

Original Studies

Delivering Stents in Congenital Heart Disease Using the Double-Wire Technique: Technical Considerations

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Objectives: To evaluate the use of a double-wire technique to deliver stents. **Background:** Placement of a stent in lesions close to bifurcations or without an anatomic obstruction can be problematic. **Patients and Methods:** Stents were implanted in 12 patients between August 2010 and August 2012. Indications were complex anatomic obstruction in nine, external compression of pulmonary veins in two, and exclusion of an aortic aneurysm in one patient. **Results:** Median age and body weight of the group were 11.6 years (range: 1.6–34.8) and 36 kg (range: 10–78), respectively. All stents were delivered safely and the patency of all side vessels was maintained; the distal end of the stent was flared to a median ratio of 1.4 (range: 1.2–1.8). The clinical objective was met in all patients: in lesions with stenosis, diameter increased from 5.9 mm (range: 1–13) to 9.9 mm (range: 8–17) [$P < 0.01$; 95% confidence interval (CI): 2.0–7.2]; oxygen saturations improved in the 2 patients after relief of the external pulmonary venous compression and in another an aortic aneurysm was excluded. One patient developed a hemothorax and one required blood transfusion for bleeding from the valve of the sheath. **Conclusions:** The double-wire stenting technique is effective to accurately deliver and anchor stents into lesions close to side branches and bifurcations. Side branch patency is maintained; the clinical objective (gradient relief, aneurysm exclusion, relief of external compression) can safely be reached. Technique and balloon selection should be based on the underlying anatomical substrate. © 2013 Wiley Periodicals, Inc.

Key words: double wire; congenital cardiology; interventional catheterization; stent

INTRODUCTION

Endovascular stents have been established as effective treatment for several congenital cardiac lesions including obstructions of the pulmonary arteries and aorta [1–5]. Challenges remain, however. Placement of a stent—especially a covered stent—can be problematic with stenoses close to bifurcations and origins of side branches, or in cases of external compression without a discrete anatomical obstruction. Risks of jailing or exclusion of adjacent vessels, difficult positioning, and migration have limited percutaneous stent placement in such areas [6].

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TABLE I. Patient characteristics.

Patient no	Age (yr)	Cardiac lesion	Stent position	Delivery sheath Size (F)	Balloon 1		Balloon 2		Type balloon	Stent
					Diam (mm)	Profile (F)	Diam (mm)	Profile (F)		
1	18.4	Coarctation, hypoplastic Ao arch	Coarctation	13	20	10	Catheter	4	BIB	CP, covered
2	19.6	Coarctation, hypoplastic Ao arch	Coarctation	14	10	6	Catheter	4	UDT	CP, covered
3	13.1	Coarctation, dilated subclavian artery	Coarctation	11	12	5	10	5	Tyshak	CP, covered
4	20.2	CoA, bicuspid aV, subAS	Coarctation	12	8	6	6	5	Opta	CP, covered
5	10.0	Coarctation, two aneurysms	Coarctation aneurysm	11	8	4	8	4	Tyshak	CP, covered
6	3.0	Truncus arteriosus	Bifurcation PA conduit	10	7	5	7	5	Opta	Genesis
7	1.6	Tetralogy	Bifurcation PA	8	7	5	6	3	Opta, coronary	Genesis
8	10.0	Bifurcation stenosis post patch plasty	Bifurcation PA	10	10	6	8	4	Opta, Tyshak	CP, bare
9	7.0	Tetralogy	RPA hilus	11	5	5	7	5	Opta	Genesis
10	34.8	Pulmonary artery stenosis	RPA hilus	12	8	7	6	5	Z-med, Opta	Genesis
11	18.4	TA, BDG, and DKS	Left pulmonary vein	12	7	5	10	6	Opta	Genesis
12	8.5	uAVSD, Fontan, TCPC	Right pulmonary vein	14	10	6	10	6	Opta	CP, bare

Ao, aorta; BDG, bidirectional Glenn; BIB, balloon-in-balloon; CP, Cheatham Platinum; DKS, Damus Kaye Stansel; PA, pulmonary artery; RPA, right pulmonary artery; TA, tricuspid atresia; TCPC, total cavopulmonary connection; uAVSD, unbalanced atrioventricular septal defect; UDT, ultra-thin diamond balloon.

Catheter indicates use of one balloon and two guidewires.

