CHOICE CLOSURE

RANDOMIZOVANÁ STUDIE SROVNÁVAJÍCÍ RŮZNÉ STRATEGIE UZÁVĚRU PUNKCE TEPNY O VELKÉM PRŮMĚRU

MARTIN MATES, NEMOCNICE NA HOMOLCE, PRAHA

Circulation

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

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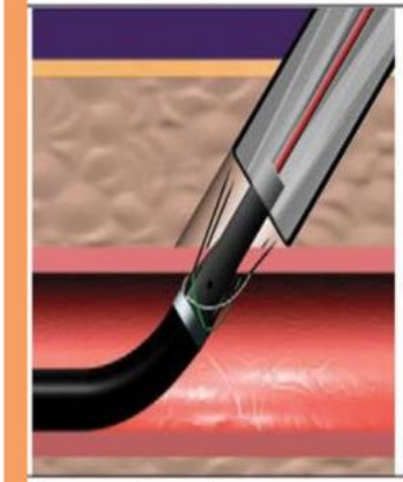
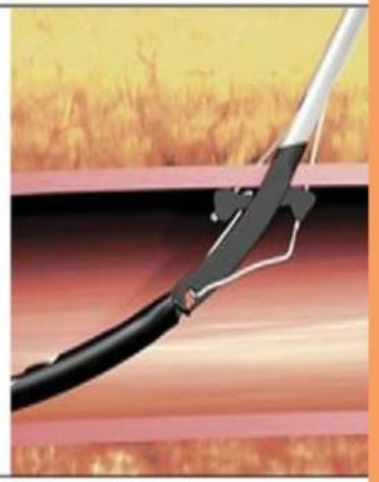
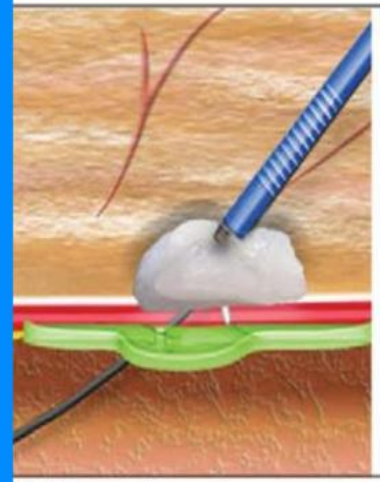
Suture-based

