Uzávěr PFO
Pro

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KARDIOLOGICKÁ KLINIKA
2. LF UK a FN MOTOL

Uzávěr PFO – jsme pro?

- Je PFO opravdu viníkem?
- Jsou pacienti ohroženi rekurencí?
- Je katetrizační uzávěr PFO efektivní, bezpečný a lepší než OMT?
- Jaká OMT?

Kryptogenní CMP – je PFO opravdu viníkem?

- Prevalence PFO
  - V obecné populaci ~27%
  - Kryptogenní CMP do 60 let ~ 50%
- PFO-related stroke ~ ½
- Další faktory – mobilní septum, Eustachova chlopeň, velikost PFO, koagulopatie, absence klasických RF

Katetrizační uzávěr PFO - evidence

- 5 randomizovaných studií
- Metaanalýza pacientských dat
- Prodloužené sledování studie RESPECT
- FDA approval

RESPECT - design

- N=980 (25 cílových událostí)
- 1:1 Amplatzer PFO occl. + OMT vs. OMT
- OMT: ASA/Clopidogrel/Warfarin
- 18-60 let, kryptogenní CMP (270d)
- Primární cíl: fatální + non-fatální CMP, úmrtí do 45 dnů
- Sek. Cíle: kompletní uzávěr, absence CMP/TIA

