

OFFICIAL JOURNAL OF THE ZEENAT QURESHI STROKE INSTITUTE

Vertebral Artery Origin Stent Placement Using the Dual Lumen Qureshi-Jiao Guidecatheter

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Abstract

Objective—We report the first experience with a new dual lumen guide catheter with lumen A with curved tip designed for delivery of stent and angioplasty catheters and lumen B with side exit for coaxial placement of stiff 0.014 inch wire.

Methods—We prospectively determined technical success, intended procedure (stent delivery at target lesion and a final residual stenosis <30%) completed without a need for a different catheter, and technical ease, intended procedure completed without \geq 3 unsuccessful attempts in patients with symptomatic vertebral artery origin stenosis. Vertebral artery origin was classified as type A if originated from ascending segment and type B if originated from an arch or horizontal segment of subclavian artery.

Results—The mean age of the four treated patients was 66.2 years (range 64–68 years). The mean percentage of vertebral artery origin stenosis was 82.7% (range 60–92%). The origin of vertebral artery from subclavian artery was classified as type A and type B origins in two patients each. The dual lumen catheter was advanced over an exchange length of 0.035 inch glide wire in one patient and directly through transfemoral insertion in three patients. Technical success and technical ease was achieved in all four procedures. Post procedure residual stenosis was 6% (range 5–7%). The primary operator rated the performance of guide catheter as superior compared with another catheter used in such procedures.

Conclusion—The present study demonstrates the feasibility of performing stent placement for vertebral artery origin stenosis by using a dual lumen catheter with superior performance.

Introduction

Stent placement is a treatment option for patients with extracranial vertebral artery stenosis when patients are having symptoms despite optimal medical treatment (Class IIb; Level of Evidence C) [1]. Due to tortuosity of subclavian artery particularly in the proximal segment and sharp angulation of the origin of vertebral artery from subclavian artery, stable placement and angulation of the distal end of guide catheter to allow passage of devices into extracranial vertebral artery can be difficult. The guide catheter has been stabilized by coaxial placement of a 0.018-inch microwire into the distal subclavian artery in previous reports [2]. However, because coaxial wire is placed through the same lumen as the intended stent delivery catheter, unavoidable straightening of the distal end prevents appropriate manipulation of distal end of guide catheter. A dual lumen catheter technique was developed to overcome current challenges in the stabilization and manipulation of catheter in tortuous arteries such as right subclavian artery and left common carotid artery [3,4]. The new diagnostic

catheter had two lumens: first lumen had a curved shape at the distal end and accommodated a 0.035-inch guide wire (lumen A); the second lumen (lumen B) terminated at the beginning of the distal curve of the first lumen and accommodated a 0.018-inch guide wire. The catheter was retracted or advanced over the 0.018-inch guide wire and the curved free end of catheter manipulated to engage the origin of the target artery. Subsequently, either contrast was injected or a 0.035-inch guide wire advanced into the target artery. We developed a new catheter that can be used for therapeutic procedure and report the initial experience in stent placement for extracranial vertebral artery stenosis.

Methods

Catheter specifications

The dual lumen Qureshi-Jiao guide catheter (AQURE Medical Inc., Shoreview, MN) with 110 cm in overall

Journal of Vascular and Interventional Neurology, Vol. 9

Vol. 9, No. 6, pp. 38-42. Published December, 2017.

length was used. Both lumens have separate entry points within the exterior hub of the catheter. Lumen A continued as curved tip (65° angulation) beyond the exit point for lumen B. The inner diameters of lumen A and lumen of catheter were 0.067 and 0.016 inches. The outer diameters of the catheters were 0.105 and 0.083 inches at distal end. Lumen A was designed for delivery of devices that required a 6 F guide catheter and lumen B was added for coaxial placement of stiff 0.014-inch wire. There were two radio-opaque marker bands located at the end of lumen A and another 2-mm distal to the exit point for lumen B. The radio-opaque markers were 0.5 inch apart.

Patients

All patients were treated at Beijing Xuanwu Hospital, China. Patients in whom extracranial vertebral artery stent placement was indicated for stenosis of 50% or greater limited to the first centimeter of the cervical vertebral artery after its origin from the subclavian artery associated with transient ischemic attack or minor ischemic stroke were considered. The severity of stenosis was quantitated by expressing the minimum lumen diameter as a fraction of reference normal distal vertebral artery as described previously [5]. The nondiseased portion of the sixth segment which extends classically from the subclavian artery to the transverse foramen of sixth cervical vertebrae was used as the reference artery for quantifying the stenosis. All patients provided written informed consent prior to the procedure. Patients with any of the following characteristics or conditions were not treated: (1) history of bleeding diathesis, including disorders treated with warfarin therapy (however, patients who had been administered warfarin but had stopped taking the medication 3 days before the procedure and had an international normalized ratio of less than 1.2 were eligible for treatment); (2) major surgery within the previous 6 weeks; (3) previous hemorrhagic stroke; (4) pregnancy or lactation; or (5) gastrointestinal or genitourinary bleeding within the previous 30 days. Patients were administered aspirin (100 mg daily) and clopidogrel (75 mg daily) orally starting 3 days before the procedure. If clopidogrel could not be initiated 3 days before the procedure, a loading dose of 300 mg was administered.

