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Effect of Drug-Coated Balloon Versus Stent Angioplasty in Patients With Symptomatic Intracranial Atherosclerotic Stenosis

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BACKGROUND AND OBJECTIVES: Drug-coated balloons (DCBs) have exhibited promising results in coronary and peripheral artery diseases, but conclusive evidence is lacking in intracranial vasculature. We assessed the safety and efficacy of DCBs vs stent angioplasty for symptomatic intracranial atherosclerotic stenosis (sICAS) and initially identified patients who might have benefited most from DCB treatment.

METHODS: A single-center, retrospective cohort study was conducted from June 2021 to May 2022 with 154 patients with sICAS divided into 2 treatment groups: a DCB group (with or without remedial stenting, n = 47) and a stent group (n = 107). The treatment outcomes were compared using 1:2 propensity score matching. The primary safety end point was perioperative stroke or mortality, and the primary efficacy end point was the rate of target vessel restenosis at 12 months. The degree of luminal change was analyzed as a subgroup, defined as the difference between the degree of stenosis at follow-up and immediately after intervention.

RESULTS: One hundred eighteen patients were enrolled using propensity score matching, with 43 patients in the DCB group and 75 in the stent group. The incidence of perioperative adverse events was 2.3% in the DCB group and 8.0% in the stent group ($P = .420$). At a median follow-up of 12 months, the incidence of restenosis (11.9% [5/43] vs 28.0% [21/75], $P = .045$) and the median degree of stenosis (30% [20%, 44%] vs 30% [30%, 70%], $P = .009$, CI [0-0.01, 0.2]) were significantly lower in the DCB group than in the stent group. DCB angioplasty effectively prevented adverse events in the target vessel area and significantly reduced the degree of luminal change in the M1 segment of the middle cerebral artery (0 [0, 15%] vs 10% [0, 50%], $P = .016$).

CONCLUSION: DCB angioplasty might be a safe and effective alternative to stent angioplasty to treat sICAS, particularly among patients with M1 segment of the middle cerebral artery stenosis.

KEY WORDS: Angioplasty and stenting, Drug-coated balloon, Intracranial atherosclerosis stenosis, Restenosis

Intracranial atherosclerotic stenosis (ICAS) is the leading cause of ischemic stroke worldwide, accounting for 46.6% to 54% of cases in Asian populations.[1,2] Patients with symptomatic ICAS (sICAS) with inadequate hemodynamics have a one-year stroke recurrence rate of up to 37% and do not benefit from medical therapy.[3] Currently, stent angioplasty is a relatively safe alternative treatment for such patients.[4] However, a high rate of long-term in-stent restenosis (ISR) results in an increased risk of recurrent ischemic events, severely limiting stent angioplasty efficacy.[5,6]

Recent studies have revealed that drug-coated balloons (DCBs) effectively prevent ISR[7] and are superior to stent angioplasty in treating patients with sICAS.[8,9] At present, DCBs and drug-eluting stents are designed to reduce ISR by inhibiting the proliferation and migration of endothelial cells and smooth

ABBREVIATIONS: DAPT, dual antiplatelet treatment; **DCBs,** drug-coated balloons; **ICAS,** intracranial atherosclerotic stenosis; **ISR,** in-stent restenosis; **MCA-M1,** M1 segment of the MCA; **PSM,** propensity score matching; **sICAS,** symptomatic ICAS.

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muscle cells after local angioplasty.[10-12] After the drug is released, the DCB is immediately removed from the blood vessel without leaving a permanent foreign implant in the body, which may be the most promising treatment. This study reported the results of DCB and stent angioplasty for sICAS.

METHODS

Study Population

This study was approved by the Institutional Review Board of our institution and adhered to the Declaration of Helsinki. Patients in the DCB group or their authorized family members understood the risks and benefits of DCB angioplasty, including the off-label use of the DCB, and gave informed consent before the procedure. For patients in the stent group, the Committee waived the requirement for informed consent because of the retrospective study design. Based on inclusion and exclusion criteria,[13] clinical and imaging data from 154 patients with sICAS treated with DCB or stent angioplasty between June 2021 and May 2022 were retrospectively collected from our prospective stroke intervention database. The study flowchart is shown in Figure 1.

