



Peter C. Block M.D.
Andreas Gruentzig Cardiovascular Center
Emory University

Relation of Cryptogenic Stroke and Evidence that PFO Closure Improves Outcomes

TCT

October 2005

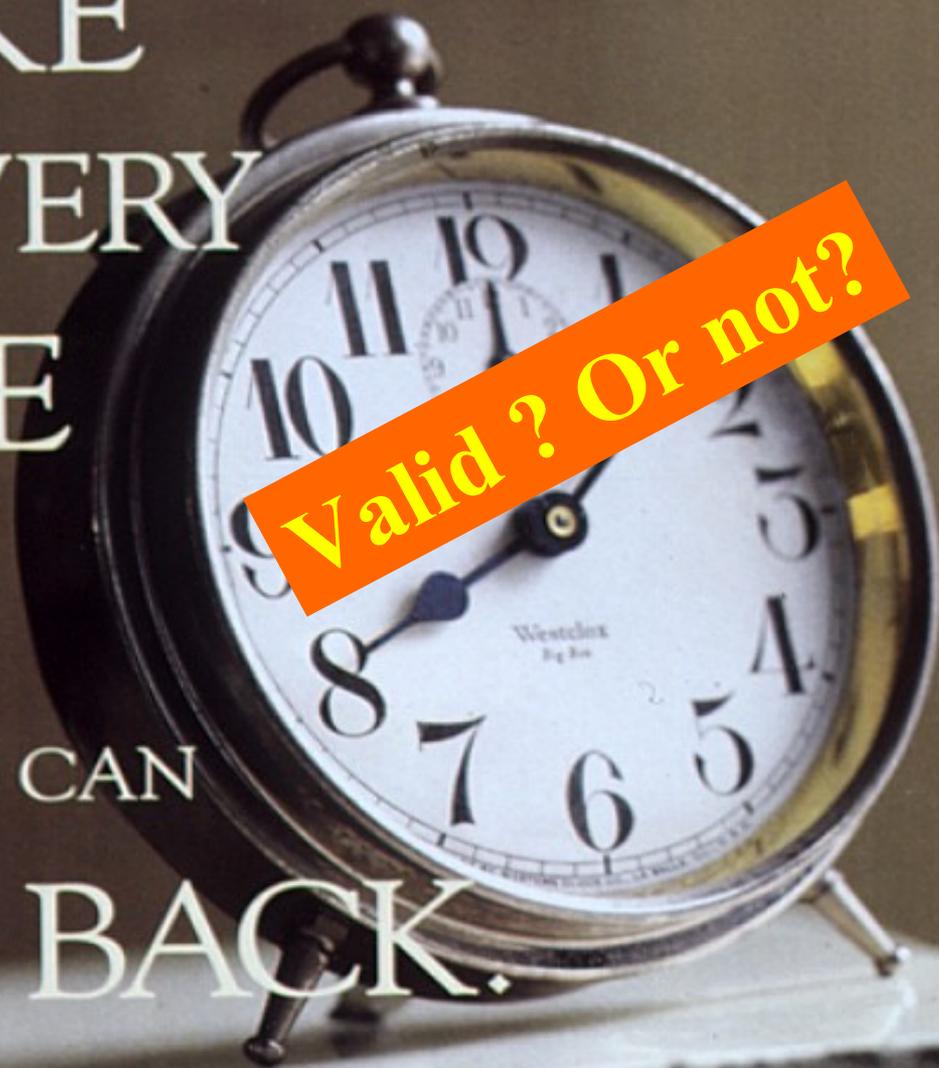
Presenter Disclosure Information

Name: Peter Block, M.D.

Within the past 12 months, the presenter or their spouse/partner have had the financial interest/arrangement or affiliation with the organization listed below.

Nothing To Disclose

A STROKE
STRIKES EVERY
MINUTE
IN AMERICA.
NOW WE CAN
STRIKE BACK.



Valid? Or not?

