REmote cardiac MOnitoring of at-risk SYNCope patients after EmergencyDepartment discharge – A Multicenter Randomized Controlled Trial: REMOSYNCED – RCT

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BACKGROUND

Syncope is a frequent cause of Emergency Department (ED) visits and hospitalizations. Identifying which patients will benefit from further investigation, ongoing monitoring and/or hospital admission is essential to reduce both adverse outcomes and high costs. Cardiac rhythm monitoring will lead to identification of underlying arrhythmias that caused the syncope and the treatment of which can lead to reduction in morbidity and mortality. Such monitoring can improve patient safety, healthcare efficiency and patient satisfaction. **Canadian Syncope Risk Score (CSRS)** was derived and validated from two large prospective studies to predict the risk of 30-day serious after ED disposition. Data from these studies reported that medium and high-risk CSRS patients may benefit from ***prolonged (15-day) cardiac rhythm monitoring*** to improve the identification of underlying arrhythmias. This tool in conjunction with 24/7 live prolonged cardiac rhythm monitoring can transform the post-ED care of at-risk syncope patients.

OBJECTIVES

The overall objective of this study is to evaluate a strategy of **15-day live cardiac rhythm monitoring versus usual care** at improving the identification of an arrhythmia that required treatment among at-risk syncope patients (CSRS medium and high-risk) discharged from the ED through a patient level randomized controlled trial (RCT).

The **primary objective** is compare the proportion of patients (CSRS ≥ 3 discharged) with arrhythmia that requires treatment between the two study arms and the **secondary objectives** are to assess 30-day serious outcomes and re-evaluate the optimal duration of cardiac rhythm monitoring.

METHODS

- This is a prospective patient-level RCT in 13 EDs across Canada for 18 months.
- Syncope patients aged ≥18 years old who present to the ED within 24 hours of syncope with CSRS score of ≥3 will be randomized to usual care or prolonged outpatient cardiac rhythm monitoring.
  - Usual care: participants will receive all care as prescribed by the discharging physician.
  - Intervention arm: Participants will receive 24/7 live cardiac rhythm monitoring (Cardiophone) for 15 days. If a participant was prescribed outpatient cardiac monitoring such as Holter monitor, this will be replaced by the 24/7 live monitoring.

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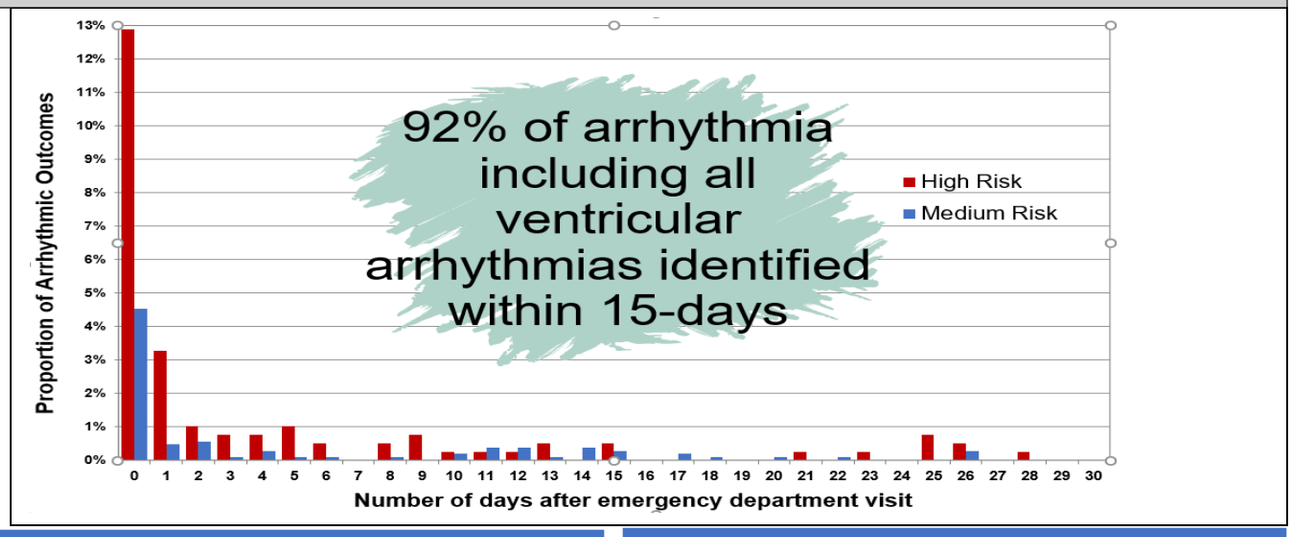
Canadian Syncope Risk Score

Category	Points
Clinical evaluation	
Predisposition to vasovagal symptoms*	-1
History of heart disease†	1
Any systolic pressure reading <90 or >180 mm Hg‡	2
Investigations	
Elevated troponin level (>99th percentile of normal population)	2
Abnormal QRS axis (<-30 or >100°)	1
QRS duration >130 ms	1
Corrected QT interval >480 ms	2
Diagnosis in emergency department	
Vasovagal syncope	-2
Cardiac syncope	2
Cause unknown	0
Total score (-3 to 11)	

Total Score	Estimated risk of serious adverse event§ %	Risk category
-3	0.4	Very Low
-2	0.7	Very Low
-1	1.2	Low
0	1.9	Low
1	3.1	Medium
2	5.1	Medium
3	8.1	Medium
4	12.9	High
5	19.7	High
6	28.9	Very High
7	40.3	Very High
8	52.8	Very High
9	65.0	Very High
10	75.5	Very High
11	83.6	Very High

Timing and Proportion of Medium and High-Risk CSRS Patients suffering Serious Arrhythmic Outcomes within 30-days



Results

With this study we aim to show that prolonged outpatient cardiac monitoring of at-risk syncope patients who are discharged from the ED is far better than the current management of these patients.

Conclusion

We believe that prolonged outpatient cardiac monitoring of at-risk ED syncope patients after discharge will improve patient safety, healthcare efficiency and patient satisfaction, and will become the standard of care in the future.