i-MEET

NEXT GENERATION

Multidisciplinary European Endovascular Therapy

Ambulatory management of PAD: This is “state-of-the-art”

Peter A. Schneider, MD

Kaiser Foundation Hospital

Honolulu, Hawaii

Disclosure of Interest

Peter A. Schneider

I have the following potential conflicts of interest to report:

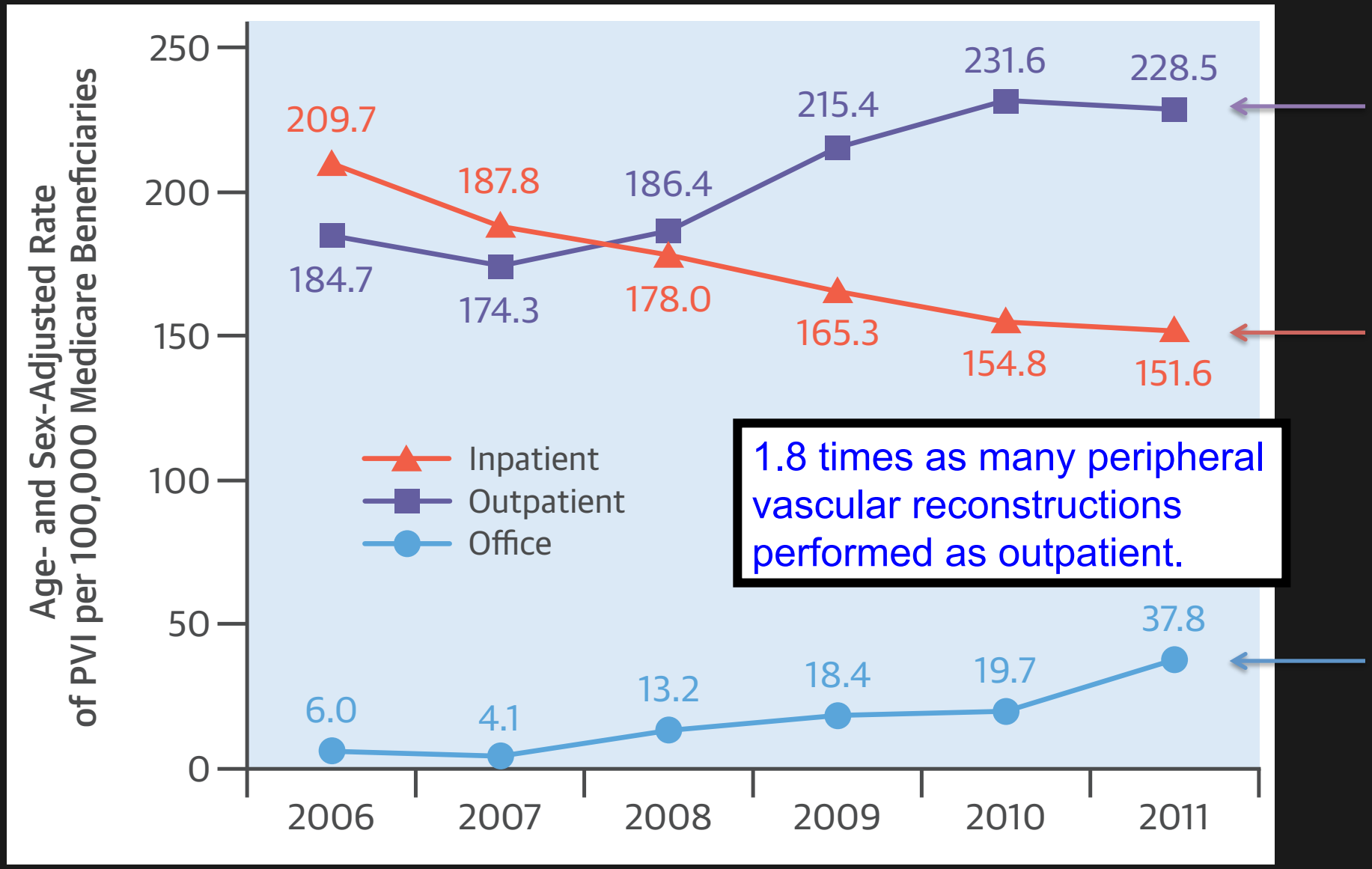
- Noncompensated advisor: Cardinal, Abbott, Medtronic
- Royalty: Cook (modest)
- Co-founder and Chief Medical Officer: Intact, Cagent
- Board member: VIVA (nonprofit)

Ambulatory Management of PAD
Rationale

- Goal: Send patients home day of procedure
- Patient comfort
- Efficient use of resources
- Must be same or better quality and safety

- Is it safe?
- What are the pitfalls?
- Hospital outpatient or office based lab?

