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Reviews

Treatment of critical hand ischemia via orbital atherectomy and focal force balloon angioplasty: A mini-review

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ABSTRACT

Calcified lesions in below-the-elbow (BTE) arteries are common in patients with diabetes or end-stage renal disease and can lead to critical hand ischemia (CHI). Treatment of calcified lesions with atherectomy has proved useful in the lower extremities, however, atherectomy in the upper extremities and especially BTE, is not typically considered due to the small vessel size. We review and discuss these studies along with other CHI-related articles and also present a case of a severely calcified ulnar artery lesion treated with orbital atherectomy and plain Chocolate balloon angioplasty.

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Table of contents summary

Calcified below-the-elbow (BTE) lesions can be treated with endovascular techniques. We report a case where a severely calcified ulnar artery lesion was treated with orbital atherectomy and plain Chocolate balloon angioplasty. We also review and discuss the articles published in the past decade on the endovascular treatment of BTE arteries in critical hand ischemia.

1. Introduction

Below-the-elbow (BTE) artery disease, and especially calcification, is not uncommon in patients with diabetes or end-stage renal disease (ESRD) and can lead to critical hand ischemia (CHI) [1,2]. There have been a few reports of successful plain old balloon angioplasty (POBA) of BTE arteries, however, there is minimal data available regarding the treatment of calcified lesions BTE [1–4].

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Fig. 1. Gangrenous changes to the left middle and ring fingers.

It is well known that balloon angioplasty of severely calcified lesions is limited by angiographic complications and poor long-term outcomes [5]. Lesion modification with atherectomy results in better angioplasty outcomes and less adverse events in severely calcified lesions [6].

Even though atherectomy has proved useful in the treatment of calcified lesions in the lower extremities, atherectomy in BTE arteries is not typically considered due to the small vessel size. The Diamondback 360° Peripheral Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc.; St. Paul, MN); however, is an atherectomy device that can access treatment areas with a small reference vessel diameters (<2.0 mm), as well as larger vessel diameters.

In this report, we present a case of CHI (due to a severely calcified lesion in the distal ulnar artery) treated with OAS and plain Chocolate balloon percutaneous transluminal angioplasty (PTA) that resulted in an immediate angiographic success. The Chocolate balloon features a unique nitinol constraining structure ('nitinol cage') specifically designed for uniform, controlled inflation and rapid deflation. The nitinol cage creates balloon segments ('pillows') that uniformly distribute the pressure along the entire balloon surface resulting in greater safety and less recoil [7].

We also review and discuss the data available on endovascular treatment of CHI, published in the last decade.

2. Case report

The patient was a 59-year-old Native American male with past medical history of hypertension, diabetes, ESRD on hemodialysis three times a week, and former tobacco use. He presented to the hospital with gangrenous ulcerations to the middle and ring fingers of left hand (Fig. 1). Open amputation was performed on the proximal interphalangeal of left middle finger with incision and drainage of the mid palmar space. He then underwent left arm angiogram revealing widely patent brachial and radial arteries, as well as a widely patent dialysis shunt graft in the distal radial artery. The ulnar artery, which is the major supply to the hand; however, had a short severely calcified lesion at the wrist level (Fig. 2). The recommendation was to proceed with an endovascular intervention of the ulnar artery.

The right groin was prepped and draped in the usual fashion. Lidocaine 1% was used for local anesthesia. A 5Fr sheath was used to cannulate the right femoral artery. A 5Fr Bernstein catheter and an Advantage wire were used to cross into the proximal left ulnar artery. Over this wire, a 6Fr long destination sheath was advanced. Heparin and Aggrastat were given intravenously. Using a Seeker catheter and ChoICE PT guidewire, the lesion in the distal ulnar artery at the wrist level was crossed. The wire was exchanged to ViperWire after Verapamil was injected through the catheter. The ulnar artery lesion was treated with the peripheral OAS (1.25 mm Micro Crown) and then with a 2.0 × 40 mm Chocolate PTA Balloon (Cordis), which was inflated up to 4 atm for 2 min (Fig. 3). Final angiogram revealed excellent results

