FAKULTNÍ NEMOCNICE® OLOMOUC

Lékařská fakulta
Univerzita Palackého v Olomouci

KOMPLEXNÍ KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC

Combined Strategy for Large-Bore Arteriotomy Closure after Transcatheter Aortic Valve Implantation

M Sluka, R Nykl, J Ostřanský

Backround

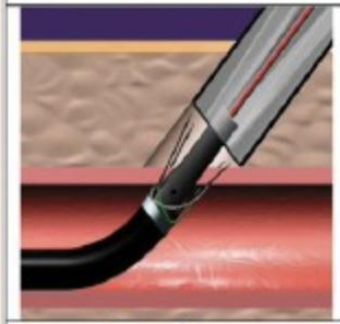
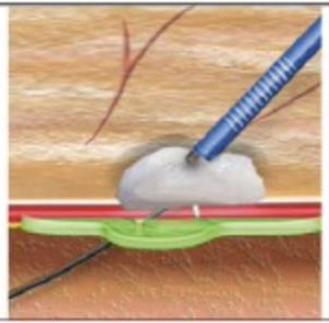
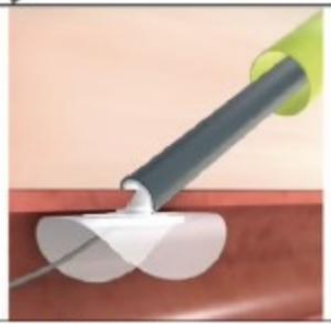
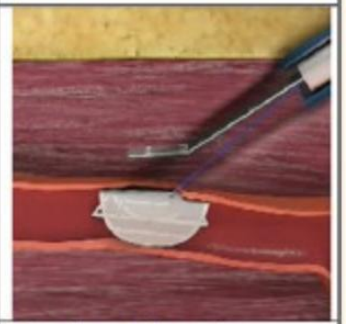
- The vascular complications remain a relevant following transcatheter aortic valve implantation (TAVI)
- They are frequently caused by vascular closure device (VCD) failure
- Moreover they might be associated with serious bleeding events requiring complex treatment strategy and contributing significantly to morbidity and mortality

Steinvil A, et al. Vascular complications after trans- catheter aortic valve implantation and their association with mortality re-evaluated by the valve academic research consortium definitions. Am J Cardiol. 2015

Backround

- The incidence of vascular complications depends on different factors (clinical characteristics, vascular morphology, delivery system insertion profile, operator technical experience) with reported rate between 4-19%

VCDs

Prostar® XL	ProGlide®	MANTA™	PerQseal®	InSeal
				
				
Suture-based	Suture-based	Collagen-based	Patch-based	Membrane-based
8.5–10 Fr (off-label use > 10 Fr)	5–8 Fr (off-label use > 8 Fr)	10–14 Fr (14 Fr system) 14–22 Fr (18 Fr system)	< 24 Fr	14–21 Fr
CE mark	CE mark	CE mark	CE mark	CE mark

ProGlide®/ProStyle®

CONS:

Longer learning curve

Higher probability of technical mistake

Higher need of additional VCD use

Longer average time for complete hemostasis

MANTA™

CONS:

Minimal lumen diameter for MANTA™ 18F 6 mm

Internal anchor size – risk of unexpected interaction with AS plaque leading to VCD failure

