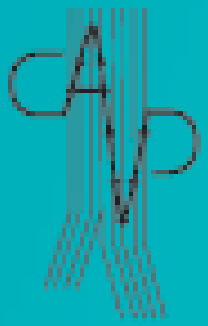
CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE WWW.CACVS.ORG



Routine percutaneous approach for EVAR. What are the results?

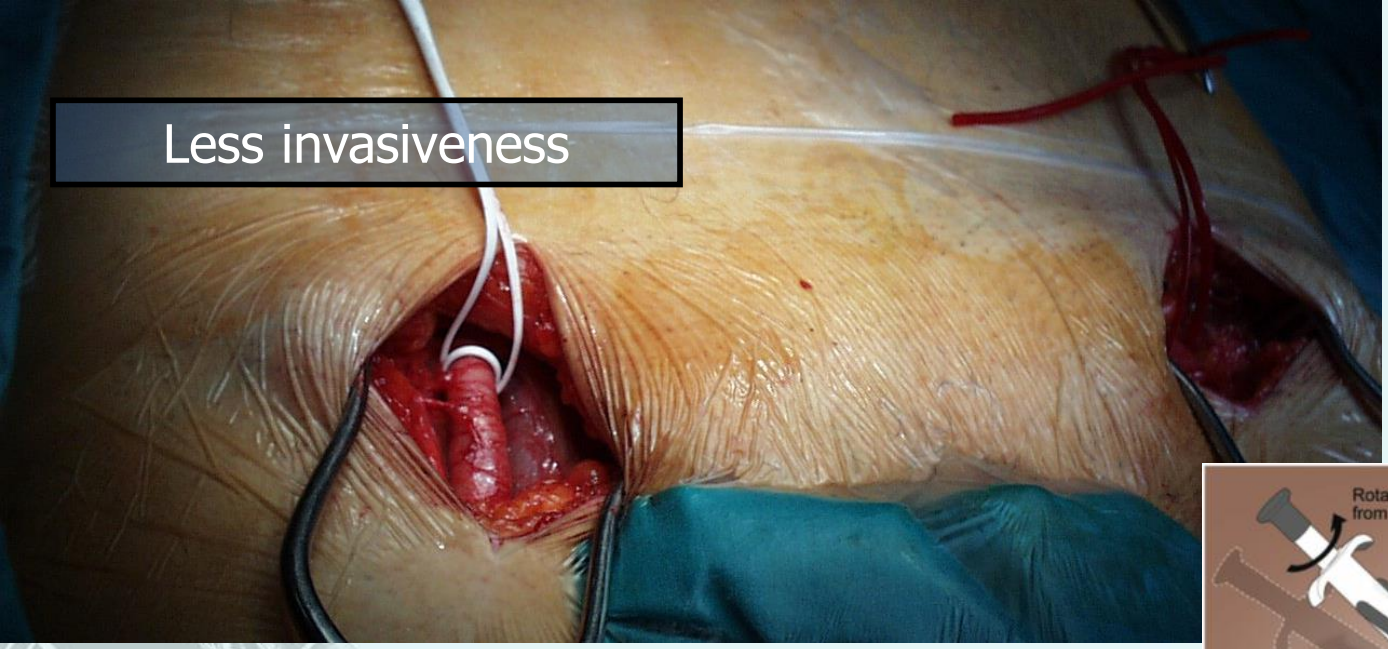
Gianbattista Parlani, Perugia, Italy

Disclosure

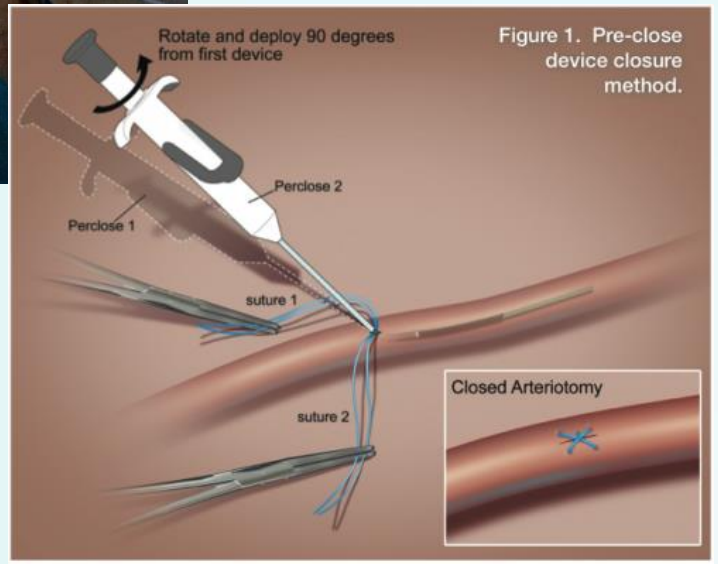
GIANBATTISTA PARLANI

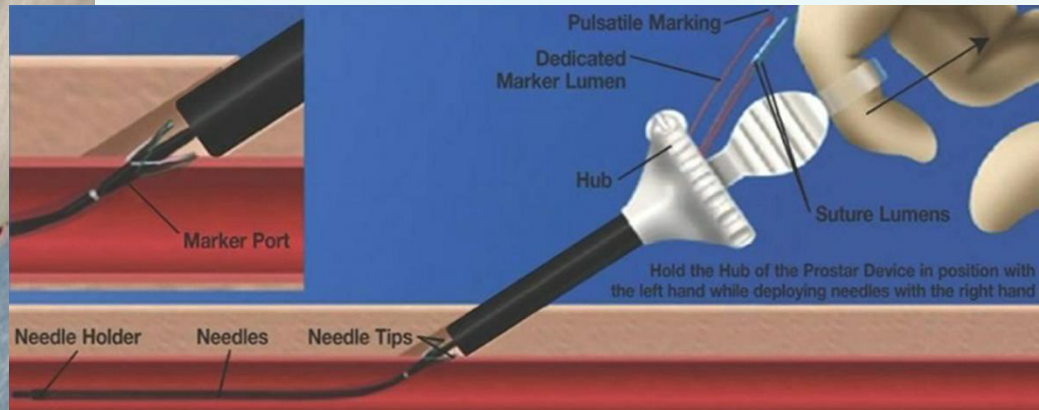
- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☑ I do not have any potential conflict of interest

Why percutaneous?