Recently, a novel technique has been described with two guidewires and one or two balloons to address some of the problems encountered when delivering stents in aortic coarctation, main pulmonary artery, or conduit bifurcation stenosis [7,8]. The technique was demonstrated to be safe and effective while virtually abolishing the risk of jailing or excluding side branches.

The aim of this study was to assess whether stents could be accurately and safely delivered, assess the results, and describe technical modifications where it may be helpful.

PATIENTS AND METHODS

Patients were included if they had stenosis or lesions amenable to stenting in close approximation to side branches and/or bifurcations as well as obstruction because of external compression. Stents were implanted in 12 patients using a double-wire technique between August 2010 and August 2012 (Table I).

Standardized protocols for catheterization, heparin, and antibiotic administration were used. Access was gained through either the femoral arteries or veins except in patient no. 12, where a thoracotomy with transapical left ventricular access was used. The technique was employed as previously described [7,8]. It consists of first placing an appropriately sized long sheath over a guidewire. A second guidewire is then inserted into the adjacent branch or side vessel. If required, a soft compliant balloon was used to interro-

gate the stenosis or diameter and compliance of side branches. Subsequently, one or two balloons covered by a single stent were then advanced and expanded.

The primary objective of this technique is to deliver a stent accurately ensuring adequate anchoring as well as maintaining patency of the adjacent vessel or bifurcation; the stent was subsequently further flared and expanded as required. Two distinct techniques for delivery emerged. Scenario 1 consists typically of a fixed anatomical obstruction closely associated with side branches/bifurcations (Figs. 1 and 2). The primary aim is to anchor the stent in the stenosis keeping side vessels accessible. The distal aspect of the stent can subsequently be further flared to open passage to the side branches maximally. Scenario 2 exists in the absence of discrete anatomical obstruction (e.g., external compression of a pulmonary vein—Fig. 3); the stent will have little or no “grip” and may therefore dislodge easily. Anchoring in this situation is achieved by flaring the distal aspect of the stent as wide as possible into the bifurcation.

Preparation and Selection of Components

When sheath size is important, the lowest profile angioplasty balloons to get the stent delivery properly done should be selected: a high-pressure balloon with bigger profile may thus not be required. If stenosis is present, a single balloon mildly larger than the anatomic stenosis will anchor the stent. The purpose of the second guidewire is to keep the side branch accessible; a small diameter catheter (3–4F) can be used to cover the guidewire and

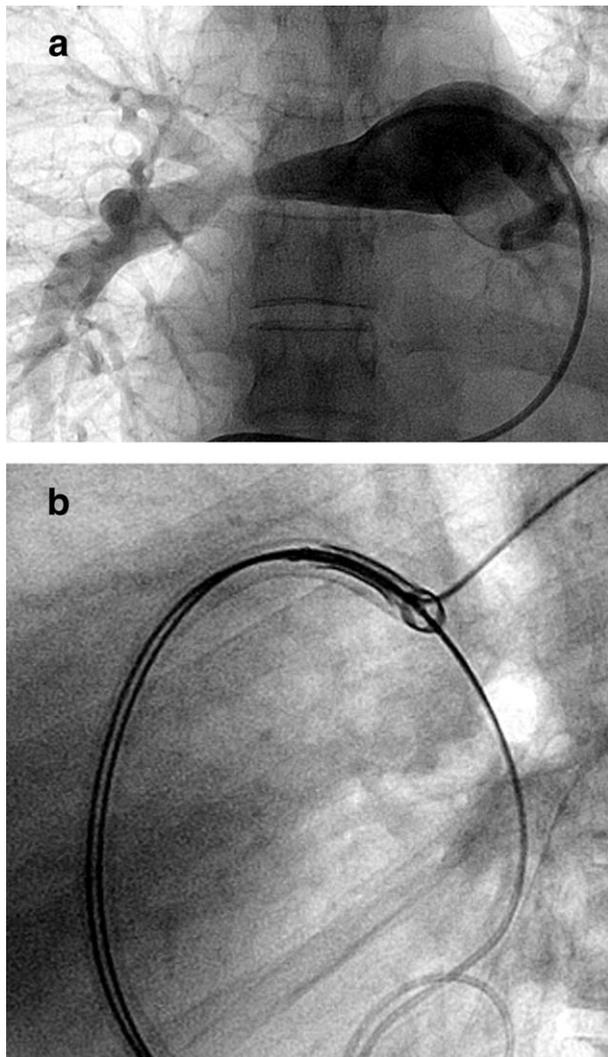


Fig. 1. Anatomic obstruction hilar branch pulmonary artery. (a) Anatomic obstruction branch pulmonary artery in patient no. 10. (b) Two guidewires as divergent as possible in upper and lower pulmonary artery branches; stent implanted in hilus, good result, and distal vessels patent.

