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Impact of stent retriever size on clinical outcomes in the RECO registry

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ABSTRACT

Objective: In the RECO study, we investigated the impact of the operator's choice of stent retriever size on patients with internal carotid artery (ICA) occlusion.

Methods: Data from the RECO Registry, a prospective multicentre study, were utilized. Patients who underwent mechanical thrombectomy (MT) were divided according to the size of the stent into the RECO 4 \times 20 group, the RECO 5 \times 30 group and the RECO 6 \times 30 group. The outcome measures assessed in the study were the 3-month modified Rankin Scale (mRS) score, occurrence of any intracranial haemorrhage (aICH), workflow timing, recanalization success rate, number of attempts, and all-cause mortality within a 3-month period.

Results: Analysis was conducted on a total of 89 patients with ICA occlusion. RECO 4 × 20, 5 × 30, and 6 × 30 stent retrievers were used in 19 (21.3%), 52 (58.4%), and 18 (20.2%) patients, respectively. The demographic and baseline characteristics showed considerable similarity across the three groups. The puncture-to-recanalization time of the RECO 6 × 30 group [56.5 min (IQR, 41.5–80.8)] was significantly shorter than that of the RECO 4 × 20 group [110 min (IQR, 47–135)]. In 10 out of 18 patients (55.6%), the RECO 6 × 30 stent retriever achieved reperfusion (modified Thrombolysis in Cerebral Infarction [mTICI] score 2b-3) after the initial attempt, surpassing the rates of 31.6% in the RECO 4 × 20 group and 32.7% in the RECO 5 × 30 group. In the RECO 4 × 20 group, the median number of passes was 2 (IQR, 1–3); in the RECO 5 × 30 group, it was 2 (IQR, 1–3); and in the RECO 6 × 30 groups, it was 1 (IQR, 1–2.5). There were no statistically significant differences observed among the three groups concerning aICH or good outcomes (mRS score 0–2).

Conclusion: Our study demonstrated the practical implications of stent-retriever size selection in the context of the MT for ICA occlusion. The routine use of a RECO 6×30 stent retriever holds the potential for early revascularization in clinical practice. The significant reduction in the

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puncture-to-reperfusion time and the greater first-pass effect associated with this stent size underscore its efficiency in treating ICA occlusion.

1. Introduction

Acute ischaemic stroke (AIS) results in neurological fatalities and long-term disabilities in adults, imposing substantial burdens on healthcare systems, economies, and public health worldwide [1]. Large-vessel occlusion (LVO) is the most severe complication [2]. The evidence supports the high effectiveness of mechanical thrombectomy (MT) as a therapeutic intervention for the treatment of AIS caused by LVO [3]. Stent retrievers play a crucial role in patient intervention during MT; nevertheless, some patients may still experience physical disability [4]. However, further clinical evaluation is needed to assess the risk factors that impact the prognosis of MT and optimize approaches for this procedure based on these findings.

The size of the stent retriever may affect the outcome of MT. Osama O. Zaidat et al. noted that a longer stent retriever (4×40) had the highest success rate in achieving the first-pass effect (FPE) [5]. The use of stent retrievers with smaller diameters and shorter lengths has been linked to increased rates of adverse events, which may include complications such as vascular injury, thrombus reocclusion, and bleeding [6–9]; however, another study did not find differences in the effect of stent selection [10]. Nevertheless, these research projects have not delved into a thorough analysis regarding the selection of stent for MT in cases of internal carotid artery (ICA) occlusion. Due to the variation in size between the ICA and the M1 segment, we believe that conclusions about stent selection cannot be drawn for patients with ICA occlusion.

In this study, the impact of the stent retriever size chosen by the surgeon on patients with ICA occlusion in the RECO study was analysed to assess the safety and effectiveness of RECO in AIS patients with LVO.