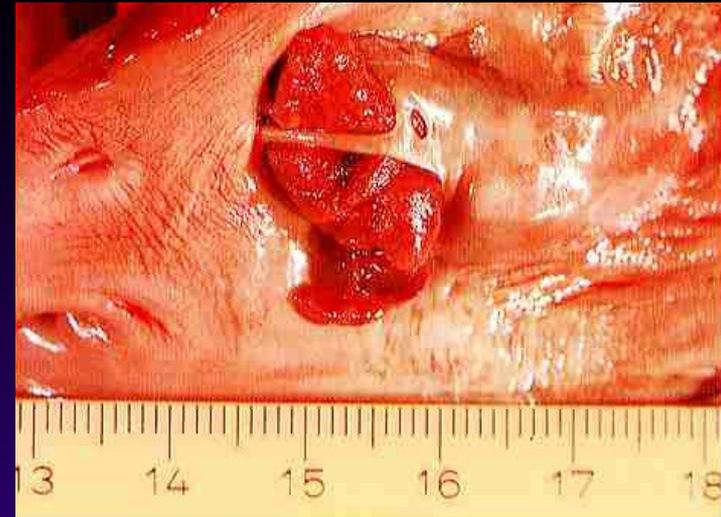
The Evidence

clinical

pathology

59 y.o. woman
2 wks s/p knee op – sudden onset
dyspnea, cyanosis. To ER – better

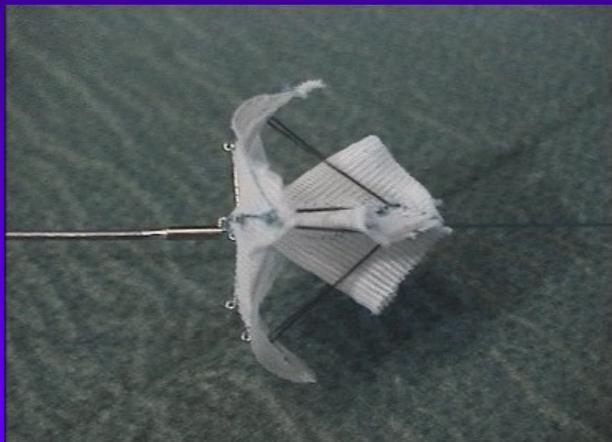
In ER – onset aphasia: echo = PFO



Thrombus lodged in
PFO as seen at
surgery.

Picture taken from Colour
Atlas of the CV System,
Thomas et al.

CardioSEAL and CardioSEAL-STARflex



Amplatzer



Or.....

Are there other ways to close the PFO?

Perc Suture closure

Biodegradable devices

Micro clips

“No Foreign Body” Technology (RF energy)

etc.....

STAY TUNED

PFO Closure

What to Expect?

Acute Closure ~75%

Closure in 3 months > 90%

Complications ~ 5 %
(driven by Parox AF)

Recurrent Events NOT 0%
(but < 3-5%)

Take Home Messages

- PFO closure has become a standard procedure
- Closure rates at high ~ 90+% at 3 mos
- Can be performed regardless of the morphology of the PFO
- Complications are rare
- There is still a need for:
randomized trials.....

Finally:

**What do we know about
closure?**

Is PFO closure worthwhile
or not?

