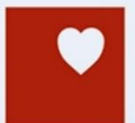




Kardiostimulátor je jedinou léčbou bradyarytmií

Dan Wichterle

Klinika kardiologie IKEM



Intervenční léčba bradyarytmií

Tachykardie → Ablace

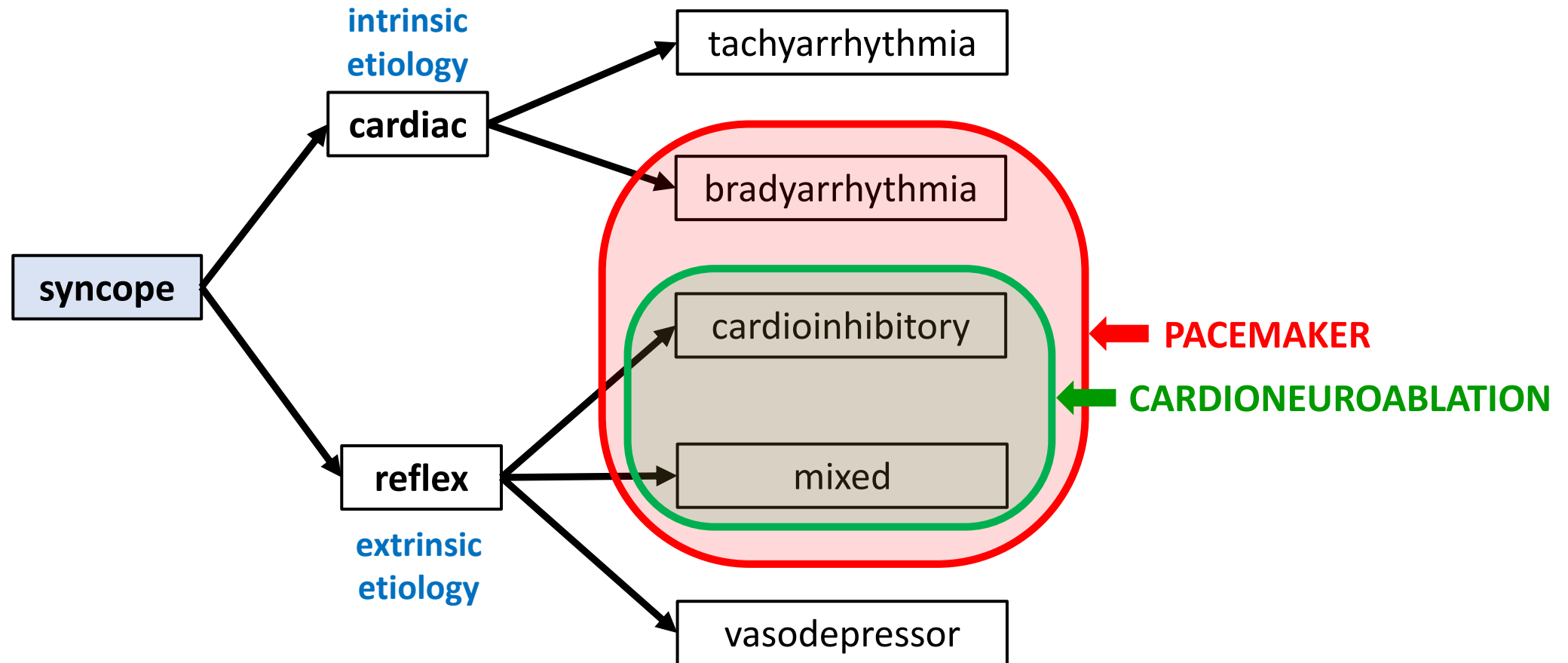
Bradykardie → Pacemaker

Bradykardie → Kardioneuroablace

... na kardioneuroablaci je žádoucí pomyslet u mladších pacientů se **symptomatickými** bradyarytmiemi ...

- pokud dominuje **funkční etiologie**
- bez ohledu na klinickou manifestaci
 - ✓ *synkopa*
 - ✓ *jiné bradyarytmické symptomy*
- bez ohledu na EKG manifestaci
 - ✓ *sinus arrest / sinusová bradykardie*
 - ✓ *AV blokáda*

Intervenční léčba synkop

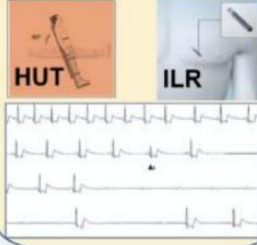
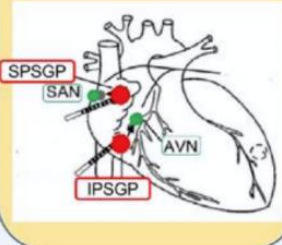
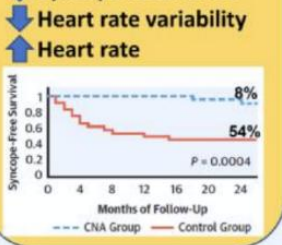


