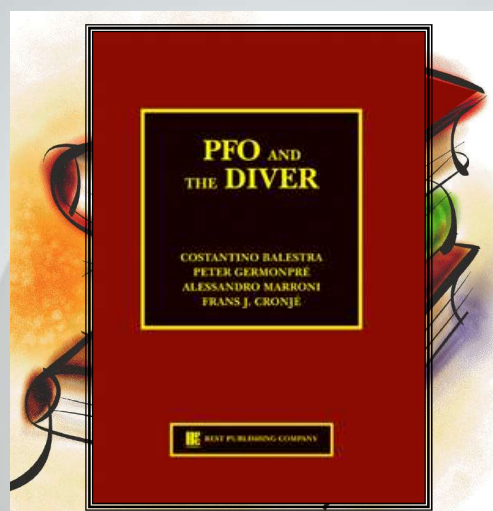


## Patent Foramen Ovale

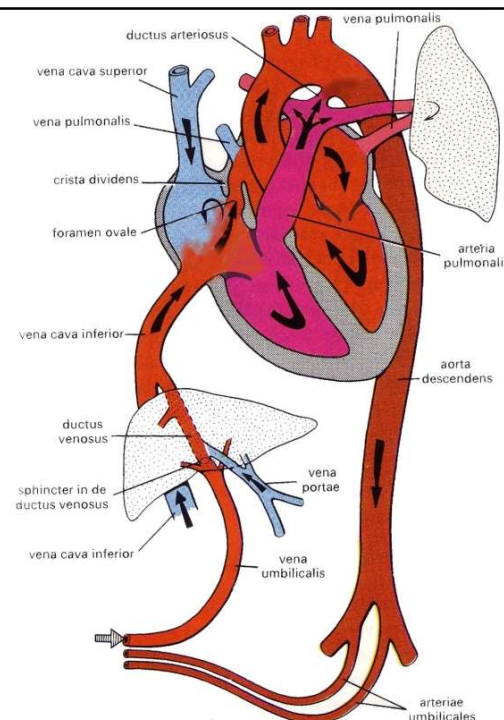
- Anatomy
- Prevalence
- Diagnosis
- Impact
- Advice
- Treatment





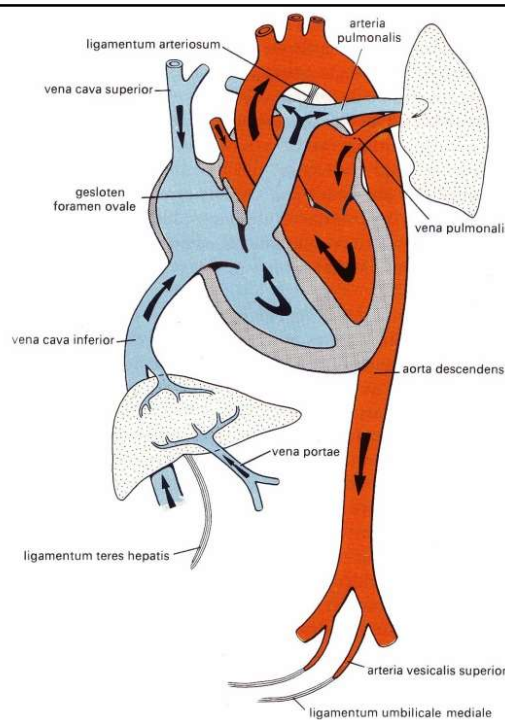
## PFO Anatomy

- Neonatal circulation
  - RA Pressure > LA
  - Fossa Ovalis
  - Valvular structure



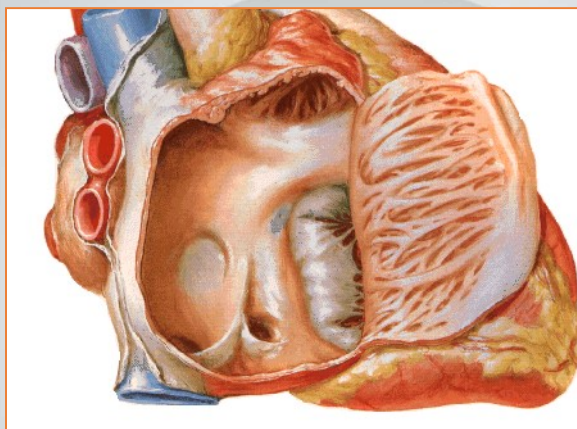
## PFO Anatomy

- Neonatal circulation
  - RA Pressure > LA
  - Fossa Ovalis
  - Valvular structure (remnant of Septum Primum)
- Closure after birth
  - 5 days - 12 months
- 30+ %: persistent residual opening = "PFO"



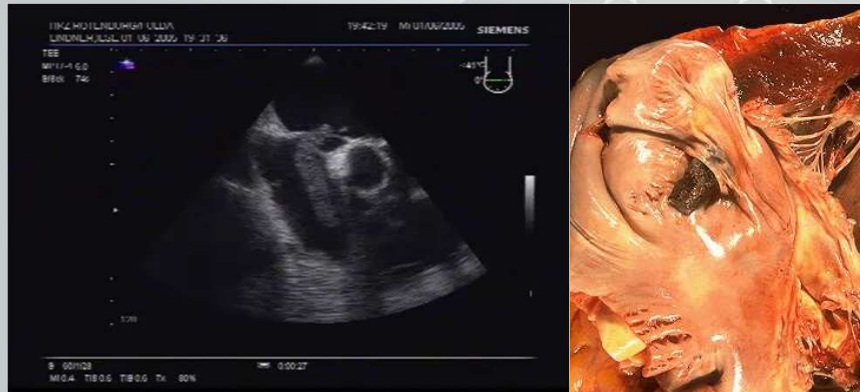
## PFO Anatomy

- Common in young children
- Adults:
  - Right-to-left shunting – rarely of clinical significance
  - Left-to-right shunting (ASD Atrial Septal Defect) – R of L atrial enlargement, cardiac insufficiency



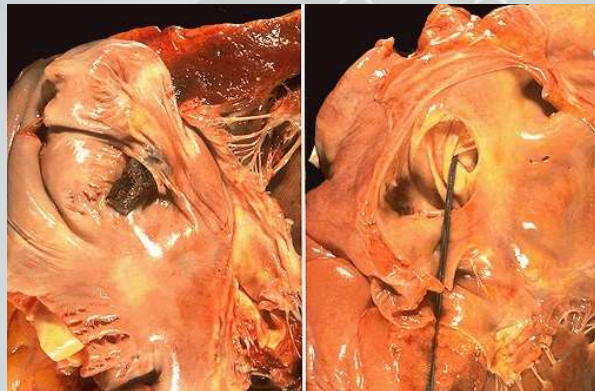
## PFO Pathophysiology

- Possible pathway for paradoxical embolus (thrombus)



## PFO Pathophysiology

- Possible pathway for paradoxical embolus (thrombus)





## PFO Prevalence - autopsy

### Hagen et al. 1984

- 965 autopsy specimens – normal hearts
- PFO evenly distributed by sex, over all age groups
- *Prevalence decreased with age*
  - Overall prevalence: 27.3%
    - 0-29 years: 34.3%
    - 30-69 years: 25.4%
    - 80-99 years: 20.2%
- *PFO size increased with age:*
  - PFO size (n=263)
    - 1-19 mm diameter (mean: 4.9 mm)
    - 98%: 1-10 mm diameter
    - 3.4 mm (0-9 years) to 5.8 mm (80-90 years)

Hagen PT, Scholz DG, Edwards WD. Incidence and size of patent foramen ovale during the first 10 decades of life: an autopsy study of 965 normal hearts. Mayo Clin Proc. 1984 Jan;59(1):17-20.