2. Methods

2.1. Study participants

Information was obtained from the RECO database. The RECO trial is a prospective multicentre study conducted across 9 stroke centres. The participants were enrolled from May 22, 2020, to July 30, 2022, as a component of a postmarket study to evaluate the effectiveness and safety of RECO in AIS patients with LVO. The unique identifier for this study is NCT04840719 on Clinicaltrials.gov. Approval from the ethics committees of Beijing Tiantan Hospital (KY 2019-080-03) and all participating centres was obtained for this study. The subjects or their representatives provided written informed consent.

Participants eligible for this research were required to be at least 18 years old, have a diagnosis of AIS, show ICA occlusion on imaging, undergo RECO stenting as the initial device for thrombus removal, and be capable of signing the informed consent form themselves or through a legal representative. Exclusion criteria involved patients with additional intracranial LVO, such as blockage in the middle cerebral artery (MCA M1/M2), vertebral artery (VA V4), basilar artery (BA), posterior cerebral artery (PCA P1), or anterior cerebral artery (ACA A1/A2). Patients were divided according to the size of the stent into three groups: the RECO 4 \times 20 group, the RECO 5 \times 30 group and the RECO 6 \times 30 group.

2.2. Data collection and outcome measures

All variables, including demographic information, medical history, prestroke modified Rankin Scale (mRS) score, baseline National Institutes of Health Stroke Scale (NIHSS) score, vital signs, laboratory and neurovascular imaging results, workflow times, and clinical outcomes, were collected in a systematic manner before the event.

The main outcome measures included the 3-month mRS (3 m-mRS) score, functional independence at 3 months (mRS score 0–2), presence of any intracranial haemorrhage (aICH) based on the Heidelberg Bleeding Classification [11], evaluation within 12–36 h after the procedure, duration from symptom onset to recanalization, and time from puncture to reperfusion.

Secondary measures included the rates of reopening, which were defined as reaching a modified Thrombolysis in Cerebral Infarction [mTICI] score of 2b or 3 [12]) during the first procedure, recanalization rate at the end of the entire process, the number of attempts needed, and the mortality rate from any cause within a 3-month period.

2.3. Statistical analysis

Statistical analyses were performed using SPSS software (version 21.0; SPSS, Inc., Chicago, IL). Continuous or ordinal variables are described using medians with interquartile ranges, while categorical variables are presented with frequency distributions. For nominal comparisons involving two independent subgroups, continuous variables were analysed using the Wilcoxon rank-sum test, while categorical variables were assessed using Pearson's χ^2 test or Fisher's exact test. A P value less than 0.05 was considered to indicate statistical significance. Then, we investigated the independent risk factors associated with poor outcomes at 3 months by univariate and multivariate analyses. In the multivariate analysis, only indicators with a P value lower than 0.2 according to the univariate analysis were considered.

3. Results

Of the 268 patients in the RECO registry, 93 had ICA occlusion, while 3 lacked available stent size data, resulting in 89 patients suitable for analysis. In total, 4×20 , 5×30 and 6×30 stent retrievers were used in 19 (21.3%), 52 (58.4%), and 18 (20.2%) patients, respectively.

3.1. Demographic and baseline features

The median (interquartile range [IQR]) age of the patients in the entire group was 69 (62–75.5) years, 56 (62.9%) patients were male, the median prestroke mRS score was 0 (IQR, 0-0), and the baseline NIHSS score was 18 (IQR, 14.5–23.0). Sixteen patients (18.0%) were administered received recombinant tissue plasminogen activator (rt-PA) before undergoing MT. The demographic and baseline characteristics were largely comparable across the three stent retrieval categories, as shown in Table 1.

3.2. Workflow intervals

The time metrics are displayed in Table 2. The median symptom onset-to-door times were 259 min (IQR, 140–360), 121 min (IQR, 50–231.5) and 83 min (IQR, 28.8–154.8) in the RECO 4 \times 20 group, RECO 5 \times 30 group and RECO 6 \times 30 group, respectively. The median puncture-to-recanalization times were 110 min (IQR, 47–135), 68 min (IQR, 48–105) and 56.5 min (IQR, 41.5–80.8). The puncture-to-recanalization time of the RECO 6 \times 30 group was significantly shorter than that of the RECO 4 \times 20 group.