What Is Happening in the US?



Jones et al. J Am Coll Cardiol 2015;65:920

Ambulatory Management of PAD
Procedures to Consider

Preferentially treated as outpatients in our practice

- Arterial
  - Subclavian
  - Iliac
  - SFA
  - BTK
- Varicose vein surgery
- Dialysis access creation/revision
- Embolizations

Ambulatory Management of PAD
Procedures to Consider

Which ones are treated as inpatients?

	Inpatient
• Arterial	
– Subclavian	IMA graft
– Iliac	>8Fr
– SFA	Bad foot
– BTK	Bad foot
• Varicose vein surgery	Forced elevation
• Dialysis access intervention	Inpt dialysis
• Embolizations	Pain control

Lower Extremity Interventions
Patient Selection: Medical Exclusions

- Active cardiac/pulmonary decompensation
- Significant dementia
- Bleeding diathesis
- Active requirement for anticoagulation
- Not AAA or carotid or renovasc (BP management)

Lower extremity Interventions
Patient Selection: Social Issues

- Compliant
- Lives with someone, even if temporary
- Must have companion for transportation
- At least minimally ambulatory

Lower Extremity Interventions
Setting Expectations

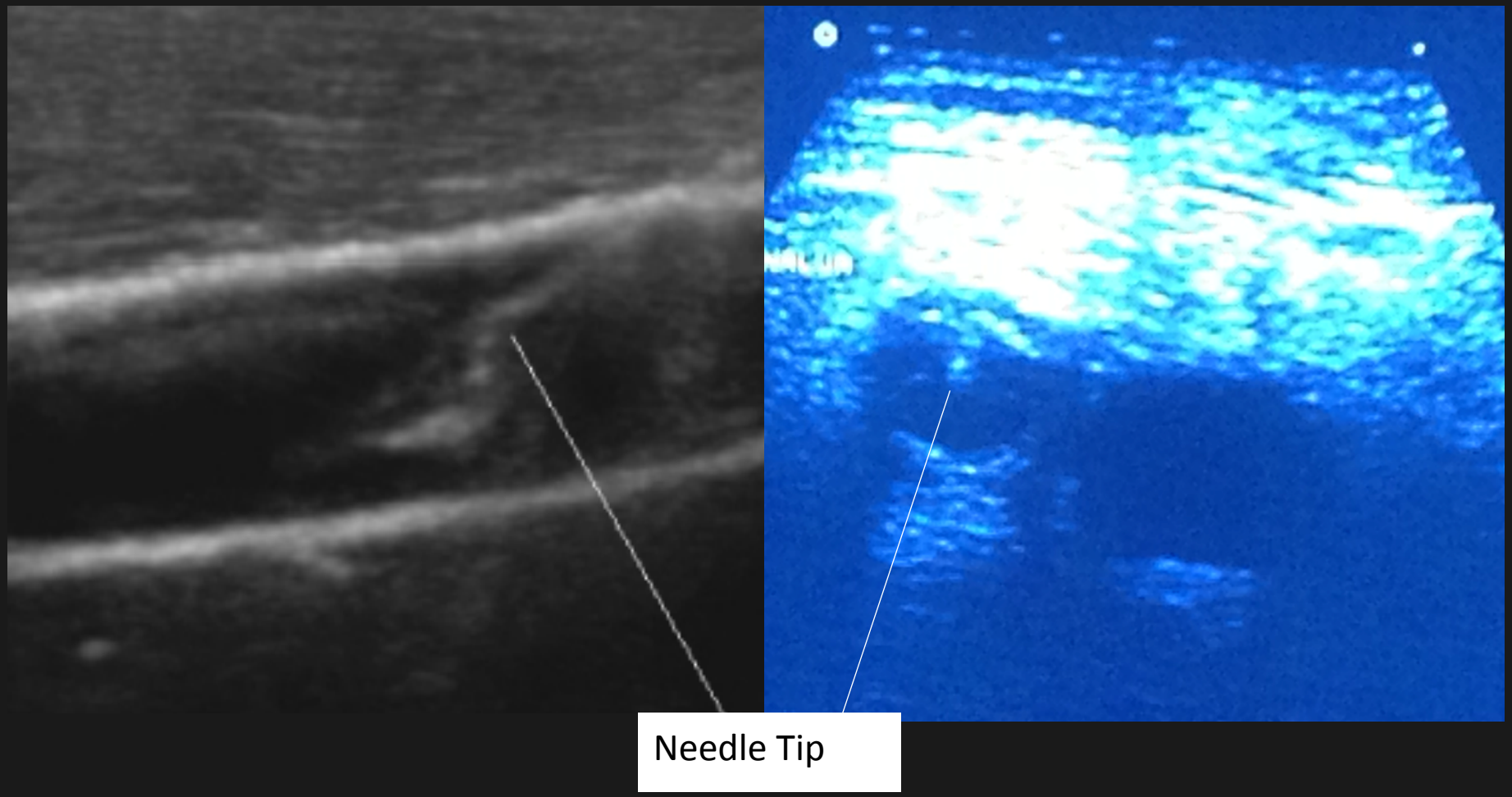
- "Almost everyone who has this done goes home on the same day"
- Arrangements made pre-op
  - Companion identified
  - Approx time of procedure determines dischg time
  - Neighbor Island flight arrangements
  - Follow up appointment