## PFO Prevalence - indirect studies

- *Meissner et al. 1999* demonstrated a 25.6% prevalence of PFO by TEE in 588 patients
  - 46% 1 mm or larger
  - 57% shunting at rest
- *Fisher et al. 1995* found a 9.2% of PFO by TEE in 1000 consecutive (non-cardiac) patients

*Meissner I et al. Prevalence of potential risk factors for stroke assessed by transesophageal echocardiography and carotid ultrasonography: the SPARC study. Stroke Prevention: Assessment of Risk in a Community. Mayo Clin Proc. 1999;74(9):862.*

*Fisher DC et al. The incidence of patent foramen ovale in 1,000 consecutive patients. A contrast transesophageal echocardiography study. Chest 1995 107: 1504-1509*

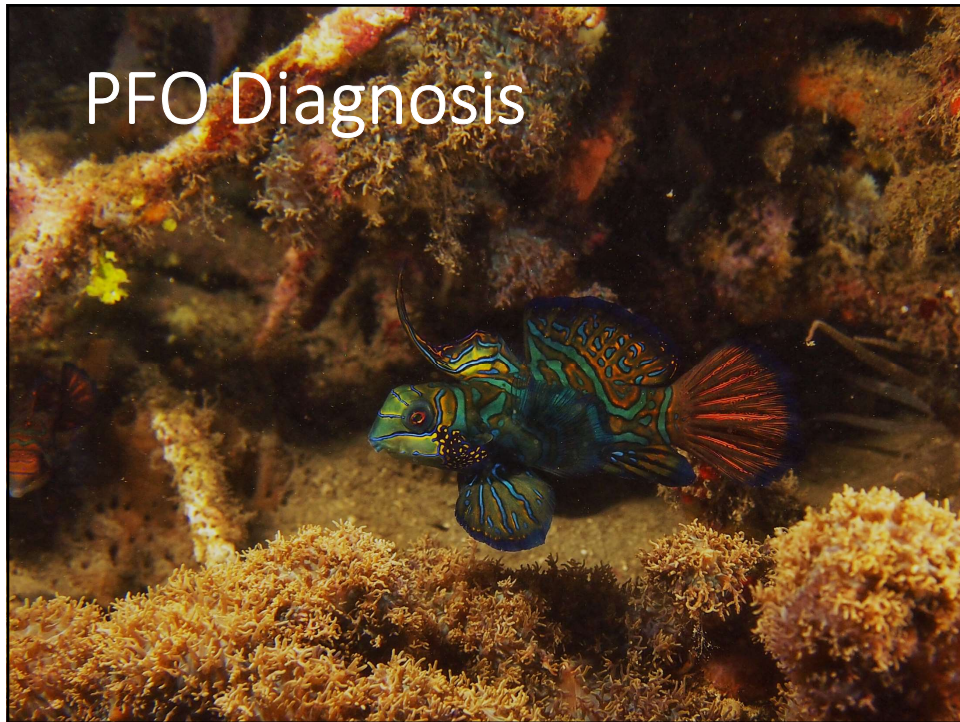
## PFO Prevalence - comparison

Autopsy Studies

Year	Hearts	PFO (%)
1897	399	26
1900	306	32
1918	1809	29
1931	4083	25
1934	500	17
1948	492	23
1972	144	35
1979	64	31
1984	965	27
1994	500	15
TOTAL	9262	25

C-TEE Studies

Year	Hearts	PFO (%)
1988	40	2.5
1989	50	12
1989	64	27
1989	479	6.1
1991	50	26
1991	50	8
1991	150	20
1991	79	17
1991	63	3.2
1995	1000	9.2
TOTAL	2025	10



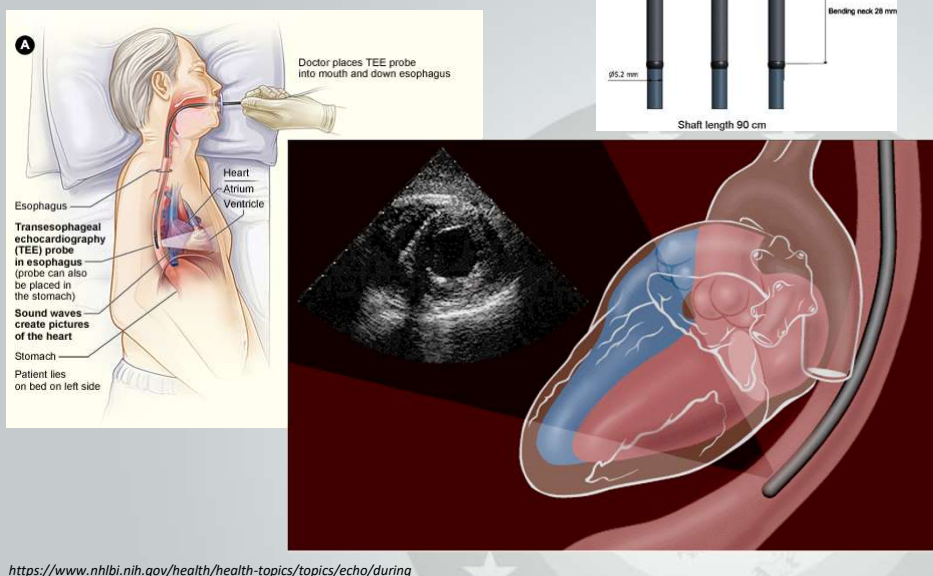
## PFO Diagnosis - overview

- Contrast TEE (Trans-Esophageal echocardiography)
- Contrast TTE (Trans-Thoracic Echocardiography)
- Contrast TCD (Trans-Cranial Doppler)
- Contrast Carotid Doppler
- Ear Lobe SpO<sub>2</sub>
- Multi-slice CT
- Cardiac Catheterisation
- Direct Visualisation (surgery, autopsy)

## PFO diagnosis – gold standard

- Historically – c-TEE
  - However: reports of c-TEE based prevalence of PFO in normal people vary from 9.2 % to 27%
  - Whereas autopsy studies give an “absolute” prevalence of 27.3% (34.5 to 20.2 according to age)
- Pitfalls in contrast studies
  - Visualisation
  - Intracardiac blood flow patterns
  - Insufficient awareness of “false negatives” and “false positives”

