Original Article

Outcomes of different treatments on Takayasu's arteritis

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Background: Takayasu's arteritis (TA) is a nonspecific chronic inflammation of the aorta and its branches. This study compared the outcomes of surgical treatments including bypass surgery, cutting balloon angioplasty and conventional balloon angioplasty to TA patients exhibiting supra-aortic arterial (SAA).

Methods: This retrospective study was conducted on 42 TA patients, obtained from hospital database, who underwent surgical therapy due to SAA lesions from January 2010 to March 2015. Ten patients were reconstructed using cutting balloon angioplasty, 16 patients received conventional balloon angioplasty and 16 patients from bypass surgery. The primary patency, recurrent symptoms, re-intervention, early (<30 days) and late complications associated with treatment were evaluated.

Results: In the conventional balloon angioplasty group, two patients were converted to bypass surgery as the guidewire could not traverse the lesions. The follow-up at 30.07±17.96 months (range, 1–60 months) showed restenosis or occlusion development in 40.9% arteries in conventional balloon angioplasty, compared with 6.3% after bypass surgery (P=0.018). The restenosis or occlusion rate between cutting balloon angioplasty and conventional balloon angioplasty groups were insignificant (P=0.738). In the re-intervention, three out of four (75%) treated by cutting balloon angioplasty were patent as compared to the three out of nine arteries (33.3%) dealt with by conventional angioplasty that was patent (P=0.266). Intracerebral hemorrhage (n=1) was developed in the bypass surgery group. Mortality was not observed in any of the groups.

Conclusions: Cutting balloon angioplasty can be considered as a safe, effective, and less-invasive alternative for non-diffuse SAA lesions, especially in young TA patients. However, bypass surgery has better primary patency rate than endovascular treatment.

Keywords: Takayasu's arteritis (TA); supra-aortic arterial (SAA); cutting balloon; bypass; patency rate

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Introduction

Takayasu's arteritis (TA) is a nonspecific chronic inflammation of the aorta and its branches. The frequency of supra-aortic arterial (SAA) lesions, including innominate, subclavian, carotid, and vertebral, in TA patients, was 31% to 45% (1-3). Mwipatayi, et al reported that 17% of TA patients suffered from transient ischemic attack (TIA) or stroke, which resulted in 9.5% mortality (4). Furthermore, 50% patients needed surgical treatment for TA disease and most patients underwent reintervention (5). The efficacy of surgical treatment in patients with TA has not been established.

Surgical bypass is considered as the efficient therapy for TA patients with symptomatic, irreversible SAA lesions;

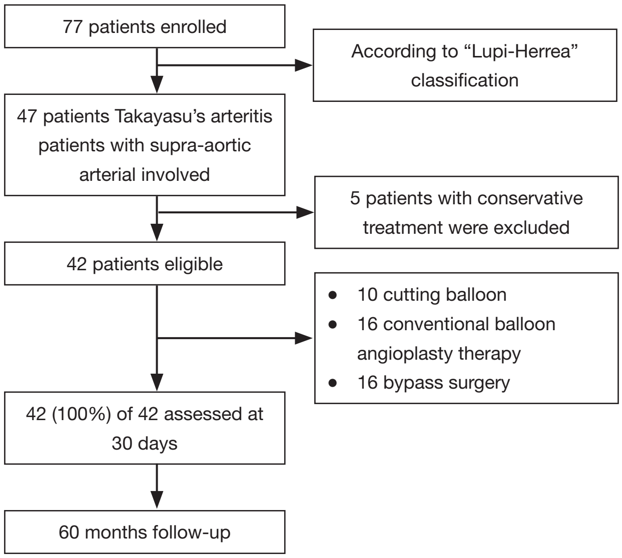

Figure 1 Flow chart of article selection.

however, the early and late complications after bypass surgery, such as postoperative bleeding, cerebrovascular accidents, anastomotic aneurysm were the primary causes of mortality (6,7). Furthermore, previous reports of endovascular treatment of SAA lesions in TA patients were limited by the endovascular instruments such as conventional balloon, the frequency of active disease at the time of intervention, the type of endovascular technique used (e.g., use of a stent), and the differences in the post-procedural medical treatment (8-10).