Ambulatory Management of PAD
Lower Extremity Interventions

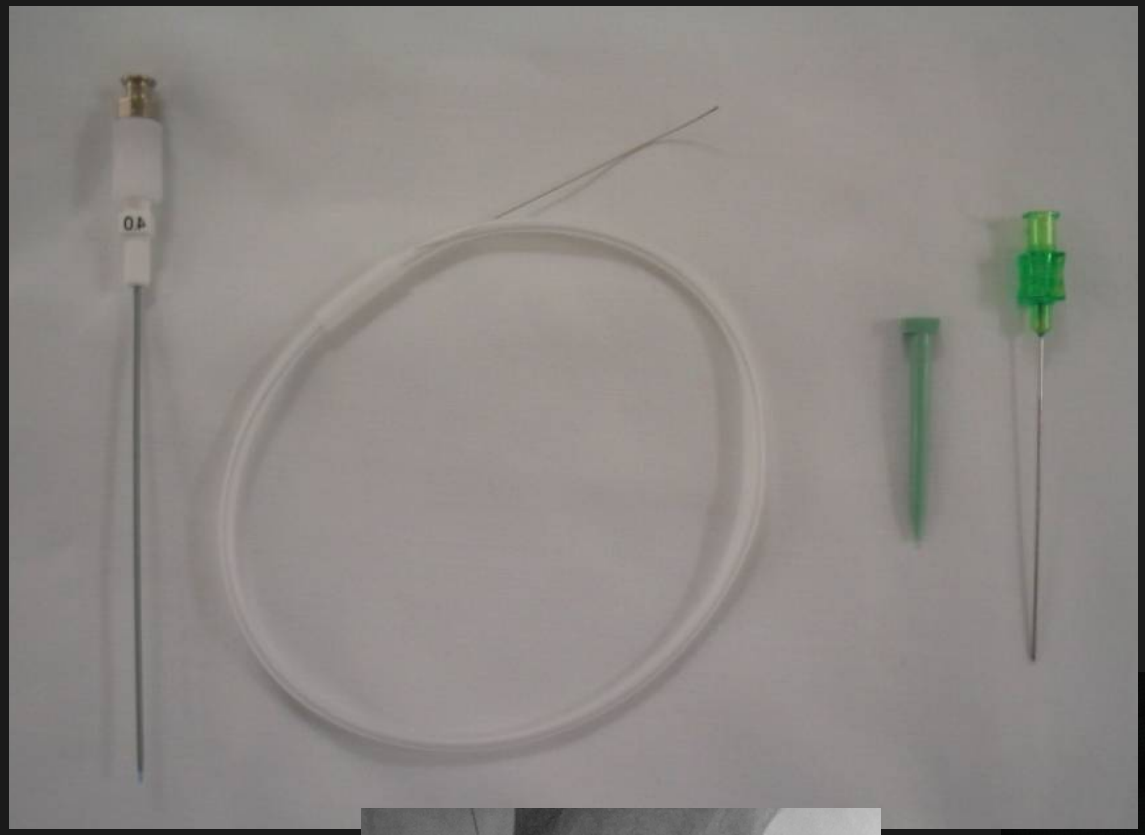
- Local anesthesia with sedation
- Perfect Access
  - Ultrasound guidance
  - Micropuncture
- Perfect Closure
  - Closure device
  - Stitch at puncture site