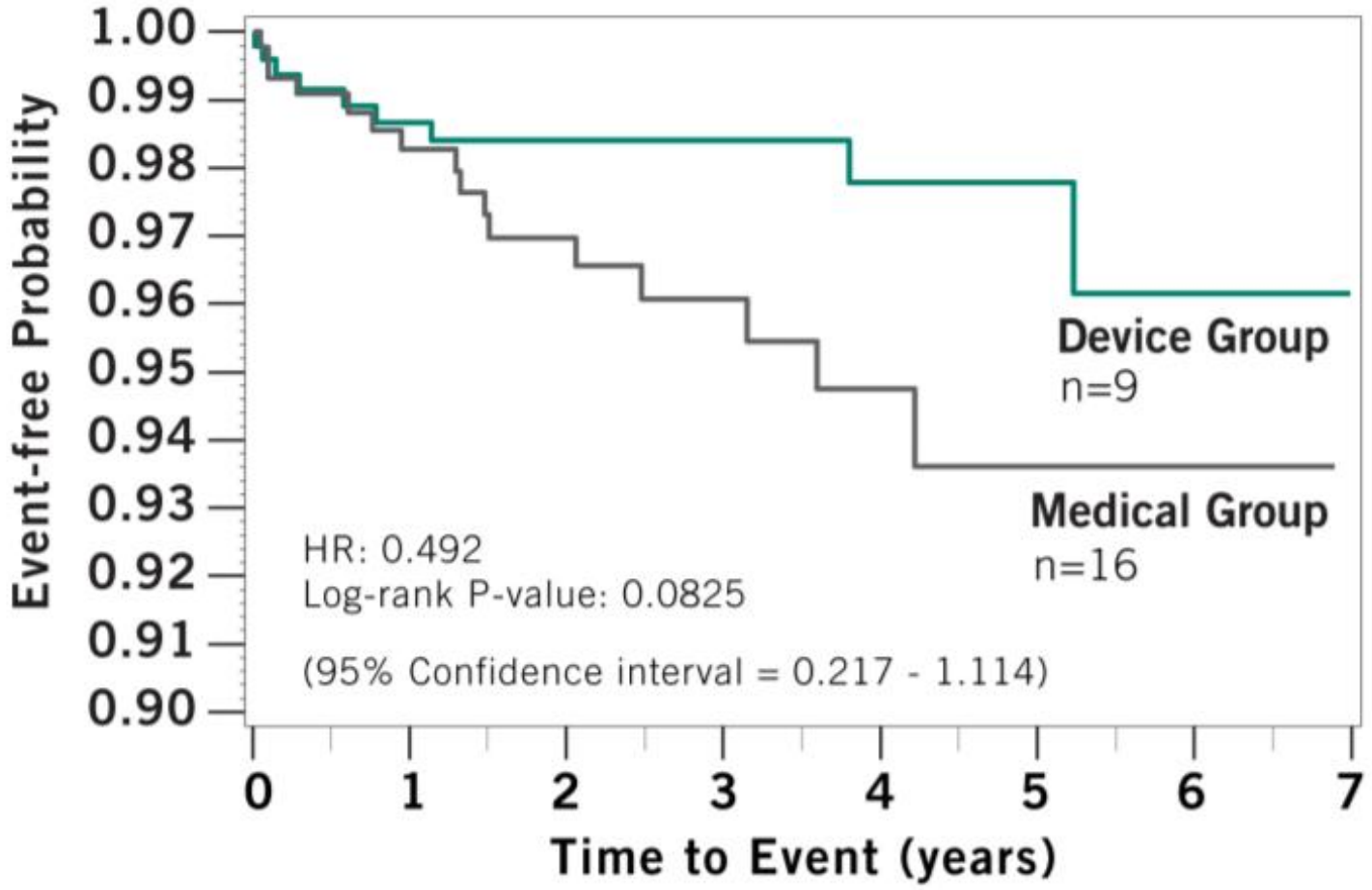
RESPECT - výsledky

Analysis	Risk Reduction	P-Value[1]
Intent to Treat Raw Count	46.6%	0.157
Intent to Treat KM	50.8%	0.083
Per Protocol KM	63.4%	0.032
As Treated KM	72.7%	0.007