Ganglionic plexus ablation. Radiofrequency ablation of vagal ganglia located close to the sinus node and AV node was reported to abolish the vagal efferent output during VVS in some observational studies and case reports.^{290,291} However, owing to a weak rationale, small populations, weak documentation of follow-up results, procedural risks, and lack of control groups, the current evidence is insufficient to confirm the efficacy of vagal ganglia ablation.

Kardioneuroablace – přehledové dokumenty typu „state of the art“

Clinical controversy: methodology and indications of cardioneuroablation for reflex syncope

Michele Brignole^{1*}, Tolga Aksu², Leonardo Calò³, Philippe Debryne⁴, Jean Claude Deharo⁵, Alessandra Fanciulli⁶, Artur Fedorowski^{7,8,9}, Piotr Kulakowski¹⁰, Carlos Morillo¹¹, Angel Moya¹², Brian Olshansky¹³, Roman Piotrowski¹⁰, Sebastian Stec¹⁴, and Dan Wichterle^{15,16}

Cardioneuroablation for reflex syncope				
	IDENTIFY the proper candidate	ABLATE the proper ganglia	VERIFY the effect of ablation	PROVE the efficacy of therapy
What is known	<p>Asystolic reflex syncope documented by:</p>  <p>HUT ILR</p>	<p>Target: SPSGP - IPSGP</p>  <p>SPSGP SAN AVN IPSGP</p>	<p>At 2 years:</p> <ul style="list-style-type: none"> ↓ Syncope recurrence ↓ Heart rate variability ↑ Heart rate  <p>Syncope-Free Survival</p> <p>Months of Follow-Up</p> <p>P = 0.0004</p> <p>--- CNA Group — Control Group</p>	<ul style="list-style-type: none"> • Need for large RCTs • Need for longer follow-up
What is not known	<p><i>Less suitable in:</i></p> <ul style="list-style-type: none"> • Mixed forms • Non-syncope extrinsic SND/AVB <p><i>Do not perform in:</i></p> <ul style="list-style-type: none"> • VD forms • Intrinsic SND/AVB 	<ul style="list-style-type: none"> • SPSGP only or SPSGP+IPSGP • RA vs LA vs RA+LA • Optimal ablation technique • Assessment of acute procedural success 	<ul style="list-style-type: none"> • Long-term efficacy (reinnervation) • Patient's expectation effect • Physician's expectation effect • Subgroup efficacy 	<ul style="list-style-type: none"> • Non-inferiority of CNA vs pacemaker in pts >40 yrs • Superiority of CNA vs conventional therapy in pts <60 years • Superiority of CNA vs sham CNA • Potential harm of long-term vagal denervation

Venice Chart International Consensus Document on Neuromodulation for Atrial Fibrillation, Bradyarrhythmias and Neurally Mediated Syncope