Longitudinal/In-plane

Transverse/Out-of-plane



Ultrasound Guidance of Optimal Puncture Site



Ultrasound Guidance: Reduced Complications
Retrograde Femoral Approach

Variable	Palpation-guided (n =100)	US-guided (n =108)	P value
Technical success rate	96 (96%)	108 (100%)	0.052
Median number of attempts	1 (1–5)	1 (1–3)	**0.001**
The first pass success rate	78 (78%)	101 (93.5%)	**0.001**
Mean time to access (sec)	94.3 ± 66.4	68.6 ± 45.1	**0.001**
Additional sedoanalgesia	18 (18%)	16 (15%)	0.182
Complication rate (local hematoma)	4 (4%)	0 (0%)	0.052

Gedikoglu, et al. Catheter Cardiovasc Intervent 2013 Jan, epub.

Complication	Fluoroscopy (n = 501)	Ultrasound (n = 503)	p Value
Hematoma ≥5 cm	11 (2.2%)	3 (0.6%)	0.034
Pseudoaneurysm	0	1	NS
Dissection	3	2	NS
Access bleeding, transfusion	2	1	NS
Hematoma with DVT	1	0	NS
Any complication	17 (3.4%)	7 (1.4%)	0.041

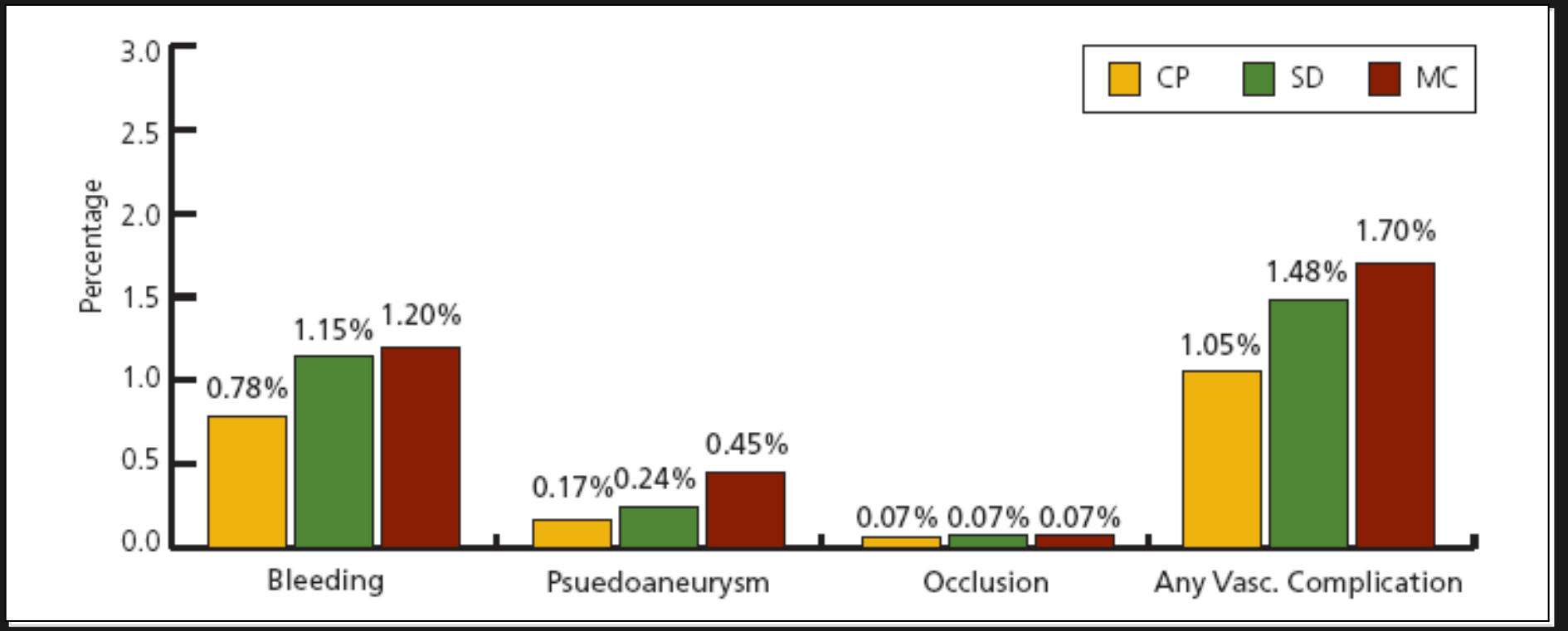
Seto, et al. JACC Cardiovasc Intervent. 2010;3:751.

