Actualités sur les fermetures de FOP

Pierre Aubry, Eric Brochet, Jean-Michel Juliard
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Bichat - Claude-Bernard

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

Liens d’intérêts à déclarer : aucun

Reste-t-il des indications à la fermeture du Foramen Ovale Perméable ?

Pierre Aubry, Eric Brochet, Jean-Michel Juliard
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Paris

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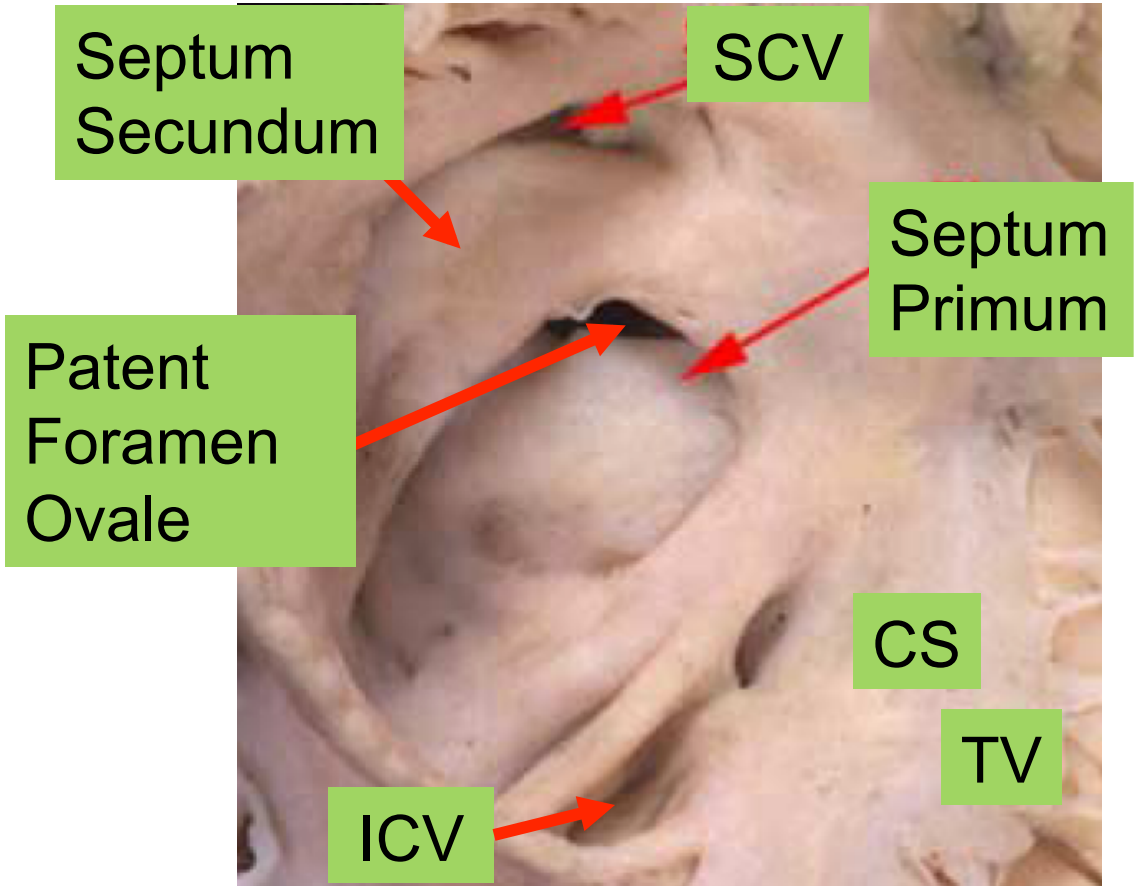
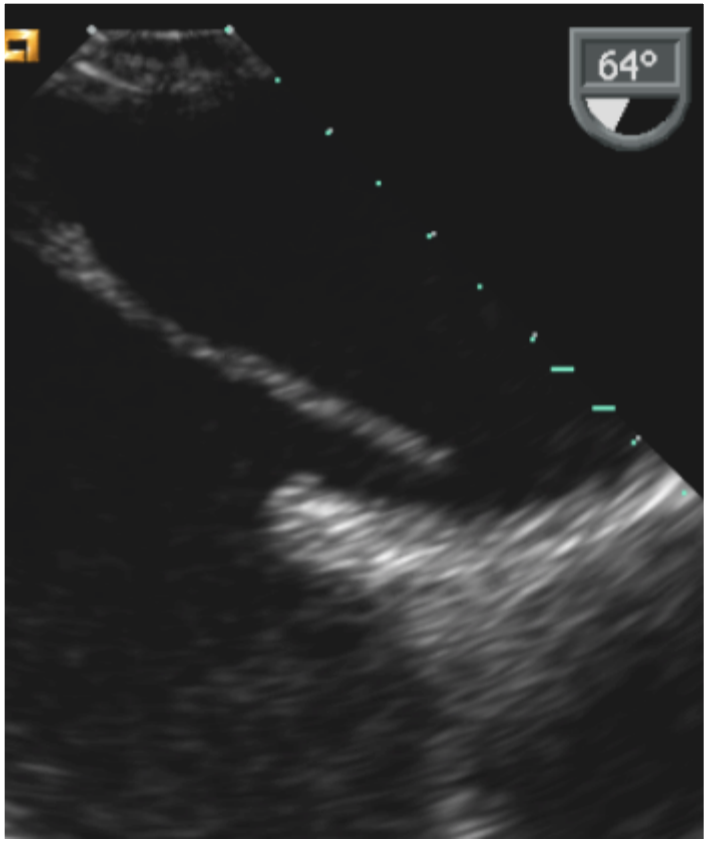
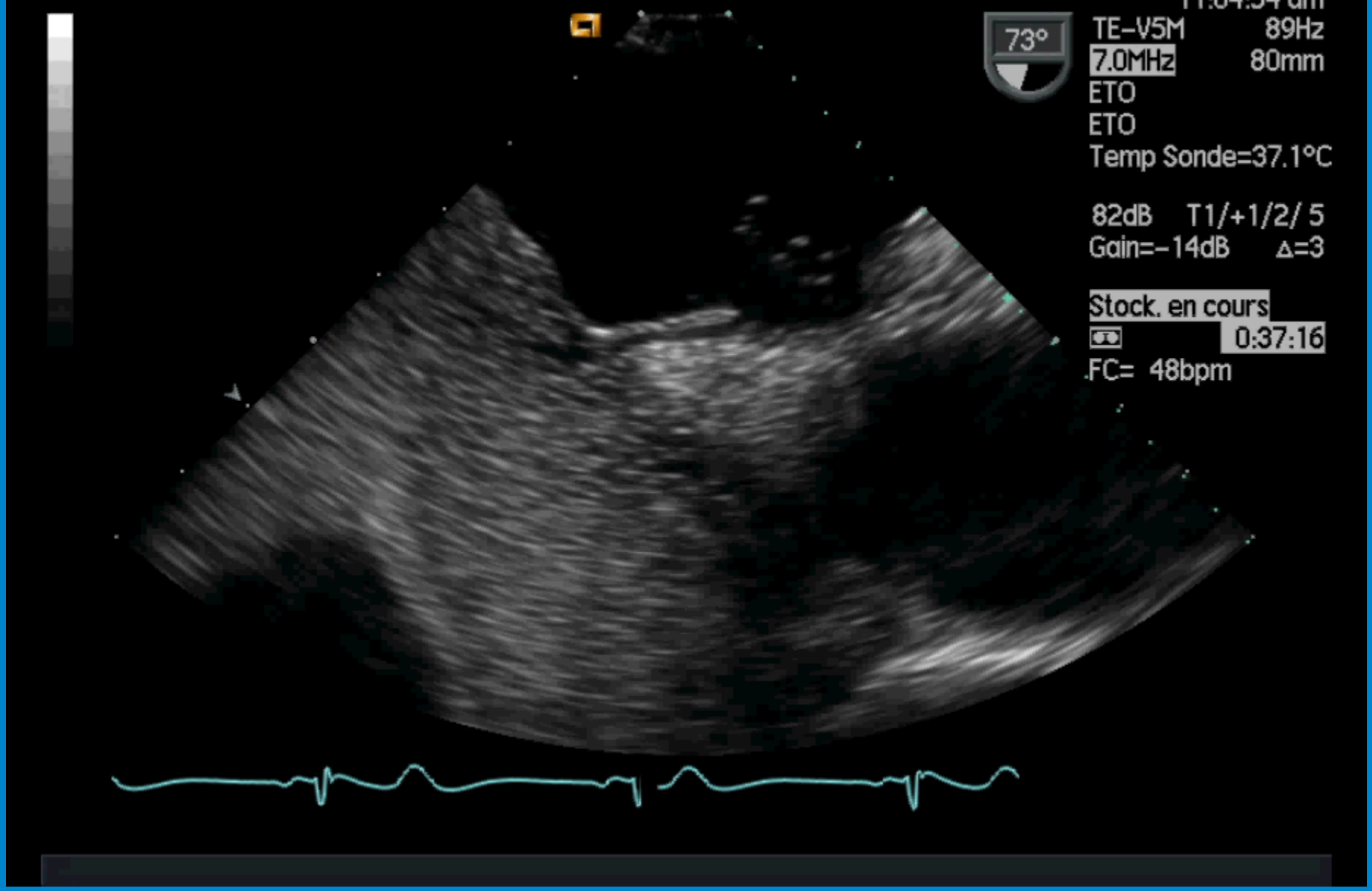
GROUPE HOSPITALIER BICHAT-CLAUDE BERNARD





Royal Brampton NHS


73°
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ETO
ETO
Temp Sonde=37.1°C
82dB T1/+1/2/ 5
Gain=-14dB Δ=3
Stock. en cours
0:37:16
FC= 48bpm

prévalence du FOP dans la population générale

1100 patients
sans antécédents vasculaires cérébraux
ETT + test avec bulles + Valsalva

test positif
164 (14.9%)

Di Tullio MR et al. J Am Coll Cardiol 2007

Patent Foramen Ovale (PFO)

ESC Guidelines for the management of grown-up congenital heart disease (new version 2010)

The Task Force on the Management of Grown-up Congenital Heart Disease of the European Society of Cardiology (ESC)

Management of PFO: **no informations**

EUROPEAN SOCIETY OF CARDIOLOGY®

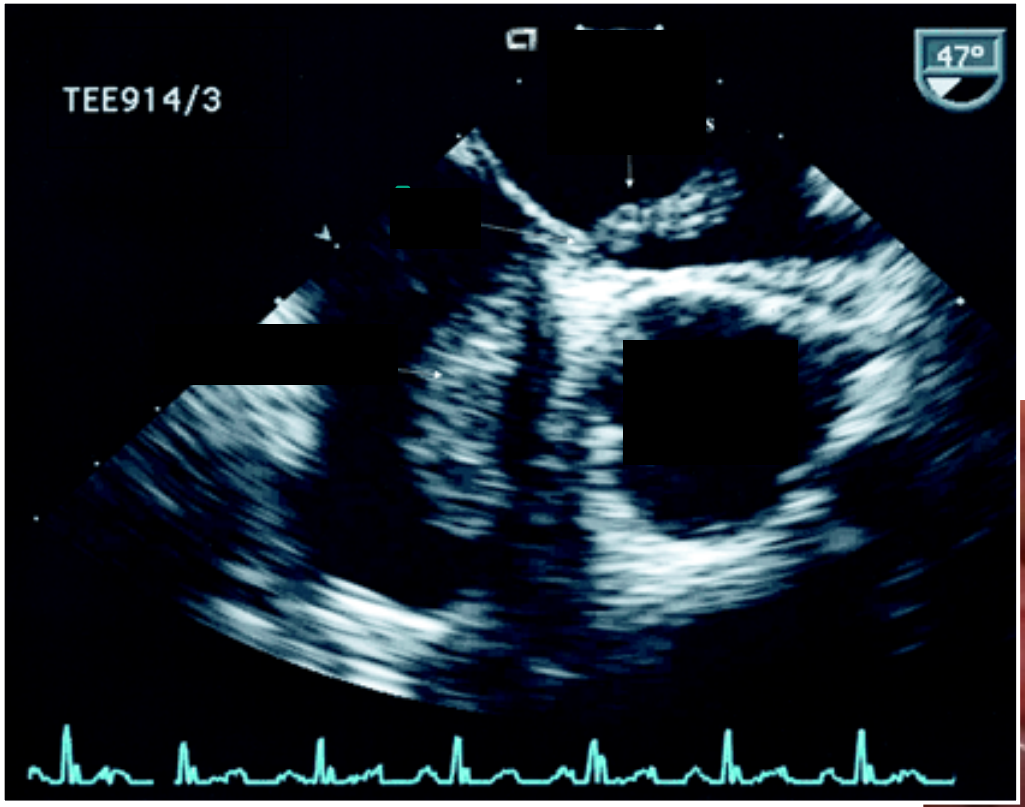
Eur Heart J 2010;31:2915-57

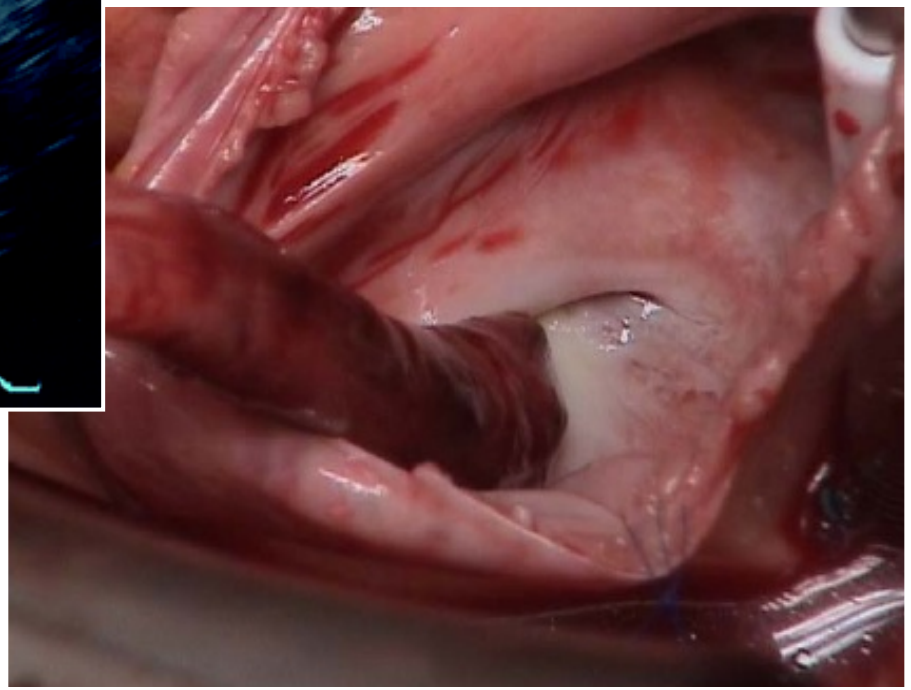
Foramen Ovale Perméable (FOP)

pathologies potentiellement liées à un FOP

	Lien	Agent
▪ Accident ischémique cérébral	possible	thrombus veineux
▪ Embolie paradoxale	certain	thrombus veineux
▪ Accident de décompression	probable	bulles azote
▪ Migraine	incertain	neuromédiateur
▪ Syndrome carcinoïde	probable	sérotonine
▪ Hypoxémie	certain	sang veineux