Aksu / Morillo / Raviele

Venice
Arrhythmias

Cardioneuroablation: State of the Art Cardioneuroablation Working Group

Pachon / Kusumoto

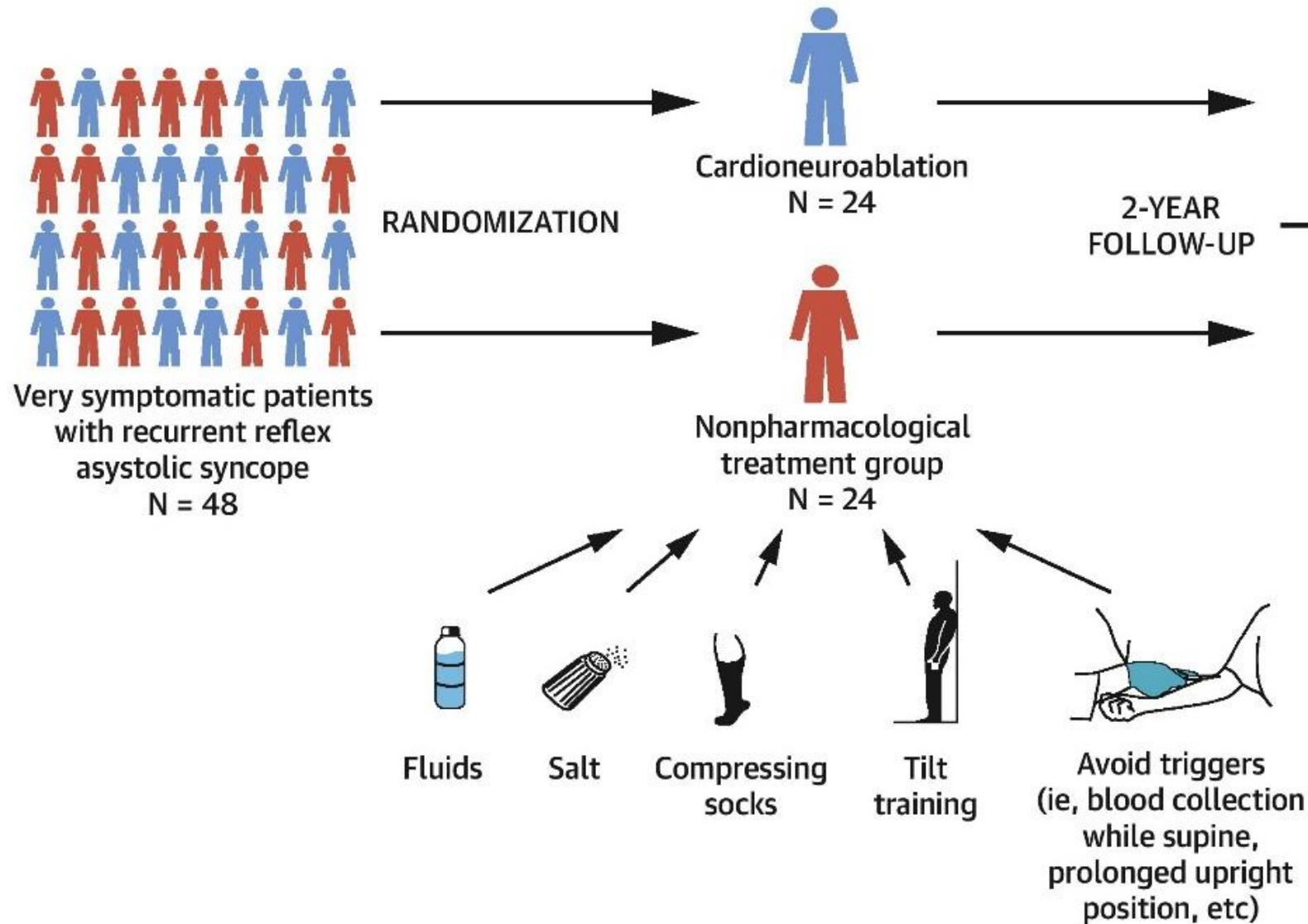
Mayo Clinic
HRS

Cardioneuroablation for the treatment of reflex syncope and functional bradyarrhythmias. A Clinical Consensus Statement of the European Heart Rhythm Association (EHRA) of the ESC, the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS) and the Latin American Heart Rhythm Society (LAHRS)