Procedure

Arterial access was acquired by placing an 8 F introducer sheath in the femoral artery. The guide catheter was placed in the ipsilateral subclavian artery over a 0.035-inch glide wire. An exchange length of 0.035 glide wire was placed using a diagnostic catheter if a

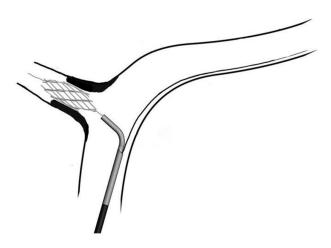


Figure 1. The schematic illustrates the concept underlying dual lumen Qureshi-Jiao guide catheter.

diagnostic angiogram was required to determine the severity of stenosis prior to performing the procedure. After the guide catheter was placed in the subclavian artery, a stiff 0.014-inch wire was placed through lumen B into the distal subclavian artery. A bolus dose of intravenous heparin was administered. The guide catheter was retracted and manipulated to position the ostium of the distal curved end in proximity to the vertebral artery origin. Bare metal or drug-eluting balloon expandable stents (6 F guide catheter compatible) were introduced over a 0.014-inch wire through lumen A (see Figure 1). The lesion was traversed with the 0.014-inch wire and stent was placed across the lesion and deployed using standard protocol. Angioplasty before or after stent was permissible as required for achieving optimal results.

Data collected

We collected demographic and clinical data on each of the patients using standard data collection form. The presence of hypertension, diabetes mellitus, hyperlipidemia, active cigarette smoking, and coronary artery disease was ascertained. Medications used prior to procedure including antiplatelet medication, statins, and other pertinent medication were recorded. The patients presenting symptoms were classified as either transient ischemic attack, minor (National Institutes of Health Stroke Scale score <4), or major (National Institutes of Health Stroke Scale score ≥4) ischemic stroke. Procedural data included target lesion, severity of stenosis before and after procedure, and devices used (included microwires in both lumens and stent placed), and heparin and contrast agents used. The type of origin of vertebral artery from subclavian artery was classified as previously described [5]. The subclavian artery is divided

Variables	Patient # 1	Patient # 2	Patient # 3	Patient # 4
Age (yrs) gender	67 M	64 M	66 M	68 M
Cardiovascular risk factors	Hypertension	Hypertension, diabetes melli- tus, active cigarette smoking,	Hypertension	Hypertension, diabetes melli- tus, active cigarette smoking,
		coronary artery disease, and hyperlipidemia		coronary artery disease, and hyperlipidemia
Presenting symptom	Transient ischemic attack	Minor ischemic stroke	Transient ischemic attack	Transient ischemic attack
Procedure	Type B left vertebral	Type B left vertebral artery	Type A left vertebral	Type B right vertebral artery
Troccure	artery stenosis	stenosis	artery stenosis	stenosis
Preprocedure medications	Aspirin, clopidogrel, and statins	Aspirin, clopidogrel, and sta- tins, antihypertensive medi- cation and oral hypoglycemic agent/insulin	Aspirin, clopidogrel, and statins	Aspirin, clopidogrel, and sta- tins, antihypertensive medica- tion and oral hypoglycemic agent/insulin
Contrast agent used	Visipaque 270 iodixanol, 80 ml	Visipaque 270 iodixanol, 95 ml	Visipaque 270 iodixanol, 100 ml	Visipaque 270 iodixanol, 90 ml
Heparin dose used	40 mg	46 mg	50 mg	45 mg
Vessel catheterized	Left subclavian artery	Left subclavian artery	Left subclavian artery	Right subclavian artery
Devices used through lumen A				
Device type	Wire # 1	Wire # 1	Wire # 1	Wire # 1
Guide wire type	HI-TORQUE	HI-TORQUE PILOT Guide	HI-TORQUE	HI-TORQUE PILOT Guide
	PILOTGuide WirePilot	WirePilot 150 cm 0.14	PILOTGuide WirePilot	WirePilot 150 cm 0.14
	150 cm 0.14 (Abbot,	(Abbot, Santa Clara, Califor-	150 cm 0.14 (Abbot,	(Abbot, Santa Clara, Califor-
	Santa Clara, California, USA)	nia, USA)	Santa Clara, California, USA)	nia, USA)
Device type	Stent	Stent	Stent	Stent
Stent type	Cordis PALMAZ BLUE Peripheral stent (Cordis, Baar,Switzerland)	Apollo stent(MicroPort Med- ical, Shanghai, China)	XIENCE Everolimus Eluting Coronary stent(Abbot, Santa Clara,	XIENCE Everolimus Eluting Coronary stent(Abbot, Santa Clara, California, USA)
)		California, USA)	,,,
Stent size	$5 \times 12 \text{ mm}$	$3.5 \times 8.0 \text{ mm}$	$4 \times 12 \text{ mm}$	$4 \times 15 \text{ mm}$
Devices used through lumen B				
Device type	Wire # 2	Wire # 2	Wire # 2	Wire # 2
size	HI-TORQUE	HI-TORQUE PILOTGuide	HI-TORQUE	HI-TORQUE PILOTGuide
	PILOTGuide WirePilot	WirePilot 150 cm 0.14	PILOTGuide WirePilot	WirePilot 150 cm 0.14
T (19)	150 cm 0.14	a :	150 cm 0.14	a :
Total fluoroscopy time	7 min	7 min	8 min	7 min
Total procedure time (from femoral puncture to femoral clo- sure time) Endpoints	15 min	18 min	20 min	15 min
Technical procedure completed	Yes	Yes	Yes	Yes
without need for a different catheter				
Pre procedure stenosis	89%	90%	92%	60%
Post procedure stenosis	7%	5%	7%	5%
Rated performance with	Superior	Superior	Superior	Superior
another catheter used in such				
procedures				