Cutting balloon angioplasty proved to be safe and efficient in the treatment of graft-to-vein anastomotic stenosis and non-arteriosclerotic renal artery stenosis, with significantly higher assisted primary patency than that of the conventional balloon angioplasty (8-10). Gumus *et al.* reported that cutting balloon angioplasty was an efficient surgical treatment to treat renal artery stenosis due to TA, however, there is a lack of clinical studies about the cutting balloon angioplasty in the treatment of SAA lesion involvement in TA patients (11).

In this study, we compared the endovascular treatment including cutting balloon angioplasty and conventional balloon angioplasty, along with the surgical bypass in TA patients with SAA lesions.

Methods

Patients

Between January 2010 to March 2015, forty-two patients (32.88±10.28 years), including seven males and thirty-five females, with SAA lesions underwent surgical treatment in our institution. The diagnosis of TA was confirmed by the presence of three or more criteria of The American College of Rheumatology (12). Preoperative clinical characteristics, surgical therapy manners of cutting balloon, conventional angioplasty and bypass surgery, primary and secondary patency, re-intervention, as well as early (<30 days) and late complications, were reviewed retrospectively. Blood pressure difference between arms >10 mmHg in systolic blood pressure was defined as clinic signs of left subclavian artery stenosis or occlusion. Percent stenosis, binary open or closed was measured on CT before surgery and repeated confirm during surgery by angiographic. Stenosis percentage was compared with proximal part diameter. Stenosis type was classified by the length of the stenotic lesion, focal (<2 cm) and diffuse (≥2 cm). Most diffuse lesion patients were treated by bypass surgery, whereas the focal lesion was first treated with the conventional angioplasty and its inefficiency resolved by the cutting balloon (Flow chart: *Figure 1*). The study complied with the Helsinki Declaration and was approved by the local ethical committee.

Procedure

Patients that underwent operation in the inactive phase were assessed by erythrocyte sedimentation rate (ESR, <15 mm/h in men, <20 mm/h in women) and C-reactive protein (CRP, <0.9 mg/dL). All endovascular procedures were performed under the control of anticoagulation; heparin was administered at 70 IU/kg and the activated coagulation time was controlled above 200 s during the procedure. A 6 Fr sheath and guiding catheter (RDC-I) were inserted from the common femoral artery. The size of the balloon was decided by the angiographic measurement of the reference diameter as follows. In the case of a non-ostial lesion, the ostium diameter was determined as a reference. In the case of an ostial lesion, the portion distal to the lesion or the contralateral artery was measured. In the event of post-stenotic dilatation, we also measured the distal portion of the dilated site, especially in the patient with the bilateral artery. The conventional balloon sized identically to the reference diameter was chosen for the initial treatment. It was inflated from within to assess the rate of rated burst pressure, and not inflated further when the patient complained of a headache.

For cutting balloon angioplasty, we selected a cutting balloon similar or smaller in size than the reference

