The Syncope Stopper Study

Comparison of upfront pacing with standard care for high-risk patients with unexplained syncope.

Background

Up to 50% of patients presenting to hospital with syncope will be discharged without a clear diagnosis. Better risk profiling may allow prediction of patients with unexplained syncope who will benefit from a pacemaker, which could prevent further syncope and injuries.

Study design

Patients with unexplained syncope and a high DROP score (≥2) will be randomised 1:1 to either receive an upfront permanent pacemaker or standard care.

The DROP score	
D	**D**istal conduction disease (any of RBBB, LAFB, LPFB and LBBB)
R	**R**elated historical precipitating factors absent (e.g. overheating, posture, exercise)
O	**O**lder age (>65 years)
P	**P**rolonged PR interval (>200ms)

*1 point for each, score 0-4. ≥2 implies high risk.

Population:

We aim to recruit 200 participants from Alfred Health, Cabrini Health, The Royal Melbourne Hospital, and Western Health.

Inclusion criteria:

- At least one 'unexplained' syncopal episode in the past 12 months
- ≥55 years old
- DROP score ≥2

Exclusion criteria

- Likely neurocardiogenic or vasovagal syncope
- LV ejection fraction <40%
- Previous PPM, ICD, or ILR implant
- Existing Class I indication for PPM/ICD implant
- Contraindication to transvenous pacemaker
- Comorbidity precluding 12 months follow-up

Intervention

- Treatment group (n=100): Pacemaker implantation within 1 month of enrolment
- Control group (n=100): standard care. May include Holter monitoring or ILR.

Follow-up

Enrolled patients will be followed up for 12 months. A study visit will be completed every 3 months to review clinical progress and perform a rhythm assessment (e.g. PPM interrogation, ECG, Holter, as appropriate).

Outcomes

The primary outcome will be a composite of

- Cardiovascular death
- Recurrent syncope
- Bradycardia resulting in pacemaker implantation
- Device-related complications

Secondary outcomes will also include

- Recurrent cardiovascular hospitalisation
- All-cause mortality
- Quality of life and syncope symptom score
- Total length of hospital admission
- Cost to healthcare system
- Need for PPM implant (control group)
- Prevalence of tachy/bradyarrhythmia
- Percent pacing burden (PPM group)

Our hypothesis

Early pacemaker implantation (**a 'Syncope-Stopper'**) is the safest and most cost-effective strategy for managing high-risk patients with unexplained syncope, with the novel DROP score able to identify patients at highest risk of bradycardia.

Research team

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Any Questions? Contact Alex Voskoboinik
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