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Cephalic Arch Stenoses: A Technology to Leave Nothing Behind

By Deepak N. Deshmukh, DO, FACS

Cephalic arch stenoses are a challenge to treat. Given the anatomy, increased venous flow, and rapid development of neointimal hyperplasia, repeat interventions are often necessary to keep access circuits functioning.[1]

When thinking about my choice of tools to treat cephalic arch stenoses, my goal as a surgeon and interventionalist is to preserve future access options and ensure that every fistula functions as long and as well as it can. This begins prior to creation in working with patients to discuss their preferred access, a process I do in tandem with their nephrologist. It continues through maturation, maintenance, and salvage of a given access and critically thinking about the tools I use to do so. Unfortunately, restenosis in arteriovenous (AV) access will occur, and the tools used for previous treatments will influence future treatment options.

CURRENT APPROACH TO CEPHALIC ARCH STENOSIS

There is clinical evidence showing the effectiveness of cephalic arch stents compared with plain balloons.[2,3] However, the downsides of these stents are too great for me, so I do not use them for primary therapy. As shown in Figure 1, stents can cause many challenges for the patient and their interventionalist. During stenting procedures, maldeployment can occur. If a stent jumps and the axillary vein is jailed, future access creation options will be diminished. With covered stents, edge stenosis can develop between the termination of the stent and the native vein, and the stent can make crossing with a guidewire challenging. Stents can also fracture. Finally, if a lesion is not responsive to balloon angioplasty, any surgical modifications must be done around these permanent implants, losing valuable real estate as a result. If a turndown can't be performed, the access site will be lost, and the patient may need to use a central venous catheter for dialysis while a new fistula is created and matured. That, of course, comes with increased morbidity and mortality.[4] However, it is important to note that covered stents are a critical tool that I use for bailout in the case of perforation or rupture.

When I started practicing, my algorithm to treat cephalic arch stenoses included mainly high-pressure balloons. I used a lower-profile balloon to avoid rupture, increasing the size by approximately 1 mm until I achieved a good angiographic result. Unfortunately, I would see consistent recoil and recurrence, so I started to add scoring and cutting balloons into my procedures. I also started to use larger balloons and higher pressures, but my preference to avoid rupture (and the subsequent use of a stent) meant that I saw patients for reinterventions often, as expected.

Figure 2 shows a case example in which the lesion recurs in the same exact spot. I wanted to avoid placing a stent given the proximity to the venous outflow, so I continued treating this patient with only balloons.

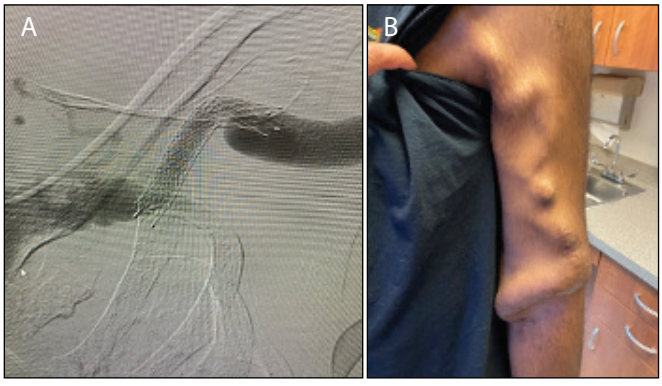

Figure 1. A stent was placed in the cephalic arch in this patient at another facility. Both the angiogram (A) and photo (B) demonstrate some of the potential consequences of cephalic stenting.

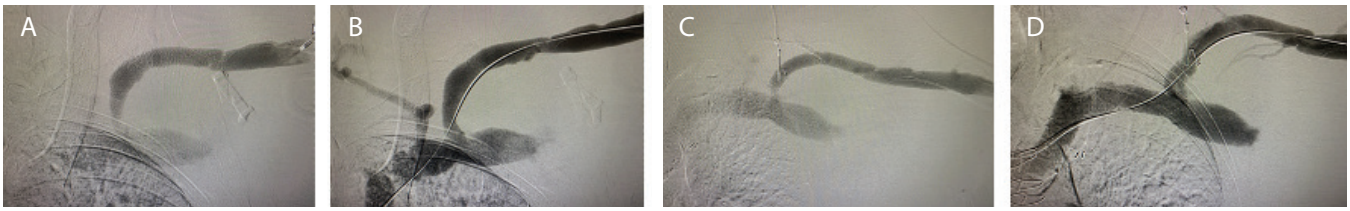

Figure 2. A recurrent case of cephalic arch stenosis was treated with plain balloon angioplasty alone. Initial baseline angiogram shows the lesion in the cephalic arch (A) and the final angiogram shows the lesion after initial treatment (B). Angiogram showing the lesion in the cephalic arch 5 months later (C) and the final angiogram showing the lesion posttreatment (D).

