Catheterization and Cardiovascular Interventions 72:790–796 (2008)

Subintimal Tracking and Re-entry Technique With Contrast Guidance: A Safer Approach

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Objectives: To assess the procedural and clinical outcomes from a modified subintimal tracking and re-entry (STAR) procedure performed using contrast guidance. Background: Previous data showed that recanalizing a chronic total occlusion (CTO) with the STAR technique was possible. However, this technique was considered difficult and therefore has only been adopted by a limited number of experienced operators. Methods: Patients (*n* = 68) with a CTO of a native coronary artery treated by a single operator with this technique were included. Results: The right coronary artery was involved in 79.4%, the morphology was blunt in 77.9%, and CTO length was longer than 20 mm in 67.6%. Angiographic success rate was 80.9% with a 70.6% rate of complete recanalization. Stent implantation was performed in 82.3% of cases, with drug-eluting stents (DES) implanted in the majority (92.7%). Procedural complications occurred in 10.3% of cases. There were no episodes of myocardial infarction during follow-up, with 1 case (1.5%) of cardiac death. There were no cases of definite or probable stent thrombosis, and there was 1 (1.5%) possible stent thrombosis. The overall rate of in-segment binary restenosis was 44.7%, and target lesion revascularization (TLR) was performed in 25% of lesions. The rate of TLR in lesions treated with DES was 29.4% and in those treated with bare-metal stents was 50%. Conclusion: The contrast-guided STAR technique appears to be feasible and relatively safe. However, this procedure is limited by a high rate of restenosis even with DES, and a second procedure may be necessary to obtain a definitive result.

Key words: chronic total occlusion; drug-eluting stent; percutaneous coronary intervention; major adverse cardiac events

INTRODUCTION

Percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) is one of the major challenges in interventional cardiology [1,2]. We have previously shown that recanalizing a CTO with the subintimal tracking and re-entry (STAR) technique was feasible and relatively safe, with a low rate of procedural complications [3]. However, this technique was considered difficult with a long learning curve and therefore has only been adopted by a limited number of experienced operators. In this study, we report the procedural and clinical outcome data from a modified STAR procedure performed using contrast-guided STAR that may simplify the technique and make it more widely applicable.

METHODS

All consecutive patients treated using the STAR technique in native coronary arteries by a single first operator (MC) in our institution between January 2005 and October 2007 were included. The indications for PCI were symptomatic myocardial ischemia or evidence of reversible myocardial ischemia from perfusion or stress testing. The STAR technique was used following failed attempts or dissection with conventional CTO techniques using standard wires, dedicated CTO wires, or investigational devices for CTO during the same and/or prior procedure. Before attempting to produce a subintimal channel, the over-the-wire balloon was advanced up to the occlusion site, and con-

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Conflict of interest: Nothing to report.

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Received 24 April 2008; Revision accepted 7 June 2008

DOI 10.1002/ccd.21699
Published online 3 November 2008 in Wiley InterScience (www.interscience.wiley.com).

trast injection was attempted to visualize any possible microchannels [4]. If the microchannels were seen, the artery was opened using the microchannel technique (see below). However, if a dissection occurred as a consequence of microinjection, the procedure was converted into a STAR.

Demographic and procedural data of all patients undergoing PCI at our center are prospectively entered into a dedicated database. A CTO was defined as an obstruction of a coronary artery with thrombolysis in myocardial infarction (TIMI) flow grade 0 with an estimated duration of at least 3 months. All patients provided informed consent for both the procedure and subsequent data collection and analysis for research purposes. In patients not already pretreated with a thienopyridine, a 300-mg loading dose of clopidogrel was administered before the index procedure, and dual antiplatelet therapy was prescribed for 1 month after bare-metal stent (BMS) implantation and 1 year after drug-eluting stent (DES) implantation. During the PCI procedure, patients received intravenous unfractionated heparin (100 IU/kg) to maintain an activated clotting time between 250 and 300 sec.

