


Extended time window mechanical thrombectomy for pediatric acute ischemic stroke

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ABSTRACT

Endovascular thrombectomy (EVT) for the treatment of acute ischemic stroke (AIS) remains an off-label procedure seldom utilized in the pediatric population; this holds especially true for patients presenting outside the standard 6-hour time window. In this review we describe the published literature regarding usage of the extended time window EVT in pediatric stroke. We searched PubMed for all pediatric AIS cases and case series that included patients treated with extended time window EVT. We found data from 38 cases found in 27 publications (15 case reports and 12 case series). The median age was 10 years; 60.5% males. The median NIHSS before EVT was 13 with a median time-to-treatment of 11 hours. The posterior circulation was involved in 50.0%. Stent retrievers were used in 68.5%, and aspiration in 13.2%. Angiographic outcome TIC1 \geq 2B was achieved in 84.2%, whereas TIC1 \geq 2B was reported in 10.6%. A favorable clinical outcome (NIHSS score \leq 4, modified Rankin score \leq 1, or Pediatric Stroke Outcome measure score \leq 1) occurred in 84.2%. Eight cases that did not report the clinical outcome employing a standardized scale described mild to absent neurological residual deficits. This study found data that supports that extended window EVT produces high recanalization rates and good clinical outcomes in pediatric patients with AIS. Nevertheless, the source materials are indirect and contain substantial inconsistencies with an increased risk of bias that amount to low evidence strength.

KEYWORDS: Pediatric, stroke, endovascular, thrombectomy

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Introduction

There is robust evidence for the safety and efficacy of endovascular thrombectomy (EVT) to treat acute ischemic stroke (AIS) in adults. The evidence derived from randomized controlled trials has also been successfully translated into real-world settings.¹ Nevertheless, the situation is quite different in children, and EVT remains an off-label procedure seldom utilized. Unfortunately, the burden of AIS in the pediatric population is remarkably high despite its lower incidence in children than in adults.² The causes for the lack of evidence for EVT efficacy in pediatric stroke are inherent to the remarkable differences between adults and children and between age subgroups of children. Among the most important are: lower incidence of AIS,³ substantial delay in the diagnosis,⁴ lack of standardized treatment protocols,² lack of infrastructure to perform EVT and, lack of data regarding natural history of outcome following large vessel occlusion in childhood.⁵ Because diagnosis of AIS in children is delayed with some diagnosed after 24-hours of presentation, the uncertainty surrounding EVT in pediatric patients affects disproportionately those presenting outside the standard windows of acute reperfusion treatment [4.5-hours for intravenous (IV) tissue-type plasminogen activator (tPA) and 6-hours for EVT].

To summarize the current published literature regarding the utilization of the extended time window EVT in the pediatric

population, we reviewed the published literature. We summarized the data available in the hopes of aiding to address the current gaps in the knowledge of this topic.

Materials and methods

We searched PubMed for pediatric cases of AIS treated with EVT published from January 2000 through March 2021. The search was based on the keywords: pediatric, children, child, childhood, stroke, ischemic stroke, acute ischemic stroke, endovascular, thrombectomy, case series, and case report. A thorough review of the identified articles included a search through the bibliographies to identify missed publications. **Figure 1** depicts the search strategy. From each identifiable case, we registered age, sex, onset National Institutes of Health Stroke Scale (NIHSS), time to treatment (TTT), location of the occlusion, thrombectomy device (Merci, Revive, Solitaire, Trevo, Penumbra and, combinations). To entirely focus on EVT, we excluded cases of guidewire manipulation, balloon angioplasty, and intraarterial tissue plasminogen activator (tPA). We also registered revascularization outcome expressed in the Thrombolysis In Cerebral Infarction (TICI) scores and the most extended recorded clinical outcome; the outcome was either described with the modified Rankin scale (mRS), the NIHSS, or the Pediatric