Less invasiveness

Vs…


Rotate and deploy 90 degrees from first device
Figure 1. Pre-close device closure method.
Perclose 2
Perclose 1
suture 1
suture 2
Closed Arteriotomy


Pulsatile Marking
Dedicated Marker Lumen
Hub
Suture Lumens
Marker Port
Hold the Hub of the Prostar Device in position with the left hand while deploying needles with the right hand
Needle Holder
Needles
Needle Tips

Endovascular suture versus cutdown for endovascular aneurysm repair: A prospective randomized pilot study

Giovanni B. Torsello, MD,[a] Bernd Kasprzak, MD,[a] Eckhard Klenk, MD,[a] Jörg Tessarek, MD,[a] Nani Osada, PhD,[b] and Giovanni F. Torsello,[a] *Münster, Germany*

(J Vasc Surg 2003;38:78-82.)

- Percutaneos (Prostar^{R}) vs cut down
- 30 randomized patients
- 55 femoral accesses
- Included obese pts and calcified CFA
- Operator's experience > 30 cases

Endovascular suture versus cutdown for endovascular aneurysm repair: A prospective randomized pilot study

Giovanni B. Torsello, MD,[a] Bernd Kasprzak, MD,[a] Eckhard Klenk, MD,[a] Jörg Tessarek, MD,[a] Nani Osada, PhD,[b] and Giovanni F. Torsello,[a] *Münster, Germany*

(J Vasc Surg 2003;38:78-82.)

Costs?

"Cost of materials for femoral access in the percutaneous group was significantly higher than in cut-down group , but the percutaneous technique significantly reduced hospital resource use"

	Percutaneous	Cut down	P
Time	86±27 min	107±38 min	<0.05
Fluoro	17±6 min	19+15 min	ns
Deambulation	20±4 h	33±19 h	< 0.001
Devices cost	223±6 €	18±0 €	<0.001
OR cost	251±89 €	357±153 €	<0.01

Ambulatory percutaneous endovascular abdominal aortic aneurysm repair

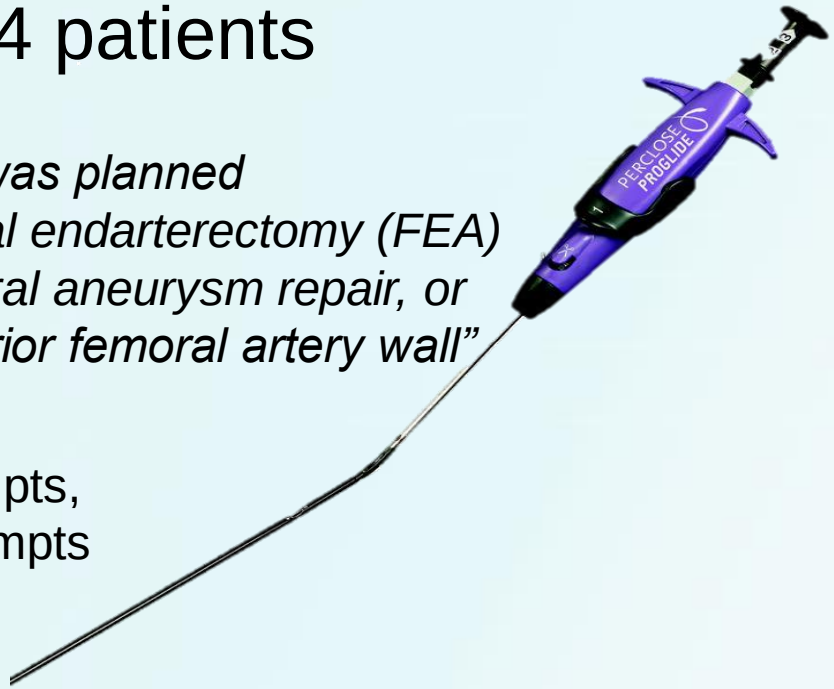
Hasan H. Dosluoglu, MD,[a,b] Purandath Lall, MBBS,[a,c] Raphael Blochle, MD,[b] Linda M. Harris, MD,[b] and Maciej L. Dryjski, MD,[b] *Buffalo, NY; and San Fernando, Trinidad and Tobago*

(J Vasc Surg 2014;59:58-64.)

