

The percutaneous way to manage large hole procedures

Vladimir Makaloski, MD, FEBVS

Department of cardiovascular surgery
Bern University Hospital, University of Bern

Disclosure

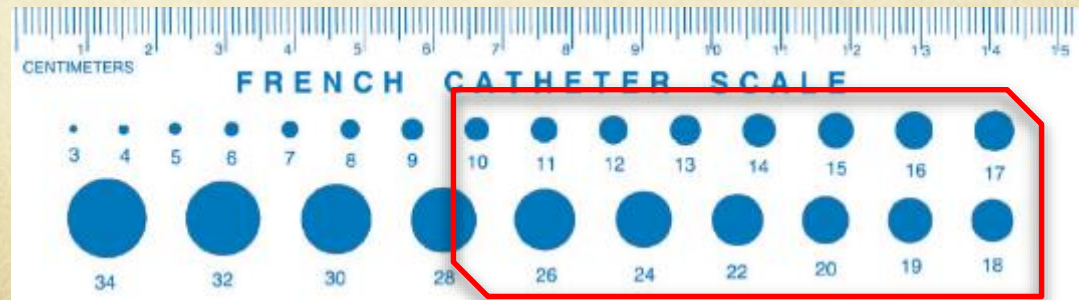
none

Content

- Overview of the current vascular closure devices
- Literature review
- How I do it - video
- Perspectives

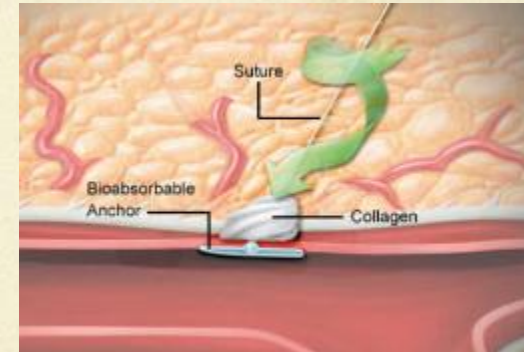
What is a large hole?

- Since 1953 (Seldinger) the puncture holes are getting “bigger”
- Complexity of procedures grows, sheath size too
- Large puncture hole ranges between 10 - 27 F (3 - 9mm)



How to control the vessel access?

- Manual compression (≤ 8 Fr)
- Vascular closure device (≥ 10 Fr)
 - Active approximators
 - Passive approximators
 - External hemostatic devices
- Cut-down/fascial closure technique



Active approximators

Device category	Device name	Manufacturer	Puncture size (F)
Clip or staple	StarClose SE	Abbott Vascular	5, 6
Suture	Perclose A-T	Abbott Vascular	5 – 8
	PerClose ProGlide	Abbott Vascular	5 – 21
	Prostar XL	Abbott Vascular	8.5 – 10

Passive approximators

Device category	Device name	Manufacturer	Puncture size (F)
Collagen based	Angio-Seal	St. Jude Medical	5/6, 7/8
	Vascade VCD	Cardiva Medical	5 - 7
Sealant or gel based	Mynx Ace	Cardinal Health	5 - 7
	Exoseal	Cordis Corp.	5 - 7
	FISH CombiClose FISH ControlClose	Morris Innovative, Inc.	5 - 8
Compression-Assist	Cardiva Catalyst II and III	Cardiva Medical, Inc.	5 - 7
	Axera 2 Access Dev	Arstasis, Inc.	5 - 6

External hemostatic devices

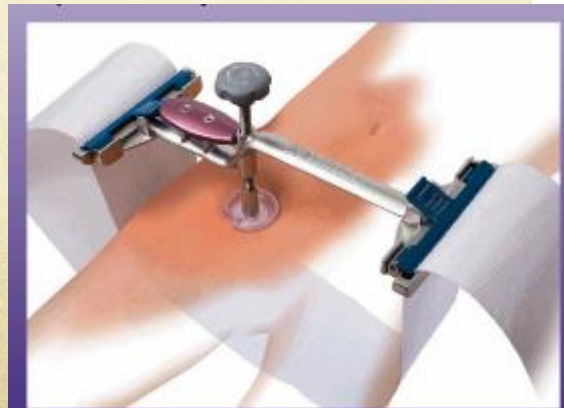
○ FemoStop



○ SafeGuard

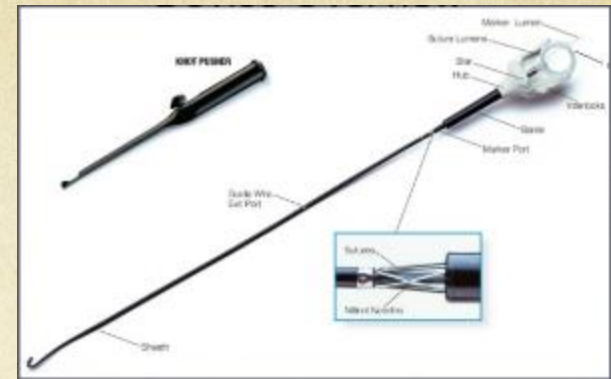


○ ExpressAR™ System



○ etc.....

