

Výskyt cerebrovaskulárních ischemických lézí po ablaci fibrilace síní pulzním polem systémem VARIPULSE™

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Úvod

Incidence ischemických lézí u termálních modalit ablace 4 – 19%

Většinou 1-2 léze, které jsou obvykle malé (<3mm)

Navzdory rozsáhlé evidenci o efektivitě, data o cerebrální bezpečnosti PFA systémů jsou kusá / metodicky problematická



1. Gaita F et al., *J Am Coll Cardiol.* 2013
2. Herrera et al., *J Am Coll Cardiol.* 2011
3. Di Biase et al. *Heart Rhythm.* 2014
4. Kimura et al., *JACC Clin Electrophysiol.* 2018



Úvod

	All	PFA	Thermal ablation	<i>P</i> value ^a	RF ablation	Cryoballoon ablation
No.	71	34	37		20	17
Age, y	61.2 ± 9.5	61.5 ± 9.1	60.8 ± 9.9	.76	60.8 ± 8.7	60.9 ± 11.1
Sex, female	28 (39.4)	17 (50.0)	11 (29.7)	.08	8 (40.0)	3 (17.6)
Body mass index, kg/m ²	28.7 ± 4.7	28.8 ± 5.1	28.6 ± 4.4	.85	26.8 ± 4.1	30.7 ± 4.0
CHA ₂ DS ₂ -VASc score	1.7 ± 1.1	1.9 ± 0.9	1.6 ± 1.2	.37	1.7 ± 1.1	1.5 ± 1.4
Left atrial diameter, mm	38.7 ± 5.2	38.2 ± 4.4	39.2 ± 5.9	.39	37.0 ± 4.3	41.9 ± 6.5
Prior stroke or TIA	3 (4.2)	0 (0.0)	3 (8.1)	.09	2 (10.0)	1 (5.9)

Pouze postprocedurální MRI

SCE = DWI+, FLAIR-

SCL = DWI+, FLAIR+

NIHSS, pre/post-procedure	MRI lesions	
	Center review	Core laboratory review
PFA group		
0 / 0	SCL	None
0 / 0	SCE	None
0 / 0	SCE, SCL	None
0 / 0	SCL	SCE
0 / 0	SCE	SCE
0 / 0	SCL	SCL
Thermal group: CBA modality		
0 / 0	SCE	None
0 / 0	SCE	None
Thermal group: RFA modality		
0 / 0	SCE, SCL	None
0 / 0	SCL	None

PFA 3/34 = 9 %

Termální ablace = 0%



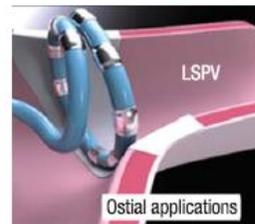
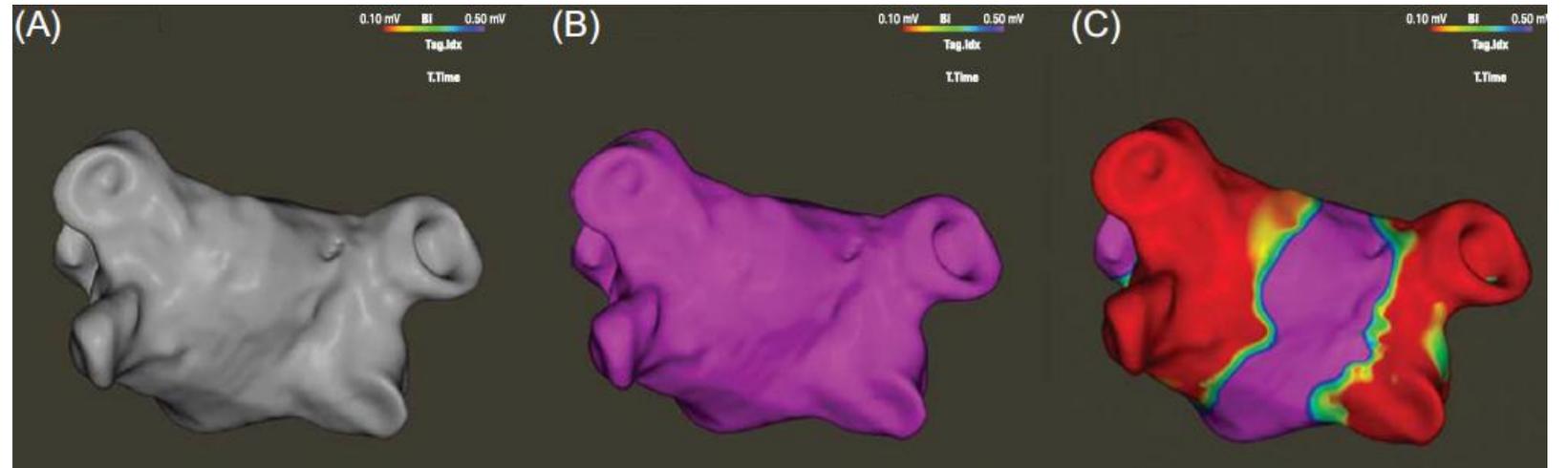
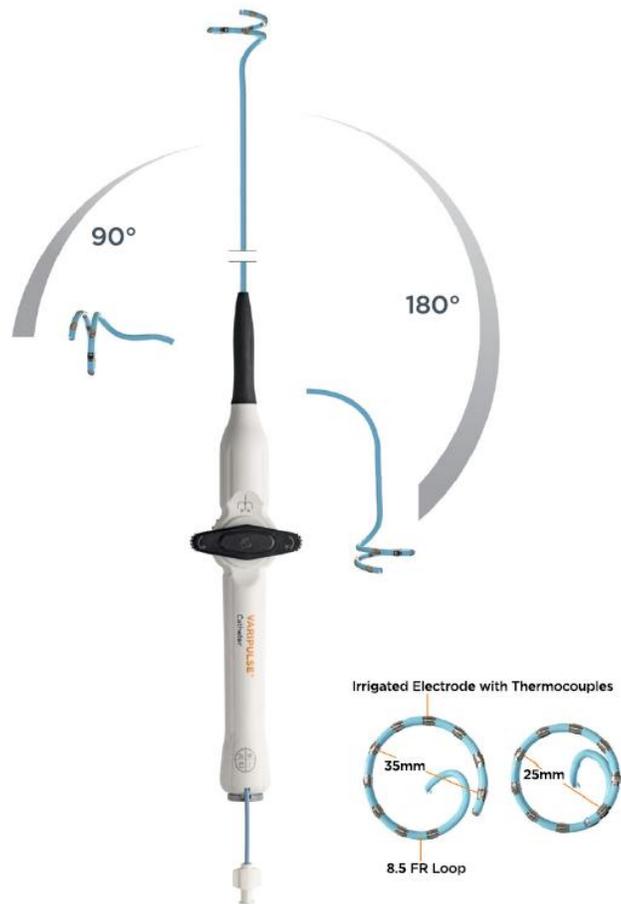
Úvod