Table 1. The clinical and procedural characteristics of the patients treated with new dual lumen catheter

into an ascending segment and a horizontal segment. The alignment of the subclavian artery was based on an imaginary line connecting the midpoint of the segment immediately proximal and distal to the origin of the vertebral artery. The origin of vertebral artery was classified as type A if the vertebral artery originated from ascending segment and type B if vertebral artery originated from arch or horizontal segment of subclavian artery.

Outcomes

The following outcomes were assessed: technical success, intended procedure completed without the need for a different catheter; technical ease, intended procedure completed without occurrence of three or more unsuccessful attempts; dissection, disruption of the arterial vessel wall on imaging studies manifesting as stenosis, intimal flap, false lumen, mural thrombus, or pseudoaneurysm; spasm, concentric narrowing of arterial lumen which resolves spontaneously or with treatment with

vasodilators; ischemic stroke, new focal neurological deficits referable to an arterial distribution which persist for a period of at least 24 hours and intracranial hemorrhage is excluded by appropriate neuroimaging study; transient ischemic attack, new focal neurological deficits referable to an arterial distribution which completely resolves within a period of 24 hours; intraluminal thrombosis, abrupt partial or complete occlusion of the affected artery with angiographic characteristics such as morphology of filling defect or pattern of resolution supportive of diagnosis; and distal embolization, appearance of an occlusion on a downstream vessel which was confirmed to be patent earlier in the procedure. Technical failures were to be further classified as inability to catheterize target proximal artery with catheter, inability to access target lesion, or inability to deliver angioplasty balloon catheter or stent device through lumen A of catheter. The primary operator also was asked to provide an opinion regarding comparison of performance with

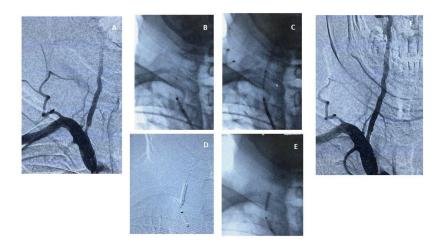


Figure 2. A and F represent pre- and post-procedure angiographic appearance and severity of right vertebral artery origin stenosis (type a origin). B–D represent the stages of the procedure of stent placement. Note the coaxial placement of 0.014-inch guide wire through lumen B into the distal subclavian artery and stent delivery catheter introduced into vertebral artery origin through lumen A.

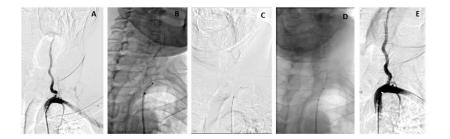


Figure 3. A and E represent pre- and post-procedure angiographic appearance and severity of left vertebral artery origin stenosis (type B origin). B–D represent the stages of the procedure of stent placement. Note the coaxial placement of 0.014-inch guide wire through lumen B into the distal subclavian artery and stent delivery catheter introduced into vertebral artery origin through lumen A.

another catheter used in such procedures and rated into one of three categories: inferior, equivalent, or superior.

