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Original Article

The use of a Colapinto TIPS Needle under cone-beam computed tomography guidance for true lumen re-entry in subintimal recanalization of chronic iliac artery occlusion

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Abstract

Background: To report the technique and clinical outcome of subintimal re-entry in chronic iliac artery occlusion by using a Colapinto transjugular intrahepatic portosystemic shunt (TIPS) needle under rotational angiography (cone-beam computed tomography; CT) imaging guidance.
Methods: Patients with chronic iliac artery occlusion with earlier failed attempts at conventional percutaneous recanalization during the past 5 years were enrolled in our study. In these patients, an ipsilateral femoral access route was routinely utilized in a retrograde fashion. A Colapinto TIPS Needle was used to aid the true lumen re-entry after failed conventional intraluminal or subintimal guidewire and catheter-based techniques. The puncture was directed under rotational angiography cone-beam CT guidance to re-enter the abdominal aorta. Bare metallic stents 8−10 mm in diameter were deployed in the common iliac artery, and followed by balloon dilation.
Results: Ten patients (9 male; median age, 75 years) were included in our investigation. The average occlusion length was 10.2 cm (range, 4−15 cm). According to the Trans-Atlantic Inter-Society Consensus (TASC) II classification, there were five patients each with Class B and D lesions. Successful re-entry was achieved in all patients without procedure-related complications. The ankle−brachial index (ABI) values increased from 0.38−0.79 to 0.75−1.28 after the procedure. Imaging follow-up (> 6 months) was available in six patients with patency of all stented iliac artery. Thereafter, no complaints of recurrent clinical symptoms occurred during the follow-up period.
Conclusion: The use of Colapinto TIPS needle, especially under cone-beam CT image guidance, appears to be safe and effective to re-enter the true lumen in a subintimal angioplasty for a difficult chronic total iliac occlusion.

Keywords: angioplasty; cone-beam computed tomography; iliac artery occlusion; subintimal angioplasty; true lumen re-entry

1. Introduction

Since Reekers and Bolia[1] introduced subintimal angioplasty, the trans-subintimal route has become the preferred technique to advance the guidewire through a totally occluded and often heavily calcified lesion, especially in the aortoiliac segment.[2] The technical failure was seen in 20−30% of cases,

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due to an inability to re-enter the true lumen by conventional guidewire and catheter-based subintimal angioplasty technique.[3−7] Several purpose-built re-entry devices, including the Pioneer catheter (Medtronic, Dublin, Ireland), Outback device (Cordis, Johnson & Johnson, Miami Lakes, Florida, USA), and Frontrunner catheter (Cordis), had been developed with successful re-entry at 90−100%.[7−9] However, availability, cost, and the lack of user experience limit their implementation.[10]

Several alternative techniques to re-enter the true lumen of the distal abdominal aorta have also been described, such as by using a coaxial transjugular intrahepatic portosystemic shunt (TIPS) needle, modified trans-septal needle, or metal cannula.[10−13] As the abdominal aortic puncture of the above-mentioned techniques were all performed simply under fluoroscopic guidance, the procedural safety may have been a concern by many interventionists. In this study, we introduced cone-beam computed tomography (CT) guidance to aid Colapinto needle re-entry into the abdominal aorta in difficult chronic iliac artery occluded lesions.

2. Methods

2.1. Study design

The present study was conducted to review retrospectively all of the patients with chronic total occlusion of the iliac artery in our institution, who failed percutaneous attempts of recanalization using conventional intraluminal or subintimal guidewire and catheter-based techniques from January 2009 to October 2013. CT angiography or magnetic resonance angiography provided routine diagnostic images for evaluation of the vasculature from the distal abdominal aorta to pedal arteries. All patients gave informed consent before the procedure, and approval from the Institute of the Review Board of Kaohsiung Veterans General Hospital was obtained for this retrospective study.