First author	Year	No. of patients	No. of SCE/SCL positive	%
Pulsed field ablation				
Reddy	2021	18	2	11
Reinsch	2022	30	1	3
Radiofrequency ablation				
Neumann	2011	44	3	6.8
Schmidt	2013	33	8	24
Wissner	2014	22	4	18.2
Tokuda	2022	193	58	30
Chen	2023	100	42	42
Boga	2023	61	5	8.2
Cryoballoon ablation				
Neumann	2011	45	4	8.9
Schmidt	2013	33	6	18
Wissner	2014	20	1	5
Nakamura	2017	160	43	26.9
Tokuda	2022	168	40	24

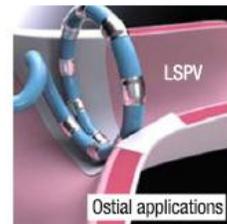
SCE = silent cerebral event; SCL = silent cerebral lesion.



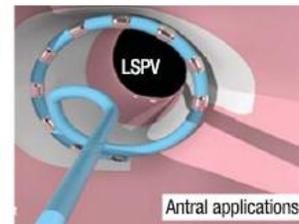
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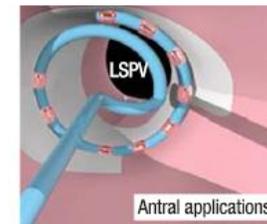
Step 1. First ostial position



Step 2. Second ostial position



Step 3. First antral position



Step 4. Second antral position

Metody

Cíl projektu: stanovit incidenci ischemických cerebrálních lézí (ICL) po PFA FiS systémem VARIPULSE™

Vstupní kritéria: indikace k ablaci, neparoxysmální FiS

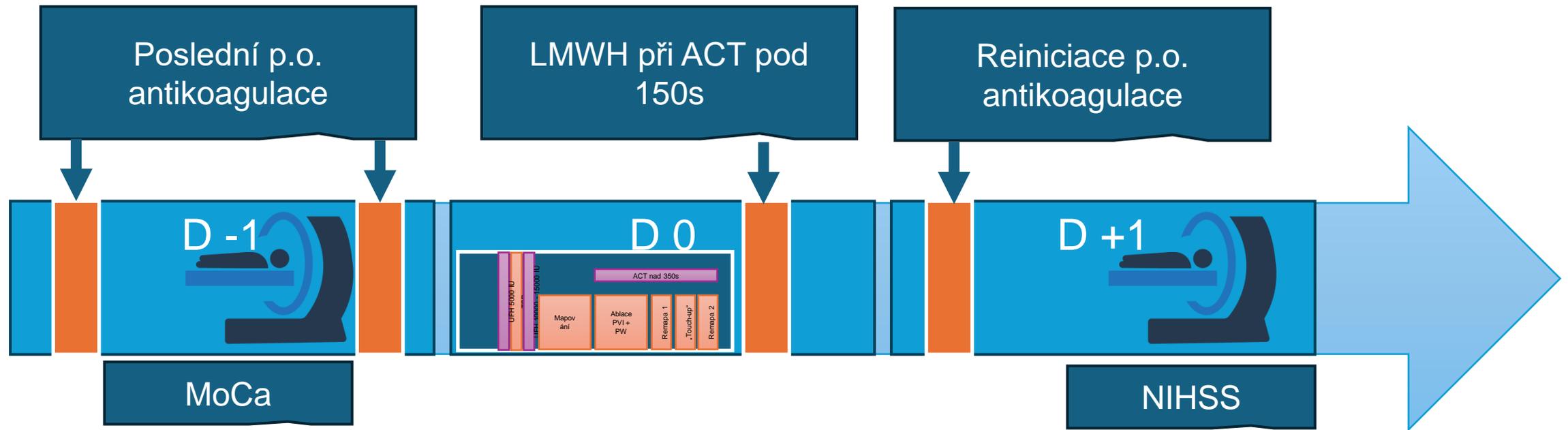
Výstupní kritéria: kontraindikace / odmítnutí MRI, předchozí ablace, hematologická onemocnění spojená s intravaskulární hemolýzou

Cílový počet pacientů = 40

ICL = hyperintenzní ložisko na DWI; malé do 3mm, střední 3 – 10mm, velké nad 10mm



