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Original Article

Combined Technique Thrombectomy with a Long Balloon-Guiding Catheter and Long Sheath Aids in Rapid and Stable Recanalization in Patients with Anterior Circulation Acute Ischemic Stroke

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Objective: The purpose of this study was to evaluate the combination of a 100-cm long balloon-guiding catheter (BGC) and 40-cm long sheath in patients treated by mechanical thrombectomy for anterior circulation acute ischemic stroke.

Methods: The subjects were 77 consecutive patients treated by endovascular recanalization for anterior circulation occlusion from January 2011. After February 2018, 24 patients were treated by mechanical thrombectomy using a long BGC and long sheath (L-BGC group), and were compared with 53 patients treated before January 2018 using a normal BGC and sheath (S-BGC group). The baseline angiographical/clinical characteristics, main procedures, BGC insertion time, internal carotid artery (ICA) cartelization rate, recanalization rate, and clinical outcome were compared between L-BGC and S-BGC groups.

Results: There was no significant difference in angiographical/clinical characteristics except for intravenous thrombolysis with recombinant tissue plasminogen activator (IVrtPA) treatment. In all, 22 patients were treated by combined technique (CoT) thrombectomy in the L-BGC group. The BGC insertion time was significantly shorter in the L-BGC group than in the S-BGC group (19 vs 13 minutes), and ICA catheterization of BGC was successful in the L-BGC group, whereas there were seven failures in the S-BGC group (100% vs 84%). The puncture-to-recanalization (PtoR) time was significantly shorter in the L-BGC group (90 vs 44 minutes). The successful recanalization (SR) rate was higher in the L-BGC group (96% vs 72%). Good outcomes (mRS 0-2) slightly increased in the L-BGC group (64% vs 49%). In the multivariable analysis, only CoT thrombectomy was associated with PtoR and SR.

Conclusion: The combination of a long BGC and long sheath results in rapid and stable BGC insertion to the ICA. CoT thrombectomy with these devices may be useful for SR and reducing the PtoR in anterior circulation mechanical thrombectomy.

Keywords▶ balloon-guiding catheter, acute ischemic stroke, thrombectomy

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Introduction

Several large-scale clinical trials demonstrated that the success of recanalization therapy by mechanical thrombectomy is associated with favorable outcomes in recent treatment of cerebral infarction induced from large vessel occlusion.[1–5)] Several methods have been investigated to increase the effects of recanalization therapy, and proximal blood flow control using a balloon-guiding catheter (BGC) was found to increase the recanalization rate, shorten the procedure time, and prevent embolism of new territory (ENT), being an effective method to improve the outcome.[6–8)] In addition, it was recently reported that BGC located at a site distal to the main trunk of the internal carotid artery (ICA) improves the recanalization rate and shortens the procedure time compared with proximal placement.[9] At our facility, the combination of 100-cm BGC and 40-cm long sheath has been used as a standard device to reliably place the BGC into a site distal to the ICA after treating a patient in whom a BGC was unable to be placed in the ICA due to an insufficient length, resulting in unsuccessful thrombectomy in 2018. In this study, we investigated the effectiveness of these devices and analyzed the background factors and therapeutic procedures associated with the improvement of the treatment results.