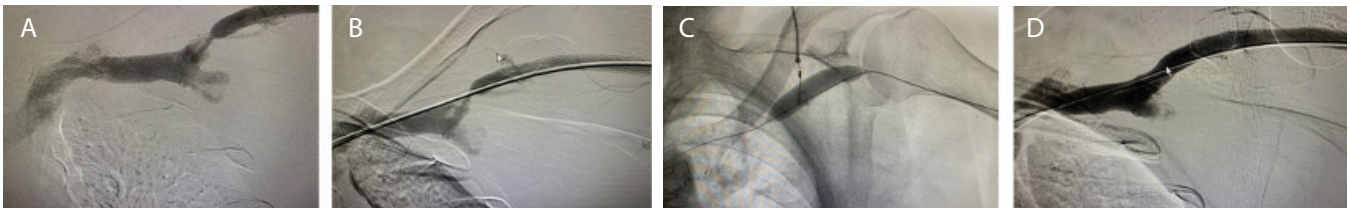

Figure 3. The initial baseline angiogram (A). Angiograms showing the lesion crossed with a wire (B) and treatment with IN.PACT AV DCB (C). The final posttreatment angiogram (D).

When I saw the new data released from the IN.PACT AV Access study at CIRSE 2019 (the annual conference of the Cardiovascular and Interventional Radiological Society of Europe),[5] it was clear that my algorithm was ready for a revision. Approximately 20% of lesions in the study were located in the cephalic arch, and although patients were excluded if they had a stent in the access circuit or thrombosis,[6] these patients represent many of the patients I see in my practice. Outcomes of the cephalic arch lesions in the IN.PACT AV Access study were released at VIVA 2019, the Vascular InterVentional Advances meeting. Target lesion primary patency through 6 months was 84% in the drug-coated balloon (DCB) group versus 50% in the percutaneous transluminal angioplasty group.[7] This demonstrated a clear benefit of the IN.PACT™ AV drug-coated balloon (Medtronic) in the cephalic arch, a result reached without leaving a permanent implant.[7]

When a man in his 60s came to me with a recurrent stenosis in his brachiocephalic AV fistula, I knew I had an alternative to avoid a stent in the lesion. Rather than simply ballooning, I used a lower-pressure balloon and a cutting balloon to prepare the vessel and I then treated the lesion with an IN.PACT AV DCB (Figure 3). At 11 months after this treatment, the lesion has not required reintervention.

CONCLUSION

These anecdotal successes in my practice and the continued presentation and publication of results from the IN.PACT AV Access study demonstrate that the IN.PACT AV DCB can reduce reinterventions and help patients continue to successfully undergo dialysis, with fewer required revascularizations to maintain patency.[6] That's something important to me as an interventionalist and to my patients. During a global pandemic, keeping these high-risk patients out of the hospital has become even more important. I now routinely use the IN.PACT AV DCB in areas where I would expect to see high rates of recoil and recurrence, including the cephalic arch.

Ultimately, maintaining the functionality of my patient's AV access circuit as long as possible matters, and if I can do that with a technology that lowers the reintervention rate while also avoiding a permanent implant, that's how I will treat my patients. ■

1. Sivananthan G, Menashe L, Halin NJ. Cephalic arch stenosis in dialysis patients: review of clinical relevance, anatomy, current theories on etiology and management. J Vasc Access. 2014;15:157-162. doi: 10.5301/jva.5000203
2. Haskal ZJ, Trerotola S, Dolmatch B, et al. Stent graft versus balloon angioplasty for failing dialysis-access grafts. N Engl J Med. 2010;362:494-503. doi: 10.1056/NEJMoa0902045
3. Dolmatch B. COVERA™ – 12-month update on AVeNEW trial for outflow stenosis in AV fistula circuits. Presented at: Leipzig Interventional Course (LINC); January 28-31, 2020; Leipzig, Germany.
4. Lok CE, Huber TS, Lee T, et al. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(suppl 2):S1-S164. doi: 10.1053/j.ajkd.2019.12.001
5. Holden A. Primary endpoint results of the IN.PACT AV access randomized trial: outcomes through six months. Presented at: Cardiovascular and Interventional Radiological Society of Europe (CIRSE); September 7-11, 2019; Barcelona, Spain.
6. Lookstein R, Haruguchi H, Ouriel K, et al. Drug-coated balloons for dysfunctional dialysis arteriovenous fistulas. N Engl J Med. 2020;383:733-742. doi: 10.1056/NEJMoa1914617
7. Lookstein R. IN.PACT AV access 6-month outcomes by lesion characteristics. Presented at: Vascular InterVentional Advances (VIVA); November 4-7, 2019; Las Vegas, Nevada.

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IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter Brief Statement

Indications for Use:
The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

Contraindications
The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

Warnings
- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.**
- Use the product prior to the Use-by date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 µg paclitaxel has not been evaluated clinically.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
- This product is not intended for the expansion or delivery of a stent.
- Do not use the IN.PACT AV DCB for pre-dilatation or for post-dilatation.
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

Potential Adverse Effects
Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms or recoil.

Potential complications of peripheral balloon catheterization include, but are not limited to, the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse effects.

Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthralgia, myelosuppression, peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.