2.2. Techniques

For patients with iliac artery occlusions, ipsilateral femoral access is routinely used in a retrograde fashion. Intraluminal recanalization with a 0.035-inch (0.88 mm) hydrophilic angled guide wire (Terumo, Tokyo, Japan) or a 0.018-inch (0.46 mm) CTO wire (Victory, Boston Scientific, Marlborough, MA, USA) was initially attempted for all occlusions. If we failed to cross the occlusion, subintimal angioplasty was attempted. We utilized a looped Terumo guidewire to advance upward in the iliac subintimal space to the desired re-entry point, which was set at 1−2 cm above the aortic bifurcation. If spontaneous re-entry failed after several forceful attempts at the desired re-entry point, an adjunctive re-entry device was applied. As the Outback re-entry catheter (Cordis) was not reimbursed by government medical insurance, we instead used a Colapinto needle (Fig. 1) in patients who could not afford the re-entry catheter. The Terumo guide wire was replaced by a 0.035-inch (0.88 mm) stiff wire (Amplatz; Boston Scientific) and a

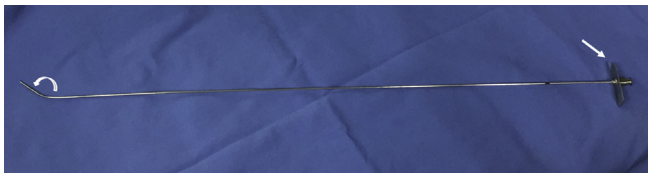

Fig. 1. Photograph of the commercially available 16-G Colapinto transjugular intrahepatic portosystemic shunt needle. The hand-held portion of the needle is shaped with an arrow on one side (arrow), which corresponds to the angle of the needle (curved arrow). Therefore, the direction of needle advancement can be controlled from the maneuver of the handle.

6-F, 45-cm guiding sheath (COOK, Bloomington, IN, USA) was inserted and advanced to the desired re-entry point at the distal abdominal aortic level. A 16-gauge, 50.5-cm Ross Modified Colapinto Needle (Cook) was inserted over the wire to the sheath tip. After the guidewire was removed from the Colapinto needle, rotational angiography cone-beam CT (dynaCT, Siemens, Erlangen, Germany) was performed. With the reconstructed axial images, the needle puncture direction was easily determined. As the cone-beam CT image had already demonstrated the best re-entry direction, we rotated the hand-held portion of the needle to the desired direction before further advancing the TIPS needle. For example, if the needle tip was at the subintimal space at the 3 o'clock position of the abdominal aorta, we directed the needle puncture toward the 9 o'clock direction. The needle was then advanced upward 1−2 cm with a feeling of puncturing through the intimal flap. If the subintimal space had been expanded too wide by a prior looped wire maneuver, and the needle tip failed to puncture through the intimal flap within a 2-cm advancement, another trial by slightly rotating the needle was done. Successful puncture was confirmed with brisk aspiration of blood from the needle, and true lumen opacification occurred with injection of contrast medium. A 0.035-inch (0.88 mm) Terumo guidewire was then inserted through the needle, followed by advancement of an angiographic catheter (KMP; Cook) into the aortic lumen to obtain an aortopelvic angiogram. All patients then received systemic anticoagulation with 3000 IU heparin after recanalization was achieved. A self-expanding Nitinol stent (Parkmore Business Park West, Galway, Ireland) of 8−10 mm diameter was deployed in the common iliac artery, with the stent end slightly protruding into the abdominal aortic lumen. If external iliac artery lesions coexist, another stent of 6−8 mm diameter was deployed, ~1.5 cm overlapping with the prior common iliac artery stent. The metallic stents were further dilated with a balloon catheter of the same size. The overlapping part of the two stents was dilated with the small balloon. A post-procedural angiogram (from pelvis to foot) was obtained to confirm anatomical success, which was defined by the ability to perform the procedure with < 30% residual stenosis. All procedures were performed under local anesthesia and intravenous sedation. Patients were prescribed antiplatelet therapy of clopidogrel 75 mg/d and/or aspirin 100 mg/d for at least 1−3 months after successful procedures.

Vascular patency was determined by medical record (recurrent symptoms/ABI measurement) and/or follow-up

image review (Doppler ultrasound, CT angiography, or magnetic resonance angiography). The median value of ABI before and after percutaneous transluminal angioplasty (PTA) was recorded. The Wilcoxon signed-rank test was used to calculate the statistical significance, and a p value < 0.05 was considered significant.

