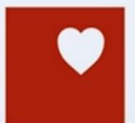




ROMAN trial

Dan Wichterle

Klinika kardiologie IKEM



Cardioneuroablation for Reflex Syncope (ROMAN trial)

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ORIGINAL RESEARCH

NEUROMODULATION

Cardioneuroablation for Reflex Syncope

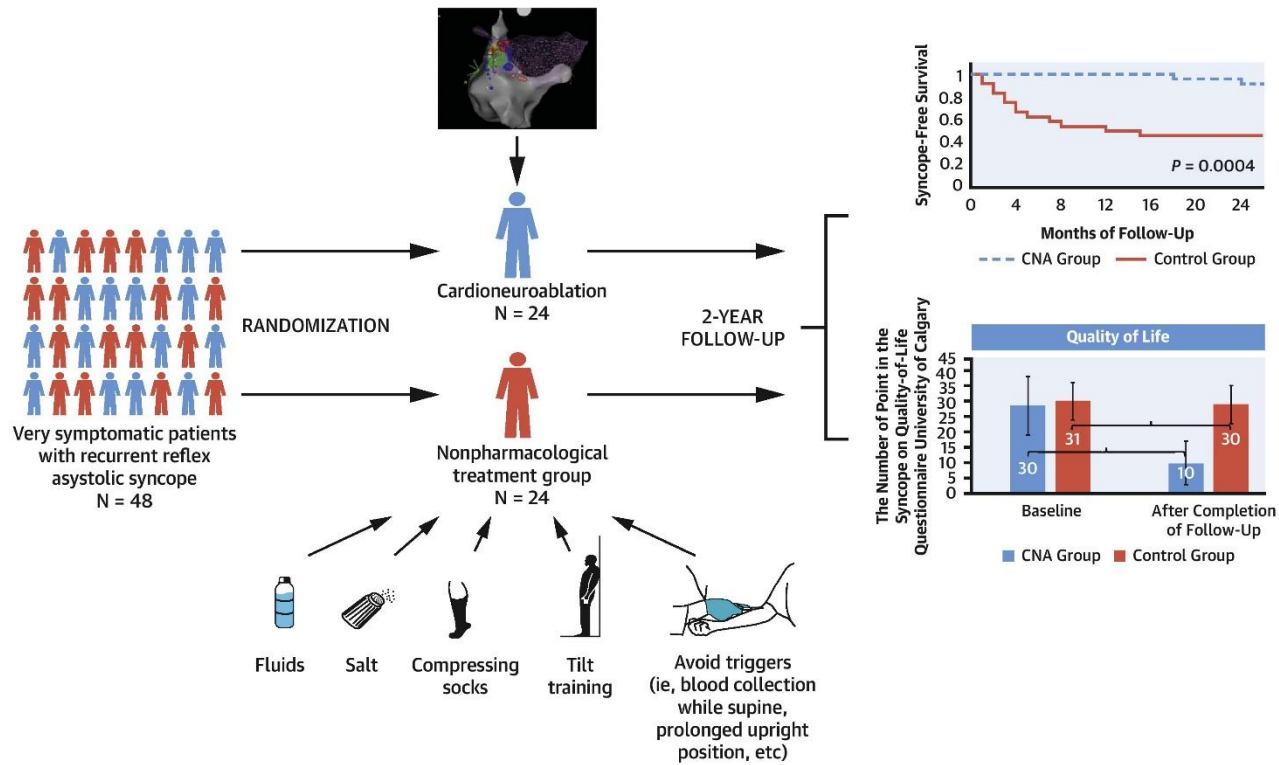


Efficacy and Effects on Autonomic Cardiac Regulation— A Prospective Randomized Trial

Roman Piotrowski, MD, PhD, Jakub Baran, MD, PhD, Agnieszka Sikorska, MD, PhD, Tomasz Krynski, MD,
Piotr Kulakowski, MD, PhD

Cardioneuroablation for Reflex Syncope (ROMAN trial)

