

# ANGIOPLASTY SUMMIT 2004

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RESULTS OF STUDIES COMPARING  
TRANSRADIAL AND FEMORAL ANGIOGRAPHY

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# ANGIOPLASTY SUMMIT 2004

## RESULTS OF STUDIES COMPARING TRANSRADIAL AND FEMORAL ANGIOGRAPHY

### DISCLOSURE

Nothing to disclose



# FEMORAL CLOSURE DEVICES

## Access Site Complications

- Diagnostic angiography 0.1-2.0%
- Intervention 0.5-5.0%
- EPIC major bleeding 14%, groin 8.2%
- Epilog major bleeding 3.5% (access site not reported)

Do Femoral Closure Devices Improve Outcomes and Patient Satisfaction?



# FEMORAL CLOSURE DEVICES

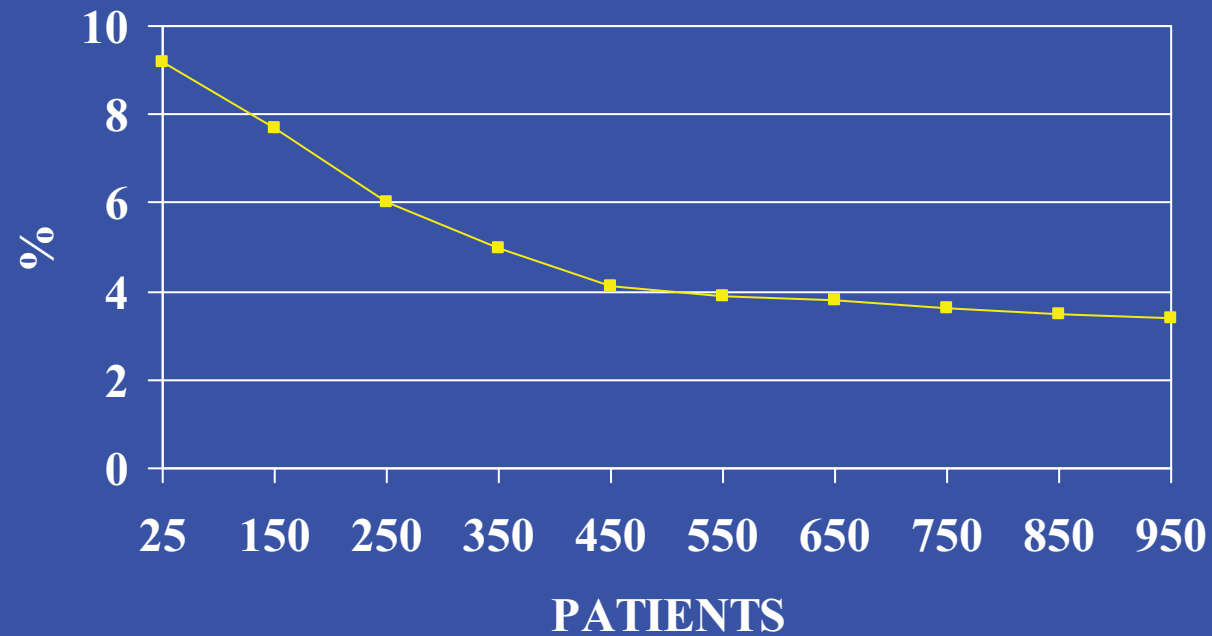
## Variables Associated with Access Site Complication

- Advanced age
- Increased weight
- Female sex
- Diabetes
- Hypertension
- PVD
- Sheath size
- Delayed removal of sheath
- Higher levels of anticoagulation
- Non compliance re bed rest
- Multiple arterial punctures to gain access
- Steroids



# FEMORAL CLOSURE DEVICES

## LEARNING CURVE SMC



Balzer JO et al. Cath and Cardiovasc Int 53:174-181, 2001



# FEMORAL CLOSURE DEVICES

## Immediate Post PTCA PC Suture of Femoral Arteries with the Perclose Device: Results of High Volume Users

- 104 consecutive patients (77.8% male, mean age 60.9 yrs)
- Device 6F 2 needles (80pts), 8F 2 needles(20pts), 8F 4 needles(4pts)
- Time 3.19 min (1.23-10.30)
- Immediately effective 93 pts (89.4%) - Group I
- Compression with femostop 8 pts (7.6%) < 1 hr - Group II
- Compression with immobilization 12 hr 3 pts (2.8%) -GroupIII, 1 patient with surgery for false aneurysm, 1 small hematoma
- After **prolonged learning curve**, the device is fast, effective and improves patient comfort