Prostar® XL	ProGlide®	MANTA™	PerQseal®	InSeal
				
				
Suture-based	Suture-based	Collagen-based	Patch-based	Membrane-based

Plug-based

Perclose ProGlide

Suture-Mediated Closure System

Deployment Steps

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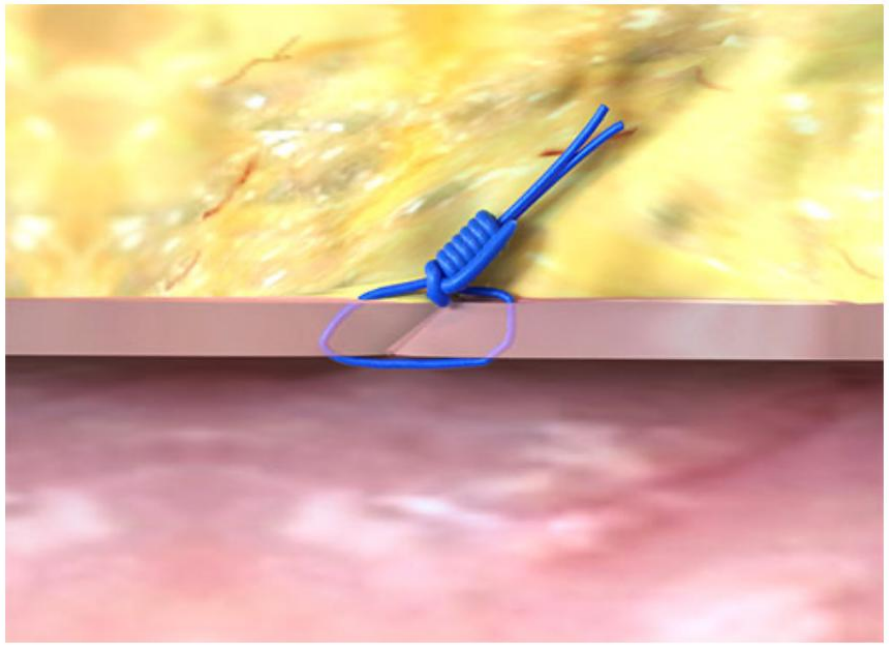
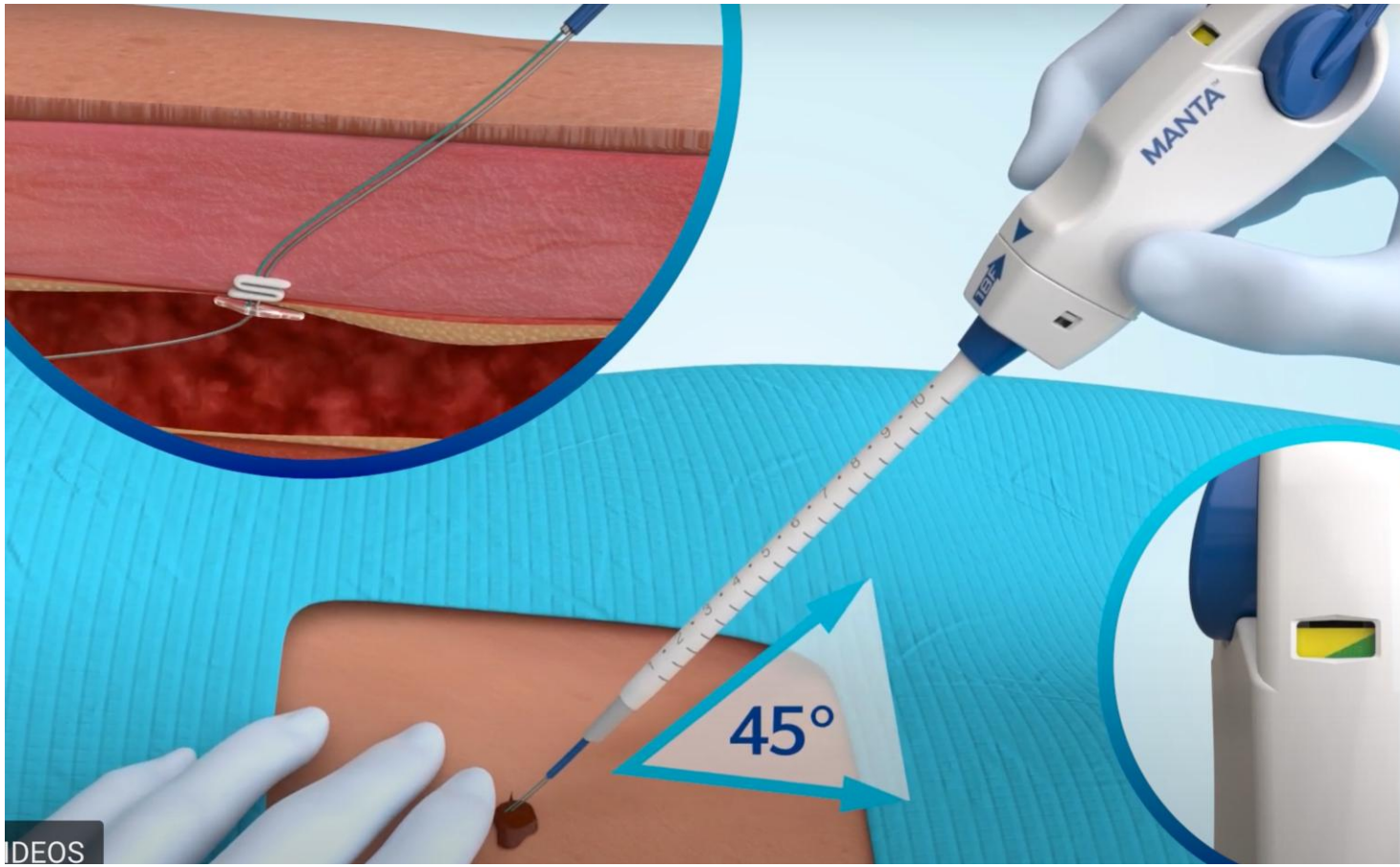
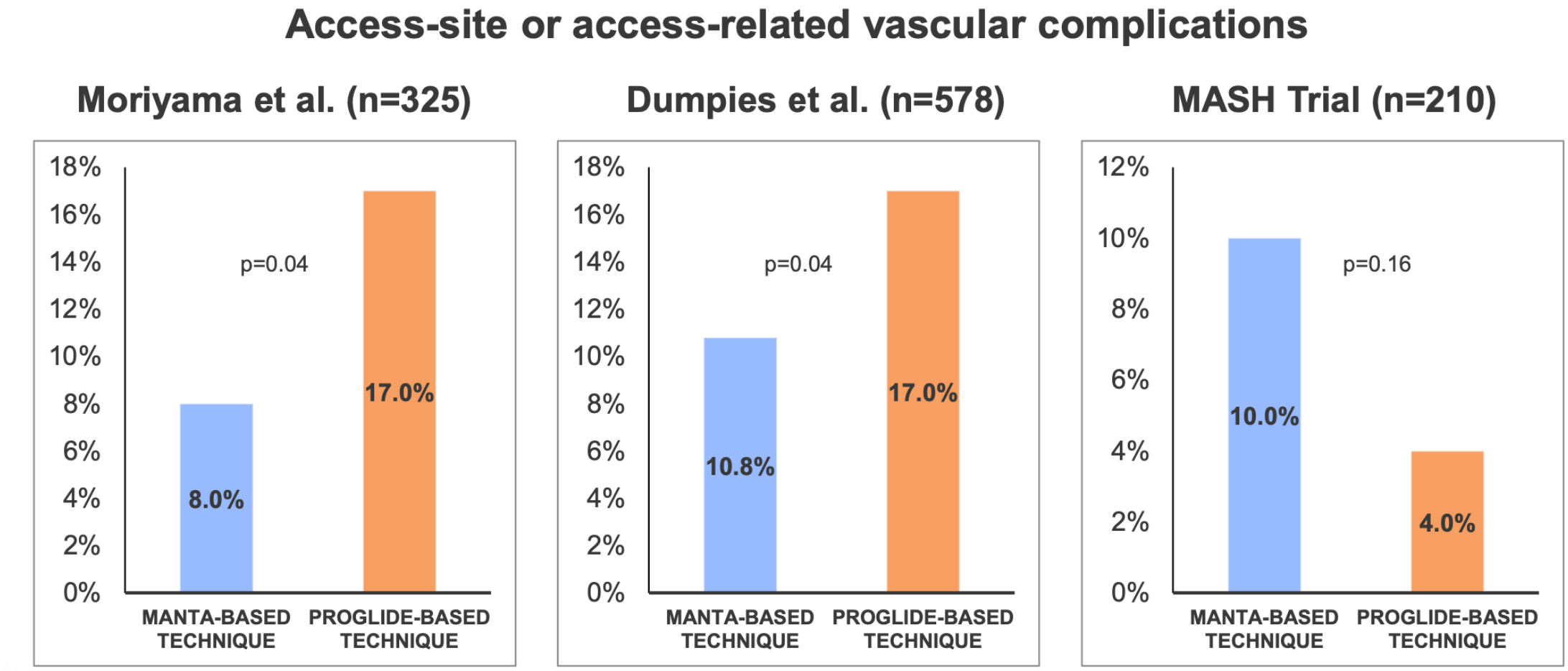
A Promise for Life