23 autorů

EHRA

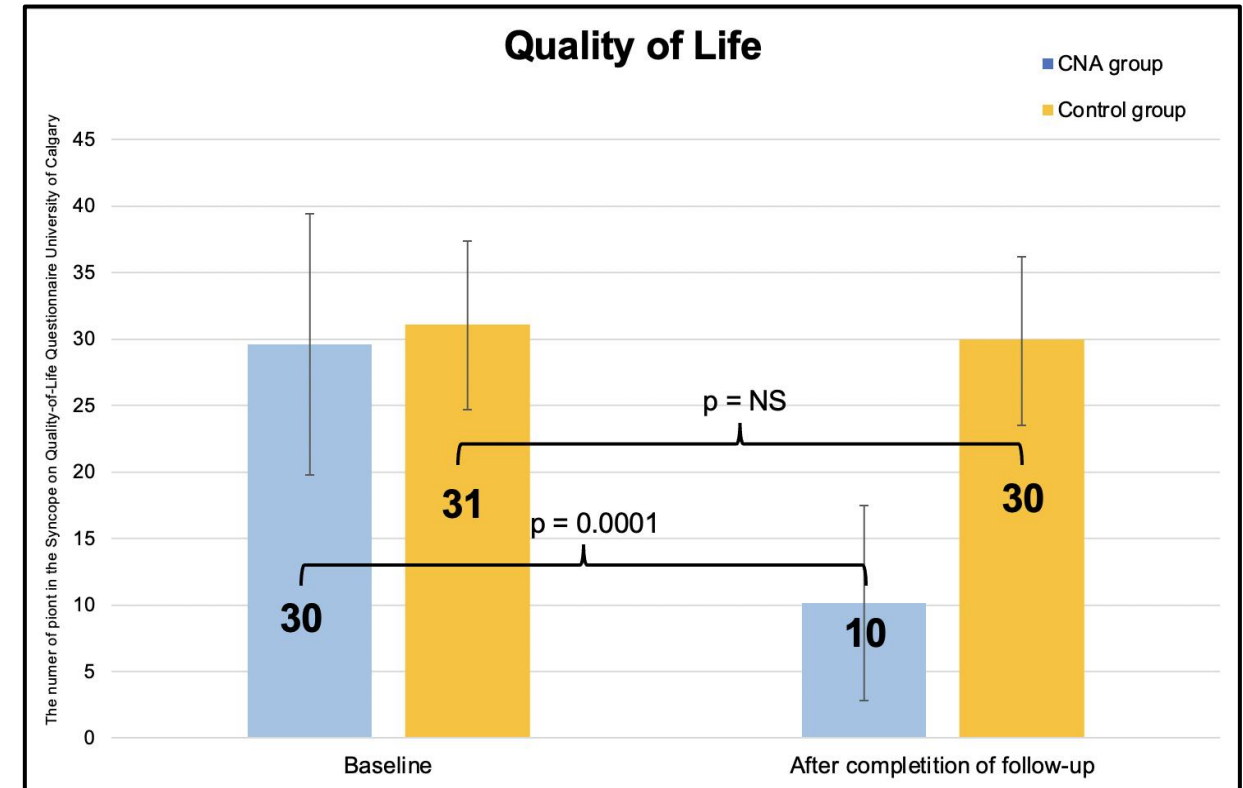
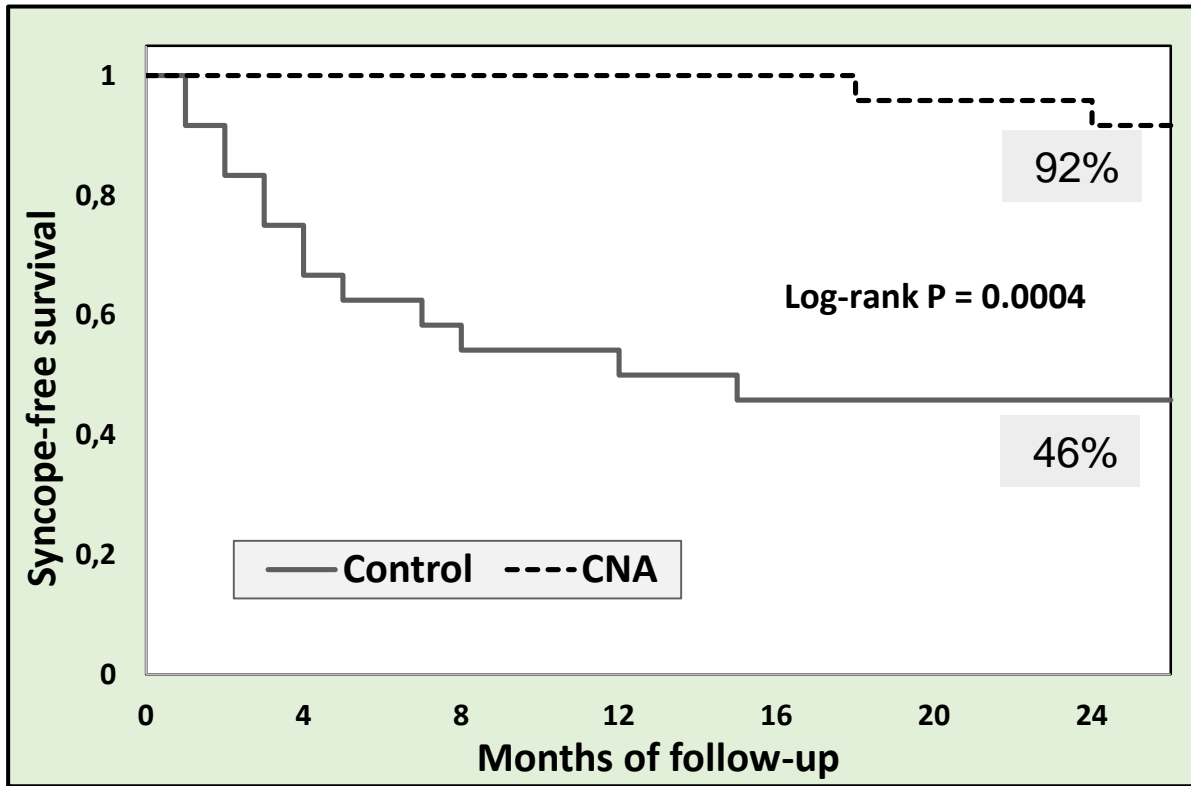
Cardioneuroablation for Reflex Syncope (ROMAN trial)



