Endovascular thrombectomy for childhood stroke (Save ChildS Pro): an international, multicentre, prospective registry study

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Summary

Background Emerging evidence suggests that endovascular thrombectomy is beneficial for treatment of childhood stroke, but the safety and effectiveness of endovascular thrombectomy has not been compared with best medical treatment. We aimed to prospectively analyse functional outcomes of endovascular thrombectomy versus best medical treatment in children with intracranial arterial occlusion stroke.

Methods In this prospective registry study, 45 centres in 12 countries across Asia and Australia, Europe, North America, and South America reported functional outcomes for children aged between 28 days and 18 years presenting with arterial ischaemic stroke caused by a large-vessel or medium-vessel occlusion who received either endovascular thrombectomy plus best medical practice or best medical treatment alone. Intravenous thrombolysis was considered part of best medical treatment and therefore permitted in both groups. The primary outcome was the difference in median modified Rankin Scale (mRS) score between baseline (pre-stroke) and 90 days (±10 days) post-stroke, assessed by the Wilcoxon rank test (α=0·05). Efficacy outcomes in the endovascular thrombectomy and best medical treatment groups were compared in sensitivity analyses using propensity score matching. The Save ChildS Pro study is registered at the German Clinical Trials Registry, DRKS00018960.

Findings Between Jan 1, 2020, and Aug 31, 2023, of the 241 patients in the Save ChildS Pro registry, 208 were included in the analysis (115 [55%] boys and 93 [45%] girls). 117 patients underwent endovascular thrombectomy (median age 11 years [IQR 6–14]), and 91 patients received best medical treatment (6 years [3–12]; p<0·0001). The median Pediatric National Institutes of Health Stroke Scale (PedNIHSS) score on admission was 14 (IQR 10–19) in the endovascular thrombectomy group and 9 (5–13) in the best medical treatment group (p<0·0001). Both treatment groups had a median pre-stroke mRS score of 0 (IQR 0–0) at baseline. The change in median mRS score between baseline and 90 days was 1 (IQR 0–2) in the endovascular thrombectomy group and 2 (1–3) in the best medical treatment group (p=0·020). One (1%) patient developed a symptomatic intracranial haemorrhage (this patient was in the endovascular thrombectomy group). Six (5%) patients in the endovascular thrombectomy group and four (5%) patients in the best medical treatment group had died by day 90 (p=0·89). After propensity score matching for age, sex, and PedNIHSS score at hospital admission (n=79 from each group), the change in median mRS score between baseline and 90 days was 1 (IQR 0–2) in the endovascular thrombectomy group and 2 (1–3) in the best medical treatment group (p=0·029). Regarding the primary outcome for patients with suspected focal cerebral arteriopathy, endovascular thrombectomy (n=18) and best medical treatment (n=33) showed no difference in 90-day median mRS scores (2 [IQR 1–3] *vs* 2 [1–4]; p=0·074).

Interpretation Clinical centres tended to select children with more severe strokes (higher PedNIHSS score) for endovascular thrombectomy. Nevertheless, endovascular thrombectomy was associated with improved functional outcomes in paediatric patients with large-vessel or medium-vessel occlusions compared with best medical treatment. Future studies need to investigate whether the positive effect of endovascular thrombectomy is confined to older and more severely affected children.

Funding None.

Research in context

Evidence before this study

We searched Pubmed (MEDLINE) for randomised controlled trials published between Jan 1, 2000, and Dec 31, 2023, using terms "EVT" and "ischemic stroke". Several randomised trials found a positive treatment effect of endovascular thrombectomy for adult patients with acute ischaemic stroke and large-vessel occlusion. Even though randomised trials would be the gold standard to determine the benefit of endovascular thrombectomy in children with intracranial arterial occlusion, conducting a randomised trial remains infeasible due to the rarity of the disease. Therefore, the best possible approach is a prospective cohort study of children with large-vessel occlusion stroke comparing functional outcomes after endovascular thrombectomy versus best medical treatment alone.

Added value of this study

We report an international multicentre registry study of 208 paediatric patients with arterial ischemic stroke caused by a large-vessel or medium-vessel occlusion treated with endovascular thrombectomy or best medical treatment. Despite higher stroke severity in the endovascular thrombectomy group at baseline, we found better functional outcomes in the endovascular thrombectomy group than in the best medical treatment group, as measured with the modified Rankin Scale and Pediatric Stroke Outcome Measure at 90 days after the stroke and decrease in the Pediatric National Institutes of Health Stroke Scale score from hospital admission to discharge. This effect was maintained after propensity score matching for age, sex, and initial stroke severity. These findings suggest that endovascular thrombectomy is associated with improved functional outcomes in paediatric patients with large-vessel or medium-vessel occlusions compared with best medical treatment alone.

Implications of all the available evidence

In the absence of randomised controlled trial data, the findings from this multinational prospective registry study with propensity score matching provide strong support for endovascular thrombectomy in children with arterial ischaemic stroke and medium or large arterial occlusion, which will inform future guidelines.