Hospital stay reduction

2011-2012 64 patients

"Percutaneous EVAR was planned except in those who needed femoral endarterectomy (FEA) for bulky occlusive disease, femoral aneurysm repair, or excessive calcification of the anterior femoral artery wall"



54 (84%) bilateral percutaneous attempts,
7 (11%) unilateral percutaneous attempts
3 (5%) bilateral femoral cutdowns

The success rate for PEVAR was 96% (111/115)
(100% for 9-16F, 93% for 17-22F sheaths)

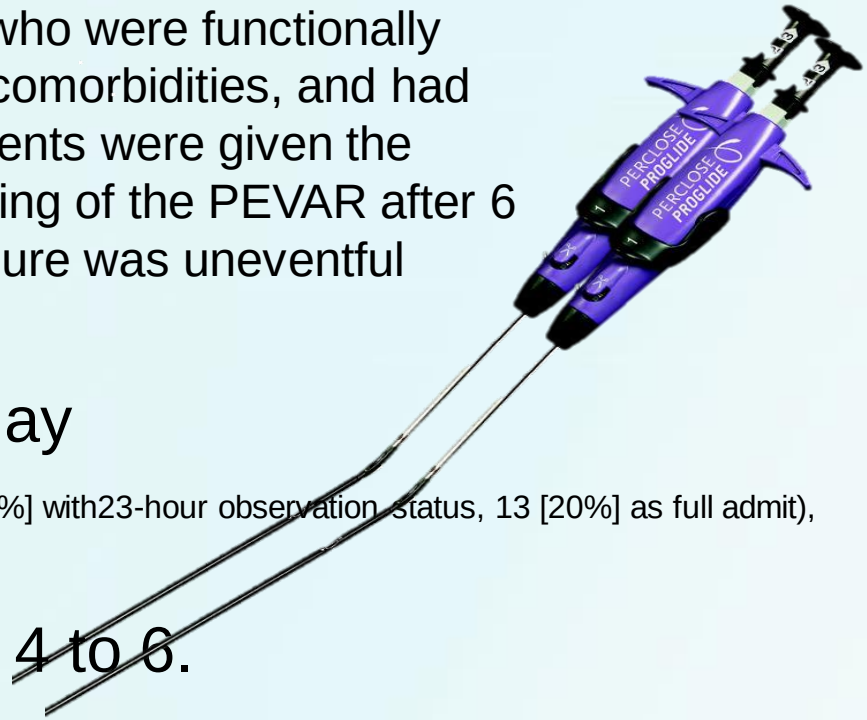
Ambulatory percutaneous endovascular abdominal aortic aneurysm repair

Hasan H. Dosluoglu, MD,[a,b] Purandath Lall, MBBS,[a,c] Raphael Blochle, MD,[b] Linda M. Harris, MD,[b] and Maciej L. Dryjski, MD,[b] *Buffalo, NY; and San Fernando, Trinidad and Tobago*

(J Vasc Surg 2014;59:58-64.)

Hospital stay reduction

SDD (same day discharge) was discussed during the preoperative visit with patients who were functionally independent, without significant comorbidities, and had favorable anatomy. These patients were given the option to be discharged in the evening of the PEVAR after 6 hours of bed rest if the procedure was uneventful



21 (33%) discharged on the same day
23 (36%) discharged on POD 1 (10 [16%] with23-hour observation status, 13 [20%] as full admit),
17 (27%) discharged on POD 2/3
3 (5%) discharged between POD 4 to 6.

Ambulatory percutaneous endovascular abdominal aortic aneurysm repair

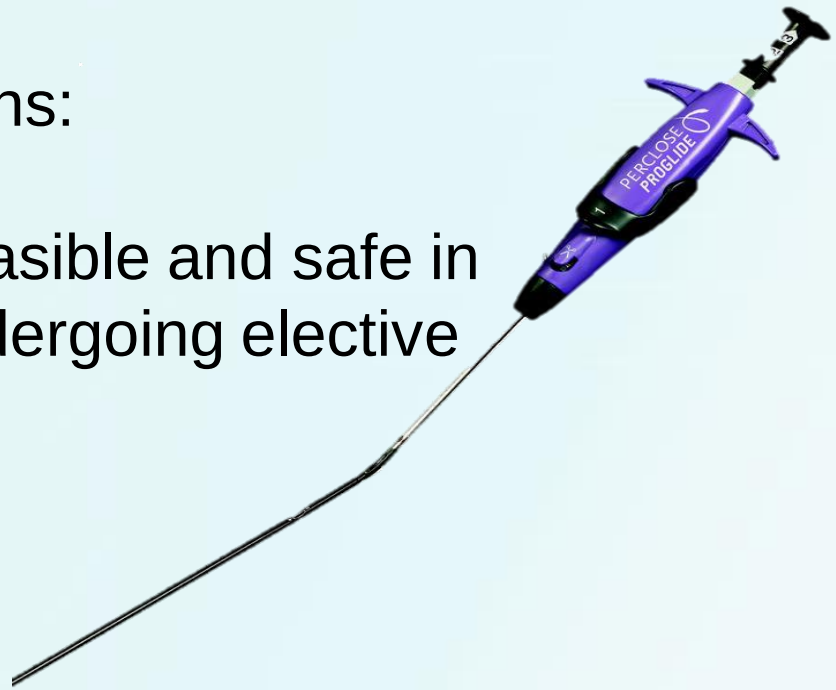
Hasan H. Dosluoglu, MD,[a,b] Purandath Lall, MBBS,[a,c] Raphael Blochle, MD,[b] Linda M. Harris, MD,[b] and Maciej L. Dryjski, MD,[b] *Buffalo, NY; and San Fernando, Trinidad and Tobago*

(J Vasc Surg 2014;59:58-64.)