M C Morice and T LeFevre. J Am Coll Cardiol 1998; 31: 101A



# FEMORAL CLOSURE DEVICES

## Safety of FCD after PTCA with IIb/IIIa RA's

Variable	Manual N=2099	AngioSeal N=411	Perclose N=408	P value
Hematoma ≥ 5cm	1.4%	1.5%	1.0%	0.80
AV fistula	0.7%	0%	0.2%	0.13
Pseudo- Aneurysm	0.9%	0.5%	0.7%	0.29
Venous thrombosis	0.1%	0%	0.2%	0.63
Retroperit Bleeding	0.1%	1.0%	0.8%	0.01

Cura et al. Am J Card 2000: 780-82



# FEMORAL CLOSURE DEVICES

## Safety of FCD after PTCA with IIb/IIIa RA's

Variable	Manual N=2099	AngioSeal N=411	Perclose N=408	P value
Tx	0.8%	1.2%	1.7%	0.16
Vascular occlusion	0.3%	0.2%	0%	0.49
Infection	0%	0%	0.5%	0.02
Vascular surgery	0.4%	0.2%	1.0%	0.25
All	3.1%	2.9%	3.2%	0.96

Cura et al. Am J Cardiol 2000; 86:780-82





# FEMORAL CLOSURE DEVICES

Safety of FCD after PTCA with IIb/IIIa RA's

Conclusions:

- The increased incidence of *retroperitoneal hemorrhage* among patients treated with both closure devices compared with manual compression is a concern. This difference was only found among patients treated with *GP 2b/3a platelet inhibition*.
- In this study, the efficacy of achieving femoral hemostasis appeared to be superior with Angio-Seal compared with perclose. However, this finding might be due to the *learning curve or first generation devices*. An excessive incidence of femoral complication was seen in those patients with failed deployment of these devices.
- *The mode of failure may be important!*

Cura et al. Am J Cardiol 2000; 86:780-82



# FEMORAL CLOSURE DEVICES

Vascular Complications after PCI Following Hemostasis with Manual Compression vs Arteriotomy Closure Devices

ACD (n=516) vs manual compression (n=5892)

Device	Number of patients
Angioseal	371
Duett	32
Vasoseal	6
SMC	107 Prostar 6, Techstar 101

Dangas et al. JACC 38:638-41, 2001



# FEMORAL CLOSURE DEVICES

	ACD'S	MANUAL	p
ACT max	296 ± 66	284 ± 58	<0.001
ACT final	277 ± 59	268 ± 54	<0.001
Total heparin	12573 ± 5025	12029 ± 5713	0.024
M Hematoma	9.3%	5.1%	<0.001
Hct↓ > 15%	5.2%	2.5%	<0.001
Surg repair	2.5%	1.5%	0.03

Dangas et al. JACC 38:638-41, 2001



# FEMORAL CLOSURE DEVICES

## VCD's and the Risk of Vascular Complications after PCI in Patients Receiving GP IIb/IIIa Inhibitors

1485/3027 (49.1%) Device Eligible patients

	Closure Device (n = 1,485)	Manual Compression (n = 1,542)
Vascular complications	45 (3.03%)	82 (5.52%)*
Surgical repair	14 (0.9%)	26 (1.7%)
Transfusion	18 (1.2%)	35 (2.3%)
Pseudoaneurysm, hematoma or other vascular complication	10 (0.7%)	19 (1.2%)
Retroperitoneal hematoma	3 (0.2%)	2 (0.1%)
*p = 0.002.		