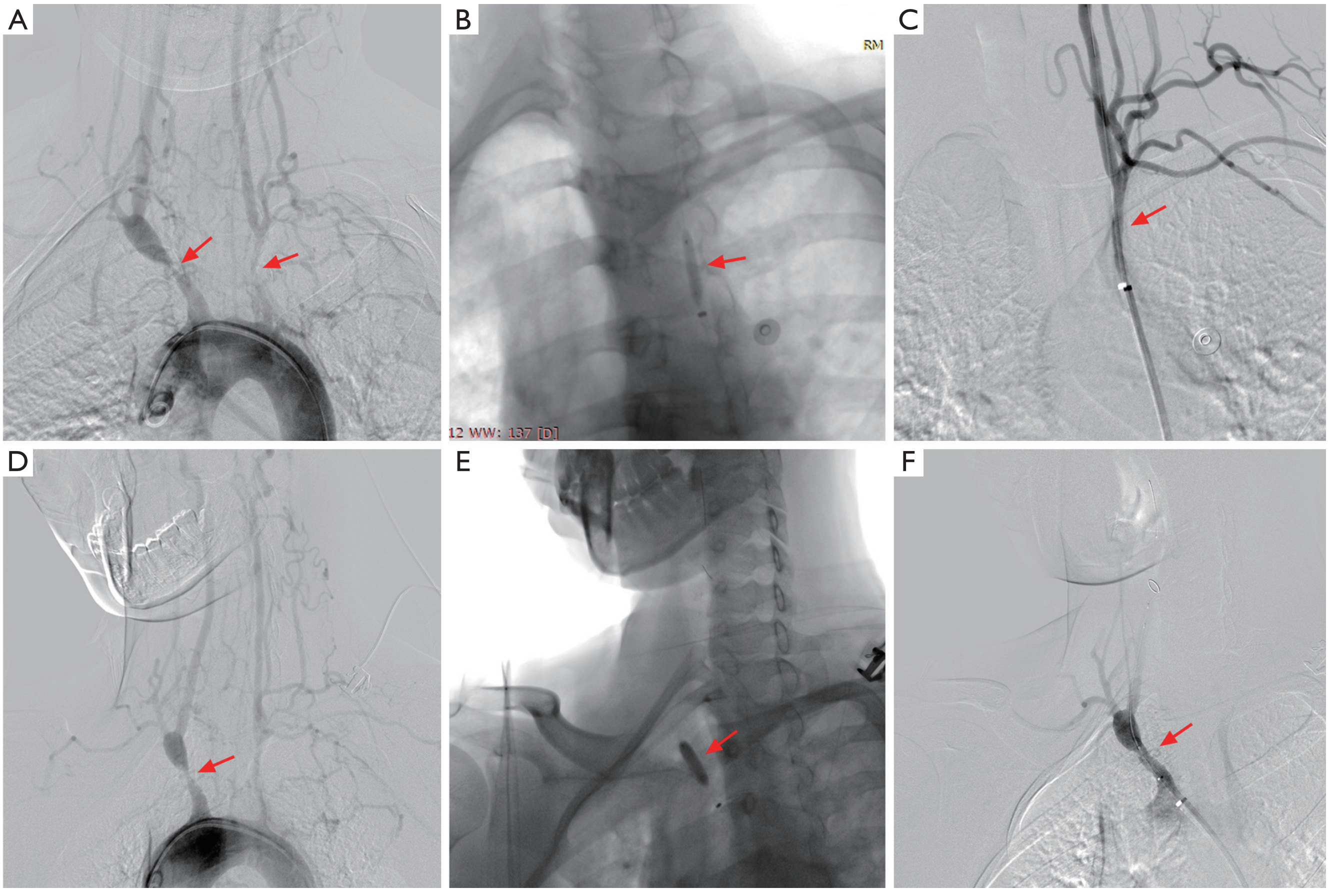

Figure 2 Images are shown for cutting balloon angioplasty therapy for patients with supra-aortic arteries affected Takayasu arteritis. A 23-year-old woman underwent cutting balloon angioplasty therapy to treat innominate artery and left subclavian artery (A) during three months interval. Cutting balloon were used in left subclavian artery stenosis (B) first, left subclavian artery stenosis was alleviated after ballooning (C). Innominate artery was treated by cutting balloon angioplasty three months later, the below three images shown extent of artery stenosis before (D), ballooning moment (E) and result after cutting balloon angioplasty (F).

diameter and never used an oversized equipment. When the lesion was narrow, an undersized cutting balloon was used initially to avoid destruction of the blade due to the bending discrepancies between the stenosis and the normal vessel. Only one size of cutting balloon was used for either of the procedure. The cutting balloon, which was not advanced through the lesion, was retracted in the sheath. All cutting balloons were inflated to the minimum pressure at which the balloon waist disappeared, to minimize the vessel injury. The inflation time of the cutting balloon was about 30s. After deflation, the cutting balloon was carefully removed, and the absence of blade destruction was confirmed immediately. The lesion diameter was also assessed after the inflation. If the balloon diameter was still smaller than the reference diameter, or the stenosis percentage >70%, the lesion was defined as insufficiently dilated, and the cutting balloon angioplasty was either repeated, or the conventional angioplasty was added, unless the patient complained. The cutting balloon angioplasty procedure and effect was shown in *Figure 2*. Stent was used in both insufficiently dilated endovascular treatment.