3. Results

Ten patients (9 male, 1 female; median age, 75 years and range, 45−87 years) were included in this study. Regarding the clinical symptoms of those participating patients, six presented with claudication, three with chronic ulcer, and the remaining one had Buerger's disease after bilateral below-knee amputation, with limb coldness. The average occlusion length was 10.2 cm (range, 4−15 cm). According to the Trans-Atlantic Inter-Society Consensus (TASC) II classification,[14] five patients had Class D lesions (occlusion of both common and external iliac artery), and five patients had Class B lesions (isolated common iliac artery occlusion). There were five lesions each on either the left or the right side. The cone-beam CT images showed that the re-entry points of the abdominal aorta were at the 8−10 o'clock direction in four of the right-sided lesions, the 12 o'clock direction in the one remaining right-sided lesion, the 2−4 o'clock direction in four of the left-sided lesions (Fig. 2), and the opposite side of the 9−10 o'clock direction in the remaining left-sided lesion (Fig. 3).

Re-entry with anatomical success was demonstrated angiographically in all 10 patients. No procedure-related complications or 30-day periprocedural mortality were encountered. The median follow-up duration of the 10 patients was 6 months (range, 3−45 months), although three patients were lost to follow-up after the procedure at 3 months, 5 months, and 6 months, respectively. One patient died at 16 months' follow-up because of malignant lymphoma. The ABI values before percutaneous transluminal angioplasty (PTA) procedure ranged between 0.38 and 0.79 (median: 0.47), then increased to 0.75−1.28 (median: 0.96) within 3 months after the procedure ($p = 0.012$). Imaging follow-up (> 6 months) was available in six patients (3 by Doppler ultrasound, 2 by CT, and 1 by magnetic resonance). All patients had patency of the stented iliac arteries, without complaints of recurrent clinical symptoms during the follow-up period. The demographic data and clinical outcome of the 10 patients are listed in Table 1.

4. Discussion

Subintimal angioplasty is now considered to be an ideal alternative for long segmental chronic total occlusion, especially in the aortoiliac segment.[2] Accurate re-entry into the true lumen during subintimal recanalization is the most crucial procedure of the interventional process. The reported overall success rates of transcatheter recanalization of chronic total occlusion (CTO) in the iliac segments using conventional techniques average around 75% (33−89%).[12,15−20] However, failed re-entry may further complicate chronic total occlusion by disruption of valuable collateral channels as a result of subintimal dissection.[7]

Several true lumen re-entry devices have been introduced into the market,[7−9] including the Outback catheter, allowing fluoroscopically controlled true arterial lumen re-entry after subintimal guidewire passage. A recent retrospective review[8] reported a successful re-entry rate of 91% in 11 patients with aortoiliac CTO after traditional methods had failed. Also, the Pioneer catheter, using a built-in, cross-sectional intravascular ultrasound (IVUS7) transducer to guide the puncture into the true lumen.[7] Krishnamurthy et al[21] reported this device to be technically successful in all of their 11 patients with unilateral iliac occlusions. Additionally, the Frontrunner catheter, using blunt microdissections inside the plaque, allows passage of the guidewire through the lesion and adjunctive angioplasty. Mossop et al[9] reported a recanalization success rate of 88% in 24 iliac CTOs, with a true lumen re-entry

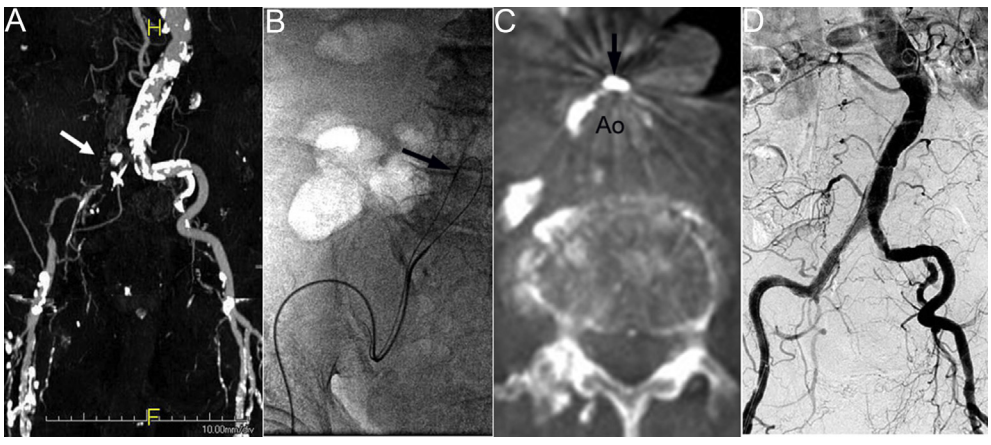

Fig. 2. A 79-year-old man with severe claudication. (A) Computed tomography angiography showed dense calcification of the abdominal aortic and marked torturous iliac arteries with total occlusion of the right iliac arteries (arrow). (B) Fluoroimage showed re-entry failure into the abdominal aorta with the looped guidewire (arrow) in the subintimal space of aortic bifurcation level. (C) Cone-beam computed tomography image identified the Colapinto needle located in the subintimal space at the 12 o'clock direction (arrow) of the abdominal aorta. The puncture direction was made toward the 6 o'clock direction. Ao = aorta. (D) Abdominal aortogram after stent placement and balloon dilation showed good patency of the bilateral iliac arteries. H = head; F = foot.