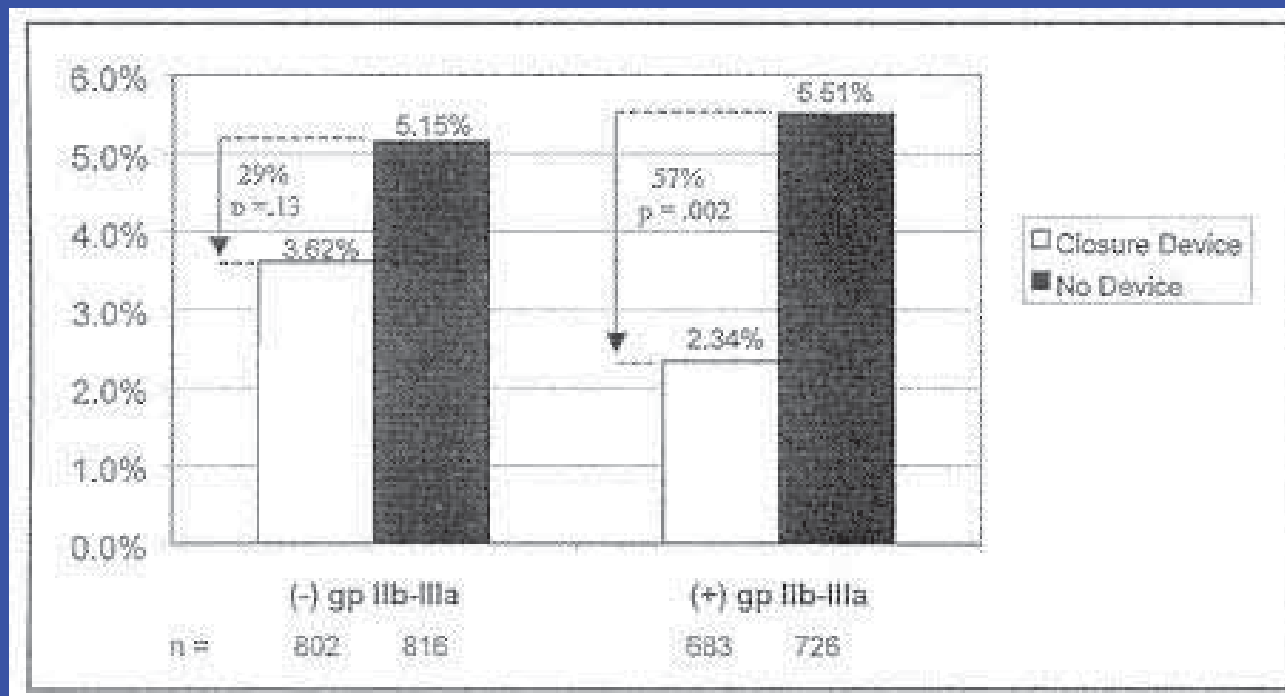
Angioseal 89.8%, Vasoseal 7.3%, Prostar 3%

Resnic et al. *The American J of Cardiology* 2001; 88; 493-96



# FEMORAL CLOSURE DEVICES

VCD's and the Risk of Vascular Complications after PCI in Patients Receiving GP IIb/IIIa Inhibitors



Resnic et al. *The American J of Cardiology* 2001; 88; 493-96



# FEMORAL CLOSURE DEVICES

Vascular Closure Device Experience				
1996	Jan '97	Nov '97	Aug '98	Sept '98-May '99
<b>control</b> 1019*	<b>Vasoseal</b> 937*	<b>Angioseal</b> 742*	<b>Techstar</b> 1001*	
				*# of closures

Fig. 1. Summary of device use in our laboratory by four experienced operators.

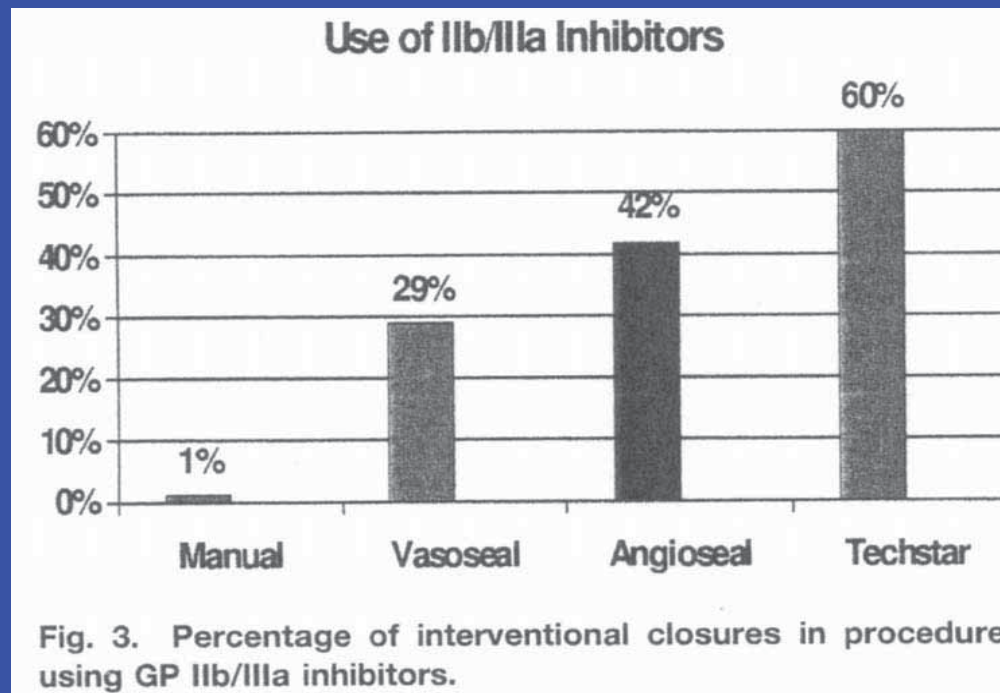
TABLE I. Patient Characteristics

	Manual pressure	Vasoseal	Angioseal	Techstar
Average age	63	61	62	62
% male	61	60	60	57
% total closures with devices	NA	65%		83% <sup>a</sup>

<sup>a</sup>P < 0.01 Techstar vs. Vasoseal/Angioseal.