Sixteen TA patients with SAA lesions were underwent bypass surgical procedure, from ascending aorta to carotid artery bypass. The bypass conduit was externally supported by polytetrafluoroethylene grafts in fifteen patients and autogenous saphenous vein in one.

Follow-up protocol

All patients were clinically followed up with outpatient.

Table 1 Patients' demographic and clinical characteristics

Clinical characteristics	Cutting balloon angioplasty	Conventional angioplasty	Bypass surgery	P value
N	10	16	16	–
Age (years)	29.6±10.53	36.37±11.89	31.44±7.64	0.207
Sex (F/M)	8/2	12/4	15/1	0.345
Main symptoms, n (%)				
TIA	4 (40.0)	5 (31.2)	7 (43.8)	0.759
Stroke	1 (10.0)	2 (12.5)	1 (6.2)	0.833
Dizziness	5 (50.0)	6 (37.5)	7 (43.8)	0.818
Pulseless	5 (50.0)	12 (75.0)	7 (43.8)	0.177
Comorbidities, n (%)				
Hypertension	1 (10.0)	3 (18.8)	4 (25.0)	0.638
CAD	0	0	0	–
Diabetes	0	0	0	–
ESR (mm/h)	11.10±2.92	9.38±2.92	9.06±2.57	0.182
CRP (mg/dL)	0.48±0.18	0.53±0.13	0.52±0.13	0.627
Medication, n (%)				
Prednisone	4 (40.0)	7 (43.8)	9 (56.2)	0.668
Antihypertensive	1 (10.0)	3 (18.8)	4 (25.0)	0.638
Lesion				
CCA (R/L)	5/3	8/6	6/10	
VA (R/L)	5/3	5/2	2/2	
LSA	5	12	7	
Stenosis rate (%)	88.0±4.21	85.6±4.78	88.1±3.59	0.202
Length of stenosis (F/D)	7/3	10/6	5/11	0.092

CAD, coronary artery disease; CCA, common carotid artery; R, right; L, left; CRP, C-reactive protein, <0.9 mg/dL; ESR, erythrocyte sedimentation rate, <15 mm/h in men, <20 mm/h in women; F/D, focal/diffuse; LSA, left subclavian artery; F/M, female/male; TIA, transient ischemic attack; VA, vertebral artery.

Every patient was requested to have a repeat computed tomography angiography (CTA) at 3, 6, 12 months in the first postoperative year, and then annually thereafter until the fifth years or the end of this study in March 2015.

Analysis and statistics

Categorical variables are reported as number (present) and continuous variables as mean (SD) or median (25th to the 75th interquartile range), depending on variable distribution. Group comparisons were analyzed with the Student's *t*-test or Wilcoxon rank-sum test for numeric variables and the chi-square or Fisher exact test for categorical variables. All analyses were performed using Empower (R) (www.empowerstats.com, X&Y solutions, Inc., Boston, MA, USA) and R (http://R-project.org). Significance was attributed at $P<0.05$. Cumulative patency rates of the grafts were estimated by Kaplan-Meier analysis. The life-table method was used to analyze the effects of various factors on the primary patency rate.

Results

Fundamental clinical characteristics of TA patients

Demographic and disease characteristics were summarized in *Table 1*. All the patients underwent surgical intervention for the inactive disease stage as assessed by ESR <20 mm/h and CRP <0.9 mg/dL. Twenty patients were administered with anti-inflammatory medicines in the perioperative time. Mean age was 29.6 years in cutting balloon angioplasty, 36.37 years in conventional balloon angioplasty, and 31.44 years in bypass surgery group. A significant difference was not observed. Four patients exhibited stroke history before the operation, two from the conventional balloon angioplasty group, one in cutting balloon angioplasty group, and one in bypass surgery group. Pulselessness (24/42, 57.1%: cutting balloon angioplasty 5, conventional balloon angioplasty 12, bypass surgery 7) and dizziness (18/42, 42.9%: cutting balloon angioplasty 5, conventional balloon angioplasty 6, bypass surgery 7) were no significant difference. Thirty-eight common carotid arteries (right 19, left 19), 19 vertebral arteries (right 12, left 7), and 24 left subclavian arteries were affected. Stenosis rate was not markedly different between the groups, 88.0%±4.21% in cutting balloon angioplasty, 85.6%±4.78% in conventional balloon angioplasty, and 88.1%±3.59% in bypass surgery. Eleven patients with diffuse artery lesions underwent bypass surgery, and 17 patients with focal lesions were subjected to endovascular therapy.