Materials and Methods

The subjects were 77 consecutive patients who received acute-phase recanalization therapy employing endovascular treatment for cerebral infarction induced by large vessel occlusion in the anterior circulation at our hospital from January 2011 to June 2019. An aspiration catheter (Penumbra 5MAX, Penumbra ACE60, Penumbra ACE68; Medico's Hirata, Tokyo, Japan) or stent retriever (Trevo; Stryker, Tokyo, Japan) (SolitaireFR; Medtronic, Tokyo, Japan) alone was employed as the first-line treatment using a normal 90-cm BGC (Optimo9Fr; Tokai Medical Products, Tokyo, Japan) and normal 25-cm sheath from January 2011 to January 2018, and 53 patients treated in this period were designated as the short BGC group (S-BGC group). After February 2018, a 100-cm BGC (Optimo9Fr, Tokai Medical Products) and 40-cm long sheath (Medikit Super Sheath; Medikit, Tokyo, Japan) were used in all patients. In addition, Mechanical thrombectomy using both aspiration catheter and stent retriever (combined technique [CoT]) including Aspiration-Retriever Technique for Stroke (ARTS)[10] was employed as the first-line procedure in this period. In all, 24 patients treated in this period were designated as the long BGC group (L-BGC group) and compared with the S-BGC group. The inner catheter used as the first-line treatment in the S-BGC group was a 125-cm 6FrJB2 diagnostic catheter (Medikit). Simons or N2 model was selected corresponding to the degrees of vascular selectivity and tortuosity and type of aortic arch shape. For the 0.035-inch guide wire (Terumo, Tokyo, Japan), standard, half-stiff, or stiff types were also used. In the L-BGC group, the inner catheter was changed to that with 130-cm 6Fr specification and a hemostasis valve was used as the connector until BGC placement to secure an approximately 5-cm extra tip length of the inner catheter. The selection criteria of the catheter tip shape and guide wire hardness were not changed, and these were similarly applied corresponding to the patients. When the aspiration catheter length became insufficient after BGC placement, T-shaped connector was used to the BGC.

The age, sex, occluded vascular region, National Institutes of Health Stroke Scale (NIHSS) on admission, stroke etiology of the TOAST classification, the presence of intravenous thrombolysis with recombinant tissue plasminogen activator (IVrtPA), lesion side (left or right), type of aortic arch shape, and endovascular procedure were retrospectively investigated as the patient background. The aortic arch shape was classified into types I–III referring to the fluoroscopic and video images during treatment and chest contrast-enhanced CT on arrival.

Regarding the endovascular procedures, the technique that contribute to the recanalization was defined as the main procedure. Treatments other than CoT were classified into three types: thrombus aspiration using an aspiration catheter alone (Aspiration catheter), thrombus retrieval using a stent retriever alone (Simple stent retriever), local fibrinolytic therapy, and other treatments such as balloon angioplasty (Others).

For the evaluation of BGC accessibility, the time from puncture to first digital subtraction angiography (DSA) after BGC placement in the ICA was measured and defined as the BGC insertion time. When diagnostic angiography preceded, the time from exchange to the long sheath to BGC placement was measured. The case that BGC was not able to be cannulated into ICA, the time from puncture to starting treatment through the common carotid artery was measured. In addition, the rate of BGC reaching the main trunk of the ICA was evaluated as the ICA catheterization rate.

The other evaluated points were the puncture-to-recanalization time (PtoR) as evaluation of the procedure, thrombolysis in cerebral infarction grade (TICI grade) 2b or higher was imaging evaluation of successful recanalization (SR). The clinical outcome was evaluated based on the modified Rankin Scale (mRS) after 3 months and mRS 0-2 was regarded as a favorable outcome. Furthermore, to evaluate factors associated with SR and PtoR, multivariate analysis using factors considered clinically associated was performed.

For statistical analysis, JMP14.0 (SAS Institute) was used. The presence of a significant difference in the distribution of each factors was investigated by univariate analysis employing the Mann–Whitney U test, χ^2 test, post-hoc test (Turkey–Kramer test), and Cochran–Armitage trend test, and $P < 0.05$ was regarded as significant. In multivariate analysis, logistic regression analysis of factors associated with SR and linear regression analysis of factor associated

Table 1 Comparison of baseline characteristics/main procedures between S-BGC and L-BGC groups