# FEMORAL CLOSURE DEVICES



Carey D et al. Cath and Cardiovasc Int 52:3-7,2001

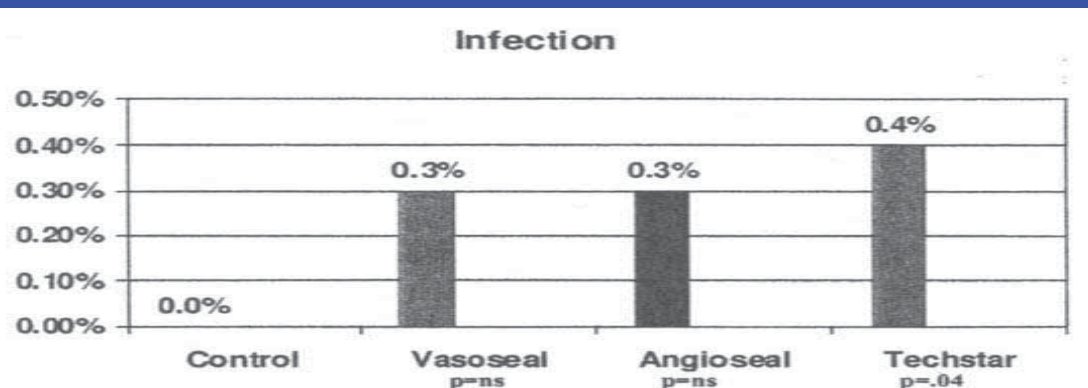


# FEMORAL CLOSURE DEVICES

**TABLE II. Complications for Each Device**

	Control	Vasoseal	Angioseal	Techstar
Number	1,019	937	742	1,001
Surgical repair	3	6	7	2
Acute occlusion	0	0	5	1
Transfusions	2	0	3	1
Readmission	0	5	2	0
Infections	0	3	2	4
Total	5 (0.5%)	14 (1.5%)	19 (2.6%)	8 (0.8%)
<i>P</i> value		0.02 <sup>a</sup>	0.0002 <sup>a</sup>	NS <sup>a</sup>

<sup>a</sup>Compared to manual compression.

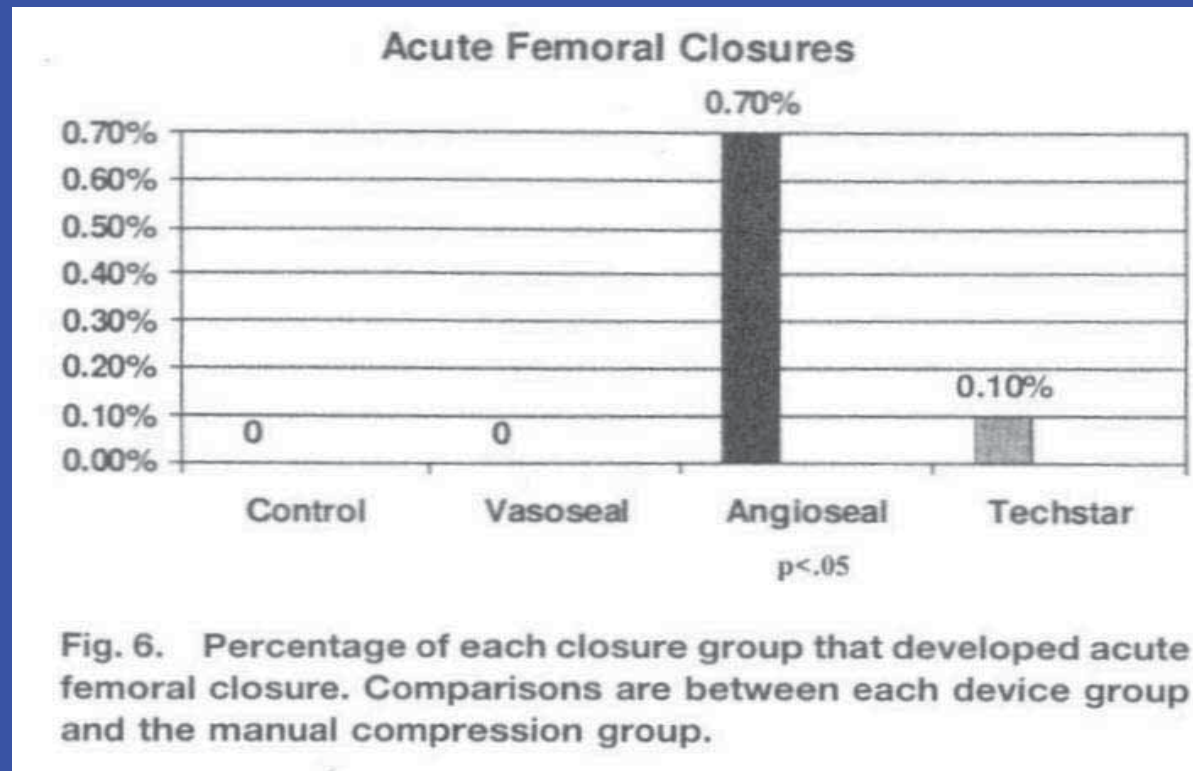


**Fig. 4.** Percentage of each closure group that developed groin infections. Comparisons are between each device group and the manual compression group.