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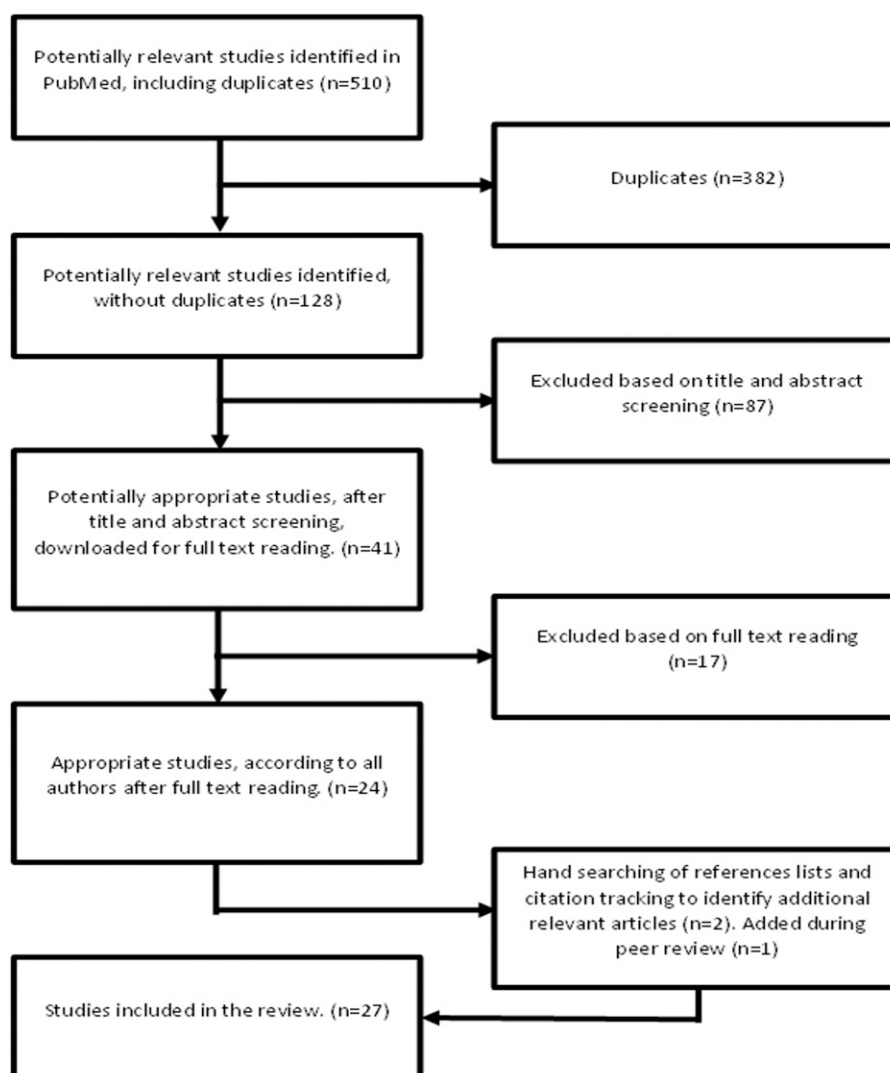


Figure 1. Search strategy.

Stroke Outcome Measure (PSOM). The PSOM is used widely in pediatric hospitals as a standardized neurologic outcome measure⁶ validated for pediatric stroke.⁷ The scale measures post-stroke neurological deficits in various domains (sensorimotor, language, and cognitive/behavioral/mental spheres). It consists of age-specific items to select according to patient age encompassing infant, child, and older child examination. The end score ranges from 0-10 (maximal deficit) and assigns 2 points to each of 5 subscales (right sensorimotor, left sensorimotor, language expression, language reception, cognitive/behavioral). Each subscale is scored according to the following scores: 0 = no deficit; .5 = minimal deficit without functional consequence; 1=moderate deficit with slowing of function; 2 = severe deficit with missing function for age.

Lastly, we recorded the use and type of imaging modality that aided the decision to perform EVT: diffusion-weighted magnetic resonance imaging (DWI), CT scan with perfusion (CTP), or none.

Statistical analysis

We present descriptive statistics; categorical data are expressed as frequency and percentages and continuous variables as median and ranges.