paradoxical embolism





Koullias GJ et al *Circulation* 2004

activité fermeture percutanée des FOP

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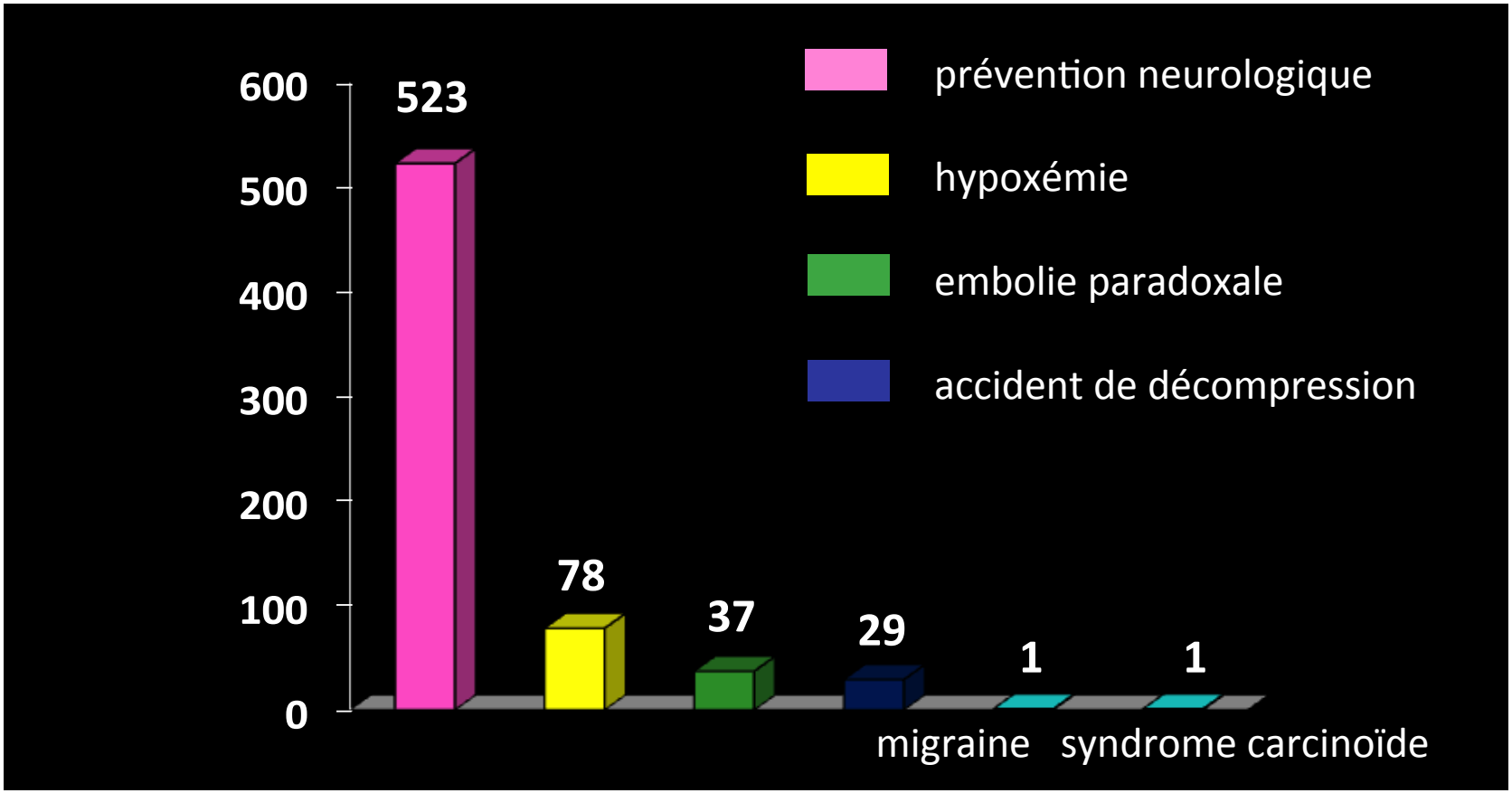
2001-2017
669 patients



activité fermeture percutanée des FOP

HÔPITAUX UNIVERSITAIRES
PARIS NORD VAL DE SEINE
Bichat - Claude-Bernard

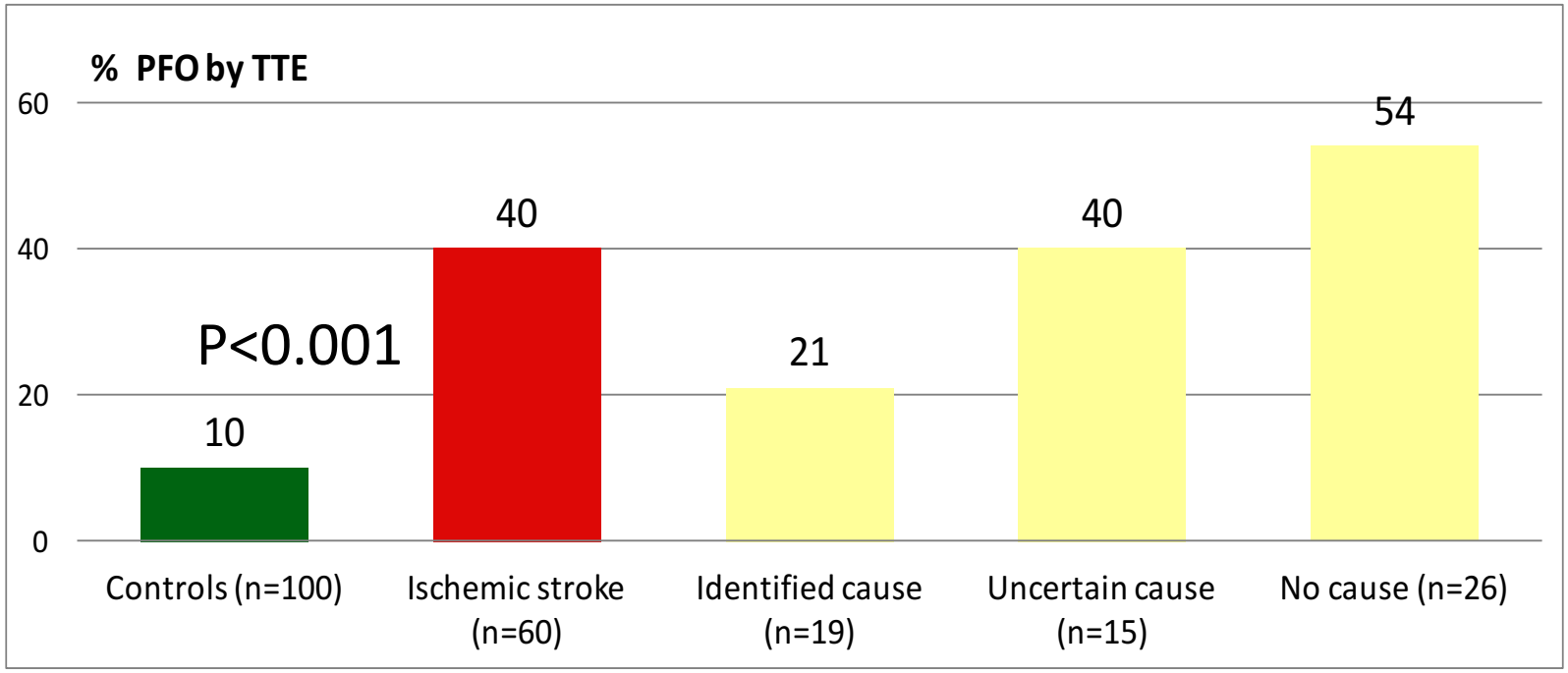
2001-2017
669 patients

	nombre	%
décès	1	0.14
AVC avec séquelles	0	0
tamponnade	0	0
complication vasculaire avec séquelles	1	0.14
embolisation prothèse	3	0.45

relation between stroke et PFO

étude cas-témoins

- 60 consecutive patients < 55 years with ischemic stroke
- 100 consecutive patients < 55 years with no prior history of stroke, referred for transthoracic echocardiography (TTE) before neurosurgery



Lechat et al. N Engl J Med 1988

relation between stroke et PFO

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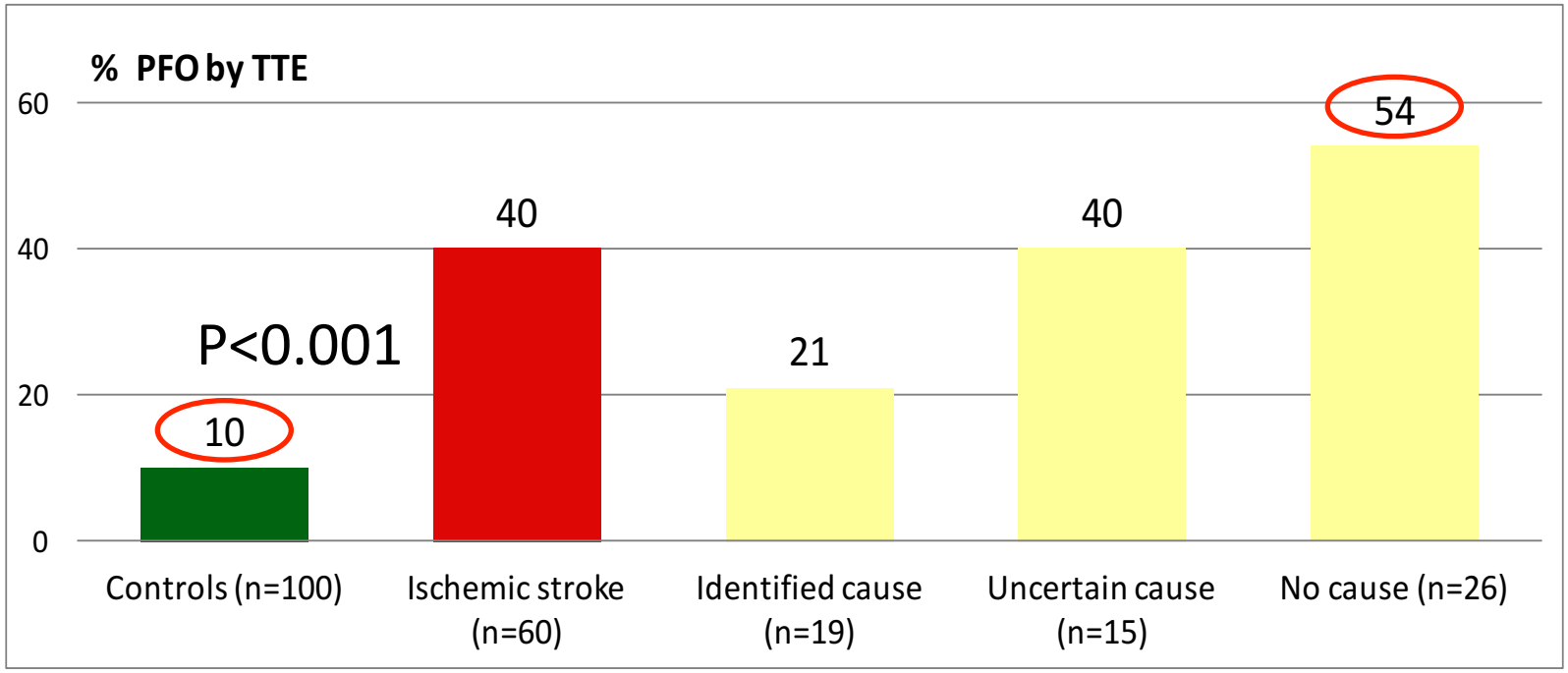
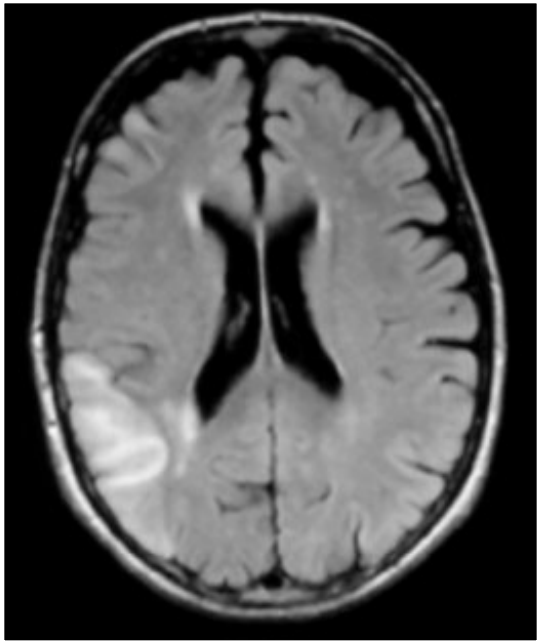


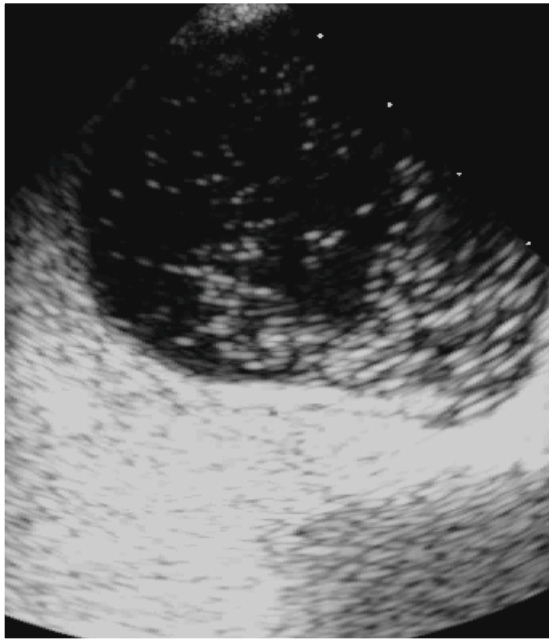
Lechat et al. N Engl J Med 1988

AIC cryptogénique associé à un FOP

association fréquente



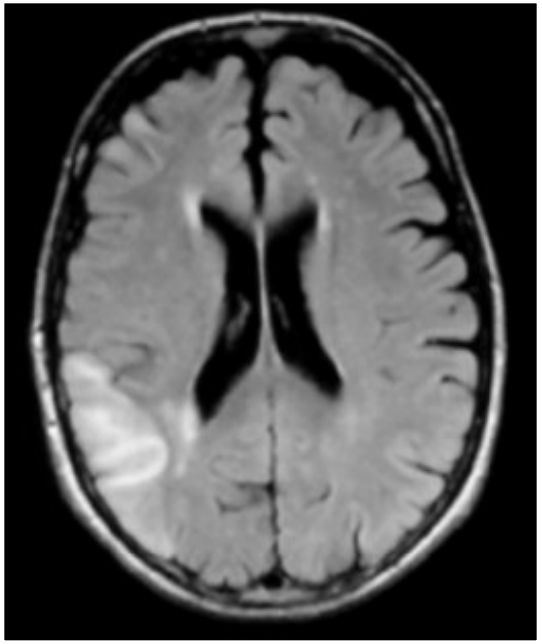
AIC
cryptogénique
25%



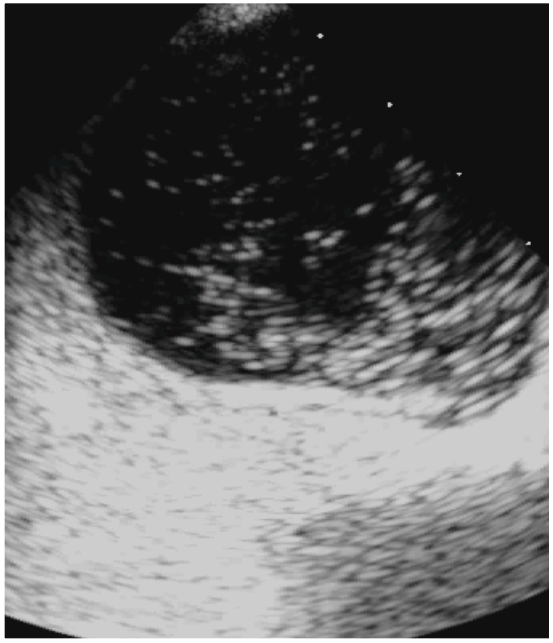
FOP
présent
40%

AIC cryptogénique associé à un FOP

lien statistique = lien de causalité mais …



?