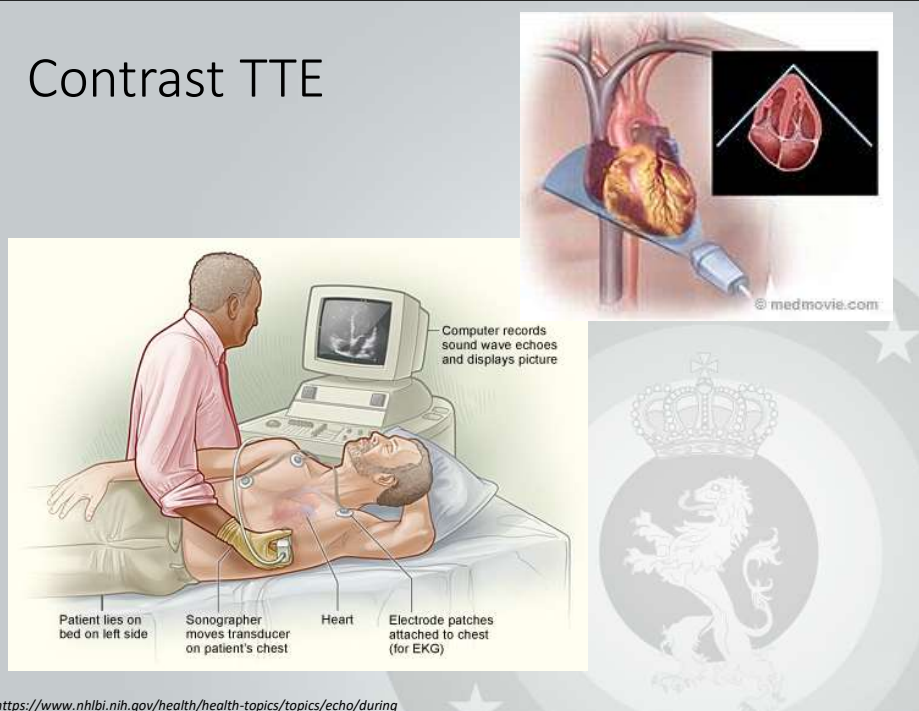
## Contrast TEE



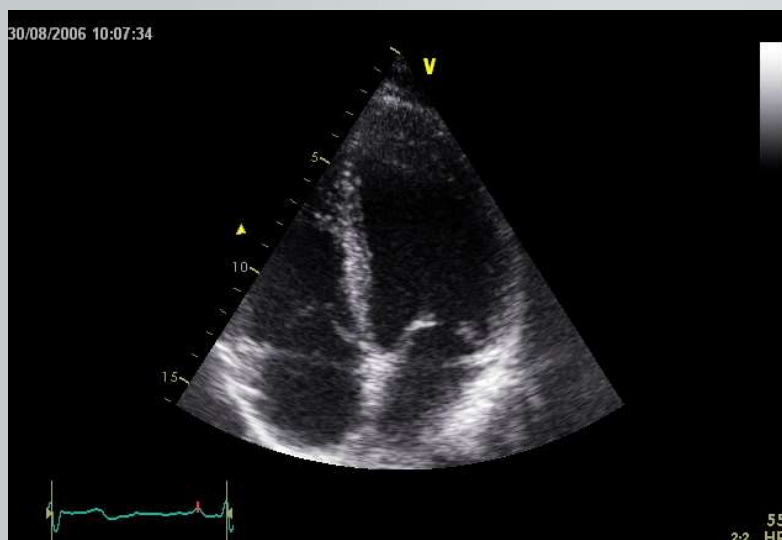
## Contrast TEE



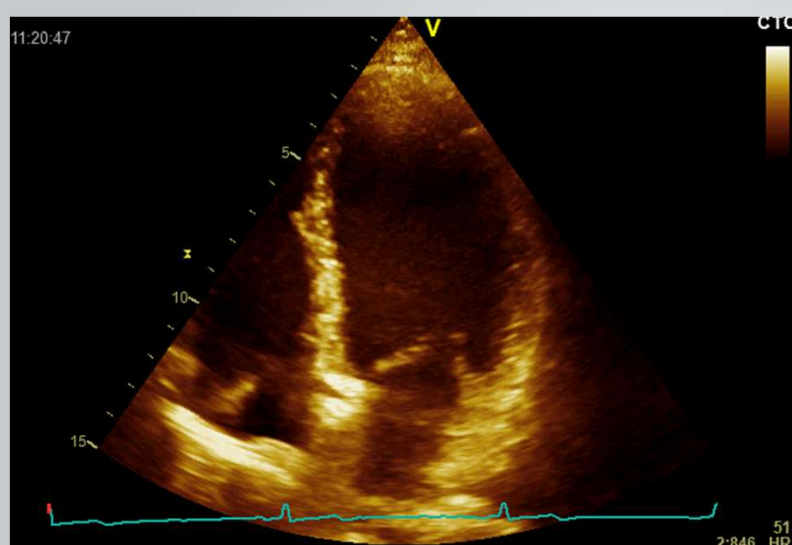
## Contrast TTE



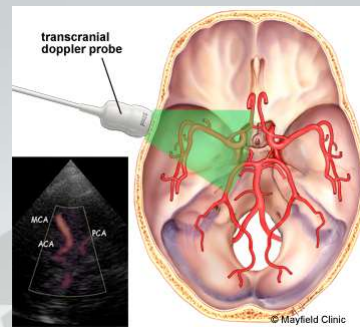
## Contrast TTE



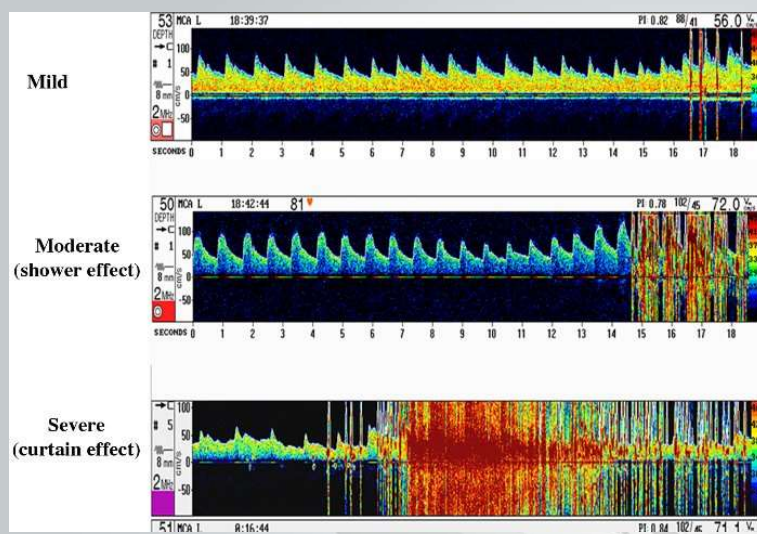
## Contrast TTE



## Contrast TCD



## Contrast TCD



González-Alujas et al. Diagnosis and Quantification of Patent Foramen Ovale. Which Is the Reference Technique? Simultaneous Study With Transcranial Doppler, Transthoracic and Transesophageal Echocardiography. Rev Esp Cardiol. 2011;64:133-9

## Technique Comparison

- Gonzalez-Alujas 2011
  - 134 patients with stroke or migraine

Table 2. Diagnosis of Patent Foramen Ovale Using Different Imaging Techniques.

	Sensitivity, %	Specificity, %	PPV, %	NPV, %
Transcranial Doppler ultrasound	97	98	99	93
Transthoracic echocardiography	100	100	100	100
Transesophageal echocardiography	86	100	100	76

NPV, negative predictive value; PPV, positive predictive value.

*González-Alujas et al. Diagnosis and Quantification of Patent Foramen Ovale. Which Is the Reference Technique? Simultaneous Study With Transcranial Doppler, Transthoracic and Transesophageal Echocardiography. Rev Esp Cardiol. 2011;64:133-9*

## Contrast studies - pitfalls

- Contrast medium
  - Agitated saline
    - With 5% air
    - With 5% blood
  - Other solutions: gelatin solutions
  - Commercial contrast media
- Agitation technique
- Injection site
  - Large antecubital vein
  - Small vein in hand ?
  - Femoral vein ?
- Straining manoeuvre
  - Technique - Timing

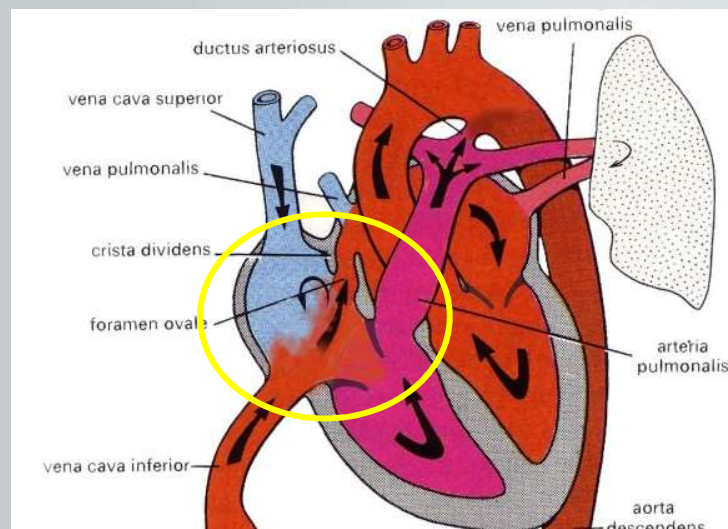
## Contrast studies - pitfalls

- Agitation technique
  - 2x 10cc syringe w/3-way valve



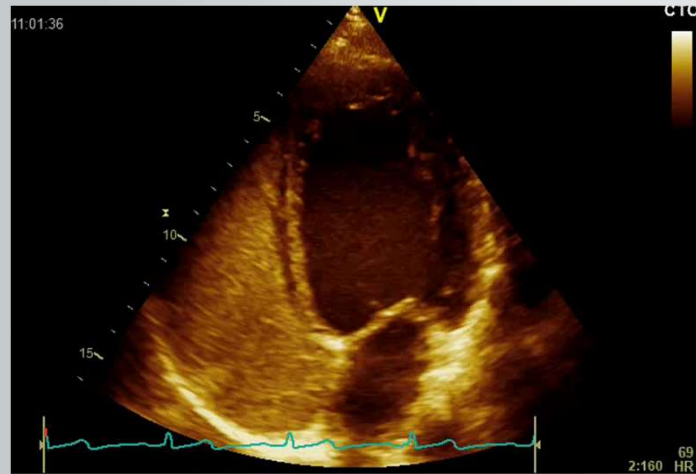
## Contrast studies - pitfalls

- Injection site – blood flow mixing in Right Atrium



## Contrast studies - pitfalls

- Injection site – blood flow mixing in Right Atrium



## Contrast studies - pitfalls

- Injection site – blood flow mixing in Right Atrium



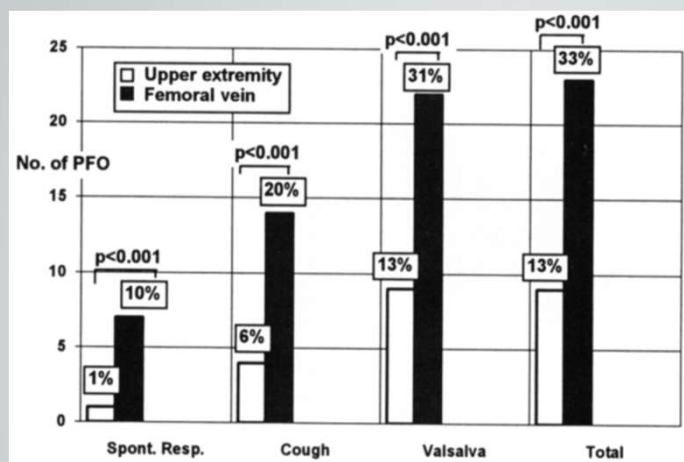
## Contrast studies - pitfalls

- Injection site – blood flow mixing in Right Atrium



## Contrast studies - pitfalls

- Femoral vein injection is superior to antecubital vein injection

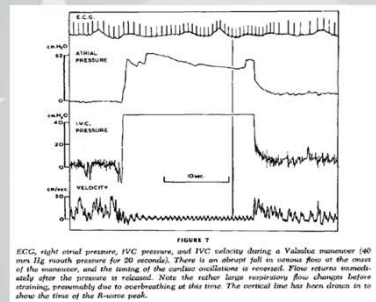


Gin K. et al. Femoral vein delivery of contrast medium enhances transthoracic echocardiographic detection of patent foramen ovale J Am Coll Cardiol 1993;22:1994-2000

## Contrast studies - pitfalls

### Straining Manoeuvre:

- Goals
  - Increase RA Pressure to open PFO
  - Provoke complete mixing of venous blood from SVC and IVC in RA
- Methods
  - Valsalva manoeuvre
  - Abdominal straining
  - Cough
  - Inspiration
  - ...