Cardioneuroablation for Reflex Syncope (ROMAN trial)

Cardioneuroablation for reflex syncope: efficacy and effects on autonomic cardiac regulation
A prospective randomized trial

24 + 24 patients



Efficacy of a Right-sided Ablation of the Anterior Ganglionated Plexus for Neurally Mediated Syncope (CardNMH3)

NCT04755101

Multicentre study: Imelda Hospital, Bonheiden
(Belgium) UZ, Leuven
AZ Sin Jan, Brugge

Investigator: Philippe Debruyne

Randomized (2:1), double-blind study

TREATMENT ARM: cardioneuroablation

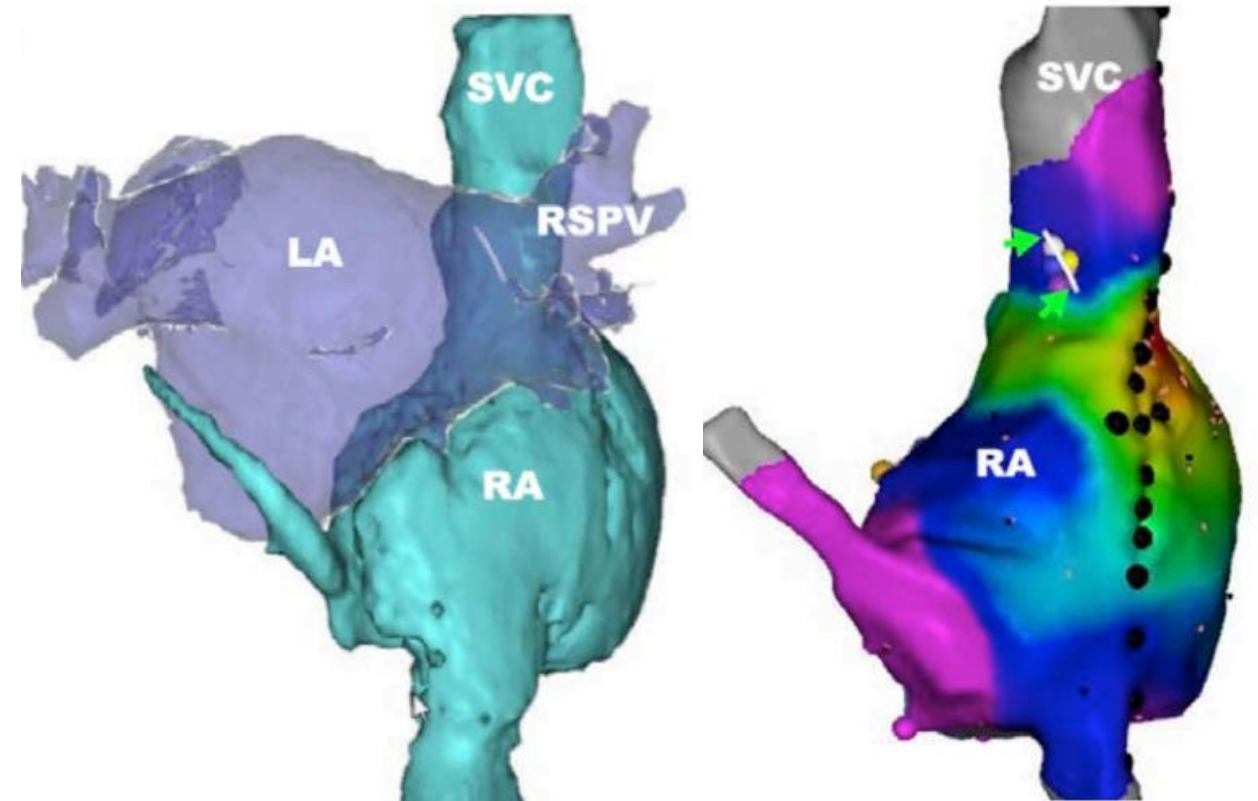
CONTROL ARM: sham procedure

- **Right-sided ablation, CT-guided**
- **Procedure endpoint: sinus rhythm acceleration**

Recruitment estimated: 110

Primary objective: Syncope-free survival

Estimated completion: 2024



Reflexní synkopy: pacemaker nebo kardioneuroablace?