to keep the sheath size to a minimum, but a combination of balloons with a low profile (e.g., 4F and 5F) may be chosen. After delivery, the stent can be further expanded as required with larger and high-pressure balloons.

In the absence of stenosis (e.g., external compression), guidewire placement should be as divergent as possible allowing to create a broad “Y” shape. Typically, two big balloons are required because anchoring is achieved by means of wide flaring of the distal aspect of stent into the side branches to prevent it from slipping back. Sizing a side branch by means of a compliant balloon may be helpful for the following reasons: it allows one to determine the size of the side branch and as a result prevent “milking” back of a stent because of the selection of an oversized balloon

on the one hand and allows one to select a larger balloon in a compliant vessel to ensure maximal flaring to anchor a stent in the absence of anatomical stenosis on the other hand.

Once balloons and stents are selected, the sheath size is determined. If two balloons with 5F profile are used together with a covered stent (3F upsize for covered stents), the final sheath size would typically be less than the mathematical sum of $5F + 5F + 3F = 13F$; an 11F sheath will be sufficient (Fig. 4). This downsizing is allowed by the oval configuration of the balloon–stent assembly compared to the standard circular shape. We currently do bench testing on the table using a cut-off short introducer sheath. Such a piece of sheath allows sizing of the whole unit, additional compression, and protective entering through the valve of the long Mullins sheath (Cook Medical Inc., Bloomington, IL).

Modified Technique of Stent Delivery

An important technique is sequential opening and partial flaring of the stent during delivery. Flaring allows the operator to deploy a stent more distally into a bifurcation because of opening of the distal aspect and limits the effects of foreshortening compared to standard methods—this is especially helpful in CP stents (Cheatham Platinum, NuMED, Hopkinton, NY) where the maximum advantage of the Z shape of struts can be taken and another 5–8 mm may be gained (Fig. 2a–e). The stent is partially exposed by uncovering the sheath halfway and inflating the two balloons to some degree. Once the distal end is nicely flared, the balloons are deflated and the whole assembly is carefully pushed further forward into the bifurcation or origin of side branch. In this position, the balloons are again inflated to ensure maximal flaring and then partially deflated, enough to allow the sheath to be uncovered and the stent to be completely exposed. The sheath should be left reasonably close to the end of the balloons in order to maintain stability of the whole assembly, with the option to push the system forward if required. Both balloons can then be inflated and the stent is fully expanded.

General Comments

At least two pairs of experienced and coordinated hands may be required to execute this procedure safely, which is ideally performed using three operators: one to hold and stabilize the sheath at the groin or entry point, one to control the balloon–wire assembly, and one to inflate the balloons (simultaneously or consecutively).

Ethics and Statistics

Demographic and clinical data were obtained from patient records and angiograms were reviewed to perform measurements. Approval was granted by the local

