Comparison of FlowGate^2 and Merci as balloon guide catheters used in mechanical thrombectomies for stroke intervention

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Abstract. The present study reports on the usefulness of FlowGate^2 (FG2) as a novel balloon guide catheter (BGC) for mechanical thrombectomy (MT) treatment. MT using a BGC device was performed on 255 patients at the authors' institution (St. Vincent's hospital, Suwon, Korea and Hangang Sacred Heart Hospital, Seoul, Korea) between January 2014 and September 2018. A total of 235 patients underwent successful application of BGCs and were divided into two groups; an FG2 and a Merci group, and a comparative analysis was performed. The failure rate in the FG2 group (2.5%) was significantly lower than that in the Merci group (10.8%; P=0.016). Occurrence of distal emboli was significantly lower in the FG2 group (4.7%) than in the Merci group (7.3%; P=0.012). According to subgroup analysis of the BGC and the intermediate catheter, the incidence rate of the distal emboli in the FG2 with an intermediate catheter (2.3%) was significantly lower than that of the Merci with an intermediate catheter (6.6%; P=0.038). The ratio of thrombolysis in cerebral infarction (TICI) 3 recanalization in the first pass was higher in the FG2 group than in the Merci group, in both total (44.7 vs. 34.7%; P=0.033) and subgroup patients (46.5 vs. 34.4%; P=0.029). In the multivariate analysis, use of an intermediate catheter [odds ratio (OR), 0.75; 95% confidence interval (CI), 0.66-0.94; P=0.029] and FG2 application (OR, 0.59; 95% CI, 0.25-0.93; P=0.020) were the predictive factors for fewer distal emboli. In summary, FG2 BGC enables an effective MT with less application failures and occurrence of distal emboli, and higher TICI 3 recanalization at the first stent passage, compared with Merci BGC.

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Abbreviations: BGC, balloon guide catheter; CT, computed tomography; FG2, FlowGate^2; ICA, internal carotid artery; ICH, intracerebral hemorrhage; ID, inner diameter; LAO, large artery occlusion; mRS, modified Rankin scale; MT, mechanical thrombectomy; TIA, transient ischemic attack; TICI, thrombolysis in cerebral infarction; t-PA, tissue-plasminogen activator

Key words: BGC, intervention, stents, stroke, thrombectomy, FG2, Merci

Introduction

Acute ischemic stroke, resulting from large artery occlusion (LAO), has been established as a major cause of mortality and severe disability. Numerous randomized controlled trials (RCTs) have indicated that mechanical thrombectomy (MT), alongside a stent retriever, represents an effective therapeutic procedure in patients with LAO (1-5). In addition to the use of the classic stent retriever for MT, several additional procedures and devices have been introduced that improve outcomes and prognoses, including the balloon guide catheter (BGC) (6-8). The principle and concept of the BGC is that when a mechanical clot is retracted using a stent retriever, simultaneous aspiration is performed through the BGC, which facilitates successful revascularization and results in the reduced occurrence of iatrogenic embolic events (6-8). However, there have been concerns regarding the use of BGCs during MT, including time consumption, technique requirements, cost effectiveness and the risk of local complications. Certain studies have reported advantages of BGCs, such as prevention of thromboembolic complications, increased suction effectiveness, facilitation of clot removal, minimization of distal embolization and a shorter procedure time (7,9-11). MT using BGCs has been indicated to facilitate improved clinical and radiological outcomes, compared with other techniques, via a reduction in both the number of stent passages' and incidence of distal emboli (10,12,13).