Contrast-Guided STAR Technique

The STAR technique has been modified from its original description by our institution. When performed as intention-to-treat, a dedicated CTO wire (Miracle or Conquest family; Asahi Intec, Japan/Abbott Vascular Devices, Redwood City, CA) mounted on an OTW balloon was used to puncture the proximal fibrous cap of the CTO sufficiently to insert the distal tip of the balloon into the occlusion. The wire was then removed, and 1–2 ml of contrast was injected into the occlusion. There were three possible outcomes from this maneuver:

1. Visualization of the true vessel lumen: Contrast media passed through microchannels, allowing distal visualization of the true lumen. In those cases, a floppy guidewire usually successfully crossed the occlusion, as previously described in the microchannel technique [4].
2. No visualization and resistance to the injection: If it was impossible to inject contrast media due to resistance, the OTW balloon was flushed, and a dedicated CTO guidewire was reinserted and advanced a few millimeters further into the occlusion. This allowed a deeper advancement of the OTW balloon, and 1–2 ml of contrast media was again injected into the CTO. To facilitate guidewire penetration, the balloon was inflated to provide additional support. However, if the guidewire failed to progress, the procedure was abandoned.

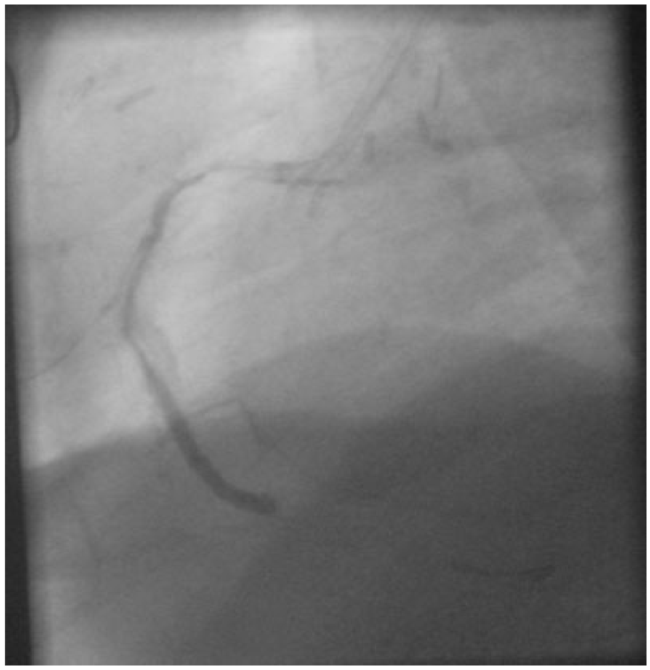

Fig. 1. An example of a tubular dissection of the right coronary artery demonstrated by contrast media staining with linear morphology consistent with the vessel outline.

3. Visualization of a dissection: If injection of contrast media into the CTO created a subintimal dissection with dye staining, we differentiated two different types of dissection according to the angiographic morphology:
   a. *Tubular dissection* with a linear morphology consistent with the vessel outline (Fig. 1). Further injections of contrast were then used in an attempt to directly open the distal dissection into the true lumen, without using additional guidewires (*true lumen re-entry by contrast injection*). A conventional floppy wire was then manipulated through the dissection plane into the distal true lumen. When contrast injection did not reveal the distal true lumen, a hydrophilic wire (Whisper or Pilot; Guidant, Santa Clara, CA) with the tip curved to an ''umbrella handle'' shape was used to extend the subintimal dissection distally and re-enter the true lumen (*true lumen re-entry by wire*). The resistance to forward pressure suddenly decreased as the true lumen was entered, and a jerk action of the wire was observed. When distal re-entry into the true lumen was suspected, the balloon was advanced, the wire was removed, and contrast was injected to confirm the true lumen. Alternatively, contralateral injection may be used to confirm distal true lumen re-entry. A floppy wire was then inserted via the balloon into the true distal vessel lumen.

b. *Storm cloud dissection* was a diffuse staining of contrast media probably indicating vessel dissection with contrast extravasation into the adventitia (Fig. 2). In this situation, it was important to determine the position of the vessel within the dissection and to attempt to convert this into a tubular dissection. A hydrophilic wire with umbrella handle tip was used if injection alone was insufficient to transform the storm cloud into a tubular dissection.