VASKULÁRNÍ KOMPLIKACE SPOJENÉ S TEPENNÝM PŘÍSTUPEM



DESIGN STUDIE

CHOICE CLOSURE

Indication for TAVR

Assessment by Heart Team

Transfemoral access possible

Assessment for eligibility

1:1 randomization

Pure plug-based vascular closure strategy (MANTA)

Primary suture-based vascular closure strategy (ProGlide)

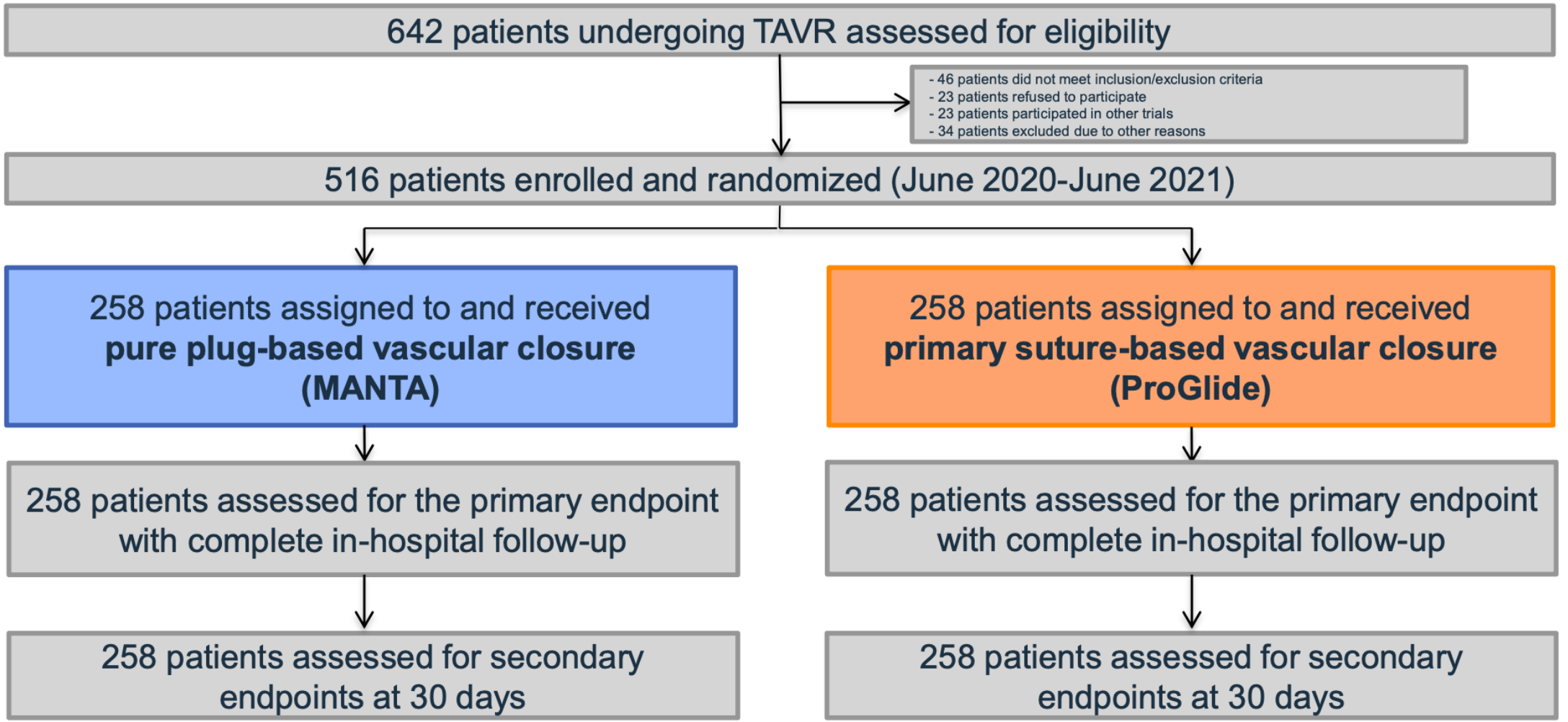
Primary endpoint: Access-site or access-related vascular complications (VARC-2 definition)

PRIMÁRNÍ ENDPOINT

The Valve Academic Research Consortium-2 (VARC 2) komplikace

Major vascular complications
Any aortic dissection, aortic rupture, annulus rupture, left ventricle
perforation, or new apical aneurysm/pseudoaneurysm OR
Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm,
hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life- threatening or major bleeding,* visceral ischemia, or neurological impairment OR
Distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
The use of unplanned endovascular or surgical

