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Experience with the novel unifemoral parallel sheath technique in percutaneous intervention of chronic total coronary occlusions

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Abstract

Background: Percutaneous interventions to address chronic coronary occlusions (CTO-PCI) often require simultaneous ipsi- and contralateral coronary injections. Although radial access is increasingly popular, bifemoral artery access is still the preferred choice of CTO operators.

The aim of this case series is to demonstrate the feasibility and safety of the unifemoral parallel sheath technique, which avoids two puncture sites, increases patient comfort, and improves procedure ergonomics.

It offers rapid second access to the femoral artery adjacent to the first sheath as well as closure by unilateral manual compression without or with 1 or 2 vascular closure devices.

Results: We retrospectively evaluated the procedure results in 90 consecutive CTO patients where an ipsilateral parallel sheath access was considered. Placement of the second sheath uneventfully failed in two because of severe femoral calcification and narrowing. In 96.6%, the first sheath was 7 F (3.4% 6F), while the second sheath was 4 F in 22.7%, 5 F in 64.7%, and 6 or 7 F in 11.4% each.

No major complications nor severe bleeding events occurred, and the mean drop of hemoglobin was low (0.6 g/dL \pm 0.86).

Conclusion: In CTO-PCI requiring contralateral coronary injections or the retrograde technique, the ipsilateral parallel sheath technique might be a feasible alternative to the standard bifemoral or femoral-radial access.

Keywords: Coronary artery disease, Chronic total occlusion, Access site, Percutaneous coronary intervention

Background

Percutaneous coronary interventions of chronic total occlusions (CTO) are considered to be the most difficult of all percutaneous interventions.

In the last 15 years, several techniques and newly developed materials have helped to lift the success rates in experienced operators from about 50 to 90% [1].

Relevant contributions to success were the use of contralateral dye injection to visualize the anatomy of the occluded vessel, evolution of better imaging modalities, specific wires, microcatheters, the parallel wire technique, and the retrograde approach [2].

Ever since contralateral dye injection was first described in 1986, it has been done via a second sheath at a different access site [3].

With the increasingly popular transradial access for CTO-PCI, there are various access site combinations that might be used for contralateral opacification: bilateral femoral access, bilateral radial access, or femoral plus left or right radial access.

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The novel unifemoral parallel sheath technique was first described in 2001, but reports of routine use in patients are missing.

A different method which does not require a second puncture site using only one guiding catheter for recanalization and for contralateral injections was described by Kiemeneij in 2014 and Yoshimachi in 2016. After coronary intubation and wiring, the operator must maintain wire or microcatheter position and turn the guide towards the contralateral vessel, a cumbersome technique that was not adopted since it appears unsuitable for most procedures [4, 5].

The parallel sheath technique initially was invented to lower the hurdle of contralateral injection during the course of a CTO-PCI (no need to prepare a second access site), to increase the patient's comfort (only one compression bandage instead of two) and reduce the risk of access site-related complications which intuitively should be lower with 1 access site instead of 2 [6, 7].

In most individuals, the common femoral artery has a diameter of at least 7 mm so theoretically up to two 9 French sheaths (3 mm each) might be placed [8].

In this case series, we analyzed bleeding and access site complications as well as success rates of the parallel sheath technique performed by a single operator in 90 consecutive patients.

Methods

From January 2008 until December 2019, a total number of 810 patients underwent CTO-PCI performed by a single highly experienced operator. In 598 cases, contralateral injections were required to visualize the vessel distal to the occlusion, and in 587/598, the parallel sheath technique was applied.

In our study, we are analyzing a subgroup of 90 consecutive patients in which laboratory controls were systematically scheduled the day after CTO-PCI.

All patients had a chronic coronary occlusion causing angina or dyspnea and proven viable myocardium assessed by echocardiography, magnetic resonance imaging, or scintigraphy.

Chronic total coronary occlusion was defined congruent with the EuroCTO club [9].

Procedural success was defined as TIMI flow 3 and a residual stenosis of 20% or less.

Major adverse cardiac events (MACE) were defined as new intra-hospital non-Q-wave and Q-wave myocardial infarction (defined as myocardial infarction by laboratory findings with or without development of new Q waves), recurrent angina requiring urgent repeat revascularization with PCI or coronary artery bypass grafting, stroke, death, pericardiocentesis, or surgical drainage of pericardial hematoma [10].

Minor bleeding was defined as any bleeding or reported large hematoma (with Hb drop < 3 g/dL) that led to a prolonged hospital stay for surveillance (BARC type 1 or 2) [11].

Major bleeding was defined as bleeding with hemoglobin drop of > 3 g/dL or requiring transfusion of any blood products (BARC 3a criteria or greater).

