Foramen ovale perméable:
fermer ou ne pas fermer, là est la question

7e Colloque neurovasculaire SSVQ
12 septembre 2014
Centre Mont-Royal
Montréal

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UNIVERSITÉ LAVAL

Divulgation de conflits d'intérêts potentiels

Société des sciences vasculaires du Québec (SSVQ)

7ème Colloque neurovasculaire

12 septembre 2014

Dr Steve Verreault, Co-conférencier

Conférencier	Bristol-Myers Squibb et Pfizer	2012-2013-2014
Conférencier	Bayer	2012-2103-2014
Conférencier	Boehringer Ingelheim	2012-2013-2014

Objectifs

- Au terme de cette séance plénière, le participant pourra:
  - Identifier les patients chez qui la recherche de FOP est pertinente;
  - Décrire l'approche interventionnelle et nos résultats québécois;
  - Comparer les traitements médical et interventionnel à la lumière des nouvelles données et en analyser les limites.

Stroke
JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association | American Stroke Association

Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

Walter N. Kernan, Bruce Ovbiagele, Henry R. Black, Dawn M. Bravata, Marc I. Chimowitz, Michael D. Ezekowitz, Margaret C. Fang, Marc Fisher, Karen L. Furie, Donald V. Heck, S. Claiborne (Clay) Johnston, Scott E. Kasner, Steven J. Kittner, Pamela H. Mitchell, Michael W. Rich, DeJuran Richardson, Lee H. Schwamm and John A. Wilson

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PFO Recommendations

For patients with a cryptogenic ischemic stroke or TIA and a PFO without evidence for DVT, available data do not support a benefit for PFO closure *(Class III; Level of Evidence A).* (Revised recommendation)

AVC ischémique cryptogénique: définition

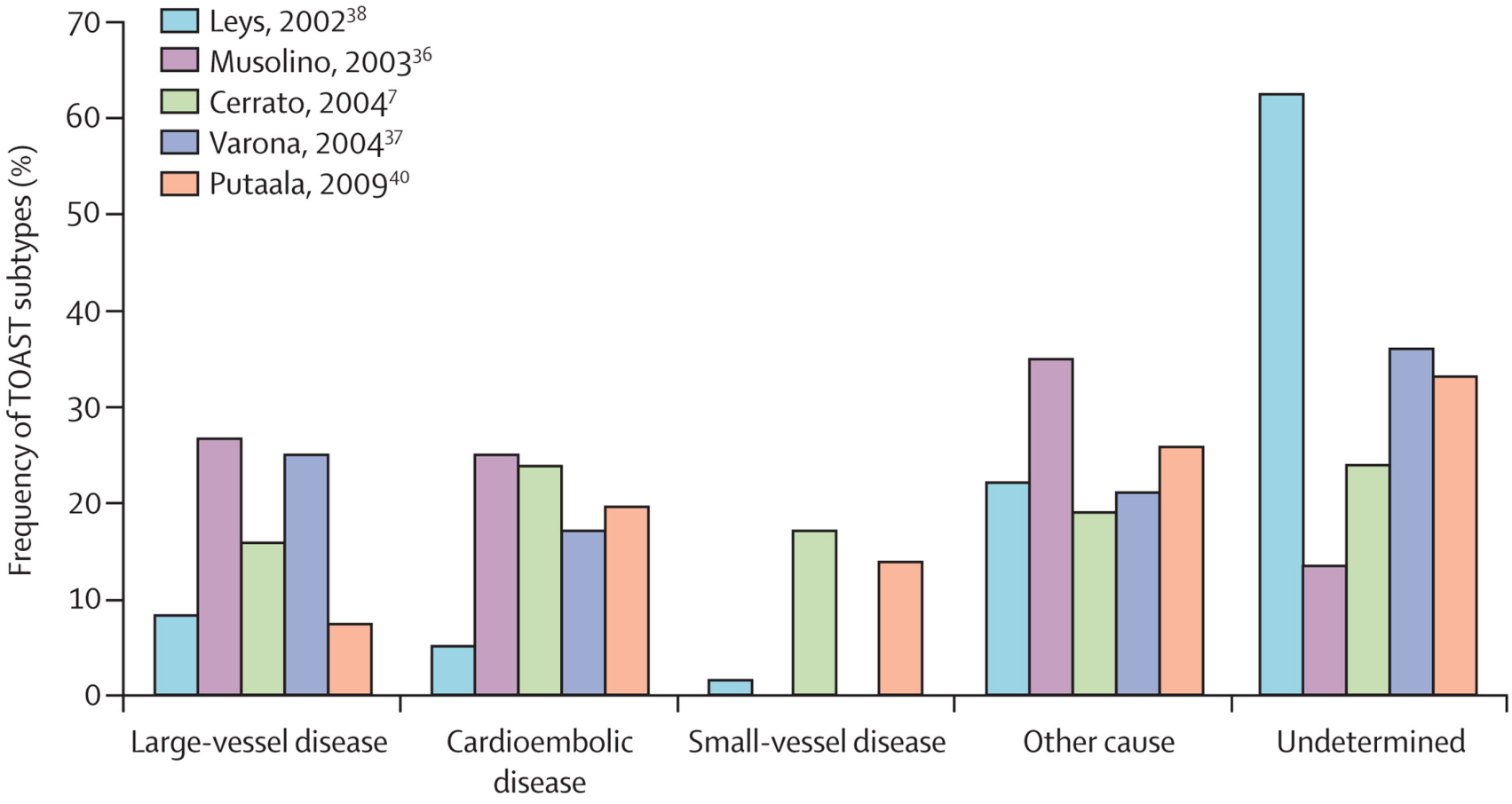
TABLE 1. TOAST Classification of Subtypes of Acute Ischemic Stroke

Large-artery atherosclerosis (embolus/thrombosis)*
Cardioembolism (high-risk/medium-risk)*
Small-vessel occlusion (lacune)*
Stroke of other determined etiology*
Stroke of undetermined etiology
a. Two or more causes identified
b. Negative evaluation
c. Incomplete evaluation

TOAST, Trial of Org 10172 in Acute Stroke Treatment.
*Possible or probable depending on results of ancillary studies.