	S-BGC group (n = 53)	L-BGC group (n = 24)	P value
Age	68.0 ± 13.9	68.3 ± 14.7	0.5312
Female	34 (64%)	17 (71%)	0.6132
Stroke etiology (CES)	43 (81%)	17 (71%)	0.3771
Lesion side (Left)	25 (47%)	13 (54%)	0.6280
Occlusion location			0.2441
ICA	19 (36%)	4 (17%)	
ICA+MCA M1	1 (2%)	2 (8%)	
ICA+MCA M2	2 (4%)	2 (8%)	
MCA M1	19 (36%)	9 (38%)	
MCA M2	12 (23%)	7 (29%)	
Initial NIHSS (mean)	17.2 ± 6.6	19.1 ± 7.5	0.8769
Aortic Arch type			0.8829
Type I	19 (36%)	7 (29%)	
Type II	23 (43%)	13 (54%)	
Type III	11 (19%)	4 (17%)	
IVrtPA	28 (52%)	6 (25%)	0.0275*
Main procedure			0.0001*
Combined technique	5 (9%)	22 (92%)	
Simple stent retriever	18 (34%)	0 (0%)	
Aspiration catheter	16 (30%)	1 (4%)	
Others (PTA, LIF)	14 (26%)	1 (4%)	
Pass number (average)	1.77	1.30	0.0138*
Combined technique	1.20	1.27	
Simple stent retriever	1.83	–	
Aspiration catheter	1.94	2.00	

*P <0.05. CES: cardiogenic embolic stroke; ICA: internal carotid artery; IVrtPA: intravenous recombinant tissue plasminogen activator; L-BGC: long sheath balloon guiding catheter; LIF: local intra-arterial fibrinolysis; MCA: middle carotid artery; NIHSS: National Institute of Health Stroke Scale; PTA: percutaneous transcatheter angioplasty; S-BGC: sheath balloon guiding catheter

with PtoR were performed. This study was approved as a retrospective clinical study by the ethics committee of our facility.

Results

No significant difference was noted in the age, sex, cerebral infarction disease type, side (left or right) with the lesion, occluded vascular region, NIHSS on arrival, or aortic arch shape on comparison of the background between the S-BGC and L-BGC groups, but IVrtPA was performed significantly more frequently in the S-BGC group (**Table 1**).

Regarding the procedure, CoT was employed in 5 patients, aspiration catheter in 16, simple stent retriever in 18, and others in 14 in the S-BGC group. In contrast, 22 patients were treated by CoT in the L-BGC group. The mean number of passes in each procedure was calculated and it was significantly lower in the L-BGC group (**Table 1**).

The mean and median BGC insertion times in the S-BGC group were 21.9 and 19 minutes, respectively. In the L-BGC group, that were 14.9 and 13 minutes, and demonstrated significant shortening compared to the S-BGC group (P = 0.0137). The BGC insertion time significantly increased as the aortic arch shape changed from type I to III (**Fig. 1**).

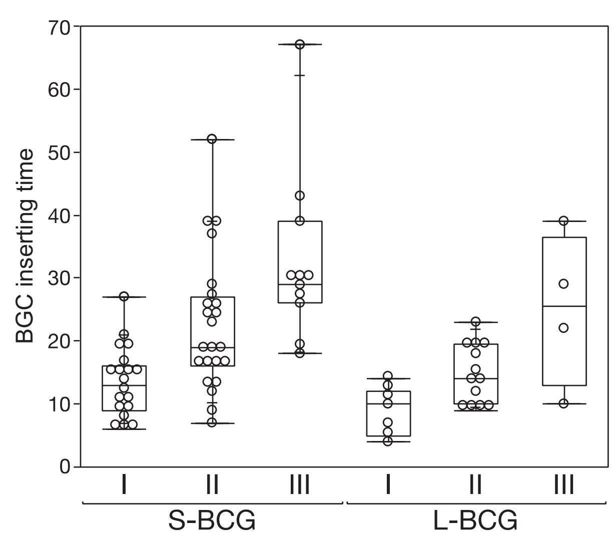

Fig. 1 There are significant differences in the BGC insertion time between aortic arch type III and type II (P = 0.0007), between type II and type I (P = 0.0167). BGC:

Table 2 Comparison of catheterization results, procedual/clinacal outcomes between S-BGC and L-BGC groups

	S-BGC group (n = 53)	L-BGC group (n = 24)	P value
BGC inserting time (median) (min)	19	13	0.0137*
ICA catheterization rate	46 (87%)	24 (100%)	0.0861
Puncture-to-recanalization time (median) (min)	90	44	0.0001*
Successful recanalization rate	38 (72%)	23 (96%)	0.0156*
Good clinical outcome	26 (49%)	15 (63%)	0.2735

*P <0.05. L-BGC: long sheath balloon guiding catheter; S-BGC: sheath balloon guiding catheter

Regarding the ICA catheterization rate, BGC was able to be cannulated into the main trunk of the ICA only in 46 patients (87.3%) in the S-BGC group and was impossible in 7 patients. In contrast in the L-BGC group, the BGC was able to be cannulated into ICA in all patients (100%), although the difference was not significant (**Table 2**).