Wexler L et al. Velocity of blood flow in normal human venae cavae. *Circ Res* 1968 23:349-359

## Contrast studies - pitfalls

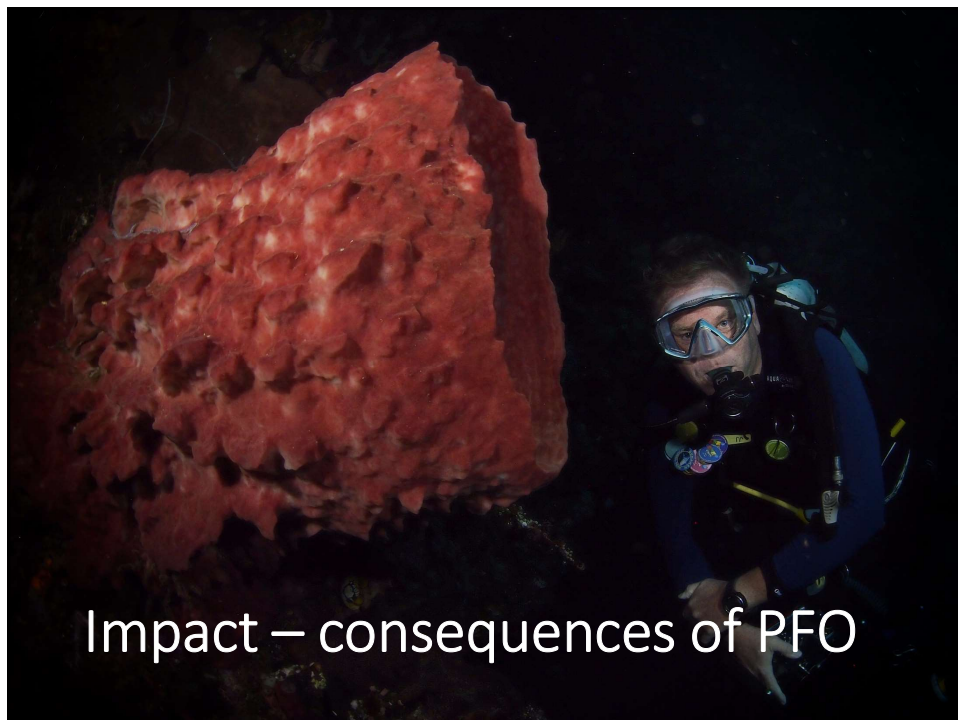
- Straining Manoeuvre:
  - Release of straining manoeuvre is as important as ITP reached
  - Timing is critical !
- Detailed descriptions of “optimal” contrast injection technique:
  - Germonpré P. et al. *Am J Cardiol* 2005
  - Attaran et al. *Echocardiography* 2006

Germonpré P. et al. Evidence for increasing patency of the foramen ovale in sports divers. *Am J Cardiol* 2005; 95: 912-915.

Attaran RR et al. Protocol for optimal detection and exclusion of a patent foramen ovale using transthoracic echocardiography with agitated saline microbubbles. *Echocardiography* 2006; 23: 616-622

## PFO diagnosis – goal ?

- Screening → favour Sensitivity
  - Ideally: no false negatives
  - Drawback: some false positives
  - As less invasive as possible
  - Ear lobe SpO<sub>2</sub> > Carotid Doppler > TCD > TTE
- Diagnosis → favour Specificity
  - Ideally: no false positives
  - Drawback: false negatives = false security
  - Safety, cost
  - TTE vs TEE

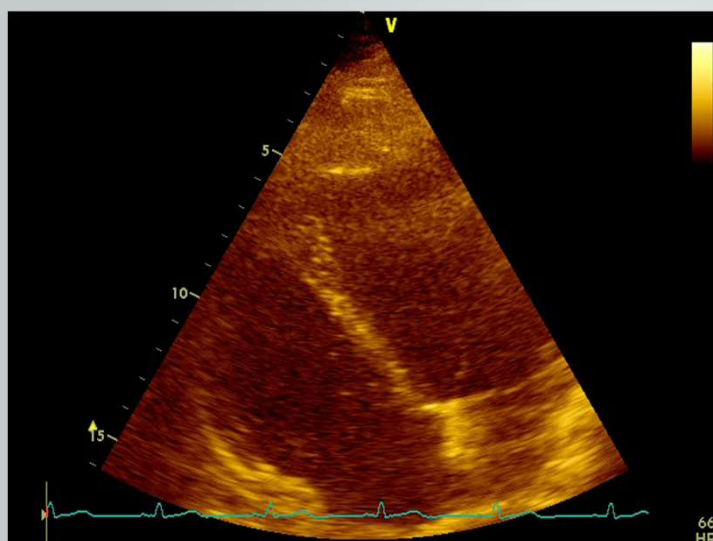


Impact – consequences of PFO

## Impact – consequences of PFO

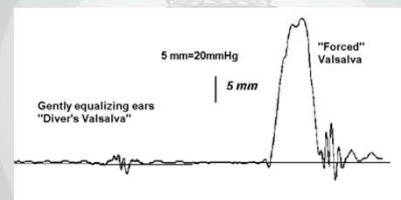
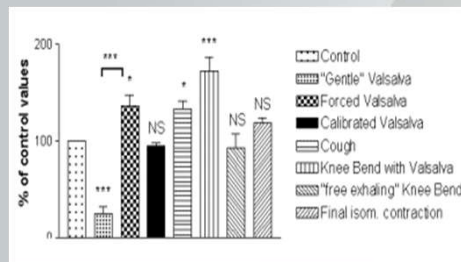
- PFO has been implicated in several pathologies
  - Stroke / TIA / Cryptogenic stroke
  - Decompression sickness (diving, flying, astronauts)
  - (Migraine with aura)
  - (other, rare: Platypnea Orthodeoxia syndrome)
- Risk depends on
  - Presence of emboli (thrombus, gas bubbles)
  - Patency (size) of PFO

## VGE after SCUBA dives



## PFO shunting after intrathoracic pressure changes

- Real-life activities with “straining effect” may provoke PFO opening (like the manoeuvres used in contrast studies)
  - Isometric exercise (lifting tanks, blocking respiration...)
  - Passing stool
  - Thoracic compression



Balestra C et al. Intrathoracic pressure changes after Valsalva strain and other maneuvers: implications for divers with patent foramen ovale. *Undersea Hyperb Med.* 1998 Fall;25(3):171-4.



## PFO and DCS risk

Bove AA. Risk of decompression sickness with patent foramen ovale. *Undersea Hyperb Med* 1998; 25:175-178

- OR for all DCS: 1.93
- OR for Type II DCS : 2.52
- Risk for DCS in diving: 2.28 / 10,000 dives

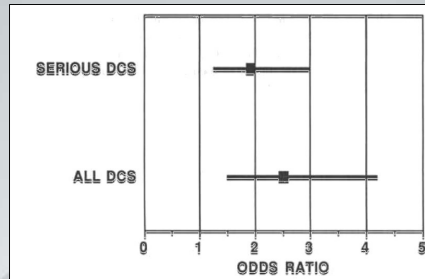


FIG. 1—Plot of odds ratios and 95% confidence intervals for risk of DCS comparing presence of PFO to absence of PFO. Ratio for all forms of DCS and for type II DCS are both significantly greater than one at  $P < 0.001$ .

Table 1: Frequency of DCS in Sport, Military, and Commercial Air Diving Populations

Source Reference	Military (13)	Sport (11,12)	Commercial (14)	All
Total dives <sup>a</sup>	648,488	2,577,680	43,063	3,269,231
Total DCS <sup>a</sup>	172	878	152	1,202
Type II DCS <sup>a</sup>	86	649	9	744
Incidents DCS <sup>b</sup>	2.65	3.41	35.3	3.68
Incidents DCS II	1.33	2.52	2.09	2.28

<sup>a</sup>Values are number of events; <sup>b</sup>incidents per 10,000 dives, DCS II - DCS type II.