First experiences



- Prostar XL was first used in EVAR in 1999*
- First feasibility study showed high failure rate of 50%!!!**
- Two Proglides standardized as “Preclose” technique***

*Haas PC, Krajcer Z, Diethrich EB. J Endovasc Surg. 1999 May

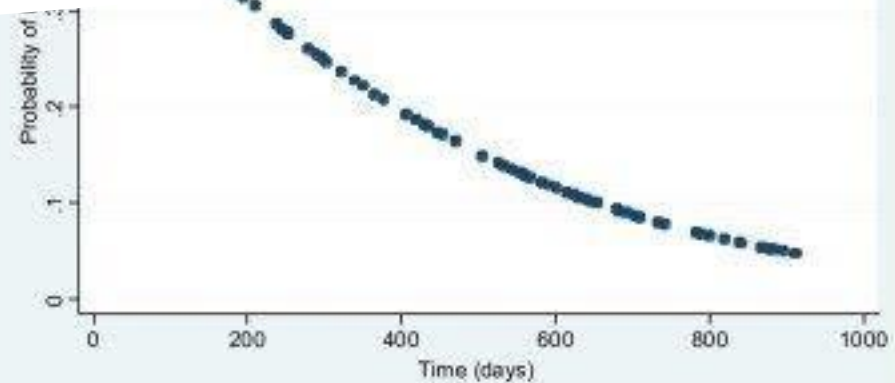
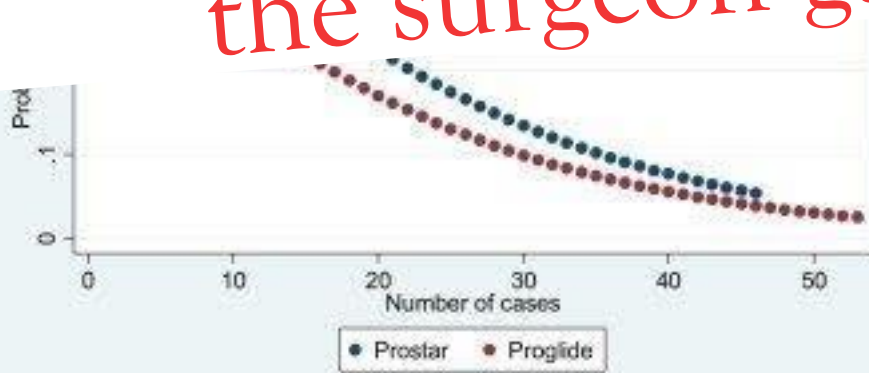
**Traul DK, Clair DG, Gray B, O’Hara PJ, Ouriel K. J Vasc Surg. 2000 Oct

***Lee A et al. J Vasc Surg. 2007 Jun

Predicting the learning curve...

- 99 patients over 30 month – single center study
- Overall PEVAR technical success was 82%

