ED.

syncope are mostly benign with a small proportion of patients experiencing potentially life-threatening conditions such as ventricular arrhythmia, myocardial infarction and pulmonary embolism.<sup>1,5</sup>

Differentiating benign from more sinister causes can be challenging as patients often appear well with little clinical features to suggest an underlying cause upon arrival to ED.<sup>6</sup> Syncope guidelines provide some direction on diagnostic and disposition strategies. However, recommendations are often consensus based relying on local context and resources, therefore not always generalisable.<sup>1</sup> As a result, wide practice variations exist across

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different countries and institutions leading to high hospitalisation rates between 30 and 70%.<sup>2,7,8</sup> Admission to hospital, while seen as a safe strategy is costly with low diagnostic yield and no evidence to suggest an improvement in discharge diagnosis or overall outcome.<sup>9–13</sup>

With current pressures on healthcare resources and increasing hospital congestion, clinicians need a safe and efficient approach in managing patients presenting to ED with syncope. This includes identifying those at high-risk who would benefit from admission and further testing but also avoiding unnecessary admission of low risk patient groups.<sup>14</sup> Given a definitive diagnosis is not often achieved in ED, the cornerstone of management relies on accurate risk stratification to determine safe disposition.<sup>2,9,15–17</sup>

Multiple clinical decision rules have been developed over the years to aid in this decision process.<sup>12,16,18–20</sup> None have been universally adopted because of performance inconsistencies in validation studies across different populations.<sup>14,18,21–23</sup>

The Canadian Syncope Risk Score (CSRS) is the latest syncope decision rule to be developed.<sup>24</sup> The study enrolled over 4000 patients in its derivation phase and represents the largest syncope study to date. Nine predictors were derived, encompassing clinical evaluation, investigations and likely ED diagnosis to produce a patient risk score between –3 and 11. Risk scores are grouped into risk categories based on the likelihood of serious adverse events (SAEs).<sup>24</sup> In their derivation study, the sensitivity of the rule was 97.7% (95% confidence interval [CI] 93.5–99.5%) for a threshold score of –1 or higher.<sup>24</sup> A recent multi-centre validation study by the same authors confirmed the robustness of their decision rule which demonstrated high accuracy and reproducibility with patients in the very-low to low-risk category having a likelihood of 30-day SAE in the order of 0.2 and 0.7% respectively.<sup>25</sup> This represents a cohort of low risk patients where hospital admission could be avoided without further significant risk of harm.<sup>14</sup> Our goal in the present study was to externally validate the accuracy

and safety of the CSRS in an Australian setting.

## Methods

### Study design

We conducted a single centre prospective observational study at Redcliffe Hospital, an outer metropolitan public hospital near Brisbane with an annual ED attendance of approximately 67 000 patients. The study was conducted over 1 year, from March 2018 to March 2019. Ethics approval was obtained through the Prince Charles Hospital Human Research Ethics Committee and granted approval as a low risk project (reference, HREC/17/QPCH/48). Clinical trials registration was not required.

### Patient selection and recruitment

Adult patients, 18 years and older, who experienced syncope within the last 24 h were considered eligible if they met the inclusion criteria for syncope, defined as a transient loss of consciousness lasting less than 5 min with prompt and spontaneous recovery to their baseline mental state. Patients were excluded if they were under 18 years old, had persistently altered conscious levels measured using the Glasgow Coma Scale, obvious seizure, limited ability to provide history because of dementia, language barrier or intoxication, and any major trauma requiring hospitalisation. Patients who had a serious condition diagnosed during the index ED evaluation were treated accordingly and excluded because of known cause for syncope.

Patients were recruited by the treating clinician at their index visit to ED, provided written consent before enrolment and assigned sequentially numbered study packs. As the study was purely observational, patient management and disposition were left to the discretion of the treating or supervising clinician.

### Data collection

ED physicians, registrars and residents were trained to prospectively enrol patients and collect CSRS predictors

using a data collection proforma. An ECG and troponin level were mandated as part of the study protocol.<sup>14</sup> An Internal Medicine physician reviewed and interpreted all ECG variables required to calculate the CSRS for each patient. The CSRS score was calculated for each patient by a research nurse and not included in the data collection proforma given to medical staff. Patients were categorised based on the CSRS scale as either very-low-risk (–3 to –2), low-risk (–1 to 0), medium-risk (1 to 3), high-risk (4 to 5) or very-high-risk (6 to 11). Training was delivered through regular information sessions during the study period. We collected patient demographic data such as age, sex, independent living status, ED and hospital length of stay, disposition status (home, short stay unit, ward), representations, SAEs and the location for occurrence of these events. Data were collected and entered into an Excel spreadsheet by a research nurse who was employed through grant funding 2 days a week.

