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Safety of Procedures in the OIS

Disclosure

- Founder and CEO of Vascular Management Associates, which helps doctors set up and manage outpatient angioplasties

OEIS Quality Initiatives : SCOCAP in the OIS

- Safety
 - Accreditation
- Credentialing
- Outcomes Measures
 - Registry
- Compliance
- Appropriateness
- Peer Review



OUTPATIENT ENDOVASCULAR

AND INTERVENTIONAL SOCIETY

Safety well-established

- Jain, et al. reported results on 6458 procedures 2007-2012

Procedure Type	Complication Rate
Venous	2.2%
Aortogram without intervention	1%
Aortogram with intervention	2.7%
Fistulogram	0.5%
Catheters	0.3%
Venous filter-related	2%
Overall	0.8%

Office-based endovascular suite is safe for most procedures

Jain, Krishna et al.

Journal of Vascular Surgery , Volume 59 , Issue 1 , 186 – 191. January 2014.

Safety well-established

- Osuki, et al. reviewed 500 consecutive procedures in outpatient cath lab 2012-2013

Procedure type	Success rate (<30% residual stenosis)	Complication rate
AVF-related procedures	90%	1.49%
PAD-related	82%	1.3%
Miscellaneous	92%	0%

[J Invasive Cardiol.](#) 2015 May;27(5):243-9.

The safety and efficacy of peripheral vascular procedures performed in the outpatient setting.

[Mesbah Oskui P¹](#), [Kloner RA](#), [Burstein S](#), [Zhiroff K](#), [Kartub BR](#), [Economides C](#), [Brook J](#), [Mayeda GS](#)

Safety well-established

- Lin, et al. reported complications on 5134 consecutive procedures in office-based suite 2006-2013

Procedure Type	# Cases	% complications
Diagnostic arteriogram	1024	3%
Arterial interventions	1568	1.5%
Venous interventions	3073	1%
Dialysis access interventions	621	1.1%
Venous catheter management	354	0.7%
Overall	5134	1.4%

Treatment outcomes and lessons learned from 5134 cases of outpatient office-based endovascular procedures in a vascular surgical practice. Peter H Lin, Keun-Ho Yang, Kenneth R Kollmeier, Pablo V Uceda, Craig A Ferrara, Robert W Feldtman, Joseph Caruso, Karen Mcquade, Jasmine L Richmond, Cameron E Kliner, Kaitlyn E Egan, Walter Kim, Marius Saines, Rhoda Leichter, Samuel S Ahn. *Vascular* Vol 25, Issue 2, pp. 115 - 122

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<https://doi.org/10.1177/1548863916668506>

The basics of safety

Approved procedures

Proper patient selection

Physician credentials/criteria

Appropriate angiosuite setup

Staffing and training

Appropriate policies and procedures – and adherence to them

Avoid complications



Approved Procedures?

Almost all endovascular diagnostic and therapeutic procedures can be done on an outpatient basis

Governing board of facility to review and approve procedures

The Exceptions: what cannot be done in OIS

Aortic
aneurysm
endograft

Carotid
stents

Limitations

- Physician's training and expertise
- Physician's privileges (in hospital and in suite)
- Medicare or other payer's reimbursement
- Inpatient-only status
- Patient condition/co-morbidities

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Patient Selection

Hospital	Office
ASA 1-4	ASA 1-3
Occasional 5 and 6	Occasional 4
	Baseline cr ≤ 2.0
	Potassium < 5
	Not morbidly obese

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Credentialing/Privileging

- Procedure-specific education, training, experience, successful evaluation
- Board certification or eligibility
- Peer and quality review participation
- CME
- Malpractice coverage
- Hospital privileges
- Licensure

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Angiosuite Setup for Safety

- Ideal location: within 5 miles of a hospital
- Emergency equipment (airway, suction, all ACLS-required equipment)
- Easy in and out of building (ground floor preferred)
- Quick access to main highway

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Avoid complications

Staffing and training

Adequate staffing

- State guidelines
- Local standards of care

Staff trained in
typical complications
and emergency
procedures

Emergency Procedures



- Emergency Care and Transfer Plan
 - Age appropriate emergency supplies
 - ACLS/BLS up to date and available on crash cart
 - Personnel must be familiar with documented emergency plan– avoid confusion
 - Employees trained in emergency procedures vs. knowing how to handle things as a team