Hospital stay reduction

Conclusions:

ambulatory PEVAR is feasible and safe in one-third of patients undergoing elective EVAR



A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Peter R. Nelson, MD, MS,[a] Zvonimir Kracjer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Reduction in complications

Procedural Technique

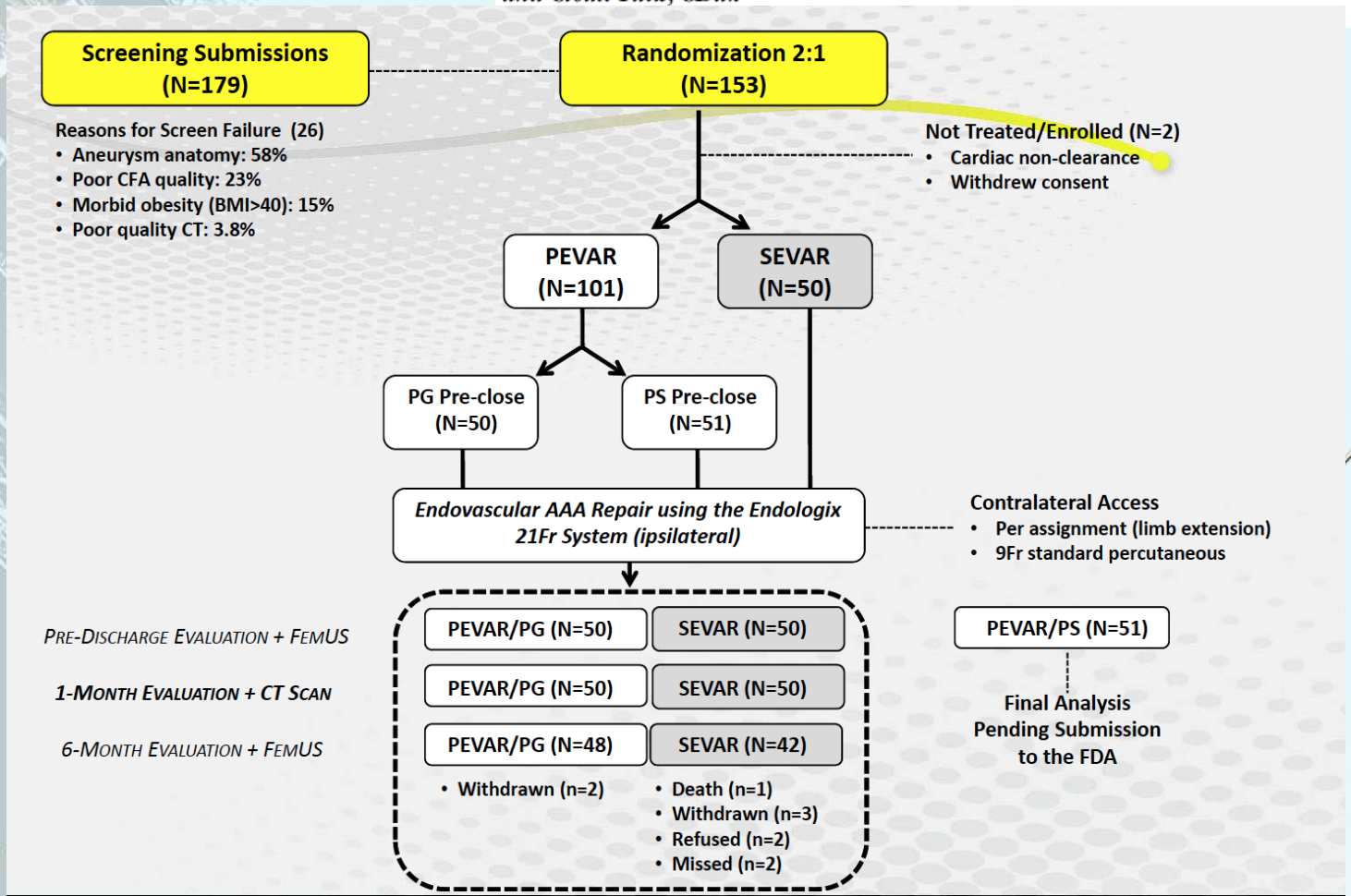
- PEVAR-ProGlide® (PG)
  - Two devices deployed in a cross-hair configuration
- PEVAR-Prostar XL® (PS)
  - Single device deployed into femoral arteriotomy
- SEVAR
  - Standard open femoral exposure with management of arteriotomy left to the discretion of the operating surgeon

A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Peter R. Nelson, MD, MS,[a] Zvonimir Krajcer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Reduction in complications



A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Peter R. Nelson, MD, MS,[a] Zvonimir Kracjer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Reduction in complications

Endologix Primary Endpoint Component Results

Outcome	PEVAR-PG N=50	PEVAR-PS N=51	SEVAR N= 50
Patients with Treatment Success	**44 [88%]**	**40 [78%]**	**39 [78%]**
Unsuccessful Treatment (Failure)	6 (12%)	11 (22%)	11 (22%)
COMPONENT RESULTS			
Procedural Technical Failure	3 (6.0%)	6 (12%)	1 (2.0%)
Ipsilateral CFA Access Failure	3 (6.0%)	6 (12%)	0
Endovascular Device Failure	0	0	1 (2.0%)
Major Adverse Event	2 (4.0%)	5 (9.8%)*	5 (10%)
Vascular Complications	4 (8.0%)	8 (16%)	8 (16%)

** 3/5 MAEs were CHF or arrhythmia related and adjudicated as cardiac events*

A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Peter R. Nelson, MD, MS,[a] Zvonimir Kracjer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Reduction in complications

Endologix Primary Endpoint Results

- **PEVAR-ProGlide®** achieved non-inferiority to SEVAR with respect to 1-month Treatment Success
  - P=.0036, one-sided Blackwelder's test
  - Data submitted to US FDA; approval pending
- **PEVAR-Prostar XL®** did not satisfy non-inferiority to SEVAR with respect to 1-month Treatment Success
  - P=.1021, one-sided Blackwelder's test
  - Data not yet submitted to US FDA pending additional analyses; further results will not be presented