Study Flow


642 patients undergoing TAVR assessed for eligibility
- 46 patients did not meet inclusion/exclusion criteria
- 23 patients refused to participate
- 23 patients participated in other trials
- 34 patients excluded due to other reasons
516 patients enrolled and randomized (June 2020-June 2021)
258 patients assigned to and received pure plug-based vascular closure (MANTA)
258 patients assigned to and received primary suture-based vascular closure (ProGlide)
258 patients assessed for the primary endpoint with complete in-hospital follow-up
258 patients assessed for the primary endpoint with complete in-hospital follow-up
258 patients assessed for secondary endpoints at 30 days
258 patients assessed for secondary endpoints at 30 days

ZÁKLADNÍ CHARAKTERISTIKA SOUBORU

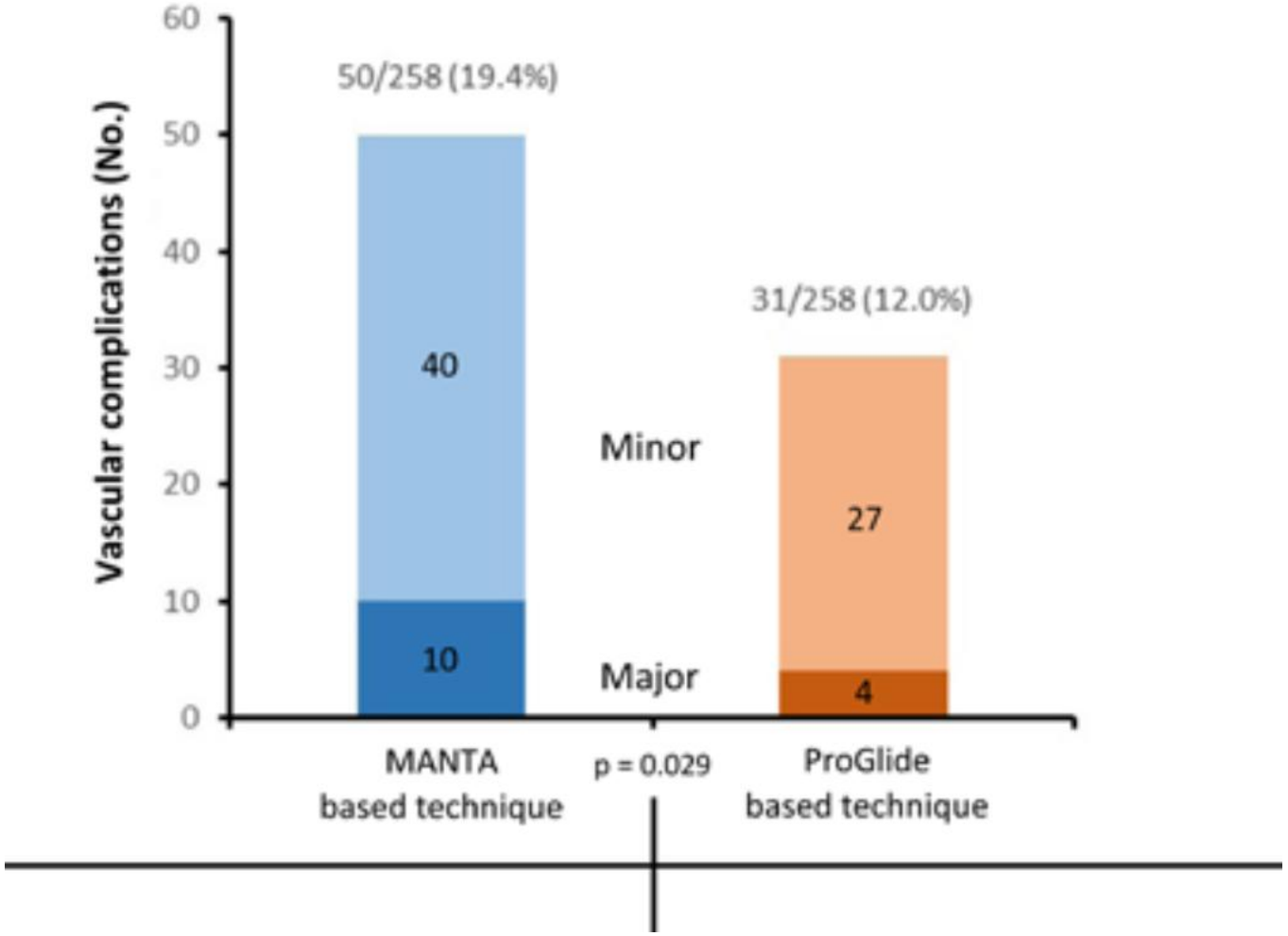
	MANTA-based group (n = 258 pts.)	ProGlide-based group (n = 258 pts.)	p-value
Age (years)	80.7 ± 5.7	80.4 ± 6.5	0.703
Female sex	115 (44.6%)	115 (44.6%)	1.000
Body mass index (kg/m2)	28.5 ± 5.1	28.6 ± 5.3	0.789
EuroSCORE II	4.5 ± 4.8	4.6 ± 4.3	0.401
STS score	4.0 ± 3.0	4.1 ± 2.8	0.352
Diabetes mellitus	98 (38.0%)	103 (39.9%)	0.718
Coronary artery disease	141 (54.7%)	118 (45.7%)	0.053
Previous CABG	25 (9.7%)	21 (8.1%)	0.643
Previous valve surgery	22 (8.5%)	27 (10.5%)	0.548
Cerebral vascular disease	26 (10.1%)	26 (10.1%)	1.000
Peripheral vascular disease	18 (7.0%)	21 (8.1%)	0.739
Previous peripheral intervention	4 (1.6%)	7 (2.7%)	0.542
Permanent pacemaker	32 (12.4%)	34 (13.2%)	0.895
Atrial fibrillation	88 (34.1%)	71 (27.5%)	0.127
Severe chronic renal failure	25 (9.7%)	24 (9.3%)	1.000
Baseline Hemoglobin (mmol/l)	7.7 ± 1.1	7.7 ± 1.1	0.999
Baseline INR	1.2 ± 0.4	1.2 ± 0.4	0.383