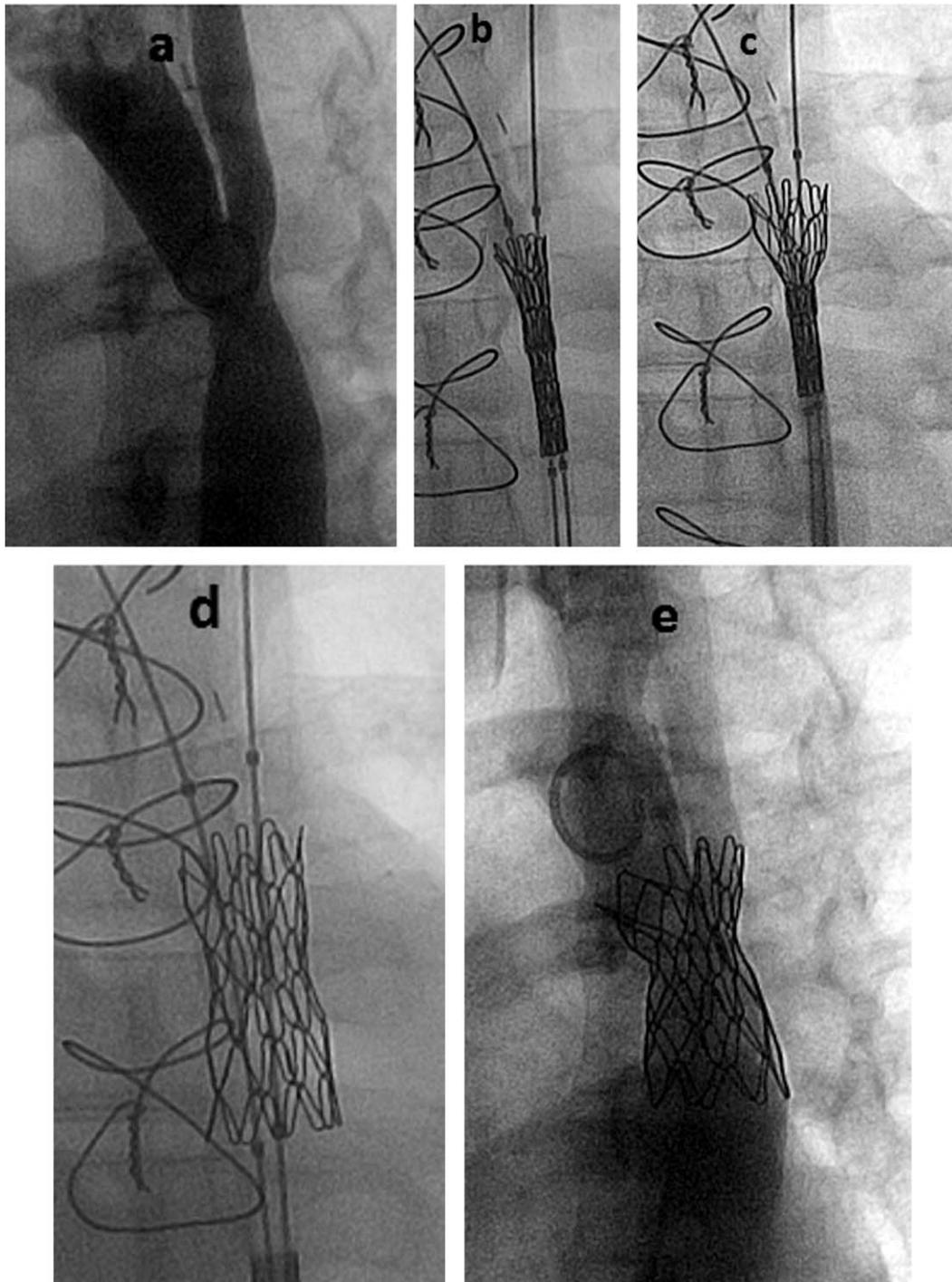


Fig. 2. Technique of sequential flaring. Sequential flaring (patient no. 4). See text for details. (a) Anatomic lesion. (b) Initial flaring. Note that long sheath is only partially withdrawn to ensure distal flaring of stent. (c) Balloons deflated and system pushed forward. (d) Stent exposed, full inflation of both balloons. Sheath close to proximal ends of balloons to lend

support. (e) Final result. Stent in position, flared open. Note how far the distal aspect of the stent could be positioned. The stent was not fully expanded at the time of this procedure because the gradient is reduced to 8 mmHg. Further expansion may be required at a later stage.

ethics committee before onset of the study. Informed consent was obtained in all patients from either the parents and/or from the patients where appropriate.

Data was analyzed using standard statistical software (SPSS for windows, SPSS Inc., IBM company, Chicago, IL, version 18). A paired *t*-test was used to