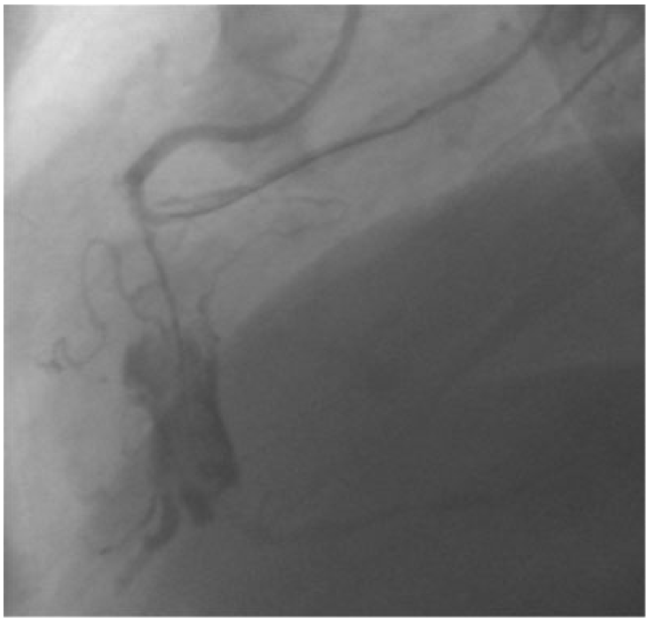

Fig. 2. An example of a storm cloud dissection of the right coronary artery demonstrated by diffuse staining of contrast media probably indicating vessel dissection with contrast extravasation.

Recovery and salvage of the distal side branches. In some cases of tubular dissection, the origin of a side branch was seen as a small hump on the main vessel. In this situation, a floppy or intermediate wire was advanced into the origin of the side branch, and the balloon was advanced to this point. After removal of the wire, further contrast injection in the OTW balloon often led to re-entry into the true lumen.

Tips to avoid complications. In our opinion, the following are important to avoid complications using this technique:

1. When performed as intention-to-treat, we suggest contrast microinjection immediately rather than extending the dissection with a guidewire.
2. If contrast microinjection results in a storm cloud dissection, most of the times you should stop. If you have experience, you can attempt to convert it into a tubular one if
   a. the dimension of the dissection is not too large;
   b. you are able to identify the lumen of the vessel