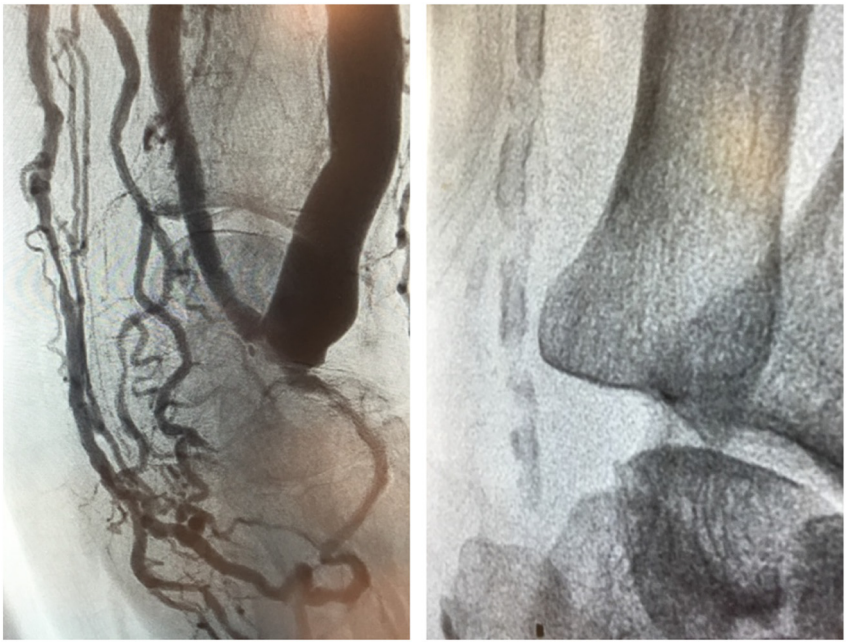

Fig. 2. Severely calcified lesion in the distal ulnar artery.

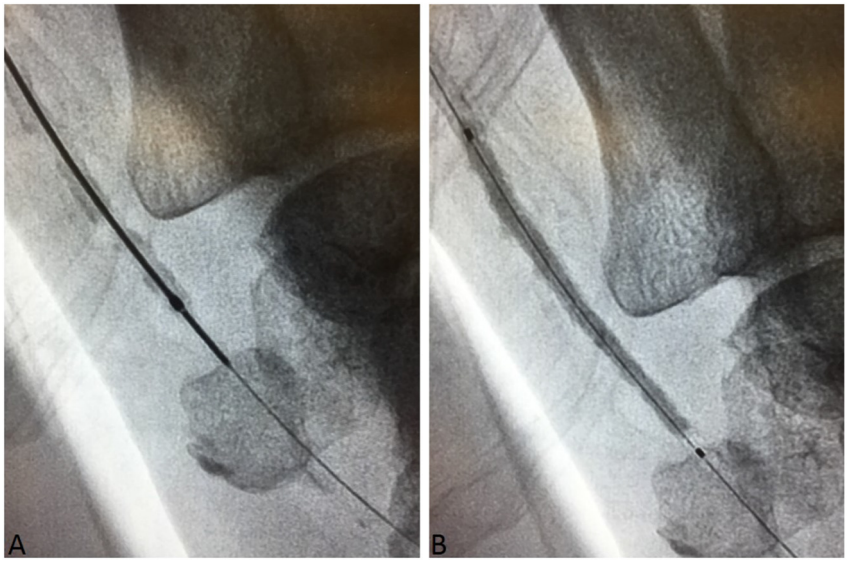

Fig. 3. (A) Atherectomy with 1.25 mm OAS Micro Crown (Diamondback 360®), and (B) balloon angioplasty with Chocolate PTA Balloon Catheter (Cordis) (2.0 × 40 mm) inflated up to 4 atm for 2 min.

(Fig. 4). At the conclusion of the procedure, the sheath was pulled once the ACT level was below 180. The procedure was performed without complications.

Two days after the procedure, the patient was taken back to the operating room for flap closure of the left middle finger. He was also treated with antibiotics for *Staphylococcus aureus* and Morganella. Two weeks later, his sutures were removed and the incisions had completely healed.

3. Discussion

This is a novel case report of a severely calcified ulnar artery lesion being treated with OAS and Chocolate balloon PTA. Endovascular treatment of the upper extremity occlusions and especially BTE, is rarely described in the literature and the majority of them are case reports (Tables 1 & 2). The few published studies are mainly single center retrospective studies with <40 patients. The treatment modalities in these case reports and studies were mainly balloon angioplasty and/or stenting using femoral or brachial access to treat occluded or calcified axillary, brachial, radial or ulnar arteries (Table 1). The first report on the use of PTA for the treatment of CHI comes from Ferraresi and colleagues who treated a patient with heavily calcified ulnar and radial arteries [2]. They obtained good final angiographic result with immediate pain relief and the patient was asymptomatic at 8 months. The same group was the first to describe a drug-coated balloon case of a patient with calcified radial and ulnar arteries [8]. The patient was still alive and symptom free after three years of the procedure, even though the mortality rate is high in patients with CHI and diffuse calcification [8].