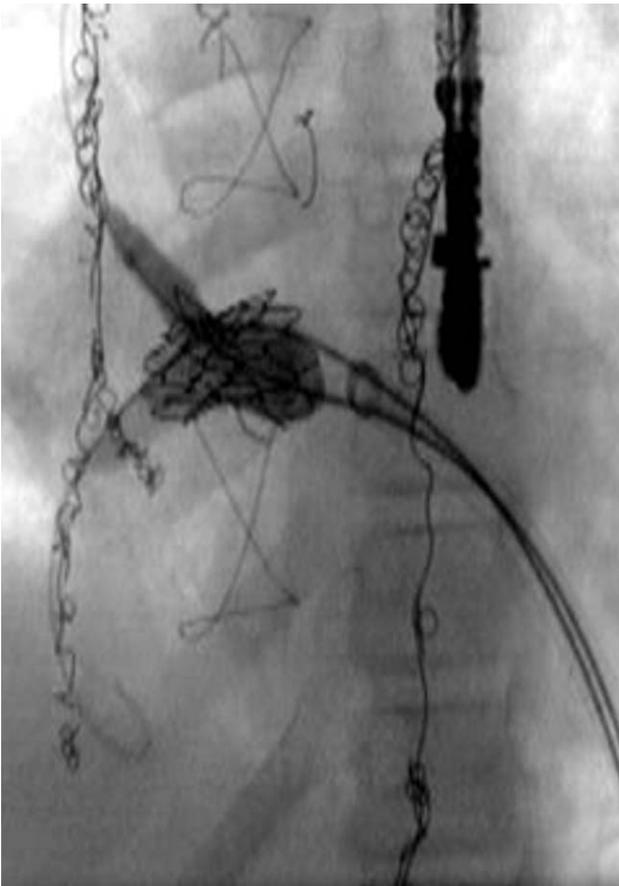


Fig. 3. Management of pulmonary vein compression (patient no. 12): Through transapical access two guidewires are placed in different pulmonary veins, simultaneous balloon insufflation for delivering stent.

compare normally distributed data. Continuous data were expressed as medians with the minimum and maximum values and 95% CIs where appropriate. A P -value < 0.05 was considered significant.

RESULTS

There were five males and seven females with a median age of 11.6 years (range: 1.6–34.8) and median body weight of 36 kg (range: 10–78). Indications, stent, and balloon selection for individual patients are detailed in Table I. Anatomical obstructions were present in nine patients: coarctation ($n = 4$), distal pulmonary hilar stenosis ($n = 2$), and main pulmonary artery/conduit bifurcation stenosis ($n = 3$). Three patients had no fixed anatomical obstruction: aortic aneurysm adjacent to the left subclavian artery (after previous balloon angioplasty for native coarctation) ($n = 1$) and external compression of the pulmonary veins with desaturation and failing univentricular circuits ($n = 2$). In a pre-

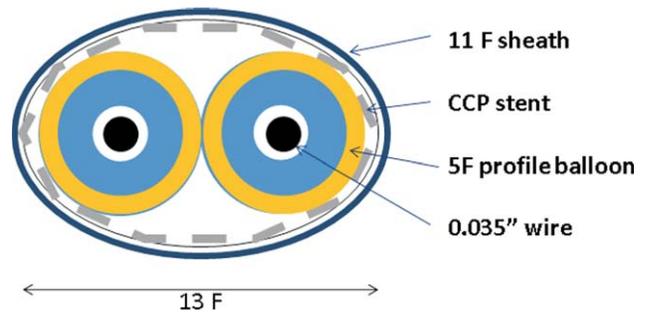


Fig. 4. Shape and selection of sheath size after assembly. Schematic transection of assembled unit depicting the different components. Two 5F profile balloons and a covered stent (3F thickness) fit inside an 11F sheath. Note that oval shape of assembly allows downsizing for appropriate sheath. CCP, covered CP stent.

Fontan patient (no. 11), compression of the left pulmonary vein was because of the veins crossing the thoracic aorta together with excessive infolding of the left atrial wall; in the second patient (no. 12) with fenestrated Fontan circulation, the right pulmonary veins were compressed between the right-sided thoracic aorta and the right-sided fenestrated Fontan conduit. Transesophageal echocardiography (TEE) showed significant narrowing at this junction together with a clearly discernible jet on color Doppler.

Stents were accurately delivered and side branch patency was maintained in all cases. In patients with anatomical stenosis, a significant increase in diameter of the stenotic area was obtained: median diameter increased from 5.9 mm (range: 1–13) to 9.9 mm (range: 8–17) ($P < 0.01$; 95% CI: 2.0–7.2) after stent implantation. The flared distal aspect of the stent was larger than the proximal aspect by a median ratio of 1.4 (range: 1.2–1.8). In both patients with pulmonary vein compression, the constricted area increased on TEE from a slit-like diameter of 2 mm to a circular shape with a diameter in excess of 10 mm; flow through the lung was improved, resulting in increased percutaneous saturations from 74% to 86% and 84% to 88%, respectively.