# FEMORAL CLOSURE DEVICES



Carey D et al. Cath and Cardiovasc Int 52:3-7,2001



# FEMORAL CLOSURE DEVICES

Vascular Closure Devices in Patients Treated with Anti-coagulation and IIb/IIIa Receptors Inhibitors During PCI

- 4525 consecutive patients undergoing PCI with heparin and abciximab
- Manual 1824 patients, Angioseal 524 patients, and Perclose 2177 patients
- ACT target 200-250 sec

Applegate RJ et al JACC 40:78-83, 2002



# FEMORAL CLOSURE DEVICES

**Table 5.** Closure-Device Outcomes

	Manual (n = 1,824) (% Incidence)	Combined Closure Device (n = 2,701) (% Incidence)
Minor		
Hematoma >10 cm	1.0	0.7
AV fistulae	0.3	0.1
Pseudoaneurysm	0.5	0.4
Major		
Bleeding	1.1	1.6
Retroperitoneal	0.5	0.6
Other†	0.6	1.0
Vessel occlusion	0.1	0.1
Loss of distal pulse	0.4	0.1
Vascular surgery	0.8	0.5
Death		
Overall	3.2	1.0*
Vascular	0.3	0.1
Any minor	1.8	1.2
Any major	1.3	1.0
Any minor and major	2.5	1.9

\*p < 0.05 vs. Manual. †Significant bleeding other than retroperitoneal bleeding as defined in the text.

Applegate RJ et al JACC 40:78-83, 2002



# FEMORAL CLOSURE DEVICES

	Manual (n=1824)	Angioseal (n=524)	Perclose (n=2177)
Procedural Success	98.7%	99.6%	99.3%
Any minor Complication	1.8%	0.896%* <i>Combined</i>	0.896%* <i>Combined</i>
Any major Complication	1.3%	0.996% <i>Combined</i>	0.996% <i>Combined</i>
Any minor/major complication	2.5%	1.596%* <i>Combined</i>	1.596%* <i>Combined</i>