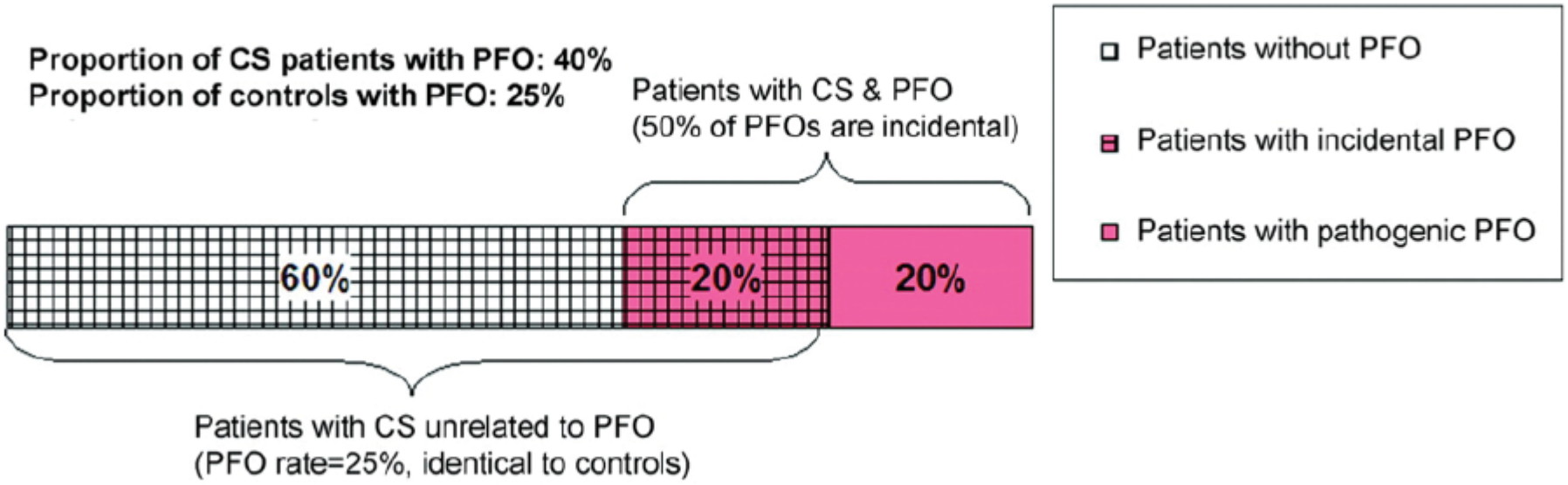


AIC cryptogénique 25%

FOP présent 40%

incidental or stroke-related PFO

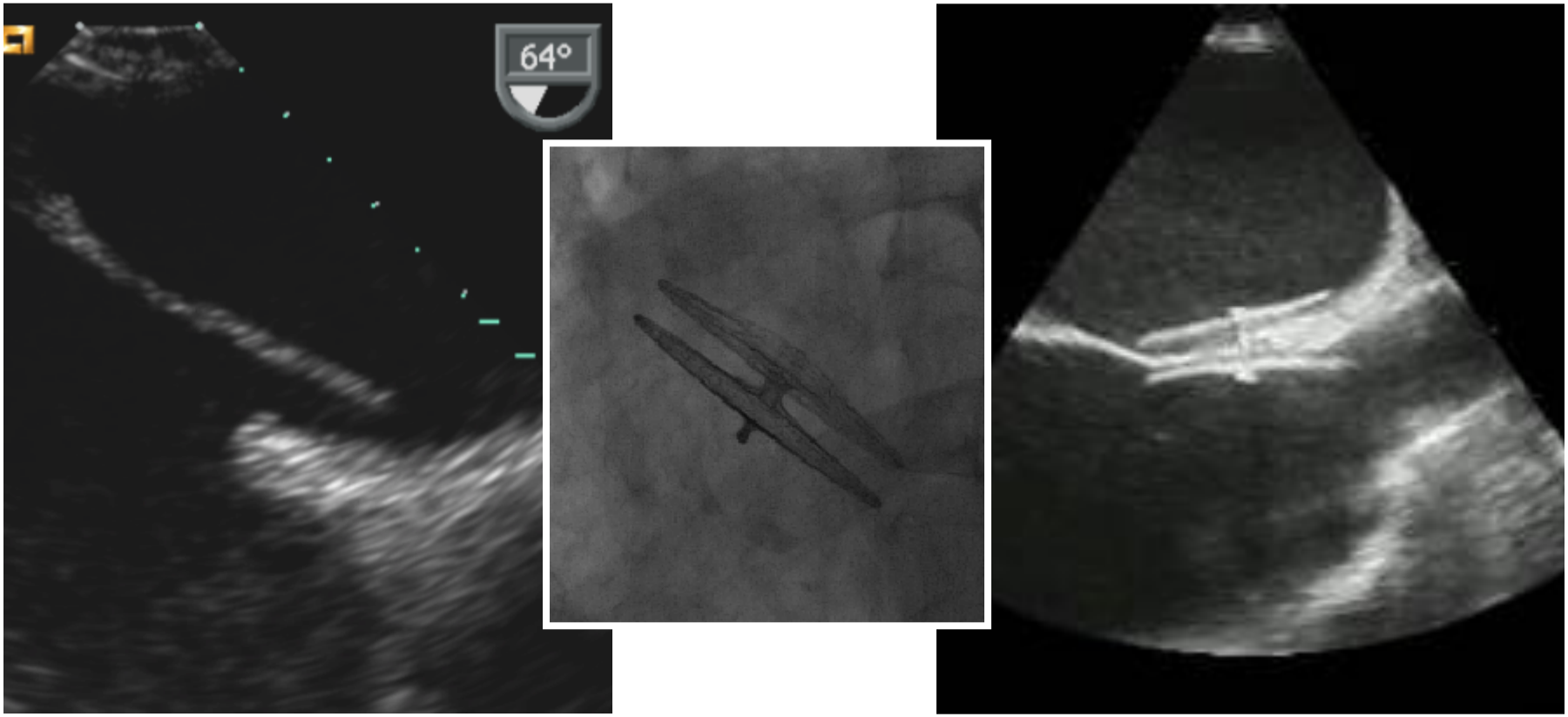
100 patients with cryptogenic stroke (CS)



BY DAVID E. THALER, MD

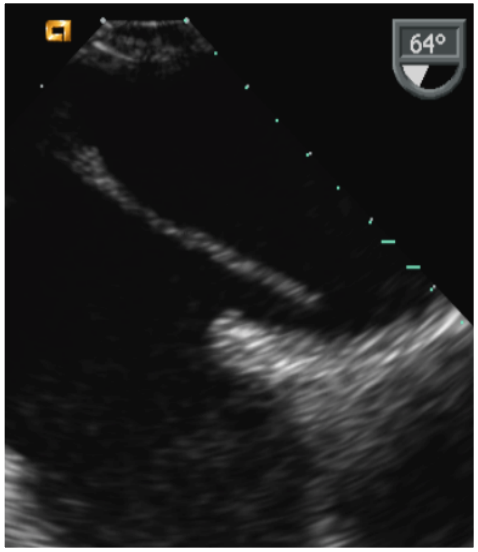
fermeture percutanée de FOP

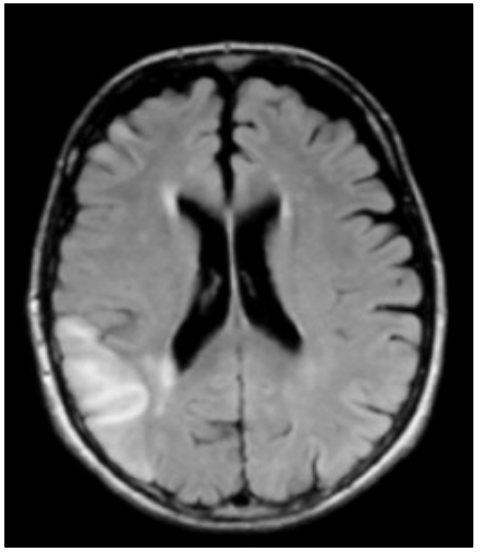
concept



AIC cryptogénique associé à un FOP

preuve d'un lien de causalité





FOP symptomatique → fermeture FOP → réduction récidive

Premières études randomisées

percutaneous PFO closure

controlled studies

CLOSURE I
Investigating the PFO Stroke Connection

negative study

RESPECT
CLINICAL TRIAL

negative study

PC Trial

negative study

RESPECT study

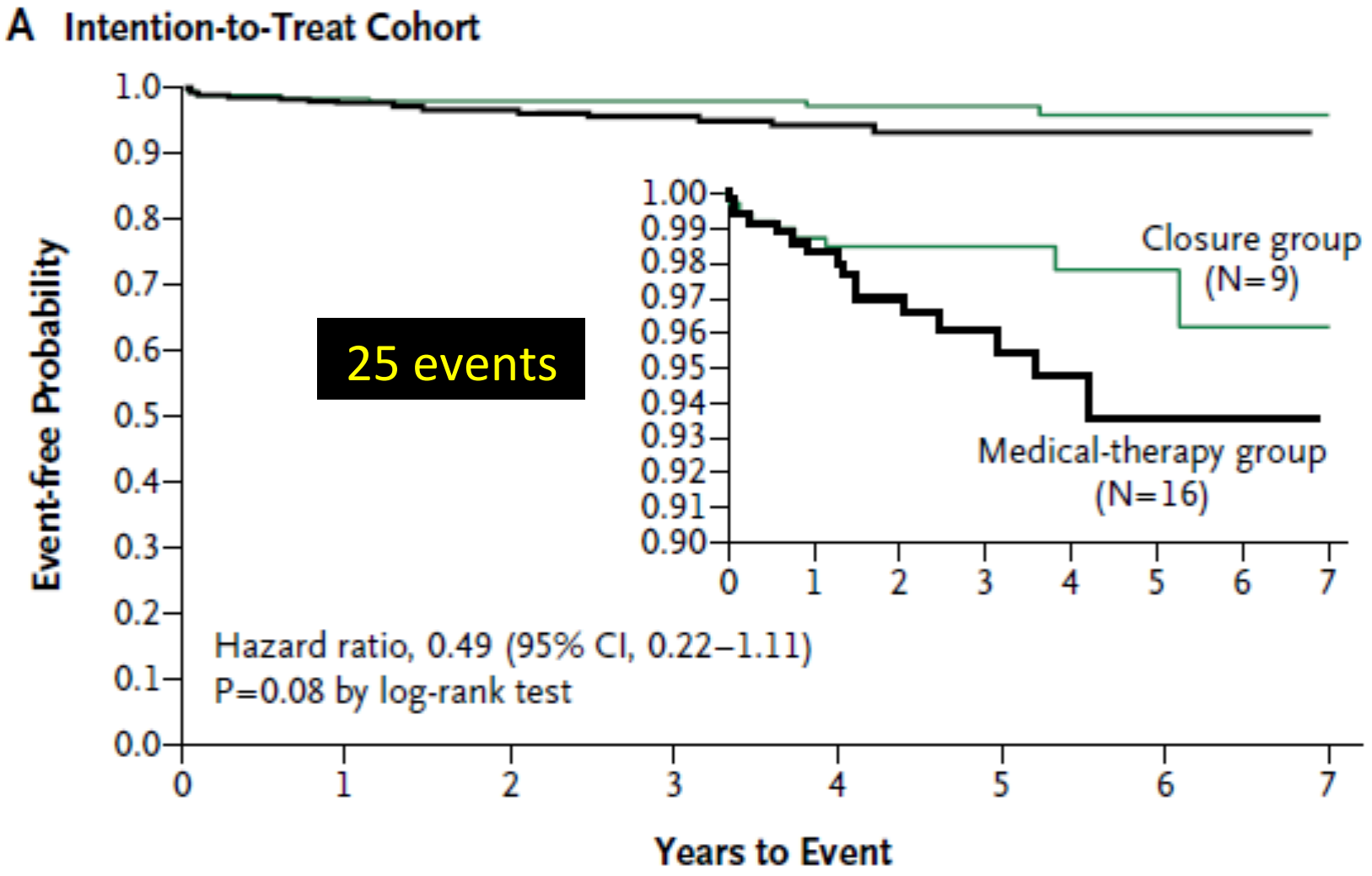
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Closure of Patent Foramen Ovale versus Medical Therapy after Cryptogenic Stroke

John D. Carroll, M.D., Jeffrey L. Saver, M.D., David E. Thaler, M.D., Ph.D., Richard W. Smalling, M.D., Ph.D., Scott Berry, Ph.D., Lee A. MacDonald, M.D., David S. Marks, M.D., and David L. Tirschwell, M.D., for the RESPECT Investigators*

RESPECT study



fermeture percutanée des FOP

limites des études

- Difficultés de recrutement
- Population hétérogène (FOP incident inclus)
- Hypothèse testée : supériorité versus équivalence
- Critère de sélection et/ou d'évaluation : AIT versus AIC
- Traitement non uniforme dans groupe contrôle
- Taux d'événements bas (pouvoir statistique diminué)
- Périodes d'évaluation courtes (< 3 ans)
- Evénements liés à une cause connue (FA, HTA, …)

AHA/ASA Guideline

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

The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists.

Endorsed by the American Association of Neurological Surgeons and Congress of Neurological Surgeons

Walter N. Kernan, MD, Chair; Bruce Ovbiagele, MD, MSc, MAS, Vice Chair; Henry R. Black, MD; Dawn M. Bravata, MD; Marc I. Chimowitz, MBChB, FAHA; Michael D. Ezekowitz, MBChB, PhD; Margaret C. Fang, MD, MPH; Marc Fisher, MD, FAHA; Karen L. Furie, MD, MPH, FAHA; Donald V. Heck, MD; S. Claiborne (Clay) Johnston, MD, PhD; Scott E. Kasner, MD, FAHA; Steven J. Kittner, MD, MPH, FAHA; Pamela H. Mitchell, PhD, RN, FAHA; Michael W. Rich, MD; DeJuran Richardson, PhD; Lee H. Schwamm, MD, FAHA; John A. Wilson, MD; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Peripheral Vascular Disease

Stroke **July 2014**

AHA/ASA Guideline

PFO

For patients with an ischemic stroke or TIA and a PFO who are not undergoing anticoagulation therapy, antiplatelet therapy is recommended *(Class I; Level of Evidence B)*.

For patients with an ischemic stroke or TIA and both a PFO and a venous source of embolism, anticoagulation is indicated, depending on stroke characteristics *(Class I; Level of Evidence A)*. When anticoagulation is contraindicated, an inferior vena cava filter is reasonable *(Class IIa; Level of Evidence C)*.

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)*.

In the setting of PFO and DVT, PFO closure by a transcatheter device might be considered, depending on the risk of recurrent DVT *(Class IIb; Level of Evidence C)*.

Stroke **July 2014**

HAUTE AUTORITÉ DE SANTÉ

RECOMMANDATION DE BONNE PRATIQUE

Prévention vasculaire après un infarctus cérébral ou un accident ischémique transitoire

Actualisation

Méthode Recommandations pour la pratique clinique

RECOMMANDATIONS

Juillet 2014

Mise à jour février 2015

HAUTE AUTORITÉ DE SANTÉ

Traitement spécifique après un IC ou un AIT associé à une affection cardiaque		
Anomalies du septum inter-auriculaire	Foramen ovale perméable (FOP) associé à un IC ou un AIT : • traitement antiplaquettaire en première intention • traitement par anticoagulant oral en cas de pathologie thromboembolique veineuse concomitante	**AE**
	Fermeture du FOP non recommandée chez les patients ayant un premier IC ou un AIT associé à un FOP	**B**
	Fermeture du FOP envisageable après concertation neuro-cardiologique chez les patients d'âge inférieur à 60 ans ayant un IC ou un AIT de cause indéterminée, récidivant sous traitement antithrombotique bien conduit	**AE**

percutaneous PFO closure

RESPECT
CLINICAL TRIAL

mean follow-up period : 2.6±2.0 years (0 to 8.1years)

Recurrent stroke	Closure group	Medical group
At 1 year	1.3%	1.7%
At 2 years	1.6%	3.0%
At 5 years	2.2%	6.4%

N Engl J Med 2013

RESPECT
Extended Follow-up Results

John D. Carroll, M.D.

Acknowledgements

Jeffrey L. Saver, M.D.
David E. Thaler, M.D., Ph.D.
Richard Smalling, M.D., Ph.D.
Lee A. MacDonald, M.D.
David S. Marks, M.D.
David L. Tirschwell, M.D.