Results

From 2000 to March 2021, we found 27 publications describing 37 cases of extended time window EVT in pediatric patients with AIS; to these, we added the information of one additional case treated by the authors (Figure 2). The publications corresponded to case reports (n = 15) and case series (12), including at least one patient who received extended time window EVT. In the 12 case series that we found, the proportion of cases treated during the extended window time ranged from 8% to 75% (median 40%). The case series contained a median of five subjects (range 11).

The median age was 10 years (range 15.5); 60.5% (n = 23) males. Before EVT, the median NIHSS was 13.0 (range 34)

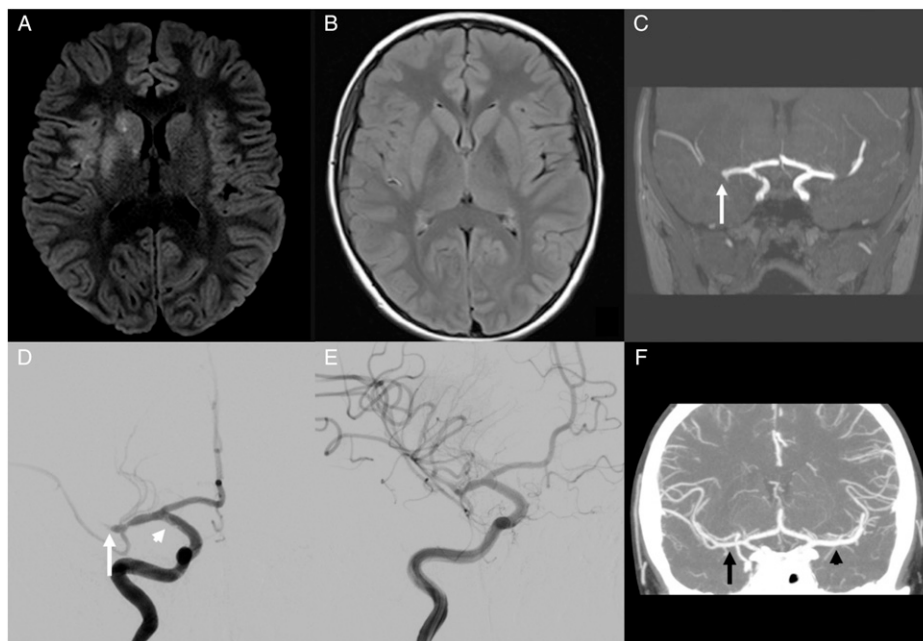


Figure 2. Illustrative case. A 12-year-old male with Henoch-Schönlein purpura with NIHSS of 13 at 15 hours from onset of symptoms. (A) Diffusion-weighted magnetic resonance imaging shows significant restriction in the territory of the right middle cerebral artery (MCA), absent in the FLAIR sequence (B). Time-of-flight magnetic resonance (TOF-MR) shows distal M1 occlusion. (C) Digital subtraction angiography corroborated the occlusion (arrow) and showed luminal thrombus in the internal carotid artery (white arrowhead). (D) Thrombectomy was performed via a 5F guide catheter with a Trevo 4×20 mm delivered via a Rebar 18 microcatheter, resulting in Thrombolysis in Cerebral Infarction 3 recanalization after one pass at 17 hours from onset of symptoms. (E) 3-month follow-up TOF-MR shows the right MCA (black arrow) with a narrower caliber compared to the left MCA (black arrowhead) (F).

with a median TTT of 11 (range 68.5) hours, and there was one case of wake-up stroke. The occluded vessels were the basilar artery (BA) in 19 (50.0%), the medial cerebral artery (MCA) in 12 (31.6%), and the internal carotid artery (ICA) in seven (18.4%) cases. The most common devices utilized to perform EVT were stent retrievers (SR) in 24 cases (63.2%), followed by aspiration in seven cases (18.6%); four cases of aspiration alone (13.2%) and three more cases in combination, one with the Merci device and two with stents. We found four EVT reports with the Merci device alone and one case treated with the Revive SE clot retrieval device.

