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Effects of clinical outcomes by modification of patient selection protocol based on premorbid independence for mechanical thrombectomy in older adult patients

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Abstract:

OBJECTIVES: Since the beneficial effect attained by mechanical thrombectomy (MT) seems to be worse in older than in the younger population, the establishment of an ideal and distinctive patient selection protocol in older is warranted. Herein, we modified our patient selection protocol based on age and premorbid independence in older adult patients.

MATERIALS AND METHODS: We retrospectively reviewed 141 consecutive patients with acute ischemic stroke who were treated with MT between 2015 and 2020. We started to restrict the indication of MT in very old patients (≥85-year-old) with severe premorbid functional independence (≥modified Rankin Scale [mRS] 3) in 2018. Clinical outcomes before the modification of protocol (period 1) were compared to after (period 2).

RESULTS: Although there were no significant differences in median mRS at 90 days and the rates of favorable outcomes (mRS 0–2) between both periods, rates of poor outcomes (mRS 5, 6) significantly decreased (37.3% vs. 19.7%, $P = 0.021$) during period 2 compared with period 1. For older adults (≥80-year-old), median mRS was significantly better ($P = 0.012$) during period 2 than period 1. During period 1, rates of favorable outcomes were significantly lower ($P = 0.004$) in older than in younger. However, this significant difference was diminished ($P = 0.28$) during period 2.

CONCLUSION: Our modified patient selection protocol in older adults, not only limited by age but also premorbid function, improved the therapeutic outcome of MT. In rapidly aging society, further investigations facilitating a better understanding are necessary to establish an optimal patient selection protocol.

Keywords:

Acute ischemic stroke, elderly, endovascular treatment, mechanical thrombectomy

Introduction

Several independent randomized controlled trials (RCTs) and a subsequent meta-analysis have demonstrated a significant clinical benefit of mechanical thrombectomy (MT) for acute ischemic stroke (AIS).[1-6] However, some of these large clinical trials excluded very old patients, which comprised those older than 80–85 years of age.[4,5] Recently published clinical trial[7] of MT, the DAWN trial, have set their original inclusion criteria based on age, prestroke disability, and stroke severity. Although advanced age is not considered a contraindication for MT, the

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reports on its therapeutic safety and efficacy in very old patients are inconsistent.[8-10]

A meta-analysis of reliable RCTs, which are Highly Effective Reperfusion evaluated in the Multiple Endovascular Stroke (HERMES) Trials,[6] showed a consistent benefit of MT over standard medical treatment, even in older adult patients (≥80-year-old). However, some authors argue that the clinical outcomes of AIS treated with MT get worse in an age-dependent manner.[6] It seems that MT in older adults and younger patients does not show similar benefits.[6,11] Some authors[12] have concluded on the importance of refining the patient selection criteria of MT in older adults to maximize the benefit of MT for AIS patients while minimizing harm.

Based on these prior reports,[8,12] we modified our patient selection protocol, particularly for very old patients (≥85-year-old) in 2018. At this timing, the result of large clinical trials (DAWN[7] and DEFFUSE[13] trial) come out, which motivated and encouraged us to modify the patient selection criteria. As part of this modification, we determined the indication of MT based on the premorbid neurological function and the degree of independence of very old patients in their daily life activities. To test whether our patient selection modification could improve the therapeutic outcomes of MT, we performed a retrospective assessment using the data of patients who were treated at our institute. Since society is rapidly aging globally, we believe that the present study will help establish an optimal patient selection protocol for MT for clinicians in "real-world" clinical practice.

Materials and Methods

Clinical data collection

We performed a retrospective analysis of a prospectively maintained database of patients treated at our hospital for AIS between August 2015 and March 2020. The study protocol was reviewed by the institutional review board and performed in accordance with the Helsinki declaration.