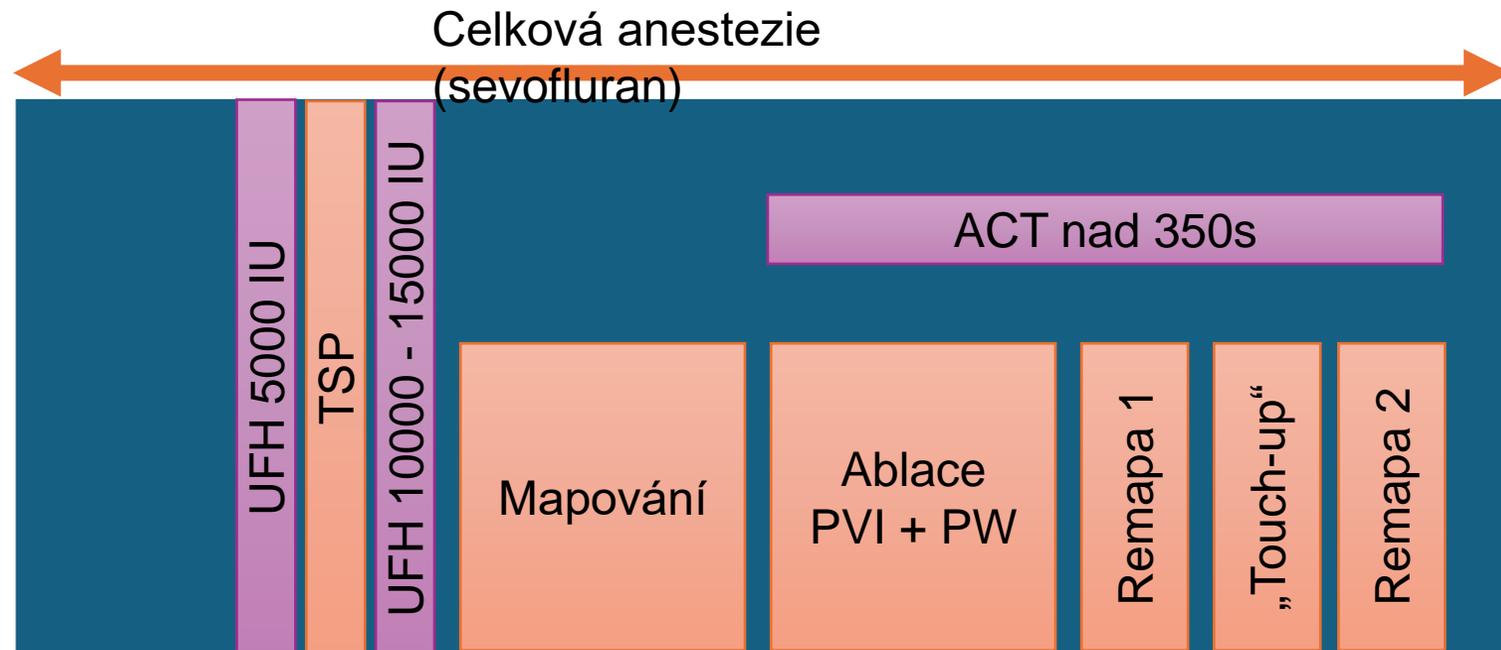
Metody



+ 10-12 měsíců po ablaci klinické neurologické vyšetření + MoCa



Ablace



Proplach 2 ml/min v klidua a 4 ml/min při
ablaci



Výsledky

Baseline Characteristic	
	n = 21
Age, y	66.1 ± 9.2
Female gender	8 (38.1%)
Body mass index, kg/m ²	30.0 ± 5.6
Non-paroxysmal AF	21 (100%)
Hypertension	17 (81%)
Diabetes	3 (14.3%)
History of stroke	1 (4.8%)
Coronary artery disease	1 (4.8%)
Heart failure	14 (66.7%)
CHA ₂ DS ₂ -VASc score	3 (1.0–2.0)

Echocardiographic parameters	
LVEF, %	55 (45–60)
LA size, mm	46.4 ± 5.9
LAVi, ml/m ²	46.3 ± 10.4



Výsledky

Procedural Characteristics	
	n = 21
Procedure time, min	98.3 ± 23.7
LA dwell time, min	80.6 ± 19.9
Total fluoroscopy time, sec	336.7 ± 239.2
Total heparin dose, IU	17,131.6 ± 4,795.4
Electrical cardioversion	13 (61.9%)
LA volume (EA mapping), ml	137.8 ± 25.9
N of PF applications per patient	25 (22–28)
Number of PF applications per patient in PVI	16 (14.5–17.5)
Number of PF applications per patient in LAPWI	9 (8–10)



Výsledky

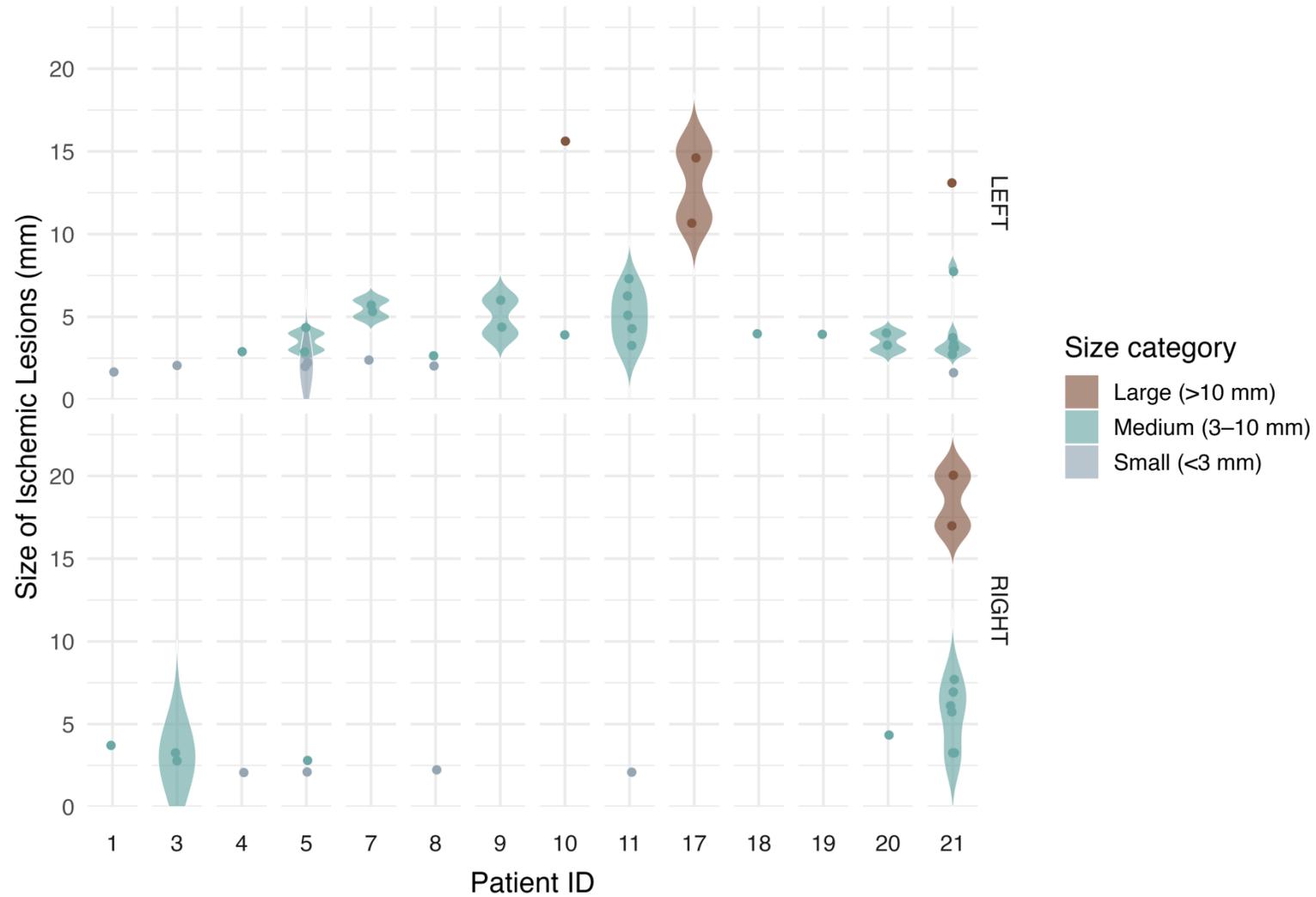
- 1x TIA
- Studie předčasně ukončena pro těžký iktus 21. pacienta

Brain MRI Findings	
Stroke patient	
Number of ICLs	16
ICL size, mm	5 (3–8)
Cumulative ischemic burden, mm	109

