Long-term outcomes of successful chronic total occlusion percutaneous coronary interventions using the antegrade and retrograde dissection and re-entry approach.

（LOTUS-ADR/RDR）

Protocol

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ABSTRACT

BACKGROUND： Chronic total occlusion (CTO) angioplasty is one of the most challenging procedures remaining for the interventional operator. Today, with contemporary CTO negotiation available strategies and significant operator expertise, the literature reports a 50-95% success rate for recanalizing CTOs. But PCIs of CTO lesions still carry a high rate of in-stent restenosis (ISR). Because previous reports have not specifically compare contemporary antegrade and retrograde dissection and re-entry dissection (ADR/RDR) technique on the long-term impact of ISR, so the investigators focused on the objective.

OBJECTIVES: This study hope to evaluate the frequency of angiographic ISR and further elucidate some ISR related higher risk factors among CTO PCI patients in intimal stent group using antegrade or retrograde wire escalation (AWE/RWE) techniques and sub-intimal stent group using contemporary antegrade or retrograde dissection and re-entry (ADR and/or RDR).

METHODS: A total of 300 consecutive selected patients with CTO lesion who will undergo successful revascularization by AWE/RWE and ADR/RDR techniques treatment will be enrolled in this prospective multicenter registry from December 1 2018 to December 31 2019. The primary study endpoint of the protocol is the bionary in-stent restenosis of CTO vessels at angiographic follow-up about 13 months. The secondary endpoints are: 1) CTO technique and procedure success rate; and 2) in-hospital and 30 days MACE (Cardiac death, acute myocardial infarction, urgent repeat tratget vessel revascularization with either pericardiocentssis or surgery and stroke and stent thrombosis and stroke); 6months and 1-year and 2-year MACE including death, MI, and target CTO vessel revascularization and stroke ; and 3) Restenosis scores (R-scores) of related risk factors.

CONCLUSIONS： This study expect to identify long-term effect of ADR and RDR methods on the ISR incidence and predictors.

INTRODUCTION

Chronic total occlusion (CTO) angioplasty is encountered in 18.4% to 52% of patients with coronary artery disease (CAD) undergoing coronary angiography[1–4]. Observational studies suggest that successful CTO PCI can provide significant clinical benefit to patients, including symptom relief, improved left ventricular function, reduced risk of arrhythmias, and better tolerance of an acute coronary syndrome[5]. CTO is considered one of the most difficult lesion types to treat. With the development of new techniques and dedicated devices, procedural success rates for CTO recanalization have vary between 60% and 90% in recent years [6-10].

However, CTO lesions have a 1.4- to 5-fold higher rate high risk of in-stent restenosis (ISR), compared with non-occlusive stenosis[11–16]. ISR, induced by neointimal hyperplasia, is a long-recognized, chronic complication following PCI. Previous studies have reported clinical or lesion-related characteristics (i.e., complex lesion morphology or comorbidities, such as diabetes mellitus) [17, 18] and calcification and CTO length are known as ISR predictors [19]. Whereas Valenti et al. reported that specific techniques (the subintimal tracking and re-entry technique (STAR) was associated with ISR [11].

The STAR technique was the first reported antegradesubintimal dissection and reentrymethod to re-open occluded arteries[20,21]. Although this technique has some limitations, notably the inability to control the reentry point in the distal lumen, it did effectively demonstrate that blunt dissection through the subintimal space could rapidly and safely traverse even very long, tortuous, and calcified occluded segments without vessel perforation[20-24]. This demonstration provided the confidence to further explore the use of the subintimal space for therapeutic purposes[23]. STAR was integrated into a retrograde approach (e.g. Controlled Antegrade and Retrograde subintimal Tracking (CART)) [25-27], and a dedicated antegradedissection and re-entry system (CrossBossTM Catheter and StingrayTM System) [28]. As a result of these advances and greater operator experience, success rates of CTO PCI have increased[29].

There have been concerns raised that the high restenosis rate after STAR[30-33] may

be a direct consequence of subintimal stenting. If the cause of the high incidence of restenosis is, in fact, due to use of the subintimal space, newer CTO techniques, which are based on controlled subintimal dissection and reentry methods, also would be expected to be associated with this adverse outcome [25–28] Now there are only limited data about procedural success of ADR and RDR and retrograde technical have been demonstrated and the use of subintimal stenting did not adversely impact outcomes [34, 35]. While prospective studies with longer follow-up are needed to assess the long-term safety and efficacy of sub-intimal stenting.

The purpose of the study was therefore to examine the longer-term outcomes of patient who underwent successful CTO PCI in our program, compare the effect of ADR/RDR on outcomes with everolimus-eluting stents (EES) and assess predictors of long-term events.

METHODS

1. Trial overview and study population.

① This clinical trial is a prospective, exploratory, nonrandomized, multicenter trial evaluating the frequency of angiographic restenosis and clinical outcomes among patients undergoing CTO PCI in intimal stent group using antegrade or retrograde wire escalation (AWE/RWE) techniques and sub-intimal stent group using contemporary antegrade or retrograde dissection and re-entry (ADR or RDR) with everolimus-eluting stents (XIENCE Coronary Stent).