We reviewed 141 consecutive patients (males, 82 [58.2%]; females, 59 [41.8%]; age, 77.4 ± 9.8-year-old) with anterior circulation AIS treated with MT. To assess the effect of our patient selection modification, we compared the clinical outcomes before and after the modification. In this paper, "period 1" refers to the period before, whereas "period 2" refers to the period after, the patient selection protocol modification.

Patient selection protocol modification

Patient selection criteria for MT included patients with neurological deficits admitted within 8 h from symptom onset or 24 h from the time the patient was last observed to be well when the time of symptom onset was unknown. Both computed tomography (CT) and magnetic resonance (MR) imaging were conducted before MT. Occlusion of the artery of the anterior circulation was confirmed with MR angiography. Patients with an Alberta Stroke Program Early Computed Tomography Score (ASPECTS) of >6 who underwent ASPECTS-diffusion-weighted imaging (DWI) were considered to be candidates for MT. During this study period, perfusion imaging including CT perfusion and MR perfusion was not performed, to shorten the time of imaging. We assessed the presence of "Clinical-Diffusion mismatch" to judge if MT would be beneficial in each patient.

During period 1, between August 2015 and December 2017, we did not set any restrictions for inclusion for MT. After January 2018, during period 2, we decided to set the criteria for MT based on age and premorbid activities of daily life. In very old patients (≥85-year-old), we collected information about patients' daily life activities from their families or an appropriate person. We carefully evaluated each patient's premorbid independence, neurological function, history of neurological disorders (stroke, dementia, neurodegenerative disease, and so on), systemic comorbidities, and any malignancies based on the obtained information and determined the premorbid modified Rankin Scale (mRS) of each patient. The criterion for MT in very old patients was set as mRS ≤3. For patients who were considered to be contraindicated for MT, appropriate information was provided to their families about the merit and risk of MT. With their agreement, if the patient was eligible, intravenous administration of t-PA (tissue plasminogen activator) alone was administered.

Mechanical thrombectomy

All procedures were performed under conscious sedation. Before 2017, the stent retriever system, Trevo ProVue (Stryker, MI, USA) or Solitaire FR and Platinum (Medtronics, MN, USA), was used as the first-line device. Subsequently, the direct aspiration first-pass technique (ADAPT), using large-bore aspiration catheters (5 MAX ACE and ACE 68 [Penumbra, CA, USA]), was mainly used as first-line.

Data collection and study endpoints

For the study endpoint, the functional outcome was the 90-day mRS. An mRS score of 0–2 at 90 days was considered a "favorable outcome" whereas an mRS score of 5–6 was considered a "poor outcome." For a very few patients who was not able to attain the data of 90-day mRS from neither medical chart or telephone questionnaire, a 30-day mRS was alternatively used (period 1, 2 cases; period 2, 1 case).

For the procedural outcomes, the number of reperfusion attempts (number of passes), the success of recanalization, and time to reperfusion were assessed. Successful recanalization was defined as modified thrombolysis in cerebral ischemia (mTICI) score of 2b or 3.[14] Complete recanalization was defined as an mTICI score of 3.

Statistics

Standard descriptive statistics were employed for all the study endpoints. All statistical analyses were carried out using GraphPad Prism 8 (GraphPad, La Jolla, CA, USA) and EXCEL toukei Ver. 6.0 (Esumi Inc., Tokyo, Japan). The Mann–Whitney *U*-test (nonnormally distributed data) and the unpaired Student's *t*-test (normally distributed data) were adapted to compare variables. The results were considered statistically significant at $P < 0.05$.

Results

Demographics

Of the 141 patients who underwent MT for AIS in the anterior circulation, 75 (53.2%) were treated during period 1, which was before the patient selection protocol modification. Sixty-six (46.8%) patients were treated during period 2, which was after the modification. Table 1 summarizes the baseline characteristics of all the patients. Of the baseline characteristics of both groups, there were significant differences between their ages and premorbid mRS. Since we restricted the inclusion criteria for MT in very old patients with worse premorbid functional independence, the median age during period 2 (75.4 ± 10.5) was significantly ($P = 0.020$) lower than that during period 1 (79.2 ± 8.8). The number of patients with premorbid mRS scores worse than 3 significantly ($P = 0.040$) decreased during period 2 (4.5%), compared with period 1 (14.7%).