3.3. Clinical outcomes

The safety parameters and clinical outcomes are shown in Table 3. In 10 of the 18 patients (55.6%), the RECO 6×30 stent retriever achieved successful reperfusion after the first pass, which was greater than the 31.6% in the RECO 4×20 group and 32.7% in the RECO 5×30 group. The median numbers of passes were 2 (IQR, 1–3), 2 (IQR, 1–3) and 1 (IQR, 1–2.5) in the RECO 4×20 group, RECO 5×30 group and RECO 6×30 group, respectively. At the end of the operation, all patients achieved successful reperfusion. No significant differences were observed among the three groups concerning aICH or 3-month good outcomes (mRS score 0–2). The all-cause mortality rates within 3 months were 26.3%, 23.1% and 33.3% in the RECO 4×20 , RECO 5×30 and RECO 6×30 groups, respectively. The distribution of mRS scores according to the RECO stent-retriever size is shown in Fig. 1.

3.4. Predictors of clinical outcomes

Univariate analysis indicated that male sex, current smoking status and a lower initial NIHSS score were predictors of a good clinical outcome. Variables with a P less than 0.2 in the univariate analysis, including sex, smoking habits, alcohol consumption, initial NIHSS score, and use of rt-PA, were considered in the multivariate analysis. According to the multivariate analysis, having a higher initial NIHSS score was the only independent risk factor associated with a negative outcome (P = 0.007; adjusted OR = 1.140; 95% CI = 1.036–1.253), as shown in Table 4.

Table 1

Baseline variables among patients with different RECO diameters and lengths.

	RECO 4 \times 20 (n = 19)	RECO 5 \times 30 (n = 52)	RECO 6 \times 30 (n = 18)	P Value		
				4×20 vs 5×30	4×20 vs 6×30	5×30 vs 6×30
Male	12/19 (63.2%)	32/52 (61.5%)	12/18 (66.7%)	0.901	>0.999	0.698
Age (y)	67 (58–75)	71 (65–76)	66.5 (56.8–74.3)	0.104	0.726	0.046
Smoker	1/13 (7.7%)	6/50 (12.0%)	3/18 (16.7%)	>0.999	0.621	0.924
Drinker	1/18 (5.6%)	7/52 (13.5%)	3/18 (16.7%)	0.632	0.603	>0.999
Cerebral haemorrhage	0/19 (0%)	1/51 (2.0%)	0/18 (0%)	>0.999	/	>0.999
Heart valve disease	1/18 (5.6%)	2/52 (3.8%)	1/18 (5.6%)	>0.999	>0.999	>0.999
Hypertension	7/18 (38.9%)	35/52 (67.3%)	12/18 (66.7%)	0.034	0.181	0.96
Diabetes	2/18 (11.1%)	5/52 (9.6%)	2/18 (11.1%)	>0.999	>0.999	>0.999
Hyperlipidemia	1/18 (5.6%)	1/52 (1.9%)	0/18 (0%)	>0.999	>0.999	>0.999
Previous stroke	4/19 (21.1%)	12/52 (23.1%)	5/18 (27.8%)	>0.999	0.714	0.935
Coronary heart	3/19 (15.8%)	8/51 (15.7%)	1/18 (5.6%)	>0.999	0.604	0.490
disease						
Atrial fibrillation	8/19 (42.1%)	22/52 (42.3%)	6/18 (33.3%)	0.988	0.737	0.503
TIA	1/19 (5.3%)	1/52 (1.9%)	2/18 (11.1%)	>0.999	0.604	0.325
pr_mRS	0 (0–0)	0 (0–0)	0 (0–0)	0.217	0.304	0.763
Initial NIHSS	18 (14–19)	18.5 (15.5–24)	17.5 (13.8-22.3)	0.061	0.444	0.338
rtPA	3/19 (15.8%)	9/52 (17.3%)	4/18 (22.2%)	>0.999	0.693	0.912

TIA, transient ischemic attack; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; rtPA, recombinant tissue plasminogen activator.