The BGC 8-French FlowGate$^{2™}$ (FG2; Stryker Neurovascular) has been introduced and used. Teleb *et al* (14) reported a single center observational study for Flowgate BGC, and the authors of the present study have also previously reported their experience using the FG2 (15). However, these reports were not of comparative studies that included other BGCs, and therefore studies regarding the efficacy of FG2 compared with other BGCs are yet to be performed. These previous studies indicated that FG2 has good trackability which allows for smooth navigation to the target

proximal artery, due to its atraumatic and flexible design. In addition, it is readily able to control proximal flow using a maximal 10-mm compliant balloon. Compared with other BGC products, it has the largest distal inner luminal diameter (0.084 inch), and therefore theoretically offers a higher aspiration flow rate and greater force of clot capture (Fig. 1). The majority of previous studies evaluating BGCs have focused on two BGCs: Merci (Concentric Medical) and Cello (Medtronic Neurovascular). Previously, Merci was used at the authors' institution, and its efficacy compared with non-BGCs has been previously reported (12). From June 2017, FG2 was used as the BGC during MT, instead of Merci BGC. Therefore, the present study aimed to assess the potential benefits of using an FG2 BGC for stent retrieval during MT, in comparison to the Merci BGC. The primary focus of the present study was to compare FG2 efficacy with that of Merci, by assessing the technical feasibility, clinical and radiological outcomes, time-associated factors and safety concerns of each device.

Materials and methods

Study population. The current study comprised prospectively collected data and a retrospective review, and was approved by the local Institutional Review Board of each participating center. A total of 245 patients (median age 69.0, age range 22-93, 54.9% male) underwent MT using stent retrieval procedures for acute stroke using either the FG2 or Merci BGC, between January 2015 and September 2018, and were subsequently included in the study. BGC application to the proximal lesion of target vessel was attempted in 255 patients; however, the BGC application failed due to severe tortuosity or angulation of the aorta in 20 cases. Patients who received intravenous (IV) alteplase [tissue-plasminogen activator (t-PA)] ≤4.5 after stroke onset at a maximum dose of 0.9 mg/kg were enrolled. The inclusion criteria were as follows: i) Acute ischemic stroke due to LAO confirmed by computed tomography (CT) angiography or perfusion CT; ii) National Institutes of Health Stroke Scale score ≥2 (range, 0-42; with higher scores indicating more severe neurological deficits); and iii) patients who underwent stent retrieval MT using a BGC. The exclusion criteria were as follows: i) Presence of hemorrhage on CT scan; ii) presence of a large ischemic core with an Alberta Stroke Program Early CT Score (ASPECTS) of ≤6; iii) contraindication(s) for contrast-enhanced CT; iv) MT with non-stent retrievers such as 5 MAX ACE (Penumbra, Inc.); and v) MT conducted with a BGC that was not Merci or FG2. In addition, all patients underwent follow-up non-contrast-enhanced CT immediately after the intervention to evaluate hemorrhages.

Endovascular procedure. All stroke intervention procedures were performed by two neuro-interventionists with >5 years of experience each. All procedures were performed on a Siemens Artis Zee biplane system (Siemens AG) in a dedicated neuro-angiography suite, with patients under local anesthesia. Equipment selection for each procedure was determined according to the preference of the treating neuro-interventionist. In all cases, arterial access was obtained via the common femoral artery with an 8F 45-cm sheath (Cordis Corporation). An 8F BGC (FG2 or Merci) was positioned at the proximal cervical or petrous segment of the internal carotid artery (ICA) or proximal vertebral artery (VA) for balloon inflation, and a microcatheter (0.014 or 0.021 inches) was placed over the wire of the occluded area. The typical procedure involved thrombus retraction with a retrievable stent, using the 'push and fluff' technique (16). A Solitaire Flow Restoration stent retriever (ev3; Covidien) or Trevo stent retriever (Stryker Neurovascular) was delivered through the microcatheter and positioned at the occluded site for 5 min, and the stent was subsequently retrieved. Immediately prior to stent retrieval, the balloon of the BGC was inflated to arrest the antegrade proximal flow. Aspiration was then performed through the BGC using a 50 ml syringe. After the stent was retrieved, the balloon was immediately deflated to allow for re-circulation of the proximal artery, and secondary manual aspiration was performed through the BGC. In certain cases, an additional intermediate catheter, the 5F SOFIA (MicroVention; Terumo) or 6F AXS Catalyst 6 (Stryker Neurovascular), was used.