Further assessment of the distributions of age and premorbid mRS was performed [Figure 1a]. Between periods 1 and 2, there was a significant difference ($P = 0.0488$) in the age distribution [Figure 1a left]. The proportion of older adult patients decreased during period 2 compared with period 1. For the premorbid mRS [Figure 1a right], although a significant difference was not observed, the proportion of cases of worse premorbid mRS seemed to decrease during period 2 compared with period 1. The results indicated that our patient selection protocol modification restricted the indication for MT in very old patients with worse premorbid independence in daily life activities.

Mechanical thrombectomy

All procedures were performed under conscious sedation. The endovascular procedures are summarized in Table 2. There was a significant difference between the devices used for MT during periods 1 and 2. Since an improved large-bore aspiration catheter (ACE 68 (Penumbra, CA, USA)) had become available in our country, we started to apply ADAPT as the first-line in 2017. Following this change in therapeutic strategy, the use of the stent retriever significantly decreased ($P = 0.001$, 65.3% vs. 37.9%), and the use of the direct aspiration catheter ($P < 0.001$, 61.3% vs. 95.5%) and combined technique ($P < 0.001$, 5.3% vs. 25.8%) significantly increased during period 2 compared with period 1. No significant difference was observed in the number of passes (1 pass, 37.3% vs. 43.9%) and the rate of successful recanalization (80.0% vs. 84.8%). A significant

Table 1: Baseline characteristics of all patients

Baseline characteristics	All patients (*n*=141)	Period 1 (*n*=75)	Period 2 (*n*=66)	*P*
Age (Mean±SD)	77.4±9.8	79.2±8.8	75.4±10.5	0.020
Gender, Male, % (*n*)	58.2% (82/141)	54.7% (41/75)	62.1% (41/66)	0.371
Past History, % (*n*)				
Hypertension	70.9% (100/141)	72.0% (54/75)	69.7% (46/66)	0.764
Diabetes Melitius	27.7% (39/141)	30.7% (23/75)	24.2% (16/66)	0.569
Hyperlipidemia	32.6% (46/141)	33.3% (25/75)	31.8% (21/66)	0.893
Atrial fibrillation	77.3% (109/141)	77.3% (58/75)	77.3% (51/66)	0.362
Heart disease	31.2% (44/141)	26.7% (20/75)	36.4% (24/66)	0.116
Stroke	17.7% (25/141)	14.7% (11/75)	21.2% (14/66)	0.215
Dementia	7.8% (11/141)	8.0% (6/75)	7.6% (5/66)	0.967
Median premorbid mRS [IQR]	0 [0-1]	0 [0-1]	0 [0-1]	0.320
>mRS3	9.9% (14/141)	14.7% (11)	4.5% (3)	0.040
Antithronbotic agents, % (*n*)				
Antiplatelets	22.7% (32/141)	24.0% (18/75)	21.2% (14/66)	0.693
DOAC	16.3% (23/141)	16.0% (12/75)	16.7% (11/66)	0.915
Warfarin	12.1% (17/141)	9.3% (7/75)	15.2% (10/66)	0.290
Median NIHSS [IQR]	19 [14-23]	18 [14-22]	20 [15-23]	0.147
Median ASPECTS-DWI [IQR]	8 [7-9]	8 [7-9]	8 [7-9]	0.277

Abbreviations: mRS, modified ranking scale; DOAC, direct oral anticoagulants; NIHSS, National Institute of Health Stroke Scale; ASPECTS, Alberta Stroke Program Early Computed Tomography Score; DWI, diffusion weighted images