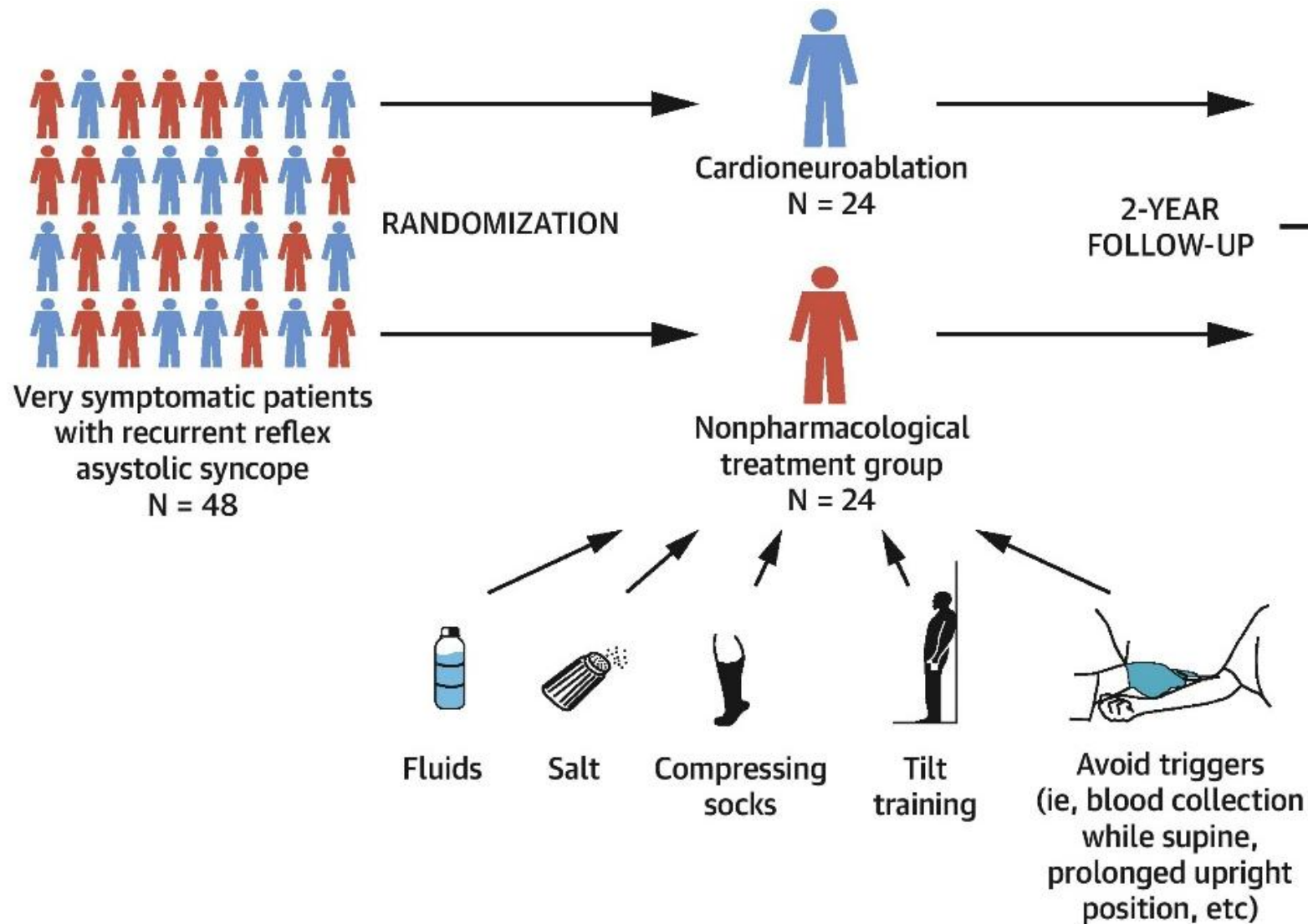
CENTRAL ILLUSTRATION: The First Randomized Study Documenting Efficacy of Cardioneuroablation in Patients With Cardioinhibitory Vasovagal Syncope



Piotrowski R, et al. J Am Coll Cardiol EP. 2023;9(1):85-95.