Outcomes and complications. Several factors were reviewed, including the failure rate of BGC application, patient sex and age, risk factors, history of previous anti-platelet or anti-coagulant use, history of prior stroke or transient ischemic attack (TIA), IV t-PA, level site of arterial occlusion, use of intermediate catheter, interventionist and stent type. All patients underwent a clinical assessment using the modified Rankin scale (mRS) score at 3 months post-surgery, and a favorable clinical outcome was defined as an mRS ≤2. Procedure time was defined as the time from groin puncture to reperfusion time (min). The radiological results were evaluated according to the Thrombolysis in Cerebral Infarction (TICI) grading system (17). A successful recanalization was defined as a TICI grade 2b or 3, and the ratio of TICI grade 3 to TICI grade 2b (TICI 3/TICI 2b) was also analyzed. The number of stent passages for successful recanalization was measured. Safety variables and complications were analyzed in terms of post-thrombectomy hemorrhage, symptom-associated hemorrhage, vessel perforation, arterial dissection, vasospasm, distal emboli and mortality for 3 months postoperatively. Post-thrombectomy hemorrhage was defined as the occurrence of intracerebral hemorrhage (ICH) or subarachnoid hemorrhage on a CT scan taken immediately following the procedure. Distal emboli were defined as visible fragmented thrombi or emboli downstream at the distal branch of the primary occlusion site or other new territory on angiography during MT. In addition, subgroup analysis of the concomitant use of BGC and an intermediate catheter, and multivariate analyses for predicting the occurrence of distal emboli, were performed. All multimodal factors and clinical data were analyzed by all the authors.

Statistical analysis. All data were analyzed using Stata statistical software v.15 (StataCorp LP). Between-group comparisons were calculated using Student's t-test/Mann–Whitney U test or χ^2/Fisher's exact test. The χ^2 test and mean comparison test (student's t-test) were employed to evaluate the differences in multiple variable factors, outcomes and complications between the two groups. Univariate analysis was used to verify the factors that correlated with distal emboli, and $P<0.20$ in univariate analysis were entered into a backward multivariate binary logistic regression analysis. Two-tailed

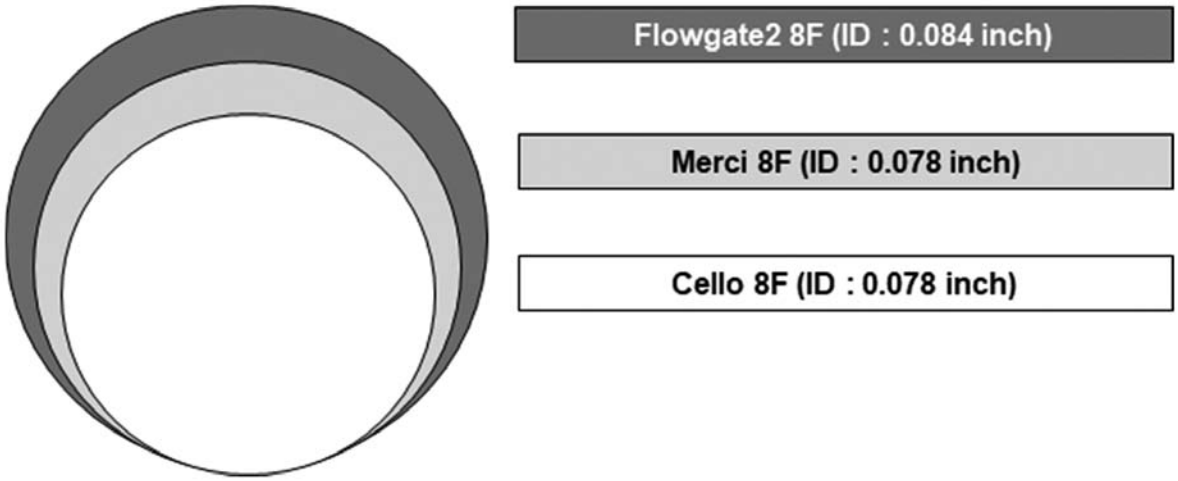

Figure 1. Comparison of the IDs of the 8 F balloon guide catheters. The Flowgate[2] has a larger ID (0.084 inch) than other BGCs, such as Merci (0.078 inch) or Cello (0.078 inch). ID, inner diameter.