Clinical summary of the seven patients in whom BGC was unable to be cannulated into ICA is presented. The vascular abnormalities ware noted, such as severe aortic tortuosity, strong type III aortic arch shape, and Bovine-type branching, in all patients (**Table 3**). The BGC was unable to reach the ICA due to insufficient length in two patients. The first case was a 78-year-old man with left MCA M1 occlusion-induced cardiogenic embolism. He was tall (182 cm) with a type III aortic arch and the BGC reached only to the carotid bifurcation even though the full length of a 90-cm BGC was used. A Solitaire was deployed in the occluded M1 segment, the thrombus was retrieved with no proximal flow control, and TICI2a recanalization was acquired with one pass. Though a Marksman was unable to crossed the region distal to the residual thrombus in the next approach, SR was not archived (**Fig. 2**). In another patient, strong tortuosity was noted throughout the region from the aortic arch to common iliac artery, the 90-cm BGC tip reached only up to the common carotid artery. Thrombectomy with a Solitaire was performed, but ENT was occurred, and SR was not archived.

The mean and median PtoR were 94.2 and 90 minutes, respectively, in the S-BGC group, and 46.5 and 44 minutes, respectively, in the L-BGC group, being significantly shortened (P = 0.0001). The SR rate was 72% in the S-BGC group and 96% in the L-BGC group, being significantly higher (P = 0.0156). Regarding the clinical outcome, a mRS 0-2 favorable outcome was noted after 3 months in 49% in the S-BGC group and 64% in the L-BGC group, demonstrating improvement, although the difference was not significant (**Table 2**). The factor most closely associated with SR was investigated among the age, occlusion site , stroke etiology, aortic arch shape, ICA catheterization rate, L-BGC group, and surgical procedure (simple stent retriever, CoT) using logistic regression analysis. The regression was P = 0.0011 and the pseudo-coefficient of determination was 0.3397, revealing that only procedure with CoT was significantly associated, and no association was noted in the modification: the use of the guiding catheter and long sheath in the L-BGC group. PtoR was subjected to multiple regression analysis. The regression was P = 0.0018 and R^2 was 0.2095, being significant, and the result was similar: significant association was noted only in procedure with CoT (**Table 4**).

Discussion

In acute ischemic stroke induced from large vessel occlusion, the time from the onset to recanalization is correlated with the outcome and it is desirable to perform recanalization as quickly as possible.[11)] In this study, using the combination of a 100-cm BGC and 40-cm long sheath secured rapid and stable access to the occlusion site. In addition, combining the progress of devices and the improvement of procedures, such as CoT, achieved reliable recanalization with a low-pass frequency, which may have resulted in improvement of the treatment outcome of SR and PtoR.

It was previously reported that in mechanical thrombectomy in acute-phase ischemic stroke, Placement of the BGC is difficult in approximately 20%, mainly in aortic arch Type III cases.[12)] The BGC insertion time in this study was analyzed in all 77 patients by the background factors such as the lesion side (left or right) and aortic arch shape. The BGC inserting time significantly increased as the aortic arch became type III (**Fig. 1**).

Advantage of the placement of BGC in ICA was reduction of ENT risk of thrombectomy with complete proximal flow control in ICA,[13)] stabilizing the distal access of the aspiration catheter, and improvement of operability during passing through the lesion using a microcatheter.[14)] It was recently reported that the BGC location to a distal site in the ICA significantly improved the recanalization rate.[9)] In this study, in addition to a 100-cm BGC, the long sheath was concomitantly used. That may be useful to improve arrival