A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Less hospital stay

Peter R. Nelson, MD, MS,[a] Zvonimir Kracjer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Results: In-Hospital Comparisons

In-Hospital Characteristic	PEVAR N	PEVAR PG (N=50)	SEVAR N	SEVAR N= 50	P-Value (PG vs. SEVAR)
Post-Procedure Information					
Time to Ambulation (hrs)	50	17 ± 7.2	50	19 ± 16	0.388
Time to Normal Diet (hrs)	49	14 ± 9.4	50	15 ± 22	0.728
ICU Length of Stay (hrs)	35	26 ± 9.0	24	35 ± 32	0.269
Meds for Groin Pain	9	18%	17	34%	0.190
Time to Discharge (days)	50	1.3 ± 0.7	50	1.8 ± 2.4	0.135
Discharged to SNF/ALF	0	0%	1	2%	1.000

P-values determined using unequal variance t-test or Fisher's exact test.

- A trend toward reduced analgesics for groin pain in PEVAR-**PG** versus SEVAR.
- PEVAR-**PG** patients discharged on average 0.5 days sooner than SEVAR patients

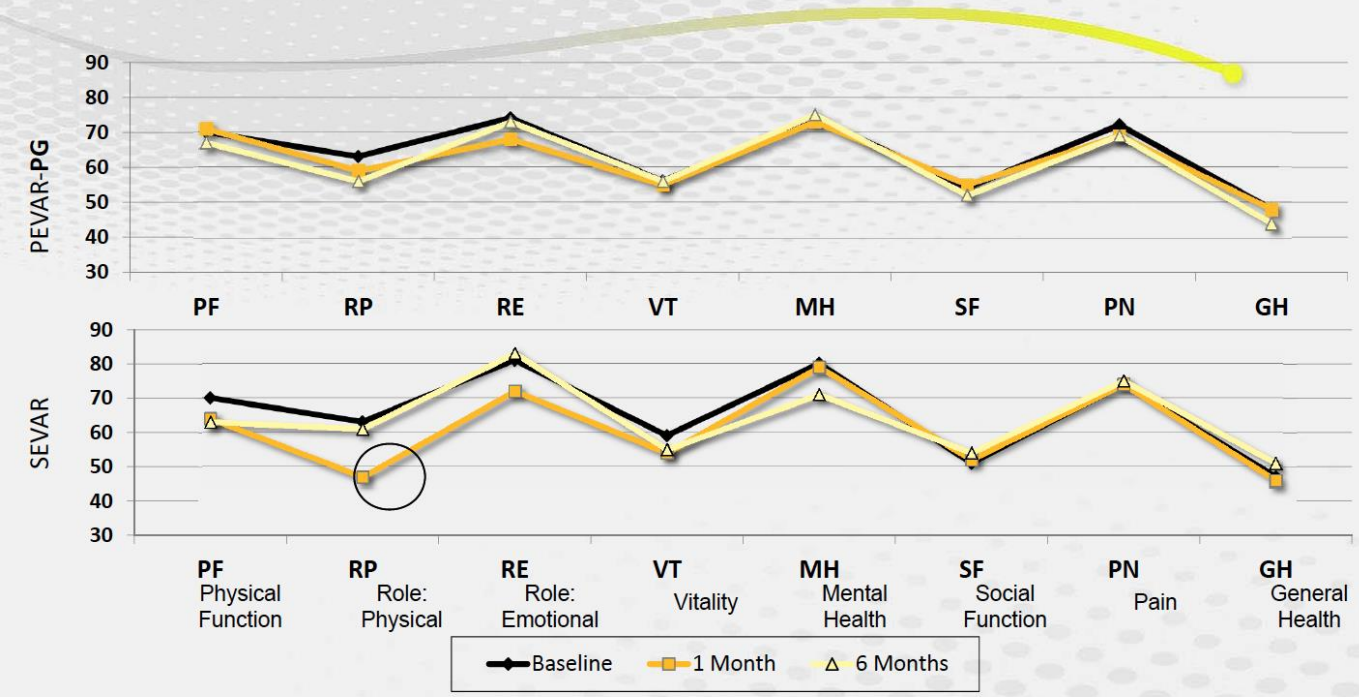
A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

Less discomfort

Peter R. Nelson, MD, MS,[a] Zvonimir Kracjer, MD,[b] Nikhil Kansal, MD,[c] Vikram Rao, MD,[d] Christian Bianchi, MD,[e] Homayoun Hashemi, MD,[f] Paul Jones, MD,[g] and J. Michael Bacharach, MD,[h] *Tampa, Fla; Houston, Tex; San Diego, Calif; Willoughby, Ohio; Loma Linda, Calif; Falls Church, Va; Chicago, Ill; and Sioux Falls, SDak*

(J Vasc Surg 2014;■:1-13.)

Health-Related Quality of Life – SF-36

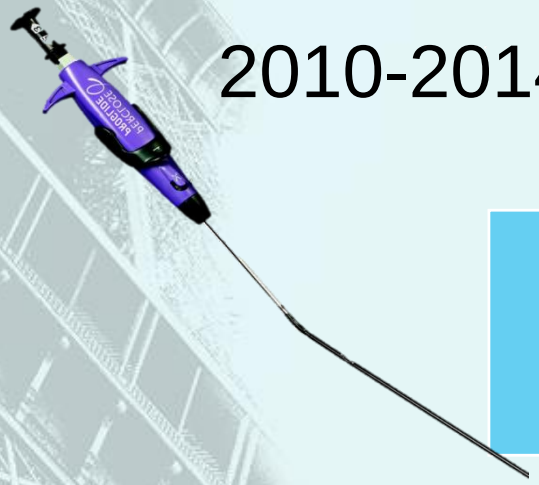


- No significant differences between groups in mean results of any SF-36 domain.
- SEVAR had greater reductions in both Role Limitation domains at one month.
- Domain mean results rebound in both groups at six months.

