Intravascular Healing is not Affected by Approaches in Contemporary CTO PCI: The CONSISTENT CTO Study.

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Condensed Abstract (94 words)

The adoption of dissection and re-entry techniques (DART) mean that success rates of >90% are achievable for unselected coronary chronic total occlusions (CTO). The impact of DART and sub-intimal stenting on durability of CTO procedures are poorly understood. A low rate of target vessel failure (TVF; composite of cardiac death, myocardial infarction related to the target vessel or any ischaemia-driven revascularisation) for CTO lesions occurred at 12 and 24 months. DART did not adversely affect intravascular healing assessed by Optical Coherence Tomography at 12 months or clinical events at 2 years.

Clinical Perspectives

This study confirms that high rates of success can be achieved for patients with complex CTO lesions with acceptable, low rates of complications. The durability of IVUS-guided CTO PCI using contemporary techniques employing dissection and re-entry techniques (DART) in addition to sub-intimal stenting is confirmed at 12 and 24 months. DART does not adversely affect intravascular healing at 12 months when assessed by intravascular imaging. Indeed, similar healing is noted within stents sited inside the previous lumen as with those where a sub-intimal course was confirmed on IVUS before stent deployment. Longer term clinical and intravascular outcomes are still required for these complex patients.

Twitter content

IVUS adjudicated sub-intimal passage does not affect clinical, angiographic or OCT outcomes at 1 year @JACCjournals #CONSISTENTCTO

Abstract (250 words)

Objectives

To provide angiographic, imaging and clinical outcomes following chronic total occlusion (CTO) percutaneous coronary intervention (PCI) with dissection and re-entry techniques (DART) and sub-intimal (SI) stenting compared to intimal techniques.

Background

Reliable procedural success and safety in CTO PCI requires the use of DART to treat the most complex patients. Potential concerns regarding the durability of DART with SI stenting still need to be addressed.

Methods

This was a prospective, multi-centre, single-arm trial of patients with an appropriate indication for CTO PCI.

Results

Successful CTO PCI was performed in 210/231 patients (91% success). At 1-year, the primary endpoint of target vessel failure (cardiac death, myocardial infarction related to the target vessel or any ischaemia-driven revascularisation) occurred in 5.7% of patients, meeting the pre-set performance goal. Major adverse cardiovascular events (MACE; all-cause mortality, myocardial infarction or target vessel revascularisation) occurred in 10% at 1-year and 17% by 2-years and was not influenced by DART. Quality of life measures significantly improved from baseline to 12-months. There was no difference in intravascular healing assessed by optical coherence tomography (OCT) at 12-months for patients treated with DART and sub-intimal stenting compared to intimal strategies.

Conclusions

Contemporary CTO PCI is associated with medium-term clinical outcomes comparable to other complex PCI cohorts, and significant improvements in quality of life. The use of DART with sub-intimal stenting does not adversely affect intravascular healing at 12 months or medium-term MACE.

Abbreviations

ADR - Antegrade dissection and re-entry

AWE - Antegrade wire escalation

BP - Bio-absorbable Polymer

CONSISTENT - Conventional Antegrade versus Sub-Intimal Synergy Stenting in Chronic Total Occlusions

DART - Dissection and re-entry technique

DP - Durable Polymer

EES - Everolimus Eluting Stent

JCTO - Japanese chronic total occlusion

RDR - Retrograde dissection and re-entry

RWE - Retrograde wiring

Introduction

Whilst chronic total occlusions (CTO) in the coronary circulation remain the most challenging lesions to treat by percutaneous coronary intervention (PCI), there has been a considerable evolution in techniques and technologies. The adoption of systematic and algorithm-based approaches [1] has resulted in technical success rates approaching 90% in unselected patients. [2-4]

Although antegrade wire techniques are predictably successful in less complex occlusions, dissection re-entry techniques (DART) are required to treat patients with more complex disease. [2-4] Despite this, comparatively little data exists to support their durability. Concerns have also been expressed based on the poor outcomes of sub-intimal tracking and re-entry (STAR) in CTO lesions, [5,6] and similar questions have been raised regarding sub-intimal stent deployment when a retrograde approach is required. [7]

Contemporary CTO PCI approaches have distinct technical differences to historical practice and good medium-term clinical outcomes have been described in larger clinical registries irrespective of approach taken, the presence or absence of dissection within the vessel, or requirement for sub-intimal stenting. [8-10]

Intravascular ultrasound (IVUS) following lesion crossing has illustrated a discordance between the presumed vs actual mode of lesion crossing (sub-intimal vs intimal). [11] As such, any previous assumptions regarding the impact of these approaches and assumed sub-intimal stent deployment in the absence of intravascular imaging are likely to be flawed. The longer term implications of DART are also incompletely understood, although smaller studies have suggested a potential for adverse intravascular healing at shorter follow-up intervals when DART are applied. [12,13]

The CONSISTENT study aimed to understand the impact of DART on procedural durability as assessed by clinical or imaging parameters.