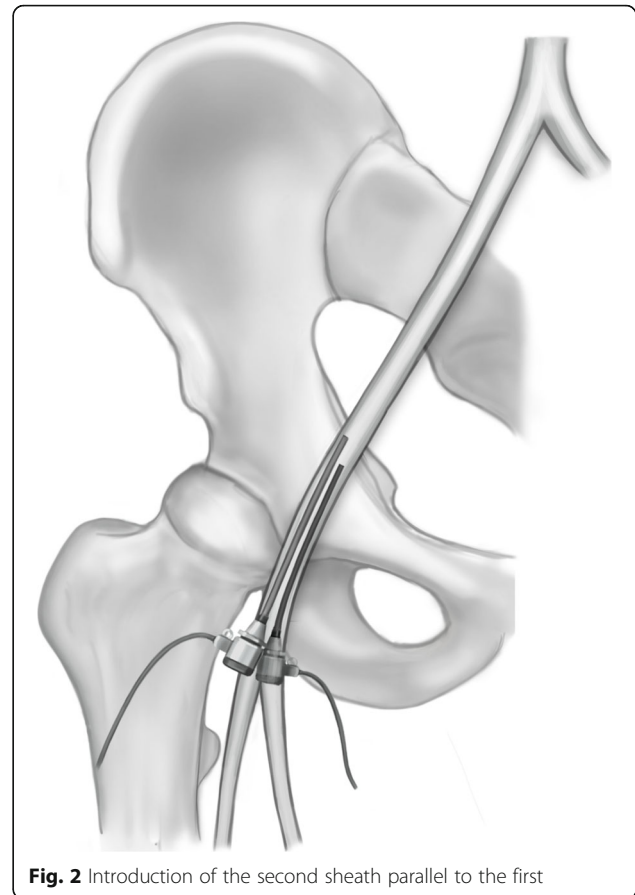
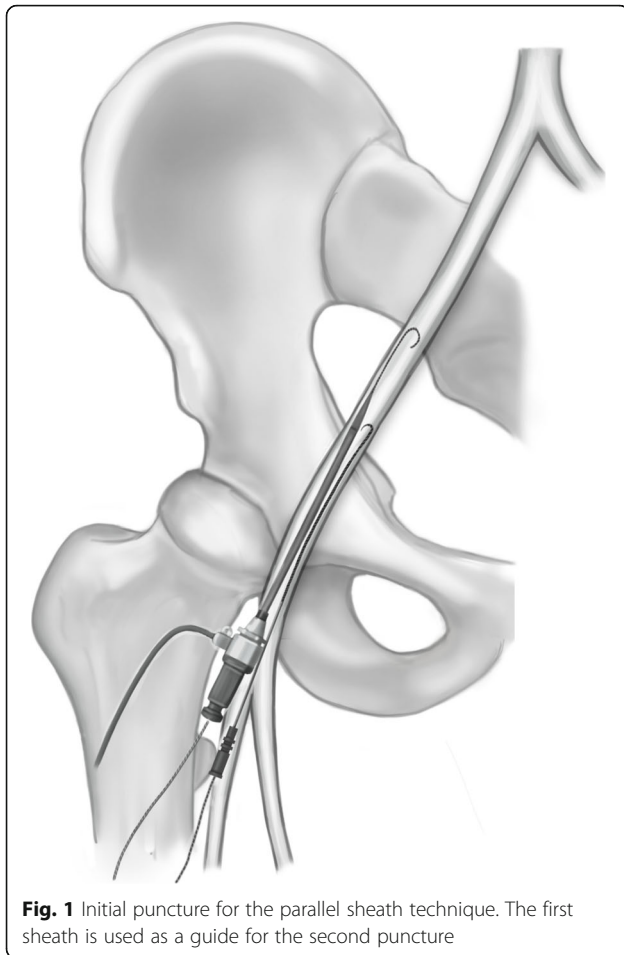
We assessed hemoglobin levels before and the day after the intervention as well as INR, thrombocytes, procedural time, and platelet inhibiting medication. Patients were allowed to eat and drink the day before as well as having a light breakfast the day of the procedure. To deal with potentially excessive dye consumption, intravenous saline was given the day before at a rate of 80 mL/h to all patients unless they had a severely reduced ejection fraction.

Patients were pre-loaded with acetylsalicylic acid 500 mg and Clopidogrel 600 mg or Ticagrelor 180 mg at the time of intervention unless they were already on dual antiplatelet therapy (DAPT). Oral anticoagulation (OAC) was stopped 24 h before the procedure.