Technical failure can be reduced as the surgeon gains experience

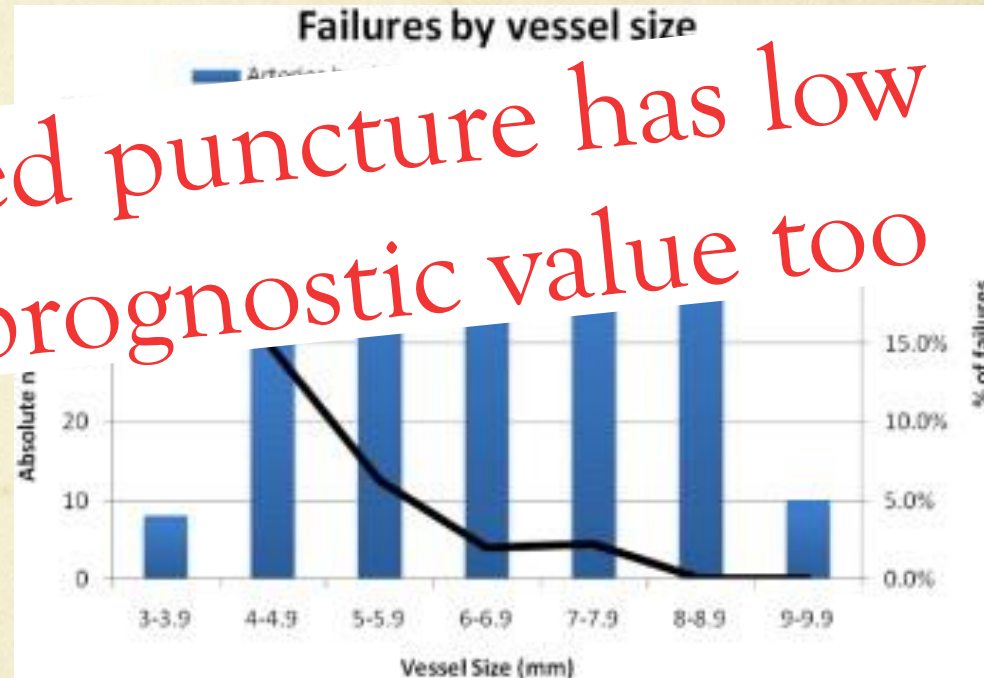


Ultrasound-guided puncture

- 88 patients with 152 large hole puncture*

Ultrasound-guided puncture has low failure rate and prognostic value too

were significantly reduced
and operative time
continued to decrease*



*Arthurs ZM, Starnes BW et al. Ann Vasc Surg. 2008 Nov

**Bensley RP et al. J Vasc Surg. 2012 Jun

PEVAR Trial

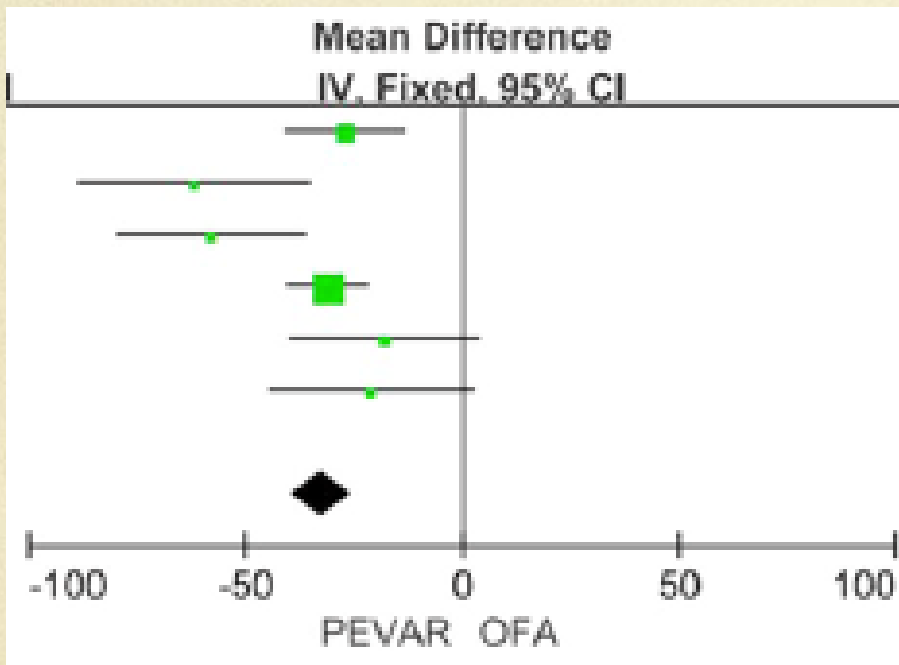
- prospective, multicenter, randomized and controlled trial in 20 U. S. centers (151 patients)

Percutaneous approach is faster and Proglide is safer than Prostar (p=0.023)

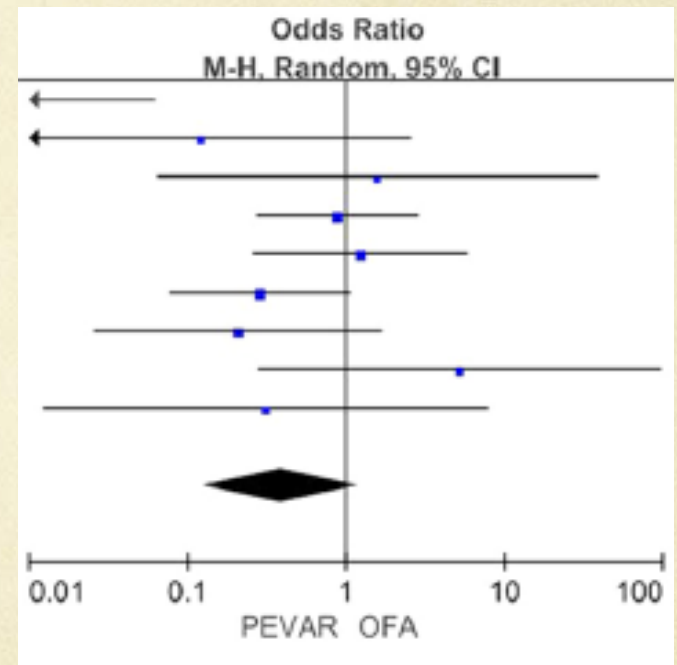
	PEVAR/PG (n = 50)	PEVAR/PS (n = 51)	FE (n = 50)
Major access-related complications	3 (6.0)	6 (12)	5 (10)
Vascular injury	1 (2.0)	5 (10)	1 (2.0)
Lower extremity ischemia	2 (4.0)	1 (2.0)	2 (4.0)
Bleeding/transfusion	1 (2.0)	1 (2.0)	2 (4.0)
Nerve injury	0	0	1 (2.0)

