Supplementary material

Pawłowski K, Klaudel J, Dziadkiewicz A, Mączkowiak A. Cardiac CathLab-based stroke thrombectomy routine service by the BRAIN team in a recently established Thrombectomy-Capable Stroke Center in Poland. Kardiol Pol. 2021.

Background

Stroke is a leading cause of death and disability in developed countries. In Poland, there are around 75,000 ischemic strokes annually. It is estimated that at least 15-20% of the events are due to large vessel occlusion (LVO) [16, 17], and may thus require cerebral reperfusion with mechanical thrombectomy (MT). Today, there is class 1, level A evidence for mechanical thrombectomy with iv-thrombolysis [18, 19]. In patients who meet appropriate criteria, MT significantly reduces stroke-related disability. The success of randomized trials in MT caused a public health urgency, with a need to address the societal demand for effective access to this treatment [1]. In Poland, with the MT service currently limited to 20 Comprehensive Stroke Centers (CSC), there is approximately 1 MT center per 2 million population [20]. Despite many years of effort and the pioneering work by neurology and neuroradiology specialists to make MT available to Polish patients [21], the access to the service is among the poorest in Europe [22] and in the world [23].

Recent data from the USA [7] and European countries [24, 25] show that the results of cardiac cathlab-based MT are comparable to angiographic and clinical outcomes of the procedures performed in CSCs, indicating that interventional cardiology, as part of a multi-specialty effort, may play an important role in filling the fundamental gap in the system [6, 14] .

Since time to intervention is crucial to optimize clinical outcomes of MT [9, 26], we have established, through a multi-specialty endeavor involving local stroke neurologists and MT-trained cardiologists, a Thrombectomy-Capable Center (TCC) that provides a 7/24/365 MT service to patients in the region. In this article, we describe major steps in our path leading to the successful development of a TCC, the fundamental role of collaboration with the local Stroke Center, and our initial series of patients treated with MT.

Neuroendovascular competence

It is unfeasible to promptly train hundreds of new neuroradiologists to provide MT to the required extent. A much more practical approach involves focused, concise and intensive MT training of operators from other specialties with vascular interventional experience. It would be both inefficient and impractical to expect invasive cardiologists to undergo a full 2-year neuroradiology training outside their facility, since they will not act as providers of intracranial procedures other than MT [27]. Outside the limited community of neuroradiologists, it is the interventional cardiologists who by sheer weight of numbers, i.e., advanced transfemoral and transradial catheter skills, robust experience in thrombolytics and GPIIb/IIIa antagonists administration, and — in significant proportion of those entering interventional stroke management — their vast experience in carotid interventions, may in fact be best suited to join the understaffed specialty of stroke interventionists. Indeed, invasive cardiologists have come forward, in collaboration with neuroradiologists, with proposals of training programs for operators based on the levels of their previous experience [28]. The World Federation for Interventional Stroke Treatment (WIST) promotes structured training in invasive treatment of stroke, emphasizes the role of simulator training, requires all results to be sent for audit, promotes quality control and a competency-based rather than time-based approach.

Polish Ministry of Health Pilot Program for Mechanical Thrombectomy in Ischemic Stroke has set a number of specific training, facility, staff and operator requirements [20].

According to the program recommendations, an MT operator should come from one of the following specialties: radiology, neurosurgery, neurology, cardiology, angiology or vascular surgery; should have experience in neurointervention defined as participation in 150 neuroendovascular procedures (with 50 performed as primary operator) or have performed 50 endovascular procedures on extra- and intracranial vasculature (including at least 5 intracranial procedures performed as a primary operator). Additionally, an operator should participate in certified MT courses in Poland or abroad, and should spend 3 months in a Stroke Neurology Department, training in all aspects of stroke-related clinical care as well as stroke imaging [20] .

Expanded methods

Kashubian Center for Heart and Vascular Diseases in Wejherowo, Poland provides a comprehensive cardiology service in the northern part of the Pomerania region with 2.3 million inhabitants. There is a neurology department committed to stroke care, with the highest Angels

Diamond Award status (European Stroke Organization quality award). The nearest comprehensive stroke unit is situated 50 km away. In the past, roughly 30-50 patients per year were sent from our center for MT. The main stimulus to start an MT program at our location was the increasing number of patients qualifying for an immediate intervention, and logistic and geographical issues including notorious traffic problems, with the lengthy transfer of LVO stroke patients to the Comprehensive Stroke Center (CSC). With an intention to reduce time to treatment in patients with stroke, we closely followed the success story of fruitful cooperation between stroke neurologists and cardiologists in numerous hospitals in the world, leading to effective implementation of interventional cardiology-based acute stroke service worldwide [7, 14, 29–31]. Wejherowo Hospital established a 24/7/365 acute myocardial infarction service more than a decade ago, and electrophysiology and structural interventions are also available. The peripheral angiography suite in our hospital is equipped in accordance with intracranial work requirements [20] and we have an effective collaboration with two neurosurgical departments.