Introduction

Arterial ischaemic stroke affects 1·3–1·6 per 100 000 children every year in high-income countries,[1] and outcomes are potentially severe, with 70% of paediatric strokes resulting in long-term neurological deficits, 20% in recurrent strokes, and 10% in death.[2–4] In adult stroke care, endovascular thrombectomy has revolutionised the treatment of arterial ischaemic stroke caused by large-vessel occlusion.[6,22,23] Several randomised clinical trials published since 2015 have shown the efficacy and safety of endovascular recanalisation for large-vessel occlusions, with large effect size.[6] However, the accumulated experience and evidence from adult stroke research cannot be directly extrapolated to children. Aside from the immense challenges of recruiting and enrolling children with acute stroke into prospective studies, the aetiology of paediatric stroke is fundamentally different from adult stroke. Whereas atherosclerosis is a major risk factor for adult stroke, cardioembolic causes and arteriopathies are dominating factors in paediatric stroke.[1,14] Moreover, the paediatric brain might better compensate for ischaemic stroke than the adult brain due to the greater neuronal plasticity,[1,24] and leptomeningeal collaterals might be more efficient in children.[25] The benefit of recanalisation might therefore be reduced in children. Although technically feasible even in newborn infants,[26] thrombectomy devices are not designed for the small artery diameters needed for mechanical recanalisation in very young children. In addition, the exact time of the stroke ictus cannot be established in neonates, whose strokes present with encephalopathy or seizures rather than focal neurological deficits. The potential risk of damaging the cerebral vasculature, with subsequent arterial dissection or thrombosis, is a major concern for endovascular thrombectomy uptake.[9,11,14]

After several paediatric case series,[7] the retrospective Save ChildS study provided the first systematic evidence for the safety and effectiveness of endovascular thrombectomy in children.[8–10] Although outcomes were generally favourable, and recanalisation and adverse events in the Save ChildS study were comparable with those reported in large randomised controlled trials with adults, the major weakness of the retrospective cohort study design (the absence of a control patient group) limited the conclusions that could be drawn.[11] However, the conclusions were subsequently confirmed in the French KidClot study.[12] Outcomes of endovascular thrombectomy did not differ by sex, but remaining questions include whether the findings are reproducible in prospective multicentre settings, whether endovascular thrombectomy is possible in even younger children, and what are the effects of specific aetiologies, such as cerebral arteriopathies, on the safety and effectiveness of endovascular thrombectomy.[8,13,14]

Confident interpretation of the existing paediatric data has been hindered by an absence of population-based reporting of the natural history of stroke in children caused by large-vessel occlusions. According to a 2022 population-based cohort study of paediatric patients with arterial ischaemic stroke, where nearly a quarter of patients had large-vessel occlusions, outcomes of conservative treatment were significantly worse among those patients with large-vessel occlusions than those with non-large-vessel occlusion arterial ischaemic stroke.[15] In a matched case–control study of

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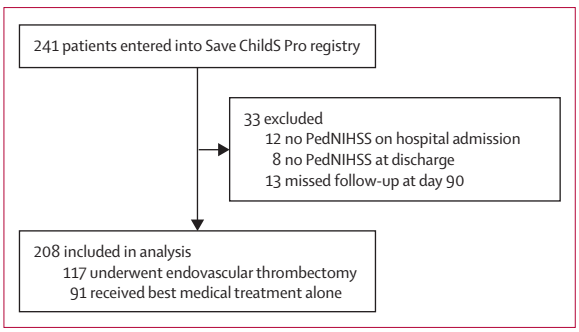

Figure 1: **Flow chart for Save ChildS Pro registry inclusion**
PedNIHSS=Pediatric National Institutes of Health Stroke Scale.

52 patients aged 2–18 years with anterior circulation large-vessel occlusion stroke,[16] clinical outcomes were better with endovascular thrombectomy than with medical management alone, even when applying a hierarchal matching system for site of occlusion, age group, side of occlusion, and sex.

Additional barriers to implementing reperfusion therapies in paediatric stroke care include slow triage and imaging pathways.[17] Historic beliefs also maintain that children with large-vessel occlusions present too late for reperfusion[18] and have better outcomes with conservative treatment than adults do.[19] Considering the difficulties of conducting a randomised trial in paediatric patients with stroke (eg, difficulties with recruitment led to the premature termination of the prospective Thrombolysis in Pediatric Stroke trial[5]), and the large treatment effect of endovascular thrombectomy in adults, a randomised trial of recanalisation treatments in children is unlikely to succeed. A prospective multicentre registry was therefore considered the best option to generate evidence regarding hyperacute recanalisation treatments in children with arterial ischaemic stroke. Drawing on data accumulated in the prospective Save ChildS Pro registry, the aim of this study was to compare functional outcomes of endovascular thrombectomy and best medical treatment in children presenting with arterial ischaemic stroke.