Table 2

Workflow intervals for different RECO diameters and lengths.

	RECO 4 \times 20 (n $=$	RECO 5 \times 30 (n =	RECO 6 \times 30 (n =	P Value			
	19)	52)	18)	$\begin{array}{l}4\times20 \textit{vs} 5\times\\30\end{array}$	$\begin{array}{l}4\times20 \text{ vs } 6\times\\30\end{array}$	$\begin{array}{l} 5\times 30 \text{ vs } 6\times \\ 30 \end{array}$	
Onset-to-door time, min	259 (140–360)	121 (50–231.5)	83 (28.8–154.8)	0.004	0.001	0.164	
Onset-to-puncture, min	365 (230–540)	218.5 (153.5–379.3)	192.5 (147.5–250)	0.029	0.008	0.364	
Onset-to-reperfusion time, min	450 (305–819)	308 (212–445)	252 (215–337.5)	0.010	0.002	0.268	
Puncture-to-reperfusion time, min	110 (47–135)	68 (48–105)	56.5 (41.5-80.8)	0.060	0.024	0.209	

Table 3

Safety parameters and clinical and angiographic outcomes.

	RECO 4 \times 20 (n = 19)	RECO 5 \times 30 (n = 52)	RECO 6 \times 30 (n = 18)	P Value		
				4×20 vs 5×30	4×20 vs 6×30	5×30 vs 6×30
aICH	6/16 (37.5%)	4/38 (10.5%)	2/16 (12.5%)	0.052	0.220	>0.999
No. of passes < 3	12/19 (63.2%)	34/52 (65.4%)	14/18 (77.8%)	0.862	0.476	0.329
No. of passes	2 (1-3)	2 (1-3)	1 (1–2.5)	0.951	0.319	0.230
FPE	6/19 (31.6%)	17/52 (32.7%)	10/18 (55.6%)	0.929	0.191	0.086
Final reperfusion	19/19 (100%)	51/51 (100%)	18/18 (100%)	/	/	/
3m-mRS 0-2	9/19 (47.4%)	26/52 (50.0%)	7/18 (38.9%)	0.844	0.743	0.416

aICH, any intracranial haemorrhage; mTICI, modified thrombolysis in cerebral infarction; FPE, first pass effect; mRS, modified Rankin Scale.



Fig. 1. Distribution of modified Rankin Scale scores at 3 months according to the RECO stent retriever size.

4. Discussion

We investigated the impact of stent retriever size on clinical and angiographic outcomes after MT for AIS patients with ICA occlusion using a prospective multicentre approach with data from the RECO registry. Our findings indicate that the stent retriever size plays a crucial role in the effectiveness of MT positioning for individuals with ICA blockage. Specifically, the use of the RECO 6×30 stent retriever demonstrated a substantial reduction in puncture-to-reperfusion time compared to that of smaller stent sizes, along with a notable increase in the FPE. These findings underscore the critical role of stent-retriever dimensions in optimizing revascularization outcomes. Moreover, the RECO 6×30 stent retriever not only exhibited improved procedural efficiency but also demonstrated a comparable safety profile. Our study represents a novel exploration of the impact of stent retriever size on ICA occlusion patients, addressing a gap in the literature. In this study, we optimized the MT for AIS patients with ICA occlusion, offering insights into stent retriever size selection for improved treatment outcomes.

Previous studies have evaluated the effect of stent-dent retriever size on thrombus extraction. The study by Osama O. Zaidat et al. included patients with ICA and MCA occlusion [5] but did not evaluate the prognosis of ICA patients separately. Other studies have evaluated only patients with MCA occlusion [8,9,13]. Therefore, there is currently little in-depth research on the selection of ICA unblocking stents. Our thorough examination of patients with ICA blockage will establish a foundation for choosing stents for these patients during MT.