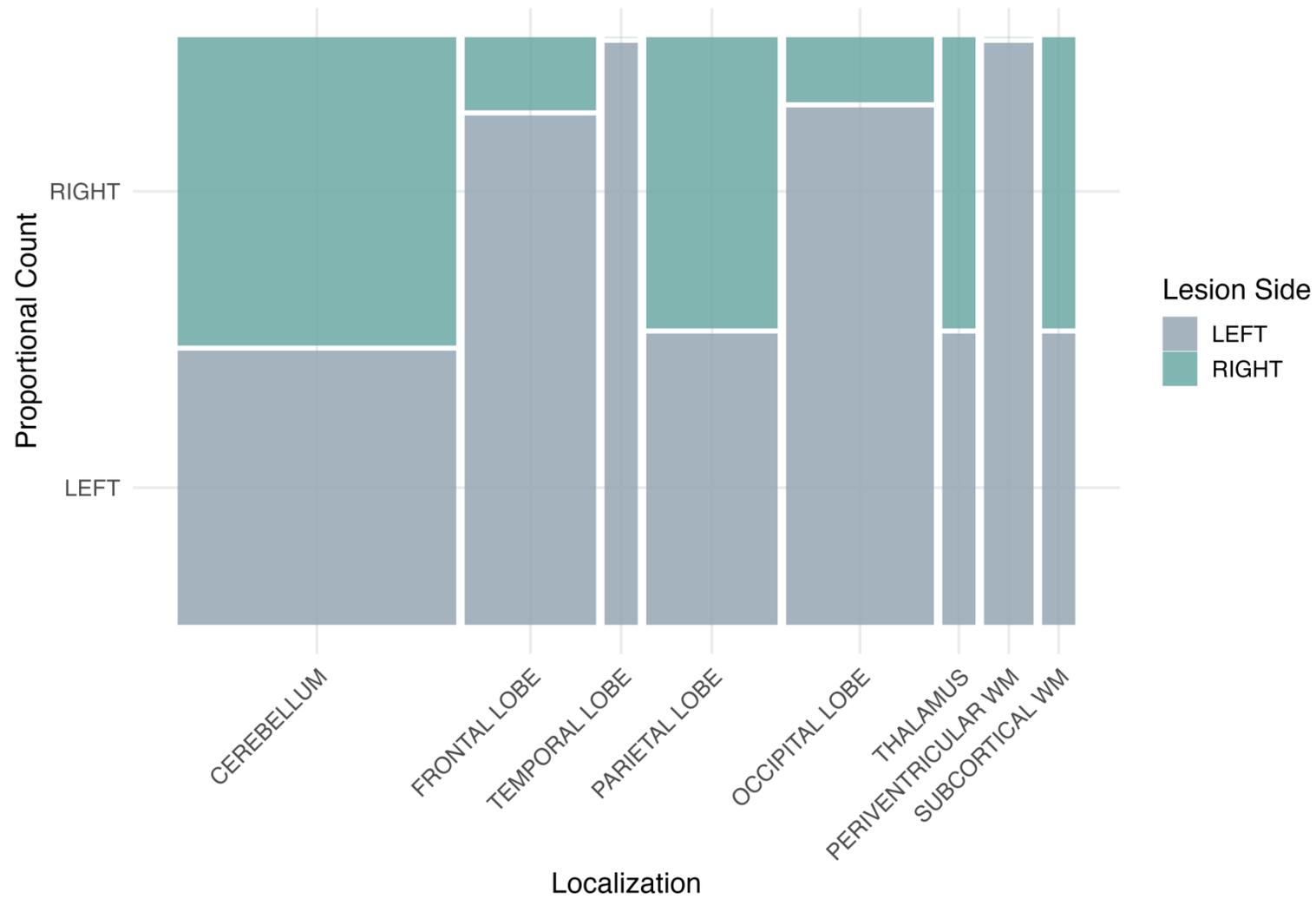
Brain MRI Findings	
	n = 21
Patients with ICL	14 (66.7%)
Total number of ICLs	52
ICLs per patient	2 (0–3)
ICL size, mm	3 (4–6)
ICLs size < 3 mm	11 (21.2%)
ICLs size 3–10 mm	35 (67.3%)
ICLs > 10 mm	6 (11.5%)
Cumulative ischemic burden per patient, mm	10.5 (6.0–15.0)