Procedures

All procedures were performed under general anesthesia. Transfemoral or transradial access was established under systemic heparinization according to the preoperative assessment. The intermediate catheter was placed high, superselectively. The microcatheter and micro-guidewire were combined to cross the target lesion with subsatisfactory predilatation, passing through the retained guidewire and using a plain balloon (Gateway Balloon, Boston Scientific). Successful predilatation was defined as a forward flow of thrombolysis in cerebral infarction grade 3, residual stenosis ≤50% after 5 minutes, and unrestricted flow dissection. In the DCB group, DCB (the paclitaxel coating on the surface of the balloon) was introduced again and, after positioning, slowly inflated to cover the entire lesion and maintained with nominal pressure for at least 60 seconds. After removing the DCB (Yinyi [Liaoning] Biotech Co., Ltd.) for 5 minutes, angiography was performed to assess the treatment result. The procedure was terminated when the residual stenosis was ≤50%, and a thrombolysis in cerebral infarction grade 3 of forward blood flow was observed. Failure of DCB dilatation or flow-limiting dissection after DCB dilatation was treated with a permanent stent implantation based on the operator's experience. The stent delivery catheter system (Prower21 Catheter or XT27 Catheter) was introduced in the stent group. Then, the self-expanding stent (Enterprise Stent or Neuroform Stent) was introduced and released after

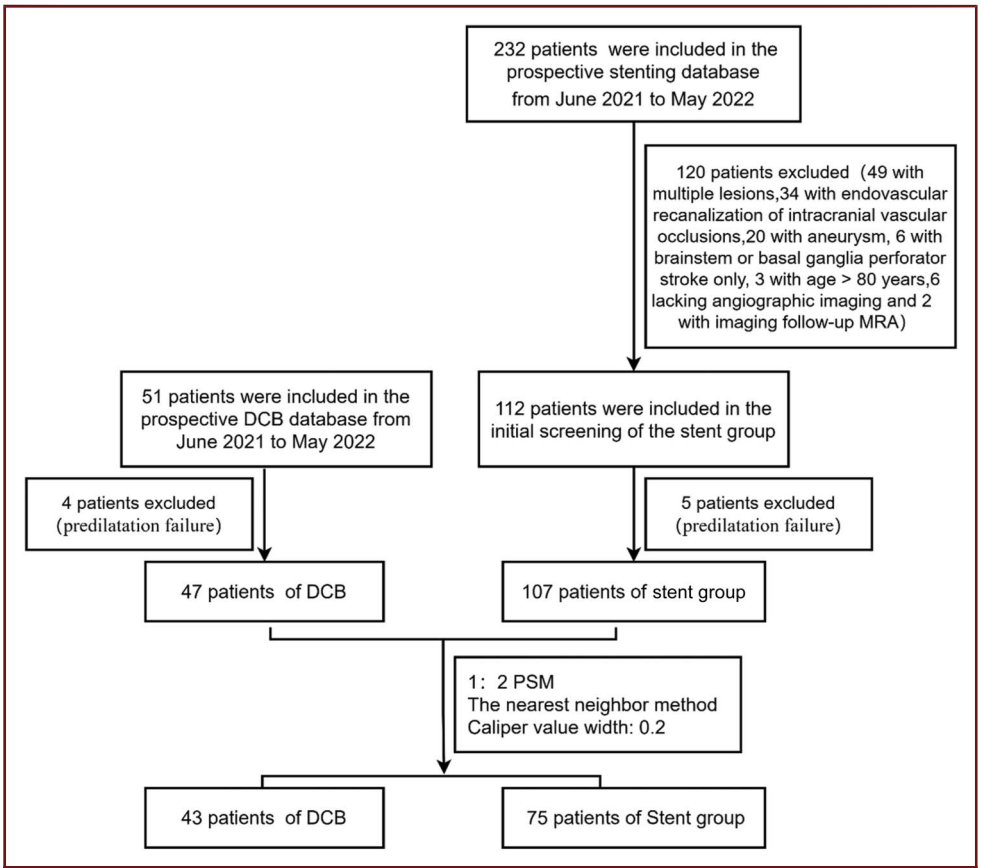

FIGURE 1. *Both groups were included in the flowchart. This figure is original to this submission so no credit or license is needed. DCB, drug-coated balloon; MRA, magnetic resonance angiography; PSM, propensity score matching.*