### Outcome measures

Patients were followed up by phone at 30 days after their index presentation to determine the occurrence of SAE. A 30-day SAE was recorded if any of the following occurred during follow-up: death, arrhythmia, myocardial infarction, serious structural heart disease, aortic dissection, pulmonary embolism, severe pulmonary artery hypertension, subarachnoid haemorrhage, significant haemorrhage, any other serious condition or procedural intervention used to treat syncope. Patients unable to be contacted were considered lost to follow-up and local health databases and death registry checked.

### Data analysis

Data was analysed using SPSS version 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarised as means with standard deviations (SD) or median and interquartile ranges (IQR) if they were not normally distributed. Categorical variables were summarised as frequencies and percentages. Pearson's chi-squared test or Fisher's exact test where more

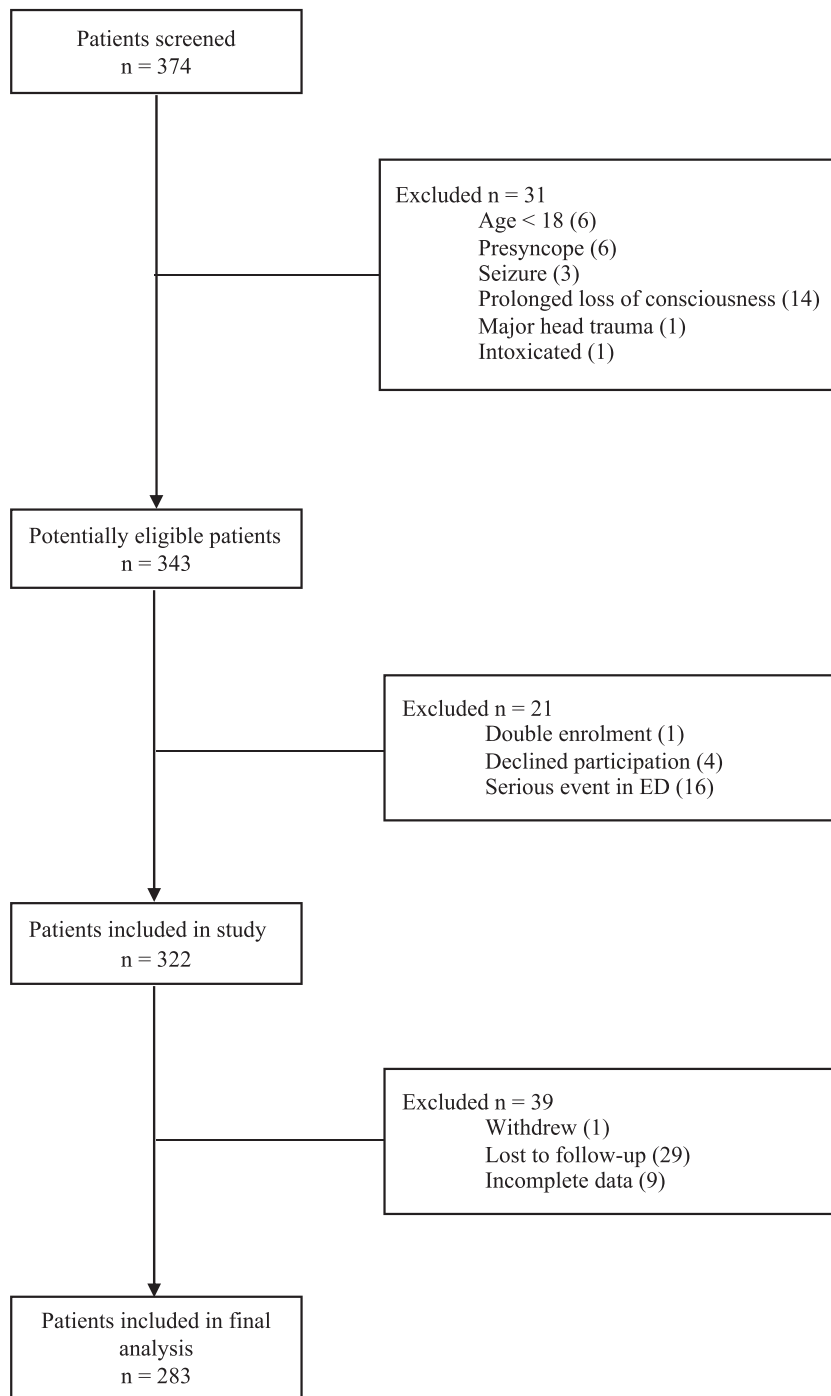


Figure 1. Study recruitment process.