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Important Patient Care Policies

- Pre-Procedure
 - Patient selection criteria
 - Immediate pre-op evaluation by physician
 - Time-out
 - Nursing evaluation

Important Patient Care Policies

- Post-procedure
 - Monitor vitals, LOC, puncture site and distal pulses
 - Constant nursing attendance
 - Discharge instructions explained and signed
 - Pre-discharge physician evaluation

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Getting to Perfection

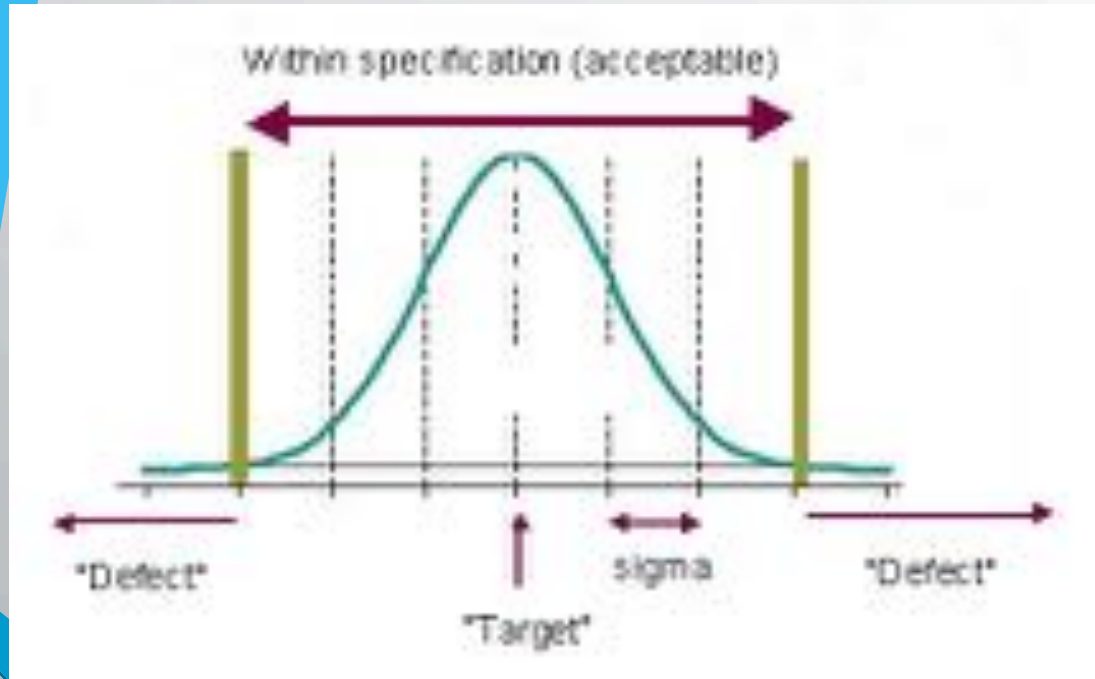
- Every procedure has to be close to perfection
- Little room for errors in outpatient endovascular center

Six Sigma

- 6σ (six sigma) is a quality discipline that focuses on creating a culture that demands perfection, every time
- σ is a statistical symbol for standard deviation
- The less deviation there is from the desired outcome, the more perfect the process is