TABLE 1. Characteristics of Patients Before and After Matching Between the 2 Groups

Characteristics	Before PSM			After PSM		
	DCB group (n = 47)	Stent group (n = 107)	*P* value	DCB group (n = 43)	Stent group (n = 75)	*P* value
Demographic data						
Age, years (mean ± SD)	54.3 ± 10.5	59.0 ± 10.2	.011	55.3 ± 10.0	56.4 ± 9.9	.575
Sex, %			.204			.249
Male	36 (76.6)	71 (66.4)		33 (76.7)	50 (66.7)	
Female	11 (23.4)	36 (33.6)		10 (23.3)	25 (33.3)	
Medical history, %						
Diabetes mellitus	13 (27.7)	38 (35.5)	.340	11 (25.6)	26 (34.7)	.306
Hypertension	32 (68.1)	73 (68.2)	.986	30 (69.8)	52 (69.3)	.961
Hyperlipidemia	29 (61.7)	60 (56.1)	.515	25 (58.1)	42 (56.0)	.821
Hyperhomocysteinemia	15 (31.9)	32 (29.9)	.803	15 (34.9)	22 (29.3)	.532
Coronary artery disease	4 (8.5)	12 (11.2)	.777	4 (9.3)	9 (12.0)	.767
Smoking history, %			.121			.236
Never	22 (46.8)	61 (57.0)		20 (46.5)	46 (61.4)	
Current	19 (40.4)	26 (24.3)		17 (39.5)	19 (25.3)	
Former	6 (12.8)	20 (18.7)		6 (14.0)	10 (13.3)	
Alcohol history, %			.379			.274
Never	24 (51.1)	64 (59.8)		21 (48.8)	47 (62.7)	
Current	19 (40.4)	31 (29.0)		18 (41.9)	21 (28.0)	
Former	4 (8.5)	12 (11.2)		4 (9.3)	7 (9.3)	
Stenosis location, %			.384			.467
Intracranial ICA	9 (19.1)	22 (20.6)		9 (20.9)	15 (20.0)	
MCA-M1	26 (55.3)	48 (44.9)		22 (51.2)	33 (44.0)	
Intracranial VA	3 (6.4)	17 (15.9)		3 (7.0)	13 (17.3)	
BA	9 (19.1)	20 (18.7)		9 (20.9)	14 (18.7)	
Qualifying event, %			.894			.897
Stroke	36 (76.6)	83 (77.6)		32 (74.4)	55 (73.3)	
TIA	11 (23.4)	24 (22.4)		11 (25.6)	20 (26.7)	
Periprocedural characteristics						
Late ischemic event to the procedure, d, median (P25, P75)	22 [16, 31]	21 [17, 30]	.804	21 [15, 30]	21 [16, 30]	.446
Degree of stenosis before intervention, %, median (P25, P75)	90 [80, 90]	85 [80, 90]	.308	90 [80, 90]	85 [80, 90]	.827
Stenosis length, mm, median (P25, P75)	8 [6, 10]	7.2 [5.3, 9.7]	.705	8 [6, 10]	6.8 [5.1, 9.6]	.496
Degree of stenosis immediately after intervention, %, median (P25, P75)	25 [20, 30]	20 [20, 28]	.016	25 [20, 30]	20 [20, 30]	.425

BA, basilar artery; DCB, drug-coated balloon; Intracranial ICA, intracranial internal carotid artery; Intracranial VA, intracranial vertebral artery; MCA-M1, M1 segment of the middle cerebral artery; PSM, propensity score matching; TIA, transient ischemic attack.

accurate positioning. Stent implantation did not require a prepositioned catheter and was delivered directly to the target lesion with slow pressure expansion and deformation. Subsatisfactory dilation ranged from 70% to 90% of the target vessel diameter. The choice of standard glycoprotein IIa/IIIa inhibitor or intraoperative agent was used at the operator's discretion.