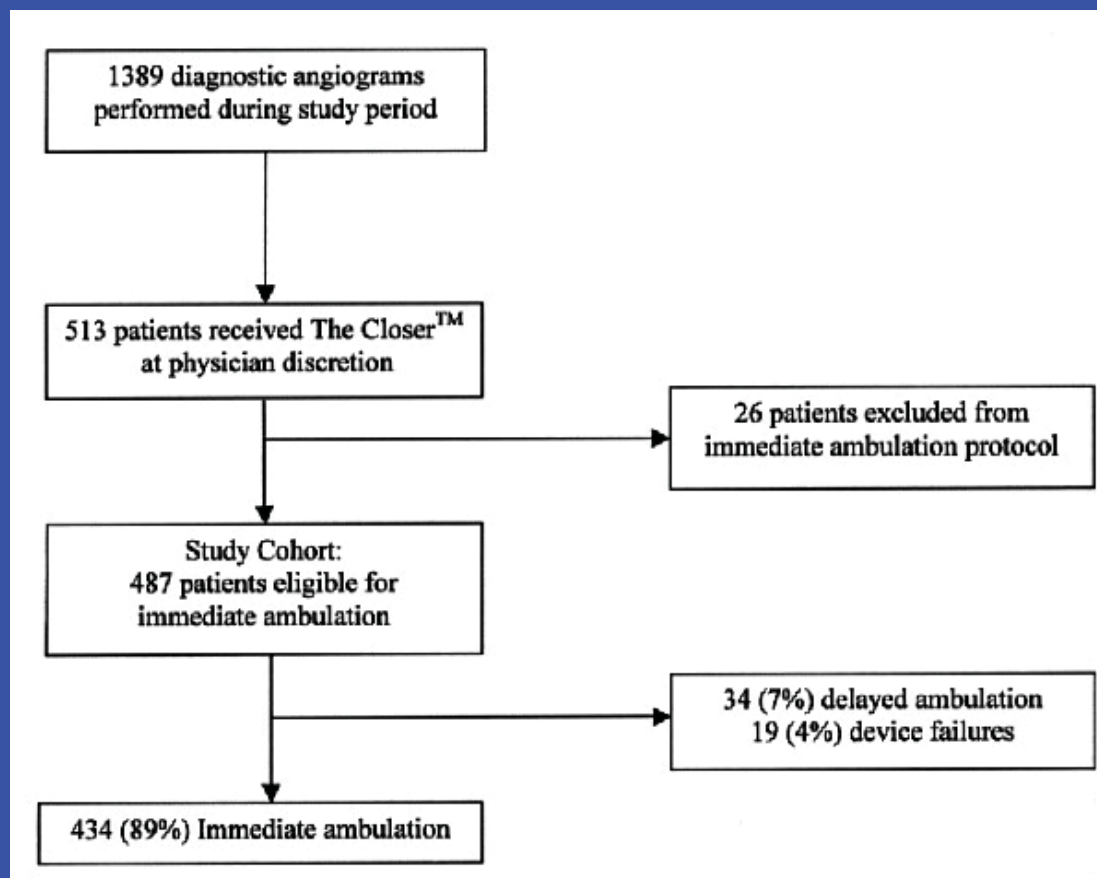
\*p<0.05 vs manual closure

Applegate RJ et al JACC 40:78-83, 2002



# FEMORAL CLOSURE DEVICES

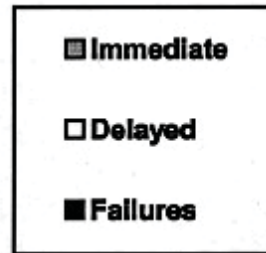
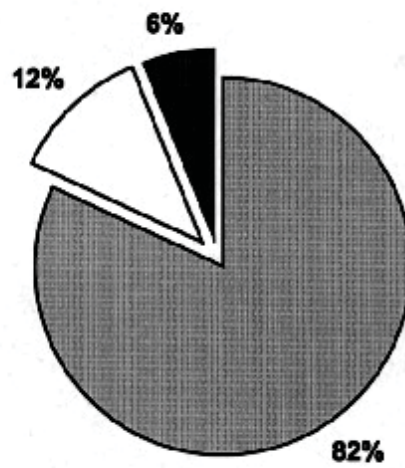
## Immediate Ambulation Following Diagnostic Coronary Angiography Utilizing a VCD (The Closer)



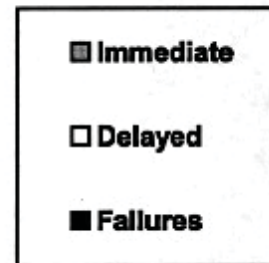
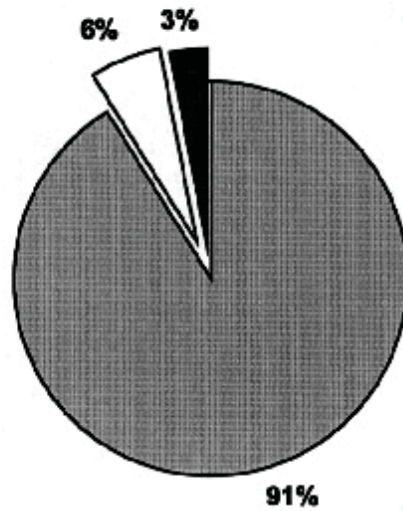
Crocker et al. The J of Invasive Cardiology 2002;14:728-32



**A.**



**B.**



# FEMORAL CLOSURE DEVICES

## Relative Advantages and Disadvantages

	Manual	Perclose	AngioS	Vasoseal	Duett
<b>Technically Difficult</b>	+	+++	+	+	+
<b>Intravascular Foreign Body</b>	-	-	+	-	-
<b>Cost</b>	+	++	+	+	+



# FEMORAL CLOSURE DEVICES

## Arterial Puncture Closure Devices Compared with Standard Manual Compression after Cardiac Catheterization

- Meta-analysis of 30 RCT's involving 4000 patients
- Many of the trials with “poor methodological quality”
- “Low trial quality biased the results in favor of APCD's.”
- “There is only marginal evidence that APCD's are effective and there is reason for concern that these devices may increase the risk of hematoma and pseudoaneurysm.”