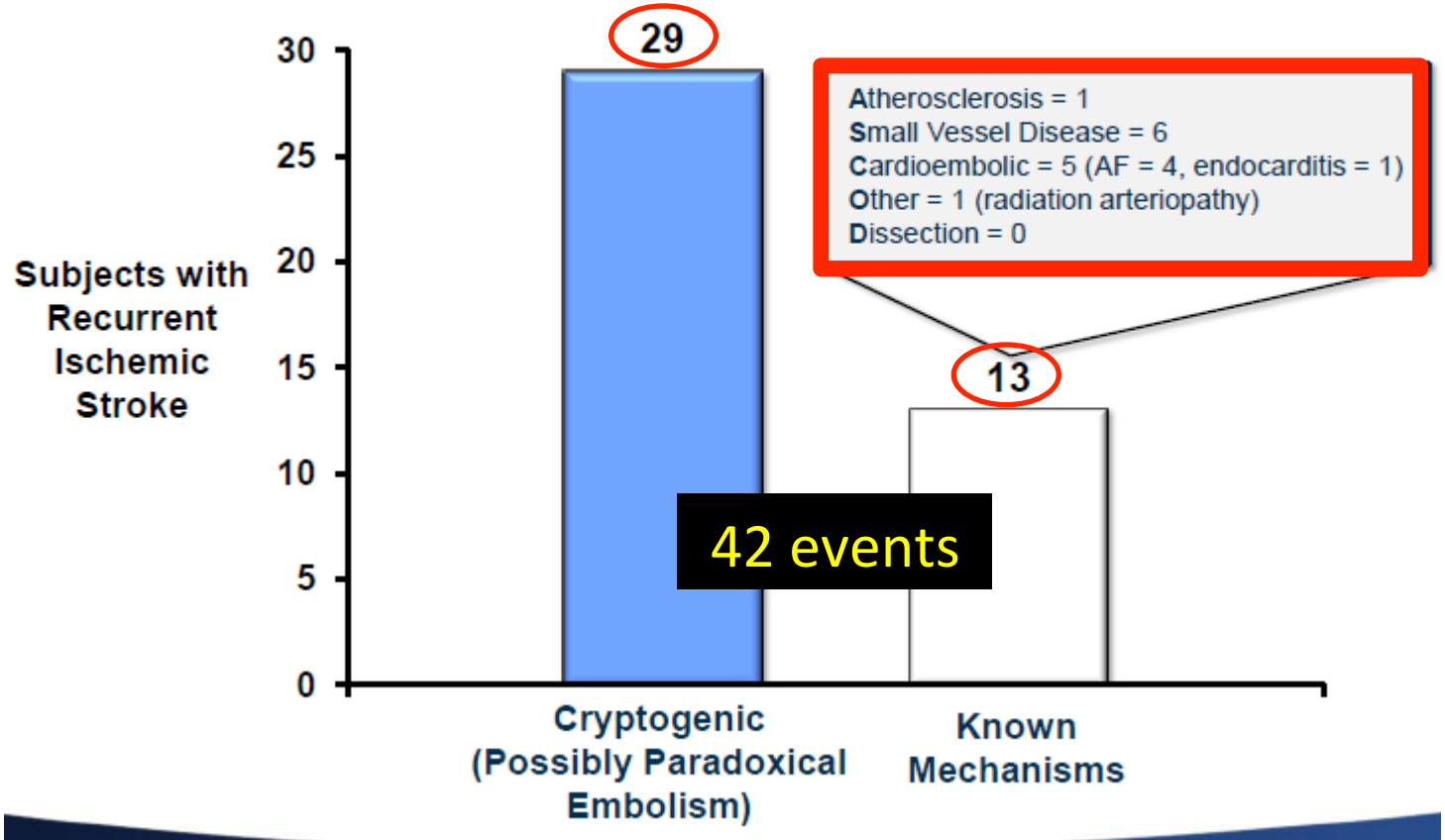
for the RESPECT Investigators

Extended Follow-up Provides Considerable New Data

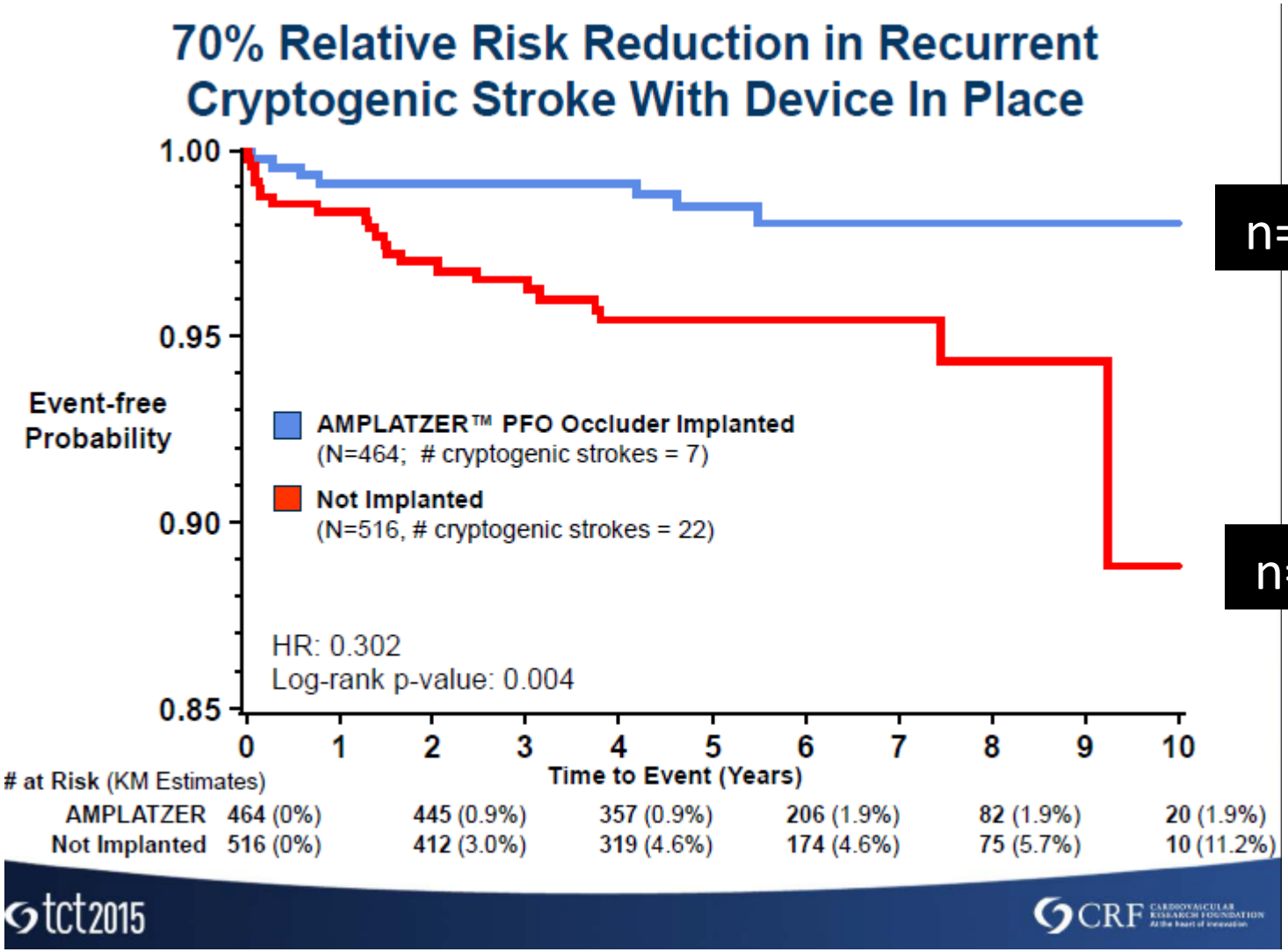
	AMPLATZER™ PFO Occluder (N=499)	Medical Management (N=481)
Mean Follow-up (years)		
Initial Analysis	3.0	2.7
Extended Follow-up	5.5	4.9
Total Patient-Years of Follow-up		
Initial Analysis	1476	1284
Extended Follow-up	2769	2376

Blinded Adjudication of Stroke Cause Using ASCOD Phenotyping

Nearly 1/3 of Recurrent Strokes in Extended Follow-up Are of Known Mechanism



percutaneous PFO closure



n=7

n=22

U.S. Department of Health and Human Services
Food and Drug Administration

Brief Summary of the Circulatory System Devices Panel Meeting – May 24, 2016

Introduction:

The Circulatory System Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on May 24, 2016 to make recommendations and vote on information related to the premarket approval application regarding St. Jude Medical's AMPLATZER Patent Foramen Ovale (PFO) Occluder System.

The sponsor has proposed the following Indications for Use:

The AMPLATZER PFO Occluder is intended for percutaneous, transcatheter closure of a patent foramen ovale (PFO) to prevent recurrent ischemic stroke in patients who have had a cryptogenic stroke due to a presumed paradoxical embolism.

U.S. Department of Health and Human Services
Food and Drug Administration

Vote:

The panel voted on the safety, effectiveness, and risk benefit ratio of the AMPLATZER™ PFO Occluder.

On Question 1, the panel voted 15-1 that the data show a reasonable assurance that the AMPLATZER™ PFO Occluder is safe for use in patients who meet the criteria specified in the proposed indication.

On Question 2, the panel voted 9-7 that there is reasonable assurance that the AMPLATZER™ PFO Occluder is effective for use in patients who meet the criteria specified in the proposed indication.

On Question 3, the panel voted 11-5 that the benefits of the AMPLATZER™ PFO Occluder outweigh the risks for use in patients who meet the criteria specified in the proposed indication.

Patient Selection for PFO Closure Based on the RoPE Study

Can a CHADS-like risk score help to predict who will benefit from PFO-specific therapy in the cryptogenic stroke population?

BY DAVID E. THALER, MD, PHD, FAHA

RoPE

RoPE (Risk of Paradoxical Embolism) score

TABLE 1. RoPE SCORE CALCULATOR		
Characteristic	**Points**	**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)		

Kent DM et al. Neurology 2013

incidental or stroke-related PFO

RoPE (Risk of Paradoxical Embolism) score

	Cryptogenic stroke (n = 3,023)		
RoPE score	No. of patients	Prevalence of patients with a PFO, % (95% CI)[a]	PFO-attributable fraction, % (95% CI)[a]
0-3	613	23 (19-26)	0 (0-4)
4	511	35 (31-39)	38 (25-48)
5	516	34 (30-38)	34 (21-45)
6	482	47 (42-51)	62 (54-68)
7	434	54 (49-59)	72 (66-76)
8	287	67 (62-73)	84 (79-87)
9-10	180	73 (66-79)	88 (83-91)

Kent DM et al. Neurology 2013

RoPE (Risk of Paradoxical Embolism) score

Probability question

$$\text{PFO Attributable Fraction} = 1 - \left(\frac{\text{Prevalence of PFO in controls} \times [1 - \text{Prevalence of PFO in CS cases}]}{\text{Prevalence of PFO in CS cases} \times [1 - \text{Prevalence of PFO in controls}]}\right)$$

Kent DM et al. Neurology 2013

RoPE (Risk of Paradoxical Embolism) score

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9-10	180	73 (66-79)	88 (83-91)

Kent DM et al. Neurology 2013

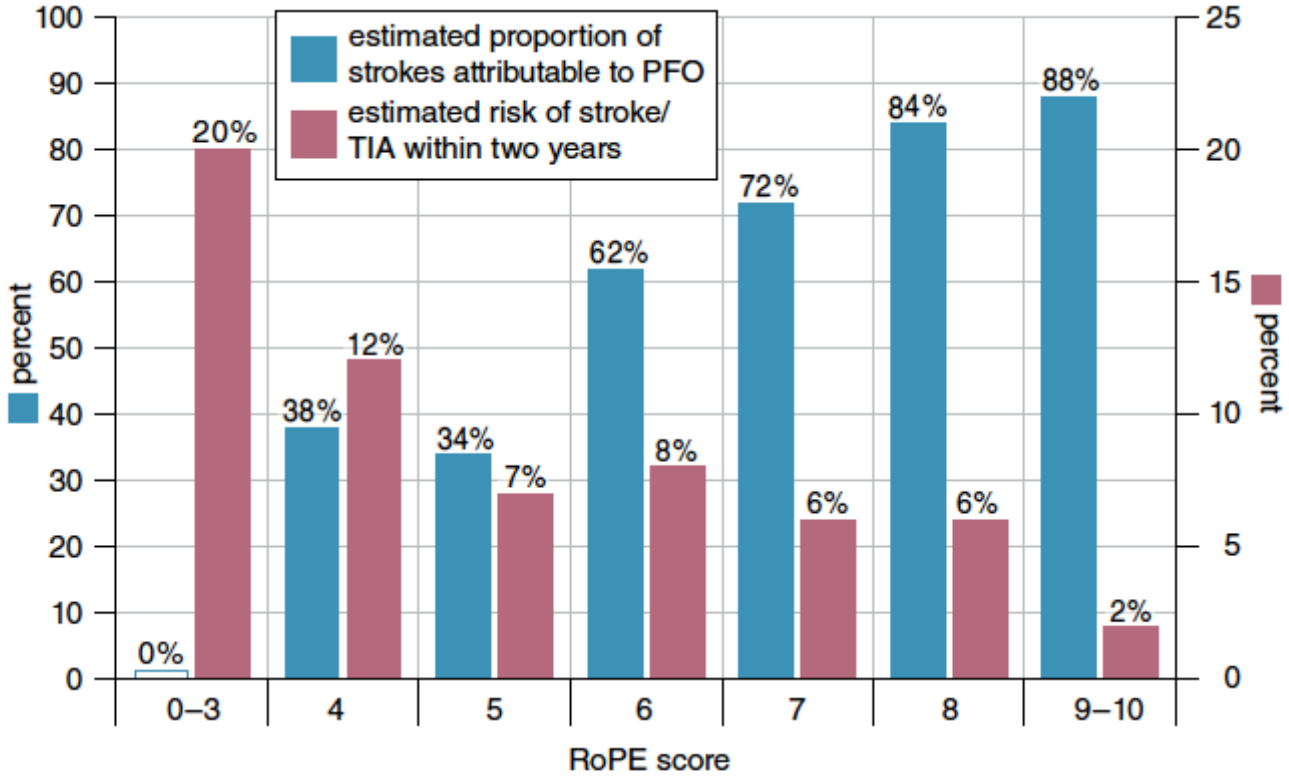
RoPE (Risk of Paradoxical Embolism) score

	CS patients with PFO (n = 1,324)	
RoPE score	No. of CS patients with PFO[a]	Estimated 2-y stroke/TIA recurrence rate (Kaplan-Meier), % (95% CI)
0-3	108	20 (12-28)
4	148	12 (6-18)
5	186	7 (3-11)
6	236	8 (4-12)
7	263	6 (2-10)
8	233	6 (2-10)
9-10	150	2 (0-4)