Patients with sICAS received preoperative dual antiplatelet treatment (DAPT), including aspirin 100 mg/d and clopidogrel 75 mg/d for at least 5 days, and a clopidogrel 300 mg loading dose if the treatment duration was <5 days. After the operation, patients without stent implantation received DAPT for 3 months. Patients with stent implantation received DAPT for 3 to 6 months, followed by aspirin (100 mg/d) long-term. All patients received atherosclerosis risk factor management and standard medical therapy before and after surgery.

Data Collection and Follow-up Outcomes

Demographic, clinical, and angiographic data were collected. All patients were followed clinically or by telephone at 1, 3, and 6 months, 1 year, and every year after that. Digital subtraction angiography or computed tomography angiography was performed at 6 months and 1 year after the procedure.

The primary safety end point was perioperative stroke or mortality. The primary efficacy end point was the one-year rate of restenosis (defined as greater than 50% stenosis of the luminal diameter in or within 5 mm of the treatment segment and absolute luminal loss >20%). Secondary end point events included technical success rate (defined as <50% residual stenosis of the target vessel after DCB [with/without remedial stent] or stent angioplasty), technical success rate of DCB angioplasty (defined as residual stenosis <50% after DCB angioplasty and no remedial stent), recurrent ischemic events (defined as ischemic stroke in the territory of the target vessel after perioperative), symptomatic restenosis (defined as restenosis associated with an ischemic event in the region), degree of stenosis and modified Rankin Scale (mRS) score at the last follow-up, and adverse events in the target vessel area (the compound end point of perioperative stroke or mortality and recurrent ischemic events). Two investigators reviewed all imaging and clinical outcomes. Disagreements were resolved by consensus.

Statistical Analysis

Statistical analyses were performed using R 4.3.2 (R Foundation for Statistical Computing). Propensity score matching (PSM) was used to adjust the baseline characteristics of the DCB and stent groups. For PSM, 1:2 matching was performed based on the nearest-neighbor matching algorithm using a caliper width of 0.2 of the propensity score. Age and residual stenosis degree after intervention were assessed as covariates. The

TABLE 2. Clinical and Imaging Follow-up Outcomes of the Matched Patients

Follow-up outcomes	DCB group (n = 43)	Stent group (n = 75)	*P* value [95% CI]
Follow-up period, m, median (P25, P75)	12 [11, 13]	12 [9, 13]	.464 [−2.72, <0.01]
Primary safety end point, %			
Periprocedural complications	1 (2.3)	6 (8.0)	.420
Ischemic stroke	0	4 (66.7)	
Hemorrhagic stroke	0	2 (33.3)	
Death	1 (2.3)	0	
Primary efficacy end point, %			
Restenosis	5 (11.9)	21 (28.0)	.045
Intracranial ICA	0	4 (5.3)	
MCA-M1	2 (4.8)	10 (13.4)	
Intracranial VA	0	4 (5.3)	
BA	3 (7.1)	3 (4.0)	
Secondary end point events			
Technical success, %	43 (100)	75 (100)	NA
Recurrent ischemic events, %	2 (4.8)	10 (13.3)	.207
Symptomatic restenosis, %	2 (4.8)	8 (10.7)	.327
Degree of stenosis at the last imaging follow-up, %, median (P25, P75)	30 [20, 44]	30 [30, 70]	.009 [0-0.01, 0.2]
mRS score at the last clinical follow-up, median (P25, P75)	1 [0, 1]	1 [0, 1]	.725 [>−0.01, <0.01]

BA, basilar artery; DCB, drug-coated balloon; Intracranial ICA, intracranial internal carotid artery; Intracranial VA, intracranial vertebral artery; MCA-M1, M1 segment of the middle cerebral artery; mRS, modified Rankin Scale; NA, Not Available.

Kaplan–Meier method and the log-rank test were used to analyze the primary end points. All statistical tests were bilateral, and *P*-values < .05 were considered statistically significant.

RESULTS

Study Population and Baseline Characteristics

Fifty-one patients were enrolled in the DCB group, and 232 patients were enrolled in the stent group between June 2021 and May 2022. After the initial screening, 120 patients were excluded from the stent group, including 49 with multiple lesions, 34 with endovascular recanalization of the intracranial artery occlusion, 20 with aneurysm, 6 with brainstem or basal ganglia perforator stroke only, 3 older than 80 years, 6 with no angiographic imaging follow-up, and 2 with only magnetic resonance angiography imaging follow-up. Four patients in the DCB group and 5 in the stent group were excluded because of predilatation failure. The study flowchart is illustrated in Figure 1. Ultimately, 154 patients were enrolled, 47 in the DCB group and 107 in the stent group. After PSM, 118 patients were matched, 43 in the DCB group and 75 in the stent group.