It is well known that in most peripheral interventions, calcification increases the risk of procedural failure and complications after POBA [9]. Atherectomy prior to POBA may improve outcomes in calcified lesions, however, only three single center studies and three case reports are available regarding the use of atherectomy in the treatment of calcified lesions located in the upper limb (Table 2). The first single center study was a feasibility and safety study of POBA in BTE arteries, and rotational atherectomy was used only in 5% of the cases [1]. They concluded that the POBA of BTE arteries is feasible and safe, with a technical success rate of 82%. In the remaining 18% that resulted in technical failure, the angioplasty was unsuccessful due to the inability to cross severely calcified lesions. In the second study, 18 radial-ulnar

Fig. 4. Patient had good flow to the hand with no complications.

Table 1
Endovascular treatment of critical hand ischemia - balloon angioplasty and/or stenting.

Author and year	Type of study	Number of patients/hands	Etiology	Involved artery	Access	Technique	Outcomes
Study							
Tomoi et al., 2016 [15]	Retrospective, multicenter	36/40	*De novo* atherosclerotic PAD Calcification (78%)	Radial (33%) Ulnar (33%) Brachial (10%) Anxillary (5%) Subclavian (40%)	Subclavian, brachial, femoral	PTA Stenting	87% technical success rate; 8% mortality within 30 days; 19% (5/26 pts. with gangrene/ulcer) complete wound healing at 12 months; At 1 year KM estimates for AFS, overall survival, limb salvage and FF MALE: 56.4%, 59.4%, 93.1%, 78.5%
Case reports							
Ferraresi, 2015 [8]	Case report	1	Calcification	Radial & ulnar	Brachial	PTA with DCB	Palpable radial and ulnar pulses
Arabi et al., 2014 [16]	Case report	1	Stenosis & calcification	Axillary, radial & ulnar	Brachial	PTA	Palpable radial pulse; Partial healing of the gangrene at 4 weeks; Amputation of the distal and middle phalanges of index finger at 2 months
Higashimori and Yokoi, 2014 [17]	Case report	1	Total occlusion	Ulnar	–	PTA	Immediate pain relief; Ulcer healed 3 months later
Nasser et al., 2014 [18]	Case report	1	Occlusion	Brachial	Femoral	Stenting + PTA	Complete recanalization, patent distal arteries; Almost complete healing of necrotic lesions at 1 month; Complete wound healing at 1 year
Tasal et al., 2013 [19]	Case report	1	Severe calcified total occlusion	Radial	Brachial	PTA	Immediate pain relief; Almost healed wound at 2 months
Ferraresi et al., 2013 [20]	Case report	1	Long occlusion	Ulnar	Brachial	PTA 3 months later PTA + DCB	Complete wound healing at 1 month; Excellent final angiographic result; Good vessel patency up to 24 months
Annabestani et al., 2013 [21]	Case report	1	Severe stenosis	Brachial	Femoral	PTA	Complete wound healing at 2 months
Itaya and Nakamura, 2012 [4]	Case report	1	Severe stenosis	Subclavian, brachial, radial & ulnar	Femoral	PTA	Complete wound healing at 1 month
Ruzsa et al., 2010 [22]	Case report	1	Occlusion	Radial	Brachial	Subintimal PTA	Patient asymptomatic 2 months after the procedure
CHI due to TRA angioplasty							
Kawarada et al., 2010 [23]	Case series	4/5	Stenosis or occlusion	Ulnar (4) Radial (1) Palmar arch (2)	Brachial	PTA	100% technical success with no complications; Clinical success in all cases at 11 ± 8 months
Gandini et al., 2010 [3]	Case report	1	Total occlusion	Ulnar up to the level of the wrist	Brachial	"The radial to ulnar artery loop technique' [PTA of ulnar artery and Palmar arch through radial artery]	Immediate relief of pain; Complete wound healing at 6 months
Rhyne and Mann, 2010 [24]	Case report	1	Total occlusion	Radial	Brachial	PTA	Immediate improvement in symptoms; Patent radial artery 4 months after procedure
CHI due to TRA intervention							
Samaha et al., 2009 [25]	Case report	1	>80% stenosis	Ulnar	Brachial	PTA	Patient's symptoms resolved; No procedure-related complications
CHI due to dialysis access							
Cremonesi et al., 2009 [26]	Case report	1	Severe and diffuse stenosis	Radial and deep palmar arch	Femoral	PTA	Good result with residual stenosis <30%; Complete wound healing at 6 months
Namdari et al., 2008 [27]	Case report	1	Occlusion	Radial	Brachial cut-down	PTA	Complete wound healing at 1 month; Patient asymptomatic up to 21 months
Dineen et al., 2007 [28]	Case report	1	Occlusion	Radial	Brachial	PTA + stenting	Immediate decrease in pain and subjective improvement in sensation of patient's hand; Complete healing at 3 months, patent at 6 months
Ferraresi et al., 2006 [2]	Case report	1	Heavy calcification	Ulnar & radial	Brachial	PTA	Immediate pain relief Patient asymptomatic 8 months post procedure