Rationale

Ultrasound Guidance>Micropuncture>Closure

- Reduce access site complications
  - Lower risk of hematoma, bleeding, AV fistula
  - Single puncture, first pass, single wall
  - Avoid-branches, calcification, lesions
- Optimal use of closure
  - Avoid arterial access site disease
  - Best choice of closure

Closure Devices



>166,000 patients from 214 institutions

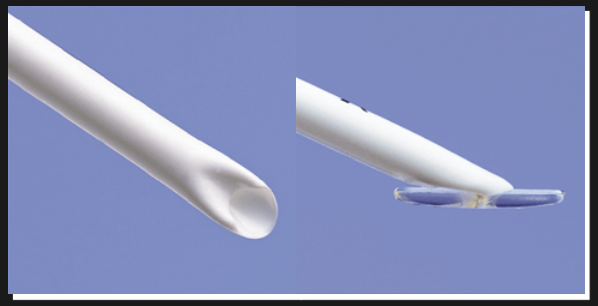
Both collagen plug and suture mediated devices were better than manual compression: 26% RR reduction of complications overall, and 38% with collagen plug.

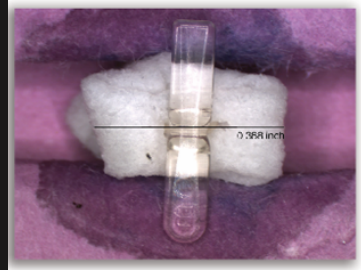
Tavris et al. J Invas Cardiol 2004;16:459