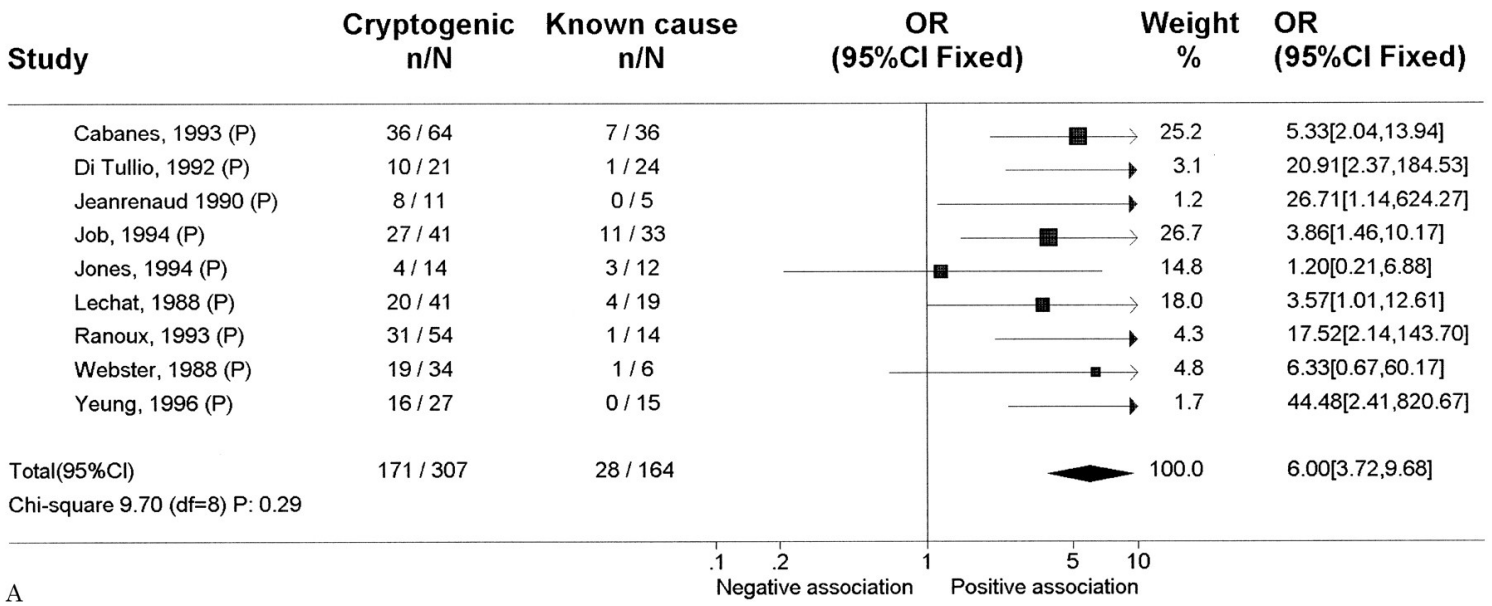
Adams HP et al. Stroke 1993;24:35-41.

L'AVC ischémique cryptogénique est fréquent chez les patients jeunes

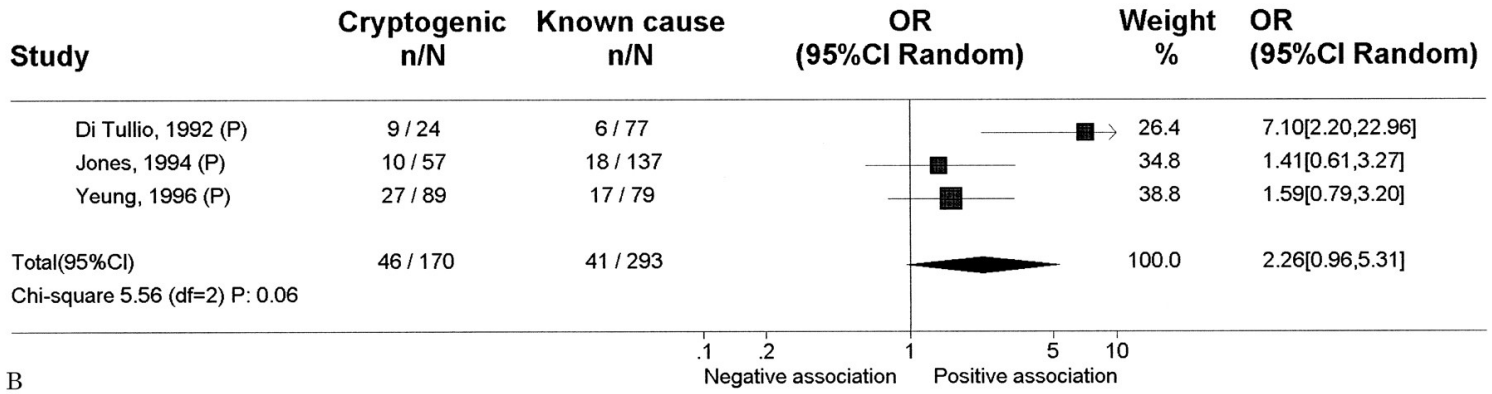


Ferro JM et al. Lancet Neurol 2010;9:1085-1096.

Figure 2. Prevalence of patent foramen ovale (PFO) in patients with cryptogenic stroke and with known stroke cause, classified according to age: less than 55 years (A) and more than 55 years (B).



A



B

Overell J et al. Neurology 2000;55:1172-1179

AMERICAN ACADEMY OF NEUROLOGY

Foramen ovale perméable et AVC ischémique cryptogénique

- Malgré une investigation exhaustive, la cause de l'AVC ischémique demeure inconnue chez environ 30-40 % des patients.
- Il existe une association significative entre les AVC cryptogéniques et la présence d'un foramen ovale perméable (FOP chez 40-50% des patients environ).
- Ceci suggère que le mécanisme d'embolie paradoxale (embolie traversant de la circulation veineuse à artérielle via un FOP) pourrait expliquer un bon nombre d'AVC cryptogéniques.
- Néanmoins, la détection d'un FOP chez un patient avec un AVC cryptogénique ne prouve pas qu'il existe une relation de cause à effet.

Foramen ovale perméable : Point de vue du neurologue

- La prévention secondaire de l'AVC devrait tenir compte d'au moins 3 éléments chez un patient avec un FOP:
  1. La probabilité que le FOP soit responsable de l'AVC (lien de causalité);
  2. Le risque de récidive d'AVC;
  3. Les risques et bénéfices de chacun des traitements.

Messé SR et al. Neurology 2013;81:610-611.

FOP dans l'AVC ischémique cryptogénique : découverte fortuite ou reliée à l'AVC ?