Before PSM, significant differences were observed between the DCB and stent groups regarding age (54.3 ± 10.5 vs 59.0 ± 10.2, $P = .011$) and residual stenosis degree after the intervention (25% [20%, 30%] vs 20% [20%, 28%], $P = .016$). After PSM, the baseline and periprocedural characteristics were balanced between the 2 groups (Table 1).

Perioperative Outcomes

The rate of perioperative stroke or mortality was higher in the stent group than in the DCB group (8.0% [6/75] vs 2.3% [1/43], $P = .420$) (Table 2). There were 4 ischemic events (66.7%), 2 hemorrhagic events (33.3%), and no deaths in the stent group. One patient in the DCB group died of acute myocardial infarction. Detailed perioperative complications are shown in the **Supplementary Table**, http://links.lww.com/ONS/B115.

The technical success rate for both groups was 100% (Figure 2), 43 in the DCB group (Figure 2A-2C) and 75 in the stent group

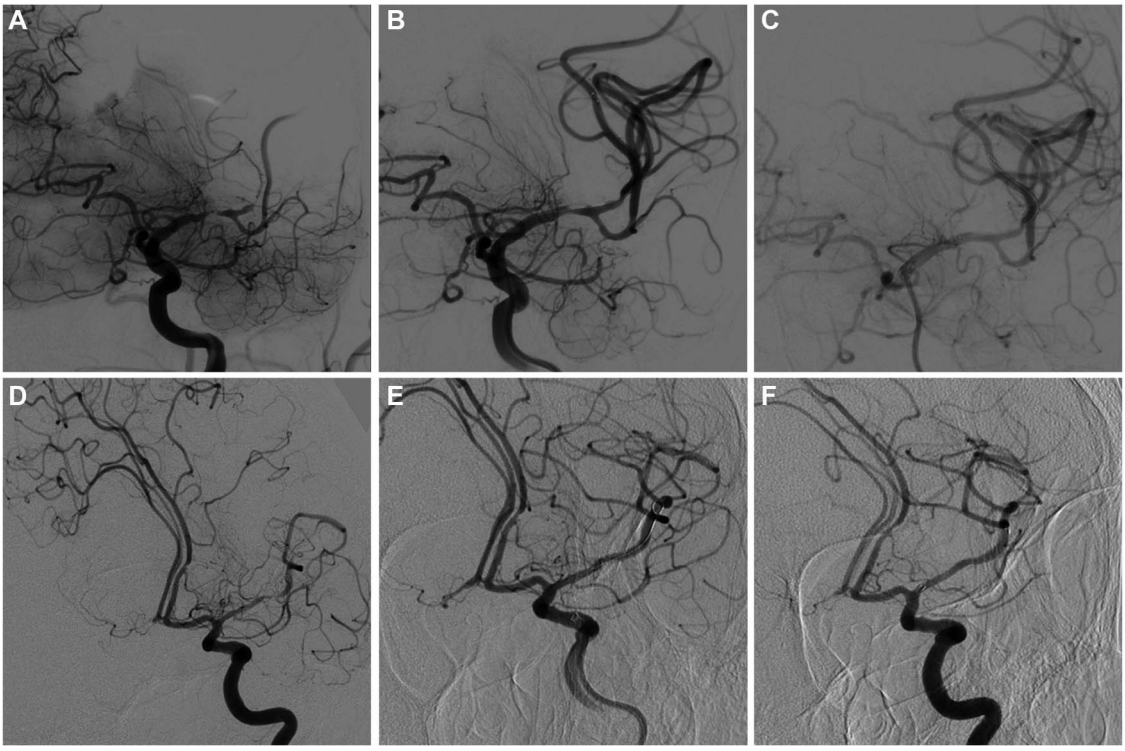

FIGURE 2. *Examples of DCB or stent angioplasty for patients with sICAS. (**A**, **B**, **C**) The first row shows DCB angioplasty images. **A**, Severe stenosis of the left MCA M1 segment. **B**, Angiographic result after successful predilatation. **C**, After DCB angioplasty. (**D**, **E**, **F**) The second row shows stent angioplasty images. **D**, Severe stenosis of the left MCA M1 segment. **E**, Angiographic result after successful predilatation. **F**, After stent angioplasty. This figure is original to this submission so no credit or license is needed. DCB, drug-coated balloon; MCA-M1, M1 segment of the middle cerebral artery; sICAS, symptomatic intracranial atherosclerotic stenosis.*