P≤0.05 was considered to indicate a statistically significant difference.

Results

Baseline characteristics. The failure rate of BGC application to the proximal lesion of the target vessel was significantly lower in the FG2 group (2.5%) compared with the Merci group (10.8%; P=0.016). Overall, FG2 was successfully applied in 85 patients (48 men, 56.5%) and the Merci was used in 150 patients (81 men, 54.0%) for MT with LAO. The mean and median age of patients who underwent BGC application were 67.9 years [standard deviation (SD), 13.1] and 69.0 years (interquartile range, 22-93 years), respectively. There were no significant differences between the FG2 and Merci groups in multiple risk factors, such as hypertension, diabetes mellitus, atrial fibrillation, coronary artery disease, dyslipidemia, smoking, history of anti-platelet or anti-coagulant use and history of prior stroke/TIA. The site of arterial occlusion was as follows: (FG2: Merci) Middle cerebral artery M1 segment, 42:80; Middle cerebral artery M2 segment, 11:20; distal ICA, 11:18; proximal ICA, 9:15; and posterior circulation, 8:9). The rate of left hemispheric stroke was 44.7% (38/85) in the FG2 group and 50.0% (75/150) in the Merci group. IV t-PA was applied in 35 (41.2%) patients in the FG2 group and 65 (43.3%) patients in the Merci group. In 101 (42.9%) patients, an additional intermediate catheter was used (FG2:Merci groups, 43:61). Regarding the interventionists, 131 procedures were performed by one interventionist (A), while the other interventionist (B) performed 104 procedures. A total of 120 Solitaire and 115 Trevo retriever stents were used. There was no statistically significant difference between the two groups in multiple factors such as arterial occlusion site, left hemisphere stroke, IV t-PA, interventionists, use of intermediate catheter, and the type of retriever stent (Table I).

Outcomes and complications. The proportion of patients who achieved favorable 3-month mRS scores (mRS 0-2) was 54.1% in the FG2 group, and 50.7% in the Merci group; the difference was not statistically significant (P=0.144). In addition, there were no significant differences in the median value of procedure time between the two groups (FG2, 39 mins vs. Merci group, 48 min; P=0.208). The mean value (SD) of stent passes was 1.8 (1.1) in the FG2 group and 2.2 (1.8) in the Merci group, the difference not being statistically significant. Overall, the number of stent passes were as follows: (FG2:Merci; 1 pass, 40:61; 2 passes, 34:64; 3 passes, 5:7; >3 passes, 6:18). Successful recanalization (TICI 2b or 3) was achieved in 79 patients (92.9%) in the FG2 group and 133 patients (88.7%) in the Merci group. There were no significant differences in each TICI score (0, 1, 2a, 2b, and 3) nor the rate of successful recanalization between the groups. However, the ratio of TICI 3 recanalization with the first stent passage was significantly higher in the FG2 group (44.7%) than in the Merci group (34.7%; P=0.033). Furthermore, the FG2 group revealed a significantly higher TICI 3:2b ratio (1.93) than that in the Merci group (1.18; P=0.031). Regarding the complications, the FG2 group showed a 5.9% rate of post thrombectomy hemorrhage, 0% rate of symptomatic hemorrhage, 0% rate of vessel perforation and arterial dissection, 4.3% rate of vasospasm and 5.9% rate of mortality, compared with those of Merci group (6.7, 1.3, 0 and 0.7%, 6.0, and 7.3%, respectively). These values were not significantly different between the groups. However, the incidence rate of distal emboli in the FG2 group (4.7%) was significantly lower than that in the Merci group (7.3%; P=0.012; Table II).