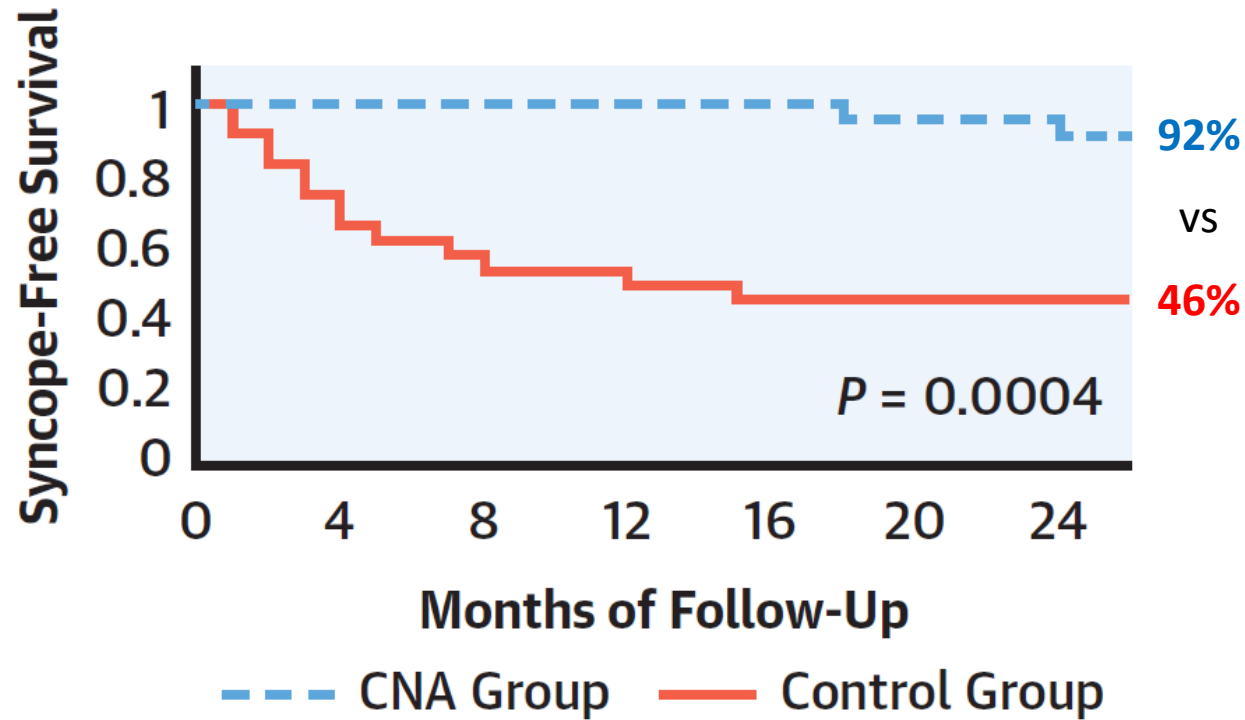
Cardioneuroablation for Reflex Syncope (ROMAN trial)

Design



Cardioneuroablation for Reflex Syncope (ROMAN trial)

Syncope Outcome



recurrent syncope

2/24 (8%)