EVT achieved an angiographic outcome $\text{TICI} \geq 2\text{B}$ in 84.2%; 19 cases with $\text{TICI} 3$ and 13 additional cases with $\text{TICI} 2\text{B}$, whereas $\text{TICI} < 2\text{B}$ was reported in 10.6% ($n = 4$), we found only two cases of $\text{TICI} 0$.

Clinical outcome was reported more frequently with the mRS (36.8%, $n = 14$), followed by the NIHSS (31.6%, $n = 12$) and the PSOM (10.5%, $n = 4$). For the patients whose outcome was expressed with the NIHSS, the median value was 2 with a range of 23 points; 91.7% had an NIHSS score ≤ 4 . In the patients with mRS, 64.3% had a score ≤ 2 , three patients (21.4%) had an mRS of 3, and two deaths (mRS = 6). Lastly, median PSOM was .25 (range 1) with all the patients with a score ≤ 1 . Based on the aforementioned reported outcomes, we found a favorable outcome defined as an NIHSS score ≤ 4 , modified Rankin score ≤ 1 , or Pediatric Stroke Outcome measure score ≤ 1 in 30 patients (84.2%).

Missing data

Across the different publications, some details were missing within the description of the cases. Three cases (8.8%) did not include information about the age, and six (17.6) did not report the sex of the patient. The pre-EVT NIHSS score was not stated in 10 cases (29.4%). The device utilized to perform EVT was declared in all but one case that reported a mechanical thrombectomy procedure. Two publications did not include TICI score; one stated “significant improvement in blood flow,” and the other “Good flow was established in the basilar and posterior circulation.”

Regarding clinical outcome, Table 1 shows the individual scores for each case. Nevertheless, eight publications did not report the clinical outcome employing a standardized scale. Residual deficits varied from no residual neurological deficits to a substantial neurological disability, and the follow-up length ranged from one to 14 months.

Discussion

In this review, we analyzed data from 34 pediatric AIS cases treated with extended time window EVT. We found a median age of nine years and a moderate median severity by the NIHSS. Median TTT was 16 hours which is longer than the current standard in adults. There was an equal representation of AIS in the anterior/posterior circulation, which also differs from adult populations’ reported data. The usage of endovascular devices

Table 1. Summary of the published mechanical thrombectomy cases performed in the pediatric age group.

	AUTHORS YEAR	AGE	SEX	NIHSS	TTT	THROMBUS LOCATION	TREATMENT TECHNIQUE	TICI	CLINICAL OUTCOME	DWI
1	Felker et al. ¹⁶ 2010	14	M	NR	9	MCA	Merci	0	^a	NR
2	Grunwald IQ et al. ¹⁷ 2010	16	F	36	8	BA	A	3	NIHSS 23	NR
3	Taneja et al. ¹⁸ 2011	14	F	NR	24	BA	SR	3	^b	NR
4	Xavier et al. ³² 2012	16	M	11	72	ICA	A + Stent	2A	mRs 1	CTP
5	Tatum et al. ³³ 2013	10	M	12	7.5	MCA	A + Merci	3	mRs 1	NR
6		4	NR	2	10	BA	Merci	3	mRs 0	NR
7		17	NR	5	22	BA	Merci	3	mRs 0	NR
8	Bodey C et al. ³⁴ 2014	10	M	27	36	BA	RD	NR	mRs 3	NR
9		6	M	28	16	BA	SR	NR	mRs 0	NR
10	Ladner TR et al. ³⁵ 2014	5	M	22	9	BA	SR	2b	PSOM 0	Yes
11	Rhee et al. ³⁶ 2014	9	M	6	7	MCA	SR	3	NIHSS 3	No
12		9	M	10	7	MCA	SR	3	NIHSS 3	
13	Sainz de la Maza et al. ³⁷ 2014	12	F	18	8	ICA	SR	2B	NIHSS 1	CTP
14	Stidd et al. ³⁸ 2014	2	M	NR	7	MCA	SR	2B	mRs 1	NR
15	Huded V et al. ³⁹ 2015	6	M	15	26	BA	SR	3	NIHSS 0	NR
16	Savastano et al. ⁴⁰ 2015	22 months	F	NR	16	BA	SR	3	^c	Yes
17	Garnés Sánchez CM et al. ⁴¹ 2016	9	M	35	36	BA	SR	3	NIHSS 3 PSOM 0	CTP
18	Madaeilil et al. ⁴² 2016	16	M	9	10	BA	A	3	^d	NR
19	Weiner et al. ⁴³ 2016	15	M	9	8	ICA	SR	2B	NIHSS 0	Yes
20	Lena et al. ⁴⁴ 2017	NR	NR	NR	>17	BA	A	2B	mRs 1	Yes
21	Nicosia G et al. ⁴⁵ 2017	23 months	NR	NR	18	BA	SR	3	^e	Yes
22	Tabone et al. ²⁰ 2017	4	M	21	7.4	MCA	NR	1- 2A	mRs 3	Yes
23	Wilkinson et al. ⁴⁶ 2017	17 months	F	NR	50	BA	SR	2B	^f	NR