Methods

Study design and participants

Save ChildS Pro is an international prospective cohort study of children who presented with acute arterial ischaemic stroke across 53 centres in Europe, North America, South America, Asia, and Australia.[13] Participating centres are listed in the appendix (pp 8–14). 45 centres contributed eligible patient data that were included in this analysis.

Registry inclusion criteria were age 28 days to 18 years, a clinical diagnosis of arterial ischaemic stroke, confirmed diagnosis of intracranial arterial occlusion consistent with symptoms including occlusion of terminal internal carotid artery, middle cerebral artery (M1, M2 segments), basilar artery, vertebral artery (V4 segment), anterior cerebral artery (A1, A2 segments), posterior cerebral artery (P1, P2 segments), and proximal superior cerebellar artery. Neonates with stroke were excluded.

Procedures

All patients included in the Save ChildS Pro registry received best medical treatment, including systemic thrombolysis, platelet inhibition, and anticoagulation The endovascular thrombectomy group included all patients in whom endovascular thrombectomy was attempted (ie, patients with groin puncture initiated and all cases in which endovascular thrombectomy failed or was interrupted). The best medical treatment group included patients in whom endovascular thrombectomy was not attempted.

Local study teams recorded patient demographics and disease characteristics at time of hospital admission, treatment, 24–48 h after treatment, hospital discharge, and 90 days (±10 days) after the stroke (collected variables are listed in the appendix pp 15–16). To ensure accuracy, completeness, and exhaustivity of collected data, all centres committed to collecting these predefined patient variables and all variables were checked for plausibility by the study team. Patient outcome measures were regarded as essential for registry inclusion, so patients or datasets without outcome measures were not included. Local teams also completed standard aetiological investigations according to the Childhood AIS Standardized Classification and Diagnostic Evaluation (CASCADE) classification,[20,21] and patient sex was obtained from clinical records. Modified Rankin Scale (mRS) scores and Pediatric Stroke Outcome Measure (PSOM) were measured by local clinical teams during routine clinical care. Details of the collected variables are provided in the appendix (pp 15–16). In summary, patient data, medical history, mRS, PedNIHSS, and imaging findings were recorded at time of admission. Details of treatment (time and dose of intravenous tissue plasminogen activator for patients in the best medical treatment group; and time, anaesthesia type, morphological appearance, type of treatment and device, and treatment-related complications for patients in the endovascular thrombectomy group) were recorded. At 24 h after admission, PedNIHSS, imaging findings, and adverse events were recorded. At time of hospital discharge, patient logistics, PedNIHSS, mRS, PSOM, stroke aetiology, and adverse events were recorded. Finally, mRS, PSOM, and adverse events, were recorded at day 90 (±10).

Save ChildS Pro is registered at the German Clinical Trials Registry (DRKS00018960) and was approved by the ethics committee of the University of Münster (Münster, Germany; 2019-677-f-S), in accordance with the Declaration of Helsinki, with waiver for informed consent. The participating centres also obtained local ethics approvals and waivers for informed consent.

	Endovascular thrombectomy (n=117)	Best medical treatment (n=91)	p value
Age, years	11 (6–14)	6 (3–12)	<0·0001
Sex	..	..	0·43
Female	55 (47%)	38 (42%)	..
Male	62 (53%)	53 (58%)	..
PedNIHSS score at hospital arrival*	14 (10–19)	9 (5–13)	<0·0001
Pre-stroke mRS score†	0 (0–0)	0 (0–0)	0·95
Known time of symptom onset	91 (78%)	66 (73%)	0·28
Referral from other hospital	36 (31%)	43 (47%)	0·013
Medical history (selected)			
Cardiac anomaly	46 (39%)	16 (18%)	..
Hypertension	5 (4%)	0	..
Diabetes	0	1 (1%)	..
Sickle cell disease	0	2 (2%)	..
Other	22 (19%)	27 (30%)	..
None	54 (46%)	52 (57%)	..
Occlusion site	..	..	..
Internal carotid artery	37/127 (29%)	16/97 (16%)	..
Middle cerebral artery, M1 segment	53/127 (42%)	48/97 (49%)	..
Middle cerebral artery, M2 segment	12/127 (9%)	16/97 (16%)	..
Anterior cerebral artery, A1 segment	4/127 (3%)	3/97 (3%)	..
Anterior cerebral artery, A2 segment	1/127 (1%)	0/97	..
Basilar artery	15/127 (12%)	3/97 (3%)	..
Posterior cerebral artery, P1 segment	3/127 (2%)	5/97 (5%)	..
Posterior cerebral artery, P2 segment	0/127	3/97 (3%)	..
Vertebral artery, V4 segment	2/127 (2%)	2/97 (2%)	..
Superior proximal superior cerebellar artery	0/127	1/97 (1%)	..
Imaging method used for enrolment			
CT	70 (60%)	44 (48%)	..
MRI	47 (40%)	47 (52%)	..
ASPECTS baseline‡	8 (6–9)	8 (5–10)	0·38
Intravenous alteplase administered	20 (17%)	25 (27%)	0·086
Time between symptom onset and hospital admission for strokes with known onset, min	130 (51–273)	229 (79–424)	0·046
Time between symptom onset and recanalisation, min	388 (277–545)	..	..
Time between symptom onset and first recanalisation pass, min	340 (243–506)	..	..
Anaesthesia performed	..	..	..
Conscious sedation or none	15 (13%)	..	..
General anaesthesia	102 (87%)	..	..
Type of device used for thrombectomy	..	..	..
Aspiration catheter alone	31 (26%)	..	..
Stent retriever alone	72 (62%)	..	..
Both aspiration catheter and stent retriever	14 (12%)	..	..
Attempts for thrombectomy	2 (1–3)	..	..
CASCADE classification (aetiology)	..	..	<0·0001
1 (small vessel arteriopathy)	0	0	..
2 (focal cerebral arteriopathy)	19 (16%)	35 (38%)	..
3 (bilateral cerebral arteriopathy)	1 (1%)	7 (8%)	..
4 (aortic or cervical arteriopathy)	7 (6%)	5 (5%)	..
5 (cardioembolic)	51 (44%)	15 (16%)	..
6 (other)	32 (27%)	24 (26%)	..
7 (multifactorial)	7 (6%)	5 (5%)	..