than 20% of the expected values were less than 5 was used for categorical variables. Continuous variables were examined using the Student's *t*-test. Sensitivity analysis was conducted to compare patient characteristics and medical history of patients lost to follow-up with patients who had

complete outcome data. Diagnostic accuracy of the CSRS was assessed for a threshold of  $-1$  or higher identifying low to very-high-risk patients and 1 or higher identifying medium to very-high-risk patients with sensitivity, specificity, positive predictive values, negative predictive values and area

under the receiver operating characteristic curve with 95% CIs reported for each.

## Results

We examined 374 patients presenting with syncope to our ED. After applying exclusion criteria, 343 patients were eligible for enrolment. Sixteen patients were diagnosed with a serious event in ED, one was a double enrolment and four declined participation. Twenty-nine patients were lost to follow-up, one withdrew and nine had incomplete CSRS data leaving 283 patients for final inclusion and analysis (Fig. 1). Sensitivity analysis showed there was no statistically significant differences in patient characteristics and medical history between included patients and those lost to follow-up (Appendix S1). None of the patients lost to follow-up were found to be deceased after examining the state death registry.

Table 1 presents patient characteristics and ED management. The average age was 55.6 years (SD 22.7) with 37.1% being male. The majority (98.6%) of patients were living independently. One hundred and thirteen patients (39.9%) were admitted to hospital.

No deaths were recorded during the 30-day follow-up. Seven patients (2.5%) suffered a 30-day SAE, two were categorised as very-low risk and five as medium-risk. Six of the patients with 30-day SAE were admitted to hospital on their index visit. The seventh patient was discharged from ED and readmitted within 48 h. Two SAEs, pulmonary embolism and symptomatic bradycardia, occurred during the index hospital admission. Both patients were medium-risk with a CSRS of 1. Thirty-day SAEs occurred for the other four admitted at index presentation following discharge from hospital. Details of 30-day SAEs are described in Table 2.

The distribution of CSRS scores by 30-day SAE and admission status is described in Table 3. There were 141 (49.8%) very-low-risk, 62 (21.9%) low-risk, 61 (21.6%) medium-risk, 12 (4.2%) high-risk and 7 (2.5%) very-high-risk patients identified. Twenty-two (15.6%) very-low-risk

**TABLE 1.** Patient characteristics and ED management for patients admitted with syncope (n = 283)

Patient characteristics and medical history	n (%)
<b>Characteristic</b>	
Sex (male)	105 (37.1%)
Age (years, mean [SD])	55.6 (22.7)
Living independently (n = 282)	278 (98.6%)
<b>Medical history</b>	
Hypertension	105 (37.1%)
Predisposition to vasovagal symptoms	69 (24.4%)
Dizzy/presyncopal on standing (n = 278)	63 (22.7%)
Ischemic heart disease	46 (16.3%)
Diabetes mellitus (n = 282)	39 (13.8%)
AF or flutter (n = 282)	23 (8.2%)
Postural hypotension (n = 273)	21 (7.7%)
Pregnancy (n = 178)	11 (6.2%)
COPD	17 (6.0%)
Systolic BP less than 90 mmHg	12 (4.2%)
Valvular heart disease	10 (3.5%)
Congestive heart failure	8 (2.8%)
Cardiomyopathy	5 (1.8%)
<b>Disposition</b>	
Medical admission	113 (39.9%)
Discharged by the ED	170 (60.1%)
<b>Length of stay</b>	
ED (min, median [IQR])	237 (194–304)
Short stay unit (n = 45, min, median [IQR])	216 (123–341)
Ward (n = 109, min, median [IQR])	1232 (923–1819)
Total length of stay (n = 279, min, median [IQR])	375 (221–1370)
<b>Outcomes</b>	
CSRS median (IQR)	−1 (−2 to 1)
Range	−3 to 9
Serious AE within 30 days	7 (2.5%)

and 24 (38.7%) low-risk patients were admitted.