Neuroendovascular MT training

Initially, two of our interventional cardiologists with over 15-years of cathlab experience trained intensively in both theoretical and practical aspects of thrombectomy. A third member of the team, a stroke neurologist is on his path to become an MT operator, consistent with Polish requirements [20]. The training began in 2017 and included participation in international (ICCA Stroke, SLICE) and Polish stroke conferences, numerous thrombectomy courses with a simulator, animal and silicone lab hands-on training (Karolinska Institute in Stockholm, University Hospital of Montpellier, Split and other centers). We spent one year in the vascular surgery department training in all aspects of peripheral endovascular interventions, including carotid stenting, Then for over a year, we underwent training in a neurovascular intervention cathlab in a Polish stroke center of excellence, where we participated in acute stroke treatment on a 24/7 rota. We also assisted in other neurointerventional procedures, and performed carotid stenting to meet the training requirements for MT operators certification [20]. We regularly took part in radiology/neurology/neurosurgery meetings where MT (and non-MT) stroke cases were analyzed and discussed. Two dedicated nurses with experience in interventional procedures completed MT training. We regularly organized 'simulated thrombectomy' sessions in the cathlab with practical training on a balloon guide catheter, distal access catheter, stent retriever handling, and a step-by-step mechanical thrombectomy drill according to our predefined MT protocols. The training process was consistent with Polish requirements [20].

Patient identification for mechanical thrombectomy

The process of patient selection for MT had already been in place since our neurology department has long belonged to leading centers in stroke thrombolysis implementation and MT patients qualification. Our standard criteria have been consistent with international guidelines [18, 19] and with routine clinical practice in the CSCs that have provided training to us, and have included NIHSS (National Institutes of Health Stroke Scale) ≥ 6 (or aphasia), presentation within 6 hours from symptom onset, LVO occlusion on CT angiography, and ASPECTS (Alberta Stroke Program Early CT score) score above ≥ 6 . We are currently introducing CT perfusion protocols with a view of including patients according to DAWN and DEFUSE-3.

Service organization

We created step-by-step MT protocols as standard operating procedures. Every step of the procedure is check-listed and performed accordingly. We set up a 24/7/365 on-call rota with 2 interventionists, 2 dedicated nurses and an interventional neurologist in training. The first MT procedure took place in August 2020, amid the COVID-19 pandemic. During the first six months, 15 MT-eligible patients were identified. The majority were local inhabitants referred directly from our A&E department. In our model, a neurologist on duty performs thorough examination, determines NIHSS and modified Rankin Score (mRS), and, if symptoms suggest stroke, arranges an urgent plain CT. As soon as severe cerebral damage and hemorrhage are excluded, thrombolytic therapy is started as per guidelines and is immediately followed by CT angiography. The thrombectomy team and anesthesiologists are activated when an LVO is detected.

Mechanical thrombectomy protocol

Most of the procedures have been performed under general anesthesia (GA). Our default vascular access is transfemoral, using an 8 or 9F sheath. In light of excellent first pass effect, we decided to adopt the SAVE (Stent-retriever Assisted Vacuum-locked Extraction) technique. It is a maximalistic approach proposed by the team in Goettingen, Germany. Thus, whenever feasible, we use a balloon guide catheter (BGC) combined with a distal access catheter (DAC) and a stent retriever. Such strategy has been reported to achieve an exceptional first pass effect with complete reperfusion (Thrombolysis In Cerebral Infarction -TICI 3) reaching > 70% cases [32]. Systolic blood pressure is maintained throughout the procedure within 160-180 mmHg range with constant intravenous noradrenaline infusion which is titrated and stopped once reperfusion has been achieved. After the procedure, the access site is controlled and secured with a closure device and a patient is transferred to the Stroke Unit.

Table S1. Fundamental clinical and angiographic data

Patientnumber	Age	Occludedvessel	NIHSSatadmission	NIHSSatdischarge	mRSatdischarge	rtPA IV	Initial TICI	Final TICI
1	67	L-MCA	24	3	2	0	0	2b/2c
2	74	R-MCA	17	6	3	1	0	3
3	64	RICA	19	12	4	1	0	3
4	65	LICA	24	17	4	1	0	3
5	82	L-MCA	19	4	1	1	0	3
6	73	LICA	28	21	5	1	0	2b
7	83	LICA	26	9	3	0	0	3
8	87	R-MCA	18	-	6	1	0	1
9	67	L-Tandem	6	2	1	1	0	2c
10	85	L-Tandem	26	-	6	1	0	3
11	58	L-MCA	22	21	5	1	0	2b/3
12	61	L-MCA	13	14	4	1	0	2b/3
13	86	RICA	19	-	6	1	0	2b

