ARTESp

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Study Results

ARTESp - **A**cute **R**ecanalization of **T**hrombo **E**mbolic **S**troke with **p**RESET

ARTESp is a prospective, multicenter, single-arm Post Market Clinical Follow-up study in which effectiveness, safety and long-term success of the pRESET Thrombectomy Device (phenox GmbH, Bochum, Germany) was analyzed in acute occlusions of major cerebral arteries of both anterior and posterior circulation.

The main cause of an ischemic stroke is the obstruction of intracranial blood vessels. A reduced blood flow leads to the well-known neurological symptoms of a stroke, the main reason for permanent disability and the second cause of death in the western world. The purpose of ARTESp was to evaluate the safety and efficacy of the pRESET Thrombectomy Device by assessing the recanalization rate and the clinical outcome at 90 days.

Characteristics I	Intervention
no. of patients	100
no. of treated vessels	109
age yr. *mean* (SD)	68.3 (13.8)*
age min-max *yr*.	20-90*
female sex (%)	55
NIHSS score at admission *median* (n; range)	15 (99; 5-29)**
Prestroke mRS	**%**
0	83.0
0-1	91.0
0-2	96.0
>2	4.0
Medical History	**% (n/n)**
atrial fibrillation	57.1 (56/98)
systemic hypertension	67.3 (66/98)
diabetes	17.2 (17/99)
former stroke	16.3 (13/80)

*Three patiens were > 85 years old
**Three patients had a NIHSS <8

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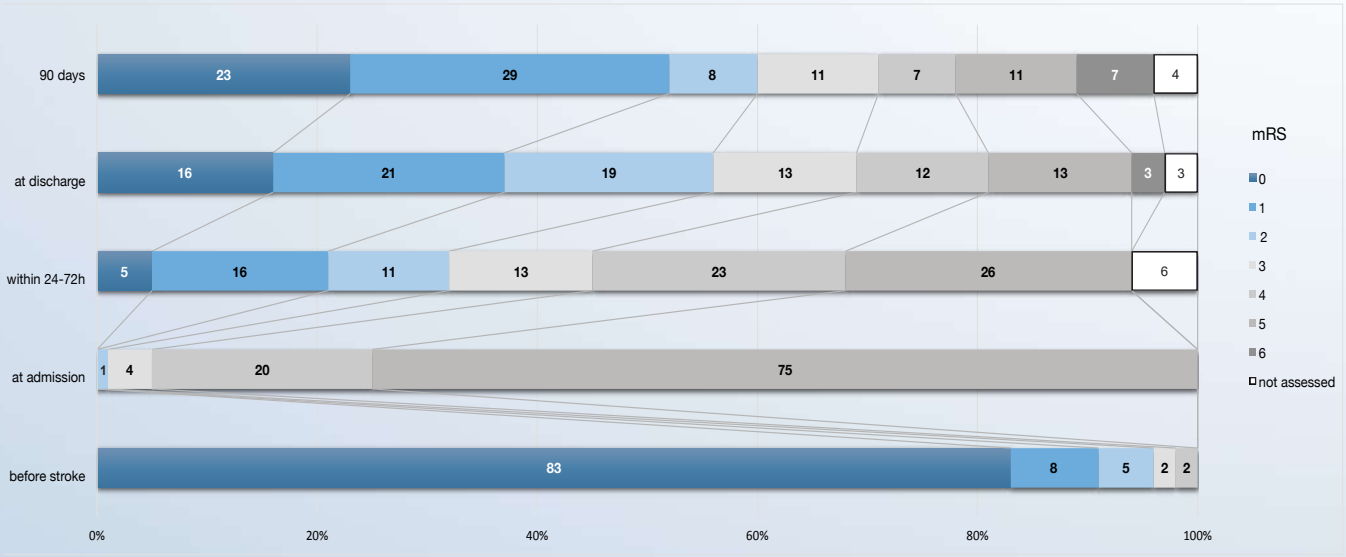
Characteristics II	Intervention
ASPECT Score	**% (n/n)**
8-10	95.8 (91/95)
5-7	4.2 (4/95)
0-4	0 (0/95)
preprocedure iv lysis - % (n/n)	63.0 (63/100)
general anesthesia - % (n/n)	88.0 (88/100)
Higashida collateral score median (n; range)	2 (92; 0-4)
Treated Vessels	**% (n/n)**
MCA	74.3 (81/109)
ICA	13.8 (15/109)
BA	7.3 (8/109)
PCA	3.7 (4/109)
ACA	0.9 (1/109)
multiple occlusions % (n/n vessels)	7.3 (9/109)
stenting cervical ICA % (n/n)	14 (14/ 100)

Overall Development of mRS



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Outcome				
Process Time Parameters	all patients (n=100)	excluding prestroke mRS >1		p-value
		transferred patients (n=53)	directly admitted patient (n=53)	
stroke onset to admission min. - median (n; range)	145 (92; 9-396)	188 (51; 73-369)	61 (34; 9-220)	**p<0.001**
admission to groin puncture min. - median (n; range)	58.5 (92; 5-187)	45 (51; 5-150)	76 (34; 15-187)	**p<0.001**
groin puncture to reperfusion min. - median (n; range)	40 (100; 6-159)	49 (53; 6-159)	36 (38; 8-116)	p=0.943
stroke onset to reperfusion min. - median (n; range)	247 (99; 112-469)	289 (53; 172-469)	180 (38; 112-386)	**p<0.001**