Primary Endpoint Analysis – ITT Cohort

50.8% risk reduction of stroke in favor of device

RESPECT CLINICAL TRIAL

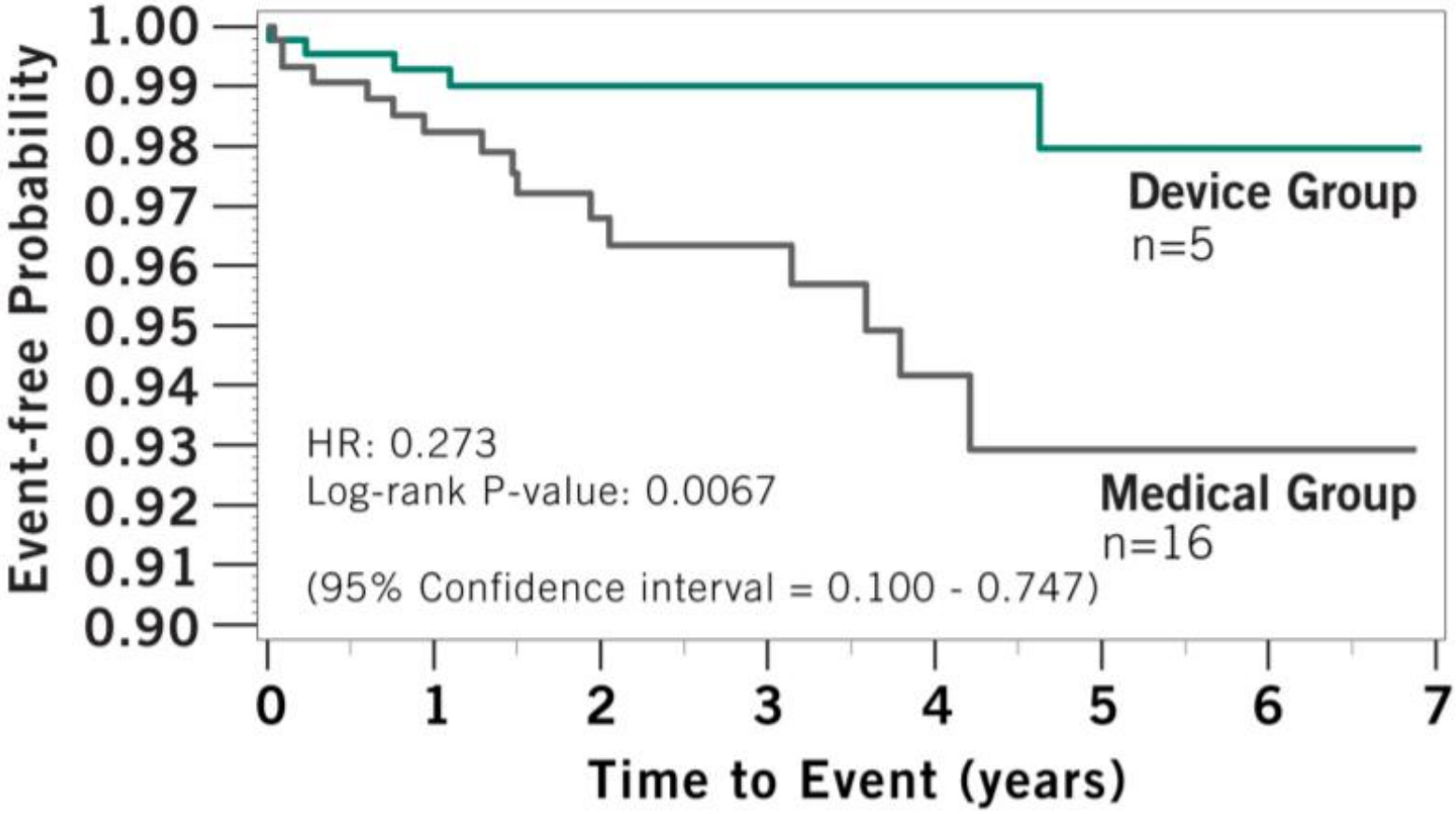


- **3/9** device group patients did not have a device at time of endpoint stroke

1. Cox model used for analysis

Primary Endpoint Analysis – As Treated Cohort
72.7% risk reduction of stroke in favor of device