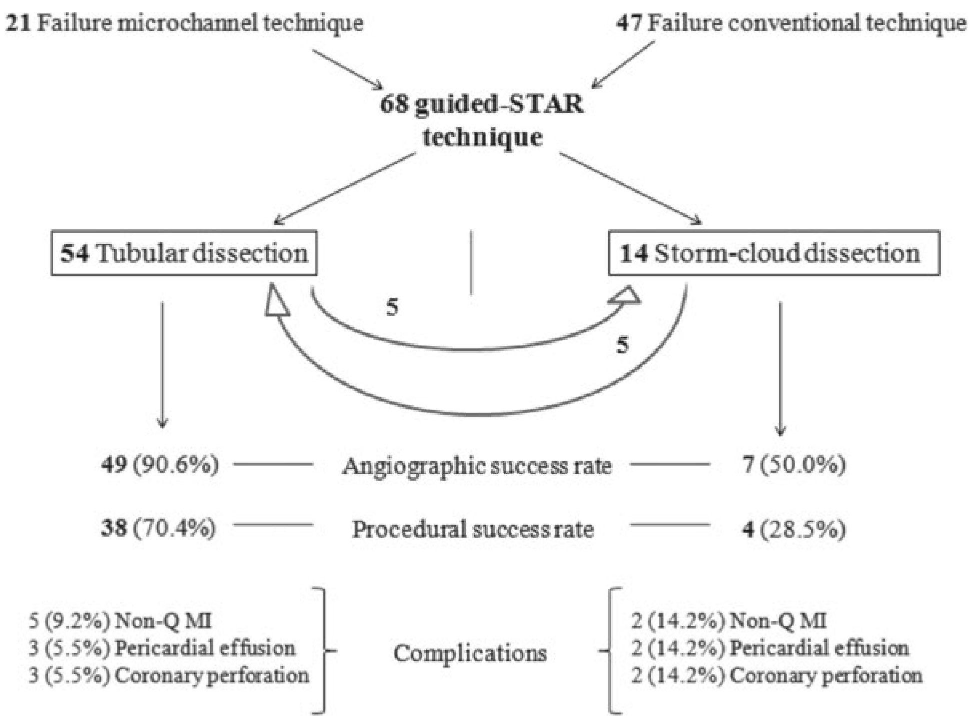

Fig. 3. Flow chart showing the angiographic results and the procedural complications according to characteristics of the dissection.

distal to the dissection, you could attempt to direct the tip of the wire toward this site and perform a microinjection of contrast to convert this dissection into a tubular one.

3. When extending the dissection or trying to re-enter the distal lumen with a guidewire, avoid using a large guidewire loop in a distal branch because of the risk of perforating the vessel as pushing a large loop exerts wider force with the stiffer part of the guidewire.
4. Use contralateral injection if the distal bed is well visualized by contralateral collaterals.

STAR Technique Failures

There were a number of situations in which the risk of continuing with the STAR procedure was considered risky, and the procedure was abandoned:

1. Inability to create a dissection plane in the CTO.
2. Failure to convert a storm cloud dissection into a tubular dissection.

Balloon Dilatation and Stenting

Following passage of a floppy guidewire through the OTW balloon into the distal true lumen, the OTW balloon was replaced with a monorail balloon. Serial inflations were performed through the subintimal dissection plane and into the proximal true lumen. In most cases, DES was implanted with minimal overlap, with the distal stent positioned into the distal true lumen with an attempt to fully cover the dissection plane.

Clinical Definitions and Follow-Up

Angiographic success was defined as a final residual stenosis less than 20%, with TIMI grade $\geq$ 2 flow. Angiographic success with complete recanalization was defined as full recanalization of the main vessel and most distal branches. Myocardial infarction (MI) was defined as an elevation of creatine kinase-MB > three times the upper limit of normal and divided into Q-wave MI or non-Q-wave MI if new pathological Q-waves in the electrocardiogram were present or absent [5]. Procedural success was defined as angiographic success without in-hospital major adverse cardiac events (MACE). MACE was a composite of death, MI, or the need for target vessel revascularization (TVR) with either percutaneous intervention or coronary artery bypass graft surgery (CABG).

Clinical follow-up was performed by telephone contact or office visit at 1 and 6 months after the index procedure. Angiographic follow-up was scheduled between 3 and 6 months postprocedure unless clinically indicated at an earlier time. All deaths were considered cardiac unless attributable to a specific noncardiac cause. Target lesion revascularization (TLR) was defined as a repeat intervention for a stenosis >50% within the stent or in the 5 mm distal or proximal segments adjacent to the stent. TVR was defined as any repeat revascularization within the treated vessel. Stent thrombosis was defined in accordance with the Academic Research Consortium trilevel certainty (definite, probable, and possible) and timing (acute, subacute, late, and very late) classifications [6].

Quantitative Coronary Angiographic Analysis

Coronary angiograms were analyzed using validated edge detection system (CMS, version 5.2, MEDIS, The Netherlands). The reference vessel diameter (RVD) and lesion length were measured on the pre-PCI angiography. The occlusion length was measured from the beginning of bridging collaterals filling to distal vessel reconstitution, from proximal occlusion to distal retrograde filling, or from contralateral collaterals through dual injection technique, or from the length of the lesion visible after guidewire crossing. Angiographic restenosis was defined as diameter stenosis >50% by QCA within a previously stented vessel segment (stent and 5 mm proximal and distal) at the follow-up angiography. Focal restenosis was defined as a restenotic lesion <10 mm long and diffuse restenosis as $\geq$10 mm [7]. We defined severe calcification as radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen [8].