Closure Devices

Collagen Plug or Suture Mediated

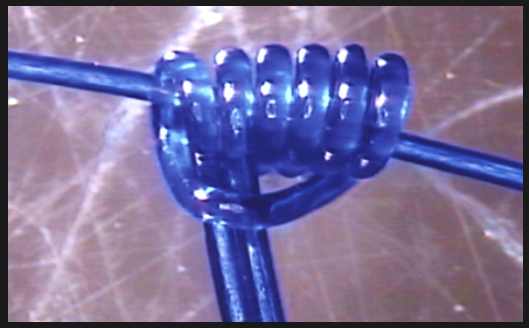
Angio Seal

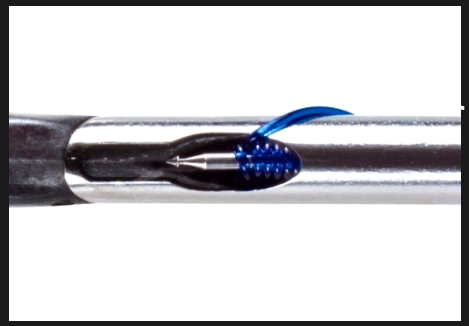


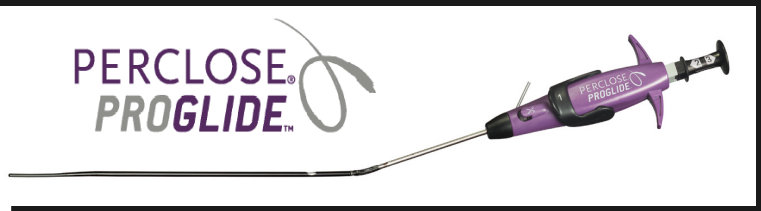


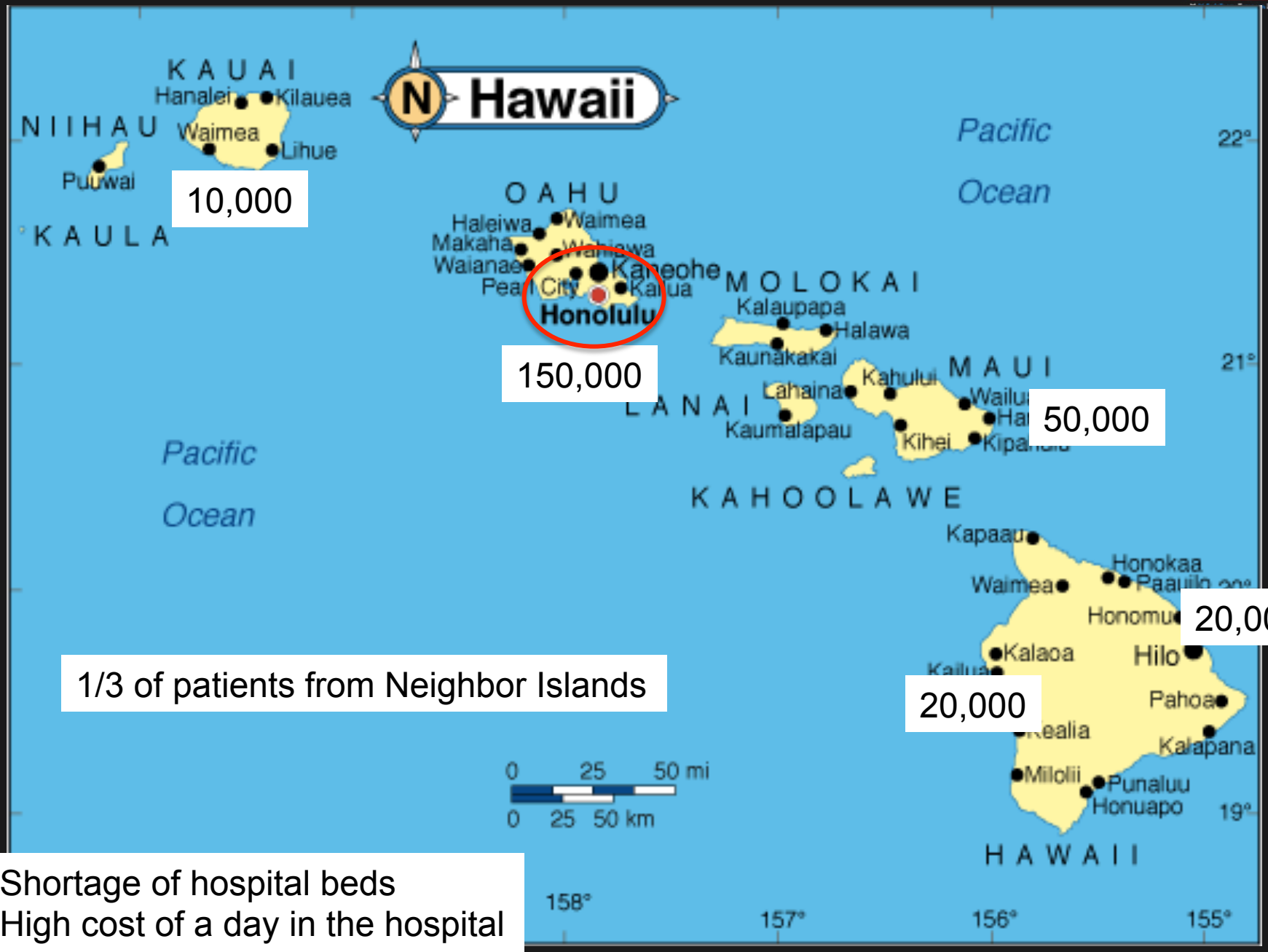
Angio-Seal™ VIP Device

ProGlide









1/3 of patients from Neighbor Islands

Shortage of hospital beds
High cost of a day in the hospital

Ambulatory Management of PAD
Lower Extremity Interventions

- Stay for 4 hours
- Ambulate
- Private car or Shuttle to airport
- Last flight to Wailuku Maui, Kona or Hilo
  - Stay in a hotel near the airport and go the next morning

Lower Extremity Interventions
How Many Patients Can't Go Home?