Results

A total of four procedures were performed in four patients; men aged 66.28 years (range 64–68 years). Three patients had presented with transient ischemic attacks and one patient had suffered a minor ischemic stroke. All patients were treated with aspirin and clopidogrel prior to the procedure. Three patients had stenosis of left and one patient has stenosis of right extracranial vertebral artery as its origin from subclavian artery. The origin of vertebral artery from subclavian artery was classified as type A and type B origins in two patients each (see Table 1). The guide catheter was advanced into the target subclavian artery after an exchange length of 0.035-inch guide wire was placed in the subclavian

artery via a diagnostic catheter (right subclavian artery in one patient) or directly through the femoral route over a 0.035-inch glide wire in the left subclavian artery in three patients.

A HI-TORQUE **PILOT**Guide **Wire**Pilot 150 cm 0.14 (Abbot) was placed through lumen B into distal subclavian artery (see Figures 2and 3). A second HI-TORQUE **PILOT**Guide **Wire**Pilot 150 cm 0.14 was placed through lumen A and used to traverse the stenosis and distal end was placed in distal cervical segment. The lesion was treated using Cordis **PALMAZ BLUE Peripheral Stent (Cordis), Apollo stent**(MicroPort Medical) 316 L stainless-steel **stent**, and **XIENCE Everolimus Eluting Coronary Stent**(Abbot) in 1, 1, and 2 patients, respectively. The lengths of stent were 8 and 15 mm in one patient each and 12 mm in two patients. The mean fluoroscopic time for procedure was 7.2 min (range 7–8 min). The procedure was technically successful and met the definition of technical ease in all patients. The mean pre procedure stenosis was 82.7% (range 60–92%) and post-procedure stenosis was 6.7% (range 5–7%). None of the patients suffered arterial dissection, thrombosis, or distal embolization during the procedure. No new ischemic stroke or transient ischemic attack was observed in the post procedure period. The primary operator rated the performance of guide catheter as superior in all cases.

Discussion

We report the feasibility of using a dual lumen catheter for performing vertebral artery origin stent placement. In addition to the catheter being adapted for performance of therapeutic procedures by availability of a large lumen, three additional features were added to the previous diagnostic catheter [3,4]. The radio-opacity of the distal end of the catheter was improved by radio-opaque marker bands, the exit point of lumen B was devoid of a step off which had created an irregularity, and Y hub was placed at the proximal end of the catheter to facilitate external rotation at the complex double-entry point system. The advantages of the new system is the provision of a stable platform and retention of ability to manipulate and angulate the distal end in the subclavian artery for performing angioplasty or stent placement of vertebral artery origin stenosis.

The current challenges include difficulty in stabilization and manipulation of catheter in tortuous arteries such as subclavian artery to achieve a particular configuration is desired to engage the tortuous origin of the vertebral artery [6–9]. Prolonged procedures, the use of multiple catheters, and difficult selective catheterizations in such scenarios increase the risk of cerebral embolization and ischemic events during the procedure [6-9]. The dual lumen catheter has certain limitations. A larger introducer sheath (8 F) is required to secure femoral arterial access to accommodate the larger outer diameter of the catheter. The ability to torque the dual lumen catheter in tortuous aortic arch and engage the supra-aortic arterial origin may be limited like other angulated or straight guide catheters. An exchange with a diagnostic catheter placed in the subclavian artery maybe necessary in some procedures.

There is renewed interest in the performance of stent placement to reduce the risk of recurrent ischemic events associated with extracranial vertebral artery stenosis after the results of Vertebral artery Ischemic Stenting Trial have been reported [10]. The trial randomized 182 patients with intra- or extracranial ver-

tebral artery stenosis to either best medical treatment or stent placement. The primary endpoint was any stroke was seen as 12 of the medically treated patient and five in the stent treated patients over a median period of 3.5 years. There was a reduction in risk of any stroke in patients treated with stent placement after adjustment for days from last symptoms to randomization (Hazard ratio of 0.34, 95% confidence interval 0.12-0.98; P= .046). The benefit was greater in patients who were treated for extracranial vertebral artery stenosis relative to those treated for intracranial stenosis. The new catheter is expected to reduce the complexity and associated complications with guide catheter placement that is necessary for performance of stent placement in patients with tortuous arterial anatomy. The design of the catheter also makes it a useful device for performance of therapeutic procedures in branches of the aorta such as renal or mesenteric arteries and coronary arteries with highly angulated origins that require high degree of stability of the distal end of the catheter. The distal end of the catheter can be conformed to lengths and configurations that may be best suited for particular applications.

Acknowledgements

None.

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