Methods

This was a single-arm, investigator-led, prospective, multi-centre trial with patient recruitment undertaken in 6 centres in the United Kingdom. The trial was administered and overseen by a Clinical Research Organization (Cardiovascular European Research Center; CERC) and the data were overseen, assessed, and adjudicated by a Clinical Events Committee, angiographic core laboratory, intravascular ultrasound (IVUS) core laboratory, optical coherence tomography (OCT) core laboratory and Data and Safety Monitoring Board. The study protocol was approved by the relevant authorities in each centre and there was compliance with the Declaration of Helsinki. All patients provided written, informed consent prior to trial participation. The research was funded by an unrestricted grant from Boston Scientific who had no oversight or input on data gathering, data interpretation or this manuscript. The trial was registered on clinicaltrials.gov (NCT02227771). Recruitment commenced in December 2014 and was completed in December 2016. The angiography and OCT core-lab was at CERC and the IVUS core-lab was in Belfast.

Once the inclusion and exclusion criteria (Appendix 1) were fulfilled and informed consent had been provided, the patient completed pre-PCI quality of life assessments before planned CTO PCI. This study stent was a 3rd generation Everolimus eluting stent with a bio-absorbable polymer (EES-BP). [14] (Synergy stent Boston Scientific, Marlborough, MA, USA). After the lesion was successfully crossed and EES-BP stents were implanted, the patient was considered included in the study. A detailed description of the procedures is also outlined in Appendix 1.

Study Endpoints

The primary device related endpoint was the 12-month target vessel failure (TVF) rate, defined as a composite of cardiac death, myocardial infarction (MI; Q-wave and non–Q-wave) related to the target vessel or ischaemia-driven revascularization of the target vessel.

Cardiac death was defined as death due to any of the following: acute MI, cardiac perforation/ pericardial tamponade, arrhythmia or conduction abnormality, cerebrovascular accident (CVA) through hospital discharge or CVA suspected of being related to the procedure, death due to any complication of the procedure or any death in which a cardiac cause could not be excluded. MI was defined according to the third universal definition. [15] Target vessel revascularisation (TVR) was any ischaemia-driven repeat percutaneous intervention to improve blood flow in the successfully treated target vessel or bypass surgery of the target vessel. A TVR was considered as ischaemia-driven if the target vessel diameter stenosis was ≥50% by quantitative coronary analysis and there was presence of clinical or functional ischaemia which could not be explained by other coronary or graft lesions. Definite, probable or possible stent thrombosis were defined according to Academic Research Consortium (ARC) criteria. [16]

In contrast to studies of non-CTO lesions, a scheduled angiogram and/or resultant lesion optimisation (i.e. not ischaemia driven) within 12 weeks of the CTO PCI did not represent an adverse event according to the protocol. In the experience of the investigators these procedures are often required to allow complete revascularisation and/or optimisation of the index PCI result. This approach is consistent with the recent ARC-2 white paper that recognises the need for repeat procedures in complex lesions and the relevance of clinically and functionally indicated TVR as an adverse endpoint as opposed to protocol-allowed planned procedures. [17]. The procedural result was defined as the result at the index CTO PCI.

Results

A total of 231 patients were admitted to hospital for a clinically indicated CTO PCI and provided informed consent to be enrolled if a successful CTO PCI was undertaken. Subsequently, 210 patients had a successful procedure (91% of attempted cases) and were included in the study. Patient flow through the study is outlined in Figure 1. Baseline demographics are described in Supplementary Table 1. The mean age was 63.5, 81.4% were male and 48.6% had normal left ventricular function. In total 21% were diabetic, 18.1% had prior CABG, 72.9% had single vessel disease with the majority of lesions in the right coronary artery (61.9%).

Procedural characteristics are outlined in Supplementary Table 2. The CTO lesions were complex (mean JCTO score 2.4) and long (mean occlusion length 29mm) with a mean stent length of 85.6mm implanted per patient. Dual catheter access was used in 78.6% of cases. Procedural strategies are outlined in the online Appendix. The final successful strategy was antegrade wire escalation (AWE) in 72/210 (34.3%), retrograde wire escalation (RWE) in 37/210 (17.6%), antegrade dissection re-entry (ADR) in 38/210 (18.1%) and retrograde dissection re-entry (RDR) in 63/210 (30%). This led to an expectation of intimal wire-based tracking in 51.9% and blunt dissection with sub-intimal tracking in 48.1%. The overall procedural complication rate was low (Supplementary Table 2).

Pre-stent IVUS was available in 190/210 (90.5%) patients. Core-lab analysis demonstrated discordance between presumed and actual equipment passage in 15.8% (Figure 2).

A per protocol, a plan for an early angiogram +/- PCI could be declared on the e-CRF after the CTO was successfully opened at the index procedure. This allowed for non-target vessel PCI as well as optimisation of the target lesion. A total of 40/210 (19.1%) patients had a protocol allowed early procedure, of whom 18 had angiography alone. Seven patients had non-target vessel PCI and 1 had SVG closure alone. A total of 5 patients had target vessel stenting for distal disease, of whom 1 also had a non-target vessel PCI and 1 also had planned SVG closure. Finally, 9 patients had POBA only of the target vessel to manage positive remodelling within the stented segment. Therefore, 14/210 (6.7%) had a protocol allowed, scheduled early target vessel intervention. These were short

procedures (procedure time 51.1 minutes ± 31.8, fluoroscopy time 10.9 minutes ± 10.5), had low radiation doses (3371 cGycm2 ± 4498) and were not associated with complications.