Table 2. Probability a PFO With or Without an ASA Is Incidental in Patients With CS, by Age Category, Based on Case–Control Studies of Cases With CS Versus Control Subjects With Stroke of Determined Cause (Main Analysis) or Versus Control Subjects With No Stroke (Sensitivity Analysis)

	Probability PFO Is Incidental	
	Main Analysis	Sensitivity Analysis
PFO		
Age-inclusive	0.33 (0.28–0.39)	0.48 (0.39–0.59)
Young	0.20 (0.16–0.25)	0.20 (0.16–0.25)
Old	0.48 (0.34–0.66)	0.84 (0.60–1.00)
PFO+ASA		
Age-inclusive	0.11 (0.04–0.31)	…
Young	0.09 (0.04–0.18)	0.04 (0.01–0.32)
Old	0.26 (0.12–0.56)	…

Alsheikh-Ali AA et al. Stroke 2009;40:2349-2355.

Quels sont les facteurs qui influencent la prévalence du FOP dans une population d'AVC cryptogéniques?

- En se basant sur une méta-analyse de cohortes observationnelles de patients avec AVC cryptogénique, le groupe Rope (Risk of Paradoxical Embolism) a identifié plusieurs facteurs associés avec la détection d'un FOP:
  - Jeune âge
  - Absence d'HTA
  - Absence de diabète
  - Absence d'ATCDs d'AVC/AIT
  - Non fumeur
  - Présence d'un infarctus cortical à l'imagerie

Kent DM et al Neurology 2013;81:619-625

Le RoPE (Risk of Paradoxical Embolism) Score : Outil permettant d'estimer la probabilité de détecter un FOP chez un patient avec AVC cryptogénique

Table 4 RoPE score calculator

Characteristic	Points	RoPE score
No history of hypertension	1	
No history of diabetes	1	
No history of stroke or TIA	1	
Nonsmoker	1	
Cortical infarct on imaging	1	
Age, y		
18-29	5	
30-39	4	
40-49	3	
50-59	2	
60-69	1	
≥70	0	
Total score (sum of individual points)		
Maximum score (a patient <30 y with no hypertension, no diabetes, no history of stroke or TIA, nonsmoker, and cortical infarct)		10
Minimum score (a patient ≥70 y with hypertension, diabetes, prior stroke, current smoker, and no cortical infarct)		0

Abbreviation: RoPE = Risk of Paradoxical Embolism.

Kent DM et al Neurology 2013;81:619-625.

Probabilité que le FOP soit reliée à l'AVC : Autres éléments cliniques

- Circonstances cliniques laissant suggérer un mécanisme d'embolie paradoxale:
  - Circonstances précédant l'AVC à l'histoire
    - Manœuvres de Valsalva (forcer, tousser, etc.)
  - Immobilisation/long voyage
  - Présence d'une TVP/EP
  - État Hypercoagulant

Probabilité que le FOP soit reliée à l'AVC : Caractéristiques neuroradiologiques

Table 4. PFO Prevalence by Presence or Absence of Radiological Variables

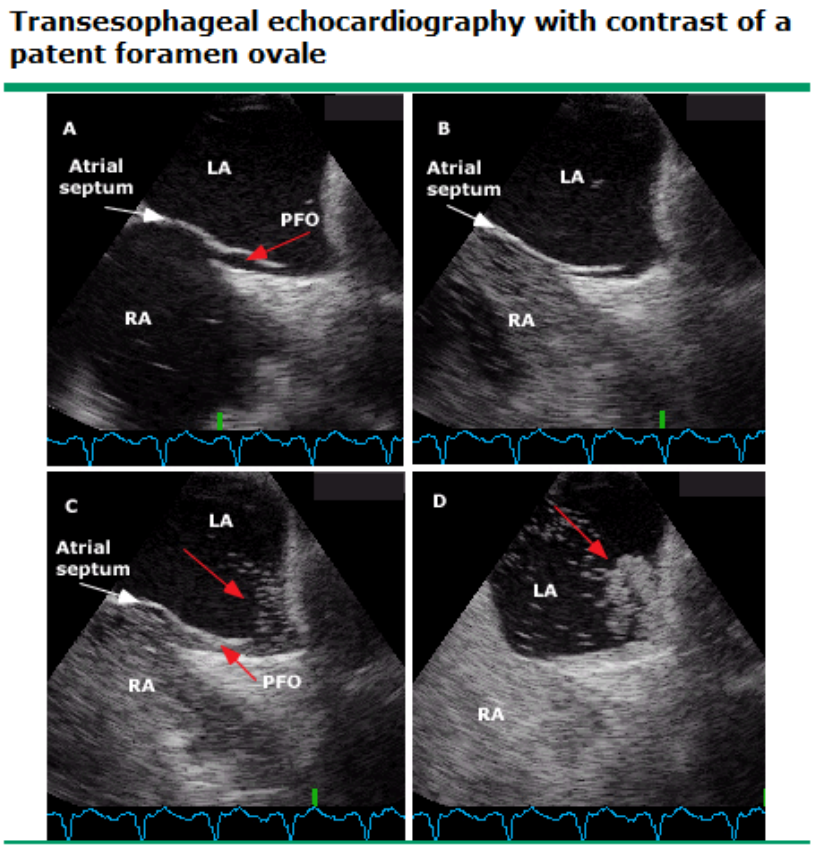
	All			
Variable	Total, n	% With PFO	Adjusted Odds Ratio	*P* Value
Index stroke large				
No	681	37		
Yes	1290	43	1.36	0.0025
Index stroke seen				
No	265	36		
Yes	2040	43	1.53	0.003
Superficial location				
No	779	37		
Yes	1018	48	1.54	<0.0001
Multiple index strokes				
No	1601	41		
Yes	278	43	1.21	0.1614
Prior stroke				
No	1547	43		
Yes	592	33	0.66	<0.0001

Odds ratios and *P* values are adjusted for site as a random effect.
PFO indicates patent foramen ovale.

Thaler DE et al. Stroke 2013;44:675-680.

Probabilité que le FOP soit reliée à l'AVC:Caractéristiques à l'ETO

- Facteurs potentiels à l'ETO :
  - Largeur du FOP
  - ASIA
  - Shunt droit-gauche spontané



Probabilité que le FOP soit reliée à l'AVC : Caractéristiques à l'ETO

TEE findings	All PFO patients with at least some TEE data (n=1294)	RoPE Score > 6 (n=637)	RoPE Score ≤ 6 (n=657)	p-value **
Large # bubbles *vs. not large*	64.4% (695/1079)	67.4% (347/515)	61.7% (348/564)	0.5286
Shunt at rest *vs. no shunt*	69.6% (484/695)	67.6% (238/352)	71.7% (246/343)	0.4474
Hypermobile septum *vs. not*	25.3% (320/1265)	23.0% (144/626)	27.5% (176/639)	0.1063

Wessler B et al. Circ Cardio Imaging 2014;7:125-131.