Korenny et al. JAMA 2004;291:350-357





# FEMORAL CLOSURE DEVICES

## Conclusions

- Complications rates are increased by 2b/3a and vigorous anti-coagulation, but this decreases significantly with experience
- There may be a learning curve for any given device, some steeper than others
- Devices continue to evolve and improve
- Probable need to tailor device to patient
- Need to consider *mode of failure* as well as safety and efficacy – post market surveillance
- ***Randomized trials are necessary*** to prove equivalency/superiority of any device



# TRANSRADIAL CATHETERIZATION

## Why Consider Trans Radial Catheterization

- Patient comfort / preference
- Patient safety re access
  - local
  - aorta (abdominal and arch)
- Potential for reduced costs
- Facilitation of PTCA / Stenting
- Improve patient outcomes and satisfaction



# TRANSRADIAL PTCA

## The Access Trial

- 900 patients randomized to radial, brachial or femoral access 1993-1995
- 6 F guiding catheters
- Heparin 5000u
- Stents 5.5% (Palmaz-Schatz)
- Primary EP's access and PTCA related
- Secondary EP's QCA, procedural and fluoro times, equipment consumption and LOS



# TRANSRADIAL PTCA

## The Access Study

	Radial N=300	Brachial N=300	Femoral N=300	p value
Successful cannulation	93.0%	95.7%	99.7%	0.001
PTCA Success	91.7%	90.7%	90.7%	ns
Access Compl	0%	2.3%	2.0%	0.035
Time	40±24'	39±25'	38±24'	ns

Kiemeneij et al. J Am Coll Cardiol 1997; 29:1269-75



# TRANSRADIAL CATHETERIZATION

## Stenting in ACS: A Comparison of Radial vs Femoral Access Sites

	Radial n=68	Femoral n=77	p Value
Primary success	65 (96%)	74 (96%)	NS
D/CABG/MI	0	0	NS
Access site complications	0	3(4%)	P<0.01

Mann et al. J Am Coll Cardiol 1998; 32:572-76



# **TRANSRADIAL CATHETERIZATION**

## Stenting in ACS: A Comparison of Radial vs Femoral Access Sites

	<b>Radial</b>	<b>Femoral</b>	<b>p Value</b>
<b>Post op LOS</b>	<b>1.4</b>	<b>2.3</b>	<b>p&lt;0.01</b>
<b>Hospital LOS</b>	<b>3.0</b>	<b>4.5</b>	<b>p&lt;0.01</b>
<b>Total hospital Charges \$</b>	<b>20,476</b>	<b>23,389</b>	<b>p&lt;0.01</b>

Mann et al. J Am Coll Cardiol 1998;323:572-76



# TRANSRADIAL APPROACH in AMI

## Feasibility of Transradial Access for Coronary Intervention in Patients with Acute MI

- 31 Consecutive patients (20 ST $\uparrow$ , 11 non ST $\uparrow$ )
- Age 39-80 years old, 68% male
- Mean time from admission to lab to access 12.6 min
- Mean time from access to FBI 25.3 min
- Successful procedure - 100%
- Major or minor complication 2 $^{\circ}$  access site - 0%
- Discharge within 3 days -87%, longer LOS not related to catheterization procedure

Mulukutla SR, Cohen HA. Cath and CV Interv 2002; 57:167-171



# TRANSRADIAL APPROACH in AMI

*Prospective Consecutive PTCA in Two Centers*

	Study Center A		Study Center B	
	RA (n=180)	FA-P (n=889)	RA(n=87)	FA-M(n=58)
Age	60±14	63±16	59±14	60±12
Male	80%	76%	91%	84%
Primary	75.6%	85.8%	79.3%	75.9%
Rescue	24.4%	14.2%	20.7%	24.1%
Anterior	43.9%	47.6%	70.1%	60.3%

Louvard et al: Cath and CV Interventions 55:206-211, 2002





# TRANSRADIAL APPROACH in AMI

## *Prospective Consecutive PTCA in Two Centers*

	Study Center A		Study Center B	
	RA (n=180)	FA-P (n=889)	RA(n=87)	FA-M(n=58)
RA to FA(%)	2		4	
Access(%)	2		2	
Spasm (%)	0		2	
Success (%)	98	97	96	98
Stent (%)	89	91	83	81
Time	45±42	43±32	67±25	68±21
Access	NA	NA	25±9	23±9
FBI	NA	NA	50±14	50±18

Louvard et al: Cath and CV Interventions 55:206-211, 2002



# TRANSRADIAL APPROACH in AMI

## *Prospective Consecutive PTCA in Two Centers*

	Study Center A			Study Center B		
	RA (n=180)	FA-P (n=889)	<i>p</i>	RA(n=87)	FA-M(n=58)	<i>p</i>
Local Comp	0	2	NS	0	10	<0.01
v repair	0	0	NS	0	3	NS
M bleed	0	2	NS	0	7	<0.05

Louvard et al: Cath and CV Interventions 55:206-211, 2002



# TRANSRADIAL VS SMC POST PTCA

Systematic Use of Transradial Approach or Suture of the Femoral Artery After Angioplasty: Attempt at Achieving Zero Access Site Complications

