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ABSTRACT

BACKGROUND AND PURPOSE: Mechanical thrombectomy with proximal flow control and forced aspiration may improve the outcome of endovascular revascularization therapy for patients with acute stroke. The purpose of this study was to compare the impact of balloon-guiding catheter locations in patients treated for anterior circulation acute ischemic stroke using mechanical thrombectomy.

MATERIALS AND METHODS: The influence of the balloon-guiding catheter location (proximal, balloon-guiding catheter tip proximal to C1 vertebral body; distal, between the skull base and the C1 vertebral body) was analyzed in patients with acute anterior circulation stroke treated with stent-retriever thrombectomy. The baseline angiographic/clinical characteristics, time intervals, recanalization rates, and clinical outcomes were compared.

RESULTS: The clinical analysis included 102 patients (mean age, 69.5 ± 12.8 years; male/female ratio = 52:50). The balloon-guiding catheter was located distally in 49 patients and proximally in 53 patients for flow control and forced aspiration during stent retrieval. The puncture-to-recanalization time was shorter in the distal group than in the proximal group (40 versus 56 minutes, $P = .02$). Successful and complete recanalizations were more frequently achieved in the distal group compared with the proximal group (98.0% versus 75.5%. $P = .003$; 67.3% versus 45.3%, $P = .04$, respectively). Multivariate analysis showed that the distal catheterization location was independently associated with successful recanalization (adjusted OR, 13.4; 95% CI, 2.4–254.8; $P = .02$).

CONCLUSIONS: Location of the balloon-guiding catheter has a significant impact on recanalization in patients with acute stroke. The balloon-guiding catheter should be positioned as distally as safely possible in the cervical ICA for maximally effective thrombectomy.

ABBREVIATION: BGC = balloon-guiding catheter

The successful recanalization and better clinical outcome of endovascular revascularization therapy in acute ischemic stroke have been proved in several randomized clinical trials.[1-5] Recently, various methods using balloon-guiding catheters, intermediate catheters, and stent-deployment techniques have been introduced that may improve the efficacy of mechanical thrombectomy.[6-8] Proximal flow control with a balloon-guiding catheter (BGC) using stent retrievers has been shown to improve recanalization rates with shorter procedural times.[9-11] Despite the improved outcome, some cases still show less-than-optimal results with prolonged procedural time and unsuccessful/incomplete recanalization.

It is intuitive that the effects of flow arrest and forced aspiration would be most effective when the distance between the thrombus and the site of balloon occlusion is short (ie, the balloon is catheterized as distally as possible). However, the actual clinical impact of achieving distal balloon catheterization is not well-known. In addition, there may be concerns for complications such as dissection related to distal navigation of the BGC into the distal cervical ICA.[12,13]

The purpose of this study was to compare the impact of BGC locations in patients treated for anterior circulation acute ischemic stroke by mechanical thrombectomy.

MATERIALS AND METHODS

Patient Analysis

The patients were collected from a prospectively maintained stroke registry. Between July 2014 and June 2018, three hundred thirty-two patients were referred for endovascular revascularization therapy of acute ischemic stroke in Severance Hospital. The inclusion criteria for the study were as follows: 1) patients pre-

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senting within 8 hours from symptom onset of an anterior circulation large-vessel occlusion on CT angiography, 2) ASPECTS of 4 or more, 3) treated by stent-retriever (Solitaire, 4 × 20 mm; Covidien, Irvine, California) thrombectomy with a BGC (Cello 95 cm; Covidien). The exclusion criteria of this study were the following: 1) posterior circulation occlusion ($n = 61$), 2) dissection ($n = 1$) as the etiology of stroke, and 3) ipsilateral stenosis or occlusion of the proximal ICA ($n = 29$). Other reasons for exclusion were the following: primary contact aspiration ($n = 18$), different-profile BGC/stent retriever ($n = 106$), no BGC use ($n = 6$), primary angioplasty ($n = 4$), failed access ($n = 2$), and multiple cerebral artery occlusions ($n = 3$). In total, 102 patients who met the criteria were included in this study. The anteroposterior and lateral DSA images were reviewed for analysis of the imaging findings, including the cervical ICA tortuosity, occlusion site, BGC location, recanalization, and number of thrombectomies.