Le RoPE Point Score : Concept de la fraction attribuable au FOP

Table 5 PFO prevalence, attributable fraction, and estimated 2-year risk of stroke/TIA by point score strata, using control rate of 25%

	Cryptogenic stroke (n = 3,023)			CS patients with PFO (n = 1,324)	
RoPE score	No. of patients	Prevalence of patients with a PFO, % (95% CI)[a]	PFO-attributable fraction, % (95% CI)[a]	No. of CS patients with PFO[a]	Estimated 2-y stroke/TIA recurrence rate (Kaplan-Meier), % (95% CI)
0-3	613	23 (19-26)	0 (0-4)	108	20 (12-28)
4	511	35 (31-39)	38 (25-48)	148	12 (6-18)
5	516	34 (30-38)	34 (21-45)	186	7 (3-11)
6	482	47 (42-51)	62 (54-68)	236	8 (4-12)
7	434	54 (49-59)	72 (66-76)	263	6 (2-10)
8	287	67 (62-73)	84 (79-87)	233	6 (2-10)
9-10	180	73 (66-79)	88 (83-91)	150	2 (0-4)

Abbreviations: CI = confidence interval; CS = cryptogenic stroke; PFO = patent foramen ovale; RoPE = Risk of Paradoxical Embolism.
[a] Note: 95% CI for PFO prevalence and attributable fraction based on normal approximation to the binomial distribution.

Kent DM et al. Neurology 2013;81:619-625.

En assumant que le FOP est relié à l'AVC, quel est le mécanisme étiologique?

- Embolie paradoxale
  - Dans la vaste majorité des cas, aucune source embolique d'origine veineuse n'est détectée et donc ceci demeure un mécanisme hypothétique.
- Autres
  - Embolie provenant directement d'un thrombus formé au sein du FOP et/ou ASIA
  - FAP
  - Autres mécanismes occultes

Certaines études de cohortes populationnelles remettent en question l'association entre le FOP et l'AVC

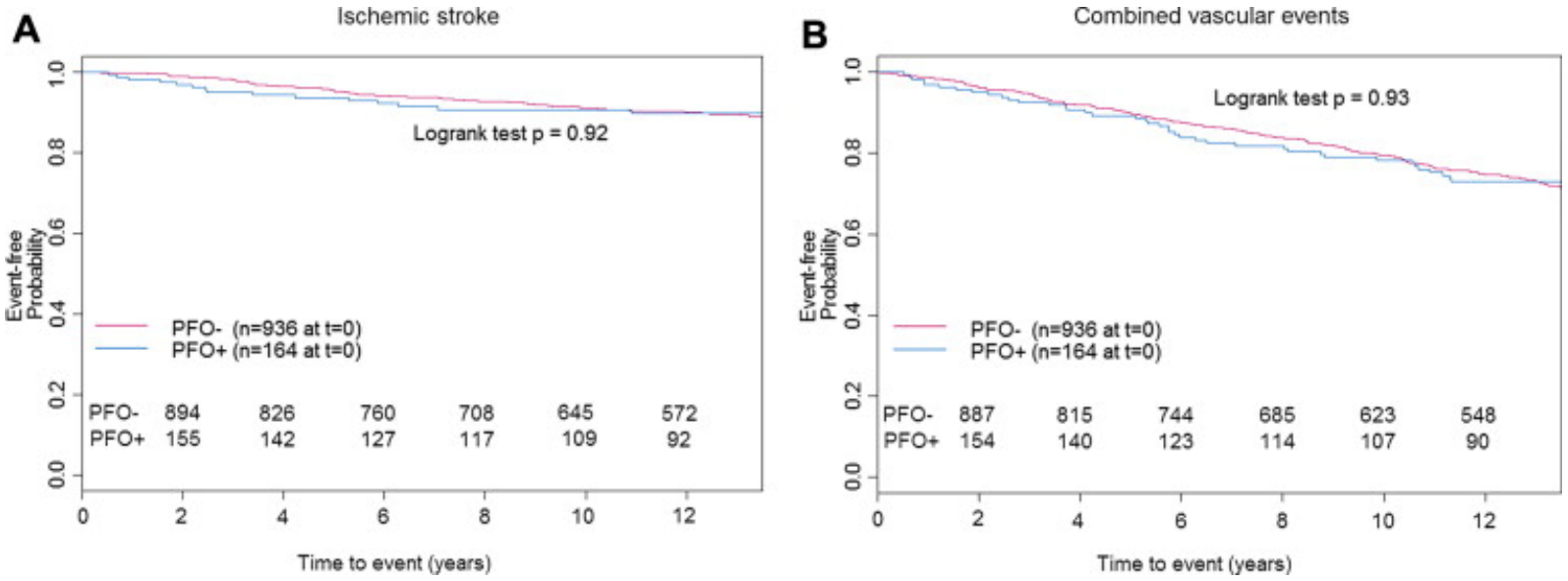


Figure 1 PFO and Vascular Outcomes Kaplan-Meier event-free survival curves according to patent foramen ovale (PFO) status for ischemic stroke (A) and combined vascular events (B) .

Marco R. Di Tullio , Zhezhen Jin , Cesare Russo , Mitchell S.V. Elkind , Tatjana Rundek , Mitsuhiro Yoshita , Char...