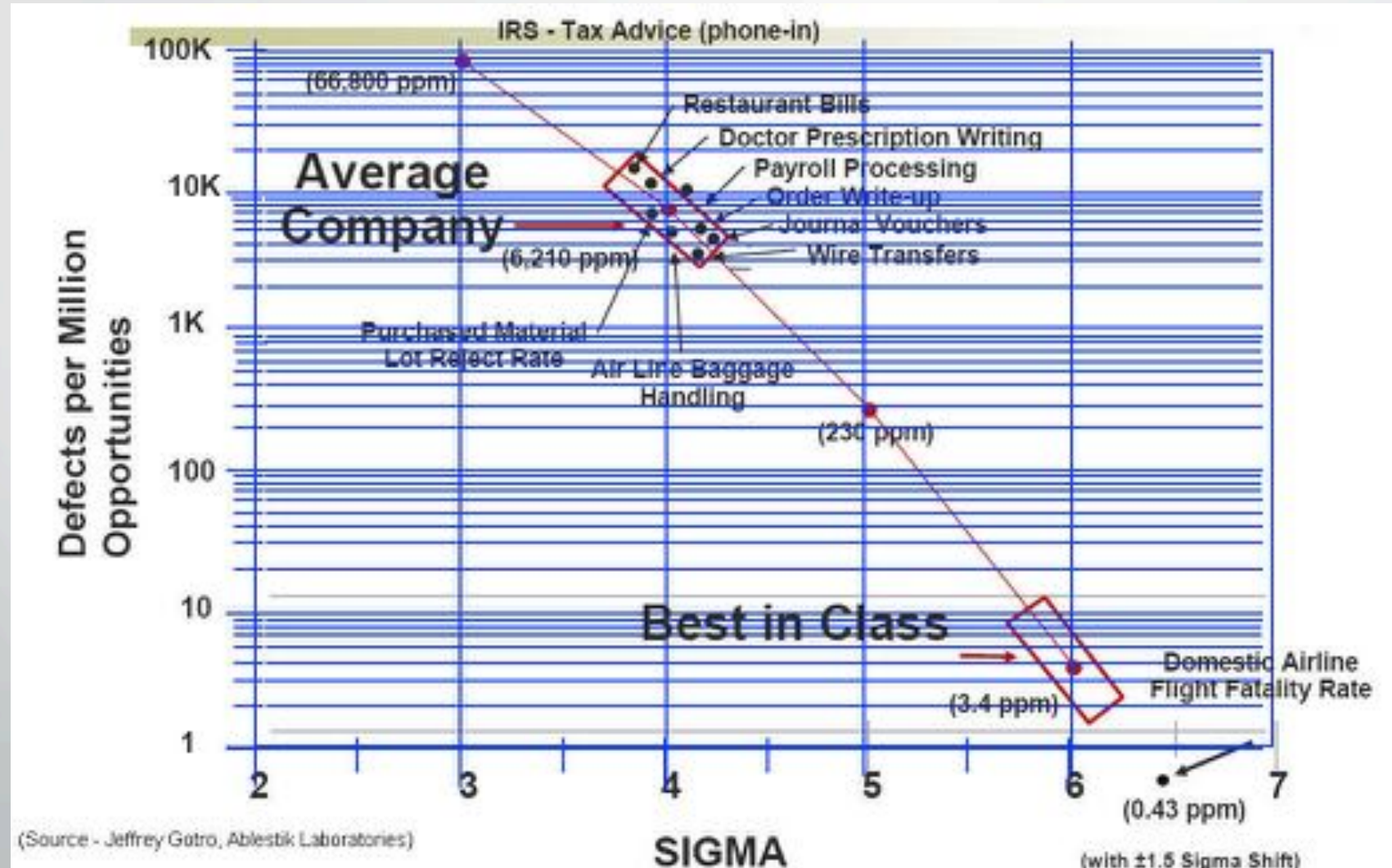
Defects in Six Sigma

- The more perfect a process is, the more σ 's you can fit within between the range of acceptable outcomes



6 Sigma = 3.4 defects per million
5 Sigma = 230 defects per million
4 Sigma = 6,210 defects per million
3 Sigma = 66,800 defects per million
2 Sigma = 308,000 defects per million
1 Sigma = 690,000 defects per million

Examples of Typical Defect Rates



Group Series Complications, a Comparison

DFW (n = 1156)

UVA (n = 884)

Complications	#	Sigma
Groin access problem	0	>6σ
Contrast induced renal failure	0	>6σ
Malignant arrhythmia	0	>6σ
Myocardial infarction	0	>6σ
Vascular rupture	0	>6σ
Infection	0	>6σ
Acute thrombosis	0	>6σ
Airway problem	0	>6σ
Respiratory failure	0	>6σ
Congestive heart failure	0	>6σ
Thromboemboli	1	>4σ
Contrast allergy	1	>4σ
Hematoma	5	>4σ
Unresponsiveness	2	>4σ
Ischemia resulting from Puncture	1	>4σ
EKG changes requiring admission	1	>4σ
Transition to open procedure	1	>4σ
Total	12	~4σ