Kent DM et al. Neurology 2013

risk of recurrent stroke

RoPE (Risk of Paradoxical Embolism) score



Kent DM et al. Neurology 2013

incidental or stroke-related PFO

RoPE (Risk of Paradoxical Embolism) score

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

Kent DM et al. Neurology 2013

fermeture percutanée des FOP

RoPE score ≤ 4 → pas de fermeture

RoPE score 5-6 → discussion de fermeture

RoPE score ≥ 7 → proposition de fermeture

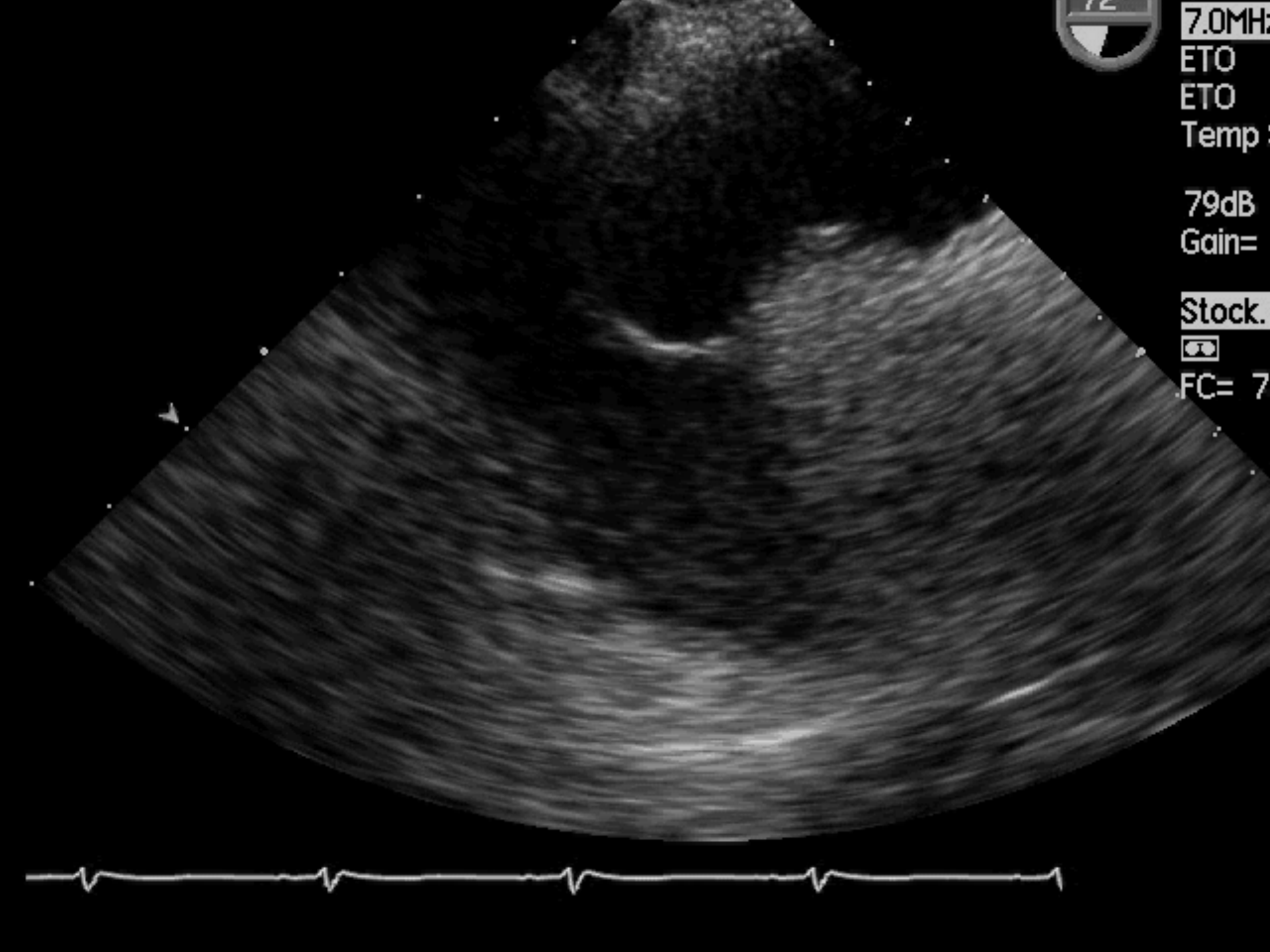
fermeture percutanée des FOP

Percutaneous PFO closure

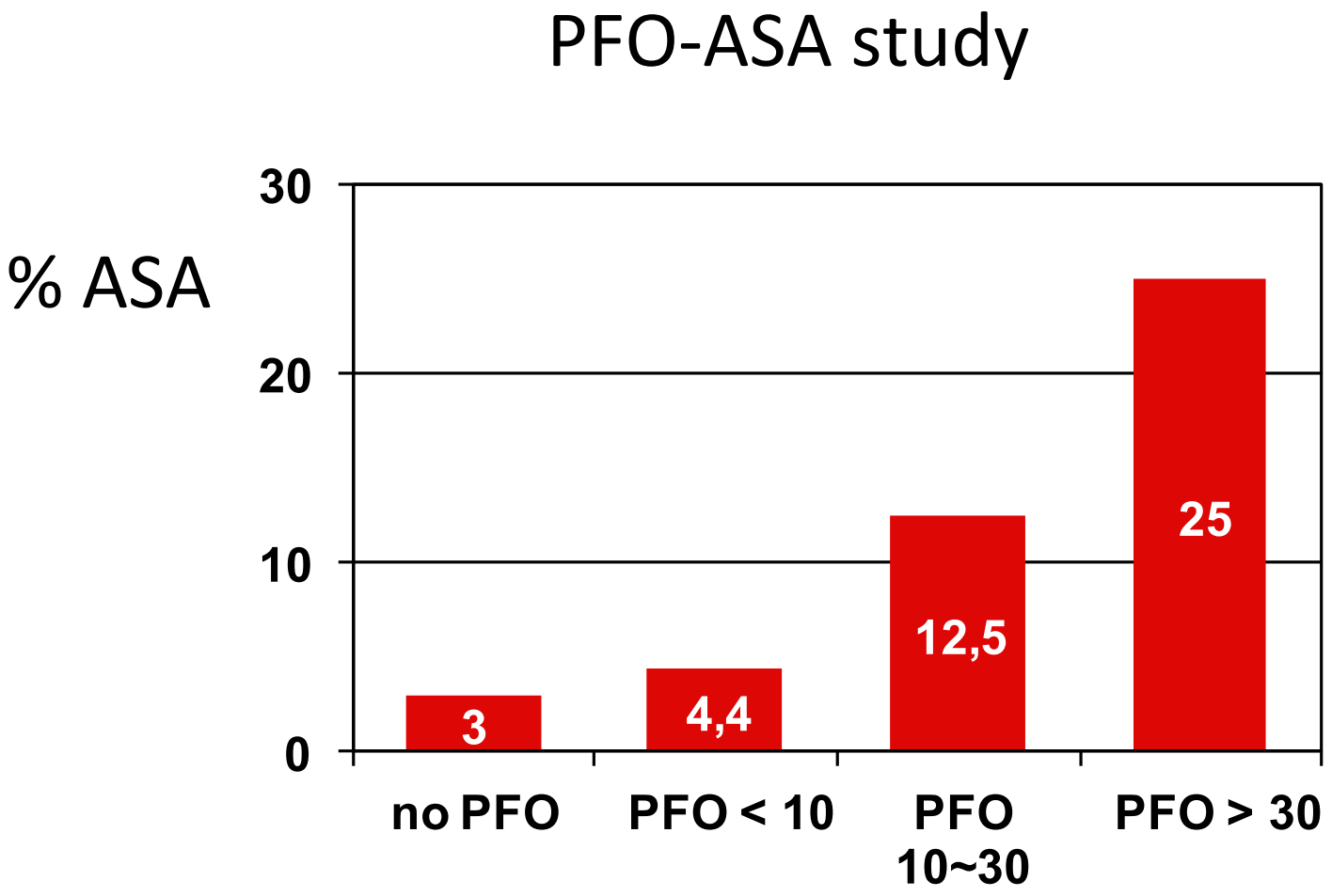
Enhanced reasons for PFO closure:

- Prior venous thromboembolism
- Multifocal cerebral defects
- Large PFO
- Atrial septal aneurysm
- Eustachian valve or Chiari network

Mojadidi, M.K. et al. J Am Coll Cardiol. 2018;71(9):1035-43.


7.0MH
ETO
ETO
Temp
79dB
Gain=
Stock.
FC= 7

relation FOP/ASIA

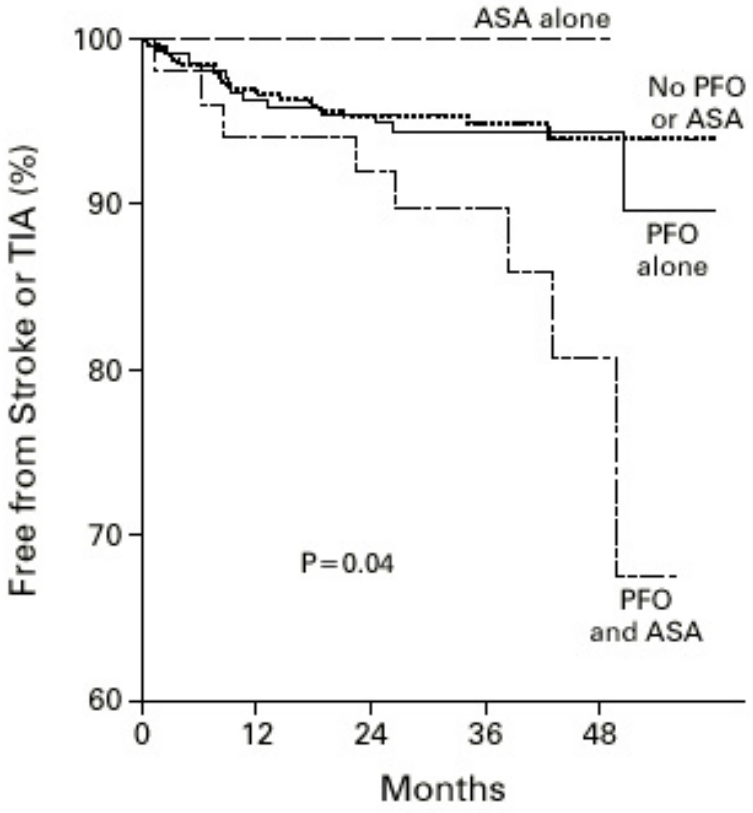


Mas et al. N Engl J Med 2001

relation FOP/ASIA

PFO-ASA study

581 patients 18-55 years of age / Aspirin 300 mg



Stroke at 4 years

PFO 2.3%

PFO+ASA 15.2%

ASA 0%

No FOP no ASO 4.2%

Mas et al. N Engl J med 2001

Etudes randomisées récentes

percutaneous PFO closure

controlled studies

RESPECT CLINICAL TRIAL

N Engl J Med 2017

positive study

GORE REDUCE CLINICAL STUDY

N Engl J Med 2017

positive study

CLOSE

N Engl J Med 2017

positive study

RESPECT study

The NEW ENGLAND JOURNAL of MEDICINE

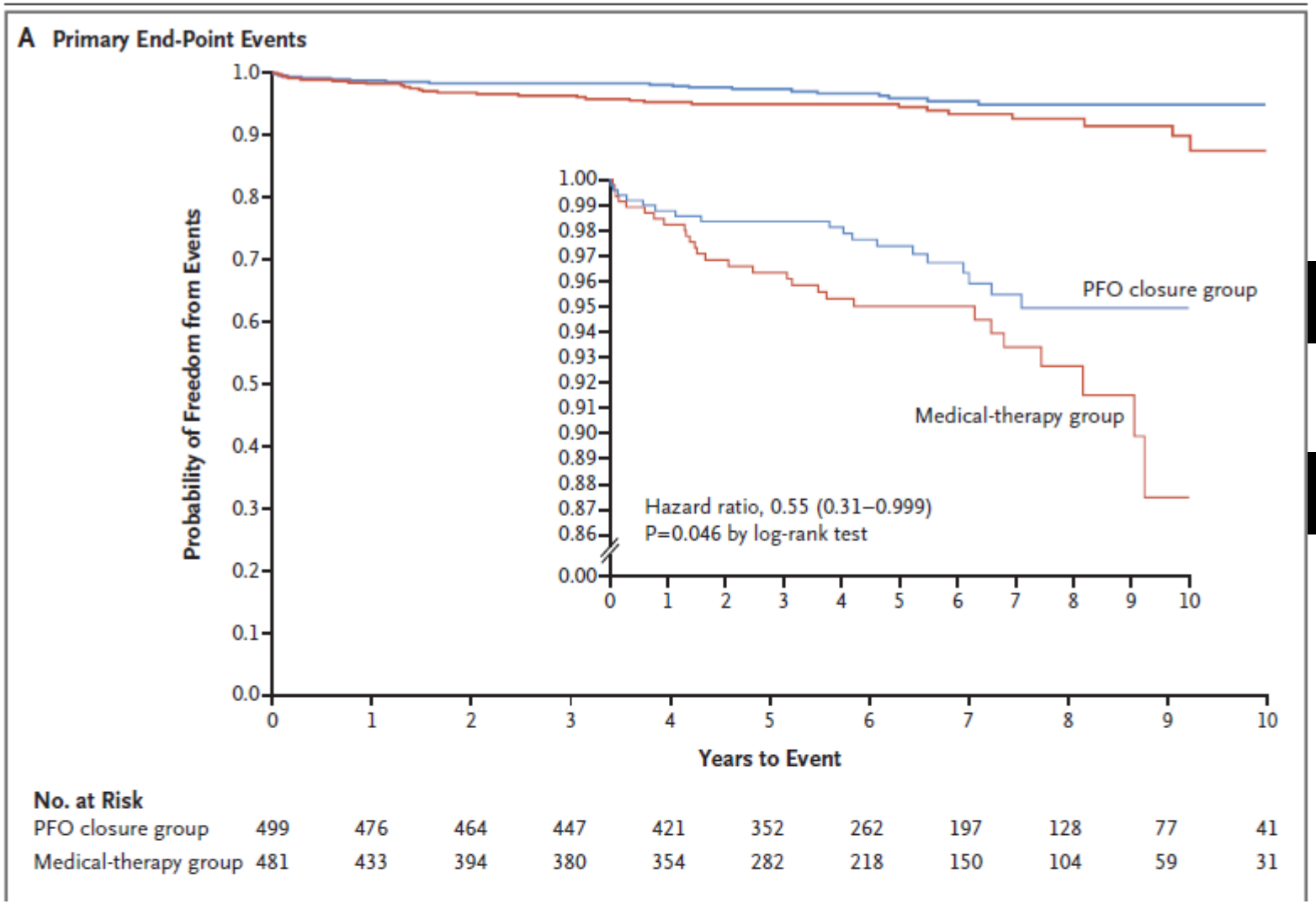
ORIGINAL ARTICLE

Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke

Jeffrey L. Saver, M.D., John D. Carroll, M.D., David E. Thaler, M.D., Ph.D., Richard W. Smalling, M.D., Ph.D., Lee A. MacDonald, M.D., David S. Marks, M.D., and David L. Tirschwell, M.D., for the RESPECT Investigators*

N ENGL J MED 377;11 NEJM.ORG SEPTEMBER 14, 2017

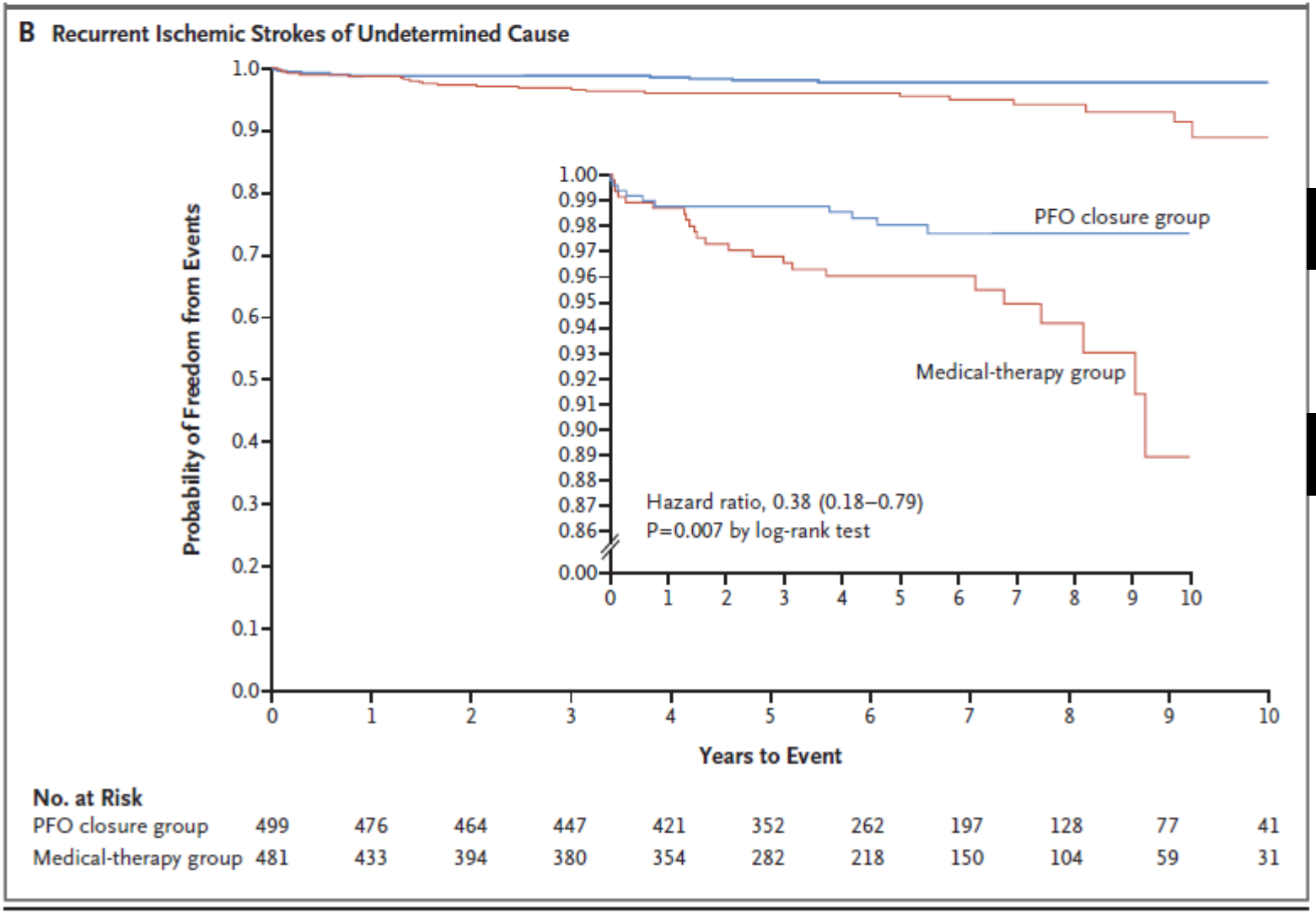
RESPECT study



n=18

n=28

RESPECT study



n=10

n=23

percutaneous PFO closure

Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke

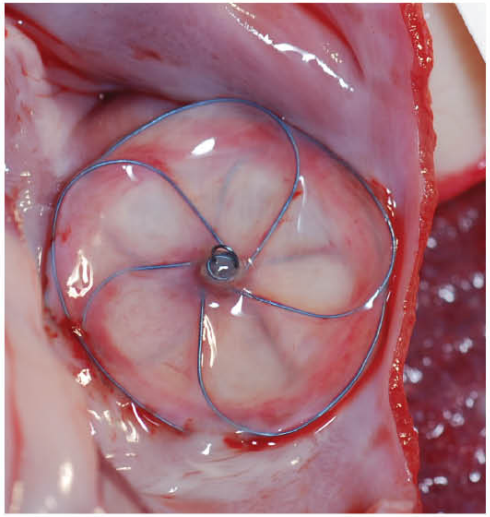
Lars Søndergaard, M.D., Scott E. Kasner, M.D., John F. Rhodes, M.D., Grethe Andersen, M.D., D.M.Sc., Helle K. Iversen, M.D., D.M.Sc., Jens E. Nielsen-Kudsk, M.D., D.M.Sc., Magnus Settergren, M.D., Ph.D., Christina Sjöstrand, M.D., Ph.D., Risto O. Roine, M.D., David Hildick-Smith, M.D., J. David Spence, M.D., and Lars Thomassen, M.D., for the Gore REDUCE Clinical Study Investigators*

Gore REDUCE Clinical Study

Protocol and primary endpoint results

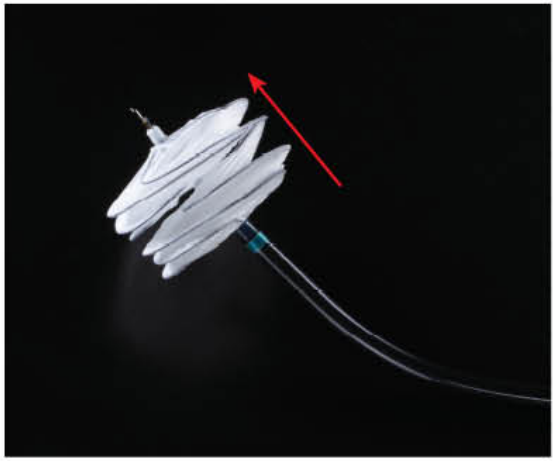
N ENGL J MED 377;11 NEJM.ORG SEPTEMBER 14, 2017