Subgroup analysis and multivariate analysis. A subgroup analysis was conducted on patients in whom a BGC and an intermediate catheter had been used simultaneously; 43 patients from the FG2 group and 61 patients from the Merci group were included. Similar factors to those of the previous analysis were investigated and there were no statistically significant differences between the two groups for the majority of factors; however, the TICI 3 recanalization rate with the first stent passage and the incidence of distal emboli was significantly different in the FG2 group. The rate of first-pass TICI 3 recanalization was significantly higher in the FG2 group (46.5%) than in the Merci group (34.4%; P=0.029). Moreover, the incidence rate of distal emboli in the FG2 group was 2.3%

Table I. Baseline characteristics.

Baseline characteristics	Total, n	FG2, n	Merci, n	P-value
Patients in whom BGC application was attempted	255	87	168	-
Failure of BGC application (%)	20 (7.8)	2 (2.5)	18 (10.8)	0.016[a]
FG2 successfully applied				
Total	235	85	150	
Sex, male (%)	129 (54.9)	48 (56.5)	81 (54.0)	0.867
Mean age, years (SD)	67.9 (13.1)	68.9 (13.0)	67.2 (13.1)	0.300
Median age, years (IQR)	69.0 (22-93)	70.0 (31-92)	68.0 (22-93)	-
HTN (%)	130 (55.3)	45 (54.9)	85 (56.7)	0.340
DM (%)	91 (38.7)	33 (38.9)	58 (38.7)	0.733
AF (%)	115 (48.9)	41 (48.2)	74 (49.3)	0.351
CAD (%)	60 (25.5)	21 (24.7)	39 (26.0)	0.663
Dyslipidemia (%)	106 (45.1)	35 (41.2)	71 (47.3)	0.270
Smoking (%)	86 (36.6)	29 (34.1)	57 (38.0)	0.258
Previous anti-platelet use (%)	92 (39.1)	34 (40.0)	58 (38.7)	0.624
Previous anti-coagulant use (%)	27 (11.5)	10 (11.8)	17 (11.3)	0.385
Prior stroke or TIA (%)	31 (13.2)	12 (14.1)	19 (12.7)	0.412
Site of arterial occlusion				
M1 (%)	122 (48.8)	42 (49.4)	80 (53.3)	0.712
M2 (%)	32 (12.8)	11 (12.9)	20 (13.3)	0.883
Distal ICA (%)	30 (12.0)	11 (12.9)	18 (12.0)	0.619
Mid ICA (%)	12 (4.8)	4 (4.7)	8 (5.3)	0.596
Proximal ICA (%)	24 (9.6)	9 (10.6)	15 (10.0)	0.601
Posterior circulation (%)	18 (7.2)	8 (9.4)	9 (6.0)	0.201
Others				
Occlusions in the left hemisphere (%)	113 (48.1)	38 (44.7)	75 (50.0)	0.696
t-PA (%)	100 (42.6)	35 (41.2)	65 (43.3)	0.418
Use of intermediate catheter (%)	101 (42.9)	43 (50.6)	61 (40.7)	0.230
Interventionists, A:B	131:104	49:36	82:68	0.423
Retriever stent, Solitaire:Trevo	120:115	40:45	80:70	0.515

P-values were calculated using χ^2 or student's t-test. [a]P<0.05. FG2, FlowGate^2; BGC, balloon guide catheter; SD, standard deviation; IQR, interquartile range; HTN, hypertension; DM, diabetes mellitus; AF, atrial fibrillation; CAD, coronary artery disease; TIA, transient ischemic attack; M1, middle cerebral artery M1 segment; M2, middle cerebral artery M2 segment; ICA, Internal carotid artery; t-PA, tissue-plasminogen activator.