Data are median (IQR), n (%), or n/N (%). ASPECTS=Alberta Stroke Program Early CT Score. CASCADE=Childhood AIS Standardized Classification and Diagnostic Evaluation. mRS=modified Rankin Scale. PedNIHSS=Pediatric National Institutes of Health Stroke Scale. *Scores on the PedNIHSS range from 0 to 42, with higher scores indicating greater neurological deficit. †Scores on the mRS range from 0 to 6, with higher scores indicating greater disability. ‡ASPECTS values range from 0 to 10, with lower values indicating larger infarction.

Table 1: **Demographic and clinical characteristics at baseline and treatment**

Outcomes

The primary outcome was the difference between mRS scores recorded before the stroke (pre-stroke) and at 90 days after the stroke. Secondary outcomes were the differences between Pediatric National Institutes of Health Stroke Scale (PedNIHSS) scores recorded at hospital admission and at discharge, the 90-day PSOM, and safety outcomes (symptomatic or non-symptomatic intracranial haemorrhage, peri-interventional vasospasm, and arterial dissection during treatment and 90-day mortality). Primary and secondary outcomes were analysed separately for patients with focal cerebral arteriopathy (CASCADE subtype 2).

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See Online for appendix

	Endovascular thrombectomy (n=117)	Best medical treatment (n=91)	p value
90-day mRS*	1 (0 to 2)	2 (1 to 3)	0·039
Difference between 90-day and pre-stroke mRS scores*	1 (0 to 2)	2 (1 to 3)	0·020
90-day PSOM†	1 (0 to 2)	2 (1 to 3)	<0·0001
Difference between hospital admission and discharge PedNIHSS scores‡	−9 (−13 to −3)	−3 (−5 to 0)	<0·0001
Hospital discharge PSOM†	1 (0 to 2)	2 (1 to 4)	0·0030
Successful recanalisation (mTICI 2b or better)	104 (89%)	..	..
Near-complete recanalisation (mTICI 2c or better)	64 (55%)	..	..
Complete recanalisation (mTICI 3)	49 (42%)	..	..

Data are median (IQR) or n (%). Successful reperfusion was defined as grade 2b to 3 on the mTICI system ranging from 0 to 3, with higher grades indicating increased reperfusion; grade 2b indicates reperfusion of 50% or more of the occluded cerebral artery territory; and grade 3 indicates reperfusion of 100% of the occluded cerebral artery territory at the end of the thrombectomy procedure. mRS=modified Rankin Scale. mTICI=modified thrombectomy in cerebral infarction. PedNIHSS=Pediatric National Institutes of Health Stroke Scale. PSOM=Pediatric Stroke Outcome Measure. *Scores on the mRS range from 0 to 6, with higher scores indicating greater disability. †Scores on the PSOM range from 0 to 10 in 0·5 steps, with higher scores indicating greater disability. ‡Scores on the PedNIHSS range from 0 to 42, with higher scores indicating greater neurological deficit.

Table 2: **Efficacy outcomes**

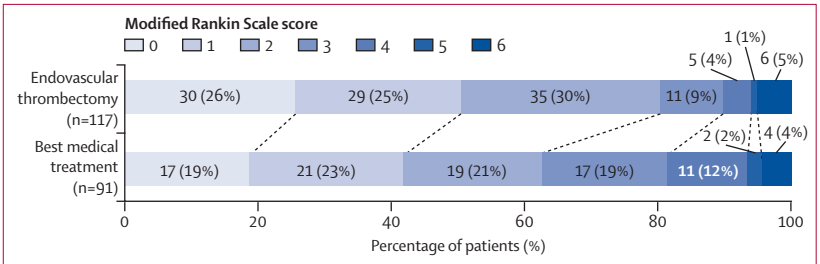

Figure 2: **Distribution of modified Rankin Scale scores at 90 days after the stroke**
Scores on the modified Rankin Scale range from 0 to 6, with higher scores indicating greater disability.