Italian Percutaneous EVAR (IPER) Registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft

J CARDIOVASC SURG 2015;56:889-98

G. PRATESI [1], M. BARBANTE [1], R. PULLI [2], A. FARGION [2], W. DORIGO [2]
R. BISCEGLIE [1], A. IPPOLITI [1], C. PRATESI [2] on behalf of IPER Registry Collaborators



2010-2014 2381 accesses in 1322 pts

1867 Prostar XL

***514* Proglide**

Italian Percutaneous EVAR (IPER) Registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft

J CARDIOVASC SURG 2015;56:889-98

G. PRATESI [1], M. BARBANTE [1], R. PULLI [2], A. FARGION [2], W. DORIGO [2]
R. BISCEGLIE [1], A. IPPOLITI [1], C. PRATESI [2] on behalf of IPER Registry Collaborators

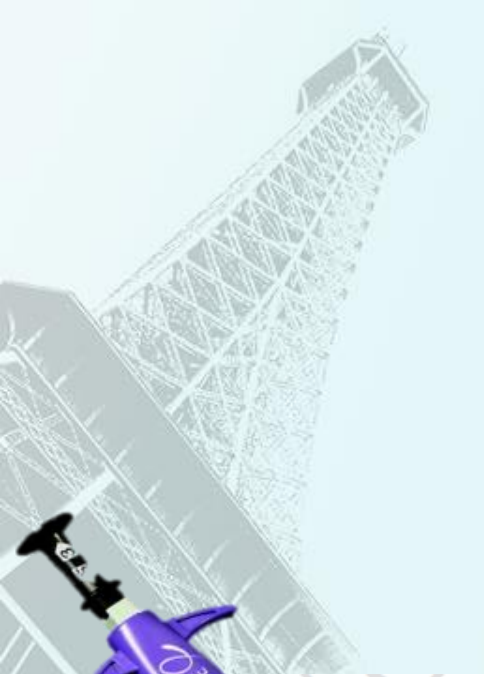


TABLE I.—*Preoperative patient demographics.*

Risk factors	(%)
Hypertension	75.9%
Smoke	41.4%
COPD	39.1%
CAD	36.6%
Obesity	24.7%
Diabetes	21.1%
Renal impairment	10.9%

COPD: chronic obstructive pulmonary disease; CAD: coronary arterial disease

TABLE II.—*Preoperative anatomical details.*

Anatomical features	N. (%)
Partial calcification	1189/2381 (49.9%)
Circumferential calcification	72/2381 (3%)
High CFA bifurcation	66/2381 (2.7%)
Mid CFA bifurcation	1269/2381 (53.3%)
Iliac tortuosity	538/2381 (22.6%)
Scarred groins	118/2381 (5%)
CFA<7 mm	172/2381 (7.2%)
CFA between 7-9 mm	1809/2381 (76%)

CFA: common femoral artery.

Italian Percutaneous EVAR (IPER) Registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft

J CARDIOVASC SURG 2015;56:889-98

G. PRATESI [1], M. BARBANTE [1], R. PULLI [2], A. FARGION [2], W. DORIGO [2]
R. BISCEGLIE [1], A. IPPOLITI [1], C. PRATESI [2] on behalf of IPER Registry Collaborators

Early outcomes	
Early major complication	103 (4.3%)
Surgical conversion	76 (3.2%)
Adjunctive manual compression	327 (13.7%)

Late outcomes	
Late conversion	8 (.3%)
Pseudoaneurysm	5 (.2%)
Stenosis/occlusion	3 (.1%)
Infection	-

Italian Percutaneous EVAR (IPER) Registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft

J CARDIOVASC SURG 2015;56:889-98

G. PRATESI [1], M. BARBANTE [1], R. PULLI [2], A. FARGION [2], W. DORIGO [2]
R. BISCEGLIE [1], A. IPPOLITI [1], C. PRATESI [2] on behalf of IPER Registry Collaborators