The locations of the BGCs were defined and grouped as follows: the distal balloon-guiding group, the balloon-guiding tip catheterization approaches the entrance of the petrous ICA—ie, balloon inflation between the skull base and the lower margin of the C1 vertebral body; and the proximal BGC group, balloon inflation proximal to lower margin of the C1 vertebral body for flow control and forced aspiration during stent retrieval. Tortuosity of the cervical ICA was defined as an angulation of ≥90° of the main flow axes of the cervical ICA. Modified TICI scores of 2b or 3 were defined as successful recanalization.[14] A modified TICI score of 3 was defined as complete recanalization. Embolization to a new territory was defined as emboli observed within the previously unaffected territory on postthrombectomy angiography.[15]

Clinical information including sex, age, vascular risk factors (hypertension, diabetes mellitus, atrial fibrillation, previous ischemic stroke), NIHSS score, intravenous rtPA therapy, time intervals (onset, puncture, recanalization time), hemorrhage, 3-month mRS score, and mortality was analyzed. The recanalization time was defined as the time to final recanalization in successful recanalizations and the time of the last angiographic series in patients with unsuccessful recanalizations. An intracerebral hemorrhage was classified according to the second European-Australasian Acute Stroke Study classification, and symptomatic intracerebral hemorrhage was defined as any hemorrhage associated with an NIHSS score increase of ≥4 within 24 hours.[16] Good clinical outcome was defined as 3-month mRS scores of 0–2. The images and clinical information were compared between the distal and proximal BGC groups.

Procedure

All procedures were performed by the femoral artery approach. In general, an 8F sheath (Radifocus; Terumo, Tokyo, Japan or Flexor Shuttle-SL; Cook, Bloomington, Indiana) and an 8F BGC were introduced into the cervical ICA coaxially with a 5F diagnostic catheter. Distal access to the cervical ICA with the BGC was preferred, but the decision was made at the discretion of the operator. A microcatheter over a microguidewire was used in all cases for catheterization of the occluded intracranial vessel. After we placed the microcatheter distal to the thrombus, the microguidewire was replaced by a stent retriever. After stent deployment, antegrade reperfusion was maintained for 3–4 minutes before retrieval. After proximal flow control with balloon inflation, the stent retriever and the microcatheter were retrieved together under continuous forced aspiration using 20-mL syringes. After mechanical thrombectomy,

15- to 20-minute delayed angiograms were obtained to detect re-occlusion of the target vessel.

Statistical Analysis

The data were analyzed using the R statistical and computing software (Version 3.5.1; http://www.r-project.org/). The continuous variables were analyzed with the 2-sample t test and presented as mean ± SD when normal distribution could be assumed; otherwise, the Mann-Whitney U test was used and presented as a median (minimum, maximum). Categoric variables were compared using the Pearson χ^2 or Fisher exact test as appropriate. Multivariate logistic analyses were performed for variables including sex, age, hypertension, initial NIHSS score, IV rtPA therapy, tortuosity of the ICA, and BGC location. A P value < .05 was considered statistically significant.

The study was approved by the Severance Hospital institutional review board with a waiver of informed consent due to its retrospective design.

RESULTS

The mean age of the patients was 69.5 ± 12.8 years (male/female ratio = 52:50). The median initial NIHSS score was 15. The baseline characteristics of the distal and proximal BGC groups are summarized in Table 1. Hypertension was more frequent in the proximal BGC group than in the distal BGC group. Other factors did not show statistically significant differences between the groups.