Patent Foramen Ovale, Subclinical Cerebrovascular Disease, and Ischemic Stroke in a Population-Based Cohort

Journal of the American College of Cardiology, Volume 62, Issue 1, 2013, 35 - 41

http://dx.doi.org/10.1016/j.jacc.2013.03.064

Risque de récidive d'AVC chez les patients avec AVC crypto et un FOP

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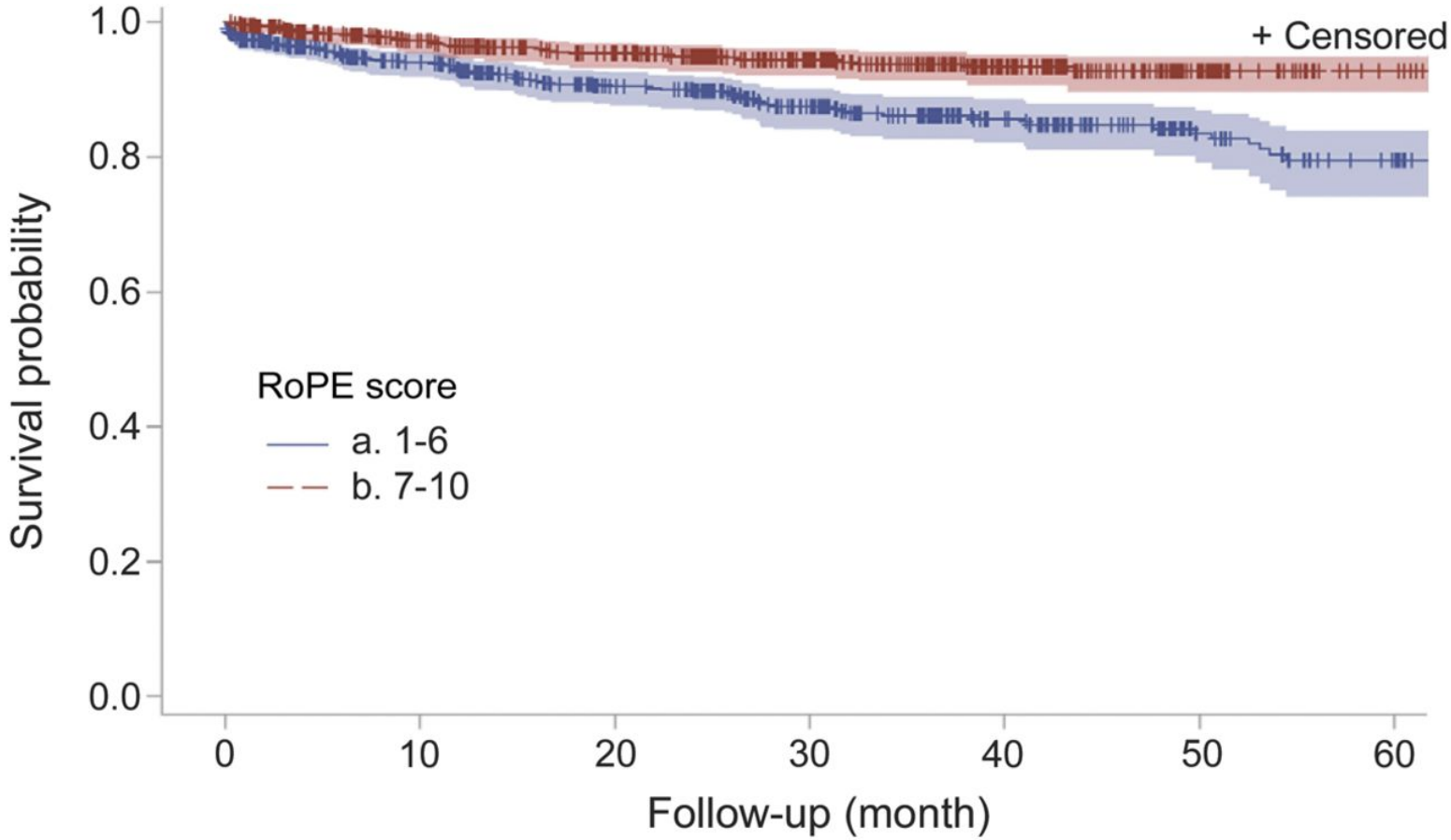
[a] Note: 95% CI for PFO prevalence and attributable fraction based on normal approximation to the binomial distribution.

Kent DM et al. Neurology 2013;81:619-625.

Figure Kaplan-Meier plot of recurrent stroke-free survival by Risk of Paradoxical Embolism (RoPE) stratum.



Thaler D E et al. Neurology 2014;83:221-226

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Facteurs prédicteurs d'une récidive d'AVC dans le RoPE database

Table 2 Adjusted hazard ratios from multivariable model of recurrent stroke/TIA

Variable	Adjusted hazard ratio (95% confidence interval)		
	Point score ≤6 (raw event rate: 87/677 = 13%)	Point score >6 (raw event rate: 35/647 = 5%)	Interaction *p* value[a]
Age (linear), hazard ratio per 10-y increase	**1.47 (1.18-1.83)[b]**	0.83 (0.57-1.20)	0.0083
Treated with antiplatelets	**1.69 (1.05-2.74)[b]**	0.74 (0.37-1.48)	0.0554
History of prior stroke or TIA	1.58 (0.89-2.44)	**3.79 (1.43-10.09)[b]**	0.0911
Small shunt	1.29 (0.82-2.03)	**3.26 (1.59-6.67)[b]**	0.0306
Hypermobile interatrial septum	0.83 (0.49-1.42)	**2.31 (1.05-5.05)[b]**	0.0350
	All subjects (raw event rate: 122/1,324 [9%])		
Incident TIA (vs stroke)	**1.69 (1.05-2.74)[b]**		

Hazard ratio >1 indicates positive association with outcome.

[a] If the *p* value of the variable or the interaction with the categorized point score (≤6, >6) was ≤0.10, then the interaction term was left in the model and hazard ratios were estimated separately for the point score subgroups. If the interaction *p* value was ≥0.10, then the interaction term was not included in the model and a single hazard ratio for the variable was estimated.

[b] 95% Confidence interval for hazard ratio is above or below 1 (with a corresponding *p* value of ≤0.05).