TABLE VI.—*Univariate and multivariate analysis.*

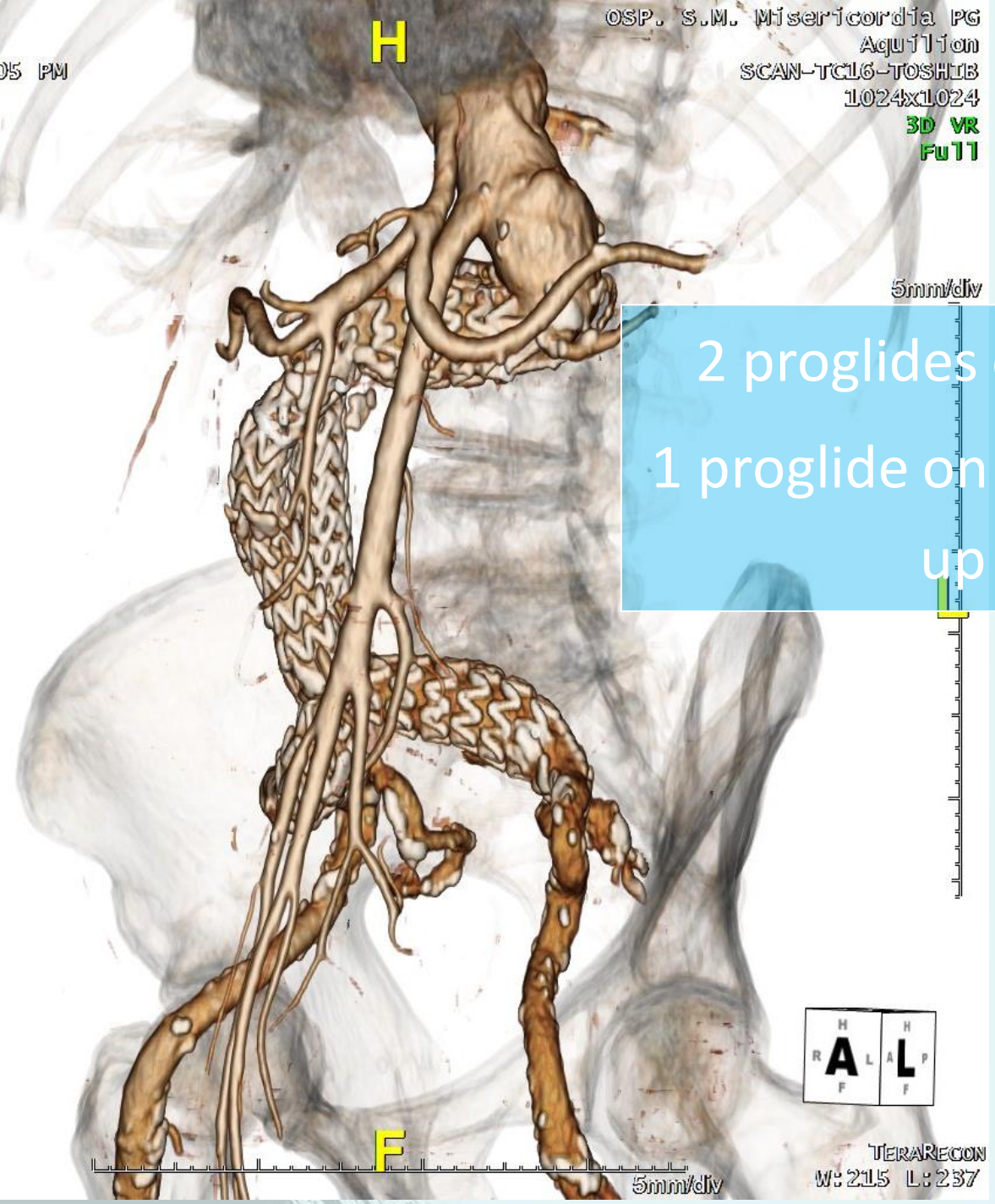
	OR	95% CI	P
Univariate analysis			
CFA calcifications	1.84	1.13-2.99	0.014
Closure device	0.74	0.40-1.36	0.33
CFA<7 mm	0.55	0.17-1.79	0.32
Obesity	0.87	0.50-1.51	0.64
High femoral bifurcation	0.94	0.22-3.94	0.94
Iliac tortuosity	1.71	1.05-2.79	0.031
Scarred groins	2.34	1.10-5.01	0.027
Sheath >18 F	1.37	0.79-2.37	0.24
Multivariate analysis			
CFA calcifications	1.69	1.03-2.77	0.036
Scarred groins	2.06	0.96-4.43	0.062
Iliac tortuosity	1.51	0.92-2.48	0.10