## PFO and DCS risk

Torti S.R. et al. Risk of decompression illness among 230 divers in relation to the presence and size of patent foramen ovale. *Eur Heart J* 2004; 25:1014–1020

- OR for major DCS : 4.8 – 5.7
- Risk for DCS overall : 2.5 / 10,000 dives

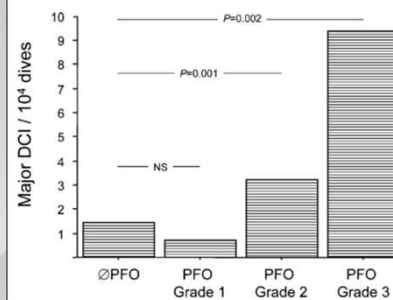


Fig. 3 Mean number of DCI events per 10<sup>4</sup> dives (vertical axis) in relation to different sizes of patent foramen ovale (no PFO: ∅PFO = PFO grade 0).

Table 3 Degree of patent foramen ovale and risk of major decompression events (corrected for number of dives)

	∅PFO	Risk ratio with PFO grade 1	Risk ratio with PFO grade 2	Risk ratio with PFO grade 3	Risk ratio per 100 dives
Number of divers	167	13	27	23	
Major DCI	—	1.1 (0.14–8.4)	4.4 (1.8–10.7)	6.6 (2.8–15.5)	1.02 (1.0–1.04)
DCI > 24 h <sup>a</sup>	—	— <sup>b</sup>	6.7 (1.9–23.8)	7.6 (2.1–28.0)	1.03 (1.0–1.06)
Stay in decompression chamber	—	— <sup>b</sup>	18.2 (4.1–81.4)	16.7 (3.5–80.8)	1.04 (1.01–1.07)

Abbreviations: DCI: decompression illness, PFO: patent foramen ovale; ∅PFO: no patent foramen ovale.

<sup>a</sup> DCI > 24 h = decompression illness lasting longer than 24 h.

<sup>b</sup> No diver in this group had a corresponding decompression event.

## PFO and DCS risk

Germonpré et al. 1998

- 37 divers with neurological DCS vs. non DCS controls
- TEE : PFO quantified (number of bubbles)
- Only DCS presentations associated with PFO
  - Cerebrum
  - Cerebellum
  - High Cervical Spinal Cord
  - Inner ear
- Low spinal cord / pain-only DCS not associated
- For “undeserved DCS”: significant for large PFOs only

Germonpré P et al. Patent foramen ovale and decompression sickness in sports divers. *J Appl Physiol* (1985). 1998 May;84(5):1622-6.

## PFO and DCS risk

Table 1. Prevalence of PFO

	No. of Divers With PFO	No. of Divers With Grade 2 PFO
All types of DCS ( <i>n</i> = 37)	22 (59.5)	19 (51.3)
All control ( <i>n</i> = 36)	13 (36.1)	9 (25)
<i>P</i>	0.06	0.03
Cerebral DCS ( <i>n</i> = 20)	16 (80)	14 (70)
Matched control ( <i>n</i> = 20)	5 (25)	3 (15)
<i>P</i>	0.012	0.002
Spinal DCS ( <i>n</i> = 17)	6 (35.2)	5 (29.4)
Matched control ( <i>n</i> = 16)	8 (50)	6 (37.5)
<i>P</i>	0.49	0.29

PFO, patent foramen ovale; *n*, no. of divers; *grade 2* PFO, important ( $\geq 20$  bubbles) contrast passage at rest or after Valsalva strain; DCS, decompression sickness. Nos. in parentheses are %total. Divers with cerebral DCS had a significantly higher prevalence of PFO than did control divers without DCS. Prevalence of PFO in divers with spinal DCS is not significantly different from that in control population.

Germonpré P et al. Patent foramen ovale and decompression sickness in sports divers. *J Appl Physiol* (1985). 1998 May;84(5):1622-6.

## PFO and DCS risk

Table 2. All shunts visualized by transcranial Doppler ultrasonography

	Yes	No	p	Odds Ratio for DCI With vs. Without Shunt (95% Confidence Interval)
Control group, n = 101	25 (24.8)	76 (75.2)		
DCI group, n = 101	59 (58.4)	42 (41.6)	.09	4.3 (2.3 < OR < 7.8)
Cochleovestibular DCI, n = 34	28 (82.4)	6 (17.6)	<.001	14.2 (5.3 < OR < 38.2)
Cerebral DCI, n = 21	17 (81)	4 (19.0)	<.001	12.9 (4.0 < OR < 42.0)
Spinal DCI, n = 31	12 (38.7)	19 (61.3)	.13	1.9 (0.8 < OR < 4.5)
Osteomyoarticular DCI, n = 15	2 (13.3)	13 (86.7)	.3	0.5 (0.1 < OR < 2.2)

DCI, decompression illness; OR, odds ratio.

Cantais E et al. Right-to-left shunt and risk of decompression illness with cochleovestibular and cerebral symptoms in divers: case control study in 101 consecutive dive accidents. *Crit Care Med.* 2003 Jan;31(1):84-8.

## Other types of Right-to-Left shunt

- Asymptomatic bubbles are very common after recreational diving
  - DAN (USA) studies on sports divers, multi-day repetitive dives
  - 91% of divers detectable bubbles
  - 73% of dives produced VGE (Doppler), 35% Grade II (Spencer scale)
- Right to Left shunting possible through PFO or intrapulmonary shunts (IPAVA) (Madden et al. 2015)
  - Up to 52% of divers without PFO arterialise VGE when performing moderate to strenuous exercise closely after the dive

Madden et al. Intrapulmonary Shunt and SCUBA Diving: Another Risk Factor? *Echocardiography* 2015; 32: S205-S210



## Should all divers be screened ?

- Incidence of DCS in recreational diving :
  - Difficult to estimate (number of dives often not known)
  - Varies according to type of diving activity

Decompression sickness (DCS and AGE)			
Military Divers (US)	1/76000 dives	Arness <sup>68</sup>	Estimation
Recreational Divers (Aus)	1/15000 dives	SPUMS <sup>69</sup>	Estimation
Recreational Divers (USA)	1/2900 dives	Bove <sup>70</sup>	Fact
Commercial Divers (USA)	1/280 dives	Bove <sup>70</sup>	Fact
Military Divers (USA)	1/3770 dives	Bove <sup>70</sup>	Fact
Recreational Divers <-30m (Europe)	1/40228 dives	DAN Europe <sup>71</sup>	Estimation
Recreational Divers (any depth) (Euro)	1/6604 dives	DAN Europe <sup>71</sup>	Estimation
Sports Divers (UK)	1/10500 dives	BSAC <sup>66</sup>	Estimation
Sports Divers (Cold Water Wrecks)	1/270 dives	DAN USA <sup>2</sup>	Fact
Dive Instructors Liveaboard	1/1000 dives	DAN USA <sup>2</sup>	Fact
Sports Divers (Cold Water)	1/1250 dives	Trevett et al. <sup>72</sup>	Fact

Germonpre P The medical risks of underwater diving and their control. Internat SportMed Journal 2006 7:1-15

## Science vs. gut feeling

- Based on a 2.5-5 times higher DCS risk when you have a PFO, most recreational divers should not be worried about it (Bove 1998)
  - 2.28 / 10,000 dives neurological DCS
  - Presence of a PFO increases DCS risk by 1.8 times the average population risk
  - Absence of a PFO reduces DCS risk to 0.67 times the average population risk
- Post-dive VGE numbers depend on depth/time/gas but also on other - unknown - factors

*Bove AA. Risk of decompression sickness with patent foramen ovale. Undersea Hyperb Med 1998; 25:175-178*

## PFO size may change over time

- Mayo Clin 1984 autopsy study: PFO size increases with age:
  - 3.4 mm (0-9years) to 5.8 mm (80-90 years)
- Longitudinal c-TEE study: 7.15 years difference

Grade	Initial cTEE Study	Evolution			Final cTEE Study
		Grade	No.	Years/Dives	
0	20 (50%)	0	16	7.24/279	19 (47.5%)
		1	3	7.68/557	
		2	1	7.0/150	
		0	3	7.04/217	
1	9 (22.5%)	1	1	5/450	4 (10%)
		2	5	7.54/218	
		0	0		
2	11 (27.5%)	1	0		
		2	11	7.15/325	
Total	40				40

*Germonpre P et al. Evidence for Increasing Patency of the Foramen Ovale in Divers. Am J Cardiol 2005;95:912-915*