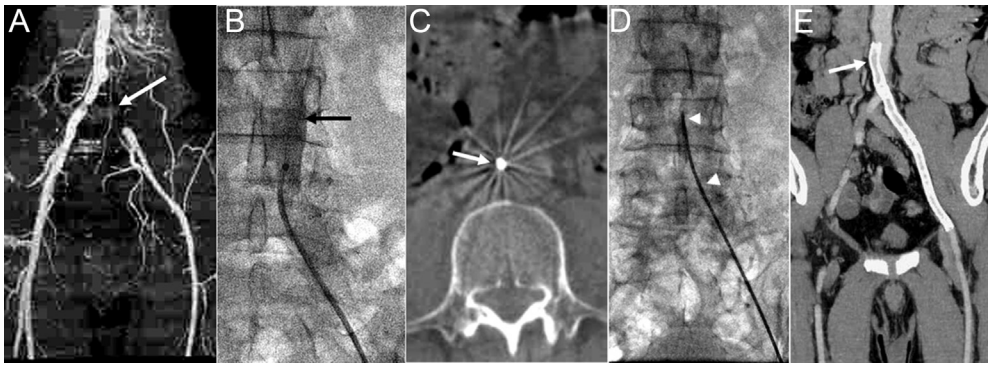

Fig. 3. A 45-year-old man with severe claudication. (A) Magnetic resonance angiography demonstrated total occlusion of the left common iliac artery (arrow) without a residual iliac stump. (B) Fluoroimage showed re-entry failure into the abdominal aorta with contrast medium retained in the subintimal space (arrow) of the distal abdominal aorta. (C) Cone-beam computed tomography image identified the Colapinto needle located in the subintimal space at the 9−10 o'clock direction (arrow) of the abdominal aorta. The puncture direction was made toward the 3−4 o'clock direction. (D) A transjugular intrahepatic portosystemic shunt needle (arrowheads) was advanced and manipulated toward the 3−4 o'clock direction for abdominal aorta re-entry. (E) Reconstructed coronal−oblique view of computed tomography angiography at 6 months' follow-up showed good contrast opacification of the metallic stent in left common iliac artery. Arrow = re-entry point.

Table 1
Basic demographic data and clinical outcome of 10 patients.

Patient No.	Age (y)/ sex	Symptom	Side	Occlusion	Occlusion length	TASC	ABI $p = 0.012$	fu image	FU (mo)
1	72/M	Claudication	Left	CIA/EIA	14 cm	D	0.52/0.86	x	3[a]
2	58/F	Claudication	Right	CIA/EIA	14 cm	D	0.48/0.75	MR	45
3	86/M	Claudication	Left	CIA/EIA	15 cm	D	0.43/0.79	x	5[a]
4	45/M	Limb coldness	Right	CIA	10 cm	B	s/p BK	x	36
5	85/M	Claudication	Left	CIA	4 cm	B	0.79/1.07	CT	16[b]
6	87/M	Chronic ulcer	Right	CIA/EIA	15 cm	D	0.46/1.28	x	6[a]
7	45/M	claud Claudication	Left	CIA	7 cm	B	0.29/0.81	CT	11
8	83/M	Claudication	Right	CIA	5 cm	B	0.8/1.26	US	8
9	78/M	Chronic ulcer	Right	CIA/EIA	13 cm	D	0.38/1.14	US	6
10	61/M	Chronic ulcer	Left	CIA	5 cm	B	0.41/x	x	6

ABI = ankle−brachial index before and after PTA; CIA = common iliac artery; CT = computed tomography; EIA = external iliac artery; F = female; FU = follow up; M = male; MR = magnetic resonance; s/p BK = post below knee amputation; TASC = Trans-Atlantic Inter-Society Consensus class; US = ultrasound; x = not done.