Follow-up rates were high. A total of 3 patients withdrew consent. Clinical follow-up was available in 206/207 (99.5%) at 12 and 24-months with angiographic and OCT follow-up in 188/207 (90.8%) and 175/207 (84.5%) at 12-months respectively.

The primary endpoint of TVF occurred in 12/210 (5.7%) by 12-months. This was adjusted subsequent to initial reporting after adjudication of a single MI event by the clinical events committee. There were 0 cardiac deaths by 12-months. Total mortality was 3 (1.4%). Any MI occurred in 3 patients in-hospital and 5 patients (1.9%) at 1 year. In total, 15/210 (7.1%) TVR events occurred by 12-months. The MACE rate (all-cause mortality, MI or TVR) was 10% at 12-months. Definite/probable stent thrombosis occurred in 4/210 patients (1.9%) by 12-months. Sub-group analysis and outcomes for patients treated according to technique and diabetic status are presented in Table 1. A multivariable analysis did not demonstrate any significant association between strategy employed and TVF (p=0.893) at 12-months.

Quality of life assessments were performed using the Seattle Angina Questionnaire (SAQ) and EQ5D questionnaire at baseline and 12 months. Outcomes are presented in Figure 3 and Supplementary Table 3.

Angiographic follow-up was performed in 188 patients at 12 months. Full QCA analysis was available from 179 patients. Binary angiographic restenosis (in-segment), as defined by QCA, occurred in 26/179 patients (14.5%). Re-occlusion of the target vessel in the absence of a clinical event was noted in 6/179 patients (3.4%). The mean in-segment minimum lumen diameter gain was 1.86mm (±0.6) with a mean late loss of 0.14mm (±0.6).

OCT was performed in 175 patients at 12 months (case example Figure 4). Full analysis was available from 167 cases with >449,000 struts assessed (Table 2). The frequency of malpapposed struts per lesion was 2.5% (±4.7). The frequency of covered struts per lesion was 91.1% (±9.8). Aneurysm formation was noted in 11 patients (6.6%), of which 5 were associated with intra-plaque equipment tracking. Outcomes according to the application of DART and / or the presence of IVUS confirmed dissection at index procedure are also presented in Table 2.

By 24-months, TVF had occurred in 10% with no additional MIs. Only 1 cardiac death had occurred with 9 (4.3%) deaths in total. TVR was noted in 25/210 (11.9%), with an overall MACE rate of 17% and definite or probable stent thrombosis occurred in 6/210 (2.9%).

Discussion

Procedural and Clinical Outcomes

Despite lesion complexity, it is now possible to recanalise ~90% of CTO lesions, with the 91% success demonstrated within this study similar to other contemporary series. [2-4, 21, 22] CONSISTENT maintained procedural outcomes in patients with high lesion complexity (mean JCTO score of 2.4), using similar contrast doses but lower radiation exposure than other recent studies. [4, 22, 23] This also did not occur at the expense of increased complication rates (Supplementary Table 2). [4, 22, 23]

Latest generation DES platforms have improved clinical outcomes for patients across the full spectrum of coronary intervention. Our finding of a TVF rate of 5.7% at 1 year using an EES-BP stent met the initial performance goal (TVF <15%). MACE in CONSISTENT was 10% at 12-months and is similar to the protocol defined MACE noted in EXPERT CTO (10%) [24] at the same time point, where durable polymer (DP) EES were studied. Indeed the 1-year MACE rates for CONSISTENT are similar to that reported in multi-vessel non-occlusive disease [21] and in elderly patients where the same stent was used. [25] The 2-year TVF and 2-year MACE rates are also in line with what would be expected for a complex patient group with advanced, but non-occlusive coronary disease.

DART and/or sub-intimal stenting are required to successfully revascularise the most complex CTO lesions. [2, 3, 26] DART are described in 40-49% of almost 7,000 cases in registries across numerous geographies. [2,4, 26, 27] CONSISTENT mirrored this practice, with the DART sub-group having more complex lesions and a higher disease burden (Table 1). As such, longer stent lengths were required to treat these patients (97mm vs 75mm). This increase in stent length was associated with a non-significant increase in TVR, but not death (only 1 cardiac death occurred in this study) or MI at 2 years. In keeping with broader PCI studies, the presence of Diabetes remained the strongest predictor of MACE and TVR (Table 1) at both 12 and 24-months.

Similar to OPEN-CTO, [4] patients included in the CONSISTENT study were highly symptomatic at baseline despite medical therapy, and demonstrated significant gains across a range of quality of life measures. This finding stands in contrast to recent randomised studies in CTO PCI, [22, 23]

where symptomatic patients likely defaulted to revascularisation rather than study enrolment (and potential randomisation to medical therapy), thus blunting any potential symptomatic benefits. CONSISTENT confirms that when symptomatic patients undergo successful CTO PCI they can expect an improved health status 12-months beyond a procedure.