Permanent pacing versus cardioneuroablation for cardioinhibitory vasovagal syncope

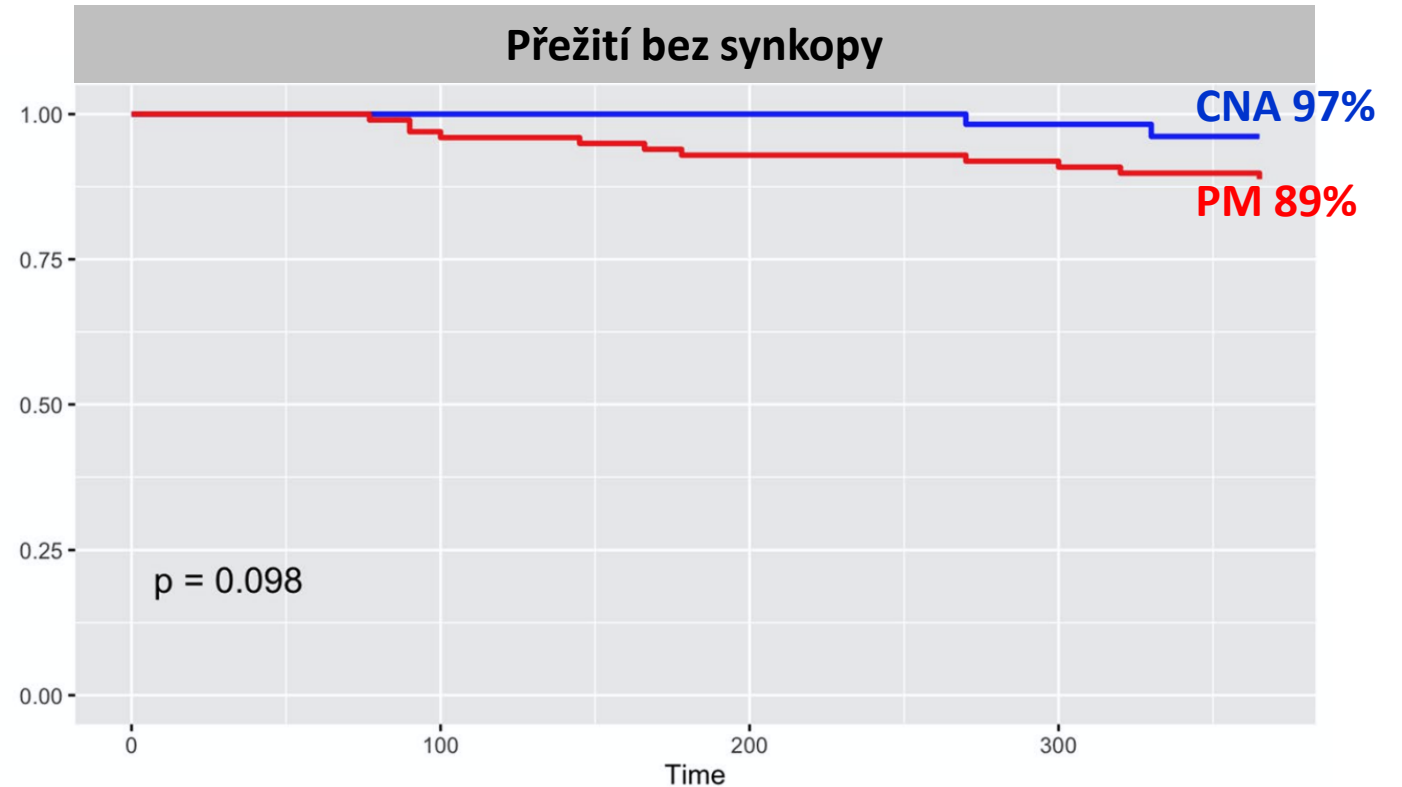
Nerandomizovaná observační studie

Kardioneuroablace (N=61)