Table 3 Summary of seven cases who failed IC catheterization in S-BGC group

Case No.	Age/ gender	Side	Lesion	Etiology	GC/inner	Anatomical feature	BGC inserting time	Procedure	PtoR	TICI	90D mRS
1	60 F	R	ICT	CES	9FrBGC/6FrN2	Aorta type III	30	Penumbra	60	0	4
2	76 F	R	ICT	CES	9FrBGC/5FrSimons	Aorta type III, Aorta tortuosity	53	Penumbra	96	2a	5
3	81 F	L	M2	CES	9FrBGC/6FrN2	Aorta + CCA tortuosity	24	Others (LIF)	127	2a	4
4	88 F	L	M2	CES	9FrBGC/5FrSimons	Bovine, Aorta tortuosity	19	Others (LIF)	62	2a	3
5	98 M	L	ICT	CES	9FrBGC/6FrJB2	Aorta type III, Aorta tortuosity	25	Combined	39	3	6
6	75 M	L	M1	CES	9FrBGC/6FrJB2	Aorta type III, Tall (182cm)	19	Stent retriever	56	2a	2
7	68 M	R	M1	CES	9FrBGC/6FrJB2	Aorta tortuosity	18	Combined	55	2a	3

CC: common carotid artery; CES: cardiogenic embolic stroke; mRS: modified Rankin Scale; PtoR: puncture-to-recanalization time; S-BGC: sheath balloon guiding catheter; TICI: thrombolysis in cerebral infarction

of the guiding catheter to a distal site because of correcting the loss of length due to abdominal aortic tortuosity and increasing the support and operability of BGC. Comparison was not feasible because records of the detailed position reached by the BGC tip were not available for many patients, but the ICA was unable to be reached due to strong tortuosity of access route including the descending aorta in seven patients, suggesting a lack of the BGC length. In contrast, the BGC obviously had sufficient length in the L-BGC group and was able to be advanced to near the entrance of the carotid canal in some patients, suggesting that the 100-cm length had a favorable influence on operability of the aspirations catheter and microcatheter.

On the other hand, advancing the BGC to the distal ICA with a small vascular diameter and inflating the balloon at this site may increase the risk of complications such as aortic dissection.[15–17] However, complication was not observed including dissection of the ICA in this study. It was possible that the aspiration catheter length became insufficient because the use of 10-cm longer BGC than the conventional one reduced the effective length of the inner catheter and the aspiration catheter at the time of placement in the ICA. Insufficient length of aspiration catheter might be afraid to result in the loss of the effectiveness of CoT procedures represented by ARTS or continuous aspiration prior to intracranial vascular embolectomy (CAPTIVE)[18] mainly used in this study, though actually, the procedure was completed without a problem by the devices described above in L-BGC patients. There were many M2 lesions in the L-BGC group, but the number of recanalization passes was small and the treatment outcome improved (**Tables 1** and **2**), suggesting that CoT with the combination of these devices was an effective method and significantly improved the treatment results compared with conventional procedures.

The clinical outcome of functional recovery slightly improved, but the difference was not significant. This may have been due to the presence of many severe cases with a high NIHSS on arrival in the L-BGC group, resulting in mRS6 and an influence of historical changes in patient selection with expansion of the indication of mechanical thrombectomy.

Regarding limitations of this study, this was a retrospective study and the study period was prolonged; therefore, strong influences of historical biases due to changes and progression of the endovascular treatment procedure and technical improvement of operators were unable to be excluded. Statistically, as there was no overlapping in the treatment period between the two BGC groups, adjustment