Aprox. 2,5 times higher price compared to 2 ProGlides®

VCD evidence – MASH trial

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 2, 2021

PUBLISHED BY ELSEVIER

Suture- or Plug-Based Large-Bore Arteriotomy Closure

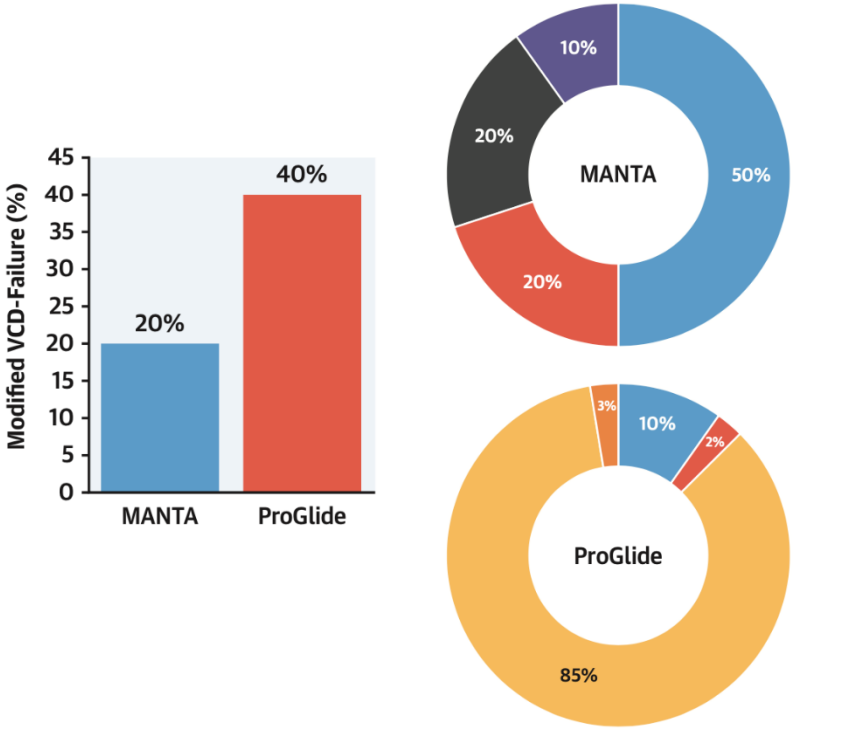
A Pilot Randomized Controlled Trial

Maarten P. van Wiechen, MD,[a,*] Didier Tchétché, MD,[b,*] Joris F. Ooms, MD,[a] Thijmen W. Hokken, MD,[a] Herbert Kroon, MD,[a] Francesca Ziviello, MD,[a] Angie Ghattas, MD,[b] Saifullah Siddiqui, MD,[b] Clémence Laperche, MD,[b] Ernest Spitzer, MD,[a] Joost Daemen, MD, PhD,[a] Peter P. de Jaegere, MD, PhD,[a] Nicolas Dumonteil, MD,[b] Nicolas M. Van Mieghem, MD, PhD[a]

MASH trial

	Overall (N = 206)	MANTA (n = 102)	ProGlide (n = 104)	p Value
Composite access site-related major and minor vascular complications, <30 days	14 (7)	10 (10)	4 (4)	0.16
Major vascular complications	2 (1)	2 (2)	0 (0)	0.24
Minor vascular complications	12 (6)	8 (8)	4 (4)	0.35
Any bleeding, <30 days	21 (10)	10 (10)	11 (11)	1.00
Access site-related	15 (7)	9 (9)	6 (6)	0.57
Need for RBC transfusion				0.30
None	186 (90)	92 (90)	94 (90)	
1 U	5 (2)	4 (4)	1 (1)	
≥2 U	15 (7)	6 (6)	9 (9)	
Modified VCD failure*	62 (30)	20 (20)	42 (40)	<0.01
Immediate hemostasis	88 (42)	49 (48)	39 (36)	0.18
Time to hemostasis, s†	77 (40-202)	53 (35-200)	120 (61-216)	0.02
Procedural length, min	58 (46-70)	61 (47-75)	57 (45-68)	0.14
Length of hospital stay, days	7 (5-9)	7 (5-9)	7 (5-9)	0.96

MASH trial modified VCD failure



VCD evidence – CHOICE-CLOSURE trial

Circulation
Volume 145, Issue 3, 18 January 2022; Pages 170-183
https://doi.org/10.1161/CIRCULATIONAHA.121.057856

American Heart Association.