Statistical analysis

The primary outcome was compared between treatment groups by the Wilcoxon rank test (α=0·05). Secondary outcomes and baseline demographics were compared between treatment groups by the χ^2 test (or Fisher's exact test where appropriate) for categorical variables and the *t* test (or Mann–Whitney *U* test, when appropriate) for continuous variables.

To account for possible confounding factors, additional ordinal regression analyses were performed for primary and secondary outcomes on all variables that differed significantly between the treatment groups. For the assessment of effect size, *r* values were calculated as the Z value (from the Mann–Whitney *U* test) divided by the square root of n, where n is the total patient number per group. For interpretation, an *r* value greater 0·1 indicated a weak effect whereas *r* values less than 0·3 or greater than 0·5 indicated moderate and strong effects, respectively.

For sensitivity analysis, propensity score matching was used to adjust for differences in baseline parameters between treatment groups. Each patient's propensity score to receive endovascular thrombectomy or best medical treatment was determined using a multivariable logistic regression model that included covariates with a significant effect on the primary outcome. Optimised propensity score matching (SAS macro psmatch_multi) was used to match patients from each group 1:1. For matching, an absolute difference between propensity scores of 0·10 was allowed.

An α value of 0·05 was used to determine significance for all analyses. Statistical analyses were performed with SAS (version 9.4).

Role of the funding source

There was no funding source for this study.

Results

41 patients were entered into the Save ChildS Pro registry between Jan 1, 2020, and Aug 31, 2023. 208 patients met inclusion criteria for this analysis, of whom 117 underwent endovascular thrombectomy and 91 received best medical treatment only (figure 1). Baseline characteristics, including location of arterial occlusion and CASCADE classification, are listed in table 1. The median age of patients in the endovascular thrombectomy was higher than in the best medical treatment group (p<0·0001). The youngest patient to be treated with endovascular thrombectomy was aged 3 months. The median PedNIHSS score upon hospital admission was higher in the endovascular thrombectomy group than in the best medical treatment group (p<0·0001). Intravenous thrombolysis was used in both treatment groups.

Efficacy outcomes are shown in table 2. In the endovascular thrombectomy group, 104 (89%) of 117 patients had successful reperfusion (modified treatment in cerebral infarction 2b or better), and 49 patients (42%) had complete reperfusion. The difference between median pre-stroke mRS score and 90-day mRS score was 1 (IQR 0–2) in the endovascular thrombectomy group and 2 (1–3) in best medical treatment alone (p=0·020; table 2; figure 2; *r*=0·14).

Median 90-day PSOM scores are compared in table 2. The change in median PedNIHSS scores between time of hospital admission and discharge are compared in table 2 and figure 3 (*r*=0·44). The comparison of median discharge and 90-day PSOM scores is shown in the appendix (p 1; *r*=0·21).

Ordinal regression analyses revealed a significant effect of age (p=0·0029), PedNIHSS score at hospital admission (p=0·0017), and treatment group (p=0·020),

whereas no other parameter showed an effect on the primary and secondary outcomes (data not shown).

Safety outcomes are shown in table 3. Six (5%) of 117 patients in the endovascular thrombectomy group and four (5%) of 91 patients in the best medical treatment group had a 90-day mRS score of 6, indicative of death (p=0·89). In the endovascular thrombectomy group, 17 (15%) patients had transient vasospasm during the intervention, which resolved in all cases, either spontaneously or after administration of intra-arterial nimodipine. Two (2%) patients had catheterisation -associated non-flow-limiting arterial dissections. During treatment, non-symptomatic intracranial haemorrhage affected nine (8%) of 117 patients in the endovascular thrombectomy group and six (7%) of 91 patients in the best medical treatment group (p=0·79). One case of symptomatic intracranial haemorrhage was seen, and this was in the endovascular thrombectomy group. Furthermore, the prevalence of persistent arterial occlusions was significantly lower in the endovascular thrombectomy group than in the best medical treatment group (18 [15%] *vs* 49 [54%], p<0·0001; table 3). Further CASCADE classification of patients with persistent occlusion revealed suspected focal cerebral arteriopathy aetiology in eight (44%) of 18 patients in the endovascular thrombectomy group and 19 (39%) of 49 patients in the best medical treatment group.

A comparison of outcomes between patients with focal cerebral arteriopathy (CASCADE subtype 2) and patients with other aetiologies showed no difference in 90-day median mRS scores among those who underwent endovascular thrombectomy and best medical treatment (p=0·074; appendix pp 2, 6). The change in median PedNIHSS score from hospital admission to discharge was –10 (IQR –18 to –2) in the endovascular thrombectomy group and –4 (–4 to 0) in the best medical treatment group (p<0·0001; appendix pp 3–4, 6). The median 90-day PSOM score was 1·0 (IQR 0·5 to 1·5) in the endovascular thrombectomy group and 1·5 (1·0 to 2·5) in the best medical treatment group (p<0·0001; appendix pp 5–6).