VS

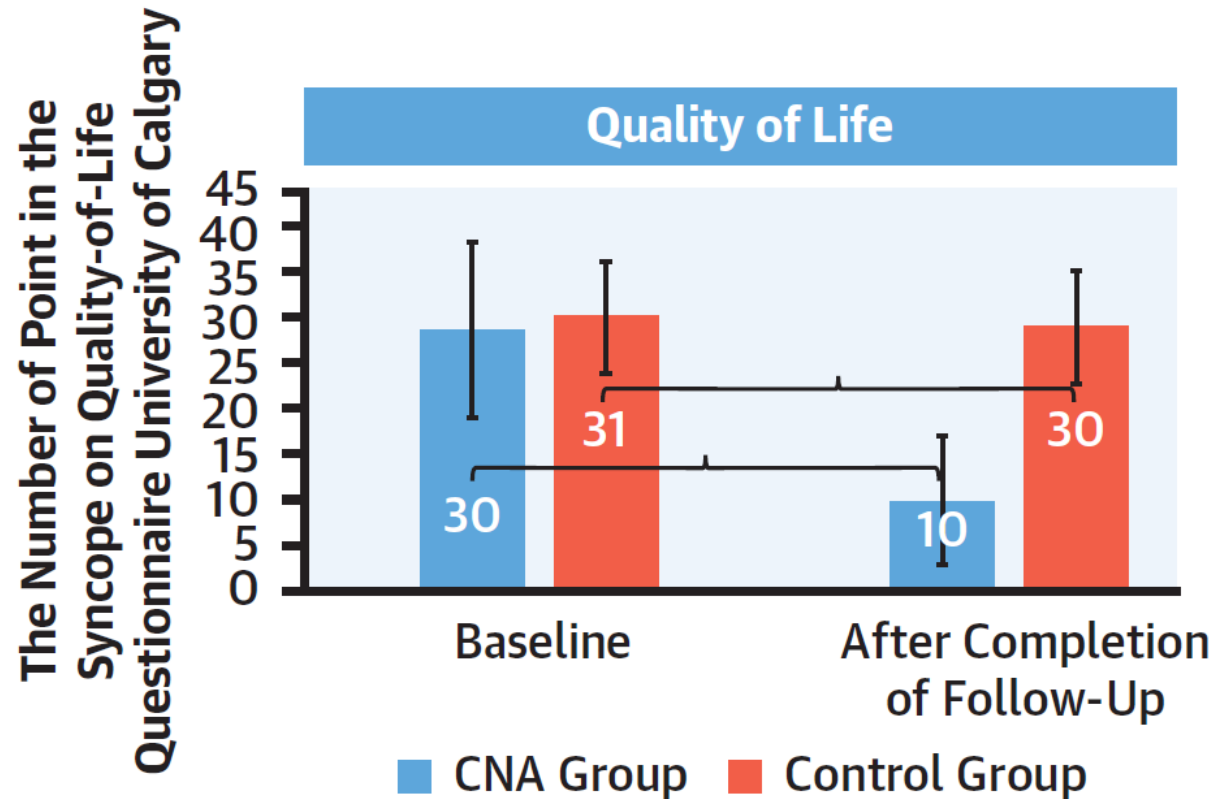
13/24 (54%)

HR = 0.11 (95% CI: 0.02; 0.47)

RRR = -89% (95% CI: -98%; -53%)