Imaging and Intravascular Healing

Angiographic follow-up showed that re-occlusion was infrequent (3.4%) and similar to that reported at 9 months in the PRISON IV study (1.8%; 5/281) where less complex lesions also underwent core-laboratory angiographic follow-up. [28] Binary angiographic restenosis at 12-months (14.5%) was comparable to contemporary rates described in EES treated bifurcation lesions at 9-months (10.5%). [29] These results stand in contrast to the smaller ACE-CTO study (n=89 with angiographic follow up) [30] that reported a very high rate of restenosis (46%) and TVR (39% versus 7.1%) at 12-months.

Intravascular healing for EES-BP stents, as assessed by OCT strut coverage, is high in shorter, non-occlusive lesions (Table 3). [31, 32] One small series has suggested that healing in CTO lesions may be delayed compared to non-occlusive disease. [33] Data for strut coverage in CTO lesions are limited to small series [12, 13, 34] where DART have been associated with poor intravascular healing. [12, 13]

The CONSISTENT imaging sub-group represents the largest post-PCI OCT follow up in the literature with an almost ten-fold higher number of struts (449,130) analysed compared to previous CTO PCI investigations (Supplementary Table 4). No meaningful difference in vessel healing at 12-months was demonstrated between DART and intimal wiring (n=167, DART = 79, IVUS confirmed dissection = 73). This may have been helped by the use of IVUS at the index procedure to confirm the intravascular course and inform subsequent stenting. [21] The overall rates of strut coverage (91.1%), malapposed struts (2.5%) and uncovered struts (6.4%) are reassuring. Although the use of protocol defined optimisation may also contribute, only a small number of patients (6.7%) had an early protocol allowed intervention on the target vessel.

Aneurysm formation occurred in 11 (6.6%) of cases, less than ACE-CTO. [12] No patients had extension of antiplatelet therapy as a result of these findings. The mechanism or even definition of aneurysm vs pseudoaneursym is ill-defined, but it is unsurprising to note that 5/11 occurred in patients with lumen-based revascularisation. Positive remodelling after CTO PCI occurs irrespective of DART and may be dramatic. Later acquired malapposition may be a result of ‘re-pressurisation’ of the vascular bed leading to ‘demand-driven’ vessel expansion. Of the 11 patients with aneurysm in CONSISTENT, 3 clinical events occurred in 2 patients. One had a peri-procedural

type 4a MI that was unrelated to the aneurysm noted 12-months later. A second patient had a non-ischaemia driven TVR at scheduled angiographic follow-up and suffered a non-cardiac death 625 days post-procedure. No patients who had an early optimisation procedure for the target vessel (n=14) presented with an aneurysm at 12-months.

Limitations

The main limitations of the study are that the cases were not randomised to a placebo arm (i.e. sham procedure), nor was there an optimal medical therapy only arm. The procedures were carried out by experienced PCI operators, all of whom have performed >1000 CTO PCI procedures and are familiar with all of the described approaches. Some patients were lost to angiographic follow-up (9.2%) and different stents were not assessed in this study. These results may not be replicated by operators or centres with less experience of these techniques.

Conclusions

Successful safe CTO PCI is now feasible for the majority of patients. The use of a latest generation EES-BP stent is safe and effective in contemporary CTO PCI. Successful revascularisation is associated with durable, highly significant gains in quality of life at 12-months. TVF rates are low at 12 and 24-months, with MACE rates comparable to other complex patient groups.

The application of DART, and/or sub-intimal stenting facilitates CTO PCI success rates of >90% to be achieved safely despite complex anatomy. Operators may be incorrect on assumed intimal or sub-intimal tracking in 1-in-6 cases. There was no difference in 12-month intravascular healing assessed by OCT, regardless of crossing technique or sub-intimal stenting. Although the 12-month TVR was higher following DART, after multivariable adjustment crossing strategy was not an independent predictor of TVF. Furthermore, there was no significant difference in TVR at 24-months. Disease burden and the presence of Diabetes are the main predictors of both TVR and MACE. Cardiologists should be reassured that modern CTO PCI techniques can be safely applied when indicated.