All patients were considered to receive two unifemoral sheaths with one primary access for intervention and the second one for contralateral dye injection. If antegrade success was likely, 4 French sheaths were chosen. Planned or potential retrograde procedures required a sheath size of 5 French or greater.

The larger size sheath was always put in first. The dilatator and Seldinger wire were left in place to help straighten the vessel and to guide the second puncture (Fig. 1). The smaller sheath was then placed medial to the first sheath unless there was not adequate space. The needle was guided strictly parallel and close to the first sheath making sure not to puncture it (Fig. 2). In some cases, the puncture and sheath placement were confirmed fluoroscopically (Fig. 3). In patients with severe femoral calcification and difficulty to insert the first sheath, the femoral artery was visualized with dye. In two cases, the operator deemed the vessel to be too narrow for a second sheath and the parallel sheath technique was abandoned (2.2%).

All procedures followed the same protocol with 10,000 IU of unfractionated heparin given as a bolus as soon as both sheaths were successfully placed. Roughly two thirds of the bolus were given through the sheath with the bigger diameter, the remaining third into the other sheath. Activated clotting time (ACT) was checked after 45 min while with BMI above 30 kg/m², the ACT was checked sooner. Subsequent doses of unfractionated heparin were given according to the operator's discretion with the goal to keep the ACT > 250 s during the procedure and

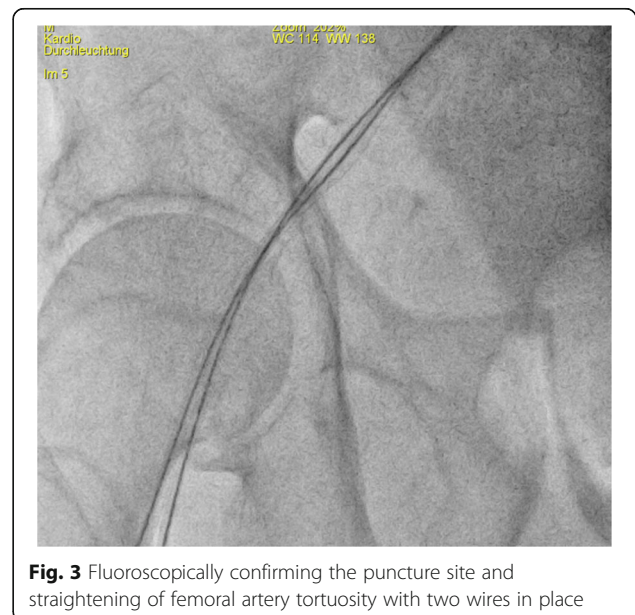


< 250 s at its end. After the PCI was concluded, both sheaths were pulled immediately unless the ACT was still above 250 s, or the patient's systolic blood pressure was above 180 mmHg. Reversal of heparin was not routinely performed.

No vascular closure devices were used in this case series, all sheaths were pulled and followed by manual compression only. More recently, two Angio-Seal vascular closure devices (Terumo Interventional Systems, Somerset, NJ) were used to close both puncture sites (if > 4 French) in most cases (Figs. 4 and 5).

Baseline data including procedural information, demographics, and comorbidities were collected prospectively in a dedicated database (ERCTO registry). Written consent was obtained. The case series was approved by the institutional research and ethics committee and complied with the Declaration of Helsinki.

Data analysis was done with the open access statistical software R 3.6.1 and R-Studio. All values are represented as mean with standard deviation.



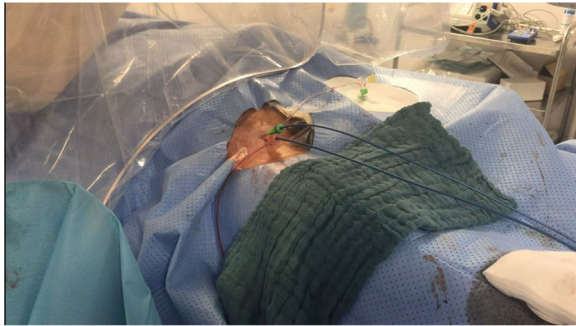


Fig. 4 Dual access with guide catheters in place

Results

The overall success rate of the CTO procedures was 86.6%.

Patient and procedural characteristics are shown in Table 1.

Retrograde technique was used in 28.8% of cases—most which had previously failed an antegrade recanalization attempt.

In 96.6%, the primary sheath size was 7 French, while the second sheath was greater than 4 French in 77%, allowing retrograde procedure.

97.7% of the prospective cases were successfully performed with two sheaths in a single artery.

There were no major or minor bleeding complications nor major adverse cardiovascular events.

The difference between pre- and post-PCI hemoglobin was 0.6 g/dL (± 0.86) (Table 1).