– = not reported.
AFS = amputation free survival; BA = balloon angioplasty; CHI = critical hand ischemia; CTO = chronic total occlusion; DCB = drug-coated balloon; FF = freedom from; KM = Kaplan-Meier; MALE = major adverse limb events; PTA = percutaneous transluminal angioplasty; TRA = transradial access.

Table 2
Endovascular treatment of critical hand ischemia - atherectomy and balloon angioplasty or stenting.

Author and year	Type of study	Number of patients/hands	Etiology	Involved artery	Access	Technique	Outcomes
Studies							
Camacho Freire et al., 2017 [10]	Retrospective, single center	18	Severe arteriosclerotic stenosis (78%) Iatrogenic dissection (22%) Severe calcification (67%)	Radial & ulnar	Radial (89%) Ulnar (11%)	PTA Stenting (1 case; 6%) RA (1 case; 6%) *To seal an iatrogenic dissection or facilitate catheterization/PCI*	100% success with no vascular complications at 1 month
Bahro et al., 2017 [11]	Retrospective, single center	11	Calcification (100%)	Radial	Femoral	OA + BA	100% angiographic success; 100% freedom from revascularization and amputation at 1 month
Ferraresi et al., 2012 [1]	Prospective, single center	28/34	Stenosis or occlusion	Radial (55%) Ulnar (45%)	Brachial	PTA RA (5%) Stenting (6%)	82% technical success; 3 minor complications; 18% unsuccessful PTA due to inability to cross severely calcified lesions; 65% hand healing rate; Mean healing time 2 ± 1.5 months; Mean follow-up: 13 ± 9 months; 18% symptomatic restenosis; 36% mortality;
Case reports							
Dishmon, 2016 [12]	Case report	1	Total occlusion	Interosseus ulnar	Brachial	OA + BA	Improved angiographic result with restoration of flow into the hand, as well as <30% residual stenosis of the interosseous ulnar artery; 1.5 years follow-up without any reinterventions
Anzuini et al., 2013 [14]	Case report	1	Heavy calcification	Axillary	Brachial	DA + BA	Immediate angiographic success; Sustained clinical benefit up to 3 years of follow-up
Pride et al., 2007 [13]	Case report	1	CTO (100% lesion with moderate calcification)	Brachial	Femoral	DA + BA	No dissection, minor residual stenosis (<10%), and normal flow; No symptoms 3 months after the procedure

BA = balloon angioplasty; CTO = chronic total occlusion; DA = directional atherectomy; OA = orbital atherectomy; PCI = percutaneous coronary intervention; PTA = percutaneous transluminal angioplasty; RA = rotational atherectomy.

angioplasty and 1 rotational atherectomy (6%) cases were performed to seal an iatrogenic dissection or facilitate coronary catheterization with immediate technical success and without vascular complications at 1 month [10]. In the third single center study by Bahro and colleagues, 11 patients with radial artery calcification were treated with OAS prior to POBA, resulting in good blood flow to the hand after the intervention [11]. One of the case reports also indicated the utility of OAS followed by POBA in a totally occluded interosseous ulnar artery [12]. The procedure was well tolerated by the patient, and positive angiography results were achieved without any acute procedural complications. Directional atherectomy was used in two other case reports, but only above-the-elbow arteries (brachial [13] and axillary [14]) were treated.

We report here the utilization of OAS and Chocolate PTA balloon for the treatment of a severely calcified ulnar artery lesion that resulted in excellent angiographic results and no complications. Future studies need to be completed to determine if OAS plus Chocolate PTA balloon has advantages over OAS plus POBA, especially long-term outcomes.

4. Conclusion

Below-the-elbow disease can be treated with endovascular techniques. Obtaining good outflow to the fingers is critical for wound healing and preventing amputation. Orbital atherectomy followed by Chocolate balloon PTA is a useful algorithm for treating small-diameter vessels, particularly in cases where calcification is present.

Declaration of conflicting interest

AB reports consultancy and travel reimbursements from Cardiovascular Systems, Inc. CW and JPA has nothing to disclose. ZsI and BJM own stock in and are employed by Cardiovascular Systems, Inc.

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