Thaler D E et al. Neurology 2014;83:221-226

Risque de récidive d'AVC : Essai clinique randomisé CLOSURE I

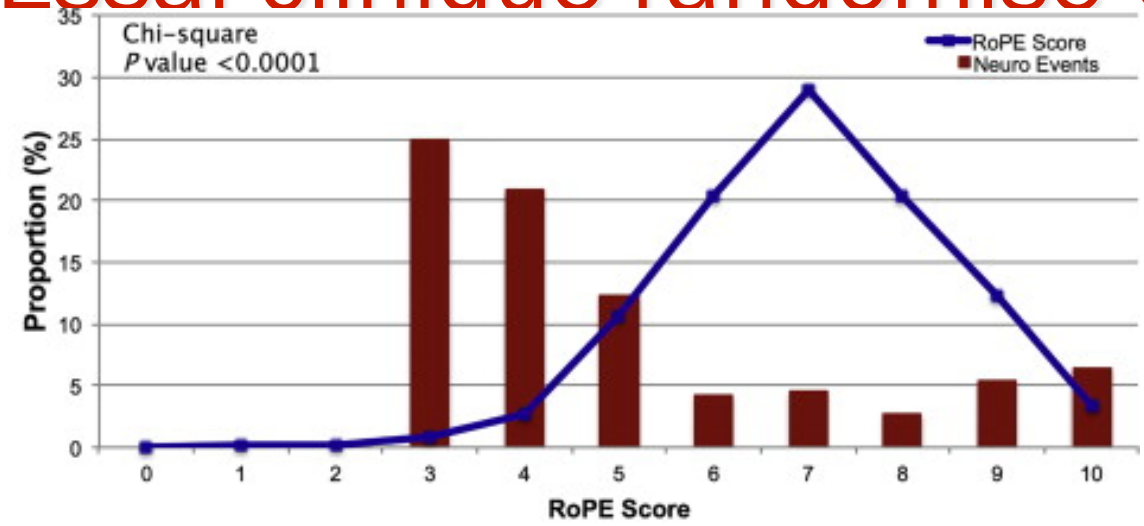
TABLE 3 Predictors of Recurrent Ischemic Strokes and TIA

	Univariable HR (95% CI)	p Value	Multivariable HR (95% CI)	p Value
Stroke				
BMI/kg/m^2	1.06 (1.00–1.12)	0.057		
Diabetes mellitus	4.76 (1.99–11.39)	0.0005	5.54 (2.27–13.57)	0.0002
Hypertension	1.74 (0.79–3.84)	0.17		
Ischemic heart disease	9.09 (2.14–38.54)	0.0028		
Index TIA (vs. stroke)	0.65 (0.24–1.73)	0.39		
Detection of AF	7.79 (2.93–20.77)	<0.0001	7.29 (2.46–21.61)	0.0003
TIA				
BMI/kg/m^2	1.04 (0.98–1.10)	0.19		
Diabetes mellitus	1.83 (0.64–5.24)	0.26		
Hypertension	1.95 (0.95–4.00)	0.07		
Ischemic heart disease	3.78 (0.51–27.73)	0.19		
Index TIA (vs. stroke)	4.66 (2.22–9.80)	<0.0001	4.71 (2.16–10.30)	0.0001
Development of AF	2.08 (0.50–8.72)	0.32		

Abbreviations as in Tables 1 and 2.

JACC: Cardiovascular Interventions, Volume 7, Issue 8, 2014, 913 - 920

Risque de récidive d'AVC : Essai clinique randomisé CLOSURE I



Number at risk	0	1	1	8	24	97	186	264	185	112	31
Estimated PFO attributable fraction:	0%	0%	0%	0%	38%	34%	62%	72%	84%	88%	88%
Estimated 2-yr recurrence rate:	20%	20%	20%	20%	12%	7%	8%	6%	6%	2%	2%

RoPE Score	Récidives AVC
>5 (85.6%)	4.2%
≤5 (14.4%)	14.5%

Figure 2 RoPE Score Within the CLOSURE I trial The prevalence of each RoPE (Risk of Paradoxical Embolism) score (0 through 10) within trial participants is depicted (blue line)

Sammy Elmariah , Anthony J. Furlan , Mark Reisman , David Burke , Moshe Vardi , Neil J. Wimmer , Shuqiong Ling , ...

Predictors of Recurrent Events in Patients With Cryptogenic Stroke and Patent Foramen Ovale Within the CLOSURE I (Evaluation of the STARFlex Septal Closure System in Patients With a Stroke and/or Transient Ischemic Attack Due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale) Trial

JACC: Cardiovascular Interventions, Volume 7, Issue 8, 2014, 913 - 920

http://dx.doi.org/10.1016/j.jcin.2014.01.170

Fermeture de FOP dans l'AVC cryptogénique : Essais cliniques randomisés

Table I Trials baseline characteristics

Author	Study acronym	Enrolment	Country	Number of patients	Mean follow-up (months)	Lost to F/U	Intervention group	Medical therapy group	Study conclusions
Carroll *et al.*	RESPECT	2003–11 multicentre, randomized	USA and Canada	980	31	Medical group 17.2% 83/481 Device group 9.2% 46/499	Amplatzer PFO occluder + aspirin and clopidogrel for 1 month followed by aspirin for at least 5 months	Aspirin 46.5% Coumadin 25.2% Clopidogrel 14% Aspirin + dipyridamole 8.1% Aspirin + clopidogrel 6.2%	No significant benefit of PFO closure for recurrent stroke prevention
Meier *et al.*	PC	2000–09 multicentre randomization by web-based system	29 Centres in Europe, Canada, Brazil, and Australia	414	49	Medical group 15% 31/210 Device group 12% 24/204	Amplatzer PFO occluder + aspirin (5–6 months) and ticlopidine OR clopidogrel	Antiplatelet OR, AND coumadin (left at the discretion of treating physician)	No significant reduction in the risk of recurrent embolic events or death in the closure group, as compared with the medical therapy group
Furlan *et al.*	CLOSURE I	2003–08 multicentre, randomized	USA and Canada	909	44	Medical group 17% 77/462 Device group 5%, 24/447	STARFlex + aspirin (2 years) and clopidogrel (6 months)	Aspirin, coumadin OR aspirin and coumadin (left at the discretion of treating physician)	No significant difference between closure with a percutaneous device plus antiplatelet therapy and medical therapy alone with respect to the prevention of recurrent stroke or TIA

PFO, patent foramen ovale.

Rengifo-Moreno P et al. European Heart Journal 2013;34:3342-3352.