Perioperative period results

Perioperative period results were shown in *Table 2*. Thirteen bare-metal stents (self-expanding) were planted in 12 patients in the conventional balloon angioplasty group, but none was used in the cutting balloon angioplasty group. The cutting balloon angioplasty procedure consumed the least time (47.3±6.7 min) as compared to the conventional angioplasty (80.1±22.5 min) and the bypass surgery (304.8±46.9 min, P<0.01). The percutaneous transluminal angioplasty of two patients was unsuccessful because the guidewire could not pass the lesions, and thus, they were converted to bypass surgery. Arterial dissection occurred in 1patient.

Follow-up results

The mean follow-up time was 30.07±17.96 months (range, 1–60 months, presented in *Table 2*). All the patients' symptoms were alleviated or improved after the surgical procedure; the dizziness without image restenosis occurred in four patients, while in one with anastomotic stenosis in bypass surgery (5, 31.2%). Blood pressure difference between arms was relieved in both the endovascular treatment groups owing to the left subclavian artery blood flow restoration. Restenosis in four patients was confirmed by CTA in the cutting balloon angioplasty group (3, 30%), among which one had no symptoms. In the conventional balloon angioplasty group, five artery restenosis or occlusions and one stent occlusion were found (6, 37.5%). There was no significant difference between cutting balloon angioplasty group and conventional balloon angioplasty group. The rate of restenosis in the bypass surgery group (1, 6%) was lower than both endovascular treatment (P<0.05).

Cumulative patency rates were shown in *Figure 3*. Primary patency rates of the cutting balloon angioplasty group at 3, 6, and 24 months were 100%, 100%, and 54.54%, respectively. The same was 95%, 78.23%, and 58.29% of the conventional balloon angioplasty group at 3, 6, and 24 months, respectively, while it was 100% and 90.9% for bypass surgery group at 3 and 36 months. The rate of primary patency in the bypass surgery group was higher than cutting balloon angioplasty and conventional balloon angioplasty group at 24 months (P<0.05).

Short-term complications

Short-term complications (<30 days) and late complications were shown in *Table 3*. Cerebral hyperperfusion syndrome with intracerebral hemorrhage occurred in one patient. This patient demonstrated left common carotid and left subclavian artery diffused stenosis and received ascending aorta-left common carotid artery bypass. Subsequently, she recovered without any left-over disability. Any cardiac accidents and bradycardia with hemodynamic instability did not occur in the TA patients.

Midterm to long-term complications

None of the patients reported either TIA or stroke during the follow-up duration. Restenosis or occlusion developed in nine out of 22 arteries (40.9%) in conventional angioplasty, compared with one of the 16 arteries (6.3%) after surgical bypass (P=0.018). The differences of restenosis or occlusion rate between cutting balloon angioplasty group and conventional balloon angioplasty group were not significant (P=0.738). The re-intervention results were presented in *Table 3*. Three patients (4 arteries) in cutting balloon angioplasty group and six patients (9 arteries) in conventional balloon angioplasty group required re-intervention. Among them, threeout of four (75%) treated by cutting balloon angioplasty were patent as compared to the three out of nine arteries (33.3%) dealt with by conventional angioplasty that was patent (P=0.266). No mortality was observed in this cohort.