RESULTS

Clinical Characteristics

Baseline clinical characteristics are reported in Table I. A total of 68 patients (65 men, 95.5%) with a CTO of a native coronary artery were treated with this contrast-guided STAR technique, with 49 patients (72.0%) having been previously treated by PCI and 26 patients (38.2%) with CABG.

Lesions Characteristics

Lesion characteristics are reported in Table II. All patients had a CTO older than 3 months, and 63 patients (92.6%) of them were de novo lesions. Previously failed attempts at PCI in the same vessel were present in 23 patients (33.8%). The right coronary artery (RCA) was the most common target vessel (54 patients, 79.4%). The morphology of the occlusion was blunt in 53 lesions (77.9%), and CTO length was longer than 20 mm in 46 lesions (67.6%).

TABLE I. Baseline Clinical Characteristics

	Contrast-guided STAR (n = 68)
Age, mean (mean ± SD)	61.53 ± 9
Male sex, N (%)	65 (95.5)
Ejection fraction (mean ± SD)	51.44 ± 10
Risk factors, N (%)	
Diabetes	17 (25.0)
Insulin-dependent diabetes	3 (4.4)
Hypertension	50 (73.5)
Hyperlipidemia	58 (85.3)
Current smoking	8 (12.5)
History, N (%)	
Chronic stable angina	51 (75.0)
Unstable angina	2 (2.9)
Previous MI	34 (50.0)
Previous PCI	49 (72.0)
Previous CABG	26 (38.2)
Chronic renal failure[a]	4 (5.8)
Prior attempt	23 (33.8)
Multivessel disease	62 (91.1)

CABG, coronary artery bypass graft; MI, myocardial infarction; PCI, percutaneous coronary intervention.
[a]Defined as the presence of previously documented renal failure and/or a baseline serum creatinine level > 2 mg/dl.

TABLE II. Lesion Characteristics

	Contrast-guided STAR (n = 68)
Target vessel, N (%)	
LAD	1 (1.5)
CX-OM	13 (19.1)
RCA	54 (79.4)
In-stent restenosis	5 (7.4)
Severe calcification	13 (19.1)
Bridging collaterals	31 (45.5)
Side branch at occlusion site	54 (79.4)
Ipsilateral collaterals only	19 (27.9)
Contralateral collaterals only	18 (26.5)
Ipsilateral and contralateral collaterals	31 (45.6)
CTO morphology, N (%)	
Blunt	53 (77.9)
Tapered	15 (22.0)
CTO location in vessel, N (%)	
Ostial	19 (27.9)
Proximal	33 (48.5)
Mid	11 (16.1)
Distal	5 (7.3)
CTO length, N (%)	
<10 mm	2 (2.9)
10–20 mm	20 (29.4)
>20 mm	46 (67.6)

LAD, left anterior descending coronary artery; CX, left circumflex coronary artery; OM, obtuse marginal; RCA, right coronary artery.

TABLE III. Procedural Characteristics

	Contrast-guided STAR (n = 68)
Procedural characteristics	
Contralateral contrast injection, N (%)	20 (29.4)
Re-entry by contrast injection, N (%)	7 (10.2)
Re-entry by wire, N (%)	49 (72.0)
Procedure time, min (mean ± SD)	143 ± 20.61
Fluoroscopic time, min (mean ± SD)	47.87 ± 18.84
Dose, Gycm^2 (mean ± SD)	364.70 ± 149.42
Contrast dose, ml (mean ± SD)	384.72 ± 139.25
Stents	
Stent implanted, N (%)	55/68 (81.0)
Number of stent/patients (mean ± SD)	1.63 ± 1.05
Mean stent length, mm (mean ± SD)	61.07 ± 22.02
BMS, N (%)	4/55 (7.2)
DES, N (%)	51/55 (92.7)
Only POBA, N (%)	1 (1.5)

BMS, bare-metal stent; DES, drug-eluting stent; MACE, major adverse cardiac events; POBA, plain old balloon angioplasty.