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Figure Legends

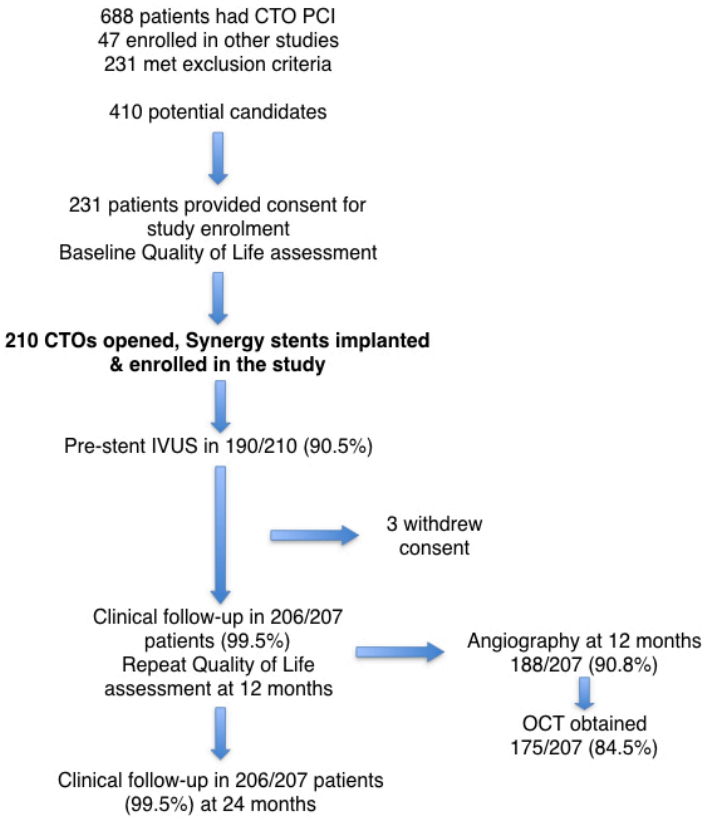
Figure 1. Patient flow through the study.
CTO; chronic total occlusion, PCI; percutaneous coronary intervention, IVUS; intravascular ultrasound, OCT; optical coherence tomography

Figure 2. Discordance between presumed and core laboratory IVUS-confirmed recanalisation path. Presumed course is intimal plaque for antegrade and retrograde wire escalation and sub-intimal for antegrade and retrograde dissection and re-entry.
ADR; antegrade dissection and re-entry, AWE; antegrade wire escalation, RDR; retrograde dissection and re-entry, RWE; retrograde wire escalation

Figure 3. Seattle Angina Questionnaire at baseline and 12 months.
SAQ; Seattle Angina Questionnaire, PL; physical limitation, AS; angina stability, AF; angina frequency, TS; treatment satisfaction, DP; disease perception. Data presented are mean values.

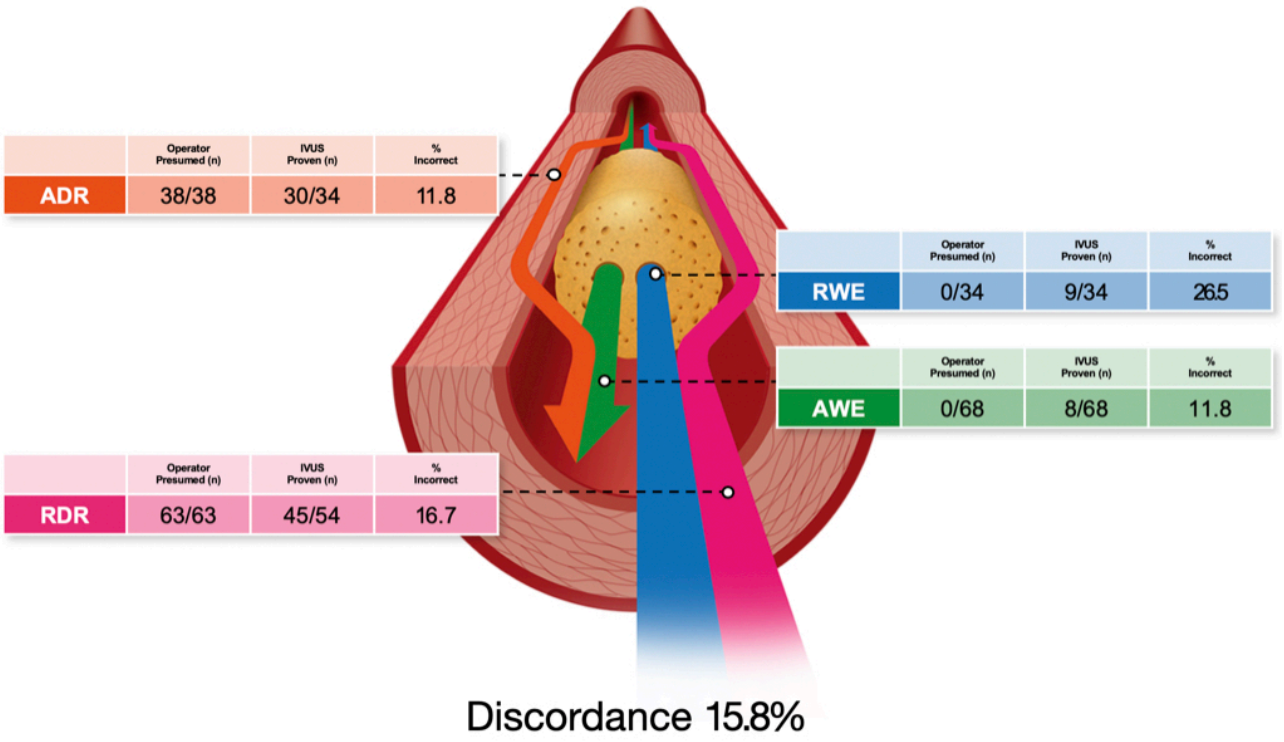
Figure 4. Example of a long LAD CTO before and after PCI, with 12-month follow-up.
Panel A: Baseline angiogram demonstrating a long CTO and Stingray balloon in position for re-entry. Panel B: Acute result after completion of PCI. Panel C: Fluoroscopic image demonstrating extent of stenting at 12-month angiography. Panel D: Corresponding 12-month angiogram. Panel E: OCT image at 12-months demonstrating vascular healing at the re-entry zone.