Discussion

Conventional balloon angioplasty treatment and bypass

Table 2 Follow-up results of the three surgical therapies

Case No.	Age/Sex	Lesion	Operation time (minutes)	Stent	Follow-up results		
					Duration (months)	Patency	Recurrent symptoms
Cutting balloon angioplasty							
1	46/F	LVA	36	0	14	Patent	None
2	29/F	LCCA/RVA	50	0	26	Restenosis	Dizziness
3*	21/F	LCCA	40	0	15	Restenosis	Dizziness
4	32/F	RVA/LSA	45	0	25	Patent	None
5	23/F	LCCA/LSA	56	0	2	Patent	None
6	49/M	LCCA	45	0	30	Restenosis	Dizziness
7	18/F	LSA	53	0	20	Restenosis	None
8	20/M	RCCA/RVA	56	0	13	Patent	None
9	30/F	LVA	45	0	16	Patent	None
10	28/F	LCCA/LVA	47	0	6	Patent	None
Conventional angioplasty							
11	43/F	LSA	90	1	40	Patent	None
12	30/M	LCCA	96	1	37	Restenosis	Dizziness
13	48/M	LVA/LSA	100	1	29	Patent	None
14	32/F	LCCA	60	0	19	Restenosis	Dizziness
15	22/F	RVA	56	0	32	Patent	None
16	37/F	LCCA/ LVA	58	0	21	Restenosis	Dizziness
17	26/F	LVA	60	1	42	Patent	None
18	30/F	LCCA/LVA	65	1	29	Restenosis	Dizziness
19	36/M	LSA	66	1	56	Patent	None
20	57/M	LSA	80	1	17	Patent	None
21	18/F	LCCA/LSA	70	0	5	LSA occluded	Dizziness
22	54/F	LSA	79	1	3	Patent	None
23	45/F	RVA	63	1	34	Patent	None
24	24/F	CCA/LSA	120	1	49	Left-occluded	Dizziness
25	50/F	LSA	90	1	42	Patent	None
26	30/F	LSA/LVA	130	2	1	Patent	None
Bypass surgery							
27	17/F	LCCA	230	0	16	Patent	None
28	32/F	LCCA	300	0	6	Patent	None
29	26/F	LCCA	290	0	39	Patent	None
30	32/M	LCCA	325	0	60	Patent	Dizziness
31	30/F	RCCA	336	0	52	Patent	None
32	36/F	LCCA	352	0	40	Patent	Dizziness
33	32/F	LCCA	327	0	54	Patent	None
34	35/F	RCCA	263	0	24	Patent	None
35	32/F	RCCA	245	0	25	Patent	None
36	26/F	RCCA	362	0	60	Restenosis	Dizziness
37	31/F	LCCA	349	0	55	Patent	None
38	27/F	LCCA	326	0	56	Patent	None
39	46/F	RCCA	315	0	55	Patent	Dizziness
40	19/F	LCCA	300	0	49	Patent	Dizziness
41	42/F	LCCA	206	0	9	Patent	None
42	40/F	RCCA	352	0	40	Patent	None

*, the patients who received bypass surgery eventually. AA, ascending aorta; BS, bypass surgery; CCA, common carotid artery; R/L, right/left; F, female; M, male; VA, vertebral artery; LSA, left subclavian artery.

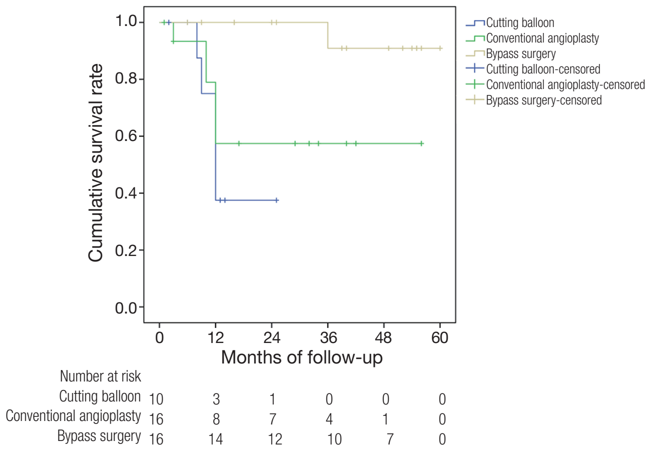

Figure 3 Kaplan-Meier analysis for primary patency rates in endovascular angioplasty and bypass surgery groups. The primary patency rate of CA was significantly higher than cutting and conventional balloon groups (P=0.005, P=0.006, separately). No significant differences in primary patency rates between CB and CA groups (P=0.841).

surgery treating symptomatic TA patients were previously reported (7,13). On the other hand, there is a lack of evidence on the efficiency of cutting balloon angioplasty in SAA lesions of TA patients.