V
E
R
S
U
S

Complications	#	Sigma
Groin access problem	0	>6σ
Contrast induced renal failure	0	>6σ
Malignant arrhythmia	0	>6σ
Myocardial infarction	0	>6σ
Vascular rupture	0	>6σ
Infection	0	>6σ
Acute thrombosis	0	>6σ
Airway problem	0	>6σ
Respiratory failure	0	>6σ
Congestive heart failure	0	>6σ
Penile Bleed	1	>4σ
Torn Femoral Vein	1	>4σ
Hematoma	2	>4σ
Total	4	4σ

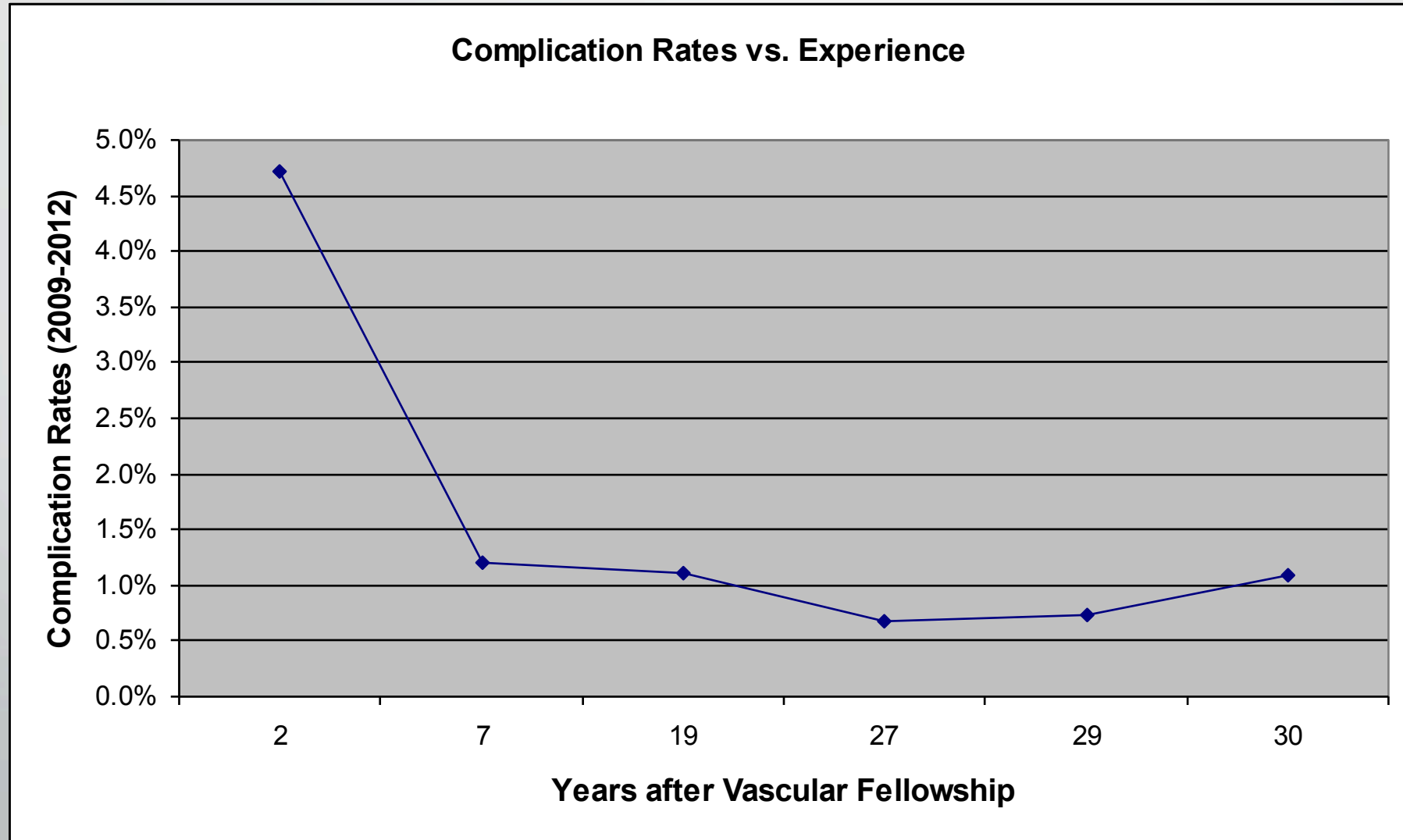
Complications (as of October 2010)