(Continued)

Table 1. Continued.

	AUTHORS YEAR	AGE	SEX	NIHSS	TTT	THROMBUS LOCATION	TREATMENT TECHNIQUE	TICI	CLINICAL OUTCOME	DWI
24	Bhatti et al. ⁴⁷ 2019	6	M	15	24	BA	SR	3	NIHSS 0	NR
25		6	M	12	24	BA	SR	3	NIHSS 4	NR
26	Lee et al. ²⁴ 2019	NR	NR	14	19	ICA	SR	3	PSOM 0.5	Yes
27		NR	NR	NR	20	BA	Merci	2B	PSOM 1	Yes
28	Sporns PB et al. ⁴⁸ 2019	14	M	5	16	ICA	SR	3	PSOM 0	NR
29	Gervelis et al. ⁴⁹ 2020	10	F	NR	17	ICA	A	2B	^g	NR
30	Sun et al. ²⁵ 2020	11	M	NR	16	BA	SR	3	^h	NR
31	Ghannam et al. ⁵⁰ 2021	7	F	4	11	MCA	SR	2B	NIHSS 1	Yes
32	van Es et al. ⁵ 2021	18 months	M	7	6.5	ICA	SR	2B	mRS 6	No
33		16	M	19	WS	MCA	SR	2B	NIHSS 4	No
34	Fragata et al. ⁵¹	14	F	3	8.2	MCA	SR	2C	mRS 2	No
35		10	F	21	8.4	MCA	SR	2B	mRS 3	No
36		2	M	15	24.3	BA	A + SR	0	mRS 6	No
37		13	M	16	8.0	MCA	A	3	mRS 2	No
38	Present case 2021	12	M	13	17	MCA	SR	3	NIHSS 0 ⁱ	Yes

was in line with current trends, with two-thirds of the cases being treated with SR, as was the overall angiographic efficacy of EVT. Lastly, a favorable clinical outcome was present in 84.2% of the cases.

Since currently, there are no high-quality data on which to base recommendations, current guidelines still consider hyperacute therapies for childhood AIS as controversial.⁸ The present review results suggest that extended time window EVT has comparable if not better angiographic and clinical outcomes in children than in adults. Nevertheless, it is also apparent from the gathered data that there are substantial flaws in the available reports on extended time window EVT in pediatric stroke.

First, there is significant heterogeneity in the reporting standards for the case reports and case series. Whereas in adults, the expected reporting includes: standardized terminology for pretreatment assessment, neurologic evaluation with the NIHSS score, imaging evaluation, occlusion sites, angiographic revascularization grading standards,⁹ follow-up imaging studies, and neurologic assessments¹⁰; across the published materials, there is a considerable variation in multiple aspects of the reported data in children.