Figure 1. Patient flow through the study.



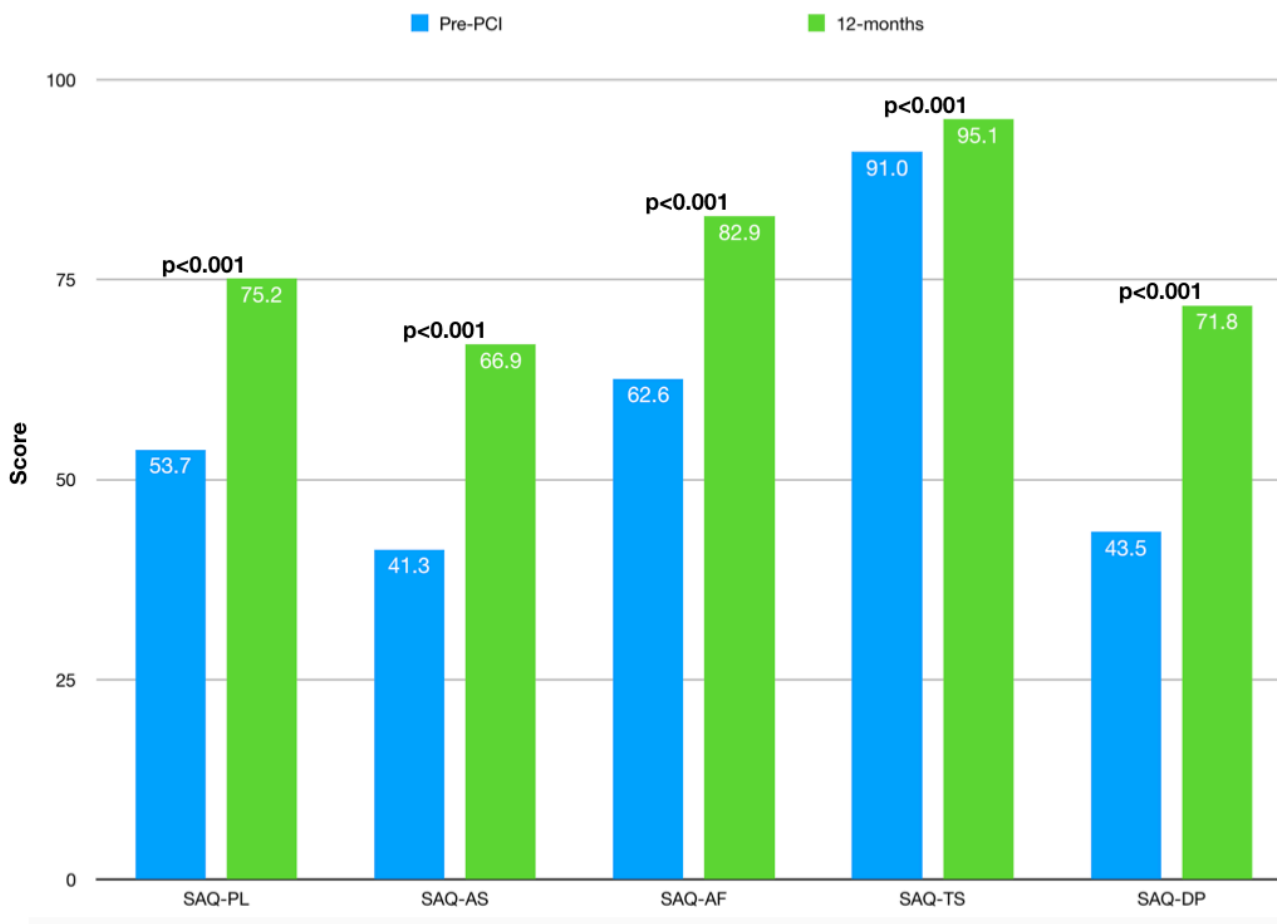
CTO; chronic total occlusion, PCI; percutaneous coronary intervention, IVUS; intravascular ultrasound, OCT; optical coherence tomography

Figure 2. Discordance between presumed and core laboratory IVUS-confirmed recanalisation path. Presumed course is intimal plaque for antegrade and retrograde wire escalation and sub-intimal for antegrade and retrograde dissection and re-entry.



ADR; antegrade dissection and re-entry, AWE; antegrade wire escalation, RDR; retrograde dissection and re-entry, RWE; retrograde wire escalation

Figure 3. Seattle Angina Questionnaire at baseline and 12 months.



SAQ; Seattle Angina Questionnaire, PL; physical limitation, AS; angina stability, AF; angina frequency, TS; treatment satisfaction, DP; disease perception. Data presented are mean values.