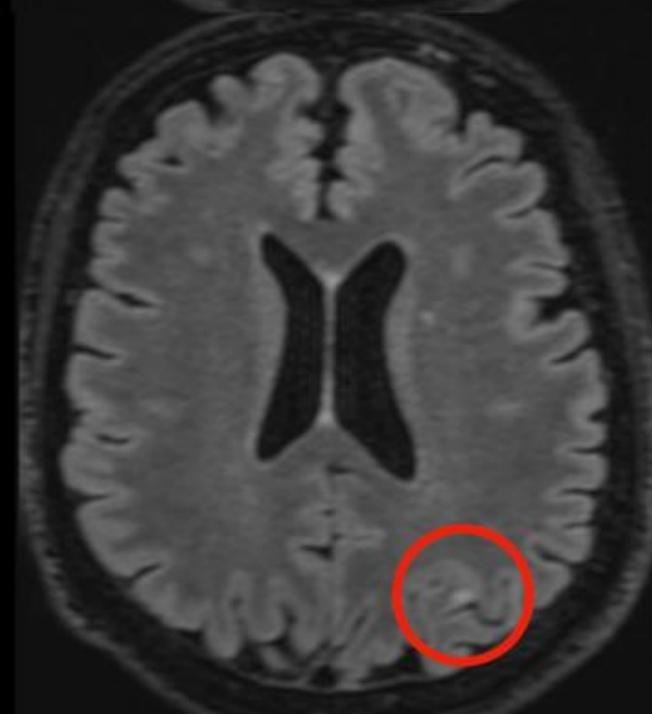
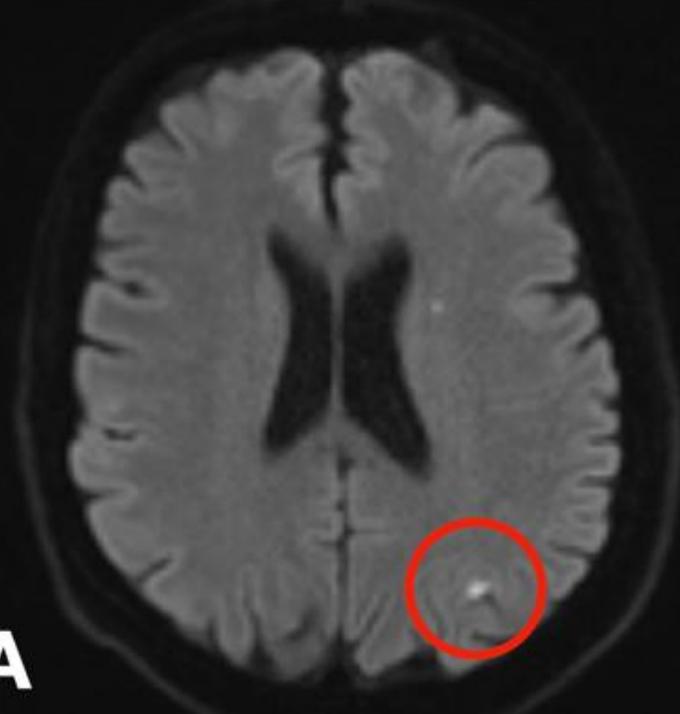
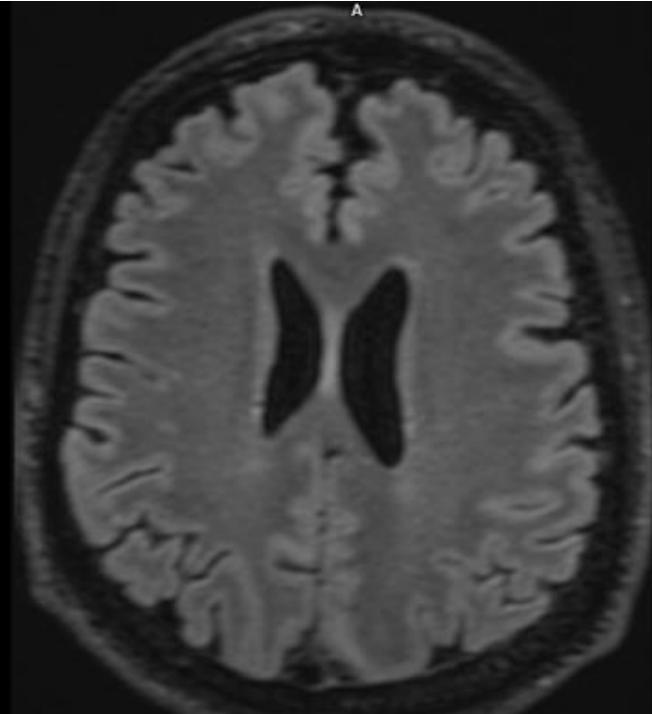
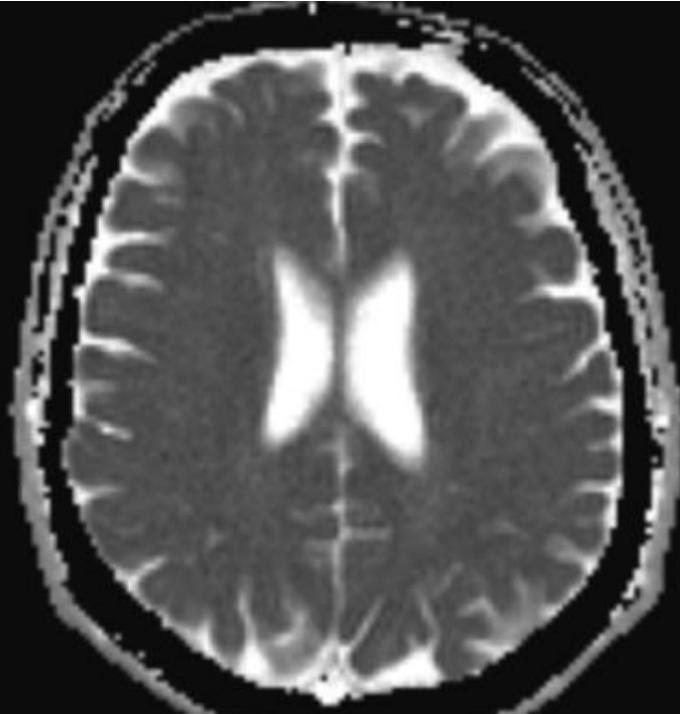
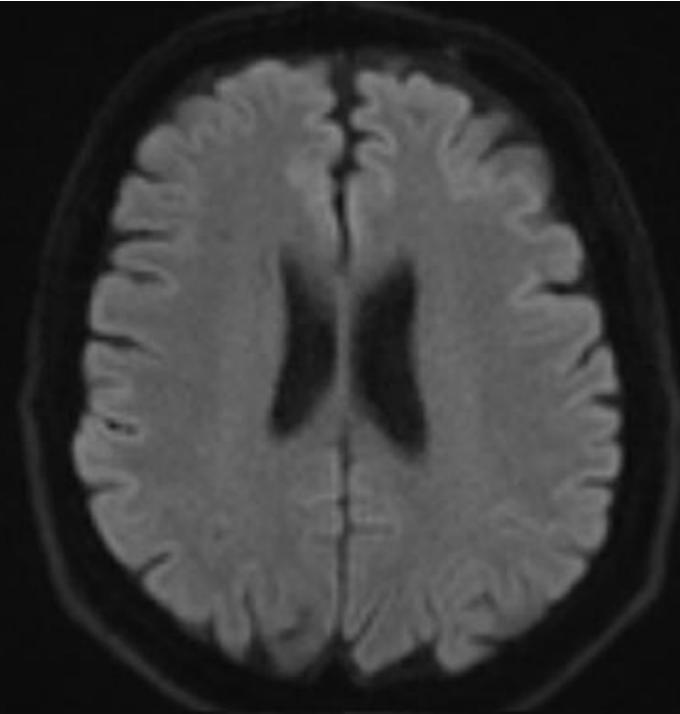