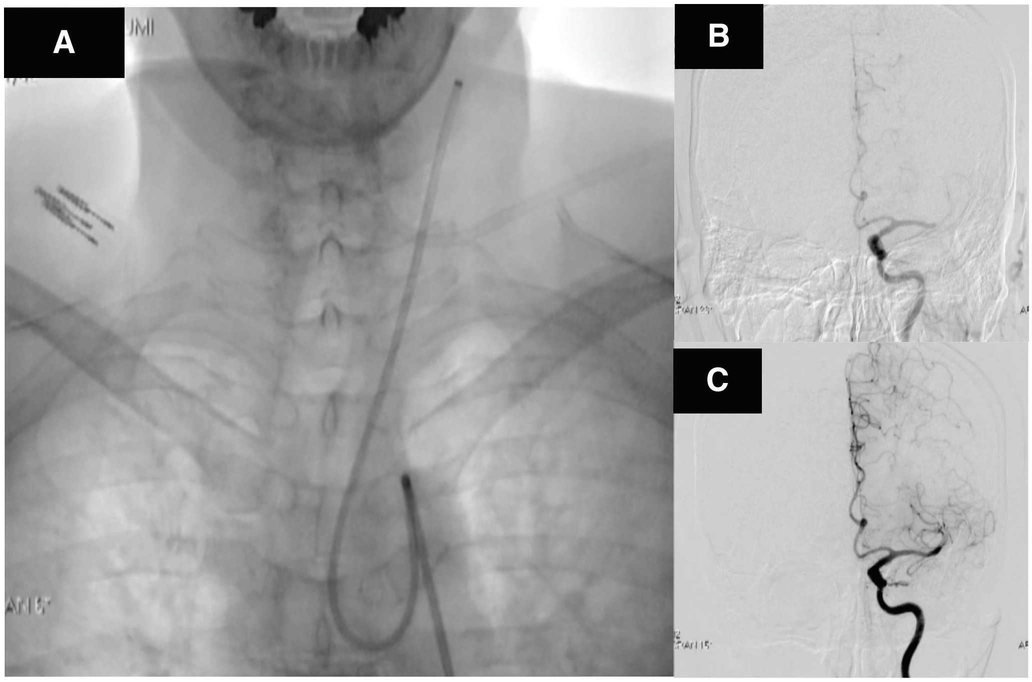

Fig. 2 (**A**) Case 6 on **Table 4**, (**B**) Initial DSA, and (**C**) Final DSA. DSA: digital subtraction angiography

Table 4 Multivariable analyses for SR and PtoR

	Univariate logistic regression analyses for SR		Multivariate logistic regression analyses for SR		Multivariate linear regression analysis for PtoR	
	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value	Scaled estimates	P value
Age	1.0400 (0.9925–1.0898)	0.0998	1.0513 (0.9778–1.1302)	0.1760	9.9380	0.1450
Occlusion location (ICA)	0.7400 (0.2257–2.4612)	0.6192	0.4347 (0.0942–2.0063)	0.2857	–1.9664	0.4627
Stroke etiology (CES)	1.1666 (0.2882–4.7226)	0.8289	0.6330 (0.0979–0.9230)	0.6310	–0.3122	0.9040
Aortic Arch type (type III)	1.6859 (0.4517–6.2914)	0.4369	1.1627 (0.1772–7.6277)	0.8752	0.4590	0.8375
ICA catheterization (success)	0.1398 (0.0274–0.7133)	0.0180*	0.0953 (0.0058–1.5461)	0.0982	0.1030	0.9836
L-BGC group	0.1211 (0.0149–0.9823)	0.0481*	0.7517 (0.0468–12.0825)	0.5878	4.6251	0.2973
Procedure						
Simple stent retriver	0.2238 (0.0271–1.8467)	0.1644	0.1155 (0.0114–1.1760)	0.0683	–4.3899	0.2052
Combined technique	0.0867 (0.0107–0.7009)	0.0218*	0.0248 (0.0014–0.4522)	0.0126*	–9.8084	0.0209*

*P <0.05. CES: cardiogenic embolic stroke; ICA: internal carotid artery; L-BGC: long balloon guiding catheter; PtoR: puncture-to-recanalization time; SR: successful recanalization

of the treatment period as a confounding factor may not have been possible. Furthermore, no significant improvement of the outcome was achieved even though the recanalization rate clearly improved, suggesting that the sample size and background homogeneity between the comparative groups were insufficient.

Conclusion

Device modification by concomitant use of a 100-cm BGC and 40-cm long sheath enabled us to secure a rapid and stable access route. Introduction of the CoT including modification of BGC and femoral sheath had a significant effect on the improvement of the outcome.

Disclosure Statement

All authors completed COI self-declaration to the Japanese Society of Internal Medicine and Japan Neurosurgical Society. There is no COI to be disclosed for publication of this report.

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