14	49	R-MCA	11	5	2	1	0	2b
15	64	L-MCA	10	2	1	1	0	3
Mean (SD) or n (%)	**71.0 (11.6)**		**18.8 (6.5)**	**9.7 (7.2)**	**3.5 (1.8)**	**13 (86.7 %)**	**100% TICI 0**	**93.3%≥2 b/3**

Abbreviations: LICA, left internal carotid artery; MCA, middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; RICA, right internal carotid artery; rtPA, recombinant tissue plasminogen activator; TICI, Thrombolysis In Cerebral Infarction scale

Table S2. Mechanical thrombectomy procedural data

Patient number	**Occludedvessel**	**GA**	**Difficult Access**	**Femoral access**	**Brachiala ccess**	**No of passes**	**BGC**	**SAVE**	**ADAPT**	**ENT**	**Distal emboli**	**TICI 2b/3**	**GpIIb/IIIainhibitors**	**Complications**
1	L-MCA	1	1^{V}	1	0	2	1	1	0	0	0	1	0	0
2	R-MCA	1	0	1	0	4	1	1	0	0	0	1	0	0
3	RICA	1	0	1	0	2	1	1	0	0	0	1	0	Retroperitoneal hemat

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4	LICA	1	1^{X}	1	0	3	1	0	1	0	0	1	0	0
5	L-MCA	1	0	1	0	1	1	0	1	0	0	1	0	0
6	LICA	1	1^{Y}	1	0	3	1	1	0	0	1	1	0	0
7	LICA	0	0	1	1 (failed)	1	1	0	1	0	0	1	0	0
8	R-MCA	0	1^{Z}	1	0	6	0	1	0	0	1	0	0	0
9	L-Tandem	0	0	1	0	3	1	1	1	0	1	1	1	Intraprocedural stentthrombosis
10	L-Tandem	1	1^{X}	0	1	6	1	1	1	0	0	1	0	0
11	L-MCA	1	0	1	0	1	1	1	0	0	0	1	0	0
12	L-MCA	0	0	1	0	7	1	1	1	0	1	1	1	0

13	RICA	1	0	1	0	6	1	1	1	1	0	1	0	0
14	R-MCA	0	0	1	0	2	1	1	0	0	0	1	1	0
15	L-MCA	0	0	1	0	1	1	1	0	0	0	1	0	0
n (%) or mean (SD)		**9(60%)**	**5 (33.3%)**	**14 (93.3%)**	**1 (6.7%)**	**3.2 (2.1)**	**14 (93.3%)**	**12 (80%)**	**7 (46.7%)**	**1 (6.7%)**	**4 (26.7%)**	**93.3%≥2b/3**	**3 (20%)**	**2 (13.3%)**

Abbreviations: ADAPT, A Direct Aspiration First Pass Technique; BGC, balloon guide catheter; ENT, embolization in new territory; GA, general anesthesia; ICA, internal carotid artery; LICA, left internal carotid artery; MCA, middle cerebral artery; RICA, right internal carotid artery; SAVE, Stent-retriever Assisted Vacuum-locked Extraction; TICI, Thrombolysis In Cerebral Infarction scale; Challenging access: ^{V}bovine arch; ^{X}transverse carotid artery; ^{Y}severe peripheral vascular disease; ^{Z}type III arch

Table S3. Fundamental time intervals (in minutes)

Patient number	**Door-to-CT (minutes)**	**Door-to-rtPA (minutes)**	**Door-to-groin (minutes)**	**Groin-to-first pass (minutes)**	**Groin-to-recanalization (minutes)**	**LVO-to-groin (minutes)**	**Door-to-recanalization (minutes)**
1	23	-	146	64	101	103	247
2	10	15	105	57	135	90	240
3	10	29	157	32	52	128	209
4	-	-	-	45	82	-	-
5	11	28	200	27	33	172	233
6	3	13	138	94	130	125	268
7	3	-	107	26	30	104	137
8	12	13	95	70	190	82	285
9	20	25	165	19	30	140	195
10	25	35	135	107	130	100	265
11	7	12	162	63	84	150	246
12	5	32	104	42	156	99	260
13	- (otherfacility)	- (otherfacility)	- (otherfacility)	51	166	- (otherfacility)	191
14	12	20	63	22	48	51	111
15	9	20	163	22	32	79	195
mean (SD)	**11.5 (7.1)**	**22.0 (8.3)**	**133.8 (37.3)**	**49.4 (26.8)**	**93.3 (55.1)**	**109.5 (32.7)**	**220.1 (50.5)**

Abbreviations: CT, computed tomography; LVO, large vessel occlusion; rtPA, recombinant tissue plasminogen activator

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