Reference	N	Coverted to Inpt	Readmit	Total
JVS 2008	113	0	7%	7%
JVS 2006	120	4%	0	4%
Clin Radiol 2006	57	10%	0	10%
Cardiovasc Interv Radiol 2002	214	7%	3%	10%

O'Brien-Irr et al. J Vasc Surg 2008;47:982
Akopian and Katz J Vasc Surg 2006;44:115
Wilde et al. Clin Radiol 2006;61:1035
Macdonald et al. Cardiovasc Intervent Radiol 2002;25:403

Ambulatory Management of PAD
Critical Limb Ischemia

- 50% of our CLI patients
- Typically on aspirin and clopidogrel
- Dry gangrene, open wound with dressings or wound vac

- No systemic signs of infection
- No undrained local infection

Ambulatory Management of PAD
Potential Savings

Total cost is significantly less for ambulatory/outpatient, whether procedure is performed in OR or radiology suite

Hospital

Procedure setting	*No.*	*Direct cost*	*Direct cost*	*Indirect cost*	*Total cost*
In-patent					
RS	24	$4169 ± $584	$5089 ± $600	$2243 ± $432	$7331 ± $764
OR	47	$6593 ± $457	$7861 ± $467	$4417 ± $192	$12,278 ± $595
Ambulatory					
RS	75	$3122 ± $191	$3572 ± $197	$2142 ± $126	$5714 ± $245
OR	38	$5109 ± $511	$5572 ± $523	$2019 ± $108	$7591 ± $616
P		.001	<.001	<.001	<.001

Outpatient procedure reduced the cost by 22% to 38%

O'Brien-Irr et al. J Vasc Surg 2008;47:982

Peripheral Vascular Interventions in the US

Ambulatory Management = Less Expensive

TABLE 4 Total Costs of Peripheral Vascular Intervention by Procedure, Setting, and Year*

Setting	2006	2007	2008	2009	2010	2011
Atherectomy						
Inpatient	11,342 ± 4,295	11,688 ± 4,094	12,583 ± 4,568	13,122 ± 5,511	12,945 ± 6,896	11,446 ± 6,383
Outpatient	2,763 ± 1,920	3,226 ± 2,291	5,720 ± 3,732	6,790 ± 3,909	7,204 ± 4,142	8,680 ± 4,970
Office	–†	–†	–†	–†	–†	13,478 ± 4,768
Stent						
Inpatient	11,589 ± 4,179	11,960 ± 4,796	11,994 ± 3,825	12,550 ± 4,634	12,901 ± 6,351	12,466 ± 7,077
Outpatient	4,367 ± 2,541	4,562 ± 2,756	6,012 ± 3,329	6,858 ± 3,356	7,341 ± 3,693	5,982 ± 3,639
Office	1,678 ± 1,724	1,432 ± 1,502	5,402 ± 2,643	5,543 ± 2,292	5,542 ± 1,914	6,379 ± 2,986
Angioplasty						
Inpatient	11,044 ± 3,736	11,554 ± 3,904	11,796 ± 3,739	11,820 ± 4,674	11,623 ± 3,590	13,197 ± 4,711
Outpatient	2,374 ± 1,441	2,361 ± 1,568	2,734 ± 1,670	3,164 ± 1,738	3,437 ± 1,902	3,742 ± 2,014
Office	3,789 ± 1,520	3,511 ± 1,478	3,781 ± 1,566	3,472 ± 1,400	3,546 ± 1,551	4,800 ± 2,028

Values are in U.S. dollars and are presented as mean ± SD. *Costs include professional and facility costs and patient deductibles and coinsurance. †The Centers for Medicare & Medicaid Services cell size suppression policy stipulates that no cell containing data for fewer than 11 observations may be displayed.

Outpatient interventions decreased the cost by approximately 50%

Jones et al. J Am Coll Cardiol 2015;65:920

Ambulatory Management of PAD
Hospital Outpatient vs Office Based Lab

Hospital Outpatient

- Access to hospital
- Hospital rules and regulations
- Payment issues
- Availability of anesthesia

Office Based Lab

- Specific criteria for transfer to hospital
- Minimal backup
- More responsibility to develop policies and procedures and standards of care

Ambulatory Management of PAD
Safety of Office-Based Lab

All registered nurses and physicians are certified in Advance Cardiac Life Support. For conscious sedation, hospital guidelines adapted for the office are followed. Triage criteria have evolved to identify patients not suitable for an office procedure: weight >400 pounds, American Society of Anesthesiologists Physical Status Classification 4, those with a history of contrast anaphylaxis, those who require general anesthesia, and those with a previous bad experience. Patients who are already admitted to the hospital undergo the procedure in the hospital.

