Evaluating patients presenting to the emergency department after syncope: validation of the Canadian Syncope Risk Score

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Study question

Our primary objective is to validate the utility and safety of the Canadian Syncope Risk Score (CSRS) as a clinical decision rule when assessing patients who present with syncope to Australian emergency departments (EDs). Our secondary objective is to evaluate the economic benefits of diverting patients who are at low risk of serious adverse events from admission to hospital.

Timetable

Phase one of the study will be conducted during March 2018 – March 2019 at the ED of Redcliffe Hospital, an outer metropolitan hospital near Brisbane, which receives 65 000 ED presentations each year.

Methods

This protocol describes phase one of a two-phase validation study. Phase one is an observational prospective validation study. Patients aged 18 or more who present to the ED with syncope, defined as a transient loss of consciousness followed by prompt recovery within the preceding 24 hours, will be recruited as participants. Patients are excluded if they have prolonged syncope (longer than 5 minutes) or persistent reduction in Glasgow Coma Scale (GCS) score, an obvious seizure, intoxication, inability to communicate in English, or major trauma requiring hospitalisation. The study is designed to not influence patient management, with the decision regarding ultimate patient disposition remaining at the discretion of the treating clinician. Demographic and clinical information required to satisfy the domains of the CSRS will be prospectively recorded by the treating clinician, and the CSRS will be calculated retrospectively. Patients will be contacted by telephone 30 days after their initial presentation to the ED for information about any subsequent adverse events.

We will undertake a cost-effectiveness analysis from the health care perspective, comparing usual care and applying the CSRS to identify patients at low risk of adverse events who can be safely discharged from the ED instead of being admitted to hospital for further evaluation. Health care costs, including those associated with inpatient stay and admission-related resource use, will be collected from routine administrative databases.

Statistical analysis

As phase one is an observational validation study, no formal sample size calculation is required, but we aim to recruit about 500 eligible patients over the one-year period. Data will be summarised as means with standard deviations, medians with interquartile ranges, or frequencies and percentages as appropriate. The diagnostic utility of the CSRS will be assessed by estimating its specificity, sensitivity, positive and negative predictive values, and the area under the receiver operating characteristic (ROC) curve.

Parameters included in the economic model will be informed by the collected study data. The outcome of interest is the number of inpatient admissions avoided, with results being presented as costs saved per avoided admission. Health care costs will be included in the economic model and analysed with previously published methods. The results of the economic analysis will be presented as incremental cost-effectiveness ratios for admissions avoided, with scenario analyses undertaken to assess other outcomes of interest, such as altered level of clinician risk acceptability, altered willingness-to-pay thresholds, and altered inpatient bed-day values. Net monetary benefit analysis will allow costs to be estimated for a range of willingness-to-pay thresholds. Probabilistic sensitivity analysis will determine the robustness of the results.

Study data will be stored in a password-protected file on a secure drive accessible only to members of the research team.

Dissemination of findings

The outcomes of this project will be disseminated widely by Queensland Health and the funding body via social media, presented to local and national emergency medicine conferences, and published in relevant international emergency medicine and health economics journals.

What this study will add to current knowledge

Our study will be first to validate the CSRS in Australia. It will improve knowledge about the utility of clinical decision rules for managing patients presenting with syncope to Australian EDs. If we establish that applying the CSRS to these patients is safe and that its results are reproducible, our findings will assist decision making by clinicians and facilitate an evidence-based approach to managing patients with syncope at low risk of serious adverse events. The potential cost savings achievable with this approach will also facilitate more efficient allocation of limited health care resources.

Ethics approval statement

This project was reviewed by the Prince Charles Hospital Human Research Ethics Committee and granted approval as a low risk project (reference, HREC/17/QPCH/48).

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Registration of study: This study is not registered.