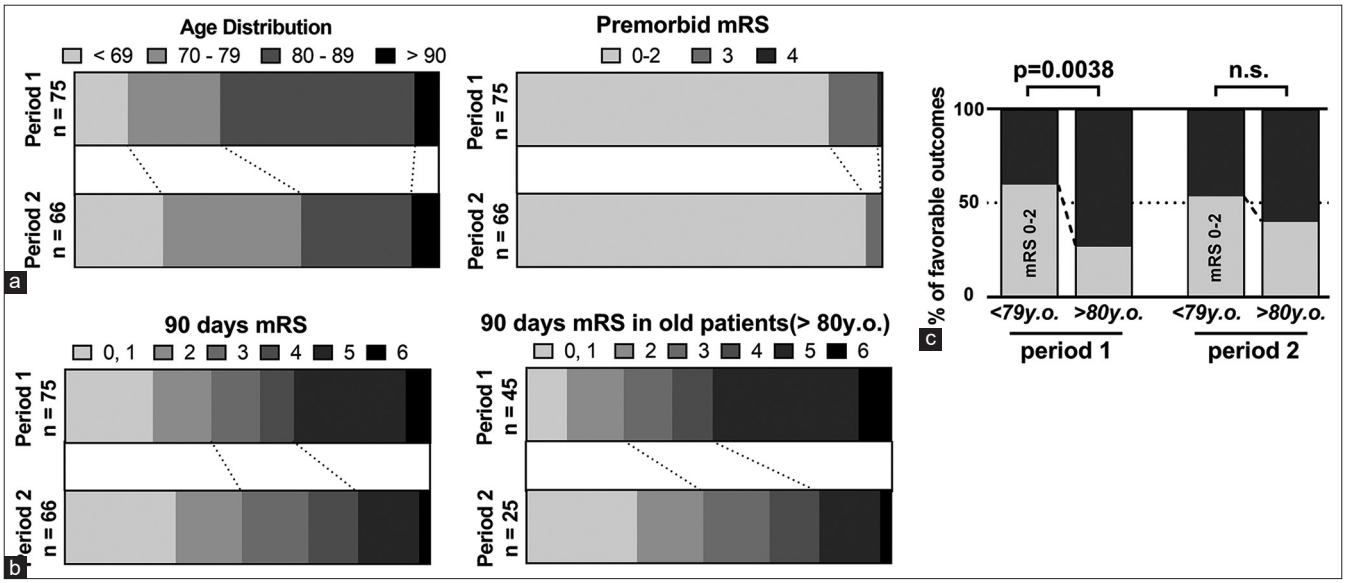

Figure 1: (a) Age and premorbid mRS score distribution in both period 1 and 2. (b) Clinical outcomes, both among all patients and old patients. (c) Comparison of the rate of favorable outcome

Table 2: Results of endovascular procedures

	All patients (*n*=141)	Period 1 (*n*=75)	Period 2 (*n*=66)	*P*
IV thrombolysis, % (*n*)	47.5% (67/141)	54.7% (41/75)	39.4% (26/66)	0.07
Occluded vessels, % (*n*)				0.660
ICA	18.4%(26/141)	16.0%(12/75)	21.2 (14/66)	
M1	63.1%(89/141)	62.7%(47/75)	63.6%(42/66)	
M2	17.0%(24/141)	20.0%(15/75)	13.6%(9/66)	
ACA	1.4%(2/141)	1.3%(1/75)	1.5%(1/66)	
Devices				
Use of stent retriever	59.6%(84/141)	65.3%(49/75)	37.9%(25/66)	0.001
Use of direct aspiratiuon catheter	77.3%(109/141)	61.3%(46/75)	95.5%(63/66)	<0.001
Use of combined technique	14.9%(21/141)	5.3%(4/75)	25.8%(17/66)	<0.001
Use of PTA and/or stenting	7.8%(11/141)	8.0%(6/75)	7.6%(5/66)	0.925
Devices				0.939
1	40.4%(57/141)	37.3%(28/75)	43.9%(29/66)	
2	17.0%(24/141)	14.7%(11/75)	19.7%(13/66)	
3 or more	42.6%(60/141)	48.0%(36/75)	36.4%(24/66)	
Successful recanalization, % (*n*)	82.3%(116/141)	80.0%(60/75)	84.8%(56/66)	0.452
Complete recanalization, % (*n*)	46.1% (65/141)	41.3% (31/75)	51.5% (34/66)	0.226
Time to recanalization, min [IQR]				
Onset to reperfusion	215 [175-285]	220 [180-281]	215 [162-301]	0.782
Puncture to reperfusion	45 [33-90]	50 [40-90]	42 [30-74]	0.047
Symptomatic ICH, % (*n*)	5.7%(8/141)	5.3%(4/75)	6.1%(4/66)	0.852