ORIGINAL RESEARCH ARTICLE

Comparison of a Pure Plug-Based Versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement: The CHOICE-CLOSURE Randomized Clinical Trial

CHOICE-CLOSURE trial

The primary outcome, rate of access-site or access-related major and minor vascular complications (defined according to the Valve Academic Research Consortium-2 criteria) for MANTA vs. ProGlide, was: 19.4% vs. 12.0%, relative risk 1.61, 95% confidence interval 1.07-2.44 (p = 0.029)

Interpretation:

This trial indicate that the MANTA VCD had higher major/minor vascular complications compared with ProGlide for access closure among patients undergoing transfemoral TAVR despite a lower need for additional VCDs and shorter time to hemostasis. This was driven by a higher rate of pseudoaneurysms and clinically significant hematomas; rates of endovascular ballooning and stenting were numerically higher as well.

Alternative strategy

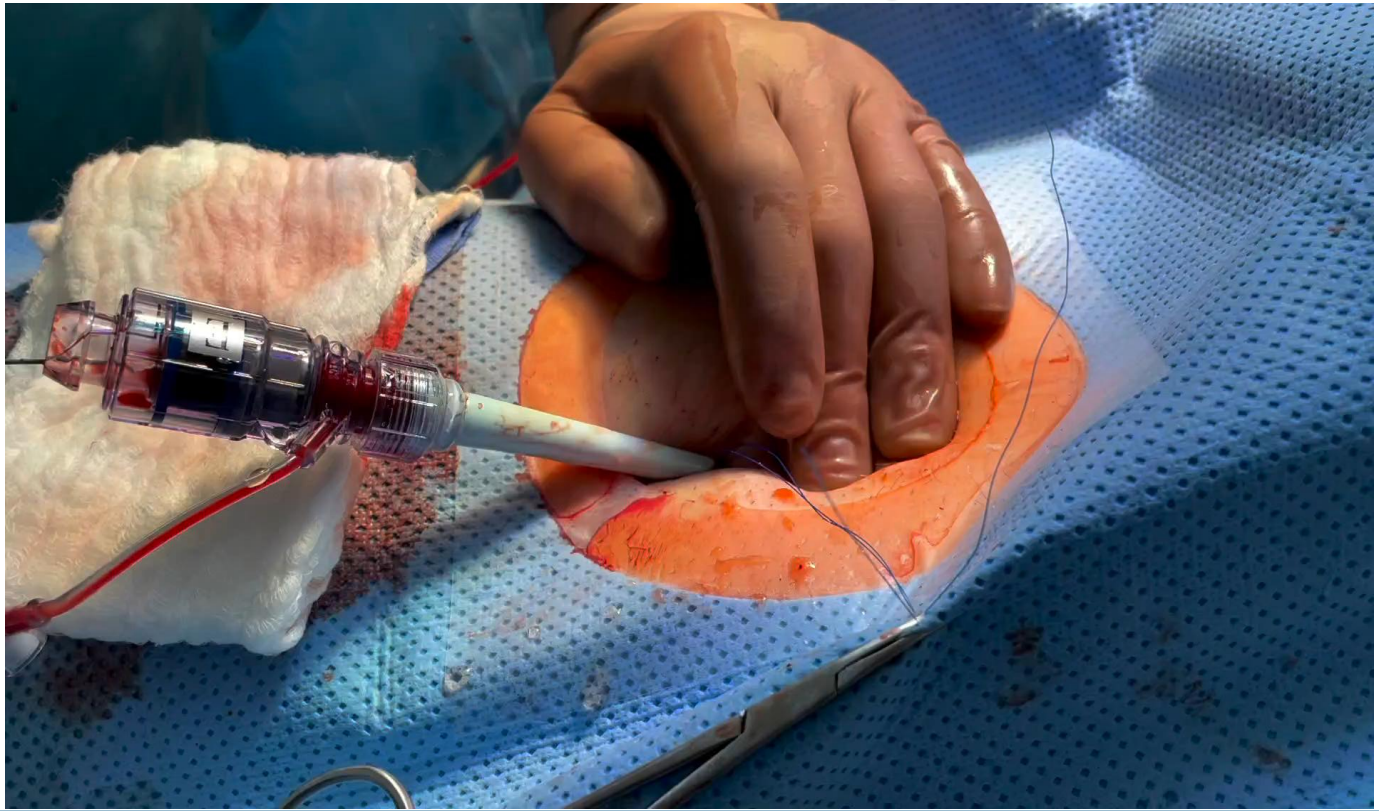
- Intentional combination of single ProGlide® (“preclose” technique without need of device rotation) a AngioSeal™ 8F