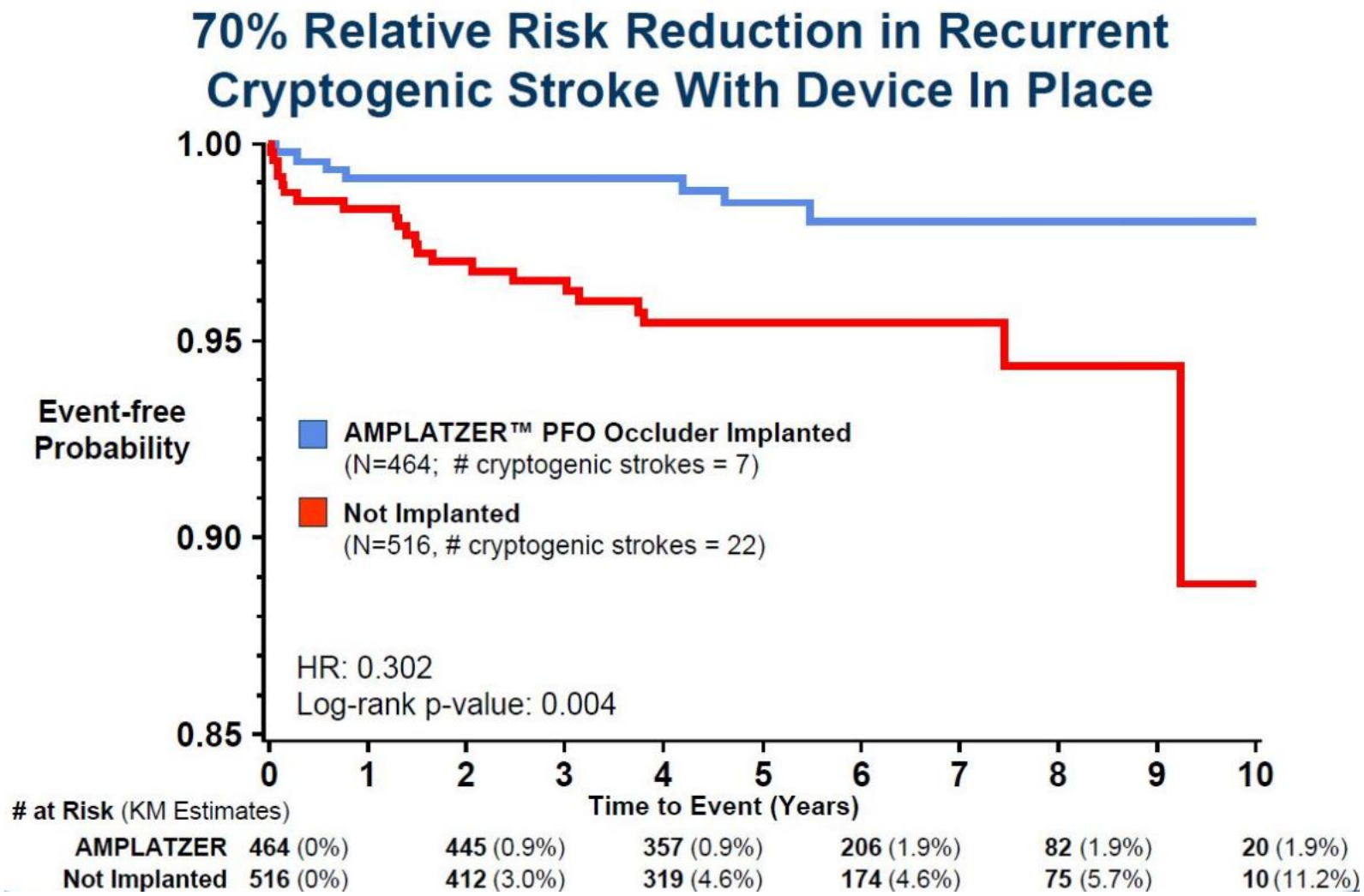
RESPECT CLINICAL TRIAL



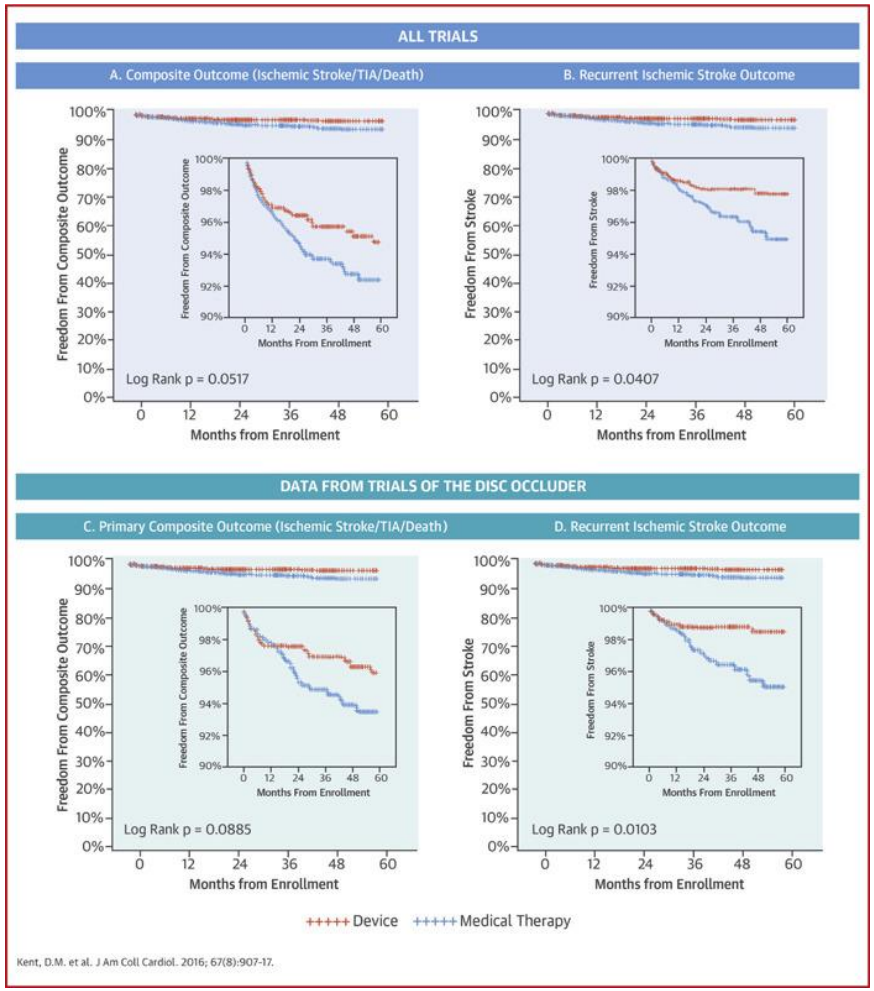
- The As Treated (AT) cohort demonstrates the treatment effect by classifying subjects into treatment groups according to the treatment actually received, regardless of the randomization assignment