Table 1. Characteristics of the Randomized Controlled Trials

	CLOSURE I (13)	RESPECT (14)	PC Trial (15)
Trial design	Prospective, 2-arm superiority trial	Event-driven, prospective, 1:1 randomized, stratified by site and ASA	Prospective, parallel assignment, safety and efficacy study
Publication of results	Published: N Engl J Med, March 2012	Published: N Engl J and Med, March 2013	Published: N Engl J Med, March 2013
Centers	Multicenter: 87 sites (United States and Canada)	Multicenter: 69 sites (United States and Canada)	Multicenter: 29 sites (Europe, United Kingdom, Australia, Brazil, and Canada)
Participants	909	980	414
Inclusion criteria	Age 18 to 60 years; history of an ischemic stroke or TIA within the previous 6 months; evidence of a PFO, as documented by TEE with a bubble study	Age 18 to 60 years with PFO; history of a cryptogenic stroke within 270 days	Age <60 years; presence of PFO ± ASA; ischemic stroke/TIA or extracranial peripheral thromboembolism—clinically and radiologically proven
Exclusion criteria	Identifiable cause of ischemic stroke/TIA; another source of R→L shunt, an acute or recent MI/unstable angina; LV aneurysm/akinesis; intracardiac thrombus or tumor	Cerebral/cardiovascular, and systemic conditions that suggest other mechanisms for stroke; contraindication to medical/device therapy; limited life expectancy, inability to attend follow-up	Identifiable cause for thromboembolic event; contraindication/other indication to medical therapy; previous PFO closure; CNS disease
Device closure	STARFlex septal closure system (NMT Medical Inc., Boston, MA)	Amplatzer PFO Occluder (AGA Medical Corp., Golden Valley, MN)	Amplatzer PFO Occluder (AGA Medical Corp., Golden Valley, MN)
Medical therapy	Warfarin (INR: 2 to 3); aspirin 325 mg/d or both	Aspirin, warfarin, clopidogrel, aspirin with dipyridamole, or aspirin with clopidogrel*	Anti-platelet therapy or oral anticoagulation as per the discretion of the treating physician
Follow-up	2 years	Until 25th primary endpoint	Up to 5 years
Primary endpoint	Composite of stroke or TIA, death from any cause (30 days), death from neurologic causes (31 days to 2 years)	All-cause mortality; recurrence of fatal or nonfatal ischemic stroke	Composite of death from any cause, nonfatal stroke, TIA, and peripheral embolism
Secondary endpoint	Major bleeding; death from any cause; stroke, TIA, and transient neurologic events of uncertain cause	Complete closure of the defect; absence of recurrent cryptogenic nonfatal stroke/TIA or cardiovascular death	MI and peripheral thromboembolism; new arrhythmia (AF); rehospitalization related to PFO or its Rx; device-related problems

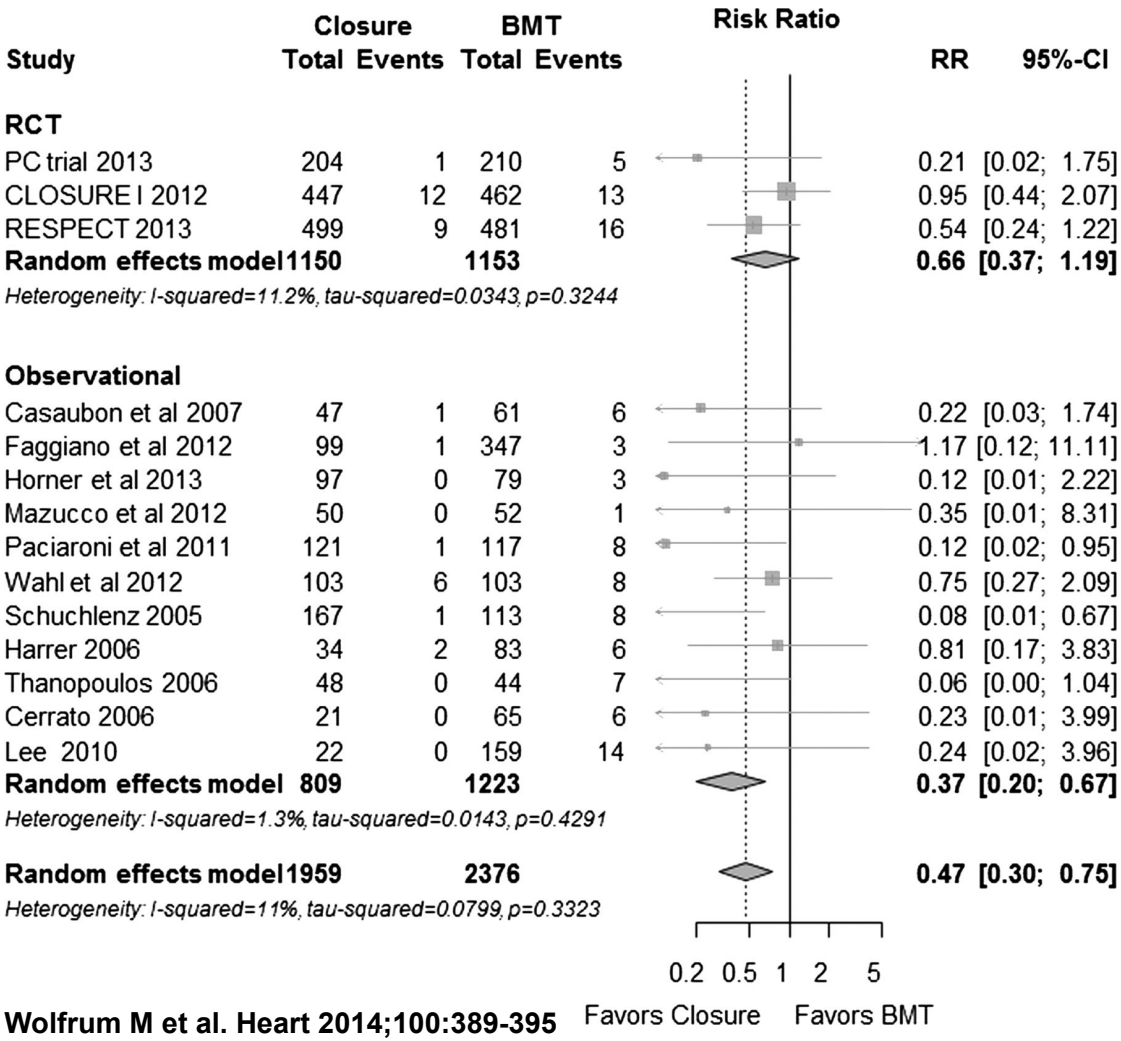
*Aspirin with clopidogrel was removed from the protocol in 2006 based on changes to the American Heart Association/American Stroke Association treatment guidelines.

AF = atrial fibrillation; ASA = atrial septal aneurysm; CLOSURE I = Evaluation of the STARFlex Septal Closure System in Patients With a Stroke and/or Transient Ischemic Attack due to Presumed Paradoxical Embolism Through a Patent Foramen Ovale; CNS = central nervous system; INR = international normalized ratio; LV = left ventricular; MI = myocardial infarction; PC Trial = Percutaneous Closure of Patent Foramen Ovale (PFO) Using the Amplatzer PFO Occluder With Medical Treatment in Patients With Cryptogenic Embolism; PFO = patent foramen ovale; RESPECT = Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment; R→L = right-to-left; Rx = prescription drug; TEE = transesophageal echocardiography; TIA = transient ischemic attack.