79 patients from the endovascular thrombectomy group were propensity score matched 1:1 based on age, sex, and PedNIHSS score at hospital admission to 79 patients from the best medical treatment group (appendix p 7). Median age among matched patients was 10 years (IQR 7 to 13) in the endovascular thrombectomy group and 7 years (4 to 11) in the best medical treatment group. The median PedNIHSS score at hospital admission was 12 (IQR 8 to 15) in the endovascular thrombectomy group and 9 (7 to 12) in the best medical treatment group. In these patients, median pre-stroke mRS score was 0 (IQR 0 to 0) in both treatment groups and increased to 1 (0 to 2) at day 90 among patients treated with endovascular thrombectomy compared with 2 (1 to 3) among patients with best medical treatment (p=0·029). The median change in the PedNIHSS score from hospital admission to discharge was –8 (IQR –12 to –3) in the endovascular thrombectomy group and –2 (–6 to 0) in the best medical treatment group (p<0·0001). The median 90-day PSOM score was 1 (IQR 0 to 2) in the endovascular thrombectomy group and 2 (1 to 3) in the best medical treatment group (p=0·0020). No sex-specific differences were observed with respect to clinical outcome measures (data not shown).

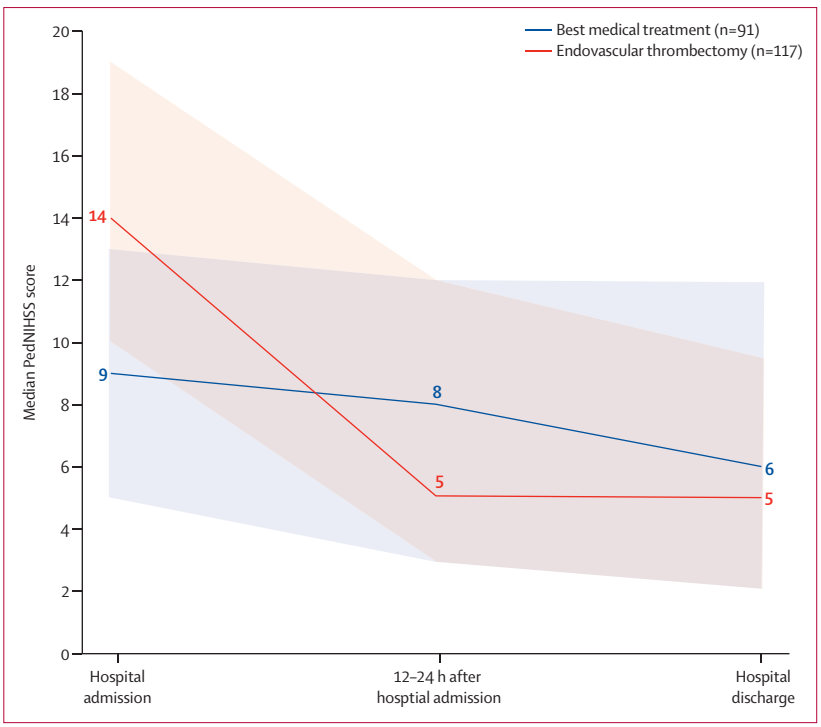

Figure 3: **Change in median PedNIHSS score between hospital admission and discharge**
Scores on the PedNIHSS range from 0 to 42, with higher scores indicating greater neurological deficit. Shaded areas indicate the IQR. PedNIHSS=Pediatric National Institutes of Health Stroke Scale.

	Endovascular thrombectomy (n=117)	Best medical treatment (n=91)	p value
Death (mRS score of 6)*	6 (5%)	4 (4%)	0·89
Symptomatic intracranial haemorrhage†‡	1 (1%)	0	1·0
Non-symptomatic intracranial haemorrhage‡	9 (8%)	6 (7%)	0·79
Transient vasospasm‡	17 (15%)	..	..
Arterial dissection‡	2 (2%)	..	..
Persistent or recurrent arterial occlusion‡	18 (15%)	49 (54%)	<0·0001

Data are n (%). mRS=modified Rankin Scale. PedNIHSS=Pediatric National Institutes of Health Stroke Scale. *Death was determined at 90 (±10) days after stroke. †Symptomatic intracranial haemorrhage was defined as an increase in the PedNIHSS score of at least 4 points with presence of parenchymal haemorrhage. ‡Recorded within 24 h of hospital admission.