Prominent examples of these disparities are:

- 1) The lack of primary epidemiologic data (age, sex);
- 2) the inconstant utilization of the NIHSS to illustrate the pre-procedure severity;
- 3) the movable time points utilized to calculate TTT (i.e., last known well, time-to-hospital, time to EVT);
- 4) the inconstant utilization of the TICI score to report angiographic result;
- 5) the various approaches to reporting the clinical outcome; and
- 6) the variability in the follow-up length.

Second, mechanical reperfusion devices are approved for use based on data from studies from which pediatric patients were excluded. Early reviews of endovascular therapy in children with AIS found a recanalization rate of 74%, with a mean TTT of 14 hours. Nevertheless, two-thirds of the patients studied received intra-arterial tPA, and only two received EVT alone.¹¹

Initial attempts of endovascular treatment of AIS in pediatric patients in the extended window time are reported since 2000,¹² these interventions utilized early retrieval devices.¹³⁻¹⁷ The use of modern recanalization techniques during the extended time window starts in 2011¹⁸ in a patient with 24 hours from symptom onset.

After 2011, extended time window EVT in the pediatric population appears in literature reports of databases,¹⁹ and case series.²⁰⁻²⁵

More recently, in a secondary analysis of the Save ChildS Study²⁶ that included 20 patients, the median time from onset to EVT was 9.8 hours, and the median improvement in the NIHSS from admission to day 7 was 10 points. The authors also compared the mRS in the DAWN and DEFUSE 3 trials and found a higher proportion of good pediatric outcomes than the adult population. Issues worth noting are the broader age range defining the pediatric population (up to 18 years of age) and the use of the clinical-DWI mismatch approach in selecting candidates for EVT. In this study, 65% of the patients were female, and 65% had anterior circulation large vessel occlusion, which differs from other case series described in the present review. Despite this, the Save ChildS Study is currently the best evidence supporting extended time window EVT in pediatric AIS of up to 24 hours.

The chronicle of acute reperfusion therapy for pediatric AIS is full of virtuous efforts and unsatisfactory results. Since the early termination of the Thrombolysis in Pediatric Stroke trial,²⁷ some authors promote adopting a more practical approach even if it means basing management in lower-level evidence.²⁸ Although supportive of the utilization of extended window EVT in the pediatric population, the results from the present review provide insufficient evidence for full endorsement. The shortcomings of the evidence on hand for the use of extended window EVT in the pediatric population are embedded in the literature available for review. The case report model favors positive-outcome findings for publication,²⁹ leading to publication bias and promoting overinterpretation.³⁰ Alas, to overcome such weaknesses, a substantial improvement in the quality of the information available is required. Therefore, we advocate creating an international registry of pediatric EVT cases that includes all consecutive patients and has standardized follow-up metrics and scheduled visits.


Summary

After reviewing the available evidence, we can conclude that successful use of EVT in the extended window of time for major artery occlusion in children of all pediatric ages has been reported. However, specific aspects of EVT in pediatric stroke remain unclear, for example, the window for successful intervention, whether or not treatment should be image-based, and the particulars of the endovascular devices better suited for children.³¹

Even though the reviewed data showed high recanalization rates and good clinical outcomes in pediatric patients with AIS treated with extended window EVT, caution is advised when interpreting these findings. The source material consisted of case reports and small case series that showed high heterogeneity in the reported data. Although it is not methodologically feasible to identify publication bias in the revised material, the inconsistencies found in the data preclude firm conclusions and

make us suspicious of the presence of such bias, which also applies to our inclusion of a case with positive results in this review. Therefore, the utilization of extended window EVT in pediatric AIS continues a matter of discussion and unsupported by evidence-based medicine.

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Appendix

Non-standard Abbreviations and Acronyms

- AIS = Acute Ischemic Stroke
- CTP = CT Scan With Perfusion
- DWI = Diffusion-Weighted Magnetic Resonance Imaging
- EVT = Endovascular Thrombectomy
- RS = Modified Rankin Scale
- PSOM = Pediatric Stroke Outcome Measure
- TICI = Thrombolysis In Cerebral Infarction
- abrTTT = Time To Treatment