Discussion

Most CTO-PCI cases require dual arterial access which is likely to increase the rate of access site complications, although this was not confirmed by a large registry [12].

Vascular complications following coronary interventions may vary between 11.3%, 9.4%, and 2.1% for transfemoral and 3.5%, 3.4%, and 0.9% following transradial approach [13–15].

The unifemoral parallel sheath technique, first described in 2001, has several advantages over bifemoral access: For one, the second access is more rapidly attained than contralateral femoral puncture. Additionally, there is increased patient comfort, and finally the technique was shown to effectively overcome severe kinking of the iliac artery [7]. However, it remained unclear if two sheaths inserted into the same femoral artery would increase access site complications.

In the observation presented here, the parallel sheath technique was feasible and safe in most cases.

The observed drop in hemoglobin of 0.6 g/dL (a greater part of which might be attributed to backbleeding and blood testing), compares well with the previously reported 0.8 g/dL drop with a single access [15].

In the literature, access site-related complications are reported to occur in about 2% with femoral/femoral access, 1.2% following femoral/radial approach, and 0.9% with radial/radial access [14].

Although radial/radial was reported to have the lowest complication rate, it is not ideal for complex cases (e.g., when parallel wires or IVUS are required) and is hampered with longer fluoroscopy and procedure time [16].

The unifemoral dual sheath technique represents a reliable alternative to dual arterial access that will increase the readiness to upgrade from single to dual sheaths using the first sheath as a track and not needing to prepare a second access site. In addition, it eases guide catheter manipulation in cases with severe tortuosity of the iliac artery [17].

Since the right femoral access site was shown to bring about the lowest radiation exposure, one might speculate that the novel technique is likely to be advantageous in this regard as well [18, 19].

Limitations

Registry patients are not monitored as rigorously as in randomized controlled studies. Since our patients were discharged the day after the procedure, we cannot exclude that late bleedings may have occurred,



Fig. 5 Optional closure with two vascular closure devices

Table 1 Patient characteristics of cohort A (n = 90)

Patient characteristics cohort A (n=90)			
Age	64.6 ± 11.6	Main access (%)	
Female (%)	13.6	7F	96.6
Risk factor (%)		6F	3.4
Hypertension	72.7	Second access(%)	
Diabetes mellitus	26.1	7F	1.1
Hyperlipidemia	70.5	6F	11.4
Smoking	34.1	5F	64.8
BMI (kg/m ²)	28.3±4.2	4F	22.7
PAD (%)	57.8	MACE (%)	0
CAD-1 (%)	11.4		
CAD-2 (%)	34.1	Laboratory findings	
CAD-3 (%)	54.6	Baseline hemoglobin (g/dL)	13.8±1.4
SAPT (%)	45.5	Post-PCI hemoglobin (g/dL)	13.3±1.8
DAPT (%)	40.9	INR	1.1 ± 0.23
OAC (%)	11.3	platelet count (x100/ μ l)	206.9 ± 46.5
CKD stage 3 & 4 (%)	19.3	eGFR (ml/min/1.73 m ²)	86.9 ± 30.3

although it would have been very likely that upon bleeding the patients would have been sent back to our hospital. Apart from the retrospective design, the study is lacking a control group that allows comparison to an alternative access. As a single operator study, the results may not be generalized and operators with less experience may need to perform the puncturing with assistance of ultrasound [20].

Conclusion

The parallel sheath technique with unifemoral dual access appears an easy and safe alternative to approaches with two access sites with complication rates similar to those of a single transfemoral sheath.

Abbreviations

ACT: Activated clotting time; CAD: Coronary artery disease; CKD: Chronic kidney disease; CTO: Chronic coronary occlusions; DAPT: Dual antiplatelet therapy; MACE: Major adverse cardiac events; MRI: Magnetic resonance imaging; OAC: Oral anticoagulation; PAD: Peripheral artery disease; PCI: Percutaneous coronary intervention; SAPT: Single antiplatelet therapy

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Authors' contributions

JR—data analysis and manuscript preparation. KS—data gathering. CWH—manuscript preparation and editing. NR—manuscript preparation and editing. All authors have read and approved the final manuscript.

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Availability of data and materials

The data presented in this article can be made shared upon request.

Ethics approval and consent to participate

Baseline data including procedural information, demographics, and comorbidities were collected prospectively in a dedicated database (ERCTO registry). Written consent to participate in the registry and consent to publish subsequent findings were obtained. The retrospective analysis of the

case series was approved by the institutional research and ethics committee of the Petrus-Krankenhaus Wuppertal on Wednesday, October 26, 2016.

Consent for publication

Not applicable

Competing interests

There are no competing interests regarding this publication.

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