- Very positive personal references from high volume centers (Toulouse, St Thomas` Hospital London) supporting this strategy despite lacking data

Alternative strategy registry

- Retrospectively analysed comparison of two strategies: use of two suture-based ProGlides (SB group) vs. intentional combination of one ProGlide with plug-based AngioSeal 8F (CB group). The primary endpoint - occurrence of access site-related vascular complications at 30-days

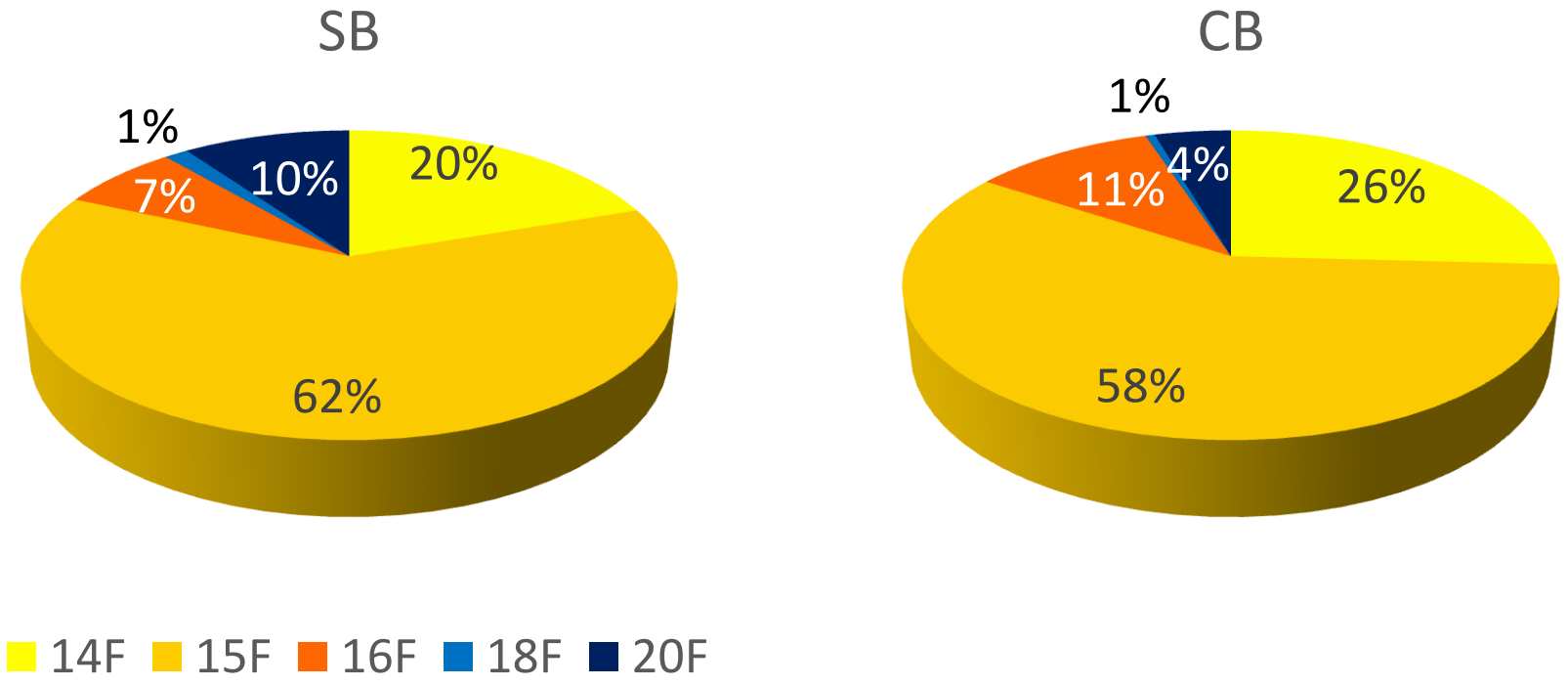
Closure technique



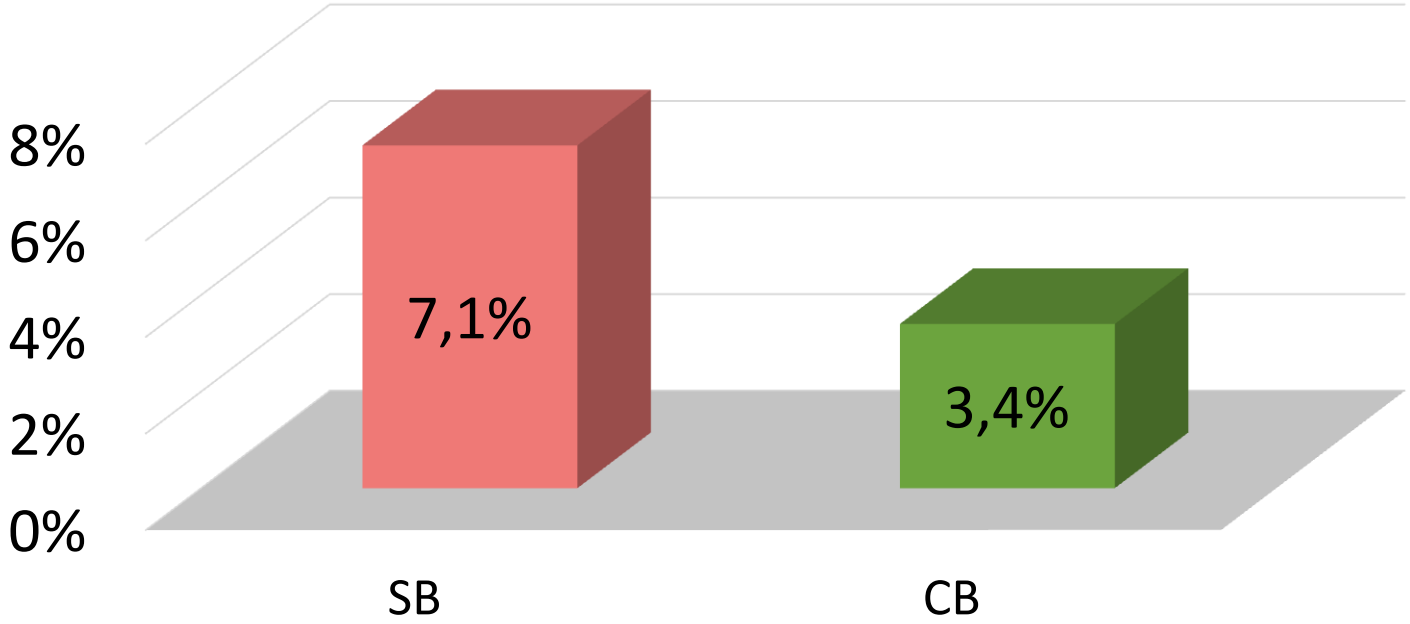
Baseline characteristics

	SB (VIII/20-V/21)	**CB** (V/21-XI/22)
Sample size	n=71	n=178
Age (mean)	81 y	80 y
Female sex	54,9%	51,1%
STS (mean)	3,47%	3,32%
Oral anticoagulation	38,6%	33,1%