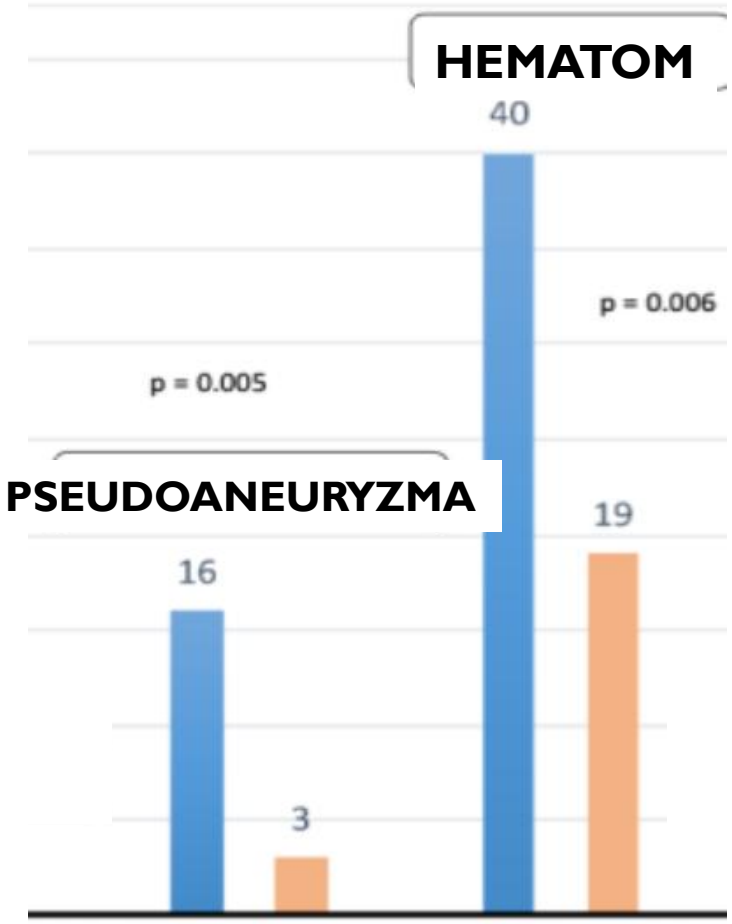
PODROBNOSTI VÝKONU

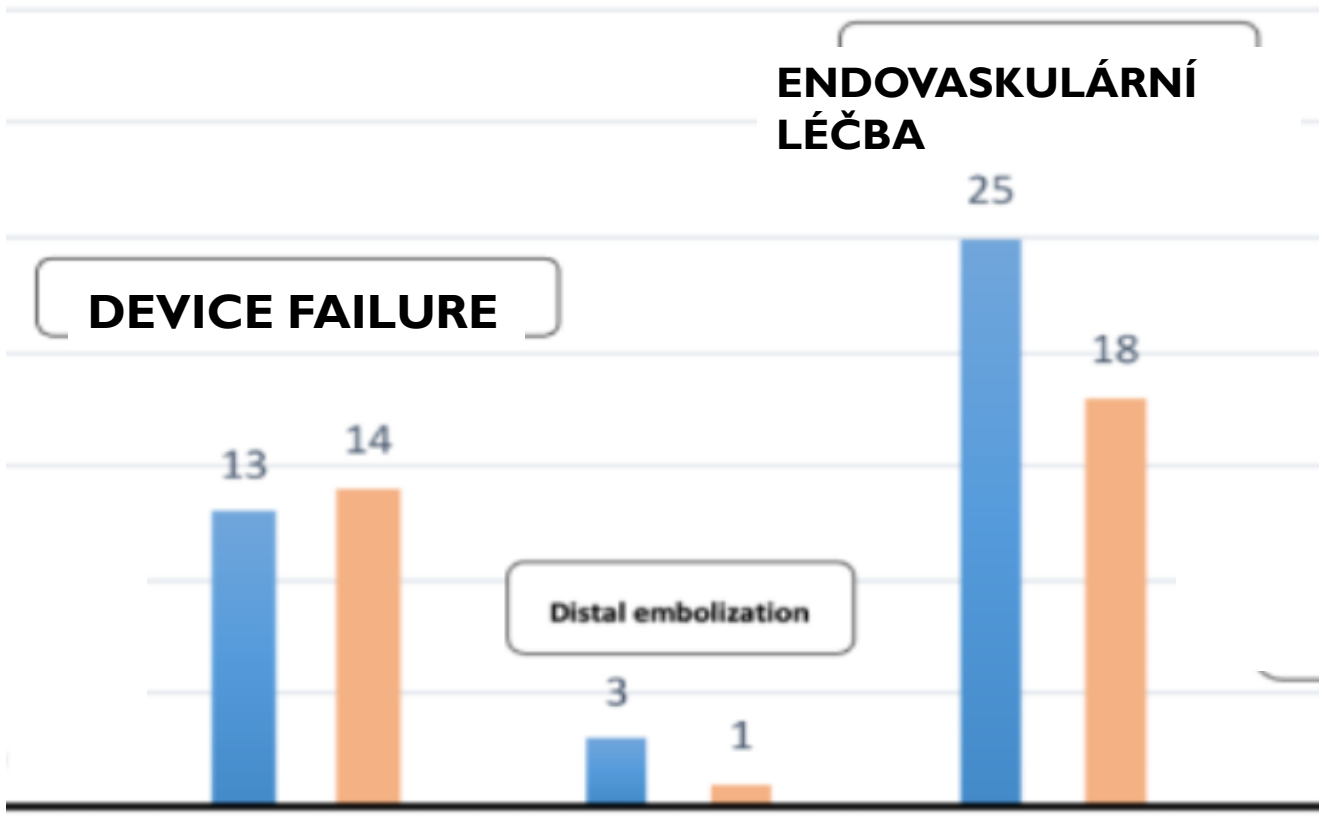
	MANTA-based group (n = 258 pts.)	ProGlide-based group (n = 258 pts.)	p-value
Ultrasound guided puncture	51 (19.8%)	43 (16.7%)	0.425
Road-map guided puncture	182 (70.5%)	194 (75.2%)	0.276
Main access site			
Right-side	228 (88.4%)	226 (87.6%)	0.892
Left-side	30 (11.6%)	32 (12.4%)	0.892
Additional access site			
Contralateral	234 (90.7%)	237 (91.9%)	0.755
Ipsilateral	23 (8.9%)	20 (7.8%)	0.750
Radial	12 (4.7%)	5 (1.9%)	0.139
Cerebral embolic protection	108 (41.9%)	120 (46.5%)	0.330
Puncture depth in the MANTA group (cm)	4.8 ± 1.3	--	--
Mean sheath size (Fr)	15.1 ± 1.7	15.1 ± 1.7	0.499
Valve type			0.425
Evolut R	37 (14.3%)	48 (18.6%)	0.235
Evolut Pro	84 (32.6%)	74 (28.7%)	0.390
Sapien 3	89 (34.5%)	87 (33.7%)	0.926
Acurate Neo	35 (13.6%)	38 (14.7%)	0.801
Lotus Edge	13 (5.0%)	9 (3.5%)	0.513
Allegra	0 (0.0%)	2 (0.8%)	0.479
Mean valve size (mm)	27.3 ± 3.0	27.3 ± 3.0	0.755
Total heparin dose (IU)	10232 ± 2258	10232 ± 2607	0.550
Fluoroscopy time (min)	15.9 ± 9.0	15.4 ± 8.2	0.587
Contrast dye amount (ml)	106.6 ± 49.6	105.5 ± 44.4	0.857