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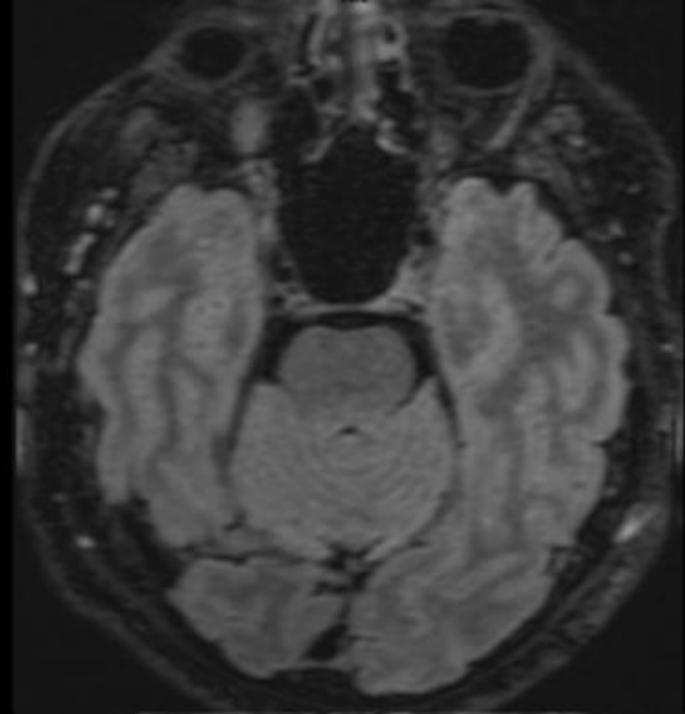
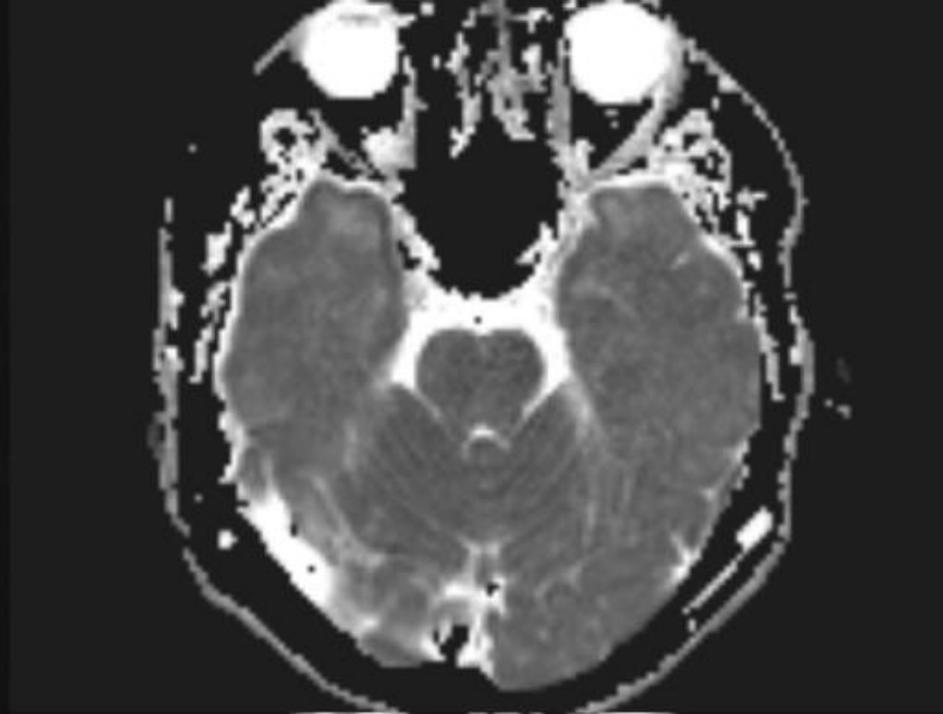
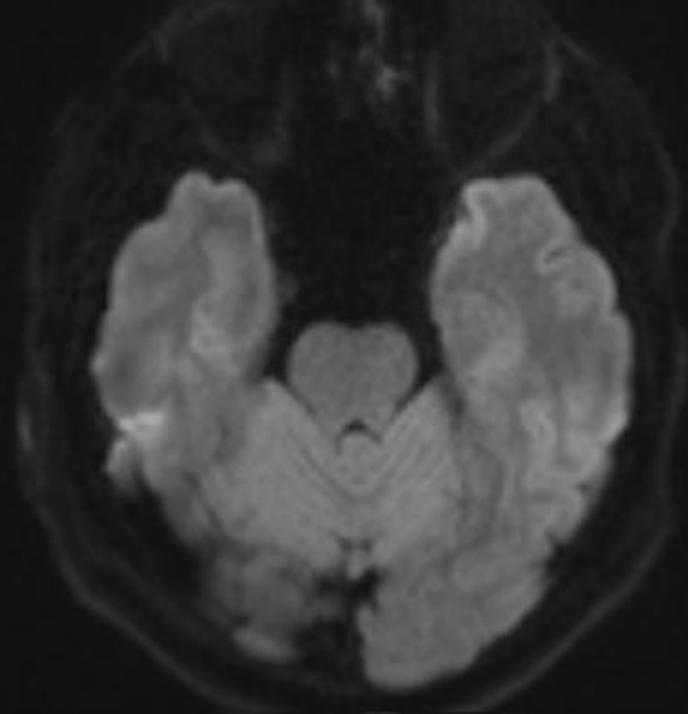