Percutaneous vs. open femoral access

- Systematic review → 11 studies = 1650 patients with 2500 groins



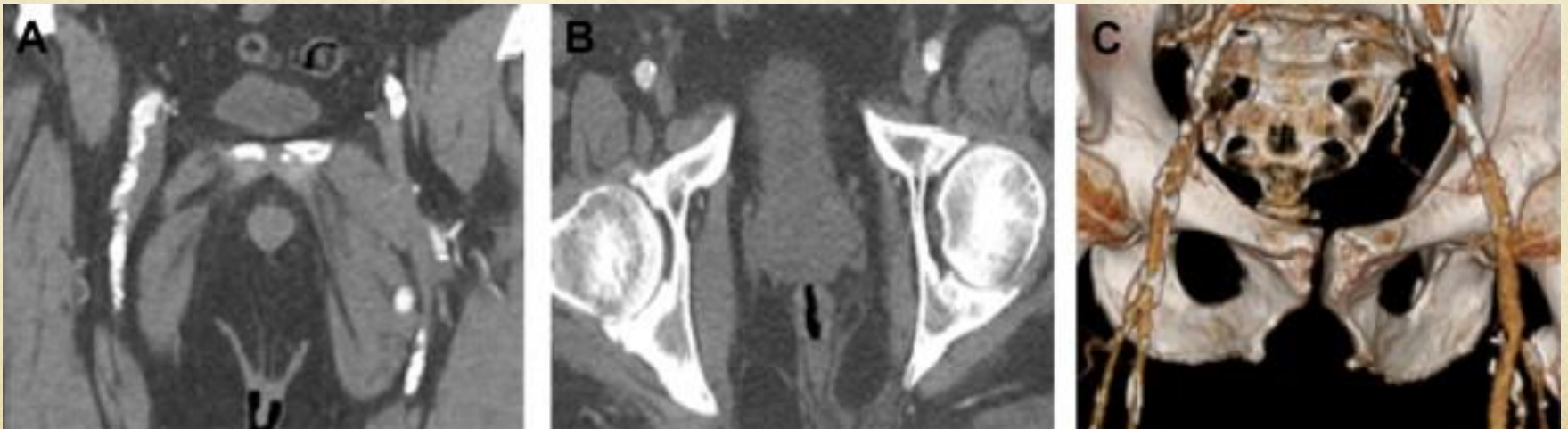
Procedure time



Overall complications

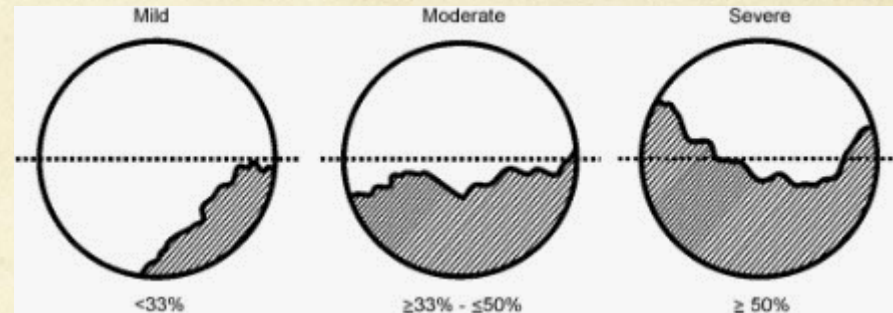
Is every femoral artery good enough?

- increased failure rate ($P < .001$) between patients with:
 - <50% anterior calcification vs none
 - <50% anterior calcification vs <50% posterior calcification



Predictors of access failure

- 266 PEVAR access sites; 32 (12.0%) had to be converted



- Female gender (OR, 3.1)
- moderately calcified arteries (OR, 2.5)
- age (OR, 2.3 [per decade])