Table 3: **Safety outcomes**

Discussion

The Save ChildS Pro registry study shows superior outcomes in children with large-vessel and medium-vessel occlusion treated with endovascular thrombectomy compared with best medical treatment alone. The primary outcome, defined as the change in median mRS score from pre-stroke baseline to day 90, and the secondary outcomes (change in the PedNIHSS score from hospital admission to discharge and 90-day PSOM score) were significantly better in the endovascular thrombectomy group than in the best medical care group. The consistency of these findings after propensity score matching for age, sex, and initial stroke severity emphasises the value of endovascular thrombectomy and represents a high-quality approach to analysing observational registry data in the absence of a randomised trial. These improved outcomes align with the results of a recent matched case–control study,[16] in which clinical outcomes for paediatric patients with anterior circulation large-vessel occlusion stroke were better with endovascular thrombectomy than with best medical treatment alone. The benefits of endovascular thrombectomy are more compelling in light of recent findings that outcomes of children with arterial ischaemic stroke due to large-vessel occlusion treated with medical management alone might not be as benign as for children who do not present with large-vessel occlusion.[15] Similar to previous studies, the efficacy outcomes of the endovascular thrombectomy procedure were high, with successful recanalisation (defined as modified treatment in cerebral infarction 2b or better) in 89% of patients and a median of two attempts per endovascular thrombectomy procedure. The decision of whether to perform endovascular thrombectomy should not be based on one single parameter (eg, the PedNIHSS), but always as a combination of multiple parameters (eg, the PedNIHSS, occlusion location, the Alberta Stroke Program Early CT Score [ASPECTS], pre-existing neurological deficits, and potentially salvageable tissue), because parameters such as the PedNIHSS and ASPECTS have limitations, such as potentially fluctuating symptoms, the lower representation of posterior circulation symptoms, or high inter-rater variability.[28]

Age and PedNIHSS score at baseline showed a significant effect on patient outcome. The interplay between age and symptom severity at presentation might present important selection criteria for or against endovascular thrombectomy in children. Although more severely affected children might benefit more from endovascular thrombectomy, the existing data up to now do not justify dedicated cutoff values for or against selecting children for endovascular thrombectomy. For the current analysis, the cohort size was too small to allow the formation of subgroups of younger and less severely affected children. Thus, it is currently possible that the observed positive treatment effect for endovascular thrombectomy is confined to older and more severely affected children. Larger studies including children with different symptom severities at presentation across all age groups will help to determine whether a potential benefit for endovascular thrombectomy similarly exists in younger and less severely affected children, and thereby create more detailed treatment recommendations.

Concerning safety, we found similar mortality rates in patients receiving endovascular thrombectomy and best medical treatment compared with patients who received best medical treatment alone. Only one patient had a symptomatic intracerebral haemorrhage in the endovascular thrombectomy group, and rates of non-symptomatic intracranial haemorrhage were similar in both treatment groups. A small number of patients who underwent endovascular thrombectomy had procedure-related adverse events: arterial dissections (2%) and radiographic vasospasm (15%). However, the dissections were not flow limiting, and the vasospasm resolved in all cases after intra-arterial administration of nimodipine and without any radiographic or clinical signs of ischaemia. More than half of all patients (54%) in the best medical treatment group had a persistent or recurrent vessel occlusion at 24 h follow-up imaging, a much higher proportion than the 15% in the endovascular thrombectomy group. Further characterising this subgroup, eight (44%) of 18 patients in the endovascular thrombectomy group with persistent occlusion and 19 (39%) of 49 patients in the best medical treatment group had a suspected focal cerebral arteriopathy aetiology. Recent studies in adults have shown that the administration of intravenous thrombolysis works in a synergistic way with endovascular thrombectomy and should therefore be administered if no contraindications are present.[29] By contrast, there is observational data that intravenous thrombolysis will fragment thrombi and cause thrombus migration and fragmentation which will be more difficult to remove mechanically and could potentially result in lower rates of complete recanalisation.[30]

A major concern is the safety and efficacy of endovascular thrombectomy procedures in patients with arteriopathies.[11,14] In the Save ChildS Pro registry, patients with arteriopathies had similar outcomes to those with other aetiologies when treated with endovascular thrombectomy. Furthermore, patients treated with endovascular thrombectomy had greater improvement of the PedNIHSS score as well as the PSOM score at day 90 regardless of the underlying aetiology. Although the primary outcome measure (difference in mRS from pre-stroke to day 90) was not significantly different for patients with focal cerebral arteriopathy between the endovascular thrombectomy and best medical treatment groups (p=0·075), the secondary outcomes were significantly improved in the endovascular thrombectomy group. Thus, regarding the primary outcome, there was equipoise for patients with suspected focal cerebral arteriopathy for endovascular thrombectomy and best medical treatment. This might reflect the smaller sample

size and heterogeneity of this focal cerebral arteriopathy subgroup, or potentially a more subtle yet still clinically relevant effect of endovascular thrombectomy in patients with focal cerebral arteriopathy. Of note, these results show that more severely affected patients with suspected focal cerebral arteriopathy will potentially benefit from endovascular thrombectomy, whereas patients with focal cerebral arteriopathy with milder stroke might not benefit in the same way. Yet, it is important to note that the mRS does not capture cognitive and academic deficits, which are more likely to be captured by the PSOM. Therefor, we chose to collect both parameters plus the PedNIHSS, with the mRS being the primary outcome because it the most widely used outcome parameter in stroke trials.[31]