For a threshold of −1 or higher there were 137 false positive cases and for a threshold of 1 or higher there were 75. The number of false negative cases (n = 2) did not change with the different thresholds examined. The CSRS had a sensitivity of 71.4% (95% CI 30.3–94.9%) and specificity of 50.4% (95% CI 44.3–56.4%) for a threshold score of −1 or higher, as shown in Table 4. The CSRS

performed with the same sensitivity for a threshold score of 1 or higher but with higher specificity of 72.8% (95% CI 67.1–77.9%).

## Discussion

To our knowledge, this is the first validation study of the CSRS to be performed in an Australian setting. Our study demonstrated a low prevalence of 30-day SAEs (2.5%) for patients presenting with syncope. The majority of

patients presenting with syncope were in the very-low to low-risk category.

Of the two very-low-risk patients who had a 30-day SAE, one was readmitted for urosepsis 2 weeks following hospital discharge despite having a negative urine culture on the index admission. The other was an oncology patient who had known neutropenia post-chemotherapy during the index ED visit. Following ED discharge, the patient developed a fever and was readmitted for febrile neutropenia. The patient was treated empirically and discharged without further complications or new diagnosis for syncope. Although these conditions required patients to be readmitted, in our opinion they were unlikely to be related to the initial syncope presentation.

In general, patients who experienced a 30-day SAE tended to be older, mean age of 80 years (SD 7), and had more comorbidities. Apart from the medium-risk patients diagnosed with pulmonary embolism and symptomatic bradycardia, all other 30-day SAEs occurred following discharge from hospital.

At our institution, the admission rate for syncope was 39.9% indicating a conservative approach. Forty-six of these patients were in the very-low and low-risk category, comprising 16.3% potentially avoidable admissions. There were no deaths and the absence of arrhythmic events in the very-low to low-risk categories suggests that a medical admission for cardiac monitoring may be of limited value in this group. Overall, only two patients had cardiac related 30-day SAE (bradycardia and pacemaker insertion) and were classed as medium risk. Patients at medium or high-risk have a greater likelihood of 30-day arrhythmic events and therefore should still be considered for medical admission or prolonged cardiac monitoring.<sup>26</sup>

The diagnostic accuracy of the CSRS was modest with a lower sensitivity of 71.4% (95% CI 30.3–94.9%) for a threshold score of −1 or higher (low to very-high-risk) compared with the derivation study (97.7% [95% CI 93.5–99.5%]) and multi-centre validation study (97.8% [95% CI 93.8–99.6%]). Specificity was 50.4%

**TABLE 2.** Details of 30-day serious adverse events for patients presenting to ED with syncope

Age	CSRS	Initial disposition	Serious adverse event	Details of the event
78	-2	Medical admission	Any other serious condition	Readmitted for urosepsis 2 weeks post-discharge from hospital. Negative urine culture on index admission
69	-2	Discharged from ED	Any other serious condition	Known cancer and neutropenia after chemotherapy during index ED visit. Returned 2 days following ED discharge with febrile neutropenia. No new diagnosis made following hospital discharge
89	1	Medical admission	Arrhythmia	Prolonged medical admission. Persistently symptomatic with recurrent bradycardia and ventricular ectopics
84	1	Medical admission	Pulmonary embolism	Diagnosed with PE during hospital admission
72	3	Medical admission	Procedural intervention used to treat syncope	Longstanding palpitations and syncope investigated by private cardiologist. Elective pacemaker insertion occurred during 30-day follow-up
82	3	Medical admission	Any other serious condition	Represented with Type 2 myocardial infarction and heart failure
85	3	Medical admission	Any other serious condition	Represented with pneumonia

and similar to the derivation study (45.1% [95% CI 43.5–46.8%]) and multi-centre Canadian study (44.3% [95% CI 42.7–45.9%]).<sup>24,25</sup> Sensitivity was maintained, but with a higher specificity of 72.8% (95% CI 67.1–77.9%) for a threshold of 1 or higher (medium to very-high-risk) reflecting a hypothetical cut-off decision for discharge of very-low and low-risk patients which was similar to previous studies.<sup>24,25</sup> The low number of 30-day SAE in the small study sample influenced the robustness of the sensitivity estimates with resultant wide CIs. Caution should be used when interpreting positive and negative predictive values. The low prevalence of 30-day SAEs in our study and syncope patients in general has been acknowledged previously as one of the challenges in validating any syncope clinical decision rule.<sup>27,28</sup>

### Limitations

Our study was conducted at a single centre with resource limitations making patient recruitment challenging, and potential patients were not recruited for a variety of reasons. As a result, the number of patients screened

and recruited is a consenting sample of the total population of syncope presenting to our institution. Thus, non-consenting or missed potential patients may have different population characteristics and outcomes. To our knowledge there is no systematic reason for non-recruitment apart from patient non-consent, lack of staff awareness or prioritisation of clinical duties in a busy ED. Retrospective recruitment was not possible as CSRS data input needed to be collected prospectively.

