Feasibility and safety of direct catheter-based thrombectomy in the treatment of acute ischemic stroke. Prospective registry PRAGUE-16.

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Introduction

- Direct (without thrombolytics) PCI is an established treatment of AMI
- Direct catheter-based thrombectomy (d-CBT) for acute ischemic stroke is still in its infancy.

- New guidelines support bridging thrombolysis (BTL) as treatment superior to iv. thrombolysis alone.
- No data exist to compare BTL versus d-CBT.

Study aim

To evaluate the feasibility and safety of d-CBT performed in close cooperation of cardiologists, neurologists and radiologists – the true interdisciplinary approach.

Methods

- Prospective observational single center study
- Protocol approved by the ethical committee
- The indication for reperfusion therapy was done by attending neurologist based on clinical picture and computed tomography (CT).
- Intracranial stent-retrievers used in all patients
- Simultaneous carotid stenting in those with proximal internal carotid lesions.




Inclusion criteria

- Moderate to severe (NIHSS ≥6) acute ischemic stroke.
- Pre-stroke mRs 0-1
- < 6 hours from stroke onset
- No large ischemia yet on CT scan
- CT evidence for occluded major artery (either CT-angio or dense artery sign on CT scan)
- Indication signed by the attending neurologist
- Ability to start intervention within < 60 minutes from CT

Exclusion criteria

- Previously known neurologic symptoms (mRS 2-5)
- Known coagulation disorders
- Severe hypoglycaemia
- Intracranial bleeding
- CT evidence of developed large ischaemia

Endpoints

Primary:

- **functional neurologic outcome (mRs) at three months (assessed by board certified neurologists)**

Secondary:

- **angiographic recanalisation rate**
- **ΔNIHSS (admission–discharge)**
- **Symptomatic intracranial bleeding (defined as ΔNIHSS ≥4)**

Patients baseline characteristics

	d-CBT	bridging TL + CBT
n=	**101**	**51**
Mean age [years]	68	62
History of atrial fibrillation	42%	33%
History of prior stroke or TIA	18%	7%
Mean NIHSS (admission)	17.8	15.75
Anterior stroke	95%	80%
Posterior stroke	5%	20%
Symptom onset - CT [mean time, min.]	105	73
CT - groin puncture [mean time, min.]	42	115

Angiographic outcomes

	d-CBT	bridging TL + CBT
Mean periprocedural UFH dose [units]	2765	1886
Tandem occlusion (ICA + MCA) or T-occlusion (terminal ICA, or MCA + ACA)	40%	30%
Isolated MCA occlusion	51%	30%
Isolated proximal ICA occlusion	4%	20%
Angiographic success (TICI 2b-3 at the end of procedure)	**75%**	**85%**

Clinical outcomes per stroke location

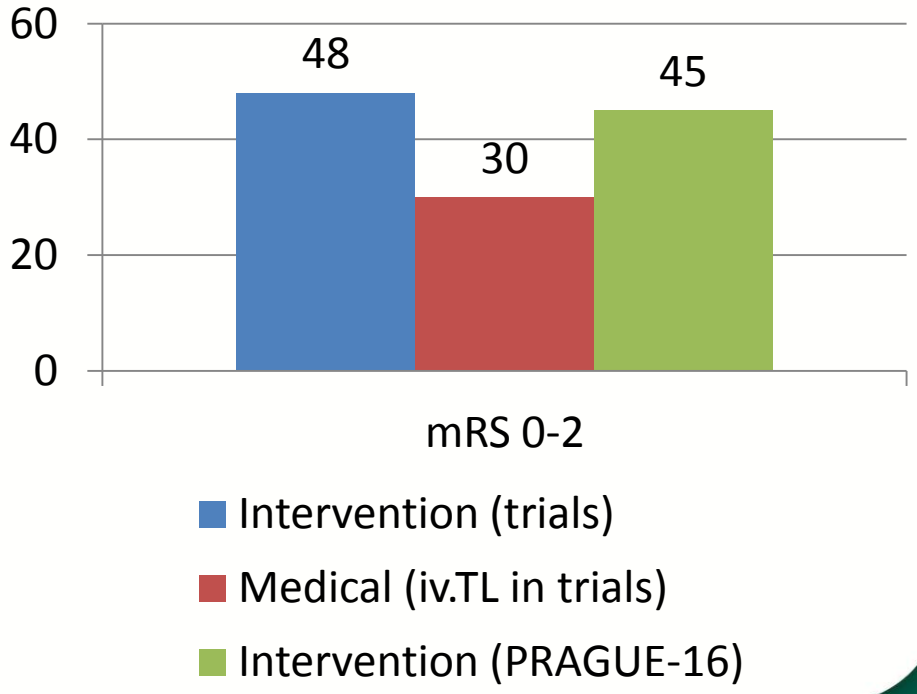
- **Overall: neurologic recovery (mRS ≤2 after 90 days) in 45% patients.**
- **Anterior: 58% mRs ≤2 in isolated occlusion of the middle cerebral artery (MCA)**
- **Posterior: 27% mRs ≤2 in basilar/ vertebral occlusions.**

Clinical outcomes per treatment

	d-CBT	bridging TL + CBT
Mean delta↓ NIHSS 24 h	5.4	1.6
Procedure-related complications (SAH, vessel perforation or dissection, symptomatic stent thrombosis within 24 hours, carotico-cavernous fistula, embolism to other territory)	9%	16%
Any symptomatic intracranial hemorhage (NIHSS change >3)	11%	8%
mRS 0-2 after 90 days	45%	42%

Comparison with data from recent large randomized trials

	Intervention + medical therapy (recovered / all patients)	Medical therapy alone (recovered / all patients)
MR CLEAN	77 / 233	51 / 267
ESCAPE	89 / 164	43 / 147
EXTEND IA	25 / 35	14 / 35
SWIFT PRIME	59 / 98	33 / 93
REVASCAT	45 / 103	29 / 103
THERAPY	17 / 41	12 / 41
THRACE	103 / 190	82 / 195



Conclusions

- **Acute stroke intervention done in close cooperation of cardiologists, neurologists and radiologists is feasible and safe.**

- **Direct catheter-based thrombectomy may be similarly effective and safe as bridging TL and may thus be considered in patients with contraindications for TL or in patients with very short CT – groin puncture times.**

- **A randomized trial is needed to confirm these hypothesis-generating results**