TABLE IV. Procedural Outcomes and Complications

	Contrast-guided STAR (n = 68)
Successful recanalization, N (%)	
Angiographic success	56 (82.3)
Angiographic success with complete recanalization	48 (70.0)
Procedural success	42 (61.7)
Complications, N (%)	
Myocardial hematoma	1 (1.4)
Dissection limiting procedure	4 (5.8)
Perforation	5 (7.3)
Perforation limiting procedure	3 (4.4)
PTFE stent implantation	0
Pericardial effusion	5 (7.3)
Pericardiocentesis	0

PTFE, polytetrafluorethylene.

Procedural Characteristics and Complications

Procedural characteristics, outcomes, and complications are reported in Tables III and IV. In 47 patients (69%), a conventional technique resulted in a dissection, and so the contrast-guided STAR technique was performed (Fig. 3). In the other 21 patients microinjection of contrast, performed as part of the microchannel technique [4], resulted in vessel dissection, and the procedure was continued as a contrast-guided STAR. Contralateral contrast injection was electively performed in 20 patients (29.4%) and was not performed when the collaterals did not satisfactorily visualize the distal bed. Angiographic success was achieved in 56 patients (82.3%), and 48 patients (70.5%) had complete recanalization. Stent implantation was performed in 55 patients (80.8%), with a DES implanted in 51 patients (92.7%). One patient was treated with balloon angioplasty due to unfeasibility in crossing the lesion with a stent. Procedural complications occurred in 7 patients (10.2%): 4 patients (5.8%) had a storm cloud dissection, and the procedure was abandoned; 2 patients (2.9%) had a coronary perforation, which was managed successfully by prolonged balloon inflation

TABLE V. Clinical and Procedural Outcomes in Different Types of Dissections

N (%)	Tubular 54 (77.9)	Storm-cloud 14 (20.5)	*P* value
Dissection limiting procedure	0	4 (28.5)	<0.001
Coronary perforation	3 (5.5)	2 (14.3)	0.2
Angiographic success	49 (90.7)	7 (50.0)	<0.001
Complete recanalization	41 (75.9)	7 (50.0)	0.04
Non-Q wave MI	5 (9.3)	2 (14.3)	0.5
Procedural success	38 (70.4)	4 (28.5)	0.003

MI, myocardial infarction.

and intravenous protamine injection; 1 patient (1.5%) had a coronary perforation, which caused a left atrial hematoma [9]. Seven patients (10.3%) had an in-hospital non-Q-wave MI. There were no in-hospital deaths, and no cases required urgent CABG surgery. One patient (1.5%) had a repeat PCI to treat a residual dissection following ventricular fibrillation 2 hrs after the procedure. There were no episodes of MACE between discharge and 30 days.

In Table V and Figure 3, the procedural outcomes based on the morphology of the dissection are reported. The contrast-guided STAR technique resulted in a tubular dissection in 54 patients (79.4%) and caused a storm cloud dissection in 14 patients (20.5%). The rates of angiographic success were significantly higher in vessels with tubular than storm cloud dissection (90.7% vs. 50%; $P < 0.001$). Five patients (7.3%) with an initial tubular dissection developed a storm cloud dissection during the procedure. This fact led to the discontinuation of the procedure in 2 patients (2.9%) with a coronary perforation in 1 patient (1.5%) of them. The remaining 3 patients (4.4%) had an angiographically successful procedure. Conversely, there were 5 patients (7.3%) in whom a storm cloud dissection was converted into a tubular dissection, which resulted in angiographic success.

Clinical and Angiographic Outcomes

Clinical outcomes are reported in Table VI. Clinical follow-up was available in 67 patients (98.5%) at a median of 209 days (IQR, 111–312). There were no episodes of MI during follow-up, with 1 death (1.5%) about 9 months after the procedure in a patient who developed severe dyspnea during the night and died before paramedics arrived at his home. There were no cases of definite or probable stent thrombosis, and there was 1 possible stent thrombosis (1.5%) due to an unexplained death at 9 months.