Figure 4. Example of a long LAD CTO before and after PCI, with 12-month follow-up.
Panel A: Baseline angiogram demonstrating a long CTO and Stingray balloon in position for re-entry. Panel B: Acute result after completion of PCI. Panel C: Fluoroscopic image demonstrating extent of stenting at 12-month angiography. Panel D: Corresponding 12-month angiogram. Panel E: OCT image at 12-months demonstrating vascular healing at the re-entry zone.

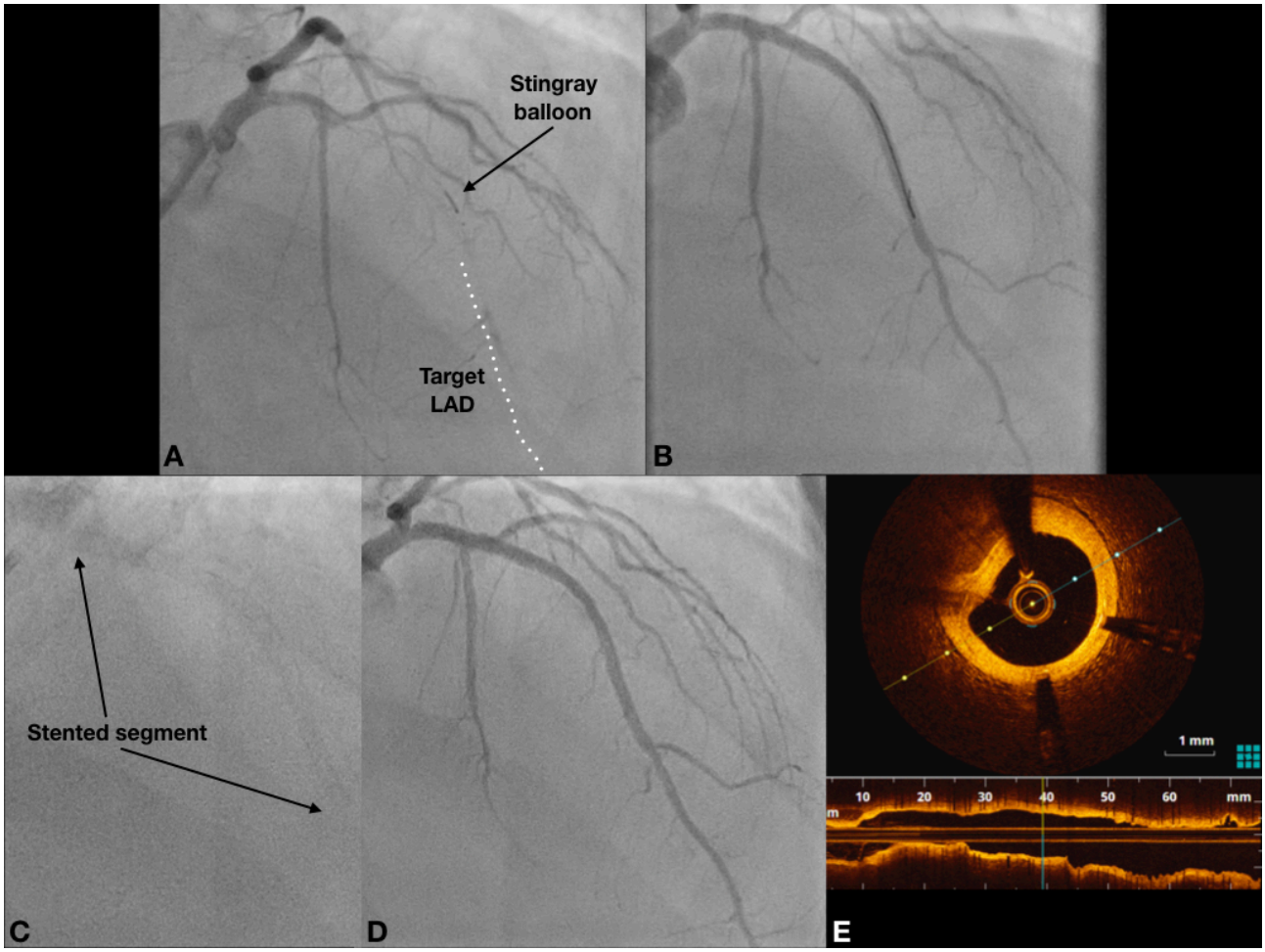


Table 1. One and 2-year outcomes according to CTO PCI final approach and Diabetic Status