Overall successful recanalization was achieved in 88 of 102 (86.3%) patients. The puncture-to-recanalization time was significantly shorter in the distal BGC group than in the proximal BGC group (56 versus 40 minutes, $P = .02$). Successful recanalization was more frequently achieved in the distal BGC group compared with the proximal BGC group (98.0% versus 75.5%, $P = .003$; Table 2). Complete recanalization was also more frequently achieved with a distal BGC (67.3% versus 45.3%, $P = .04$). The good long-term outcome rates were more favorable in the distal BGC group but did not reach statistical significance (57.1% versus 45.3%, $P = .32$).

In the multivariate logistic regression analysis (adjusted for age, sex, initial NIHSS score, IV-rtPA use, ICA tortuosity, and hypertension), the BGC location was the only independent factor of successful recanalization (adjusted odds ratio, 13.399; 95% confidence interval, 2.369–254.815; $P = .02$; Table 3).

Successful recanalization was highest in patients with nontortuous cervical ICAs and distal balloon-guiding catheterization (100%) and lowest in patients with tortuous cervical ICAs and proximal balloon-guiding catheterization (70.6%, Table 4).

There were 2 cases of iatrogenic proximal common carotid artery dissection in patients with left distal ICA and M2 occlusions, respectively. Both dissections occurred in cases of distal BGC location and were discovered during reselection of the affected carotid artery with a 5F diagnostic catheter for delayed angiograms after mechanical thrombectomy. In the former case,

Table 1: Comparison of the baseline characteristics of distal and proximal BGC groups

	Distal BGC (*n* = 49)	Proximal BGC (*n* = 53)	*P* Value
Age (yr)[a]	70 (37–96)	72 (24–87)	.32
Female	23 (46.9%)	27 (50.9%)	.84
Atrial fibrillation	26 (53.1%)	21 (39.6%)	.25
Hypertension	27 (55.1%)	41 (77.4%)	.03
Diabetes mellitus	12 (24.5%)	11 (20.8%)	.91
Ischemic stroke[b]	4 (8.2%)	4 (7.5%)	<.99
Smoking[b]	4 (8.2%)	3 (5.7%)	.71
Initial NIHSS score (mean)	13.9 ± 5.5	14.5 ± 5.4	.58
IV rtPA use	20 (40.8%)	20 (37.7%)	.91
Onset-to-puncture time (min)[a]	195 (90–758)	200 (75–1185)	.41
Occlusion location			
M1	22 (44.9%)	31 (58.5%)	.24
M2	13 (26.5%)	10 (18.9%)	.49
ICA	14 (28.6%)	12 (22.6%)	.65
Tortuous ICA	11 (22.4%)	17 (32.1%)	.39

[a] Mann-Whitney *U* test. Data are medians, and numbers in parentheses are interquartile range.
[b] Fisher exact test.

Table 2: Comparison of the results between the distal and proximal BGC groups

	Distal BGC (*n* = 49)	Proximal BGC (*n* = 53)	*P* Value
Puncture-to-recanalization time (min)[a]	40 (14–133)	56 (15–204)	.02
Puncture-to-recanalization time (mean) (min)	47.8 ± 7.6	67.9 ± 12.4	.01
No. of passes[a]	2 (1–7)	2 (1–12)	.32
No. of passes (mean)	2.3 ± 0.4	3.1 ± 0.8	.07
Emboli to new territory[b]	2 (4.1%)	3 (5.7%)	>.99
Successful recanalization	48 (98.0%)	40 (75.5%)	.003
Complete recanalization	33 (67.3%)	24 (45.3%)	.04
Cervical artery dissection[b]	2 (4.1%)	0	.23
Symptomatic hemorrhage[b]	4 (8.2%)	3 (5.7%)	.71
Discharge NIHSS score[a]	6 (0–42)	6 (0–42)	.28
Mortality	5 (10.2%)	10 (18.9%)	.34
Good clinical outcome	28 (57.1%)	24 (45.3%)	.32

[a] Mann-Whitney *U* test. Data are medians, and numbers in parentheses are interquartile range.
[b] Fisher exact test.