- 956 patients (60.7% SMC and 39.3% Transradial)
- Transradial – 0% complications
- 580 pts SMC group – 96.9% had SMC, immediately effective in 508 (90.4%) with only 3 pts requiring prolonged compression
- Significant hematoma (0.2%) requiring Tx in SMC group
- Infection at puncture site in 2 pts (0.3%) rx'ed with AB's
- “After the completion of the learning curve, the two techniques (radial and SMC) permit the almost total elimination of access site complications”



# EFFECT of TRANSRADIAL ACCESS on QUALITY OF LIFE AND COST *A RANDOMIZED COMPARISON*

	Femoral (n=99)	Radial (n=101)	p Value
Procedure Outcome			
Success	98	99	ns
Crossover	1	2	ns
Sheath Insertion (min)	5.1±0.6	8±0.8	<0.01
Cath time(min)	16.4±1	18.6±0.9	ns
Hemostasis time(min)	26.5± 2.3	4.7± 0.6	<0.001
Total Procedure (min)	47.6 ± 2.7	31.4 ± 1.7	<0.001
Hospital stay (hours)	10.4(8.3,22.7)	3.6(3.0,4.6)	<0.001
Complications			ns

Cooper et al. Am Heart J 138:430-436,1999



# EFFECT of TRANSRADIAL ACCESS on QUALITY OF LIFE AND COST *A RANDOMIZED COMPARISON*

	Femoral (n=99)	Radial (n=101)	p Value
Other Outcomes			
Costs (\$)	2229	2010	<0.001
Patient preference		++++	<0.001

Cooper et al. Am Heart J 138:430-436,1999



# RANDOMIZED COMPARISON OF TRANSRADIAL AND TRANFEMORAL APPROACHES IN OCTAGENARIANS

	RADIAL	P VALUE	FEMORAL
Crossover	11.7	NS	9.5
Angio Duration(min)	18.1±10.8	NS	16.4±10.8
Xray Duration(min)	6.1 ±4.8	0.001	4.4 ±3.4
PCI Success (%)	96.8	NS	94.7
PCI Duration(min)	27.6 ±18.2	NS	33.3 ±23.2
Xray Duration(min)	9.9 ± 8.3	NS	10.7 ±10.2
Primary EP (%)	1.4	0.08	5.9(58.5% FCD)
Hematoma >3cm(%)	2.2	0.004	11.4

Louvard et al Am J Cardiol 92:17L, 2003



# TRANSRADIAL CATHETERIZATION

## Learning Curve

	<80 Patients	>80 Patients
Access failure	14%	2%
Sheath insertion time	10.2 ± 7.6 min	2.8 ± 2.5 min
Procedure time	25.7 ± 12.9 min	17.4 ± 4.7 min

Spaulding et al. Cathet Cardiovasc Diagn 39:365-70, 1996



# TRANSRADIAL CATHETERIZATION

## ALLEN TEST

- Palmar blush
- Digital pulse oximeter
- Doppler signal
- Doppler of palmar arch





# TRANSRADIAL CATHETERIZATION

## WHICH PATIENTS TO CONSIDER

- Any patient with normal Allen Test
- Peripheral vascular disease
- Unable to comply with bed rest
  - Severe CHF
  - Back pain
  - Confusion
- Bleeding risk
  - Coumadin, GP IIb/IIIa RA's, post thrombolytic RX
  - Obesity
  - Elderly



# TRANSRADIAL CATHETERIZATION

## Which Patients to Avoid

- Shock
- Raynaud's Disease, and Buerger's Disease
- Small arteries even with normal Allen Test



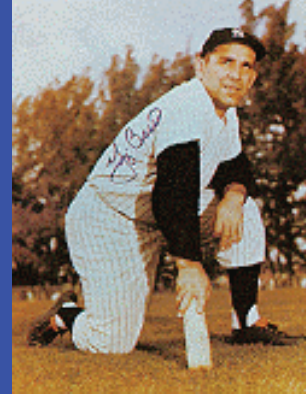
# TRANS RADIAL CATHETERIZATION

## Complications

- Radial artery occlusion 1-5% (heparin dose) of no consequence
- Severe hematoma - very rare
- Compartment syndrome - very rare – unsuspected guidewire perforation
- Hand ischemia (should not occur with normal Allen Test)



# TRANSRADIAL ACCESS



Dr. L. Yogi Berra

- “Just remember, it’s not over ‘til it’s over”
- The PCI is not over with the successful delivery of the stent
- The *successful* PCI is over when the patient leaves the hospital with a good angiographic result and no early or *late* complication



# TRANSRADIAL ACCESS

- Just remember, “it’s not over until the fat lady (your patient) sings”
- But is she singing your praises or the “blues”
- The “black and blues”
- Try radial access. Try it you’ll like it! Your patients will love it!!!