Khan AR et al. Jacc Intv 2013.

Essais cliniques randomisés : Méta-analyse

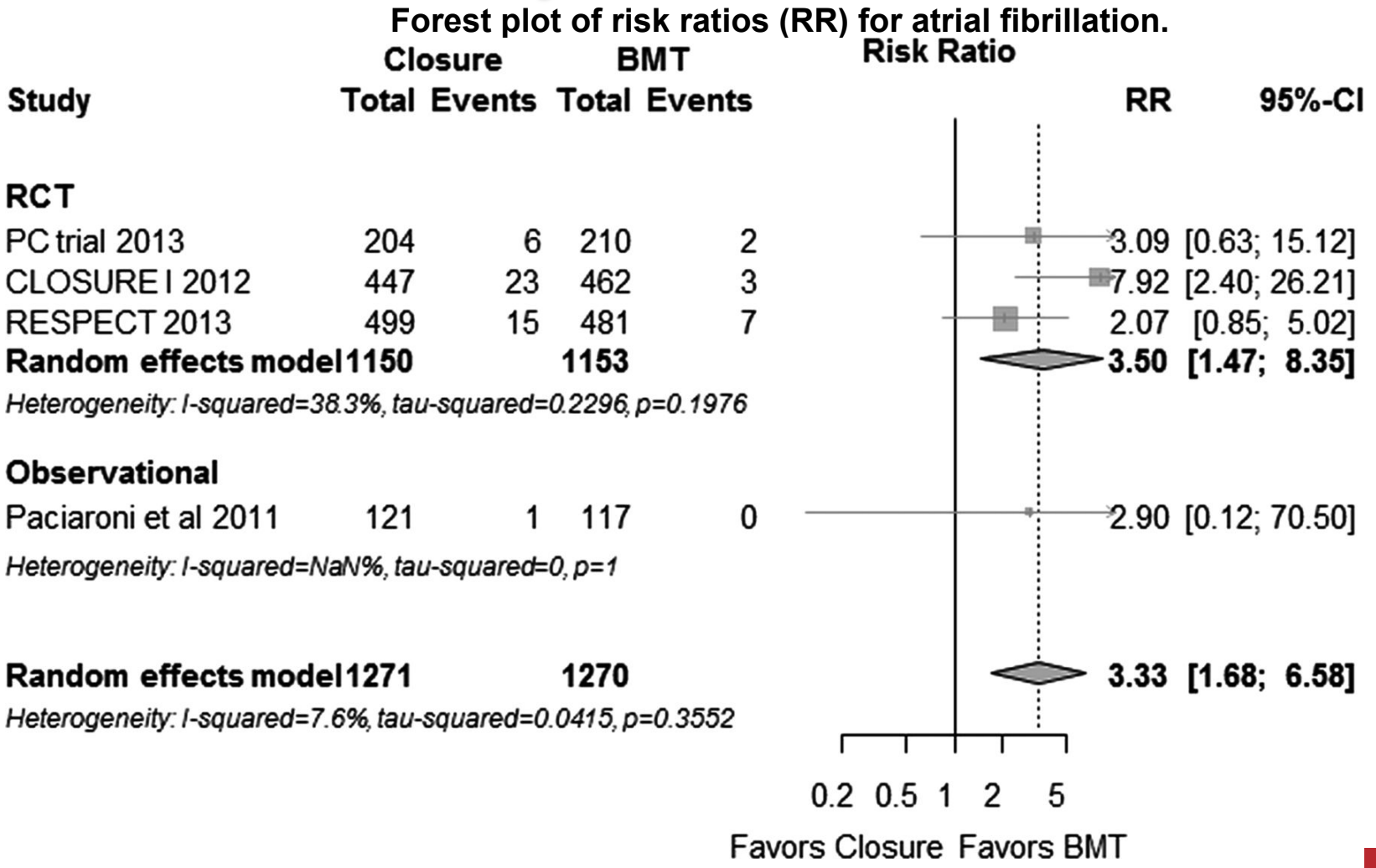
Forest plot of risk ratios (RR) for stroke.



Wolfrum M et al. Heart 2014;100:389-395

Heart

Essais cliniques randomisés : Méta-analyse



Wolfrum M et al. Heart 2014;100:389-395

Heart

Fermeture de FOP dans l'AVC cryptogénique : Limitations des essais cliniques randomisés

- Une proportion significative de FOP non impliqués dans la pathogénèse de l'AVC ont potentiellement été inclus.
- Les groupes contrôle étaient très hétérogènes.
- La puissance statistique était insuffisante.
- Le type de ¨device¨ utilisé pour la fermeture de FOP semble avoir une influence.
- Le recrutement a été très lent.

Foramen ovale perméable: Point de vue du neurologue

- La prévention secondaire de l'AVC devrait tenir compte d'au moins 3 éléments chez un patient avec un FOP :
  1. La probabilité que le FOP soit responsable de l'AVC (lien de cause à effet);
  2. Le risque de récidive d'AVC;
  3. Les risques et bénéfices de chacun des traitements.

Plus la probabilité est élevée que le FOP est la cause de l'AVCplus le risque de récidive d'AVC est faible

Messé SR et al. Neurology 2013;81:610-611.

Conclusions

- Plusieurs facteurs semblent vouloir émerger pour aider la prise de décision dans le contexte clinique de la présence d'un FOP chez un patient avec AVC cryptogénique :
  - Probabilité du lien entre le FOP et l'AVC
  - Risque de récidive d'AVC
- Ces facteurs devront être validés à l'extérieur de la base de données RoPE avant de pouvoir être utilisés par les cliniciens pour guider leurs décisions
- D'autres facteurs pourraient aussi être considérés afin d'aider à mieux sélectionner les patients à haut-risque :
  - Circonstances cliniques (Valsalva, immobilisation, TVP/EP, état hypercoagulant, hormonothérapie, etc.)
  - Facteurs paracliniques ((ASIA, largeur du shunt, etc.)

Conclusions

- Les ECR n'ont pas réussi à démontrer la supériorité de la fermeture de FOP comparée au traitement médical
- Cependant, il existe des signaux qui semblent orienter vers un petit bénéfice absolu potentiel en faveur de la fermeture de FOP
- Tel que stipulé dans les guidelines, des évidences supplémentaires sont requises avant de recommander la fermeture de FOP à grande échelle
- Plusieurs ECR sont toujours en cours sur le sujet (CLOSE, DEFENSE-PRO et REDUCE)

Questions?

Merci de votre attention