In October 2018, mid-way through the study period, a new high sensitivity troponin assay was introduced across Queensland laboratories. This is unlikely to have had an impact on the CSRS calculation for the earlier recruited cohort who were based on a lower sensitivity troponin given the low rate of serious cardiac events in our study. Patient ECGs were reviewed by an Internal Medicine physician and a second blinded reviewing cardiologist may have improved accuracy although most of these variables (QRS axis, QRS duration, QT intervals) were mainly machine reported.

Twenty-nine patients were lost to follow-up which represented 9.0% of the eligible cohort. Although not significantly different from patients

included in the study, they were slightly younger (mean age 49 years *vs* 56 years), had less comorbidities such as diabetes mellitus and ischaemic heart disease, thus were less likely have suffered any SAE.

The distribution of 30-day SAEs differed from the derivation and multi-centre validation study which may have contributed to differences in sensitivity performance of the CSRS.<sup>24,25</sup> In our study, over half of the 30-day SAEs were classed as other serious conditions which has a broad and subjective interpretation. There was no independent or consensus adjudication of these events which may have led to bias in reporting. However, we followed SAE reporting as described by the original authors with this limitation in mind. We have listed details of these events for readers to discern their relevance to the initial syncope presentation.

### Conclusion

Results of our single centre validation study show that the majority of patients presenting with syncope were predominantly very-low to low risk. The low prevalence of 30-day SAEs in this

**TABLE 3.** Range of CSRS scores by serious adverse event and medical admission status

CSRS score	Serious adverse event		Medical admission	
	No	Yes	No	Yes
-3	41	0	39	2
-2	98	2	80	20
-1	26	0	15	11
0	36	0	23	13
1	12	2	2	12
2	28	0	8	20
3	16	3	2	17
4	7	0	1	6
5	5	0	0	5
6	5	0	0	5
7	1	0	0	1
8	0	0	0	0
9	1	0	0	1

Areas highlighted: -1 is the threshold for low to very-high-risk, 1 is the threshold for medium to very-high-risk.

**TABLE 4.** CSRS performance for patients presenting to the ED with syncope (n = 283)

CSRS score	Serious adverse event	
Threshold of -1 or higher (low to very-high-risk)		
	Yes	No
≥-1	5	137
<-1	2	139
Sensitivity (%)	71.4 (95% CI 30.3–94.9)	
Specificity (%)	50.4 (95% CI 44.3–56.4)	
PPV (%)	3.5 (95% CI 1.3–8.4)	
NPV (%)	98.6 (95% CI 94.4–99.8)	
Threshold of 1 or higher (medium to very-high-risk)		
	Yes	No
≥1	5	75
<1	2	201
Sensitivity (%)	71.4 (95% CI 30.3–94.9)	
Specificity (%)	72.8 (95% CI 67.1–77.9)	
PPV (%)	6.3 (95% CI 2.3–14.6)	
NPV (%)	99.0 (95% CI 96.1–99.8)	

NPV, negative predictive value; PPV, positive predictive value.

cohort (2/203 [0.99%]) suggests that they could be discharged safely using the CSRS for risk stratification albeit with a modest rule-out sensitivity in our setting. Most 30-day SAEs occurred in medium-risk patients and were not mitigated by initial hospitalisation further supporting the argument for judicious admissions even in non-low risk patients. The CSRS performed with a lower sensitivity and similar specificity to the derivation study for the thresholds examined. However, the sensitivity estimates were less robust owing to a small sample size and number of 30-day SAEs. Further large multi-site validation studies in Australia could help determine the diagnostic accuracy and application of this clinical decision rule.

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### Author contributions

JC, EB, JH, AY, DM, DB, JH contributed to study conceptions and design. EB, JC contributed to statistical analysis and interpretation. JC, EB, DB, JH contributed to manuscript writing. All authors read and approved the final manuscript.

### Competing interests

None declared.

### Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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## Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web site:

**Appendix S1.** Sensitivity analysis of patients lost to follow-up compared to patients included in the study.