In two patients with coarctation and one with pulmonary vein compression, additional stent dilation with a larger, high-pressure balloon was carried out. In most patients, some additional flaring of the distal ends was performed. Additional stents for concomitant lesions were implanted in two patients: angioplasty of left pulmonary artery and redilation of a previously implanted stent in another.

We mostly used two stiff 0.035" guidewires, but in one younger patient, a 0.035" was combined with a 0.014" coronary guide, whereas in patient no. 3, two 0.018" guidewires were used. In patient no. 9, two

0.014" guidewires were initially used, but were displaced when the assembly was advanced into the right ventricle. They were replaced with two stiff 0.035" guidewires, which provided adequate stability.

Complications

There were no deaths. One patient needed a blood transfusion following blood loss from the valve of the long sheath and another patient needed a chest drain for a hemothorax. No hematoma or tear could be demonstrated angiographically; it resolved spontaneously after heparin was reversed.

Follow-Up

Patients have been followed up for a median of 17.8 months (range: 2.8–20.2). All side branches and bifurcations were patent with no clinical or echocardiographic evidence of obstruction. Two patients needed additional procedures: in one child (no. 3), the stent in the aortic coarctation was dilated to 14 mm to compensate for growth, and in another patient (no. 1), an additional stent was placed in the transverse aortic arch.

DISCUSSION

Our results show that the double-wire technique is feasible and effective to deliver stents in lesions in close approximation to side branches, or in compliant vessels without anatomic stenosis. All stents were accurately and safely delivered. Both stenosis and compression were addressed and side branches were not compromised. This finding is in agreement with previous reports of this technique [7,8].

This technique can particularly be helpful in the treatment of coarctation of the aorta closely related to the origin of a subclavian artery. Pulmonary artery and conduit bifurcation stenosis as well as distal hilar lesions could also be addressed using a double-wire double-balloon system. Follow-up data, although short to medium term, suggest excellent and ongoing protection of side branches and bifurcations.

Furthermore, these results show that by a novel adaptation of the technique, it is now possible to implant a stent in an area where there is no discrete anatomical obstruction to anchor the stent. To our knowledge, this is the first description of using this technique for external pulmonary vein compression and exclusion of aortic aneurysm in close approximation to a side vessel.

Stents have been used for pulmonary venous stenoses with varying success, but it should be emphasized that we implanted bare metal stents in anatomically normal pulmonary veins (opposed to stenotic veins) with relief of obstruction caused by external compression

[9]. It is of particular interest that computer tomography showed the pulmonary veins compressed between intrathoracic structures and the descending aorta in the two patients—a finding that had been described almost a decade ago [10]. Both patients had considerable improvement of pulmonary flow, percutaneous saturations, and functional status after stent implantation. In the patient with right-sided pulmonary venous obstruction, transapical approach through mini thoracotomy was preferred because it allowed better angles of approach for the bulky delivery system. Both patients will be closely followed up to monitor long-term outcome especially in view of fibrosis of the pulmonary veins. Using a compliant balloon for sizing and delineating the anatomy is valuable in this situation because the veins are flattened due to external compression. However, the aim is to determine the diameter of the distal bifurcating vessels. It is critical to select the correct size before inflation, as these veins are very compliant vessels. Adequate distal flaring of the stent is essential because this anchors the stent.

A similar technique was employed in a patient (no. 5, Fig. 5) where aneurysms of the aorta at and into a bifurcation were treated: the stent was flared in the aorta–left subclavian junction, excluding the aneurysms while simultaneously protecting the subclavian artery. These novel uses of this technique open new possibilities for transcatheter management in selected cases.

Proper guidewire selection is also important. After an initial learning curve, in pulmonary artery lesions we now prefer to use stiff 0.035" guidewires to obtain adequate support while advancing the whole assembly. However, in the aorta, the sheath trails the balloons and usually lends adequate support. Here one can use any combination of 0.035", 0.018", and 0.014" guidewires. Lower profile balloons may thus be selected, further reducing the required sheath size.

Advantages and Drawbacks

A major advantage is that stents can be implanted adjacent to side branches without the risk of occluding the vessels. None of the distal vessels were compromised using this method. The distal aspects of the stents including those of covered stents could be adequately splayed open, illustrated by the fact that the flared stent portions were a median of 1.4 times larger than the central aspects.