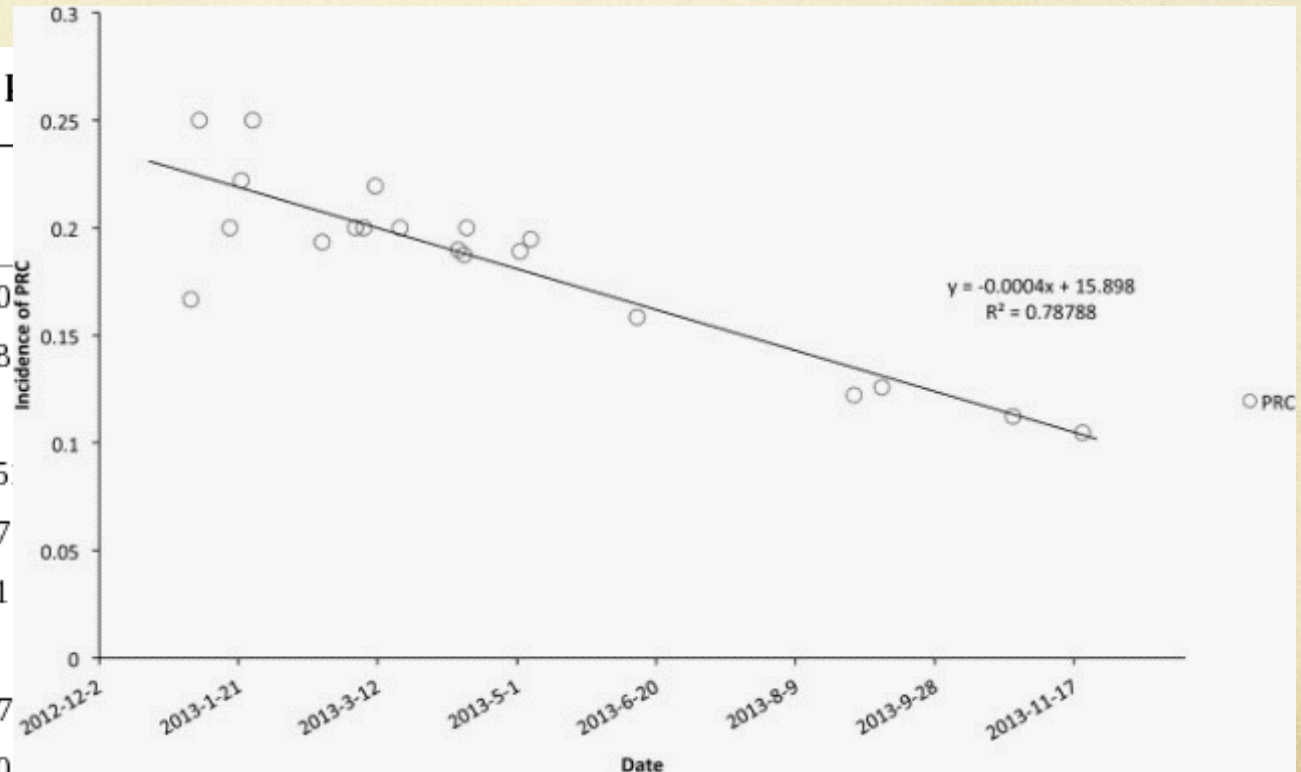
- Vessel size, sheath size and BMI were no predictors of conversion

Predictors of Proglide-related complications

- 198 PEVARs / **20 (10%) with technical failure**

Logistic regression analysis of predictors of PRC

Variables		
BMI	>30kg/m ²	11/60
	≤30kg/m ²	9/138
CFA depth	>4cm	9/47
	≤4cm	11/15
Stent cover site	Thoracic	13/77
	Abdominal	7/121
Sheath size	>20Fr	6/23
	≤20Fr	14/17
CFA calcification	<50%*	13/70

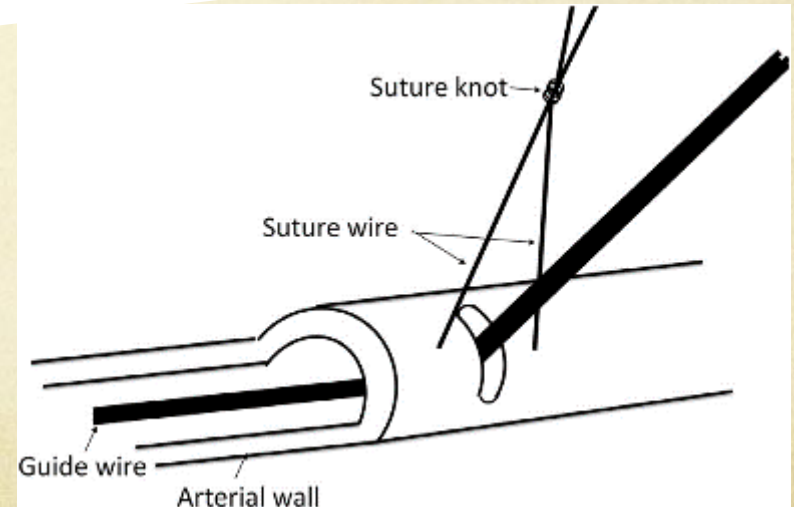


Single Proglide – is it enough?!