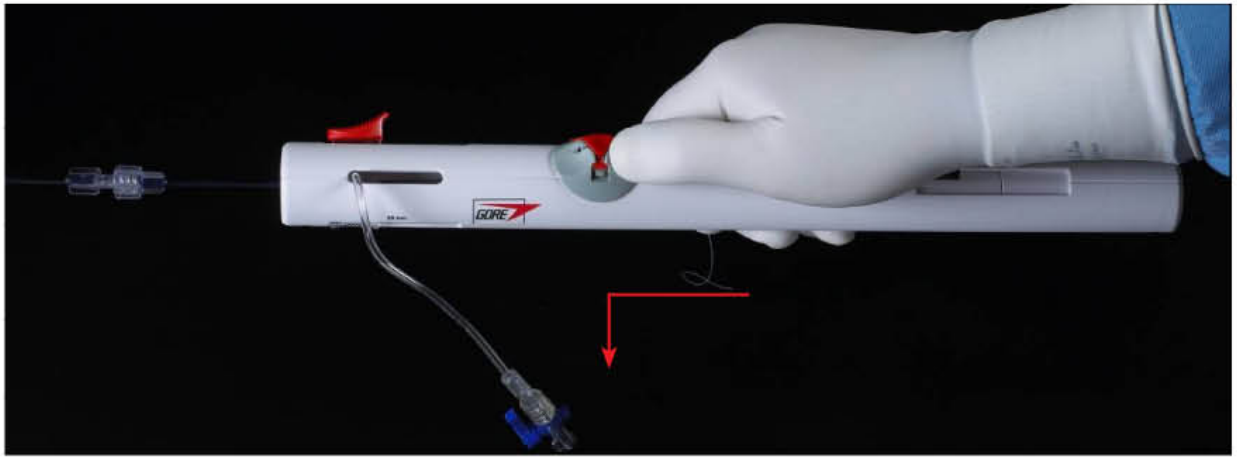
fermeture percutanée des FOP



After 30 days in canine model

Gore Septal Occluder (GSO)





Study overview

- The Gore REDUCE Clinical Study (REDUCE) is a randomized, controlled, open-label trial
- 63 multinational sites, 664 subjects with cryptogenic stroke and Patent Foramen Ovale (PFO) randomized in a 2:1 ratio to:
  - **Test:** Antiplatelet therapy plus PFO closure (with GORE® HELEX® Septal Occluder or GORE® CARDIOFORM Septal Occluder)
  - **Control:** Antiplatelet therapy alone
- Subjects prospectively followed for up to five years
- Neuroimaging required for all subjects at baseline and at two years or study exit

GORE® CARDIOFORM Septal Occluder

GORE
REDUCE
CLINICAL STUDY

Inclusion and exclusion criteria

- Age 18–59 years
- Cryptogenic ischemic stroke within 180 days
  - Ischemic stroke = clinical symptoms ≥ 24 hours or with MRI evidence of infarction
  - Cryptogenic
- No stenosis > 50 percent or ulcerated plaque in relevant intra- or extra-cranial vessels
- No atrial fibrillation or high risk source of cardioembolism
- Non-lacunar (based on syndrome and / or size)
- No evidence of hypercoagulable disorder
- No other known cause of stroke
- PFO
  - Confirmed by transesophageal echocardiography (TEE / TOE) with bubble study demonstrating right-to-left shunt at rest or during Valsalva maneuver
- No indication for anticoagulation
- No uncontrolled diabetes mellitus, hypertension, autoimmune disease, alcohol or drug abuse

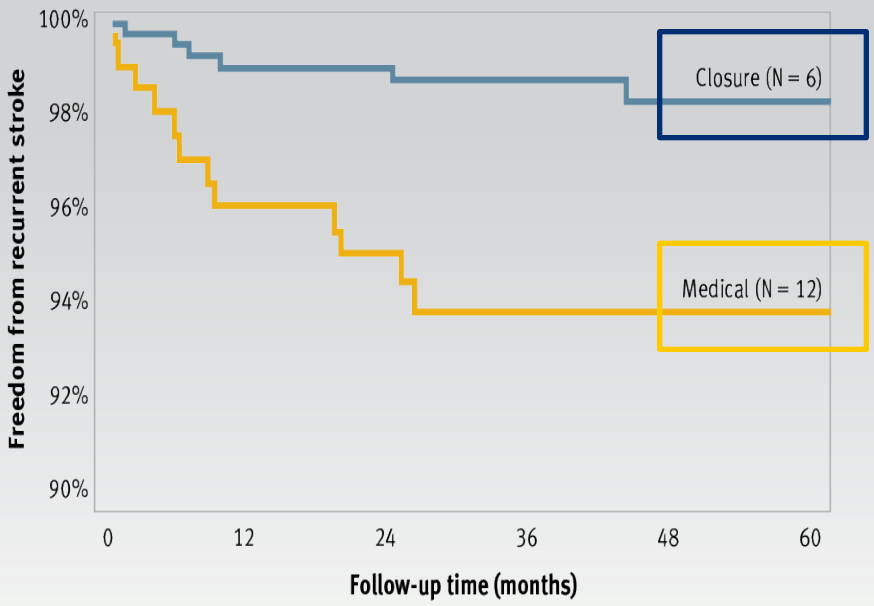
GORE REDUCE CLINICAL STUDY

Medical management for all subjects

- Medical therapy options:
  - Acetylsalicylic acid alone (75–325 mg once daily)
  - Combination acetylsalicylic acid (50–100 mg once daily) and dipyridamole (225–400 mg once daily)
  - Clopidogrel (75 mg once daily)
  - Other combinations or the use of anticoagulants was not permitted
- Prescribed for all subjects for the duration of the study
- Each site was expected to treat all subjects with the same antiplatelet therapy

GORE
REDUCE
CLINICAL STUDY

Primary endpoint result: Recurrent clinical ischemic stroke



- 77 percent relative reduction in clinical stroke with PFO closure (intention-to-treat analysis)
- PFO closure effect similar across subgroups based on age, sex, region, and baseline shunt size
- Number needed to treat (NNT) = 28 at two years

Hazard ratio: 0.23
95% CI: 0.09 to 0.62
***One-sided P* = 0.001**
Adjusted for multiple testing

Annualized event rates
Closure: 0.39 per 100 person-years
Medical: 1.71 per 100 person-years

GORE
REDUCE
CLINICAL STUDY

CLOSE

The NEW ENGLAND JOURNAL of MEDICINE

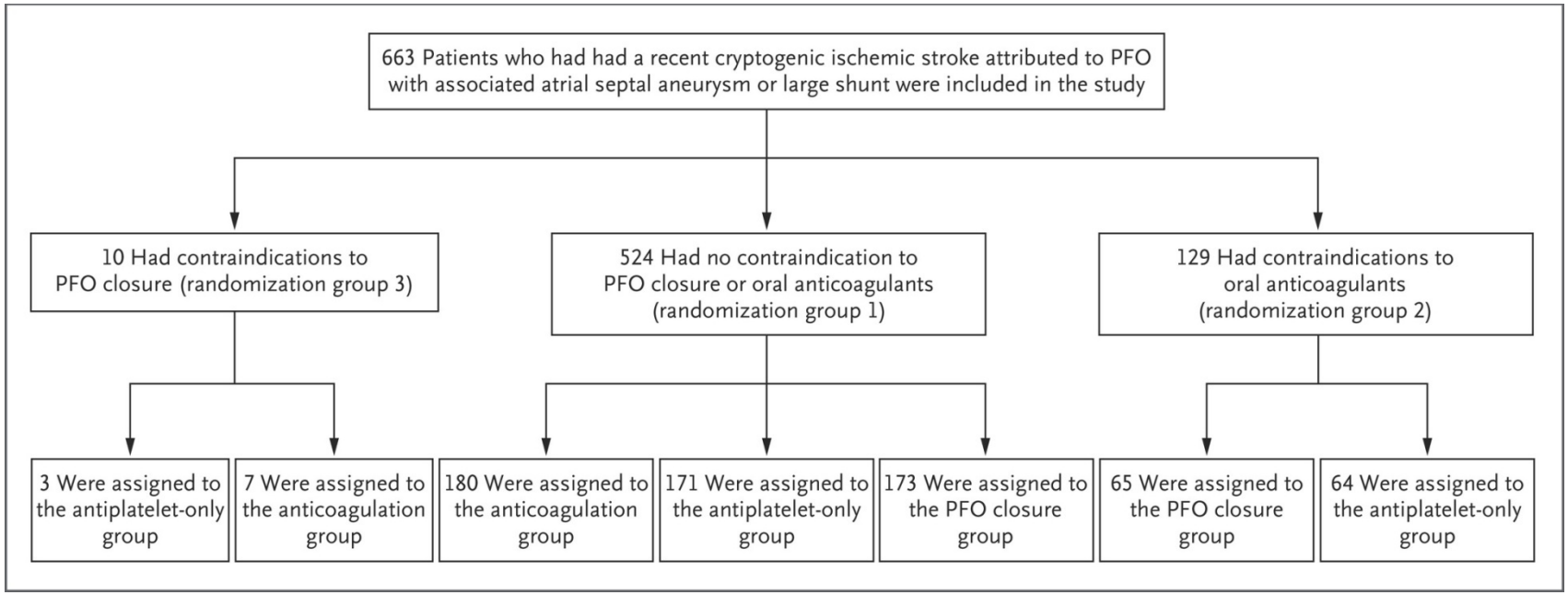
ESTABLISHED IN 1812 SEPTEMBER 14, 2017 VOL. 377 NO. 11

Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke

J.-L. Mas, G. Derumeaux, B. Guillon, E. Massardier, H. Hosseini, L. Mechtouff, C. Arquizan, Y. Béjot, F. Vuillier, O. Detante, C. Guidoux, S. Canaple, C. Vaduva, N. Dequatre-Ponchelle, I. Sibon, P. Garnier, A. Ferrier, S. Timsit, E. Robinet-Borgomano, D. Sablot, J.-C. Lacour, M. Zuber, P. Favrole, J.-F. Pinel, M. Apoil, P. Reiner, C. Lefebvre, P. Guérin, C. Piot, R. Rossi, J.-L. Dubois-Randé, J.-C. Eicher, N. Meneveau, J.-R. Lusson, B. Bertrand, J.-M. Schleich, F. Godart, J.-B. Thambo, L. Leborgne, P. Michel, L. Pierard, G. Turc, M. Barthelet, A. Charles-Nelson, C. Weimar, T. Moulin, J.-M. Juliard, and G. Chatellier, for the CLOSE Investigators*

CLOSE

- 663 patients, 16 to 60 years of age with a recent cryptogenic stroke attributed to PFO with an associated ASA or large interatrial shunt.
- 1:1:1 ratio : transcatheter PFO closure plus long-term antiplatelet therapy *vs.* antiplatelet therapy alone *vs.* oral anticoagulation.
- Mean follow up = 5.3 years.



Mas et al. N Engl J Med 2017

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fermeture percutanée + AAP vs AAP

	CLOSURE (n = 238)	APT (n = 235)
Lost to follow-up	0	2
No PFO, atrial septal defect	2	
Refused PFO closure	2	
Discontinued antiplatelet therapy	17	10*
Mean follow-up, yr.	5.4 +/-1.9	5.2 +/-2.1

* 3 had PFO closure

CLOSURE = closure + antiplatelet therapy
APT = antiplatelet therapy

Mas et al. N Engl J Med 2017

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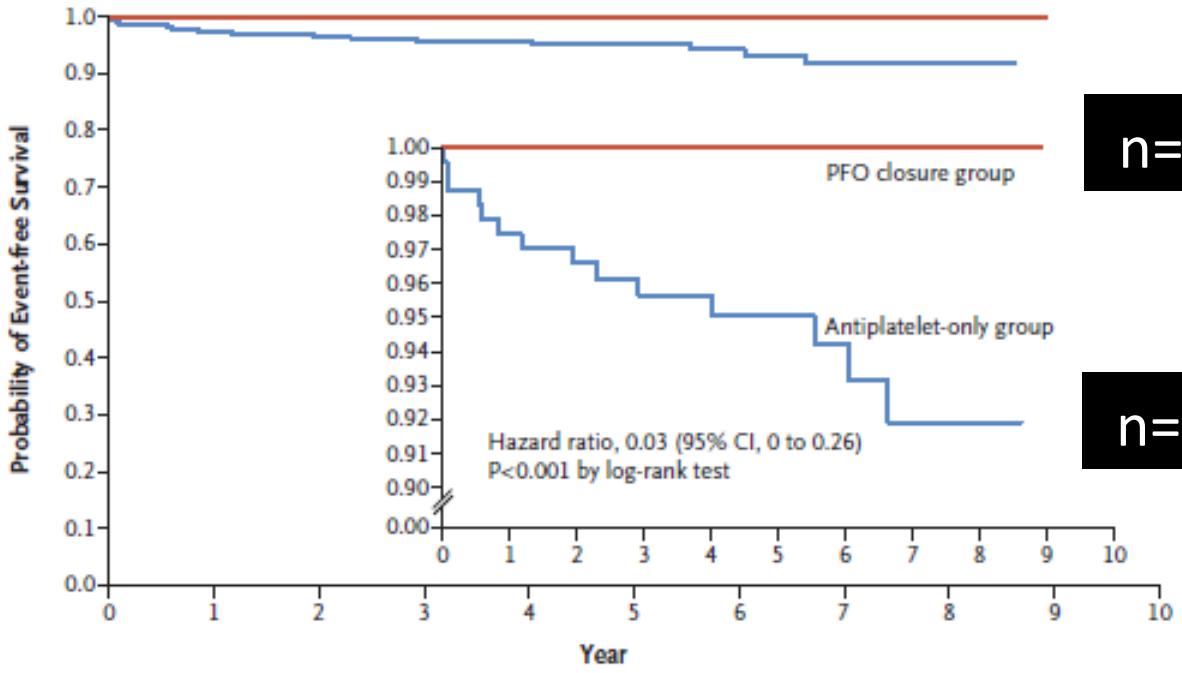

No. at Risk

PFO closure group	238	238	232	200	179	141	99	64	20	0	0
Antiplatelet-only group	235	229	223	198	160	130	96	55	19	0	0

Figure 2. Kaplan–Meier Cumulative Estimates of Probability of Stroke in the PFO Closure Group versus the Antiplatelet-Only Group.

The analysis was performed in the intention-to-treat cohort, which included all patients who were randomly assigned to a treatment. The inset shows the same data on an enlarged y axis.

Mas et al. N Engl J Med 2017

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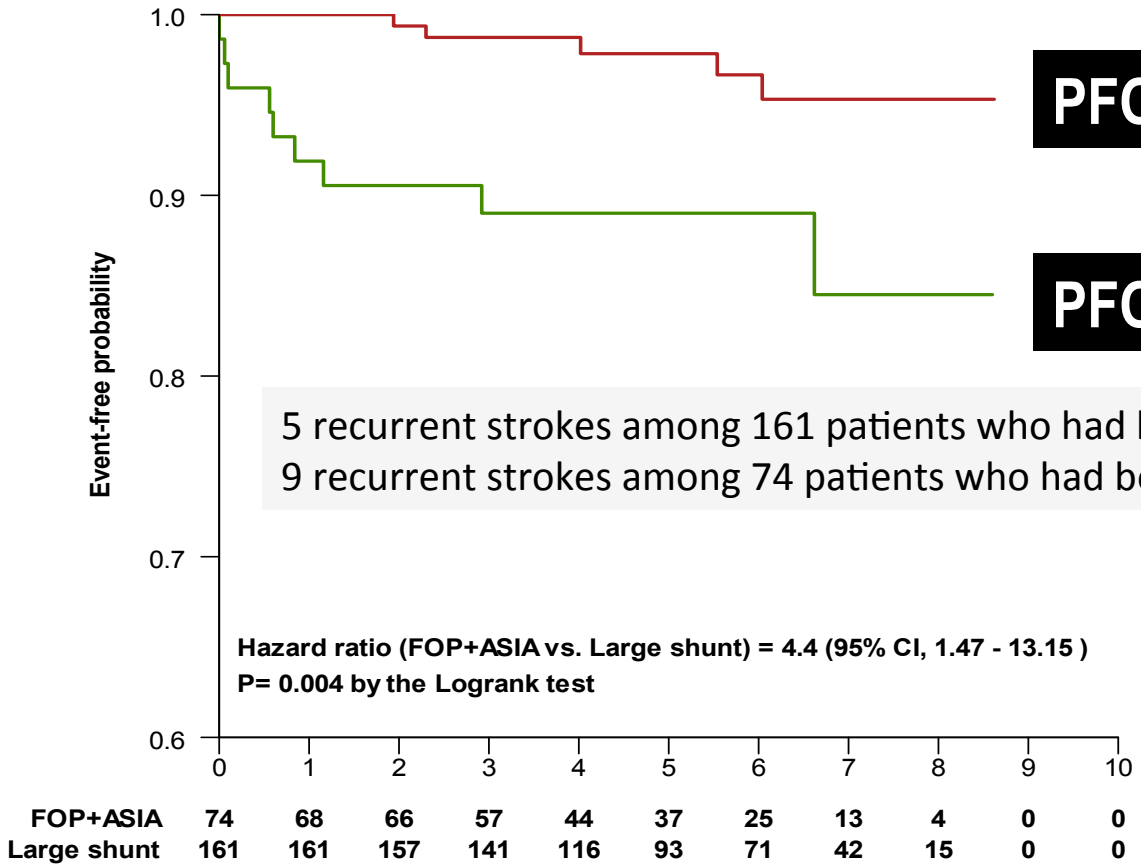

5 recurrent strokes among 161 patients who had large PFO without ASA (3.1%)
9 recurrent strokes among 74 patients who had both PFO and ASA (12.2%)