## Treatment – is the PFO to blame ?


### DCS with PFO-related characteristics

- Germonpré 1998, Cantais 1999
  - Cerebrum
  - Cerebellum
  - Inner ear / eye
  - High cervical spinal cord
  - But NOT the lower spinal cord or pain-only DCS
- Wilmshurst 1989-2001
  - Neurological symptoms within 30 minutes after the dive
  - “cutis marmorata” skin rashes early after surfacing

Justifies PFO detection – using c-TTE, TCD, or c-TEE

## Treatment – FIRST: counselling

- Explain the significance of PFO
- Explain that the presence of PFO increases the risk for developing serious neurological DCS by 2.5 times
- Advise them to dive (more) conservatively
- Avoid activities post-dive that induce right-to-left shunting
- Stop diving
- Have the PFO closed



SWISS UNDERWATER AND HYPERBARIC MEDICAL SOCIETY  
SCHWEIZERISCHE GESELLSCHAFT FÜR UNTERWASSER-  
UND HYPERBARMEDIZIN  
SOCIÉTÉ SUISSE DE MÉDECINE SUBAQUATIQUE ET HYPERBARE  
SOCIETÀ SVIZZERA DI MEDICINA SUBACQUEA E IPERBARICA

# FOP

RECOMMANDATIONS 2007  
DE LA SOCIÉTÉ SUISSE DE MÉDECINE  
SUBAQUATIQUE ET HYPERBARE  
POUR LA PLONGÉE AVEC UN  
FORAMEN OVALE PERMÉABLE

## 15 Règles pour la plongée „low bubble diving“

.... diminution de la formation de bulles:

- 1 Débuter la plongée à la profondeur maximale prévue.
- 2 Pas de plongée yoyo. Pas de descentes répétitives dans la zone des 10m.
- 3 Réduction de la vitesse de remontée à 5 m/min. pour les derniers 10 m.
- 4 Palier de sécurité entre 3 et 5 m pendant au minimum 5 à 10 minutes.
- 5 Uniquement des plongées dans la courbe de sécurité. Pas de plongée avec décompression.
- 6 Au minimum 4 heures d'intervalle de surface avant la prochaine plongée.
- 7 Maximum deux plongées par jour.
- 8 Au moins deux heures d'attente avant de rejoindre un point plus élevé en altitude que le site de plongée.
- 9 Eviter un grand réchauffement de la peau après la plongée. P ex. bain de soleil, douche chaude, sauna.
- 10 Eviter le froid, la déshydratation ainsi que l'abus de nicotine.
- 11 Plonger avec un mélange de Nitrox mais avec les tables de décompression à l'air. Attention à la toxicité de l'O<sub>2</sub>.
- 12 Des ordinateurs de plongée avec des logiciels spécialisés permettent de diminuer les risques.

.... diminution du risque de passage des bulles dans la circulation artérielle:

- 13 Pas d'effort physique dans les 10 derniers mètres de la remontée. Eviter le travail physique ainsi que le palmage dans les courants en fin de plongée.
- 14 Pas d'effort physique dans les 2 heures qui suivent une plongée. Ne pas gonfler son gilet par insufflation directe. Décapelage dans l'eau et prise en charge du matériel par des aides à la sortie. Pas de remontée en force sur le bateau ou sur la rive (sans pression!). Le matériel lourd ne sera pas transporté par le plongeur.
- 15 Défense formelle de plonger en cas de refroidissement. La toux ainsi que les manœuvres d'équilibre forcées (Valsalva) favorisent le passage de bulles.

Ces recommandations de la SUHMS correspondent à l'état d'évidence de la littérature et au consensus d'experts, fin 2006.

## Treatment – PFO closure

### Is the PFO to blame ?

**Large PFO :** *Schuchlenz et al. 2000:* The diameter of a PFO is an independent risk factor for ischemic events, especially recurrent strokes

- PFO larger than 4mm yields an odds ratio of
  - 3.4 for TIA
  - 12 for ischemic stroke
  - 27 for two or more strokes

**Atrial Septal Aneurysm:** *Mas et al. 2001:* 581 patients with recent ischemic stroke of unknown origin; all received anti-platelet treatment

- After 4 years, risk of recurrent stroke was
  - 2.3% with PFO
  - 15.2% with PFO + atrial septal aneurysm
  - 4.2% with no PFO, no aneurysm

Schuchlenz HW et al. The association between the diameter of a patent foramen ovale and the risk of embolic cerebrovascular events. *Am J Med.* 2000 Oct 15;109(6):456-62

Mas JL et al. Recurrent cerebrovascular events associated with patent foramen ovale, atrial septal aneurysm, or both. *N Engl J Med.* 2001 Dec 13;345(24):1740-6.

## Treatment – PFO closure

### Surgical Repair

- Significant morbidity (cardiopulmonary bypass)
- Closed when found during open cardiac surgery

### Percutaneous closure

- Placed over catheter wires from the femoral vein
- Early devices were bulky
- Newer devices:
  - Less metal (nitinol wires)
  - Less tissue (dacron)
  - Self-centering design
  - Easy, short (30 minutes) procedure with low morbidity

## Treatment – PFO closure



CardioSEAL-STARFlex  
Nitinol Medical Technologies, Boston, Massachusetts



CardioSEAL  
Nitinol Medical Technologies, Boston, Massachusetts



Amplatzer PFO Occluder  
AGA Medical, Golden Valley, Minnesota



Helex Occluder  
W.L. Gore and Associates, Inc, Flagstaff, Arizona



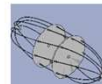
PFO-Star  
CARDIA, Burnsville, Minnesota



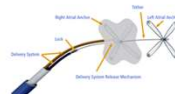
Guardian Angel  
Microvena Corporation, White Bear Lake, Minnesota



Sideris Buttoned Device  
Custom Medical Devices, Amarillo, Texas



Solysafe Device  
CARAG AG, Baar, Switzerland



Premere Device  
SJM, St. Paul, Minnesota, USA

## PFO closure - Complications

Complications <30 days (2008 review)

	Windecker <sup>30</sup>	Windecker <sup>29</sup>	Braun <sup>28</sup>
Procedures	150	78	307
Device embolization (%)	4 (2.7)	3 (3.9)	1 (0.3)
Cardiac tamponade (%)	—	1 (1.3)	—
Retroperitoneal hematoma (%)	—	1 (1.3)	—
Air embolus (%)	3 (2)	—	—
Access site problems (%)	2 (1.3)	—	—
Transient ST elevations (%)	—	2 (2.6)	5 (1.6)
AV fistula (%)	—	—	1 (0.3)

Wechsler LR. PFO and stroke: what are the data? *Cardiol Rev* 2008(16):53-57

## PFO closure - Complications

Complications <30 days (2013 review)

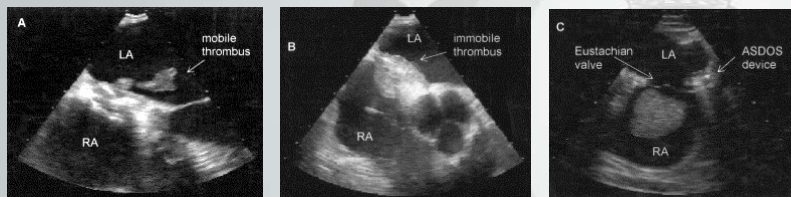
**Table 3. Short- and Long-Term Outcomes After Transcatheter PFO Closure**

Procedural success	793 (99)
30-day outcomes	
Death	0.1 (1/793)
Stroke	0.0 (0/793)
Recurrent	0.0 (0/749)
De novo	0.0 (0/749)
TIA	0.1 (1/793)
Recurrent	0.1 (1/749)
De novo	0.0 (0/44)
Device embolization	0.5 (4/793)
Tamponade	0.6 (5/793)
DVT	0.1 (1/793)

Inglessis I et al. Long-Term Experience and Outcomes With Transcatheter Closure of Patent Foramen Ovale  
*J Am Coll Cardiol Interv* 2013;6:1176-83

## PFO closure – Complications; antico

Occluder	n	TEE Due (n)	TEE Performed (%)		Thrombus (% , n)	
		6 Months	4 Weeks	6 Months	4 Weeks	6 Months
Rashkind	1	1	100%	100%	0%	0%
Buttoned Device	52	52	67%	69%	0%	0%
ASDOS	42	42	66%	83% (n = 1)	0%	0%
Angel Wings	30	30	0%	0%	0%	3.3% (n = 1)
CardioSEAL	27	27	0%	93%	7.1% (n = 1)*	0%
StarFLEX	142	142	74%	70%	5.7% (n = 6)*	0%
Amplatzer	418	375	78%	70%	0%*	0.3% (n = 1)
PFO-Star	127	127	60%	66%	6.6% (n = 5)*	1.5% (n = 1)
Helex	161	138	76%	80%	0.8% (n = 1)	0%



Krumsdorf U et al. Incidence and clinical course of thrombus formation on atrial septal defect and patent foramen ovale closure devices in 1,000 consecutive patients. J Am Coll Cardiol. 2004 Jan 21;43(2):302-9.