- 50 PEVARs (up to 24 Fr) vs. 96 EVARs with cut-down

PEVAR with single Proglide is safe!

○ Shorter operating time and hospital stay in the PEVAR group ($p < 0.01$)

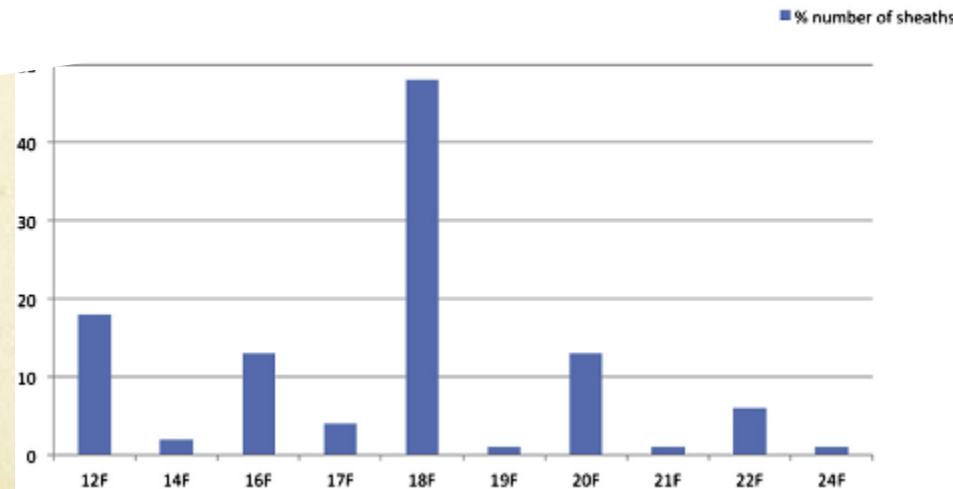


Is heparin reversal required?

- 131 percutaneous femoral

No benefit from heparin reversal

- 4 pat. (3%) open conversion after failed hemostasis



Same-day discharge possible?

- 64 elective EVARs, **only 33% (21 patients)** discharged same day

Not every patient can be early discharged

- Reasons to stay: COPD, CAD, advanced age, renal protection etc..

Percutaneous approach reduces costs

- 67 elective EVARs

Costs	PEVAR			Unilat	Failed	10,981 ± 5785	19,413 ± 4044
	Bilat	Unilat	Failed				
OR other ^c	1448 ± 382	1798 ± 570	1914 ± 380	1527 ± 425	1839 ± 655
Anesthesia	490 ± 338	1055 ± 382	1292 ± 273	615 ± 426	1182 ± 257

Bilateral PEVAR associated with lower costs and postop. day 1 discharge

Percutaneous approach is also safe in TEVAR/FEVAR/BEVAR

Percutaneous closure of large femoral artery access with Prostar XL in thoracic endovascular aortic repair.

[Skagius E1, Bosnjak M, Björck M et al.](#) Eur J Vasc Endovasc Surg. 2013 Nov

Percutaneous thoracic endovascular aortic repair is not contraindicated in obese patients.

[Zakko J et al.](#) J Vasc Surg. 2014 Oct

Outcomes of total percutaneous endovascular aortic repair for thoracic, fenestrated and branched endografts.

[de Souza LR, Oderich GS et al.](#) J Vasc Surg. 2015 Dec

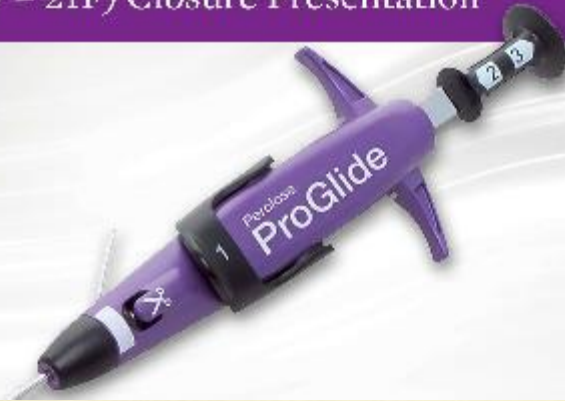
Safety and effectiveness of total percutaneous access for fenestrated endovascular aortic aneurysm repair.