Abbreviations: IV, intravenous; ICA, internal carotid artery; M1, middle cerebral artery postorbital portion; M2, middle cerebral artery insular portion; ACA, anterior cerebral artery; PTA, Percutaneous Transluminal Angioplasty; mTICI, modified thrombolysis in cerebral infarction; ICH, intracranial hemorrhage

difference was observed in the duration from puncture to reperfusion. The duration from puncture to reperfusion was significantly shorter (P = 0.047) during period 2 (42 min) than during period 1 (50 min), but there was no difference in the duration from onset to reperfusion. The change in the first-line strategy to ADAPT and the improved catheter quality may have contributed to this result. No significant difference was observed in the occurrence of postprocedural symptomatic intracranial hemorrhage.

Clinical outcomes

The clinical outcomes are summarized in Table 3. Although there was no significant difference in the median mRS during periods 1 (3 [2–5]) and 2 (3 [1–4]), the percentage of poor outcomes (mRS 5, 6) significantly decreased (P = 0.021) during period 2 (19.7%), compared with period 1 (37.3%). The distribution of the clinical outcomes of mRS after 90 days is shown in Figure 1b (left). Comparing periods 1 and 2, an increase in the percentage of patients with favorable outcomes (mRS 0–2) and a

Table 3: Results of clinical outcomes

Clinical Outcomes at 90 days	All patients (*n*=141)	Period 1 (*n*=75)	Period 2 (*n*=66)	*P*
Median mRS (IQR)	3 [1-5]	3 [2-5]	3 [1-4]	0.082
Favorable outcome (mRS 0-2), % (*n*)	44.0% (62/141)	40.0% (30/75)	48.5% (32/66)	0.381
Poor outcome (mRS 5, 6), % (*n*)	29.1% (41/141)	37.3% (28/75)	19.7% (13/66)	0.021
Outcomes in older patients (>80 y.o.)	**All patients (*n*=70)**	**Period 1 (*n*=45)**	**Period 2 (*n*=25)**	***P***
Median mRS [IQR]	3 [2-5]	4 [2-5]	3 [2-4]	0.012
Favorable outcome (mRS0-2), % (*n*)	31.4% (22/70)	26.7% (12/45)	40.0% (10/25)	0.25
Poor outcome (mRS5, 6), % (*n*)	37.1% (26/70)	48.9% (22/45)	16.0% (4/25)	0.006

Abbreviations: mRS, modified ranking scale

decrease in that of patients with poor outcomes (mRS 5, 6) were observed.

The improved clinical outcome during period 2 was more apparent when analyzing only old patients aged >80 years [Table 3 and Figure 1b right]. There was a significant difference in mRS after 90 days between period 1 and period 2 (P = 0.012, 4 [2–5] vs. 3 [2–4]). The rates of poor outcomes were significantly lower (P = 0.006) during period 2 (16.0%) than during period 1 (48.9%). The distribution of clinical outcomes among older adult patients is shown in Figure 1b right. An increase in the percentage of favorable outcomes and a decrease in the percentage of poor outcomes were also observed during period 2 compared with period 1.