1. Cox model used for analysis

Studie RESPECT – prodloužené sledování

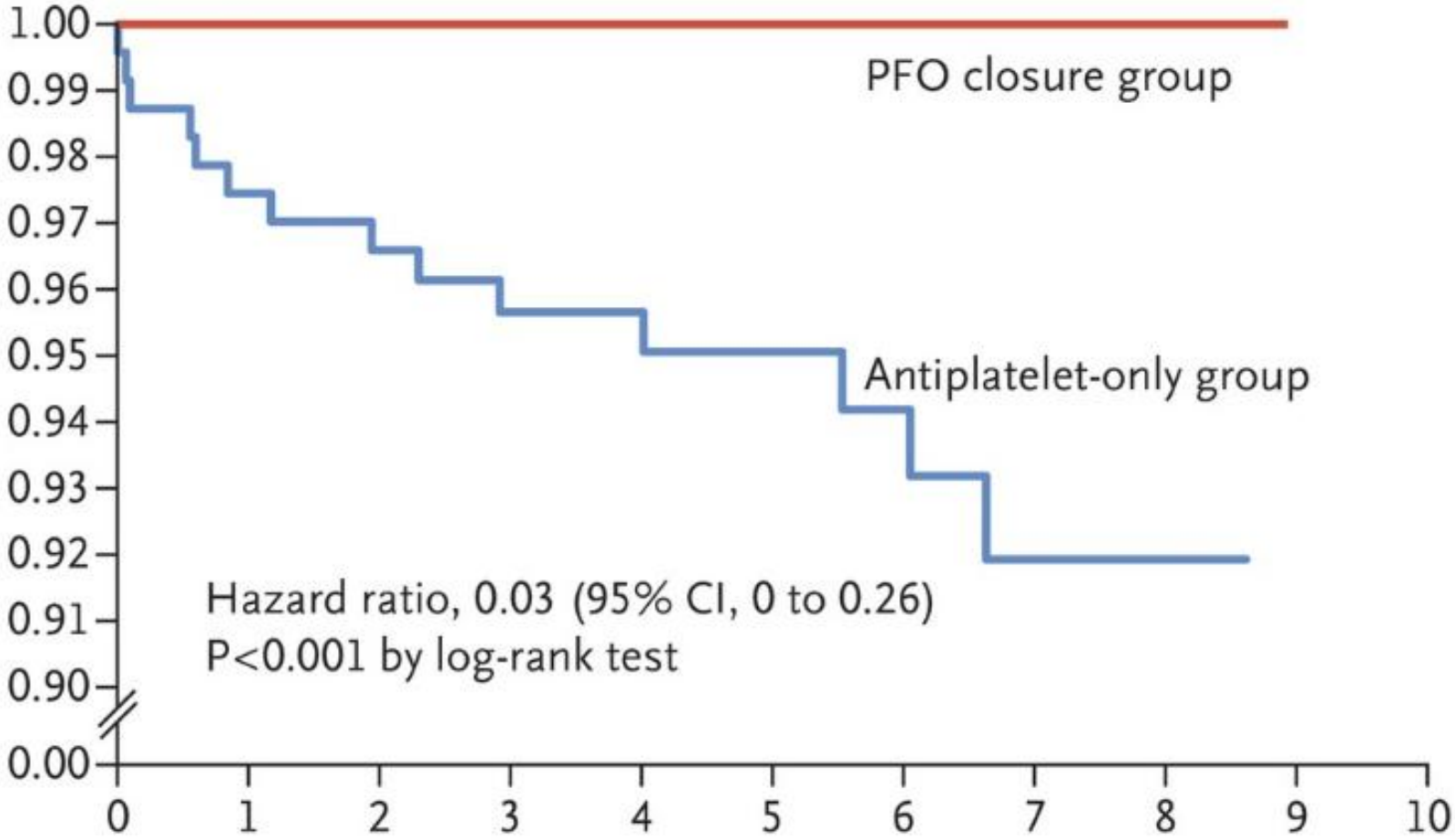


Metaanalýza



- Sloučená data -3 randomizované studie
- N= 2303
- 700 pac. nedokončilo
- Vyšší incidence FiS (STARFlex)
- Riziko rekurence