Literature review since 1/2000

Percutaneous PFO closure

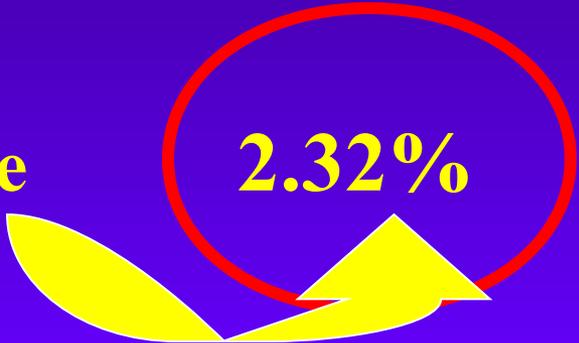
<u>Study</u>	<u>Recurrence 1 yr</u>
▪ Hung (JACC 2000)(Bos) n=63	3.2 %
▪ Windecker (Circ. 2000)(Switz) n=80	3.4%
▪ Sievert (JIC 2001)(Ger) n= 281	3.1 %
▪ Wahl (Neurol 2001)(Switz) n = 152	4.9%
▪ Martin (Circ.2003)(MGH) n=110	0.9 %
▪ Braun (JACC 2002) (Ger) n=276	1.7 %
▪ Sommer(AHA abst 2002)(DC) n=259	1.2%
▪ Rhodes (AJC abst 2002) (Cleve) n=142	1.4%

Grand Total n = 1,363 pts

(mean age 48.3 yrs)

Weighted average of recurrence

2.32%



Example study (Braun et al JACC 2002) (n=276)

- **Cardia device, 276 pts, closure >95% @ 6 mos**

At what price?

Reversible ST changes	4
Reversible AV block	1
TIA	2
Brief AF	2
Need for op(1 rash @1 wk; 1 misplacement)	2
Thrombus on device	8
Arm fracture	10
<u>Thoracic palpitations</u>	<u>26</u>
GRAND TOTAL	55/276 = 20 %

Example study (Braun et al JACC 2002) (n=276)

- **Cardia device, 276 pts, closure >95%
@ 6 mos**

At what significant price?

TIA 6

Need for surgical removal 2

Total 8/276 = 3 %

In WARRS/PICCS as age increased the incidence of CVA increased – but if PFO was present in age group >65 yrs pts were more than 3X more likely to have recurrent stroke if PFO was present.

Who says that the stroke is due to “other” factors rather than the PFO ?

–perhaps the RA pressure increase with age increases thrombo-embolic risk.

And.... There is NO evidence that antithrombotic Rx helps in preventing recurrent CVA

Minnesota Billboard

It's Your Choice:

Veterinarian

OR

Taxidermist

**Either Way --- You
Get Your Dog Back**

What Else is Out There for PFO?



Identification of Professional Scuba Divers with PFO at Risk for Decompression Illness

Cartoni et al. AJC: 94; 2004

“A wider patency diameter together with a higher membrane mobility are assoc. with the risk of developing Decompression Illness in divers with PFO.”



PFO Closure for Headache ??