[Timaran DE et al.](#) J Vasc Surg. 2016 Oct

Perclose ProGlide

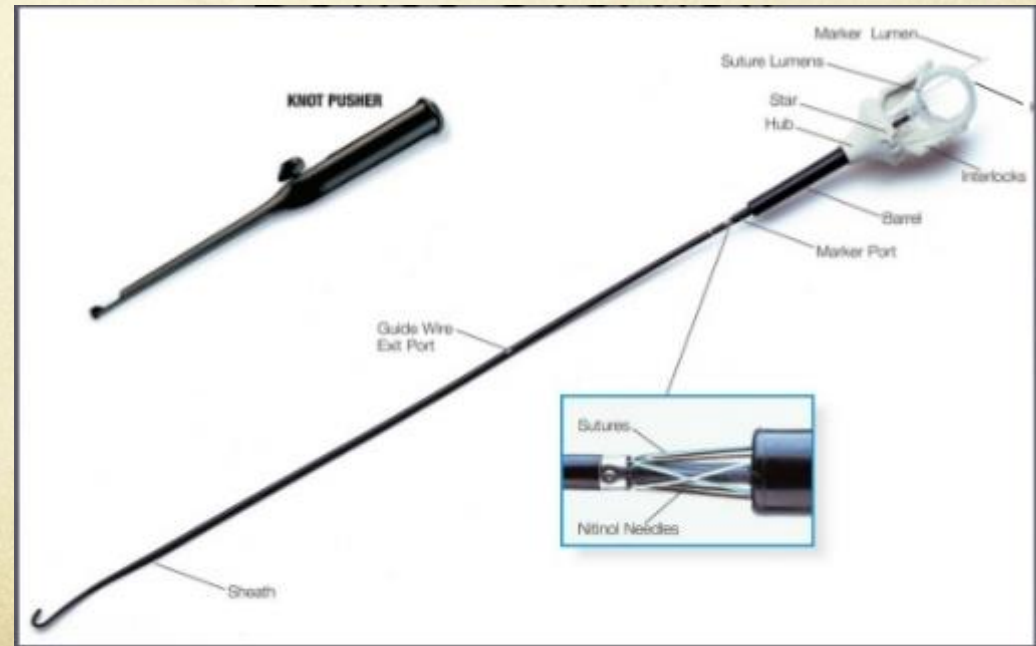
Suture-Mediated Closure System

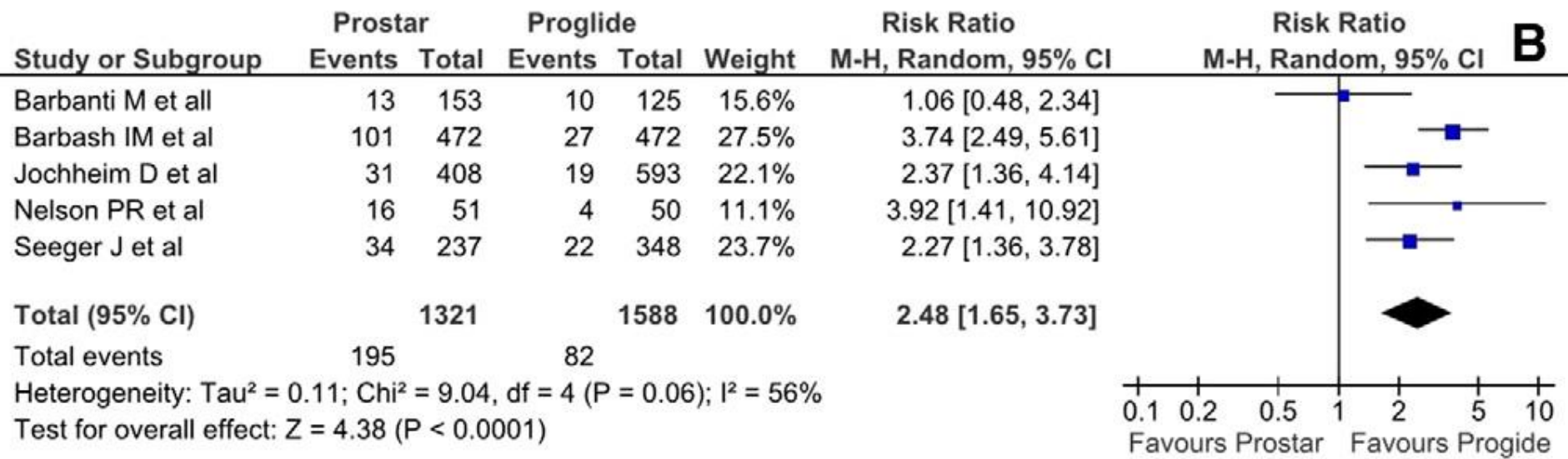
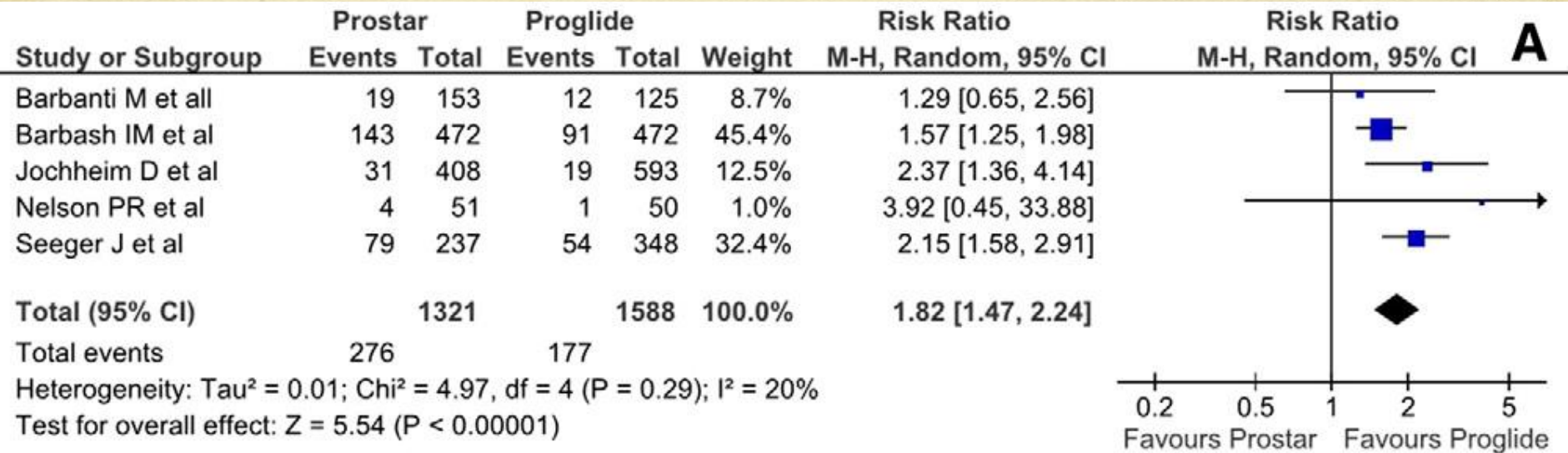
Large Hole (8.5F – 21F) Closure Presentation