  - 1 % vs. 0,5 % /rok

CLOSE


1.00
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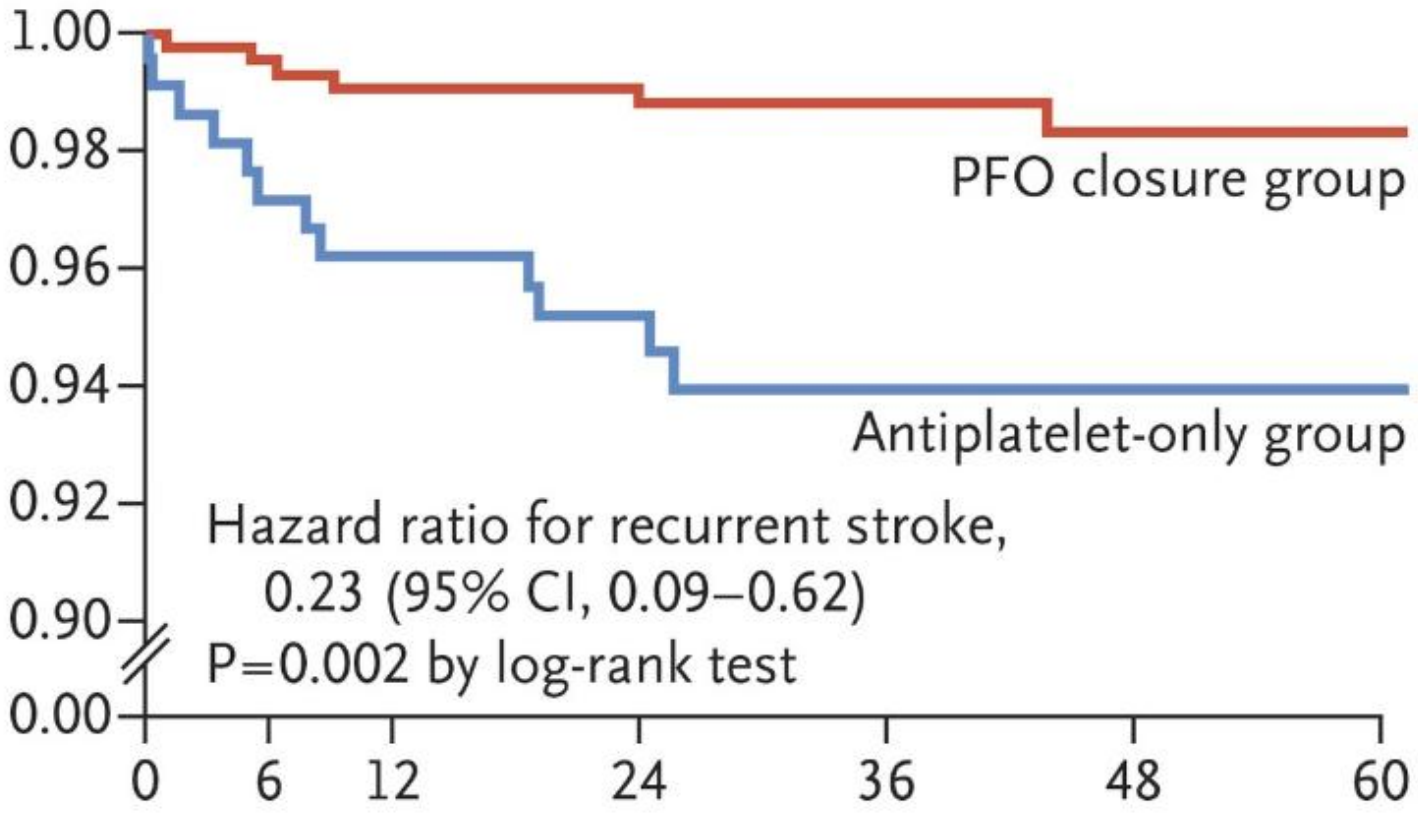
10
PFO closure group
Antiplatelet-only group
Hazard ratio, 0.03 (95% CI, 0 to 0.26)
P<0.001 by log-rank test