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Abstract

Background: Syncope is a common problem but can have any of a broad range of underlying causes. Initial evaluation of the patient in the emergency department often does not identify a specific cause, and the cornerstone of management is reliable risk stratification with clinical decision rules.

Objectives: The primary objective is to validate the utility and safety of the Canadian Syncope Risk Score (CSRS) as a clinical decision rule when assessing patients who present with syncope to Australian emergency departments. Our secondary objective is to evaluate the economic benefits of diverting patients with syncope at low risk of serious adverse events from admission to hospital.

Methods and analysis: Prospective, observational study. Patients aged 18 years or more who present to the emergency department (ED) after syncope in the preceding 24 hours and have returned to their baseline state will be enrolled. Patients will be contacted by telephone to determine whether they have experienced any adverse events within 30 days of their initial presentation to the ED. The CSRS will be applied retrospectively to determine the relationship between whether patients were admitted to hospital or discharged home and the reporting of serious adverse events for each CSRS risk level. We will also undertake a cost-effectiveness analysis from the health care perspective.

Ethics approval: Prince Charles Hospital Human Research Ethics Committee (reference, HREC/17/QPCH/48).

Dissemination of results: Outcomes will be disseminated by Queensland Health and the funding body via social media, presented at local and national emergency medicine conferences, and published in international emergency medicine and health economics journals.

Clinical trials registration: Not applicable.

Syncope is a transient loss of consciousness caused by global cerebral hypoperfusion, followed by spontaneous and prompt recovery.[1] Syncope has aetiologies ranging from the benign to the potentially life-threatening, such as malignant arrhythmias,[1,2] and how patients are managed depends upon the underlying cause.

Syncope is a common reason for presenting to the emergency department (ED), and is the cause for as many as 3% of all ED visits.[3–5] Rates of admission to hospital of patients with syncope vary between countries, but range between 30% and 70%.[3,6,7] The high rate of hospitalisation reflects the challenging nature of managing patients with syncope, especially when the initial assessment in the ED does not identify an obvious cause.

Patients are frequently admitted for cardiac telemetry after initial assessment in the ED to further evaluate whether they have a serious underlying condition or significant cardiac arrhythmia that requires specific intervention. However, the utility of this approach has been questioned because the best yield for telemetry monitoring in terms of specificity and sensitivity is achieved at about 72 hours.[8] Most patients are admitted to hospital for 24 hours or less and are discharged with outpatient follow-up, so the benefit of admission is often limited; one study found that for 42% of admitted patients an underlying cause had not been defined by the time of discharge.[9] Nevertheless, 7–23% of patients experience an adverse event within 30 days of their initial presentation, half of these events after the patient has been discharged from the ED.[10–12]

In EDs overcrowded as the result of access block associated with limited hospital capacity to meet the requirements of growing populations, clinicians need to identify which patients are at clear risk of adverse events and therefore need to be admitted for further assessment. But these patients comprise a relatively small proportion of those who present with syncope. A greater challenge is to identify patients at low risk for whom admission is unnecessary, reducing both their risk of hospital-related harms and the demand for hospital beds, as well as improving the efficiency and cost-effectiveness of the health care system.

Early risk stratification during the assessment of patients in the ED is therefore central to determining how to manage the patient and the need for further investigations. Several clinical decision rules have been developed to aid this process, but their performance has not been consistent in validation studies across different populations.[13] No decision rule has been universally adopted in Australia.

The Canadian Syncope Risk Score (CSRS) is the most recent decision rule, stratifying patients with syncope into different risk categories according to the estimated likelihood of adverse events.[14] The CSRS was developed by a highly respected clinical team in the largest syncope study to date, and has been shown to have high sensitivity and accuracy. The likelihood that a patient classified as being at very low or low risk will experience an adverse event is about 0.7% and 1.9% respectively, suggesting that hospital admission of such patients may be unnecessary. Further, the accuracy of the CSRS in stratifying patients by risk of serious adverse events within 30 days of ED disposition is high, as found by a recent multi-centre prospective validation study in Canada (area under the receiver operator characteristic curve, 0.87; 95% confidence interval [CI], 0.84–0.89).[15] The criteria for the CSRS are included in the online Supporting Information.