Výsledky



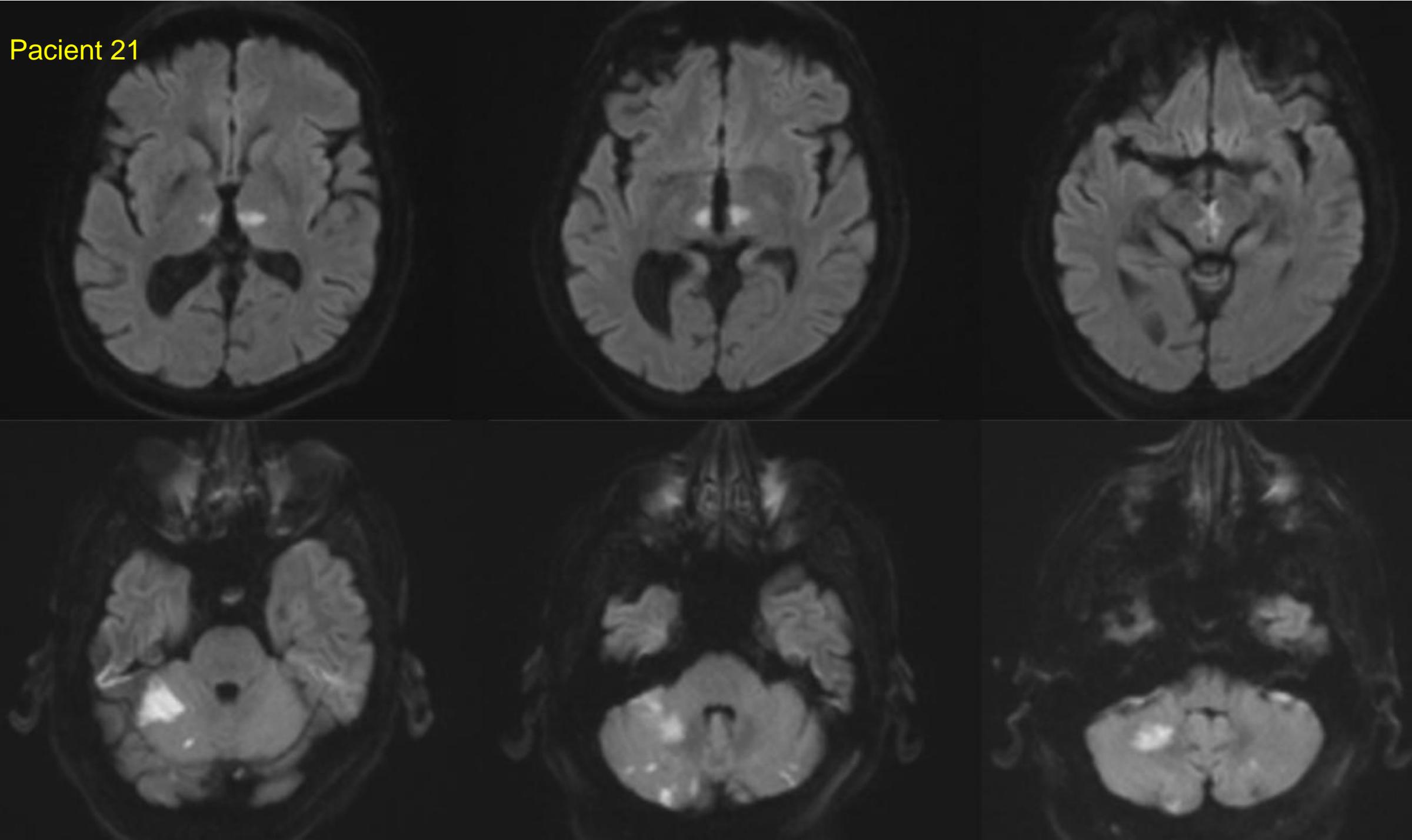


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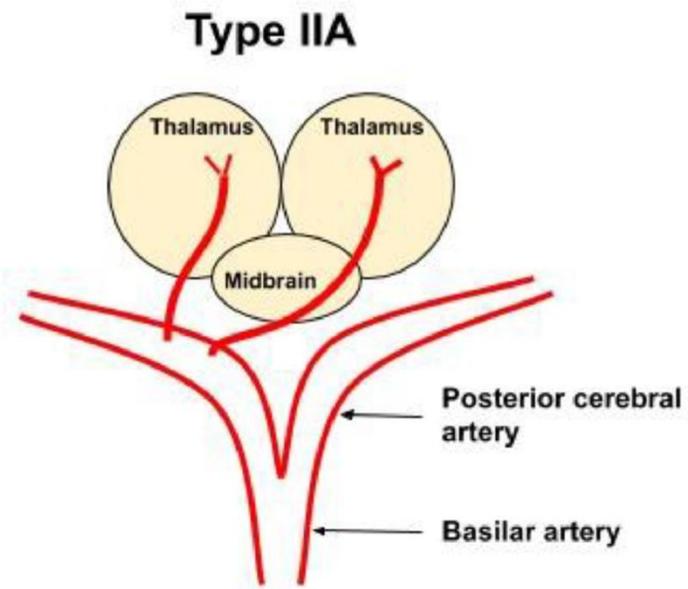
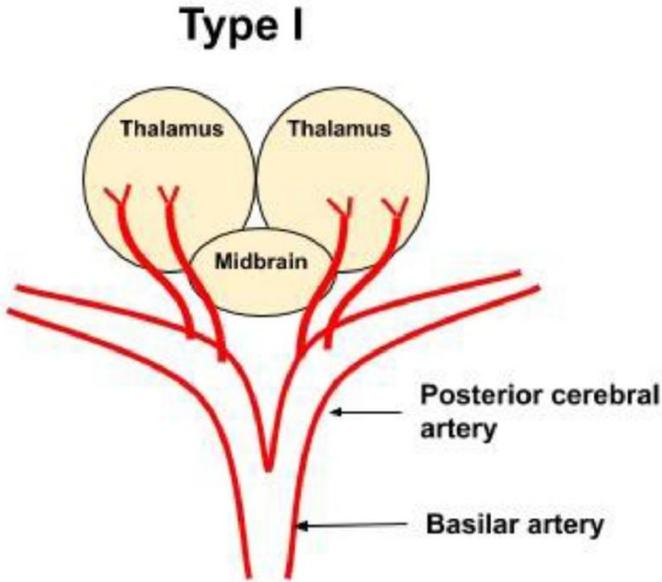
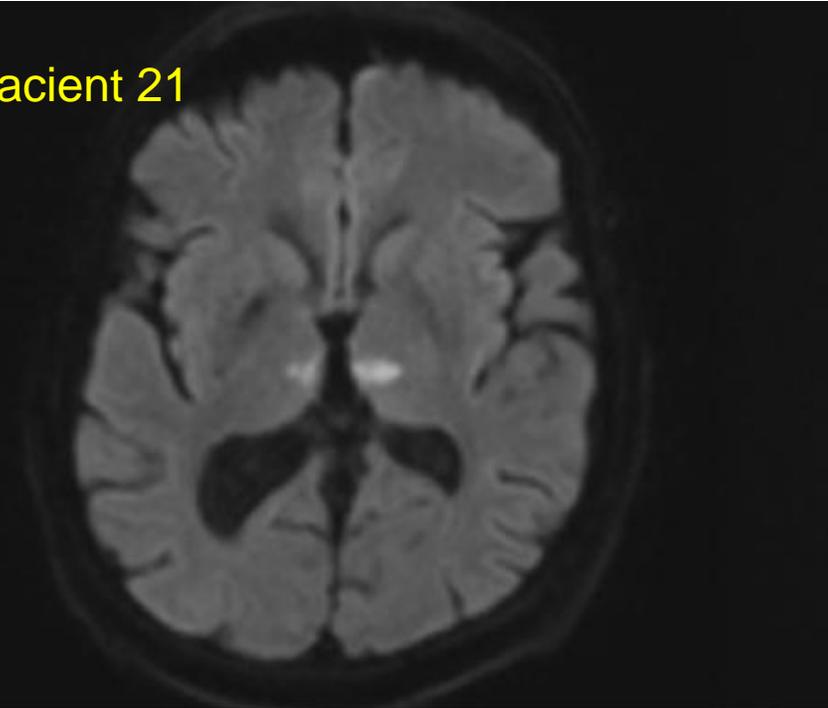