Complete or near-complete reperfusion (mTICI 2b-3) in a single pass, known as FPE, has been identified as a separate factor that predicts favourable clinical outcomes [14–16]. Our study showed that the FPE of the RECO 6 \times 30 group reached 55.6%, which was greater than the 31.6% in the RECO 4 \times 20 group and the 32.7% in the RECO 5 \times 30 group. Compared with the 5 \times 30 stent, the 6 mm diameter stent at the same length increased the FPE by nearly 70%. In addition, the median number of passes in the 6 \times 30 group was 1,

Table 4

Risk factors associated with poor outcome.

	Poor outcome ($n = 47$)	Good outcome ($n = 42$)	Univariate analysis		Multivariate analysis	
			Z/χ^2	Р	Р	OR (95%CI)
RECO			0.663	0.718		
4 imes 20	10 (21.3%)	9 (21.4%)				
5 imes 30	26 (55.3%)	26 (61.9%)				
6×30	11 (23.4%)	7 (16.7%)				
Male	26 (55.3%)	30 (71.4%)	2.467	0.116	0.927	0.951 (0.324-2.788)
Age (y)	71 (63–76)	66.5 (59.8–75)	-1.098	0.272		
Smoker	2/45 (4.4%)	8/36 (22.2%)	4.314	0.038	0.346	0.279 (0.020-3.978)
Drinker	3/46 (6.5%)	8/42 (19%)	3.149	0.076	0.896	0.845 (0.068–10.560)
Cerebral haemorrhage	1/46 (2.2%)	0/42 (0%)	0.000	>0.999		
Heart valve disease	3 (6.5%)	1 (2.4%)	1.000	0.675		
Hypertension	31/46 (67.4%)	23/42 (54.8%)	1.477	0.224		
Diabetes	6/46 (13%)	3/42 (7.1%)	0.314	0.575		
Hyperlipidemia	1/46 (2.2%)	1/42 (2.4%)	0.000	>0.999		
Previous stroke	13 (27.7%)	8 (19%)	0.912	0.339		
Coronary heart disease	8/46 (17.4%)	4/42 (9.5%)	1.154	0.283		
Atrial fibrillation	19 (40.4%)	17 (40.5%)	0.000	0.996		
TIA	3 (6.4%)	1 (2.4%)	0.158	0.691		
pr_mRS	0 (0–0)	0 (0–0)	-0.587	0.557		
Initial NIHSS	19 (18–24)	17 (12–20.3)	-2.774	0.006	0.007	1.140 (1.036–1.253)
rt-PA	6 (12.8%)	10 (23.8%)	1.834	0.176	0.266	0.429 (0.096-1.907)
Onset-to-door time, min	133 (50–275)	120 (65–244.8)	0.000	>0.999		
Onset-to-puncture, min	245 (159–370)	225 (140.3-402)	-0.674	0.500		
Onset-to-reperfusion time, min	348 (223.5-453.0)	302.5 (208.8-503.8)	-0.718	0.472		
Puncture-to-reperfusion time, min	67 (44.8–105.3)	71.5 (48–107.8)	-0.301	0.764		
No. of passes	2 (1–3)	2 (1–3)	-0.698	0.485		
No. of passes < 3	32 (68.1%)	28 (66.7%)	0.020	0.887		
FPE	17 (36.2%)	16 (38.1%)	0.035	0.851		

TIA, transient ischaemic attack; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale; rtPA, recombinant tissue plasminogen activator; FPE, first-pass effect.

which was lower than that in the other two groups; moreover, a larger-diameter stent retriever is more effective at treating ICA occlusion. The effectiveness of this process led to a puncture-to-reperfusion time of 56.5 min in the RECO 6×30 group, which was notably shorter than the 110 min in the RECO 4×20 group and 68 min in the RECO 5×30 group. Thus, for enhancing the effectiveness of MT in individuals with ICA blockage, opting for a RECO 6×30 stent retriever is the optimal decision. The reason for this phenomenon is that a larger stent diameter imparts greater radial force.

A study conducted by Machi et al. examined the effectiveness of different stent retrievers. One specific parameter assessed in the study was both the outwards and inwards radial forces. The results showed that a larger-diameter stent retriever had a greater outwards radial force than a smaller-diameter stent retriever [17]. Additional data from Trevo, combined with those from a retrospective study conducted by Yi et al., indicate that stent retrievers with larger diameters exert greater radial forces, regardless of the size of the blood vessel. This increased radial force has been associated with improved angiographic and clinical outcomes [9].