Mas et al. N Engl J Med 2017

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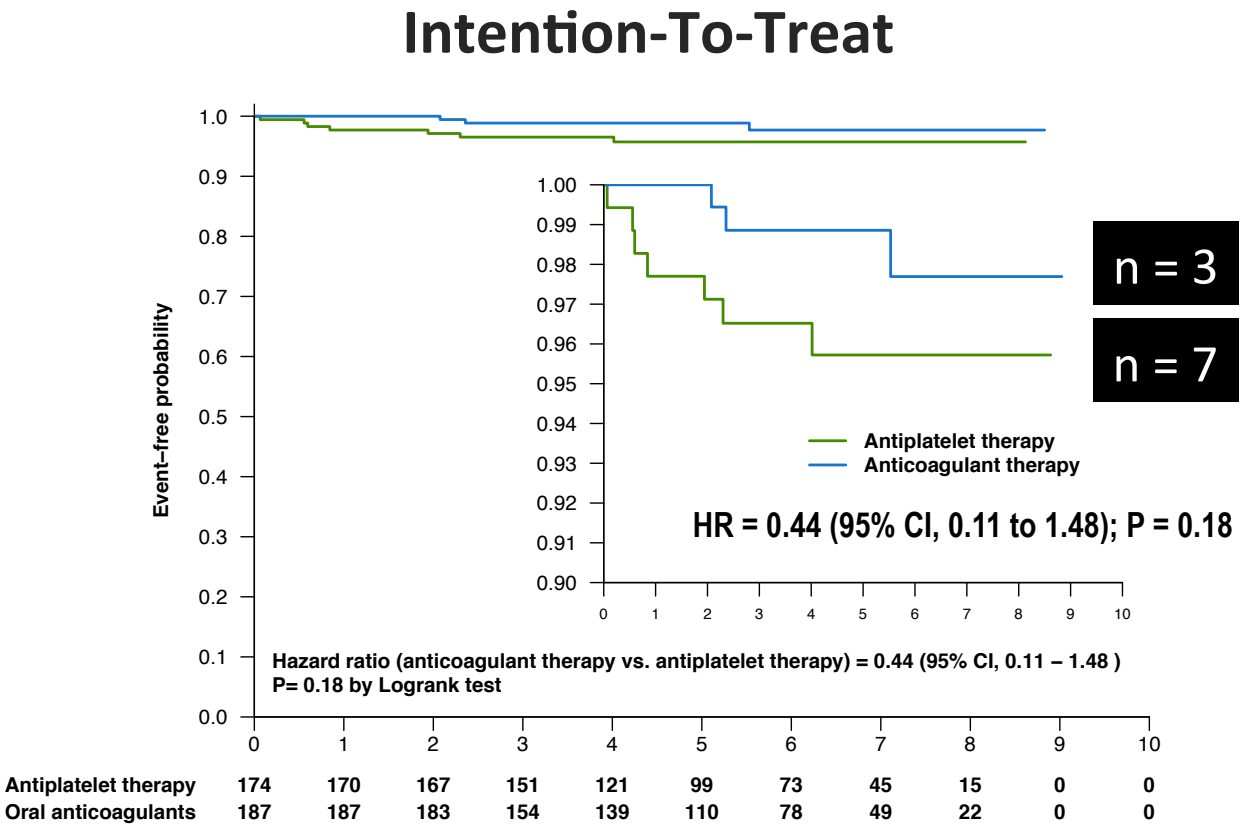
AAP vs ACO



Mas et al. N Engl J Med 2017

percutaneous PFO closure

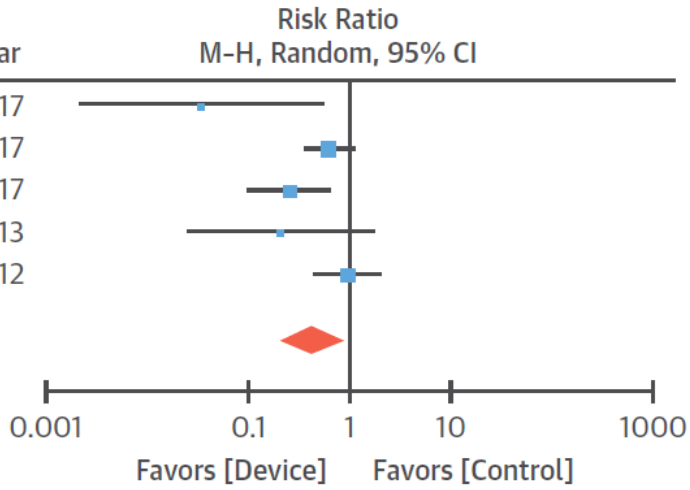
Cryptogenic Stroke and Patent Foramen Ovale

A Recurrent Stroke

Study or Subgroup	Device Events	Device Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	Year
CLOSE (40)	0	238	14	235	6.1%	0.03 [0.00-0.57]	2017
RESPECT (27)	18	499	28	481	32.2%	0.62 [0.35-1.11]	2017
REDUCE (41)	6	441	12	223	24.1%	0.25 [0.10-0.66]	2017
PC (23)	1	204	5	210	9.5%	0.21 [0.02-1.75]	2013
CLOSURE I (20)	12	447	13	462	28.0%	0.95 [0.44-2.07]	2012
Total (95% CI)		**1829**		**1611**	**100.0%**	**0.42 [0.20-0.91]**	
Total events	37		72				

Heterogeneity: $Tau^2 = 0.38$; $Chi^2 = 9.72$, df = 4 (P = 0.05); $I^2 = 59\%$

Test for overall effect: Z = 2.22 (P = 0.03)



Mojadidi, M.K. et al. J Am Coll Cardiol. 2018;71(9):1035–43.

fermeture percutanée des FOP

limites des études

- Difficultés de recrutement
- Population plus homogène (moins FOP incident inclus)
- Hypothèse testée : supériorité versus équivalence
- Critère de sélection et/ou d'évaluation : ~~AIT versus~~ AIC
- Traitement ~~non~~ uniforme dans groupe contrôle
- Taux d'événements bas (pouvoir statistique diminué)
- Périodes d'évaluation plus longues ~~courtes~~ (> 3 ans)
- Moins événements liés à une cause connue (FA, HTA, …)

percutaneous PFO closure

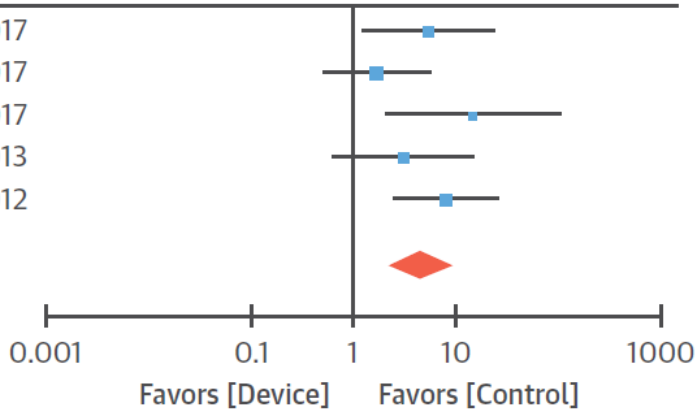
Cryptogenic Stroke and Patent Foramen Ovale

B Atrial Fibrillation/Flutter

Study or Subgroup	Device Events	Device Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI	Year
CLOSE (40)	11	238	2	235	19.0%	5.43 [1.22-24.24]	2017
RESPECT (27)	7	499	4	481	25.5%	1.69 [0.50-5.73]	2017
REDUCE (41)	29	441	1	223	12.0%	14.66 [2.01-106.95]	2017
PC (23)	6	204	2	210	17.3%	3.09 [0.63-15.12]	2013
CLOSURE I (20)	23	447	3	462	26.2%	7.92 [2.40-26.21]	2012
Total (95% CI)		**1829**		**1611**	**100.0%**	**4.55 [2.16-9.60]**	
Total events	76		12				

Heterogeneity: $Tau^2 = 0.18$; $Chi^2 = 5.33$, $df = 4$ ($P = 0.26$); $I^2 = 25\%$

Test for overall effect: $Z = 3.98$ ($P < 0.0001$)



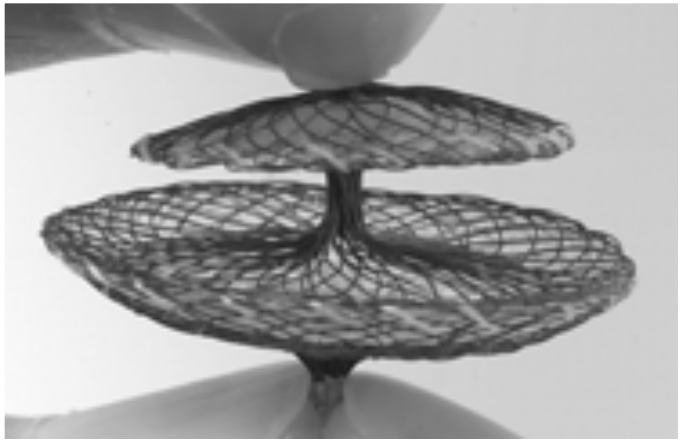
4.2% **0.7%**

Mojadidi, M.K. et al. J Am Coll Cardiol. 2018;71(9):1035-43.

fermeture percutanée des FOP

prothèses

AMPLATZER®



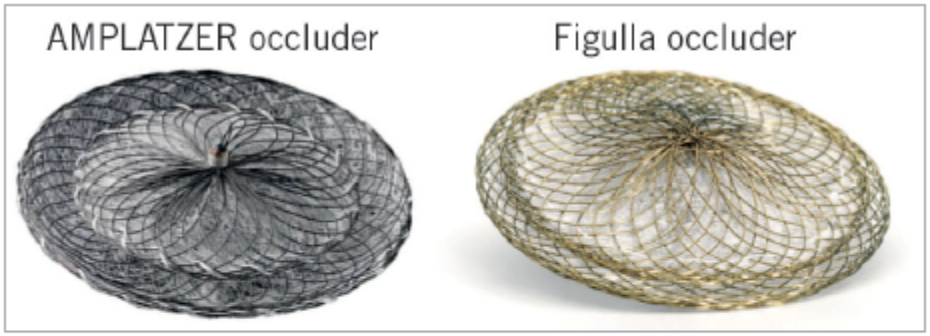
Occlutech®

GORE SEPTAL OCCLUDER

fermeture percutanée des FOP

AMPLATZER versus Figulla occluder for transcatheter patent foramen ovale closure

Daniela Trabattoni[1], MD, FESC; Achille Gaspardone[2]*, MD, MPhil, FESC; Gregory A. Sgueglia[2], MD, PhD; Franco Fabbiocchi[1], MD; Gaetano Gioffrè[2], MD; Piero Montorsi[1], MD; Giuseppe Calligaris[1], MD; Maria Iamele[2], MD; Antonella De Santis[2], MD; Antonio L. Bartorelli[1], MD, FESC



EuroIntervention 2017;12:2092-2099

fermeture percutanée des FOP

AMPLATZER versus Figulla occluder for transcatheter patent foramen ovale closure

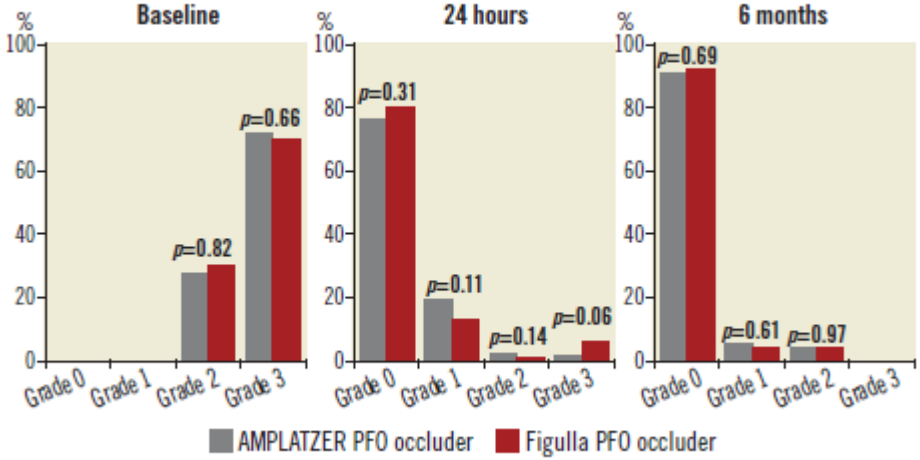
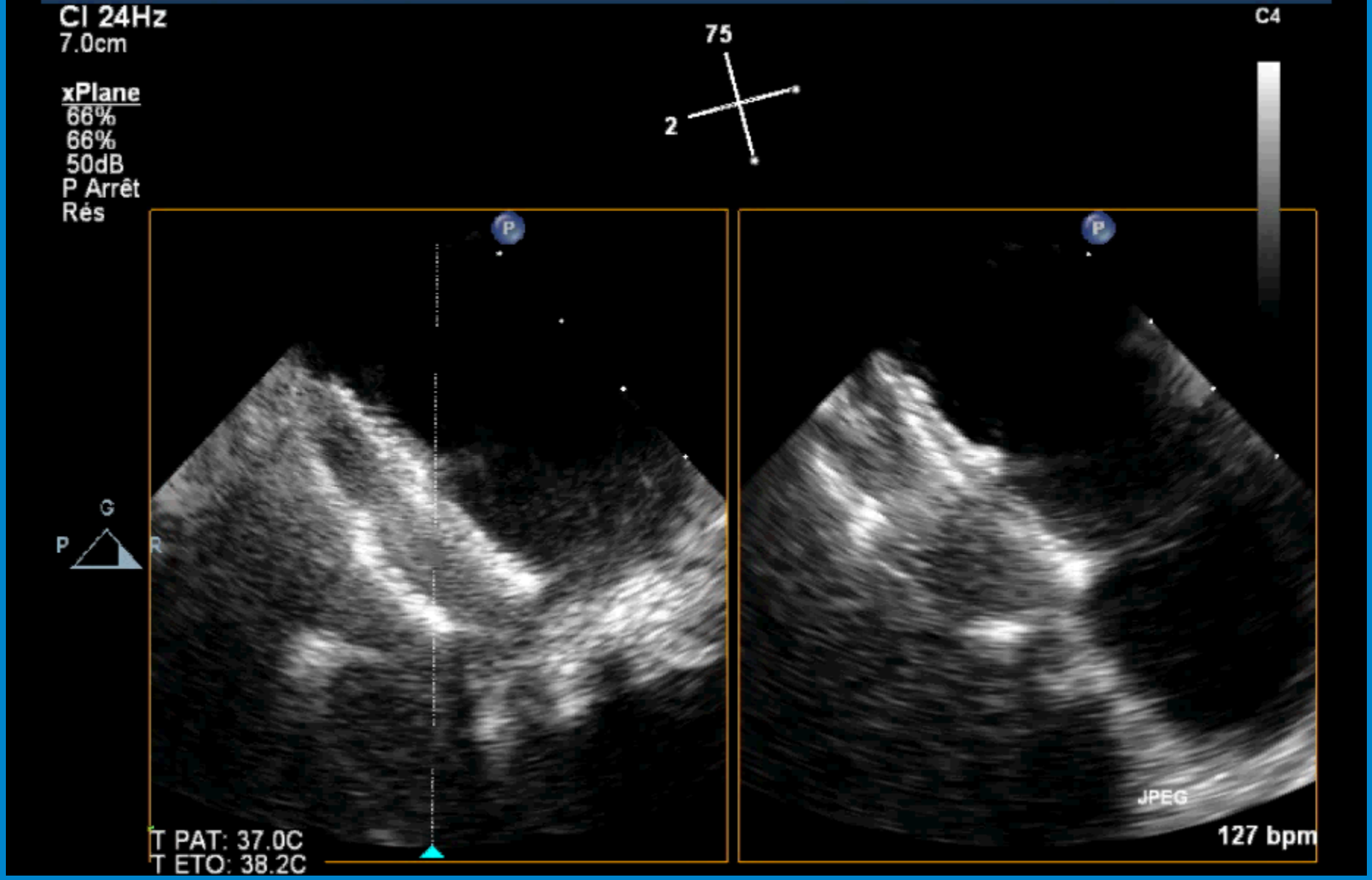


Table 4. Clinical follow-up.

	All (n=406)	AMPLATZER (n=179)	Figulla (n=227)	*p*-value
Death	0 (0%)	0 (0%)	0 (0%)	–
Ischaemic stroke	0 (0%)	0 (0%)	0 (0%)	–
Transient ischaemic attack	0 (0%)	0 (0%)	0 (0%)	–
Aortic erosion	0 (0%)	0 (0%)	0 (0%)	–
Supraventricular arrhythmias	50 (12.5%)	30 (17%)	20 (9%)	0.02
Paroxysmal atrial fibrillation	5 (1.2%)	4 (2.2%)	1 (0.4%)	0.24

EuroIntervention 2017;12:2092-2099


CI 24Hz
7.0cm
xPlane
66%
66%
50dB
P Arrêt
Rés
75
2
C4
P
P
G
P
R
JPEG
T PAT: 37.0C
T ETO: 38.2C
127 bpm

Foramen Ovale Perméable (FOP) et plongée

Accidents de décompression et shunts droite-gauche. Faut-il fermer le foramen ovale perméable chez le plongeur ?