## PFO Closure - summary

- Procedural success in 95-98% over 3 months
- Complication rate
  - Minor complications (Hematoma, ES, AFib, headaches): 9-10%
  - Major complications (air embolus, cardiac tamponade, device embolization) : 1%
  - Late complications
    - Cardiac wall erosion (Amplatzer) – up to 8 years (0.1-0.3%)
    - Metal wire break (Starflex, Cardiastar)
- Oral anticoagulation (anti Vit K) or dual anti-platelet therapy (ASA + clopidogrel) for 3 – 6 months
- Return to diving ?

Schwerzmann M. Hazards of percutaneous PFO closure. Eur J Echocardiography 2005; 6, 393-395

Christen T. et al. Late cardiac tamponade after percutaneous closure of a patent foramen ovale. Eur J Echocardiography 2005; 6, 465-469

## PFO Closure and diving safety

- PFO Closure is effective in reducing arterial gas emboli post-dive (Honek et al. 2014)
  - 20 DCS divers with Gr3 PFO – closed with AMP (25%) or Occlutech (75%)
  - 27 Control divers with Gr3 PFO
  - Dive A – “dry” dive 18m 80min (7' stop 3m) (19+ and 15- divers)
  - Dive B – “wet” dive 50m 20min (4' stop 6m, 15' stop 3m) (8+ and 5- divers)
  - Venous bubbles by TTE, arterial bubbles by TCD

Honek J. Effect of Catheter-Based Patent Foramen Ovale Closure on the Occurrence of Arterial Bubbles in Scuba Divers. *J Am Coll Cardiol Interv* 2014;7:403–8)

## PFO Closure and diving safety

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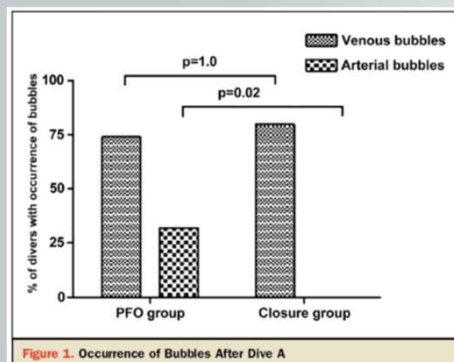


Figure 1. Occurrence of Bubbles After Dive A

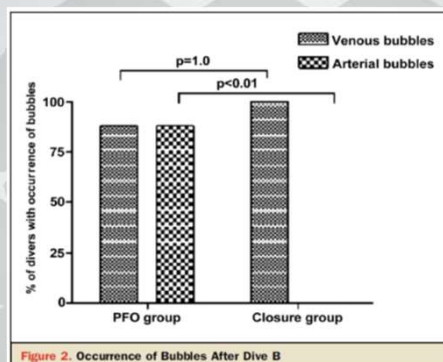


Figure 2. Occurrence of Bubbles After Dive B

Honek J. Effect of Catheter-Based Patent Foramen Ovale Closure on the Occurrence of Arterial Bubbles in Scuba Divers. *J Am Coll Cardiol Interv* 2014;7:403–8)

## PFO Closure and diving safety

- PFO Closure is effective in reducing arterial gas emboli post-dive (Honek et al. 2014)
- PFO Closure reduces DCS incidence in unrestricted diving (Billinger et al. 2011)
  - 104 divers with neurological DCS, prospective study
  - 18,394 dives in 5.3 years (approx 50 dives/yr/diver)

	No PFO	Closed PFO	Open PFO
Divers	39	26	39
Neurologic DCI / 10 <sup>4</sup> dives	0 / 10 <sup>4</sup>	0.5 / 10 <sup>4</sup>	35.8 / 10 <sup>4</sup>
Neurologic DCI events Abs	<b>0</b>	<b>1</b>	<b>4</b>
Brain lesions / 10 <sup>4</sup> dives	16	6	104

*Billinger M. et al. Patent foramen ovale closure in recreational divers: effect on decompression illness and ischaemic brain lesions during long-term follow-up. Heart. 2011 Dec;97(23):1932-7*

## PFO Closure and diving safety

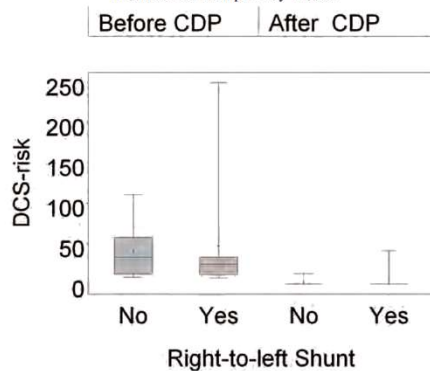
- PFO Closure is effective in reducing arterial gas emboli post-dive (Honek et al. 2014)
- PFO Closure reduces DCS incidence in unrestricted return to diving (Billinger et al. 2011)
- **“Conservative diving” reduces DCS incidence without PFO closure (Klingmann et al. 2012)**

*Klingmann et al. Lower risk of DCS after recommendation of conservative decompression practices in divers with and without vascular R/L shunt. DHM 2012; 42: 146-150*

## PFO Closure and diving safety

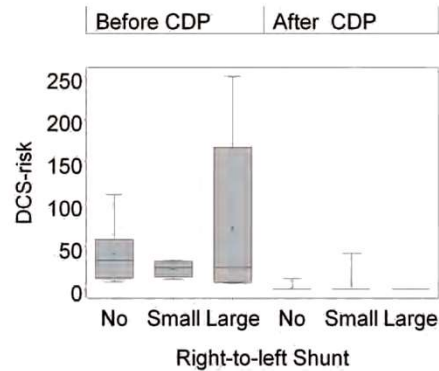
**Figure 1**

Box plots of DCS risk before and after advice on reducing nitrogen loading during diving with respect to the presence or absence of a patent foramen ovale; DCS risk – DCS events per 10,000 dives multiplied by 10,000



**Figure 2**

Box plots of DCS risk before and after advice on reducing nitrogen loading during diving with respect to right-to-left shunt size; DCS risk – DCS per 10,000 dives multiplied by 10,000



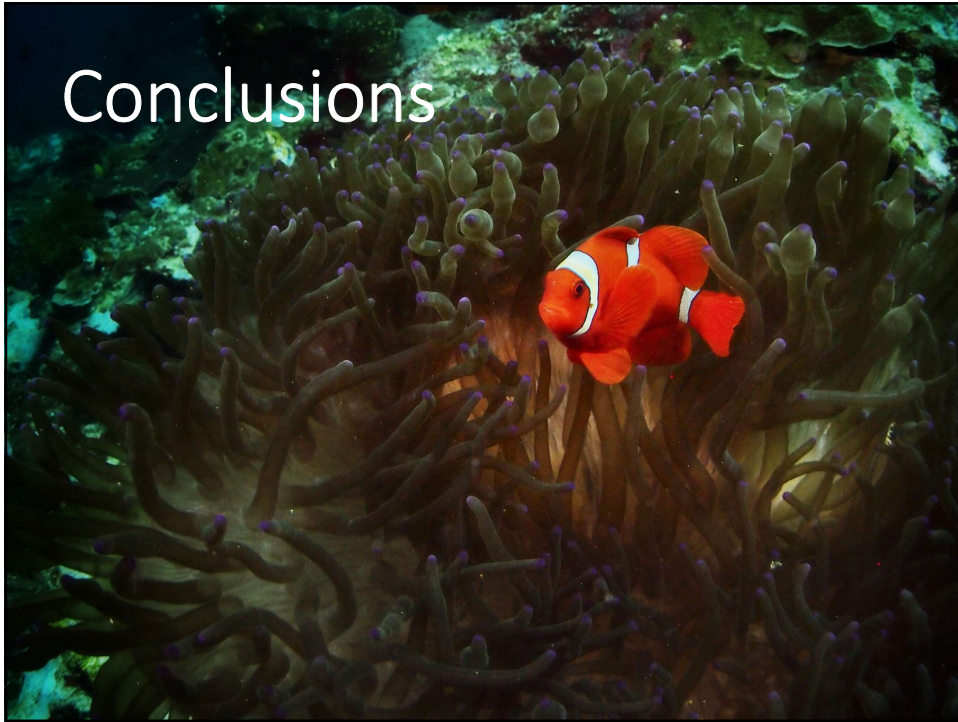
Klingmann et al. Lower risk of DCS after recommendation of conservative decompression practices in divers with and without vascular R/L shunt. DHM 2012; 42: 146-150