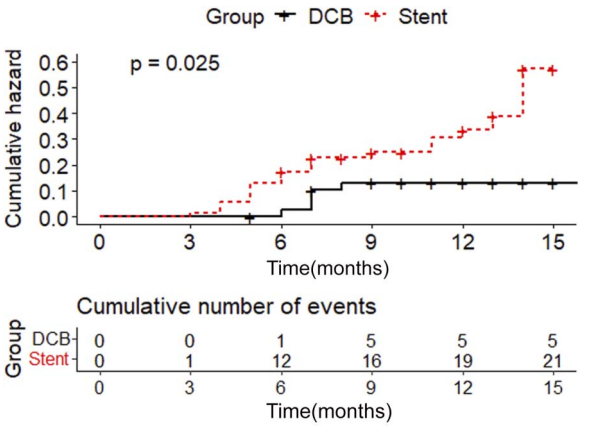

FIGURE 3. *Kaplan–Meier curve for the cumulative probability of restenosis during the follow-up. This figure is original to this submission so no credit or license is needed. DCB, drug-coated balloon.*

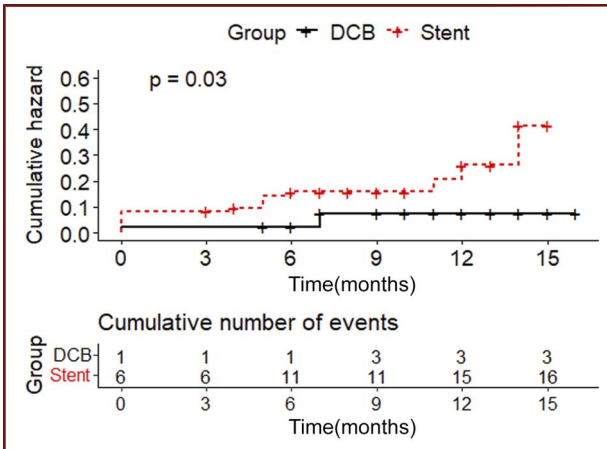

FIGURE 4. *Kaplan–Meier curve for cumulative probability of stroke and death within 30 d and recurrent stroke beyond 30 d in the corresponding territory. This figure is original to this submission so no credit or license is needed. DCB, drug-coated balloon.*

(Figure 2D-2F). In the DCB group, 8 patients underwent remedial stenting implantation (6 dissections, 1 residual stenosis >50%, and 1 thrombosis) and vascular dissection occurred in 7 patients. The technical success rate of the DCB angioplasty was 81.4%.

Long-Term Outcomes

The median follow-up time for patients in both groups was 12 months. The total restenosis incidence (11.9% [5/42] vs 28.0% [21/75], P = .045) and median degree of stenosis (30% [20%, 44%] vs 30% [30%, 70%], P = .009, CI [0-0.01, 0.2]) were significantly lower in the DCB group than in the stent group (Table 2). Two patients in the DCB group exhibited restenosis in the M1 segment of the middle cerebral artery (MCA-M1), and the remainder were in the basilar artery. The MCA-M1 (13.4%) presented the highest restenosis rate in the stent group, followed by the intracranial internal carotid artery and vertebral artery (both 5.3%), whereas the basilar artery (4.0%) was the lowest.

While the incidence of recurrent ischemic events (4.8% [2/42] vs 13.3% [10/75], P = .207) and symptomatic restenosis (4.8% [2/42] vs 10.7% [8/75], P = .327) revealed a tendency to be lower in the DCB group than in the stent group during the follow-up, no statistical difference was observed. Unfortunately, 2 patients experienced stent thrombosis in the stent group during follow-up. No significant differences were observed in clinical outcomes between the 2 groups based on the mRS score. A median mRS of 1 (0, 1) was observed for both DCB and stent patients (P = .725).