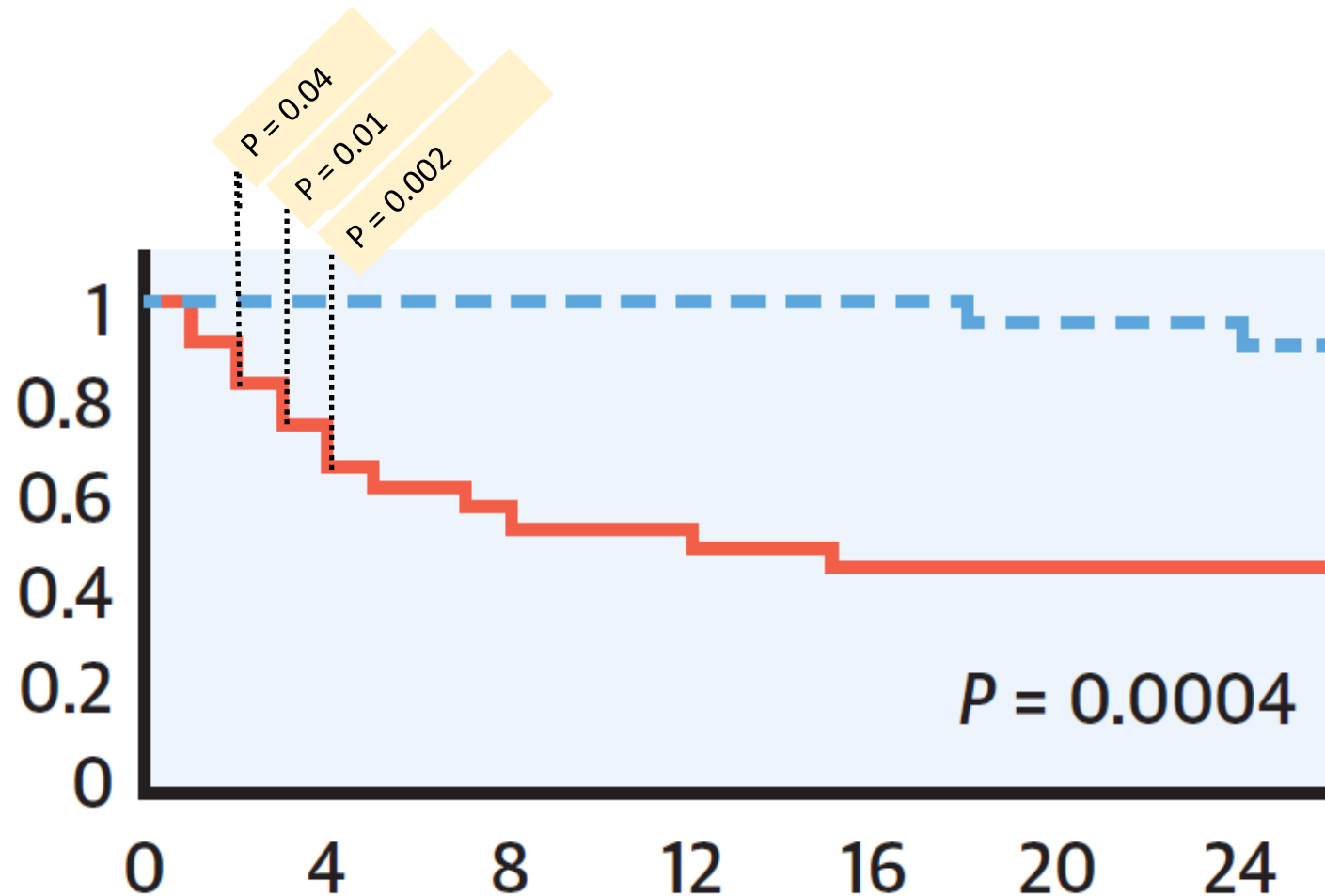
Cardioneuroablation for Reflex Syncope (ROMAN trial)

QoL Outcome



Cardioneuroablation for Reflex Syncope (ROMAN trial)

Considerations for Future



- Cox proportional hazards
- 2-sided equality
- Overall event rate: 31%
- Hazard ratio: 0.11
- Alpha: 0.05
- Power: 90%
- **Sample size: 14 + 14 patients**

Limitace

- Malý počet pacientů
- Nezaslepení pacienti ani investigátoři
- Monocentrická studie
- Absence externího auditu
- Komparátor – jen nefarmakologická neintervenční léčba (není srovnání s farmakoterapií nebo kardiostimulací)

Souhrn

- Studie ROMAN je první randomizovaná studie u pacientů s recidivujícími kardioinhibiční vasovagálními synkopami, která prokázala superioritu kardioneuroablace nad režimovou léčbou.
- Klinická účinnost kardioneuroablace je bezprecedentně vysoká, ale musí být ověřena ve větší, multicentrické, randomizované, potenciálně zaslepené a nezávisle monitorované studii.