[a] Lost to follow-up.

[b] Patient died.

catheter required in 35% of these cases. Although the overall reported technical success rate of using these re-entry devices is high, it is limited by a high catheter cost and the need for additional equipment, such as an intravascular ultrasound.[13]

Alternative methods of true lumen re-entry without the use of the above-mentioned devices had also been previously reported.[10−13] Murphy et al[11] described a case report of successful re-entry with the aid of a curved,18-gauge needle to puncture through the subintimal space with an occlusion balloon inflated in the iliac stump via contralateral femoral access. Sharafuddin et al[12] reported the coaxial use of a 21-gauge long Chiba needle in a 14-gauge Rosch−Uchida transjugular intrahepatic portosystemic shunt system to achieve re-entry, demonstrating success in nine of 11 (82%) patients. Gastaldo et al[13] used a modified 18-gauge trans-septal needle with a 21-gauge tip to recanalize the true lumen with success in 13 of 15 (86.6%) patients with chronic iliac artery occlusion. The causes of re-entry failure were primarily attributed to vessel calcification that precluded using a fine needle for through-puncture.[12,13,22] Thereafter, Sharafuddin et al[12] suggested the use of a larger needle system such as the 5-F sharp cannula in the Rosch−Uchida kit or using the 16-gauge Colapinto needle itself. In a recent study, Smyth and Hadziomerovic[10] reported the use of a 5-F metal cannula from an 8-F drainage kit with technical success in all of their 12 patients but with a severe complication of vascular perforation at aortic bifurcation in one patient. In our series, we successfully used a 16-gauge needle for re-entry puncture in all 10 of our patients. It appeared that a larger needle can achieve a higher re-entry success rate, but the complication of vascular perforation must be cautioned.

Of the above re-entry techniques, all punctures were directed by fluoroscopic guidance. Cho et al[2] considered that fluoroscopy would not be as beneficial if used alone in this kind of complicated intervention for completely occluded aortoiliac disease. Our study showed that the re-entry site of the abdominal aorta in a subintimal angioplasty may be varied and inconsistent, as demonstrated on the cone-beam CT images. The re-entry site can be anywhere from 90° to 180° different from the supposed direction (i.e., left side iliac

occlusion with re-entry point at the right lateral wall of the aorta). Although multiview fluoroscopy has been reported to be successful in guiding aortic re-entry,[12] a wrong-direction puncture in the aorta may lead to major complications. Cone-beam CT is now available as standard equipment in many angiographic suites. Although cone-beam CT is not real-time imaging similar to intravascular ultrasound, it does provide an accurate relative position of the needle tip to the aorta, which makes interventionists more capable of accomplishing aortic re-entry, even with the use of a larger needle. In fact, it eliminates the need for expensive commercially available re-entry devices.

For intraluminal recanalization of common iliac stenotic lesions, a balloon-expandable metallic stent is recommended for precise localization and deployment. When the lesion is at the ostium, the kissing-balloon or kissing-stent technique is usually mandatory to prevent compromising the contralateral iliac artery. However, in subintimal angioplasty, the re-entry site of the abdominal aorta is usually slightly cranial (1−2 cm) to the bifurcation, causing no compromise to the contralateral iliac artery after balloon dilation and/or metallic stent deployment. Furthermore, for subintimal angioplasty, a bare metallic stent is sufficient to maintain the lumen without the need for a covered stent. That is the reason why we do not perform kissing balloons/stents, instead only deploying a long self-expanding stent in the occluded common iliac artery lesion.

There were several limitations to our study. First, this was a retrospective review with a limited number of patients performed in a single institution. Second, the puncture number and procedure time of the re-entry were not recorded. Third, postprocedural follow-up images and clinical outcome were not routinely collected or available. Lastly, patient selection was nonrandomized as the technique was performed only in patients who could not afford an expensive self-paid re-entry device when the standard crossing CTO methods fail.

In conclusion, from our small patient−series study, the use of a Colapinto needle under cone-beam CT imaging guidance appears to be a safe and effective re-entry method in a subintimal angioplasty for difficult chronic total iliac occlusions. As the re-entry point into the abdominal aorta may vary, the routine use of cone-beam CT guidance (which is now standard equipment associated with an angiographic machine) may be regarded as an ideal alternative to intravascular ultrasound in providing an accurate image for reentry direction into the distal abdominal aorta.

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