Comparing the clinical outcomes of older adult and younger patients [Figure 1c], the rates of favorable outcomes were significantly worse in the older adult patients than in the younger patients during period 1. On the other hand, although the percentage of favorable outcomes was still lower in the older adult patients than in the younger patients, this significant difference diminished. The rates of favorable outcomes in the older adults increased from period 1 to period 2 (26.7% [12/45]–40.0% [10/25]). The rates observed during period 2 were similar to those observed for all patients (44.0% [62/141]). The results suggest that stringent patient selection protocols in older adults contribute to better therapeutic outcomes of MT. As a result, although it did not reach statistically significant, our patient selection protocol modification showed the improvement tendency of clinical outcome, by the increase of favorable outcome and decreased of poor outcome in the older adult patient population.

Discussion

In this study, we retrospectively analyzed the outcomes of patients with AIS in the anterior circulation who were treated with MT at our institute. During this retrospective study, the patient selection protocol for MT was modified, which restricted its indication in older adult patients (≥85-year-old) who had premorbid independence in daily life activities (mRS <3). We compared the clinical outcomes of the patients treated with MT before (period 1) and after (period 2) the modification of the patient selection criteria, which started in 2018. Significantly improved therapeutic outcomes were observed after this modification (period 2), compared with before (period 1). This improvement in therapeutic outcomes seems to be due to the reduction of patients with poor outcomes (mRS 5 or 6), even in the case of successful MT, who had prolonged severe neurological sequelae or experienced unexcepted death.

Society is aging rapidly globally. Japan is one of the most rapidly aging societies, and our hospital is located in a rural area in Japan. Therefore, our target population would have a higher rate of aging than other urban areas in Japan. In this study, the participants were older adult patients with a mean age of 77.4 ± 9.8 years. This suggests that the present study reflected "real-world" practice in rural areas of Japan. The clinical experience in "real-world" clinical practice where the society aging is rapidly aging is suggestive and essential. We believe that the presented results will facilitate the effective management of AIS in older adults who have a higher prevalence of stroke.

The reports on the therapeutic efficacy and safety of MT in older adults are inconsistent. The HERMES study,[6] a recent meta-analysis, demonstrated the benefits of MT over standard medical treatment, even in older adult patients, including those aged ≥80 years. This study included 198 patients who were ≥80-year-old, and the rate of favorable outcomes (mRS 0–2 at 90 days) was 29.8% in the patients treated with MT. However, the rate of favorable outcomes decreased with advancing age: 50–59 years, 50.0%; 60–69 years, 51.9%; 70–79 years, 43.1%; ≥80 years, 29.8%. Therefore, the authors[6] also concluded that advanced age is a strong independent negative predictor of clinical outcomes in patients treated with MT. The outcomes of MT in older adults in several *post hoc* analyses of well-designed RCTs have also been conflicting. Although the Multicenter Randomized Clinical Trial of Endovascular Treatment of AIS in the Netherlands (MR CLEAN) and DWI or Computerized Tomography Perfusion Assessment with Clinical Mismatch in the Triage of Wake Up and

Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) trials showed a significant benefit of MT in older patients, the Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) and the Randomized Trial of Revascularization with Solitaire FR Device versus. Best Medical Therapy in the Treatment of Acute Stroke Due to Anterior Circulation Large Vessel Occlusion Presenting within Eight Hours of Symptom Onset (REVASCAT) failed to show a significant superiority of MT in older adults.[1,3,4,7] This discrepancy in the subgroup analysis of several RCTs may be attributable to the variable parameters and patient inclusion criteria used in the studies.

Outside these RCTs, the efficacy and safety of MT in older adults have been assessed and reported in "real-world" practice, but the results are conflicting as well. Imahori *et al*.[9] reported a series of 36 patients aged ≥80 years and 44 patients aged <80 years treated with MT for AIS. The authors revealed no significant difference in the rate of cases with mRS of 0–2 after 90 days in the older adult patients (≥80-year-old, 42%) and younger patients (<80-year-old, 57%). Sweid *et al*.[11] also showed similar results for 26 nonagenarians (≥90-year-old) treated with MT. No significant difference was observed in the rate of good functional outcomes (mRS 0–2) after 90 days in nonagenarians (34.62%) and younger patients (49.36%). Based on these positive results in the older adult population, the authors[9,11] concluded that advanced age is not an independent risk factor for poor MT outcomes, and MT should not be avoided based only on advanced age.