Technical/ Clinical parameters	Outcome	excluding prestroke mRS >1		p-value
		transferred patients (n=53)	directly admitted patients (n=38)	
final o-TICI 2b-3 only pREset - % (n/n vessels)	84.4 (92/109)	84.2 (48/57)	82.6 (38/46)	p=0.828
final o-TICI 2b-3 overall - % (n/n vessels)	85.3 (93/109)	86.0 (49/57)	82.6 (38/46)	p=0.640
passages until final o-TICI per vessel - mean (n vessels; SD)	1 (109; 1-6)	1 (57; 1-6)	1 (46; 1-6)	p=0.898
all procedural complications - % (n/n)	10.0 (10/100)	9.4 (5/53)	13.2 (5/38)	p=0.575
emboli to new or same territory - % (n/n)	5.0 (4/100)	1.9 (1/53)	10.5 (4/38)	p=0.157
Hemorrhage Post	% (n/n)	% (n/n)	% (n/n)	
any hemorrhage	14.0 (14/100)	13.2 (7/53)	18.4 (7/38)	p=0.497
parenchymal	6.0 (6/100)	7.5 (4/53)	5.3 (2/38)	p=1.000
subarachnoid	7.0 (7/100)	3.8 (2/53)	13.2 (5/38)	p=0.124
subdural	2.0 (2/100)	3.8 (2/53)	0.0 (0/38)	p=0.508
symptomatic	2.0 (2/100)	1.9 (1/53)	2.6 (1/38)	p=1.000
NIHSS at 24-72h - median (n; range)	5 (99; 0-42)	6 (52; 0-42)	3 (38; 0-22)	**p=0.005**
NIHSS at discharge = 0	24.5 (23/94)	16.7 (8/48)	36.8 (14/38)	**p=0.033**
mRS after 90 days	% (n/n)	% (n/n)	% (n/n)	
0	24.0 (23/96)	16.0 (8/50)	40.5 (15/37)	**p=0.010**
0-1	54.2 (52/96)	48.0 (24/50)	73.0 (27/37)	**p=0.019**
0-2	62.5 (60/96)	58.0 (29/50)	78.4 (29/37)	**p=0.046**
3-5	30.2 (29/96)	36.0 (18/50)	18.9 (7/37)	p=0.082
6	7.3 (7/96)	6.0 (3/50)	2.7 (1/37)	p=0.633

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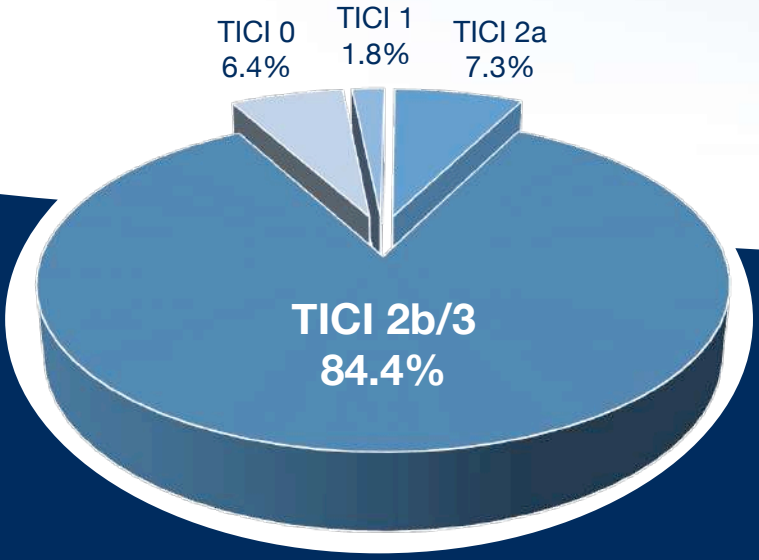
mRS 0-2 at 90 days: 62.5%

	ARTESp	MR CLEAN[1]	SWIFT-PRIME[2]	EXTEND-IA[3]	ESCAPE[4]
mRS 0-2 90days	62.5%	32.6%	60%	71%	53%
TICI 2b/3	84.4%	58.7%	88%	86%	72.4%

Recanalization



Data review by independent core lab.

CONCLUSIONS

- **safety and efficacy of mechanical thrombectomy with pRESET**
- **excellent recanalization rate**
- **excellent neurological outcome regardless of patient's age**

Sources:
Prothmann et al.; Acute Recanalization of Thrombo-Embolic Ischemic Stroke with pREset (ARTESp): the impact of occlusion time on clinical outcome of directly admitted and transferred patients; J NeuroIntervent Surg 2016; doi:10.1136/neurintsurg-2016-012556.
[1]Berkhemer et al.; A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke; N Engl J Med 2014; DOI: 10.1056/NEJMoa1411587.
[2]Saver et al.; Stent-Retriever Thrombectomy after Intravenous t-PA vs. t-PA Alone in Stroke; N Engl J Med 2015; DOI: 10.1056/NEJMoa1415061.
[3]Campbell et al.; Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection; N Engl J Med 2015; DOI: 10.1056/NEJMoa1414792.
[4]Goyal et al.; Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke; N Engl J Med 2015; DOI: 10.1056/NEJMoa1414905.

Study did not include pRESET LITE.
The pRESET Thrombectomy Device is not approved for sale nor is it available for sale or use in the United States.

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