In the present study, SAA arteries reconstructed by surgical bypass showed better patency than those treated by cutting balloon angioplasty. Because of the TA arteries injury is a vessel-specific pattern in the response of the various arterial beds to inflammatory stimuli (14), stenosis artery replaced by surgical bypass is more effective alleviate arterial inflammatory stimuli and restenosis than endovascular treatment. However, a substantial distinctness in the symptom recurrence rate between the surgical bypass group and cutting balloon angioplasty group was not observed. These findings were similar to those by AbuRahma *et al.* in a study of atherosclerotic occlusive disease in a subclavian artery (15). They reported that the surgical bypass showed better long-term patency than endovascular intervention, but with increased perioperative complications.

The primary patency between the cutting balloon angioplasty and conventional balloon angioplasty was not significantly altered. It was reported that PTA with stent implantation results exceeded the SAA lesions of the TA patients (6,7,13). However, the feasibility of stenting for SAA lesions of Takayasu disease has not been established (9). In addition, patients with Takayasu disease are usually young, and the durability of the stents for these patients is yet controversial (16). The risk of undergoing a surgical intervention increased during the first phase of the disease (particularly in the first 16 months from the onset) and likely reached a plateau from 6 years (5). Inflammatory lesions in TA are mostly generated in the activated endothelial cells (17). The Cutting balloon was designed to alleviate vascular trauma and thereby reduce neointimal hyperplasia (8) to restore stenotic arteries and improve long-term patency. Therefore, we chose to use a cutting balloon and avoided stent implantation. Moreover, cutting balloon angioplasty was reported to improve the patency rate in treating in-stenting restenosis lesions. According to the results of this study, cutting balloon angioplasty appeared to be advantageous over conventional angioplasty in SAA lesions of TA.

The procedure would carry the risk of vessel rupture if the cutting balloon was inflated by extremely high pressure. So the PTA should be conducted very carefully (11). Our result showed cutting balloon angioplasty to be advantageous for solid lesions of TA. However, its efficacy for primary patency was controversial. Further examination in follow-up phase is necessary to assess the patency, especially for cases with stent implantation and consolidated lesions.

Limitation

The results of our research might be limited by the relative small number of subjects. Thus more high-quality and large-sample randomized study are required to further verify our study. In addition, the long-term patency rate of cutting ballon therapy is still controversial. It still needs longer follow-up.

Conclusions

This study has shown that cutting balloon angioplasty may be a safe and effective procedure for SAA lesions in TA patients, in particular for youths. Cutting balloon angioplasty shows promising short-term results and can be considered as a less-invasive alternative for non-diffused lesions. However, endovascular treatment is associated with a higher risk of long-term restenosis or occlusion than

Table 3 Short (<30 days) and late complications in Takayasu's arteritis patients after cutting balloon, conventional angioplasty and surgical bypass treatment

Complications	Cutting balloon angioplasty, n (%)		Conventional angioplasty, n (%)		Bypass surgery, n (%)	
	Patients	Arteries	Patients	Arteries	Patients	Arteries
N	10	15	16	22	16	16
Short (<30 days)						
CHS with intracerebral hemorrhage	0	0	0	0	1 (6.3)	NA
Cardiac tamponade	0	0	0	0	0	NA
Severe bradycardia with hemodynamic instability	0	0	0	0	0	NA
Technical failure	0	0	2 (12.5)	2 (9.1)	0	0
Arterial dissection	0	0	1 (6.3)	1 (6.3)	0	0
Late						
TIA	0	0	0	0	0	0
Stroke	0	0	0	0	0	0
Restenosis (50% of diameter)	4 (40.0)	5 (33.3)	6 (37.5)	9 (40.9)	1(6.3)	1 (6.3)
Graft occlusion	0	0	2 (12.5)	3 (13.6)	0	0
Re-intervention	3 (30.0)	4 (26.7)	6 (37.5)	9 (40.9)	1 (6.3)	1 (6.3)
Technical failure	1 (33.3)	1 (25.0)	4 (66.7)	6 (66.7)	1 (100.0)	1 (100.0)
Death	0	0	0	0	0	0

CHS, cerebral hyperperfusion syndrome; NA, not applicable; TIA, transient ischemic attack.

bypass surgery, which has a better patency rate.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the ethics committee of Changhai Hospital. The Institutional Review Board number is CHEC-2016-67.

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