Angiographic follow-up was performed in 38 patients (55.8%). The rate of in-segment binary restenosis was 44.7% (17/38 lesions) overall and was similar in DES (15/34; 44.1%) and BMS (2/4; 50%). The pattern of restenosis was occlusive in 35% (6/17), focal in 53% (9/17), and diffuse in 12% (2/17). TLR was performed in 25% (17) of lesions, and all were treated by repeat PCI, which was successful in 82.4% (14/17). The rate of TLR in lesions treated with DES was 29.4% (15/51 lesions) and in those treated with BMS was 50% (2/4 lesions).

TABLE VI. In-Hospital and Follow-Up Clinical Events

	Contrast-guided STAR (N = 68) N (%)
In-hospital	
Acute thrombosis	0
Periprocedural myocardial infarction	7 (10.3)
Repeat PCI	1 (1.5)
In-hospital MACE	8 (11.7)
Follow-up (excluding in-hospital)	
MI	0
TLR	17 (25.0)
TLR in DES	15/51 (29.4)
TLR in BMS	2/4 (50.0)
Repeat PCI	24 (35.2)
Cardiac death	1 (1.5)
Definite or probable stent thrombosis	0
MACE	24 (35.2)

BMS, bare-metal stent; CABG, coronary artery bypass graft surgery; DES, drug-eluting stent; MI, myocardial infarction; PCI, percutaneous coronary intervention; MACE, major adverse cardiac event.

DISCUSSION

The main findings of this study are (1) the contrast-guided STAR technique appears feasible and relatively safe with an angiographic success rate of 82.3%; (2) there were no cases of acute or subacute stent thrombosis; (3) this study confirms the previous data of a high rate of restenosis with the STAR, even when a DES was implanted.

The STAR technique is currently used to treat CTO, which cannot be approached with other strategies. The main limitation of the STAR technique, as originally described [3], is that the subintimal dissection is created with little or no angiographic guidance, and the operator frequently relies on the ''usual'' anatomical distribution of the occluded vessel and on the resistance felt during attempts to advance the wire. In comparison with our previously published series of STAR [3], this larger series of patients treated with a contrast-guided STAR technique had a lower in-hospital non-Q-wave MI rate (10.3% vs. 16.1%), less number of perforations limiting the procedure (4.4% vs. 9.7%) with none of them needing PTFE stent implantation or pericardiocentesis, and there were no cases of acute or subacute stent thrombosis. The possibility to visualize the course of the artery, even if in its subintimal space, may give reassurance to the operator not only regarding the correct anatomical distribution of the vessel but also that the guidewire is in the main vessel and not in a small secondary branch or in the pericardial space. Occasionally, a useful by-product of this approach is that the injection may dissect favorably into the true lumen. In addition, in centers, where intravascular ultrasound is frequently used in CTO intervention, there may be a role for this modality in identifying the location of the true lumen and thereby increasing the success rate of this procedure.

In the current experience, despite a more liberal utilization of DES compared to the original report [3], there was a 44.1% incidence of restenosis. However, the majority of the restenotic lesions were focal (52.9%), and the success rate of retreatment was high (87.5%). Therefore, it is possible to conceive that almost 50% of the patients may need a second procedure akin to a staged procedure. The concept of secondary patency, common in peripheral interventions, could then be introduced.

In conclusion, the contrast-guided STAR technique appears to be a feasible and relatively safe strategy and can be regarded as a refined evolution to the original approach. However, the procedure is limited by a high rate of restenosis even with DES, and a second procedure may be necessary to obtain a definitive result. The STAR technique may be best considered as a two-step procedure, in which the CTO is recanalized in the first procedure and the focal restenosis treated in the second procedure. Thus, the STAR may be best positioned as a third-tier technique after the failure or nonfeasibility of the standard anterograde or retrograde techniques. Finally, we suggest that this technique should only be performed by experienced operators in selected patients (with refractory angina on medical therapy and evidence of reversible ischemia in the territory of the occluded vessel) in whom there are no alternative lower risk options for revascularization.

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