VS

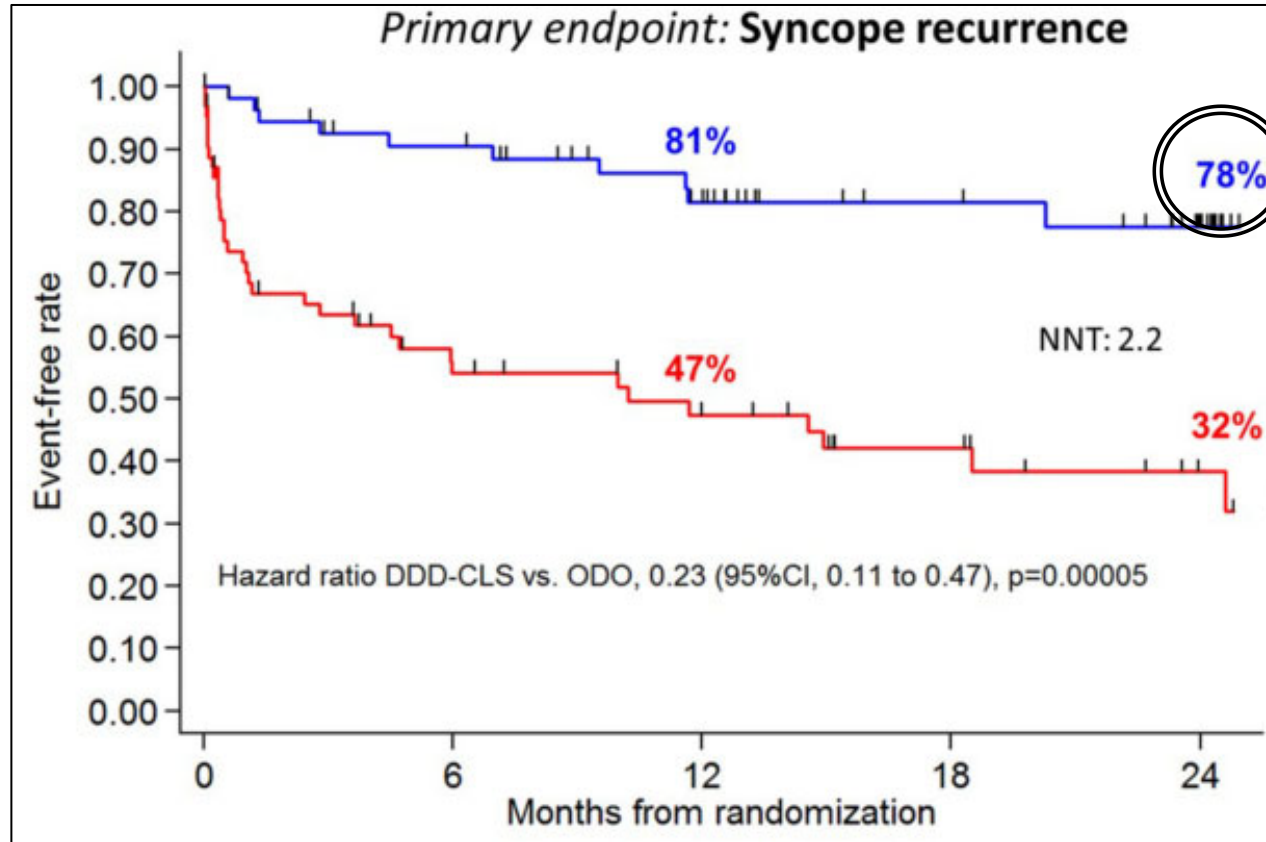
Pacemaker – RDR / CLS / leadless (N=101)

- **Věk:** 36 ± 11 let
- **Četnost synkop:** 7 ± 4 / rok
- **Sledování:** 1 rok
- **Endpoint:** Rekurence synkopy