(only 1 patient), which was statistically significantly lower than that in the Merci group (6.6%; P=0.038; Table III). In the multivariate analysis models, two factors were associated with a decrease in distal emboli: The use of an intermediate catheter [odds ratio (OR), 0.75; 95% confidence interval (CI), 0.66-0.94; P=0.029], and the use of the FG2 BGC (OR 0.59; 95% CI 0.25-0.93, P=0.020) significantly reduced the incidence rate of distal emboli (Table IV).

Discussion

The FG2 has been demonstrated to have less stiffness and improved trackability compared with the prior version of BGC, thus it facilitates smooth delivery to the distal cervical and proximal petrous segment of the ICA (14). These characteristics of the FG2 BGC allow it to function more effectively, resulting in greater reversal of proximal flow when administered at a more distal location. In the present study, the FG2 BGC demonstrated a lower application failure rate and incidence of distal emboli, whilst also exhibiting a higher percentage of TICI 3 recanalization in the first stent passage and a higher TICI 3:2b ratio, compared with the Merci BGC. Failure of FG2 application in the proximal lesion of the target vessel occurred in two cases (2.5%) due to severe tortuosity and angulation of the aorta. There is a lack of literature detailing BGC application failure, making direct comparisons between FG2 and other BGCs problematic. In addition, the 2.5% failure rate of FG2 in the present study was significantly lower than that of the Merci (10.8%). Better accessibility and trackability of the FG2 may have resulted in the lower application failure rate that for the Merci device. In fact, the authors regularly experienced a failure to approach the proximal lesion of the target vessel when using the Merci device, and often could not overcome the tortuosity of the aorta due to its poor

Table II. Outcomes, procedure time, number of passes and complications.

Outcome measured	FG2, n	Merci, n	P-value
Favorable 3-month mRS (%)	46 (54.1)	76 (50.7)	0.144
Median procedure time, min (IQR)	39 (16-91)	48 (17-115)	0.208
Number of passes, mean (SD)	1.8 (1.1)	2.2 (1.8)	0.081
1 (%)	40 (47.1)	61 (40.7)	
2 (%)	34 (40.0)	64 (42.7)	
3 (%)	5 (5.9)	7 (4.7)	
> 3 (%)	6 (7.1)	18 (12.0)	
TICI score (%)			
0	0 (0)	7 (4.7)	0.611
1	2 (2.3)	5 (3.3)	0.427
2a	5 (5.9)	5 (3.3)	0.211
2b	27 (31.8)	61 (40.7)	0.122
3 (%)	52 (61.2)	72 (48.0)	0.074
Successful recanalization (%)	79 (92.9)	133 (88.7)	0.226
First-pass recanalization with TICI 3	38 (44.7)	52 (34.7)	0.033[a]
TICI 3 to 2b ratio (TICI 3/TICI 2b)	1.93	1.18	0.031[a]
Complications			
Post thrombectomy hemorrhage (%)	5 (5.9)	10 (6.7)	0.462
Symptomatic hemorrhage (%)	0 (0)	2 (1.3)	0.182
Vessel perforation (%)	0 (0)	0 (0)	0.727
Arterial dissection (%)	0 (0)	1 (0.7)	0.422
Vasospasm (%)	3 (4.3)	9 (6.0)	0.102
Distal emboli (%)	3 (4.7)	11 (7.3)	0.012[b]
Mortality (%)	5 (5.9)	11 (7.3)	0.326

[a]P<0.05 (t-test); [b]P<0.05 (χ^2 test). FG2, FlowGate^2; mRS, modified Rankin scale; Favorable mRS, 90 days; mRS ≤2; IQR, interquartile range; TICI, Thrombolysis in Cerebral Infarction scores; Successful recanalization, TICI 2b or 3.

flexibility and trackability. In particular, flexible and trackable BGCs may be beneficial for older patients, as they tend to have increased vessel tortuosity. Therefore, in terms of accessibility, the FG2 may be more useful than the Merci, considering the recent increasing trend of elderly patients undergoing MT.