Aims of the study

This study protocol describes phase one of a two-phase prospective study for validating the CSRS in an Australian ED. The primary aim is to validate the utility and safety of the CSRS when applied to patients who present with syncope to Australian EDs. Specifically, we will evaluate how the rule performs in predicting serious adverse events within 30 days among patients at low risk; that is, patients who can safely be

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discharged from the ED but might currently be admitted to hospital for further evaluation.

The secondary objective of our study is to evaluate the CSRS from an economic perspective. We will assess the potential for reducing the number of beds occupied and the associated costs if patients at low or very low risk of serious events are discharged after their initial assessment in the ED. We will quantify the savings that could be achieved by implementing the CSRS as usual practice. The benefits of avoiding unnecessary hospital admissions would include reduced ED length of stay for patients, improved flow through the ED, and increased hospital capacity, thereby reducing access block and ED overcrowding. In general, a uniformly applied decision rule would facilitate consistency in the assessment of patients with syncope, as well as improving efficiency and freeing resources for other purposes in the hospital and the health care system.

Methods and analysis

Study design

Phase one of our investigation is a one-year prospective observational study that will evaluate the safety of applying the CSRS by retrospective validation, and will also assess the potential cost savings achievable by general implementation of this decision making tool. If the outcomes conform to expectations, phase two will be a multi-site implementation of the CSRS in EDs, including sufficient patient numbers and providing adequate data for a robust prospective validation of the tool.

Planned timetable and site for study

Phase one will be conducted at Redcliffe Hospital, an outer metropolitan public hospital near Brisbane that receives 65 000 ED presentations each year, during March 2018 – March 2019.

Patient selection and recruitment

Adult patients (18 years or older) presenting to the ED who have experienced syncope and recovered by the time of initial presentation will be eligible for recruitment. The inclusion criteria are syncope within the previous 24 hours, defined as a transient loss of consciousness (less than 5 minutes) and postural tone, followed by spontaneous and prompt recovery to baseline mental state. Exclusion criteria are persistent reduction in Glasgow Coma Scale (GCS) score, an obvious seizure, intoxication, inability to communicate in English, or major trauma requiring hospitalisation.

As phase one is a prospective observational validation study for assessing the safety of the CSRS, no formal sample size calculation is required, but we aim to recruit about 500 eligible patients over the one-year period, a goal based on hospital syncope diagnosis audit data for the period 2016– 2017. The results from phase one will provide the basis for a sample size calculation for phase two of the investigation.

Data collection

Patient demographic information (including sex and age) and clinical assessment data will be collected, as well as health care cost information for the economic evaluation. Patients will be contacted by telephone 30 days after their initial ED presentation for information about any subsequent adverse events.

Procedure

Printed information about the study will be provided to patients presenting to the ED who meet the inclusion criteria. Patients who agree to participate will then sign an informed consent form before enrolling. Demographic and clinical information required to satisfy the domains of the CSRS will be prospectively recorded by the treating clinician on the study data collection form. The CSRS will be calculated retrospectively to ensure the decision by the treating clinician or supervising consultant about patient disposition is not influenced by the as yet unvalidated tool. Patients will receive standard care, and the decision about discharge or admission will be at the discretion of the treating clinician. Patients will be informed that they will be telephoned by the study research nurse in 30 days to ask whether they have experienced any adverse outcomes. The serious adverse outcomes of interest are death, arrhythmias, myocardial infarction, structural heart disease, aortic dissection, pulmonary embolism, severe pulmonary hypertension (mean pulmonary artery pressure greater than 30 mmHg), subarachnoid haemorrhage, significant haemorrhage, procedural intervention, and any other serious condition requiring the patient to return to the ED for treatment, if not detected during the index visit. These criteria are in accordance with recommendations from international syncope panels, and were applied by the authors of the CSRS in their derivation study.[16,17] If patients are lost to follow-up, a comprehensive search of the statewide electronic database and health records will be undertaken to determine whether any adverse events, including death, have been recorded.