Table 3: Predictors of successful recanalization

	Univariable Analysis		Multivariable Analysis	
Variable	Odds Ratio (95% CI)	*P* Value	Adjusted Odds Ratio (95% CI)	*P* Value
Age	0.99 (0.95–1.04)	.94	1.03 (0.97–120.01)	.38
Sex	0.49 (0.14–1.52)	.23	0.50 (0.12–1.88)	.32
Hypertension	0.29 (0.04–1.16)	.12	0.36 (0.04–1.98)	.28
Initial NIHSS score	0.99 (0.89–1.10)	.80	1.01 (0.89–1.15)	.84
IV rtPA use	1.19 (0.38–4.14)	.77	0.97 (0.26–3.86)	.97
ICA tortuosity	0.44 (0.14–1.48)	.17	0.51 (0.14–1.89)	.30
Distal/proximal BGC location	15.6 (2.92–289.52)	.01	13.40 (2.37–254.82)	.02

Table 4: Recanalization rates according to ICA tortuosity[a]

	Total	Tortuosity (+)	Tortuosity (-)
Total	86/102 (84.3%)	22/28 (78.6%)	64/74 (86.5%)
Distal BGC	48/49 (98.0%)	10/11 (90.9%)	38/38 (100%)
Proximal BGC	38/53 (71.7%)	12/17 (70.6%)	26/36 (72.2%)

[a] + indicates present; −, absent.

modified TICI 3 recanalization had been achieved for intracranial occlusion with contrast stagnation at the common carotid artery dissection site but with no flow compromise; thus, no further treatment was performed. In the latter case, modified TICI 2b recanalization had been achieved for the intracranial occlusion. Slight flow reduction at the common carotid artery dissection site was seen, but intracranial flow was preserved from good anterior communicating artery cross-flow; thus, no further treatment was performed for the dissection. Both patients showed good clinical outcome.

DISCUSSION

Our results show that the location of the BGC may have a significant impact on the mechanical thrombectomy treatment result in patients with acute stroke. When we compared distal with proximal BGC location, flow control and aspiration at the distal cervical ICA were associated with significantly improved successful and complete recanalization rates during mechanical thrombectomy with stent retrievers.

Improved Efficacy of Mechanical Thrombectomy

Currently, clot capture with a stent retriever and contact aspiration with a distal aspiration catheter are the 2 main concepts of mechanical thrombectomy.[9,11,17,18] Various improvised techniques for improved flow control and aspiration are being introduced. The bare wire thrombectomy technique involves removal of the microcatheter before stent retrieval for increased aspiration force.[8] The concurrent use of the stent retriever with distal aspiration catheters may have a synergistic effect of local aspiration and thrombus entrapment by the stent.[19,20] Continuous aspiration before stent deployment and during distal navigation of the aspiration catheter and retrieval may decrease the incidence of clot fragment emboli and increase the near-complete recanalization rates.[7]

Proximal flow control with a BGC and forced aspiration are also an adjuvant method for improved efficacy. Analysis of the North American Solitaire Acute Stroke Registry has shown that the use of a BGC with a Solitaire stent-retriever device is associated with superior revascularization results (modified TICI grade, 3; 53.7% versus 32.5%), shorter procedure time (120 ± 28.5 versus 161 ± 35.6 minutes), and improved clinical outcome (discharge NIHSS score 12 ± 14.5 versus 17.5 ± 16) compared with patients without a BGC.[11] However, to the best of our knowledge, there are no reports analyzing the impact of location of the BGC. Thus, our study shows that the effects of proximal flow control and forced aspiration can be maximized without an increase in complications by achieving distal catheterization with the BGC.