For this study, we chose to include only patients who were 18 years old or older to concentrate on adults and did not include children. This choice aligns with the predominant occurrence of AIS in adults, ensuring a homogeneous study population for our investigation. RECO offers a range of stent specifications, including a 3-mm device designed for smaller blood vessels. During the procedural workflow, physicians, guided by their familiarity and expertise, exercised discretion in choosing stent sizes. Notably, given the diameter of the ICA, no instances where operators opted for a 3 mm stent diameter were observed throughout the study. Consequently, our grouping was based on the pragmatic utilization patterns of these stents. This study design underscores the adaptability of our approach, allowing for personalized selections aligned with individual operator preferences and the unique anatomical challenges posed by the ICA. We observed that the choice of stent did not affect patient prognosis. Compared with other stents, the RECO 6 \times 30 stent demonstrated superior effectiveness, with no notable difference in aICH occurrence or the percentage of patients with a favourable prognosis based on the final 3 m-mRS across the three groups, consistent with previous studies [5,8,9,13]. One possible reason is that ischaemia–reperfusion injury may persist despite achieving complete recanalization. Another potential explanation is that although there may be a significant difference in revascularization rate, the actual absolute improvement achieved may not be suitable enough to result in significant differences in clinical outcomes.

Our univariate analysis revealed that being a current smoker and having a lower initial NIHSS score were potential predictors of a positive clinical result. Based on the multivariate analysis, considering factors with a P value less than 0.2 in the univariate analysis, only a greater initial NIHSS score was identified as a standalone risk factor for an unfavourable result (P = 0.007, adjusted OR 1.140, 95% CI 1.036–1.253). The significance of focused interventions and close monitoring for patients with elevated initial NIHSS scores is underscored by these findings to improve the outcomes.

There are several limitations in our research. Initially, these results stemmed from observations made during a planned study with a predetermined design. Nonetheless, the distribution of stent retriever dimensions was not random, potentially leading to biased

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outcomes. Second, since our purpose was to evaluate patients with ICA occlusion, the number of patients who met the admission criteria was relatively small. Although a difference in the puncture-to-reperfusion time was observed among the groups, which indicated the efficiency of the RECO 6×30 stent retriever, we did not observe an improvement in prognosis as a function of size. Due to the impact of stent size on the success of MT procedures for patients with ICA blockage, it is crucial to conduct well-designed prospective randomized controlled trails in the future to establish the appropriate stent choices for these patients undergoing MT surgery.

5. Conclusion

Our study demonstrated the practical implications of stent-retriever size selection in the context of the MT for ICA occlusion. The routine use of an RECO 6 \times 30 stent retriever holds the potential for early revascularization in clinical practice. The significant reduction in the puncture-to-reperfusion time and the greater FPE associated with this stent size underscore its efficiency in treating ICA occlusion.

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Ethics approval and consent to participate

This study involving human participants was reviewed and approved by the ethics committees of Beijing Tiantan Hospital (KY 2019-080-03) as well as all participating centres. Written informed consent was provided by the subjects or their representatives.

Data availability statement

Data will be made available on request.

CRediT authorship contribution statement

Yunlong Ding: Writing – original draft, Supervision, Software, Project administration, Methodology, Funding acquisition, Conceptualization. Xiaoxiao Mao: Writing – original draft, Visualization, Resources, Data curation. Lei Bao: Visualization, Investigation, Writing – original draft. Tingting Zhai: Writing – original draft, Visualization, Investigation. Wenjuan Wang: Writing – original draft, Supervision, Project administration. Zhiqun Gu: Writing – original draft, Supervision, Project administration. Yan Liu: Writing – review & editing, Validation, Software, Methodology, Conceptualization. Jiali Niu: Writing – review & editing, Methodology, Conceptualization.

Declaration of competing interest

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