Insertion profile size (ID equivalent)

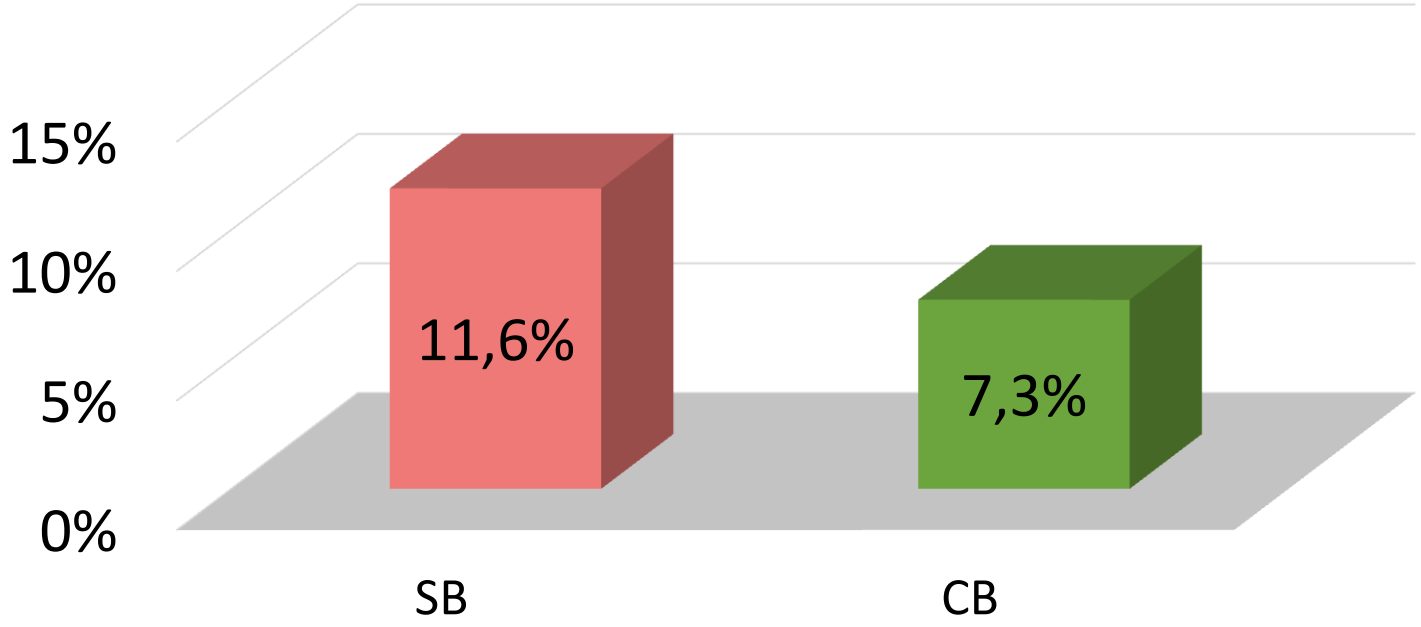


Access site-related vascular complication rate



Additional VCD had to be used in 14 pts. from SB group (19,7%) to achieve complete hemostasis

Bleeding complication rate



Conclusions

- Minimal learning curve with some experience with both Proglide® and AngioSeal™
- Very low minor vascular complication rate
- Fast complete hemostasis achieved
- The most cost-effective vascular closure strategy
- Enable fully catheter-based alternative axillary access for TAVI

THANK YOU FOR YOUR ATTENTION

UNIVERSITY HOSPITAL OLOMOUC

KOMPLEXNÍ
KARDIOVASKULÁRNÍ CENTRUM
FAKULTNÍ NEMOCNICE OLOMOUC