ProGlide

Prostar XL





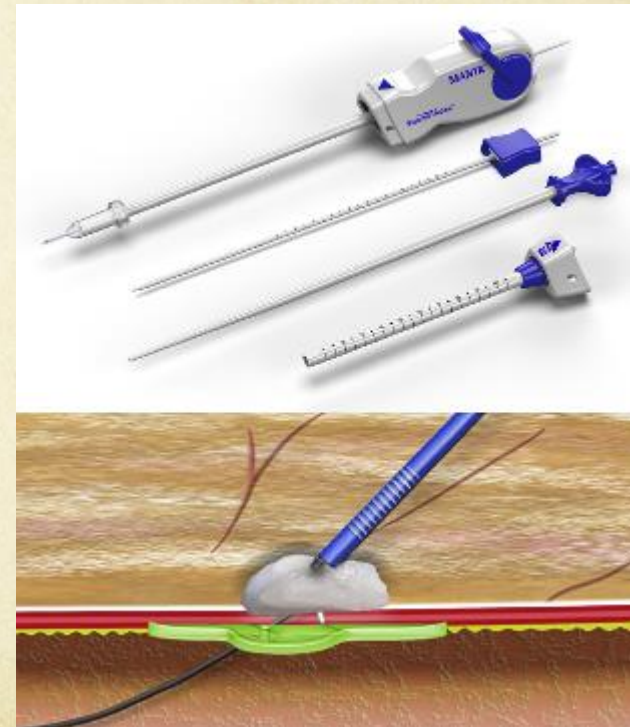
Forest plot of all bleedings (incl. life-threatening)

How I do it

- 70y old male
- COPD, BMI > 30, rheumatoid arthritis (under immunosuppression)
- Thoracoabdominal aneurysm type III (max \odot of 60mm)
- Two-stage procedure
 1. percutaneous TEVAR (24 Fr) - video
 2. 4 x BEVAR + EVAR

New VCD for large holes

- prospective, single-arm clinical investigation in 3 European centers (50 patients)
- MANTA collagen-based VCD (14 - 18 Fr)
- Rapid, reliable hemostasis and low complication rates (one conversion)



Alternatives...

- Translumbar
- Transapical
- Transsubclavian
- (Iliac) Conduit
- Transvenous Access to the Aorta

Discussion

- Vascular closure device market grows rapidly during last 20y
- Its turnover is estimated at \$1 billion per year!!!
- Early discharge and ambulation, lower costs and patient's comfort supports the use and further development of VCD
- Maybe the reimbursement policy should be reevaluated

Conclusions

- Percutaneous approach is faster and safer than the open access
- However, there are some limitations (calcification)
- No dedicated vascular closure devices exist for large arteriotomies
- The active approximators in preclose technique are gold standard