PEVAR WITH ENDURANT

Perugia Experience 2013-2016

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

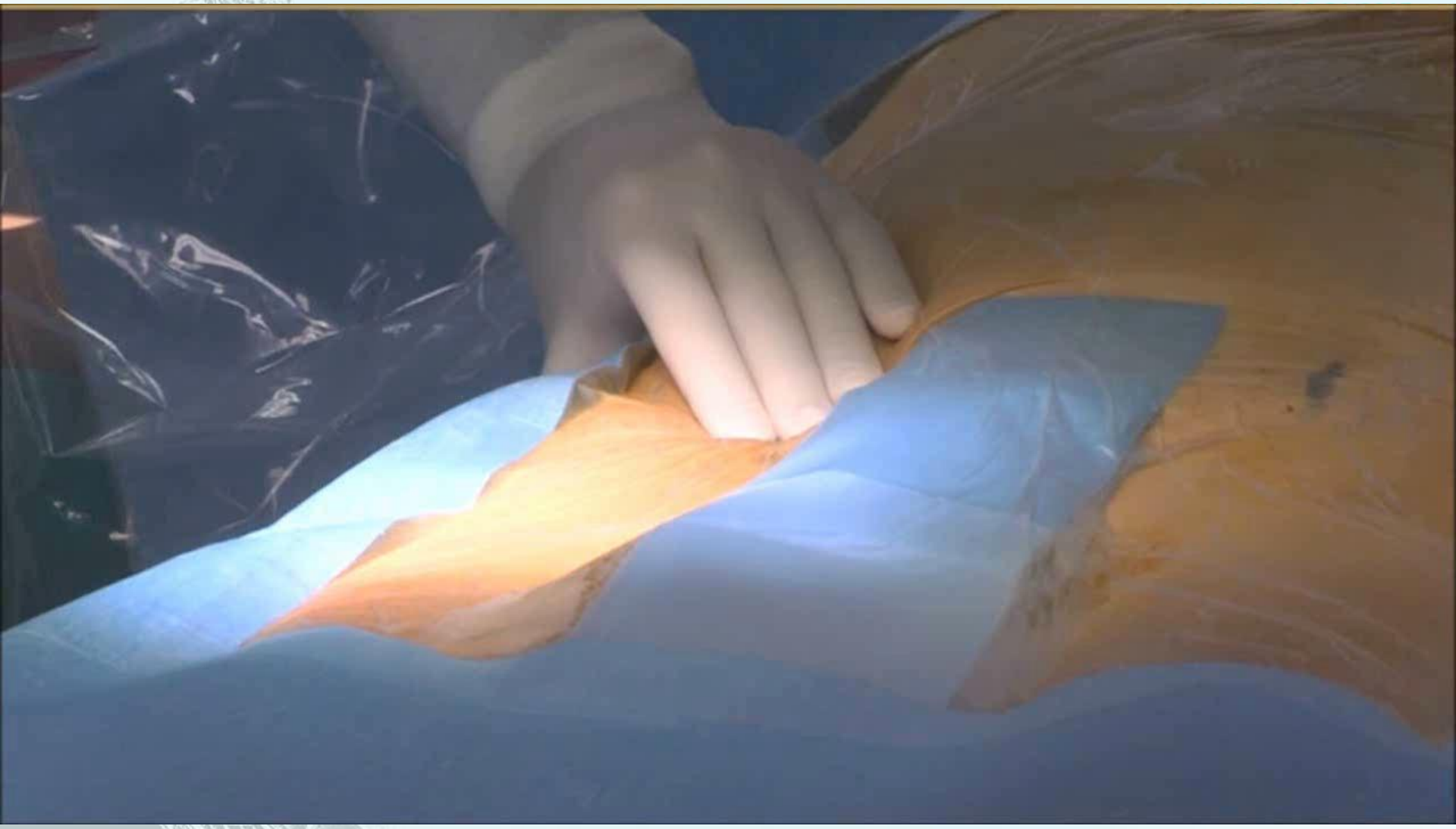
- EVAR ENDURANT 213
- PERCUTANEOUS APPROACH: 78 (36.6%)
- PERCUTANEOUS ACCESSES: 142
- TOTAL PROGLIDE® IMPLANTED : 226



2 proglides on main body side

1 proglide on contralateral access

up to 14 fr OD



PEVAR WITH ENDURANT

CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Perugia Experience 2013-2016

Intraprocedural outcomes

	PEVAR 142	SEVAR 284
Surgical conversion	5 (3.5%)	/
Adjunctive manual compression	12 (8.4%)	
Need of arterial patch or femoral by-pass	/	9 (3.1%)
Mean Procedural Time (min)	108′	127′

PEVAR WITH ENDURANT

CONTROVERSES ET ACTUALITES EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

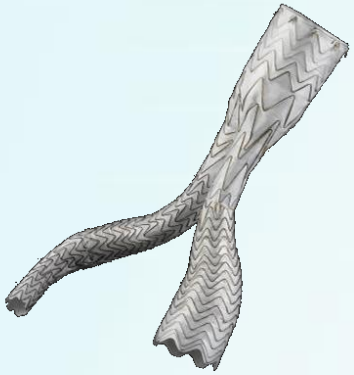
Perugia Experience 2013-2016

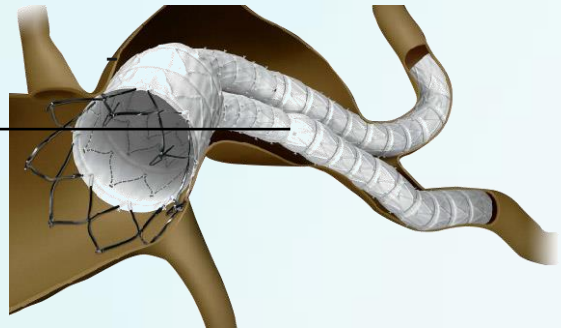
Perioperative results (30 day)

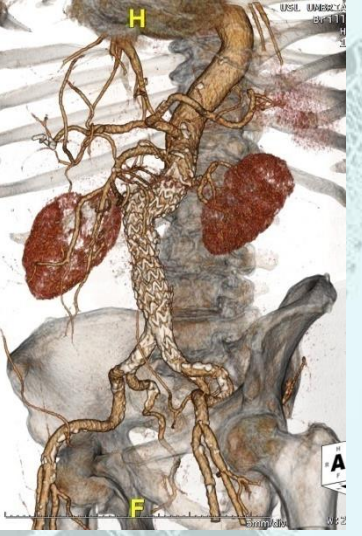
	PEVAR 142	SEVAR 284
Late Bleeding	/	1 (0.35%)
Groin Infection	/	3 (1.1%)
Seroma	/	3 (1.1%)
Pseudoaneurysm	/	/

Real diameter (OD)

	Main body	Contralateral leg
Gore C3	(18 Fr introducer Sheet) 6.8 mm	(12 Fr introducer Sheet) 4,7 mm
Endurant Medtronic	(28 mm) 6.0 mm	(16 mm) 4.6mm
Cook Alpha	(28 mm) 6.0 mm	(16 mm) 4.7mm
Cordis Incraft	(30 mm) 4.6 mm	(16 mm) 4.0 mm
Trivascular Ovation	(26 mm) 4.6 mm	(16 mm) 4.6 mm
Endologix Nellix	(any diameter single stent) 5. 7 mm	







Conclusion

- PEVAR is safe and highly effective (appropriate patient selection)
- Meticulous technique is crucial (know the device, tips & tricks and troubleshooting)
- PEVAR with Endurant endograft demonstrated optimal results in our experience