Variable	Statistic	DART N=101	No DART N = 109	No Diabetes N = 166	Diabetes N = 44	P-value
Lesion Length (mm)	N (SD)	36.3 (22.0)	22.6 (16.6)			**<0.0001**
Prior CABG Target Vessel	N (%)	22 (21.8)	11 (10.1)			**0.023**
JCTO Score	Mean (SD)	2.9 (1.2)	2.0 (1.1)			**<0.0001**
Stent Length (mm)	Mean (SD)	96.6 (31.6)	75.4 (31.4)			**<0.0001**
MACE at 12 months	N (%)	14 (13.9)	7 (6.4)			0.073
MACE at 24 months	N (%)	21 (20.8)	15 (13.8)			0.177
TVR at 12 months	N (%)	11 (10.9)	4 (3.7)			**0.042**
TVR at 24 months	N (%)	15 (14.9)	10 (9.2)			0.204
MACE at 12 months	N (%)			11 (6.6)	10 (22.7)	**0.004**
MACE at 24 months	N (%)			20 (12.5)	16 (36.3)	**0.0001**
TVR at 12 months	N (%)			8 (4.8)	7 (15.9)	**0.02**
TVR at 24 months	N (%)			13 (7.8)	12 (27.3)	**0.0004**

DART; dissection and re-entry technique, SD; standard deviation, CABG; coronary artery bypass grafting, JCTO; Japanese chronic total occlusion, TVF; target vessel failure, MACE; major adverse cardiac events, MI; myocardial infarction, TVR; target vessel revascularisation

Table 2. OCT findings for the study population, according to procedural approach and pre-stenting IVUS evidence of dissection or not.

Variable	Statistic	Result	Result	Result		Result	Result	
	All patients (n=167)		DART (n=79)	No DART (n=87)	p-value	IVUS Dissection (n=73)	No IVUS Dissection (n=93)	p-value
Struts Analysed per Segment	Mean (SD)	2689.4 (1306.4)	2665.1 (1253.2)	2689.8 (1344.9)	0.903	2854.2 (1477.9)	2539.7 (1126.1)	0.122
Proximal Reference								
Min Diameter (mm)	Mean (SD)	3.1 (0.7)	3.1 (0.6)	3.0 (0.7)	0.327	3.1 (0.7)	3.0 (0.7)	0.327
Max Diameter (mm)	Mean (SD)	3.7 (0.7)	3.8 (0.7)	3.6 (0.7)	0.068	3.8 (0.7)	3.6 (0.7)	0.068
Distal Reference								
Min Diameter (mm)	Mean (SD)	2.5 (1.3)	2.5 (0.6)	2.4 (0.5)	0.244	2.5 (0.6)	2.4 (0.5)	0.244
Max Diameter (mm)	Mean (SD)	2.9 (1.7)	3.1 (0.7)	2.8 (0.6)	**0.003**	3.0 (0.7)	2.9 (0.7)	0.362
In-stent CS Area (mm^2)	Mean (SD)	8.2 (2.5)	8.6 (2.7)	7.9 (2.2)	0.068	8.6 (2.5)	7.8 (2.4)	**0.038**
Neo-Intimal Hyperplasia Area at Maximal Obstruction (mm^2)	Mean (SD)	1.8 (1.3)	1.9 (1.4)	1.7 (1.1)	0.305	1.9 (1.4)	1.7 (1.2)	0.324
Neo-Intimal Hyperplasia Area (mm^2)	Mean (SD)	1.3 (0.7)	1.4 (0.7)	1.3 (0.6)	0.323	1.4 (0.7)	1.3 (0.6)	0.324
Neo-Intimal Obstruction (%)	Mean (SD)	16.9 (8.0)	16.3 (8.1)	17.4 (7.9)	0.377	17.1 (8.3)	16.7 (7.8)	0.750
Stent Area Stenosis (%)	Mean (SD)	31.1 (15.3)	31.8 (16.0)	30.4 (14.6)	0.556	32.2 (15.1)	30.1 (15.5)	0.382
Frequency of Covered Struts per Lesion (%)	Mean (SD)	91.1 (9.8)	90.1 (10.0)	91.9 (9.6)	0.238	91.3 (10.0)	90.8 (9.8)	0.747
Frequency of Uncovered Struts per Lesion (%)	Mean (SD)	6.4 (6.4)	7.0 (6.6)	5.9 (6.1)	0.226	6.4 (7.0)	6.4 (5.8)	1
Maximum Consecutive Length of Uncovered Struts (mm)	Mean (SD)	1.9 (1.9)	2.1 (2.0)	1.8 (1.8)	0.311	1.9 (1.8)	2.0 (2.0)	0.739
	Maximum	13.2	10.0	13.2		9.6	13.2	
Frequency of Malapposed Struts per Lesion (%)	Mean (SD)	2.5 (4.7)	2.9 (4.7)	2.2 (4.6)	0.334	2.3 (3.9)	2.8 (5.2)	0.495
Maximum Consecutive Length of Malapposed Struts (mm)	Mean (SD)	1.2 (1.7)	1.4 (1.9)	1.0 (1.6)	0.143	1.2 (1.5)	1.2 (1.9)	1
	Maximum	9.6	9.6	8.7		7.9	9.6	
Persistent Dissection In-stent	N (%)	6 (3.6)	4 (5.1)	2 (2.3)	0.425	1 (1.4)	5 (5.4)	0.231
Aneurysm Formation	N (%)	11 (6.6)	8 (10.1)	3 (3.4)	0.119	6 (8.2)	5 (5.4)	0.538

DART; dissection and re-entry technique, IVUS; intravascular ultrasound, Min; minimum, Max; maximum, CS; cross section.