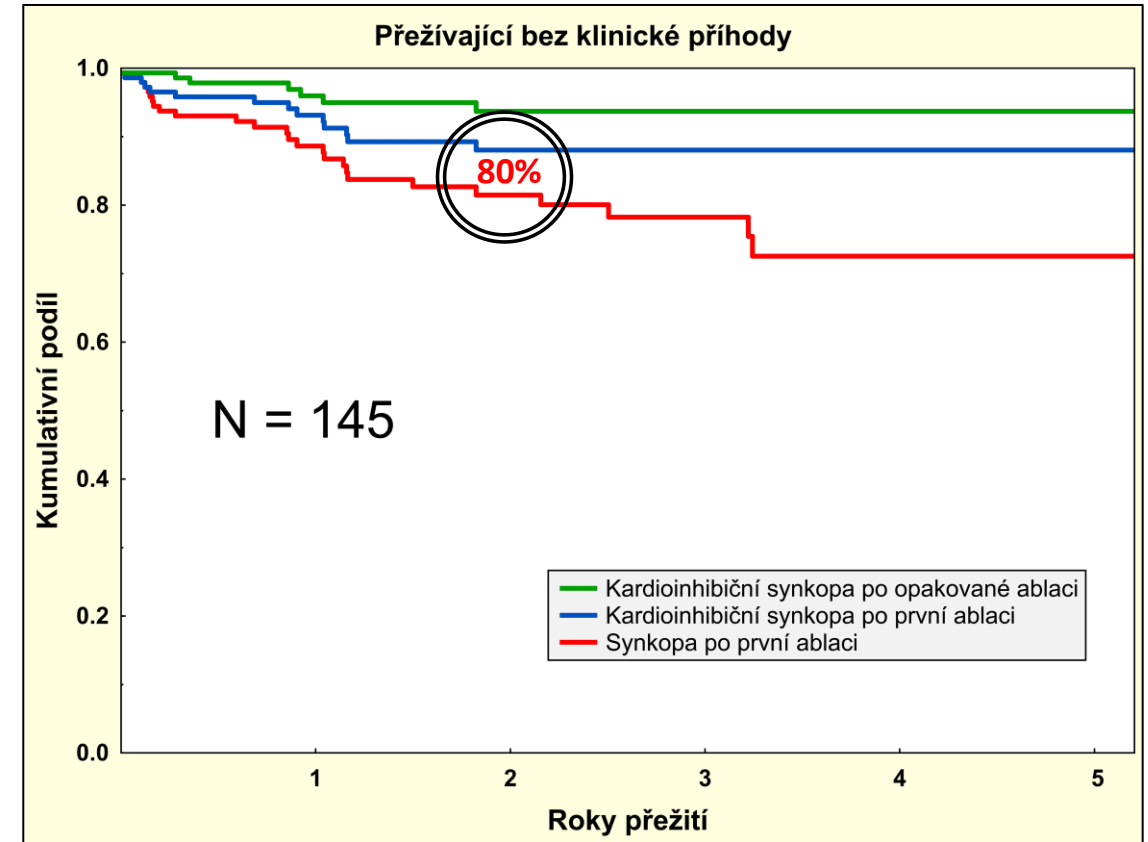


Reflexní synkopy: pacemaker nebo kardioneuroablace?

BioSync CLS Trial



Kardioneuroablace IKEM



Cardioneuroablation for sick sinus syndrom (ongoing studies)

Permanent Pacemaker Implantation or Cardioneuroablation in Sinus Node Dysfunction (SANOK)

Multicentre, randomized study (N = 60); PI: Sebastian Stec (Poland)

TREATMENT ARM: cardioneuroablation

CONTROL ARM: pacemaker implant

Primary objective: Freedom from bradycardia symptoms

Cardioneuroablation Versus Pacemaker Implantation for the Treatment of Symptomatic Sinus Node Dysfunction (DINERVAPACE)

Randomized study (N = 40), PI: Carlos Carazo (Spain)

TREATMENT ARM: cardioneuroablation

CONTROL ARM: pacemaker implant

Primary objective: Quality of life

Cardiac Ganglionated Plexus Ablation Before Permanent Pacemaker Implantation in Patients With Sick Sinus Syndrome (GAPS)

Multicentre, randomized study (N = 100), PI: Yan Yao (China)

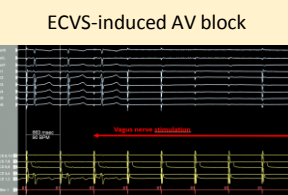
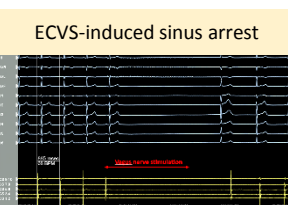
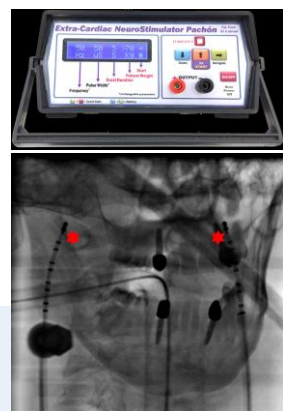
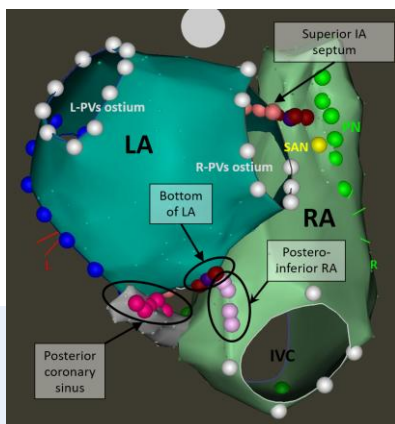
TREATMENT ARM: pacemaker implant + cardioneuroablation

CONTROL ARM: pacemaker implant

Primary objective: Percentage of atrial pacing

Kardioneuroablace

- je účinná léčebná metoda u pacientů s funkčními bradyarytmiemi
 - **reflexní kardiinhibiční synkopy**
 - **symptomatické nesynkopální bradyarytmie**
- je výhodnou alternativou implantace pacemakeru zejména u mladších pacientů
- přímé porovnání s kardiostimulační léčbou je metodologicky obtížné



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