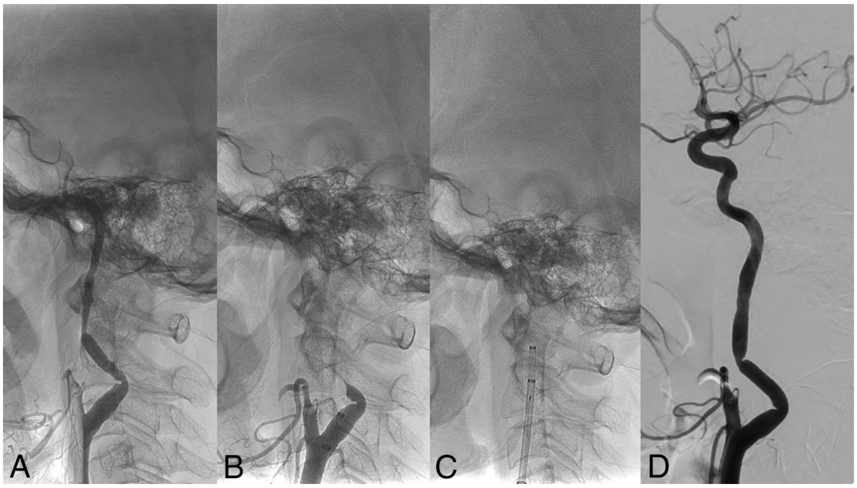

FIGURE. A 53-year-old woman who presented with acute stroke and an initial NIHSS score of 7. Delayed-phase nonsubtracted lateral DSA image shows occlusion of the left supraclinoid ICA. Acute angulation of the proximal cervical ICA is seen at the lower C2 vertebral level (*A*). The tip of the BGC is located at the C3 vertebral level proximal to the angulation of the cervical ICA (*B*). Careful balloon-guiding catheterization was successfully performed into the distal cervical ICA despite the tortuous artery. The tip of the BGC is now located at the C1 vertebral level (*C*). Stent-retriever thrombectomy with proximal flow control and continuous forced aspiration through the distally located BGC was performed. Subtracted lateral DSA image shows complete recanalization after thrombectomy. The cervical ICA shows no signs of dissection (*D*). The patient showed good clinical outcome on 3-month follow-up.

Factors Associated with Improved Efficacy of Distal Balloon-Guiding Catheterization

A number of factors including the diameter of the vessel, length, tortuosity, surface roughness, and flow velocity can influence the forced aspiration pressure.

For a straight pipe, the Darcy Weisbach equation states

$$\Delta P = f_{\mathrm{D}} \frac{\rho V^2}{2} \frac{L}{D},$$

Where ΔP is the pressure difference across the pipe, ρ is the density of the fluid, V is the average velocity in the pipe, f_{D} is the friction factor, L is the length of the pipe, and D is the diameter of the pipe.[21] Shortening of the length correlates with distal location of the BGC. Thus, distal BGC location will result in a theoretic decrease in the pressure difference within the system and an increase in the aspiration force. Our results support the theoretic advantages of distal balloon-guiding catheterization with significant improvement in recanalization rates. From the equation, we can also postulate that using a BGC with a larger inner diameter will result in an increased aspiration force; however, the feasibility and risks of navigating a larger profile BGC to the distal ICA have to be considered.

Another potential factor for improved recanalization in the distal BGC group may be related to the extravascular anatomy of the ICA. The cervical ICA is encased by the soft tissues of the neck. There may be concerns for collapse of the cervical ICA during forced aspiration of the proximally positioned BGC.[18] On the other hand, the petrous ICA may be more resistant to collapse due to the thick periosteal layer attached to the vessel and petrous bone.[22] Collapse of the cervical ICA may result in decreased suction force and dissection. It may also cause shearing of the clot captured by the stent and result in distal emboli during retrieval. These concerns may be reflected in the significantly lower incidence of successful and complete recanalizations with proximal balloon-guiding catheterization in our series.