A disadvantage is that a large sheath may sometimes be required. However, this can be minimized by using a double wire combined with a single balloon or two low-profile balloons. We have successfully used the technique in a child of 19 months (no. 7) to stent a hilar stenosis. One patient with aortic coarctation

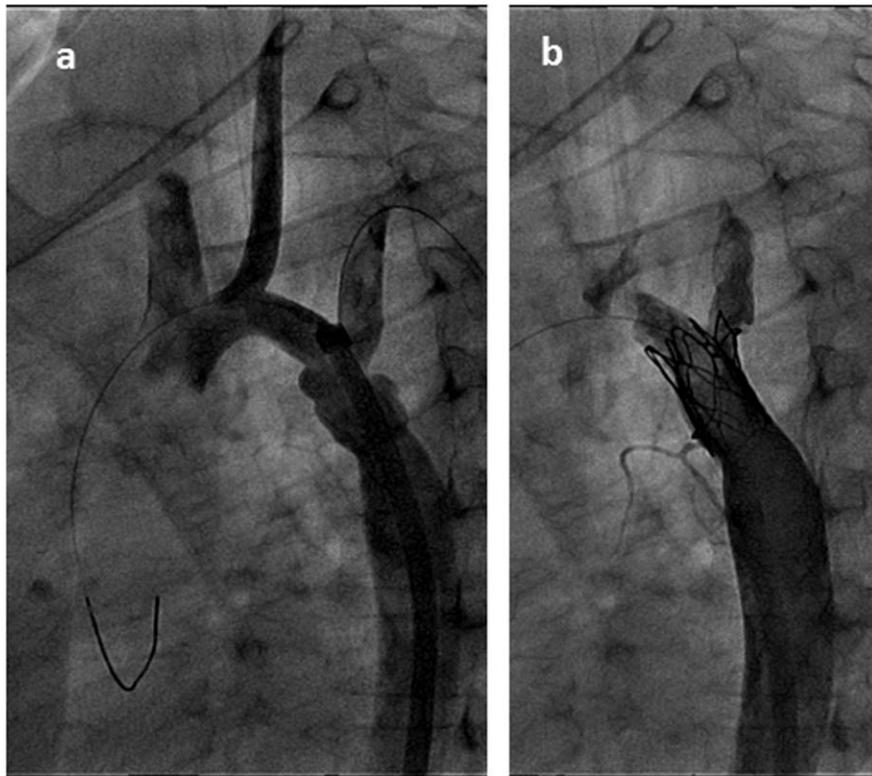


Fig. 5. Exclusion of aortic aneurysm close to origin of left subclavian artery. (a) Angiography shows aortic aneurysm closely related to left subclavian artery in patient no. 5. Sheath and guidewires in position. (b) Final result with stent in position and aneurysm excluded. Note patency of left subclavian artery.

experienced significant blood loss through the valve of the sheath and required a blood transfusion. Bleeding from this site should be continuously monitored because the valve is splayed open by the fairly bulky and asymmetric system (Fig. 4). A hemothorax occurred in patient no. 6; we immediately took the patient back to the catheterization laboratory, but no bleeding site could be found. In this patient, the wire position could not easily be maintained. We postulate that a small perforation was caused by the guidewire in a distal pulmonary vessel during the manipulations. This underlines that the assembly is cumbersome and that advancing the whole unit is a bit more problematic compared to standard single-wire techniques.

Future Use

The double-wire technique is the only method for stent delivery to address a lesion in or at a bifurcation. Other techniques include standard single-wire technique and try not to jail the side vessel, followed by flaring of the stent; the orifice of the side branch can be covered by the stent and jailing or exclusion of the side vessel can be accepted, or alternatively the side

vessel can be reopened by dilating the cells of the stent with a balloon (the wire can be positioned in an antegrade or retrograde fashion) [11].

CONCLUSIONS

The double-wire technique is feasible and effective to deliver stents in lesions in close approximation to other vessels or bifurcation. It is also effective to manage aneurysms closely related to side branches and external compression in the absence of discrete anatomic obstruction. Complications are acceptable and easily managed. This innovative technique is a valuable aid to the armamentarium of the interventional cardiologist. Technique and balloon selection should be based on the underlying anatomical substrate.

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