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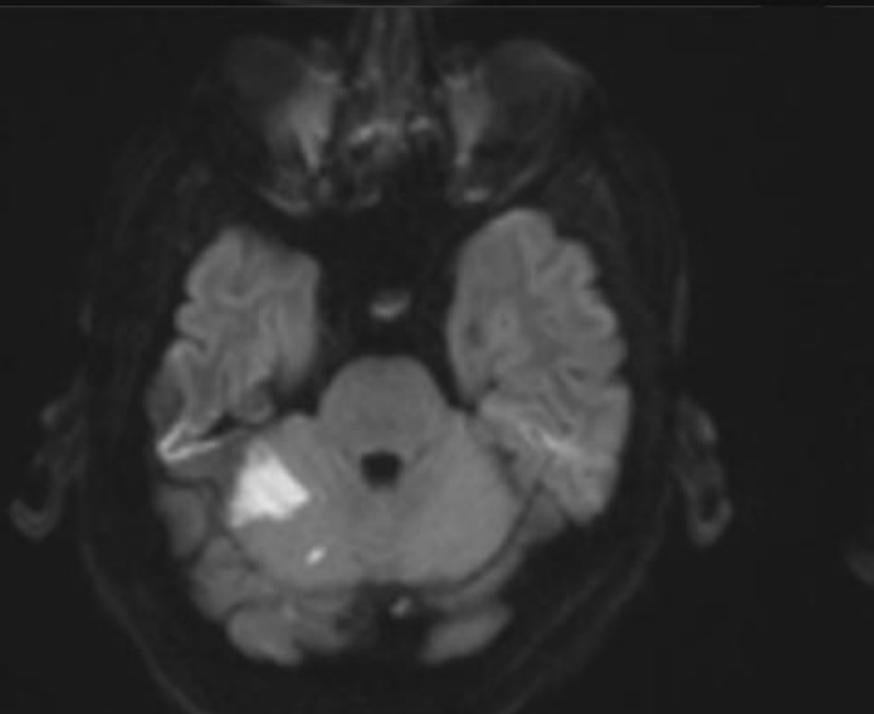
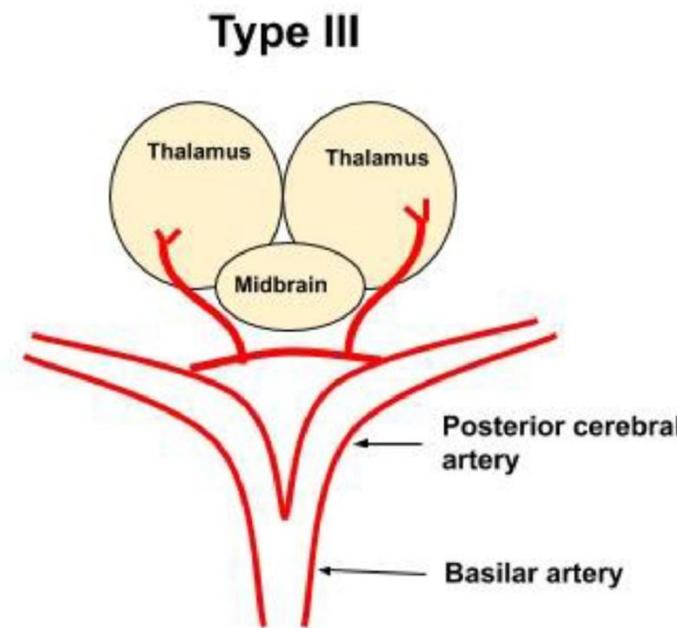
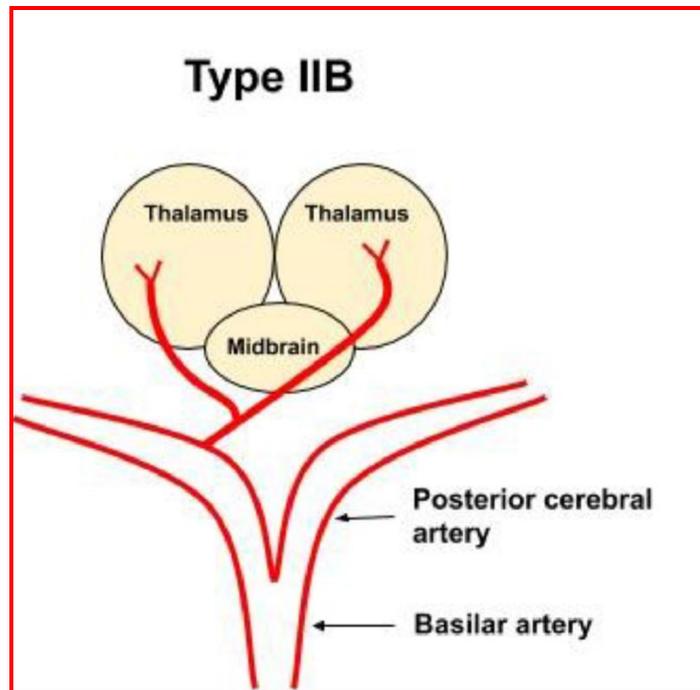
Patient 21



Patient 21



Percheronova arterie



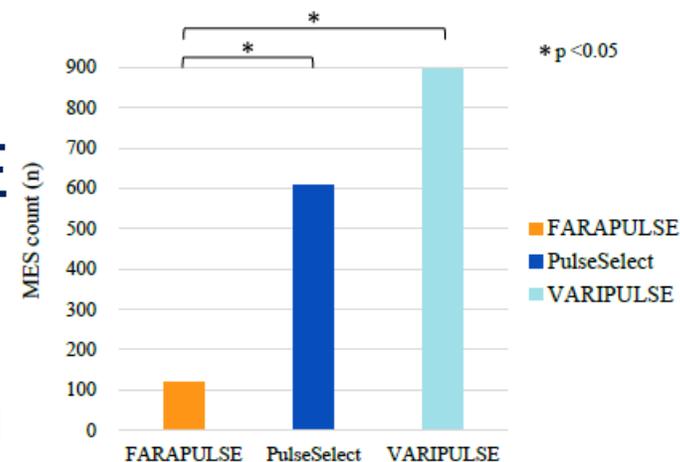
Diskuze

Etiologie ICL nebyla plně vysvětlena (termální efekt x mikrobubliny x patologická aktivace koagulační kaskády...)

Další data o vyšší rizikovosti systému VARIPULSE

- Vyšší četnost mikroembolizačních signálů (MES) dle peroperační sonografie karotid v porovnání se systémem FARAPULSE™ a PULSESELECT™

- Vyšší četnost a mnohočetná distribuce ICL v porovnání se systémem PULSESELECT™



1. Shiomi et al., HR, 2025
2. Miyazaki et al., Circ AE, 2025



Závěrem

Incidence ischemických lézí při ablaci persistentní FiS systémem VARIPULSE™ byla 66,7%

2 z těchto lézí byly klinicky významné: 1x TIA a 1x těžký iktus

Studie byla předčasně ukončena z bezpečnostních důvodů

Lokalizace ischemických lézí nebyla zcela typická pro kardioembolizační etiologii (VB povodí)