>400 Office based labs in the US
Outpatient Endovascular and Interventional Society (OEIS)

Jain et al. J Vasc Surg 2014;59:186

Office Based Lab

Complications

18,963 cases from Jan 2014-Sept 2015

Variance:	2014		Jan.-Sept. 2105	
Sentinel Events:	10	0.09%	4	0.05%
Death	6	0.06%	3	0.04%
Wrong Site	2	0.02%	1	0.01%
Loss of Limb	2	0.02%	0	0.00%
Loss of Function	0	0.00%	0	0.00%
Transfers	31	0.21%	25	0.30%
Falls	2	0.02%	3	0.04%
Infections	9	0.08%	3	0.04%
All Complications	66	0.61%	48	0.59%
Return to Surgery/Lab	13	0.03%	18	0.22%
Hematoma	27	0.25%	15	0.18%
MI	2	0.02%	0	0.00%
Stroke	1	0.01%	2	0.02%
Other	23	0.21%	13	0.16%

Jeff Carr LINC 2016

Table I. Total procedures by type

Procedure	*No. (%)*
Fistulograms	
Fistulogram—angioplasty	1704 (63)
Fistulogram—thrombectomy—angioplasty	582 (21)
Fistulogram	260 (10)
Fistulogram—angioplasty—coiling	51 (2)
Fistulogram—coiling	47 (2)
Fistulogram—angioplasty—stent	45 (1)
Fistulogram—thrombectomy—angioplasty—stent	26 (1)
Fistulogram—thrombectomy	2 (<1)
Fistulogram—angioplasty—coiling—stent	1 (<1)
Fistulogram—stent	1 (<1)
Aortograms	
Aortogram, runoff	498 (53)
Aortogram, runoff, angioplasty	234 (25)
Aortogram	73 (8)
Aortogram, runoff, angioplasty, stent	61 (6)
Atherectomy	45 (5)
Aortogram, runoff, stent	21 (2)
Aortogram, angioplasty, stent	2 (<1)
Cerebral angiogram	5 (<1)
Catheters	
Removal	773 (52)
Insertion	410 (28)
Exchange	291 (20)
Cathetergram	3 (<1)
Venous	
EVLT—microphlebectomy	512 (50)
EVLT	390 (38)
Microphlebectomy	110 (11)
Radiofrequency ablation	4 (<1)
Radiofrequency ablation—microphlebectomy	3 (<1)
Venograms	
Venogram	55 (87)
Venogram—angioplasty	7 (11)
Venogram—angioplasty—stent	1 (2)
PowerPorts[a]	
Insertion	148 (80)
Removal	31 (17)
Exchange	4 (2)
PowerPortgram	1 (<1)
Inferior vena cava filters	
Filter removal	47 (82)
Filter placement	10 (18)
Total	6458 (100)

Office Based Lab Procedures

6400 procedures over 7 years

13% of procedures were peripheral vascular
Half of these were interventions

Jain et al. J Vasc Surg 2014;59:186

Office Based Lab Complications

Table II. Patient complications and procedures

Procedure type	*Procedures, No.*	*Patients, No.*	*Complications, No.*	*Complications per*	
				Procedure, %	*Patient, %*
Venous	1019	785	22	2.20	2.80
Aortogram					
No interventions	571	464	4	1	1
With interventions	368	191	10	2.70	5.20
Fistulogram	2719	829	13	0.50	1.60
Catheters	1477	342	4	0.30	1.20
Inferior vena cava filters	57	24	1	2	4.20

Table III. Patients transferred to the hospital

Complication	*No.*	*Transfer, %*
Hematoma	9	34.50
Thrombosis	3	11.50
Cardiac	3	11.50
Pseudoaneurysm	2	7.70
Hypotension	2	7.70
Syncope	2	7.70
Hypoxia	1	3.80
Seizure	1	3.80
Bleeding	1	3.80
Dyspnea	1	3.80
Irretrievable wire	1	3.80
Total	26	

0.4% of patients transferred to hospital

About half for bleeding or clotting

5.2% of patients who underwent peripheral interventions were transferred to the hospital

Jain et al. J Vasc Surg 2014;59:186

Conclusion

- Safe and Cost-effective
- Increasing trend
- Requires patient selection and planning.
- Perfect access and closure