In the present study, there was no significant difference between the FG2 and Merci groups in terms of favorable mRS, procedure time, mean number of stent passages and successful recanalization. The FG2 used exhibited acceptable recanalization rates (92.9%), TICI 3 recanalization with the first passage (44.7%) and procedure time (39 min) compared with previous studies of other BGCs; for example, Telebs *et al* (14) reported values for each of these categories of 94, 47%, and 38.7 min, respectively, using an FG2 device. In previous studies using other BGCs (such as the Merci or Cello), varying values of successful recanalization rate (85-95%) and procedure time (24-69 min) have been reported (9-11,13). The variation in these values may have resulted from differences in factors between each study, such as the baseline characteristics, use of an additional intermediate catheter, and thrombectomy devices or techniques used. However, the FG2 group of the present study indicated non-inferior results in clinical and radiological outcomes compared with previous studies.

The BGC allows for effective MT with an increased possibility of clot removal and reduced distal emboli, via proximal blood flow arrest and increasing suction effectiveness (9,10,18). The effect of proximal blood flow control in FG2 and Merci is considered to be the same, because they have same 8 F outer diameter and balloon size; however, the incidence rate of distal emboli was significantly lower in the FG2 group compared with the Merci group, and the use of FG2 was revealed to be associated with reduced distal emboli in the multivariate analysis. The 4.7% distal emboli occurrence rate in the FG2 group was lower than that (6.8-25.0%) reported in other studies with other BGC types, such as the Merci or Cello (12,13). The increased aspiration power due to the larger inner diameter (ID) of the FG2 (0.084 inch), compared with that of the Merci (0.078 inch) may have contributed to this result. Furthermore, the higher ratio of TICI 3 at the first stent passage and TICI 3:2b ratio in the FG2 group compared with the Merci group may be associated with the improved aspiration power of the FG2. Recently, the importance of a first pass effect (FPE) has been emphasized, and the FPE yielded a good clinical outcome with a short procedure time (19). In the present study, the improved mRS score and procedure time did not significantly differ between the FG2 and Merci groups, but the TICI 3 achievement at the first stent passage of the FG2

Table III. Subgroup analysis of concomitant use of BGC and an intermediate catheter.

Factor	FG2, n	Merci, n	P-value
Total	43	61	-
Retriever stent (Solitaire:Trevo)	(16:27)	(21:40)	-
Favorable mRS (%)	22 (51.2)	33 (54.1)	0.662
Procedure time, min (IQR)	37 (16-86)	49 (17-99)	0.108
Number of passes, mean (SD)	1.8 (1.0)	2.0 (1.2)	0.482
1 (%)	21 (48.8)	26 (42.6)	
2 (%)	18 (41.8)	26 (42.6)	
3 (%)	2 (4.7)	4 (6.6)	
>3 (%)	2 (4.7)	5 (4.9)	
TICI score			
2b (%)	15 (34.9)	23 (37.7)	0.422
3 (%)	25 (58.1)	32 (52.5)	0.174
Successful recanalization (%)	40 (93.0)	55 (90.2)	0.213
First-pass recanalization with TICI 3	20 (46.5)	21 (34.4)	0.029[a]
TICI 3 to 2b ratio (TICI 3/TICI 2b)	1.67	1.39	0.318
Distal emboli (%)	1 (2.3)	4 (6.6)	0.038[a]

[a]P<0.05 (χ^2 test). BGC, balloon guide catheter; FG2, FlowGate^2; IQR, interquartile range; mRS, Modified Rankin Scale; Favorable mRS, 90 days mRS ≤2; Successful recanalization, TICI 2b or 3; TICI, Thrombolysis in Cerebral Infarction scores.

Table IV. Factors for predicting the occurrence of distal emboli.