Personal Series

Complications	#	Sigma
30-day mortality	0	>6 σ
Groin access problem	0	>6 σ
Contrast induced renal failure	0	>6 σ
Blood transfusion	0	>6 σ
Urinary retention	0	>6 σ
Malignant arrhythmia	0	>6 σ
Myocardial infarction	0	>6 σ
Vascular rupture	0	>6 σ
Infection	0	>6 σ
Acute thrombosis	0	>6 σ
Airway problem	0	>6 σ
Respiratory failure	0	>6 σ
Congestive heart failure	0	>6 σ
Thromboemboli	1	>4 σ
Contrast allergy	1	>4 σ
Hematoma	2	>4 σ
Unresponsiveness	1	>4 σ
Ischemia resulting from Puncture	1	>4 σ
Penile bleeding	1	>4 σ
Total	7	~4 σ

Number of cases = 675

Experience and Complication Rates



The Crucial Skill Sets for Getting Close to Perfection

- How to Screen Patients for Office Procedures
- How to Get Good Access
- How to Cross a CTO
- How to Avoid Disasters
- How to Close Effectively



How to Screen Patients

- ASA Classifications 1-4
- Baseline Cr ≤ 2.0
- Potassium < 5
- Not superobese
- Anticipate less than 2-3 hours
- Anticipate less than 150 cc of contrast

Pre-Op Evaluation

- **Hospital**

- H & P
- LABS
- CXR
- EKG
- Cardiac evaluation as needed

- **Office**

- H & P
- LABS
- CXR
- EKG
- Cardiac evaluation as needed

Potential Complications

- Groin access problem
- Contrast induced renal failure
- Contrast allergy
- Blood transfusion
- Urinary retention
- Malignant arrhythmia
- Myocardial infarction
- Vascular rupture
- Infection
- Acute thrombosis
- Thromboemboli
- Airway problem
- Respiratory failure
- Congestive heart failure
- Death

Intra-Op Emergency

	Hospital	Office
Access Bleed	Cut down routinely	Apply pressure for 30 mins. Be patient, if patient stable. Stay calm. No peeking. Fem- Stop.
Ruptured Artery	Inflate Balloon. Explore and repair. Covered stent-graft.	Inflate Balloon + Call 911. Avoid repair unless patient unstable.
Lost Stent	Retrieve Stent	Maintain wire control. Transfer to hospital. Will likely need shutdown.

How to Get Good Access

- Use Ultrasound to guide access
 - Identify the common femoral bifurcation
 - Identify the least diseased segment of common femoral artery
 - Identify the inferior epigastric artery



How to Get Good Access (2)

- Use Micropuncture set
- Use 15 blade to enlarge skin puncture site
- Make sure wire stays in the true lumen and main channel



How to Get Good Access (3)

- Contralateral puncture, up and over aortic bifurcation if possible
- Antegrade ipsilateral puncture, avoid if possible
- Brachial access- often needs cutdown
- Radial access preferred, if possible
- Retrograde popliteal access
- Retrograde tibial access



How to Cross a CTO

- Crossing the lesion with a wire
 - True lumen, subintimal plane, re-entry
- Helicopter technique
- Lyse and Lase technique
- Use of hydrostatic pressure
- Push and Pull technique of wires and catheters



How to Avoid Disasters

- Know where wire and catheter are at all time
- Never oversize balloons
- Never undersize stents
- Be as gentle as possible and firm as needed
- Avoid bladder catheters if possible
- Avoid over-sedation



How to Close Effectively

- Obtain good access
- Obtain good access
- Obtain good access
- Obtain sheath puncture angiogram
- Always use a closure device for arterial punctures
- Be thoroughly familiar with how each closure device works
- Choose the most appropriate device for the given situation
- Use Perclose for large sheath venous punctures

Personal Traits for Success

- Conservativeness
- Humility, don't let ego get in the way
- Patience
- Equanimity
- Empathy
- Awareness of your limits



Eyes of an eagle

Heart of a lion

Hands of a woman

Conclusion

- Procedures in the OIS proven safe and effective
- Physician credentialing, experience of utmost importance
- Avoid disaster by appropriately selecting patients and staying cool in an emergency
- Train staff in emergency procedures
- Adhere strictly to policies and procedures