Risks and Other Factors Associated with Distal Balloon-Guiding Catheterization

Although achieving distal location of the BGC is favorable in terms of recanalization efficacy, this may not always be feasible. One of the main causes of failure of distal access may be the tortuosity and/or the diameter of the cervical ICA. The tortuous vessel hinders safe balloon-guiding catheterization. However, our series shows that although tortuosity can preclude distal BGC access, it may be overcome in some cases (Figure). Distal catheterization was achieved in 11 of the 28 cases with cervical ICA tortuosity, and 10 of these 11 cases (90.9%) resulted in successful recanalization compared with 12 of 17 cases (70.6%) with proximal catheterization in patients with tortuous cervical ICAs. The tortuous vessel may be straightened by carefully navigating the guidewire or using coaxial catheters. Distal access with a coaxial intermediate catheter may reduce the gap between the 2 catheters, thus reducing the risk of dissection, and may also provide support for advancement of the BGC. Selection of a BGC with a soft distal tip may also aid in safe distal catheterization.

Another cause of failure of distal access may be length incompatibility of the BGC. In tall patients or patients with very tortuous aortas, the BGC may not be long enough to reach the distal ICA, especially when the shorter length BGC is selected. On the other hand, a longer length BGC may not always be advantageous in patients with severely tortuous cervical ICAs. Sufficient access of the distal cervical ICA with the BGC may not be achieved in these cases; this issue may impede sufficient distal access of the microcatheter to the occluded artery. Careful investigation of the cervical vessels on the preprocedural CT angiography, the tortuosity of the aorta during sheath introduction, and the habitus of the patient before selection of the length of the BGCs may aid in selecting the appropriate-length devices. Other causes may include oversight of the BGC location by the operator and kickback of the BGC during microcatheter navigation.

In our retrospective analysis, the BGC was positioned proximally in almost half of the patients (36/74 patients) despite the nontortuous cervical ICA. The difference in recanalization rates between patients with a distal-versus-proximal BGC in nontortuous ICA cases was about 30% (100% versus 72.2%, Table 4). Considering the significant impact on recanalization, the operator should be alert to confirming the location of the BGC throughout the procedure.

Despite the improved outcome from distal balloon-guiding catheterization, its benefits should be carefully weighed against the potential risks. We experienced 2 cases of left proximal common carotid artery dissection during reselection of the carotid artery with a diagnostic catheter for delayed angiograms. Although the location of the dissections was localized in the common carotid artery without ICA extension, suggesting that it was not directly related to BGC navigation in the cervical ICA, endothelial injury may have occurred during initial navigation of the Shuttle sheath and BGC into the acutely angulated left common carotid artery and may have been discovered during reselection for the delayed angiogram. Fortunately, these patients did not have any serious complications associated with the dissections. However, such risks should be carefully avoided, especially in patients with severely tortuous cervical ICAs. Our results also call for the development of softer tipped and flexible BGCs, which can be safely navigated distally into the cervical ICA.

In our study, the puncture-to-recanalization time was significantly shorter in the distal than in the proximal BGC group. This feature may be due to the tendency for a decreased mean number of passes in the distal BGC group (2.3 ± 0.4 versus 3.1 ± 0.8, $P = .07$). Also, the higher incidence of hypertension in the proximal BGC group may have been associated with more tortuous arteries, including the aorta, resulting in increased procedural time.[23]

This study is limited by the retrospective nature of the analysis. To analyze and prove the concept of BGC location and its impact on recanalization, we limited the patients in this series to those treated with a specific type of stent retriever and BGC; thus, there may be bias. It remains to be clarified whether devices with different profiles such as a longer stent retriever would compensate for the effect of the BGC position because longer stent retrievers may enhance thrombectomy performance.[24] Also, despite the significantly higher recanalization rates with distal balloon-guiding catheterization, the difference in the long-term good outcome rate did not reach statistical significance, probably due to the small size of the cohort. Future prospective studies in a larger cohort are warranted.

CONCLUSIONS

In patients with acute stroke treated with short stent retrievers and without contact aspiration, the location of the BGC has a significant impact on the recanalization of occluded arteries. The BGC should be navigated as distally as safely possible in the cervical ICA for maximally effective thrombectomy.

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