Decompression complications and right-to-left shunts. Should patent foramen ovale be closed in scuba divers?

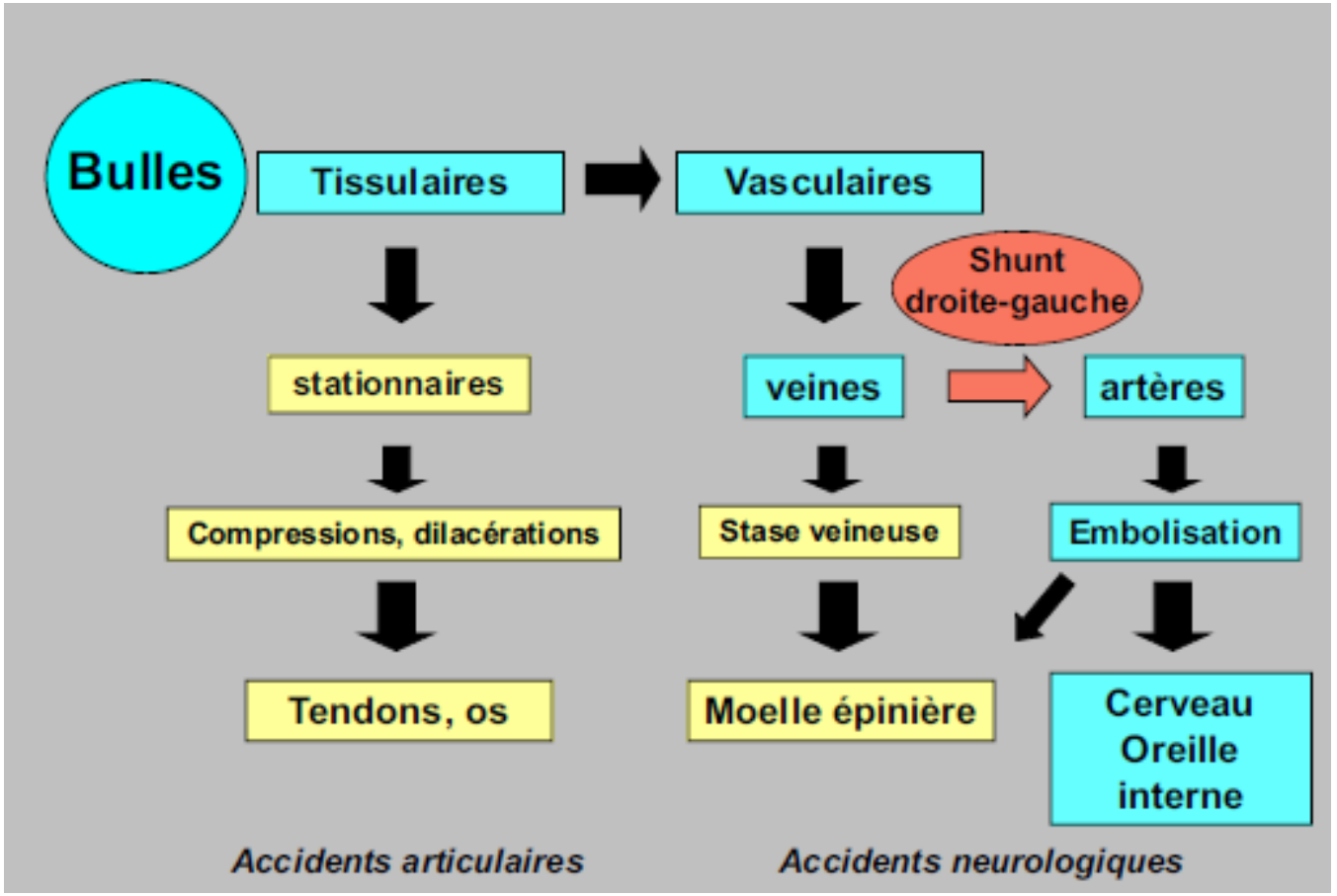
J.-E. Blatteau

Service de médecine hyperbare et d'expertise plongée, hôpital d'instruction des armées Sainte-Anne, BP600, 83800 Toulon cedex 9, France

Arch Mal Coeur Vaiss Prat 2016;2016:8–11

Foramen Ovale Perméable (FOP) et plongée

accidents de décompression (ADD)



Arch Mal Coeur Vaiss Prat 2016;2016:8–11

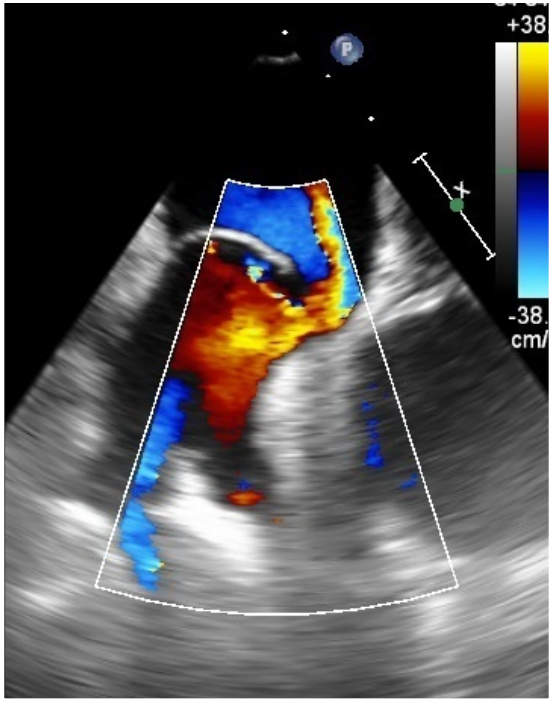
Foramen Ovale Perméable (FOP) et plongée

accidents de décompression (ADD)

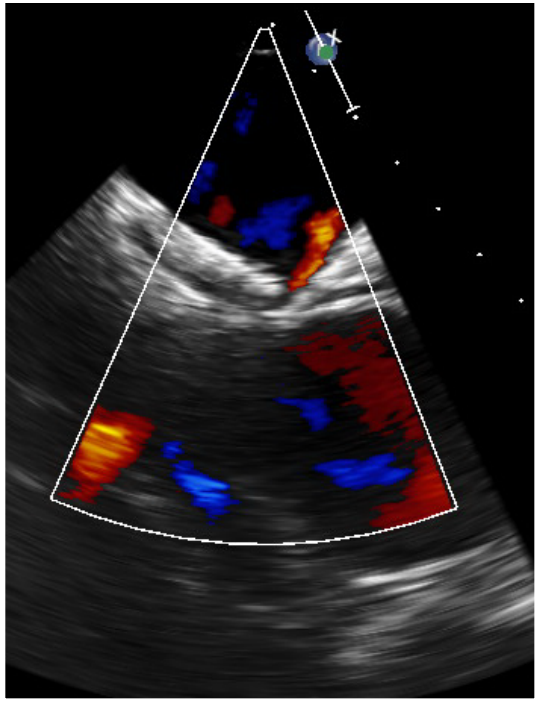
- Prévalence : 2/10.000 plongées
- Non application de certaines règles : fréquente
- Dépistage systématique FOP : non
- 25% des ADD neurologiques : séquelles
- Recherche d'un FOP après ADD neurologique : oui
- Présence d'un FOP :
  1. arrêt définitif plongée (obligatoire si séquelles)
  2. plongée autorisée avec restrictions (profondeur)
  3. fermeture FOP (pratiques non modifiables)

percutaneous PFO closure

PFO associated with hypoxemia

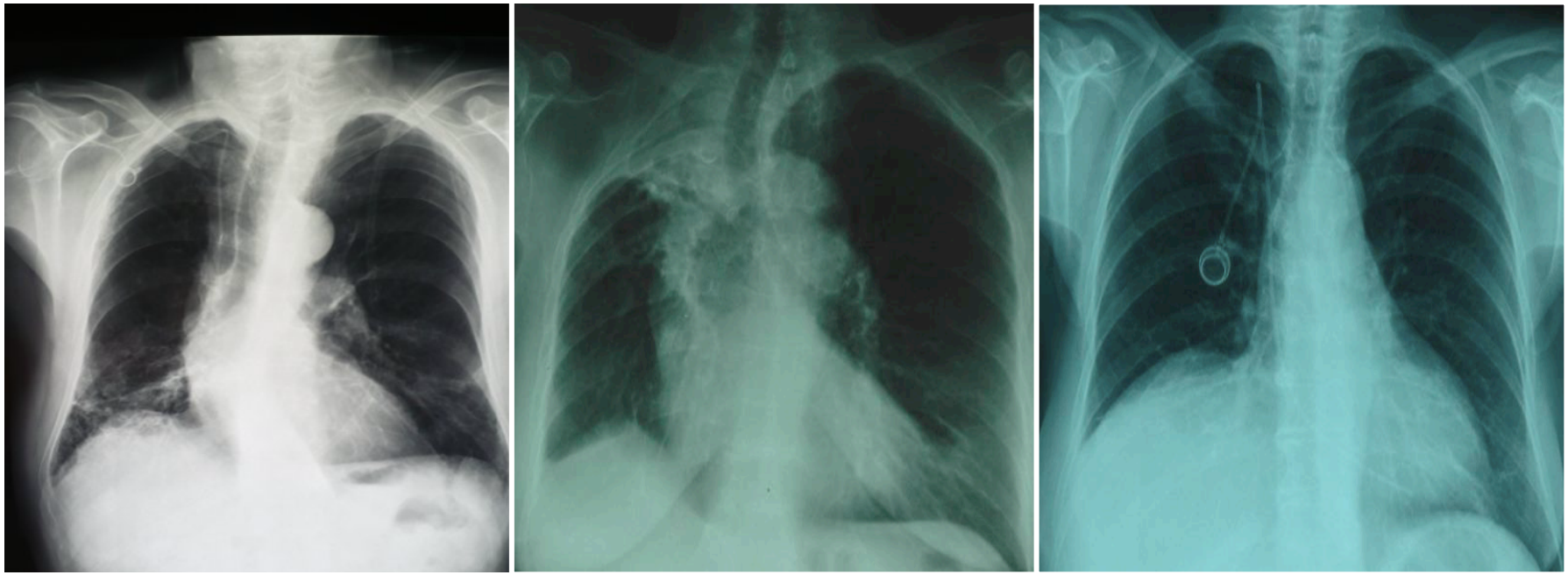


before closure



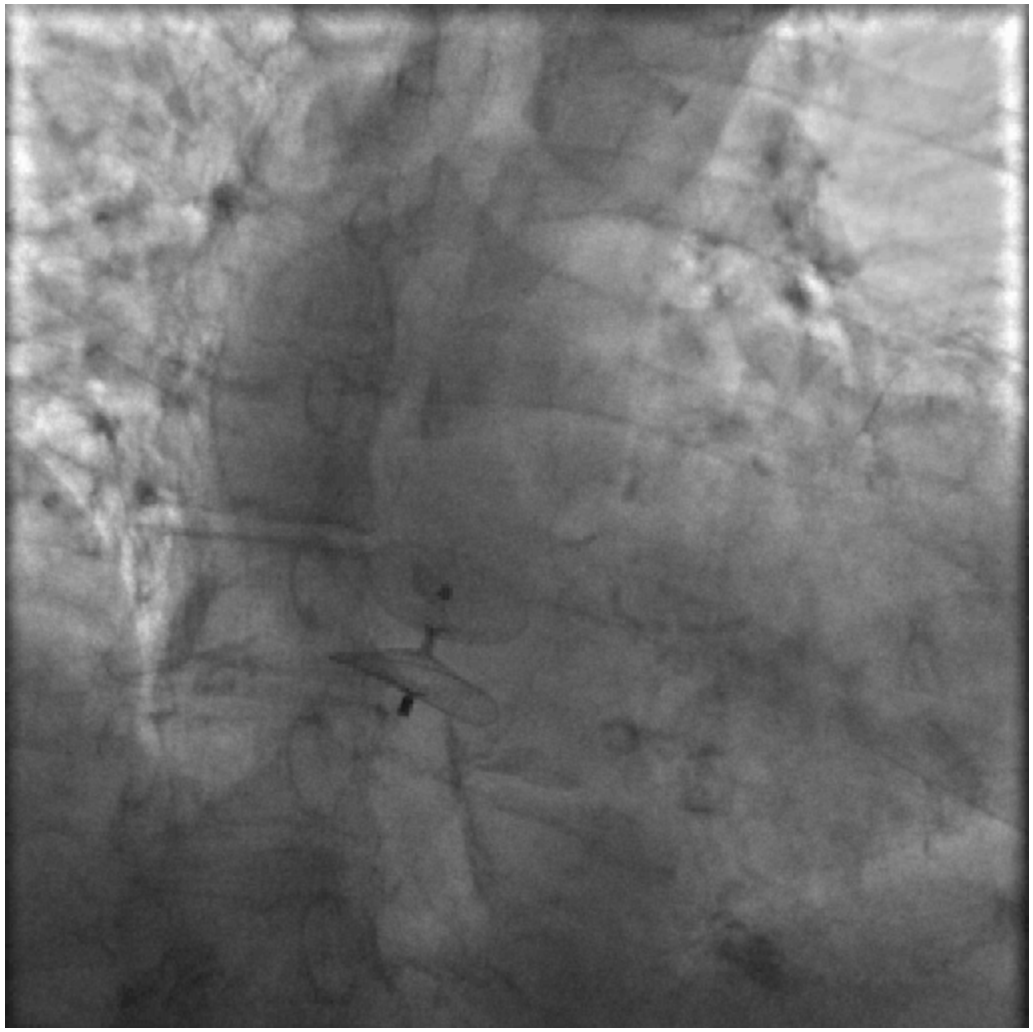
after closure

FOP et hypoxémie



FOP et hypoxémie

FOP et hypoxémie



CCAM Classification Commune des Actes Médicaux

NGAP Nomenclature Générale des Actes Professionnels

CODE	TEXTE
DASF005 [A, F, P, S, U, 7]	04.06.01.01 Actes thérapeutiques sur les cloisons du cœur, à l'étage atrial Fermeture d'un foramen ovale perméable, par voie veineuse transcutanée Avec ou sans : mesure des pressions intracardiaques Indication : platypnée-orthodéoxie chez un patient sous oxygénothérapie au long cours Formation : définie par les recommandations de bonne pratique de la Société française de cardiologie Environnement : défini par les recommandations de bonne pratique de la Société française de cardiologie Facturation : établissement de santé titulaire d'une autorisation d'activité interventionnelle sous imagerie médicale, par voie endovasculaire, en cardiologie Anesthésie (DZQM003, GELE001)

activité interventionnelle en France

≈ 650 prothèses FOP implantées en 2017
(données de l'industrie)

atih
AGENCE TECHNIQUE
DE L'INFORMATION
SUR L'HOSPITALISATION

GHM / Acte DASF005	2016	2017
	400	630

DASF005 [A, F, P, S, U, 7]	04.06.01.01 Actes thérapeutiques sur les cloisons du cœur, à l'étage atrial Fermeture d'un foramen ovale perméable, par voie veineuse transcutanée Avec ou sans : mesure des pressions intracardiaques Indication : platypnée-orthodéoxie chez un patient sous oxygénothérapie au long cours

≈ 150/an

Société Française de Cardiologie
Rythmologie - Stimulation cardiaque

GUIDELINES

Percutaneous occlusion of the left atrial appendage: An expert consensus statement

Consensus d'experts sur les modalités de l'occlusion percutanée de l'auricule gauche

Didier Klug[a,*], Philippe Commeau[b], Pascal Defaye[c], Jean-Benoît Thambo[d], Daniel Gras[e], Pierre Aubry[f], Jean-Luc Pasquie[g], Patrice Guerin[h], Emmanuel Teiger[i], René Koning[j], Olivier Piot[k], for the Heart Rhythm, Pacing Group, the Atheroma, Interventional Cardiology Group of the French Society of Cardiology

Arch Cardiovasc Dis 2015

HAUTE AUTORITÉ DE SANTÉ

SERVICE D'EVALUATION DES DISPOSITIFS

Evaluation de l'occlusion de l'appendice auriculaire gauche par voie transcutanée

(évaluation de l'acte professionnel et des dispositifs médicaux associés)

Rapport d'évaluation technologique

HAUTE AUTORITÉ DE SANTÉ

COMMISSION NATIONALE D'EVALUATION
DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDiMTS

cas clinique

- Mme L. 1963
- 2017: déficit sensitivo-moteur hémicorps gauche suite à sclérose de varices
- Récupération *ad integrum*
- Même épisode environ 1 an auparavant
- IRM: pas d'AVC constitué
- Bilan : FOP/ASIA
- Pas de facteurs de risque connus
- RoPE score = 5/10

Faut-il fermer le FOP ?

cas clinique

Aetoxisclerol : produit induisant la thrombose veineuse

2 à 8 ml de mousse injectable (liquide plus air)

Vidal
Contre-indication : foramen ovale perméable symptomatique connu

Merci de votre attention