REDUCE



N = 664, FU 3,2 r, rekurence 5,7 vs. 1,4 %

Závěrem

- PFO u 50% pacientů s kryptogenní CMP
- Mladí pacienti, nízké riziko rekurence, ale dlouhé očekávané dožití
- Uzávěr PFO je bezpečná a efektivní metoda
- Recentní randomizované studie potvrdily efektivitu uzávěru
- Selekce pacientů – spolupráce neurologa a kardiologa!
- Uzávěr PFO brání jen embolizaci skrze PFO

Procedural Complications and Serious Adverse Events.

Table 3. Procedural Complications and Serious Adverse Events.*

Complication or Event	Randomization Groups 1 and 2			Randomization Groups 1 and 3		
	PFO Closure Group (N=238)	Antiplatelet-Only Group (N=235)	P Value	Anticoagulant Group (N=187)	Antiplatelet-Only Group (N=174)	P Value
	no. of patients (%)			*no. of patients (%)*		
Major or fatal device-related or procedure-related complication†	14 (5.9)	NA	NA	NA	NA	NA
Major or fatal bleeding complication	2 (0.8)	5 (2.1)	0.28	10 (5.3)	4 (2.3)	0.18
Atrial fibrillation or flutter‡	11 (4.6)§	2 (0.9)	0.02	0	2 (1.1)	0.23
Death	0	0	NA	1 (0.5)¶	0	0.65
At least one serious adverse event	85 (35.7)	78 (33.2)	0.56	62 (33.2)	59 (33.9)	0.88

* Definitions of major or fatal device-related or procedure-related complications, definitions of major or fatal bleeding complications, and a full list of serious adverse events are provided in the Supplementary Appendix.
† Major or fatal device-related or procedure-related complications in the PFO closure group are listed for those that occurred within 30 days after the procedure and included atrial fibrillation (9 patients), atrial flutter (1 patient), supraventricular tachycardia (2 patients), air embolism (1 patient), and hyperthermia resulting in prolongation of hospitalization (1 patient).
‡ Atrial fibrillation or flutter was classified as cases that required treatment for more than 1 month.
§ In 10 patients, atrial fibrillation or flutter occurred within 30 days after the procedure.
¶ The one death was due to pancreatic cancer.

Mas J et al. N Engl J Med 2017;377:1011-1021.

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