**Does R \Rightarrow L shunting of vasoactive cmpds
produce/trigger/facilitate migraine?**

**Are brain scan defects seen in migraine pts
due to thromboemboli & not vasospasm?**

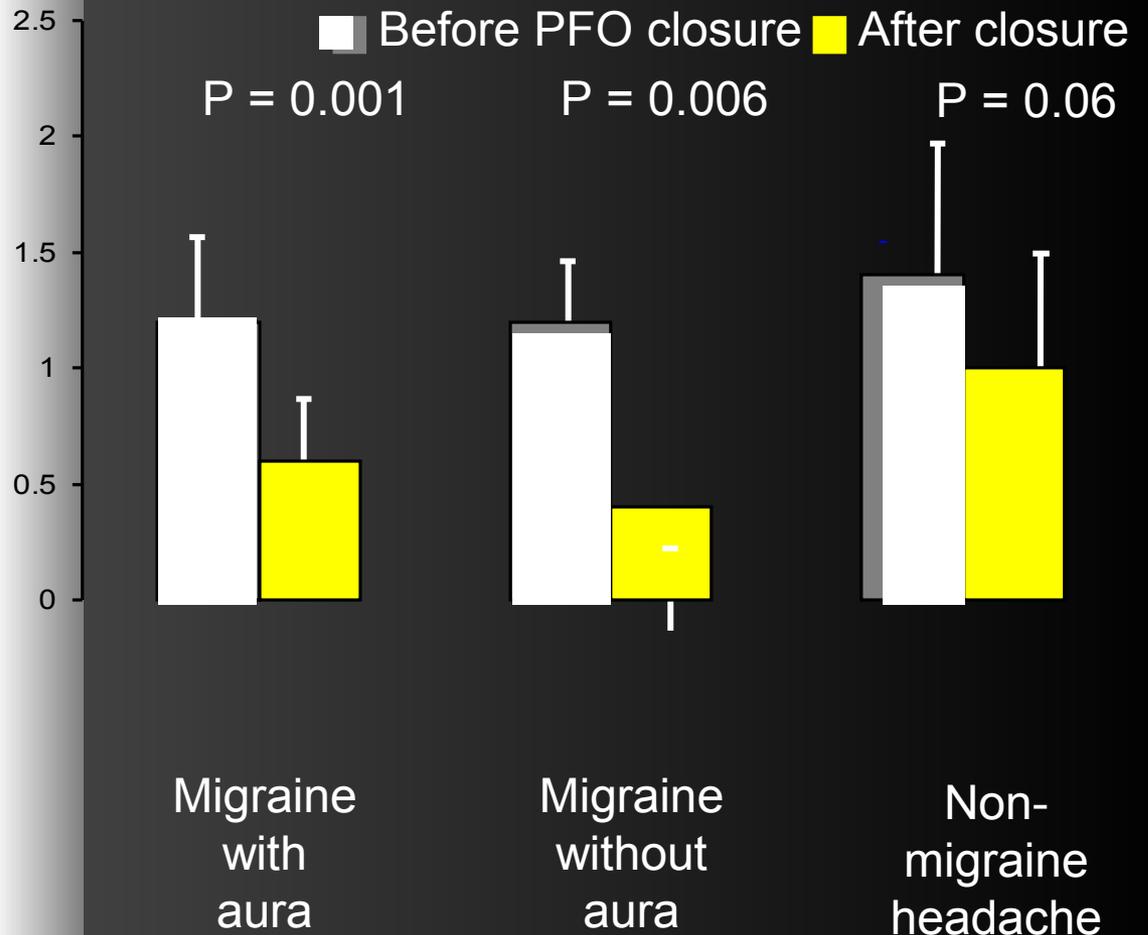
**Which migraine pts will benefit – only those
with aura? – or others?**

Will PFO closure help?



PFO Closure for Headache ? The anecdotal data.....

Headache Attacks per Month



PFO closure

275 pts

• No headache

144 pts

• Headache

71 pts

- Migraine with aura

37 pts

- Migraine without aura

11 pts

- Non-migraine

23 pts

Migraine affects 12% of population (27 million people, women 3:1)

Incidence of PFO with migraine: 48% migraine with aura; 23% without aura (~20%-25% in “controls”)

If cryptogenic CVA with PFO: 52% migraine with aura; 10/14 (71%) had suppression after closure {Kruit et al JAMA 2004}

Migraine pts have 13X incidence of MRI lesions

PET studies show no vasodilation with migraine

What does this tell us about migraine and PFO?

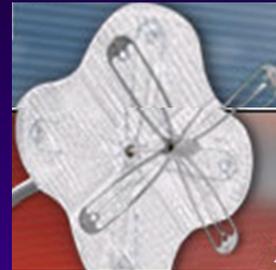
The theory is.....

- **In susceptible people migraine is initiated by substance(s) usually cleared in lungs in first pass**
- **Presence of PFO allows direct access to brain (increased assoc of migraine with PFO)**
- **PFO also increases risk of CVA in migraine population – may account for abnormalities of MRI in migraine pts (not vasospasm)**
- **If above is true, closure of PFO will reduce/eliminate >70% of migraine, esp those assoc with aura**

Currently on the racetrack...

PFO for migraine trials:

Velocimed (St. Jude)



Amplatzer



Cardia



NMT Medical



radiofrequency, microclips, bioabsorbable,

etc. etc. etc.