Kaplan-Meier curves (Figures 3 and 4) indicated that the cumulative incidence of the restenosis (12% vs 28% at a 1-year follow-up; P = .025) and adverse events in the target vessel area (7% vs 23% at a 1-year follow-up; P = .03) were lower among patients with sICAS in the DCB group compared with the stent group. The incidence of restenosis peaked in both groups 6 to 7 months after the procedure. No new restenosis was observed in the DCB group, whereas in the stent group, restenosis continued to occur and was accompanied by symptoms specific to the target vessel territory, especially after 11 months.

Patient Benefits

We compared the anterior and posterior circulations separately (Tables 3 and 4). We found that the degree of luminal change of MCA-M1 (0 [0, 15%] vs 10% [0, 50%], P = .016) was significantly lower in the DCB group than in the stent group. DCB angioplasty seemed to be more effective than stent angioplasty for intracranial internal carotid artery (5% [0, 11%] vs 20% [10%, 45%], P = .077), but the differences were not statistically significant. There was no difference between DCB and stent angioplasty in the posterior circulation.

DISCUSSION

This study examined the safety and efficacy of DCB or stent angioplasty in patients with sICAS who were followed for 1 year. In comparison with stent angioplasty, the results were as follows: (1) DCB treatment significantly decreased the incidence and degree of restenosis, (2) DCB angioplasty significantly reduced the degree of MCA-M1 luminal changes, and (3) DCB treatment significantly decreased the incidence of adverse events in the target vessel area.

ISR is a critical factor for evaluating long-term treatment outcomes and a major reason for the recurrence of stroke after stent angioplasty.[5,6] The exact mechanism of ISR remains unclear, but it is believed to result from an inflammatory response to

TABLE 3. The Degree of Luminal Change in the Anterior Circulation

Location	DCB group (n = 30)	Stent group (n = 48)	*P* value
Intracranial ICA, %, median (P25, P75)	5 [0, 11]	20 [10, 45]	.077
MCA-M1, %, median (P25, P75)	0 [0, 15]	10 [0, 50]	.016
P value	.487	.488	

DCB, drug-coated balloon; Intracranial ICA, intracranial internal carotid artery; MCA-M1, M1 segment of the middle cerebral artery.

the implanted stent by the vascular wall, leading to excessive intimal hyperplasia.[14] Both DCB and drug-eluting stent currently reduce the incidence of ISR by releasing the antiproliferative drugs to reduce inflammation and inhibit excessive neointimal formation.[12,15] However, DCB is an emerging field of research with the advantage of "intervention without implantation." The coronary and peripheral artery literature has demonstrated the long-term efficacy of DCB angioplasty for de novo lesions.[16,17] However, limited data are available regarding the safety and efficacy of DCB in patients with sICAS.

Strict lesion preparation was performed in our study before DCB or stent angioplasty. Patients with successful predilatation were screened to reduce the occurrence of complications. The perioperative complication rate in the DCB group was lower than that in the stent group. However, the risk of perioperative stroke or death was higher in the stent group compared with previous randomized trials[18] and the onset of symptoms was earlier, possibly because only 2 weeks had elapsed between the last ischemic event and the procedure. Appropriate timing of treatment is critical to reduce the risk of perioperative complications. Ischemic stroke was the dominant perioperative adverse event in this study. The enrichment of perforator vessels in narrow vessels was a major contributing factor. Fragility of the perforator vessels or displacement of atherosclerotic debris that was "snow-plowed" over the perforator origins during stent placement[7] was associated with higher rates of treatment-related complications. In addition, the radial force of the stent[19] and operator[18] need to be considered.

TABLE 4. The Degree of Luminal Change in the Posterior Circulation

Location	DCB group (n = 12)	Stent group (n = 27)	*P* value
Intracranial VA, %, median (P25, P75)	15 [7, 28]	10 [0, 35]	.835
BA, %, median (P25, P75)	0 [0, 40]	10 [0, 29]	.791
P value	.692	.764	

BA, basilar artery; DCB, drug-coated balloon; Intracranial VA, intracranial vertebral artery.