In contrast, poor clinical outcomes in older adult patients have been reported in several other clinical trials,[8,12,15] and the authors highlighted the need to establish optimal patient selection criteria, particularly in older adults. Klein *et al*.[15] reported significantly worse clinical outcomes in patients aged ≥80 years (mRS 0–2 at 90 days; 12%) compared with younger patients. Alawieh *et al*.[12] retrospectively reviewed 108 patients aged ≥80 years who underwent MT between 2013 and 2017. The therapeutic outcomes were compared with those of younger patients treated with MT and older adult patients treated with medical therapy. In this clinical trial,[12] the authors revealed significantly worse functional outcomes (mRS 0–2 at 90 days; 20.5%) and a higher mortality rate (34.3%) in older adult patients treated with MT, compared with younger patients. Furthermore, compared with older adult patients treated with medical therapy, MT in older patients failed to show better clinical outcomes. Furthermore, MT in older adults showed significantly higher rates of hemorrhagic complications (40.7% vs. 9.3%). Other studies,[8,16] which analyzed the results of nonagenarians (≥90-year-old), demonstrated further worse clinical outcomes (mRS 0–2 at 90 days, <20%) and higher mortality rates (in-hospital, 29.1%; 90 days, 46.7%). This less benefit and higher risk of mortality associated with MT in older adult patients warranted the need for more rigorous patient selection criteria, particularly for older adult patients. Herein, we modified our patient selection criteria for MT in the older adults (≥85-year-old), which restricted the indication for MT in patients aged ≥85 years with functional independence in daily life (≥mRS 3). Although it did not reach statistical significance, the clinical outcomes in the older adult population improved remarkably (mRS 0–2: 26.7%–40.0%), as shown in Figure 1c. The rates of favorable outcomes in the older adults were similar to those observed in younger populations after our patient selection protocol modification.

A previous study on the efficacy of MT in older adults revealed that complete recanalization (mTICI score 3),[9] but not partial recanalization (mTICI score 2b), was the only statistically significant influential factor ($P = 0.017$) for favorable outcomes of MT. In this paper,[9] the authors demonstrated that approximately two-thirds of patients had a favorable outcome (mRS 0–2) when complete recanalization was attained, even in older adult patients. In our series, complete recanalization was attained in 51.5% of patients during period 2, an increase from that observed during period 1 (41.3%). Although no significant difference in the complete recanalization rate was observed between periods 1 and 2, this procedural improvement may have contributed to the improvement in clinical outcomes during period 2. Although vessel tortuosity is a well-described technical problem for endovascular therapy in older adult patients,[17] the rate of successful recanalization in our series was similar to that reported by previous studies.[9] Further sophistication of the procedural technique and device advances may be essential for the improvement in the therapeutic outcomes of MT in older adult patients.

The retrospective nature of this study is its major limitation. The variable baseline characteristics and the small sample can also be considered as limitations. Although this study reflects real-world practice in this aging society, further larger and controlled prospective cohort studies are warranted to establish optimal therapeutic criteria for older adults and the therapeutic benefits of MT.

Conclusion

Our result demonstrated the poorer therapeutic outcomes of MT in older adult patients than in younger patients. However, the modification of patient inclusion criteria based on age and premorbid independency improved

the therapeutic outcomes of MT in older adults. Since MT therapy is also beneficial and safe for some older adult patients, an optimal patient selection protocol, not just limited by age but both age and premorbid daily life independence, seems to be essential to facilitate the therapeutic benefits.

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Conflicts of interest

There are no conflicts of interest.

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