	Univariate analysis		Multivariate analysis	
Factor	OR (95% CI)	P-value	OR (95% CI)	P-value
Sex	0.78 (0.50-1.72)	0.715	-	-
Hypertension	0.82 (0.23-2.02)	0.550	-	-
Diabetes mellitus	1.24 (0.28-4.20)	0.932	-	-
Atrial fibrillation	2.55 (0.80-7.04)	0.724	-	-
Dyslipidemia	0.85 (0.40-3.22)	0.478	-	-
Smoking	3.33 (0.71-9.43)	0.947	-	-
Anti-platelet use	0.88 (0.40-4.00)	0.235	-	-
Anti-coagulant use	1.74 (0.63-3.43)	0.494	-	-
Tissue-plasminogen activator	3.10 (0.59-9.12)	0.721	-	-
Interventionists	0.84 (0.44-1.79)	0.727	-	-
Stent type	1.68 (0.33-4.25)	0.602	-	-
Single passage of stent	0.88 (0.53-3.85)	0.601	-	-
Use of intermediate catheter	0.78 (0.64-0.92)	0.041[a]	0.75 (0.66- 0.94)	0.029[a]
Use of FlowGate^2	0.68 (0.44-0.92)	0.030[a]	0.59 (0.25-0.93)	0.020[a]

[a]P<0.05. OR, odds ratio; CI, confidence interval.

group was higher than that of the Merci group. This result also demonstrates the advantage of the FG2 in improving the FPE, via facilitation of improved aspiration power due to a larger ID compared with that of the Merci.

The enlarged inner lumen of the FG2 allowed for concomitant use of intermediate large-bore aspiration catheters for salvage techniques, as well as increased aspiration power. In previous studies, the use of an intermediate catheter and the 'Solumbra technique' have been reported to result in better clinical and radiological outcomes (20,21). Moreover, in the present study, the multivariate analysis revealed that the use of an intermediate catheter reduced the occurrence of distal emboli. Thus, subgroup analysis with concomitant use of a BGC and intermediate catheter was conducted and

indicated that the FG2, when used with an intermediate catheter, resulted in a higher TICI 3 recanalization ratio at the first stent passage and lower incidence rate of distal emboli compared with the Merci used with an intermediate catheter. This indicates that better results can be obtained with FG2 than with Merci, even with concomitant use of BGCs and an intermediate catheter.

The major limitations of this study are its relatively small population size and its retrospective nature. In addition, MT using the Merci BGC was performed before the use of the FG2; therefore, it may be assumed that habituation to the experimental procedure and increased experience and practice may have skewed the results towards the FG2 device. However, all procedures in this study were performed by two neuro-interventionists with >5 years of experience, both of whom perform at least 50 MT procedures annually. Baseline characteristics in the two groups were well-balanced, with no statistically significant differences. Thus, any between-group differences associated with a learning curve would not represent an important consideration. Finally, although every effort was made to control for potential confounding variables, potential confounding variables (including device selection and interpretation of angiographic images), considering the observational nature of the study, the potential effect of variables not accounted for cannot be ignored.

In conclusion, FG2 BGC enables effective stent retrieval MT with a lower application failure rate, lower incidence of distal emboli and higher TICI 3 recanalization at the first stent passage, compared with the Merci BGC. The FG2 may be suitable for MT with little application failure as a result of its good accessibility and trackability in tortuous vessels, and FG2 may induce aggressive aspiration and contribute to the reduction of distal embolus incidence due to its large luminal size. In addition, improved outcomes may also be facilitated by simultaneous use of the FG2 BGC and an intermediate catheter. Additional multicenter studies and randomized controlled trials should be performed to verify the present findings.

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Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Authors' contributions

HJY and DHL designed the study. HJY, DHL and JHS performed data acquisition, analysis, interpretation of the data and drafting of the manuscript. HJY carried out statistical analysis. DHL supervised the study. HJY, DHL, JHS checked the integrity of the data and accuracy of the data analysis. All authors read and approved the final manuscript.

Ethical approval and consent to participate

The present study was approved by the local ethical committee and institutional review board (IRB No. VC18RESI0027). Informed consent was obtained from all patients.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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