Compared with stent angioplasty, DCB angioplasty markedly reduced the restenosis incidence and stenosis degree at 1 year after the initial procedure. This was consistent with the findings of Zhang et al,[9] but the results were higher in this study. These were probably due to the high degree of stenosis remaining after the procedure (concept of "subsatisfactory angioplasty"). Meanwhile, DCB angioplasty exhibited excellent results in decreasing the incidence of adverse events in the target vessel area; however, the stent group showed a gradual increase during the follow-up. Interruption of antiplatelet therapy in the stent group during the pandemic was most likely responsible for this. Unlike stent angioplasty, DCB does not use a permanent implant, shortening the duration of postoperative antiplatelet treatment, reducing the incidence of postoperative bleeding events, and reducing the risk of stent thrombosis.[20]

Our subgroup analysis suggested that the MCA-M1 might be more suitable for DCB treatment compared with stent angioplasty, which has not been previously reported in the literature. Several explanations are possible. First, calcification can interfere with the absorption of antiproliferative drugs, limiting the effectiveness of DCB angioplasty.[21] The MCA has the lowest incidence of calcification among the intracranial arteries.[22] Second, the unique anatomical structure of intracranial arteries (thin adventitia, few elastic fibers, and no external elastic lamina[23]), along with the lowest calcification rate of the MCA,[22] results in the low incidence of MCA vascular elastic recoil after DCB angioplasty. Therefore, using DCB to treat MCA-M1 stenosis seems to be particularly encouraging.

Gruber et al[8] used only DCB to treat patients with sICAS, with a technical success rate of 63% (5/8). Although using only DCB angioplasty reduces the number of intracranial maneuvers, it increases the technical difficulty for the operator in initially dilating the stenotic artery.[7] In this study, the technical success rate of the DCB angioplasty was 81.4%, indicating that it is critical to use common balloons to dilate severely stenotic vessels successfully before DCB angioplasty. It is noteworthy that the DCB tip is stiff.[7] After a conventional balloon dilates the narrow blood vessels, the DCB dilates again, improving the technical success rate and effectively contacting the blood vessel wall to release most of the paclitaxel quickly.[10,11]

DCB angioplasty is limited primarily by the formation of arterial dissection or unacceptable recoil,[24,25] resulting in suboptimal results after stent implantation.[20] Currently, the incidence of dissection with DCB angioplasty for intracranial artery stenosis is less than 10%.[26,27] The dissection incidence was 16.3% in this study, which might be related to operator experience or the small number of ICAS lesions treated with DCB. Cortese et al[28] reported that at a 3-month follow-up, 93.8% of dissections without impaired distal flow healed completely without any specific intervention after DCB treatment of

coronary vessels. Therefore, proper delivery of paclitaxel to the vessel wall may promote dissection healing.[28] Han et al[26] reported only 2 patients with sICAS with vessel dissections without flow limitation that healed completely 7 months after the surgery. This phenomenon was not observed in our study, most likely because dissection after DCB angioplasty was observed for only a short time before a remedial stent was placed. Confirmation of whether dissection after DCB angioplasty heals satisfactorily requires additional clinical observational studies.

Limitations

Our study has several limitations. First, this is a retrospective cohort study, and although statistical methods were used to eliminate baseline differences in patients, the results were biased compared with randomized controlled trials. Second, this study has a potential selection bias because of operator experience or patient and family preference. Third, we could not determine whether the dissection formed after DCB angioplasty exhibited a satisfactory healing process because of the short intraoperative observation time. Fourth, this study was a single-center study, and the results may not be generalizable. Finally, our study did not assess the long-term safety and efficacy of DCB angioplasty because a median follow-up of only 12 months was used. Future studies with longer follow-up times are needed.

CONCLUSION

DCB angioplasty significantly reduced the risk and degree of restenosis in patients with sICAS. Thus, DCB angioplasty is a potential alternative to stenting, especially in MCA-M1 stenosis. Additional prospective randomized clinical trials with larger sample sizes are needed to verify these observations.

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Disclosures

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. During the research phase, drug-coated balloon is an unlabeled device for use in Intracranial Atherosclerotic Stenosis, which is currently in the preclinical stage.

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Supplemental Digital Content. **Supplemental Table**. Additional details about the perioperative stroke or mortality.