Data analysis

Validation of the CSRS: Data will be accumulated during the recruitment process, and analysed in SPSS 23.0 (IBM) after recruitment is complete. Continuous data will be summarised as means with standard deviations or medians with interquartile ranges, and categorical data as frequencies and percentages. The diagnostic accuracy of the CSRS will be assessed by estimating its specificity, sensitivity, positive and negative predictive values, and the area under the receiver operating characteristic (ROC) curve.

Economic evaluation: We will undertake a cost-effectiveness analysis from the health care perspective; that is, only costs associated with health care system use will be evaluated. Usual care and applying the CSRS will be compared, and the parameters for the economic model will be informed by the study data. The outcome of interest is the number of inpatient admissions avoided, with results being presented as costs saved per avoided admission. Health care costs, including those associated with inpatient stay and admission-related resource use, will be collected from routine administrative databases and included in the model in accordance with previously published methods.[18]

The results of the economic analysis will be presented as incremental cost-effectiveness ratios for admissions avoided, with scenario analyses undertaken to assess other outcomes of interest, such as altered level of clinician risk acceptability, altered willingness-to-pay thresholds, and altered inpatient bed-day values. Net monetary benefit analysis will allow costs to be estimated for a range of willingness-to-pay thresholds. Probabilistic sensitivity analysis will determine the robustness of the results.

Study data will be stored in a password-protected file on a secure computer drive accessible only to members of the research team.

Summary

The CSRS is a promising risk stratification tool for predicting serious adverse events in patients who have visited EDs after experiencing syncope, as shown by a recent multicentre validation of the decision rule in Canada.[15] Validating the CSRS in an Australian ED would provide clinicians with the confidence to accurately and safely stratify patients who have experienced syncope according to their risk of serious adverse events. Patients

who would usually be admitted to hospital could potentially be discharged to outpatient care if classified as being at low risk. This would reduce the need for longer inpatient monitoring and the number of unnecessary investigations, and would also avoid the potential harm related to these interventions. A secondary benefit would be relieving the demand on limited hospital bed capacity by averting unnecessary admissions, which also entails cost benefits and reduced ED and hospital congestion.

A novel feature of our current study is that we will evaluate the economic benefits for our hospital of reducing the number of patients at low risk of serious harm admitted to hospital for investigation of syncope. Health care decision makers are increasingly expected to balance the rising demand for health services and budgetary limitations, but have had limited access to economic evidence for informing their decisions. The results of our economic evaluation will provide decision makers with new information about managing patients who have experienced syncope, enabling them to make more informed decisions about allocating scarce health care resources.

Ethics approval

This project was reviewed by the Prince Charles Hospital Human Research Ethics Committee and granted approval as a low risk project (reference, HREC/17/QPCH/48).

Author contributions

Jason Chan planned the project and wrote the manuscript describing the protocol. Jonathan Hunter developed the concept of the study and provided feedback on the manuscript. Emma Ballard provided statistical expertise, David Brain provided health economics expertise. Douglas Morel and Alan Yan provided feedback on the project design and protocol manuscript. Julia Hocking contributed to planning the project and writing the manuscript.

Dissemination of results

The outcomes of this project will be disseminated widely by Queensland Health and the funding body via social media, presented to local and national emergency medicine conferences, and published in relevant international emergency medicine and health economics journals.

Funding statement: The study is funded by Emergency Medicine Foundation Queensland (reference, EMSS-356R28-2017-CHAN).

Competing interests: No relevant disclosures.

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Supporting Information

Additional Supporting Information is included with the online version of this article.