PRIMÁRNÍ END-POINT

VASKULÁRNÍ KOMPLIKACE SPOJENÉ S TEPENNÝM PŘÍSTUPEM BĚHEM HOSPITALIZACE




HEMATOM
40
p = 0.006
p = 0.005
PSEUDOANEURYZMA
19
16
3


ENDOVASKULÁRNÍ LÉČBA
25
18
DEVICE FAILURE
13
14
Distal embolization
3
1

	MANTA-based group (n = 258 pts.)	ProGlide-based group (n = 258 pts.)	p-value
Death	6 (2.3%)	2 (0.8%)	0.285
related to main access site complication	0 (0.0%)	0 (0.0%)	--
Bleeding – main access site related	30 (11.6%)	19 (7.4%)	0.133
Life threatening	2 (0.8%)	0 (0.0%)	0.479
Major	8 (3.1%)	4 (1.6%)	0.381
Minor	20 (7.8%)	15 (5.8%)	0.484
Vascular complications – overall	54 (20.9%)	38 (14.7%)	0.084
Major	13 (5.0%)	5 (1.9%)	0.093
Minor	41 (15.9%)	33 (12.8%)	0.379
Vascular complications – main access site related	50 (19.4%)	31 (12.0%)	0.029
Major	10 (3.9%)	4 (1.6%)	0.175
Minor	40 (15.5%)	27 (10.5%)	0.116
Access-site or access-related vascular complications, access-site or access-related bleeding and/or VCD failure	51 (19.8%)	32 (12.4%)	0.031
Need for blood transfusion for access-site or access-related bleeding or vascular complications	10 (3.9%)	3 (1.2%)	0.092
Length of postprocedural hospital stay (days)	4.7 ± 2.9	4.6 ± 2.4	0.710

ZÁVĚR

CHOICE-CLOSURE studie srovnávala dvě různé strategie pro uzávěr cévního vstupu o velkém průměru.

Výskyt závažných komplikací během hospitalizace a během 30denního sledování byl v obou skupinách nízký se srovnatelnou mortalitou a výskytem život ohrožujícího krvácení.

Použití systému MANTA bylo spojené s rychlejším dosažením hemostázy, ale tak s vyšším výskytem vaskulárních komplikací