## PFO Closure and diving safety

- PFO Closure is effective in reducing arterial gas emboli post-dive (Honek et al. 2014)
- PFO Closure reduces DCS incidence in unrestricted return to diving (Billinger et al. 2011)
- “Conservative diving” reduces DCS incidence without PFO closure (Klingmann et al. 2012, also: Honek et al. 2014 )
- VGE can become arterialized through IPAVA - Intrapulmonary Arteriovenous Anastomoses (Madden et al. 2013)
  - Physical exercise 10 min after diving increased arterialization from 13% to 52% (divers with no PFO)

Madden D, et al. Exercise after SCUBA diving increases the incidence of arterial gas embolism. J Appl Physiol 2013; 115: 716–722

# Conclusions



## PFO – dilemmas

- To screen or not to screen a diver ?
- To close or not to close a PFO ?
- Recommendations should be based on
  - Necessity of active secondary prevention
  - Risk pattern of diving (needing to – or wishing to be) performed
  - Possible relation of DCS to PFO
  - Other concerns for paradoxical embolism (migraine, thrombotic propensity)
- Guidelines for Divers are different than Guidelines for Stroke !
  - Prevention of thrombi = lifelong anticoagulation
  - Prevention of VGE after diving = change diving profiles
- For recreational diving, there is no medical need to close the PFO

## PFO – guidelines & help

Diving and Hyperbaric Medicine Volume 45 No.2 June 2015

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### Joint position statement on persistent (patent) foramen ovale (PFO) and diving

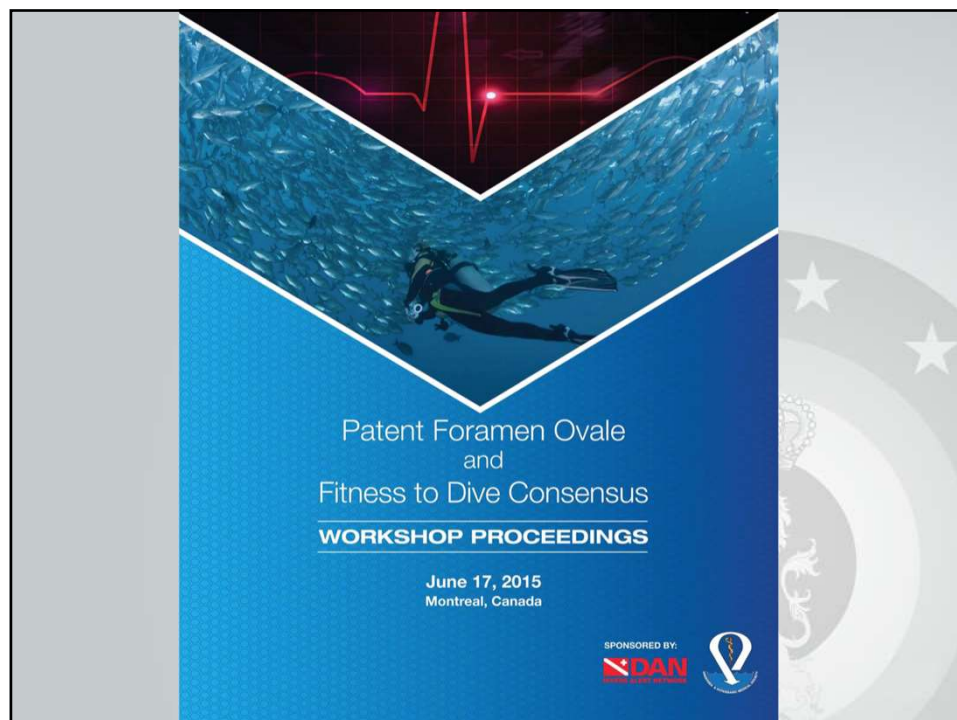
South Pacific Underwater Medicine Society (SPUMS) and the United Kingdom Sports Diving Medical Committee (UKSDMC)

David Smart, Simon Mitchell, Peter Wilmshurst, Mark Turner and Neil Banham

#### Abstract

(Smart D, Mitchell S, Wilmshurst P, Turner M, Banham N. Joint position statement on persistent (patent) foramen ovale and diving. South Pacific Underwater Medicine Society (SPUMS) and the United Kingdom Sports Diving Medical Committee (UKSDMC). *Diving and Hyperbaric Medicine*. 2015 June;45(2):NN-nn.)

This consensus statement is the result of a session at the SPUMS Annual Scientific Meeting 2014 with representation of the UK Sports Diving Medical Committee (UKSDMC) present, and subsequent discussions included the entire UKSDMC committee. Right-to-left shunt across a persistent or patent foramen ovale (PFO) is a risk factor for some types of decompression illness. It was agreed that routine screening for PFO is not currently justifiable, but certain high risk sub-groups can be identified. Divers with a history of decompression illness, migraine with aura, a family history of PFO or atrial septal defect and those with other forms of congenital heart disease are considered to be at higher risk, and for these individuals screening should be considered. If screening is undertaken it should be by bubble contrast transthoracic echocardiography with provocative manoeuvres (including Valsalva release and sniffing). Appropriate quality control is important. If a shunt is present, advice should be provided by an experienced diving physician taking into account the clinical context and the size of shunt. Reduction in gas load by limiting depth, repetitive dives and avoiding lifting and straining may all be appropriate. Divers may consider transcatheter device closure of the PFO in order to return to normal diving. If transcatheter PFO closure is undertaken, repeat bubble contrast echocardiography must be performed to confirm adequate reduction or abolition of the right-to-left shunt, and the diver should have stopped taking potent anti-platelet therapy (aspirin is acceptable).



## PFO – guidelines & help

Sykes and Clark *Extreme Physiology & Medicine* 2013, 2:10  
http://www.extremephysiolmed.com/content/2/1/10



### REVIEW

### Open Access

## Patent foramen ovale and scuba diving: a practical guide for physicians on when to refer for screening

Oliver Sykes<sup>1\*</sup> and James E. Clark<sup>2</sup>

### Abstract

Divers are taught some basic physiology during their training. There is therefore some underlying knowledge and understandable concern in the diving community about the presence of a patent foramen ovale (PFO) as a cause of decompression illness (DCI). There is an agreement that PFO screening should not be done routinely on all divers; however, when to screen selected divers is not clear. We present the basic physiology and current existing guidelines for doctors, advice on the management and identify which groups of divers should be referred for consideration of PFO screening. Venous bubbles after diving and right to left shunts are common, but DCI is rare. Why this is the case is not clear, but the divers look to doctors for guidance on PFO screening and closure; both of which are not without risks. Ideally, we should advise and apply guidelines that are consistent and based on best available evidence. We hope this guideline and flow chart helps address these issues with regard to PFOs and diving.

**Keywords:** Patent foramen ovale, Decompression illness, Arterial gas embolism, Screening

## PFO – guidelines & help

### Safe Diving Practices

- No diving deeper than 15m.
- No mandatory decompression stops.
- Do a safety stop or extend it.
- Use nitrox on air tables, but only if appropriately trained.
- Do not dive to the depth or time limits on the dive tables or dive computer.
- Remember that some dive computers only use decompression as an emergency procedure: Limits are there to stay away from, not work to.
- Stay well hydrated while diving.
- Dives involving the cold or heavy exercise should be even more conservative in terms of depths and times.
- No reverse profiles.
- Deepest depth first during the dive.
- Deepest dive first during the day.
- Slowly ascend from every dive.
- Always adhere to safe diving practises and dive within your training and experience.

### Provocative Dive Profile

- Outside the depth and time limits of DCIEM [24] or BSAC 88 tables [25].
- Fast ascents.
- Short surface intervals.
- Multiple dives in 1 day or a few days.
- Medical conditions:
  - PFO/Migraines/shunts,
  - Dehydration,
  - Previous DCI,
  - Strenuous exercise post dive.

### Factors Suggestive of a PFO

- Repetitive or severe DCI.
- DCI after non provocative dive profile.
- Neurological or Skin DCI.
- Migraines.
- DCI symptoms within 30 mins of surfacing.

## PFO – guidelines & help

Always discuss safe diving practices and no further diving

### Do not refer for Screening

- No DCI
- Migraine with and without aura and no DCI
- 1 episode of mild non neurological DCI
- DCI after provocative dive profile and the diver agrees to the safe diving practises.

### Refer for Screening

- Repetitive or severe DCI
- DCI after non provocative dive profile
- Neurological or skin DCI
- 1 episode of DCI with Migraine with aura
- DCI symptoms within 30 mins of surfacing
- DCI after provocative dives where an assessment of cardiac status will help assess the risk of continued diving
- Commercial divers with neurological, cutaneous or cardio-respiratory decompression illness, particularly with migraine with aura or where the dive profile was not obviously contributor.