Finally, regarding the translation of our findings to clinical practice, this study adds to the growing evidence that children with large-vessel occlusion stroke have superior outcomes when treated with endovascular thrombectomy.[8,15,16] Adequate training of all physicians involved in acute stroke care, development of clear selection criteria for endovascular thrombectomy, and standardisation of interventional procedures are crucial to maintain these positive treatment effects. This is especially the case for neurointerventionists, as navigation through the smaller vessels and successful technical outcome of the thrombectomy procedure itself require dedicated training and continuous practice, which depends on the case load of the centre in performing neurointerventional procedures in children and adults.[14] Because thrombectomy procedures in distal intracranial arteries are increasingly being performed in adults, neurointerventionists are gaining more experience with navigation in smaller vessels and likewise smaller and softer devices are continuously being developed, also providing tailored approaches for children. It is reassuring that in our study even children with suspected focal cerebral arteriopathies who presented with large-vessel occlusion stroke appeared to benefit from the endovascular restoration of blood flow. However, in patients presenting with classic imaging features of focal cerebral arteriopathy, such as arterial banding and narrowing of the terminal segment of the internal carotid artery, even greater caution must be applied. It should be noted that diagnosis of the inflammatory subtype of focal cerebral arteriopathy is difficult if the initial presentation is with complete arterial occlusion; most commonly focal cerebral arteriopathy presents subacutely with stenosis rather than complete acute occlusion. As such, in some cases, the diagnosis is made retrospectively on the basis of the presence of residual or progressive stenosis in the affected vessel after clot retrieval of a superimposed acute thrombus. Such retrospective diagnosis can be confounded by iatrogenic stenosis caused by intimal injury that can occur after use of a stent retriever for endovascular thrombectomy. Therefore, the CASCADE 2 stroke subtype (focal cerebral arteriopathy) is a group of patients in whom a definitive diagnosis is difficult to establish.

Our prospective study has limitations. First, given that this study is not a randomised trial, a potential selection bias has to be assumed because the selected treatment was at the discretion of the participating centre. Patients were nested under centres and centre-specific effects could potentially bias the results. Because most of the centres included an average of fewer than five patients (and only five centres reported treatment of more than ten patients), it currently cannot be concluded whether high-volume centres create different outcomes compared with lower-volume centres. In general, sites appeared to select for endovascular thrombectomy preferentially in the children with greater PedNIHSS scores. The impact of this selection bias might be less pronounced because some centres that do not offer endovascular thrombectomy participated, thus only including patients with best medical treatment alone. Second, patients in the endovascular thrombectomy group were older. However, in the propensity score matched analysis, the treatment effect was still maintained across all outcome variables. Third, children in the best medical treatment group more often had arteriopathies, whereas those in the endovascular thrombectomy group more often presented with cardioembolic aetiologies, probably reflecting the reluctance of treating physicians to refer children with arteriopathic changes for endovascular thrombectomy. However, the outcome of children with suspected arteriopathies who did receive endovascular thrombectomy was better than that of those treated with best medical treatment alone in this study. Fourth, there were no restrictive selection criteria regarding time from symptom onset and infarct size on admission imaging for this study. This also aligns with recent trials in adults, which have all shown that absolute and relative infarct size as well as the time from onset are less important as long as there is salvageable tissue on advanced imaging and a mismatch between clinical deficit and infarct.[6,22,23,32] Fifth, time from symptom onset to admission was comparably short in the Save ChildS Pro cohort and even though comparable to similar studies[12] it might be longer in less specialised centres, which might affect patient outcomes. Last, the clinicians performing the outcomes measurements were not masked to treatment, which might also have introduced bias. Although the largest cohort of children with endovascular thrombectomy compared with best medical treatment is reported in this study, the cohort size was too small for more detailed subanalyses, such as investigating different outcomes with respect to age and sex. Larger patient cohorts will provide more detailed insights in outcomes after endovascular thrombectomy with respect to different aetiologies and in children with different age, sex, and demographics.

In conclusion, in this prospective, registry-based, multicentre study, endovascular thrombectomy plus best medical treatment was associated with improved functional outcomes in paediatric patients with large and medium intracranial occlusions compared with best medical treatment alone. Future studies are needed to investigate whether the positive treatment effect of endovascular thrombectomy is confined to older and more severely affected children.

Contributors

PBS, M-NP, and MW directly accessed and verified the data, conducted the analyses, and wrote the manuscript. TB conducted the statistical analyses. All other authors contributed data, provided feedback on the manuscript, and accept responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

The study data are available from the corresponding author on reasonable request from the moment of publication and with a signed data access agreement.

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