②According to high patient's volume registry studies in CTO lesions, the patients percentage of ADR or RDR strategy application was just only 20-25%[36-37]. If to get 60 patients for ADR or RDR strategies, the minimum CTO number are 300 patients. So in our registry study, 300 CTO cases, to which PCI will be attempted, are prospectively enrolled from December1 2018 to December 31 2019 in the CTO registries of ten centers. The study was approved by the institutional review board at each site. For patients with multiple treated CTO, only the first CTO attempted was considered for the analysis.

③ Exclusions included age <18-years-old or >85-years-old, left ventricular ejection

fraction ≦30%, allergy to medications (antiplatelet drugs, heparin, metal alloys, or contrast agents), a planned surgery within 6 months of PCI or planned thrombolysis, pregnant, a life expectancy of <6 months.

④ Patients will sign written informed consent for long-term telephone FU before the interventional procedure. The patients will be followed by a clinical visit or by a telephone interview for 30 day, 6 months and 12 months and 24 months post-procedure for assessment of adverse events. All patients with successful CTO PCI and without moderate or severe renal insufficiency will be scheduled for angiographic follow-up at 13 months. Compared with CTA, coronary angiography to evaluate restenosis is appropriate in all patients especially for severe coronary heart diseases patients with atrial fibrillation and ventricular arrhythmia. It could provide accurate information about mild-severe angulation lesion andthe stentstraits like total stent length.Procedural and outcome data collection will be collected and entered by operators entered into a dedicated database.

⑤ The study will be performed in accordance with the Declaration of FMMU.

2. Study endpoints and definitions

① The primary study endpoint of the protocol is the bionary in-stent restenosisof CTO vessels at the scheduled angiographic follow-up at 13 months. The secondary endpoints are: 1) CTO technique and procedure success rate; and 2) in-hospital and 30 days MACE (Cardiac death, acute myocardial infarction, urgent repeat tratget vessel revascularization with either pericardiocentssis or surgery and stroke and stent thrombosis and stroke); 6 months and 1-year and 2-year MACE including death, MI, and target CTO vessel revascularization and stroke ; and 3) Restenosis scores (R-scores) of related risk factors.② Coronary CTOs will be defined as angiographic evidence of total occlusions with TIMI (Thrombolysis In Myocardial Infarction) flow grade 0 and estimated durations of at least 3 months. Estimation of the occlusion duration is based on first onset of anginal symptoms, prior history of myocardial infarction in the target vessel territory, or comparison with a prior angiogram.

③ Procedural success will be defined as angiographic success(final residual stenosis <30% by visual estimation and TIMI flow grade 3 after CTO recanalization).

④ Clinical success will be defined as a procedural success without In-hospital MACCEs. In-hospital MACCEs is defined as the composite of non-Q-wave and Q-wave myocardial infarction (MI), recurrent angina requiring urgent repeat revascularization with PCI orcoronary bypass surgery, stroke, and death. Non-Q-wave MI is defined as creatine kinase-MB enzyme elevation >3 times the upper limit of normal. When new pathological Q waves, in addition to enzyme elevation, will be observed on the electrocardiogram, the event is defined as a Q-wave MI. In all patients, creatine kinase and creatine kinase-MB is evaluated 6 h after the procedure and until theirnormalization iflevels is abnormal.

⑤ Lesion complexity will be judged using the J-CTO (Multicenter CTO Registry in Japan)score(0 ¼ easy,1 ¼ intermediate, 2 ¼ difficult, $3 ¼ very difficult)(20)and calculated by allocating 1 point each for:non-tapered proximal cap (ie, blunt or ambiguous), any calcification, any tortuosity, occlusion length >20 mm and any prior unsuccessfulattempt. J-CTO score of ≥2 was defined as complex.

⑥ CTO proximal cap location is defined according to American Heart Association (AHA) classification and additionally coded as either ostial or non-ostial and proximal (left main, proximal left anterior descending, proximal circumflex or proximal right coronary artery) or distal (all other sites). Cap morphology is coded as blunt or tapered, or as ambiguous when there is lack of clarity over the origin of the ongoing vessel. Calcification within the CTO is coded as none visible, mild(spots only), moderate (<50% of vessel circumference) or severe (>50% of vessel circumference). Tortuosity is assessed at baseline or after subsequent equipment passage and coded as straight (no bend or <45°single bend), slight (>45°single bend), moderate (2 bends >45°or 1 bend >90°) or severe (2bends >90°or 1 bend >120°). Disease proximal and distal to the CTO is classified as absent, mild, moderate or severe. Aproximal or distal cap side branch is considered present if occurring ≤3 mm from the respective CTO cap. Occlusion length is estimated by dual injection, or from apparent length after guidewire crossing. Collaterals are classified according to Cohen and Rentrop and deemed interventional if, on angiographic inspection, are thought amenable to crossing by a guidewire and a microcatheter by the operator.

⑦ All deaths are considered cardiac unless otherwise documented. Stent thrombosis is defined according to the Academic Research Consortium criteria (13). Reocclusionis defined as a TIMI flow grade of 0 to1in the target CTO vessel, where restenosis is defined as > 50% luminal narrowing at the segment site, including the stent and 5 mm proximal and distal to the stent edges. Target lesion revascularization (TLR) is defined as any repeat PCI or coronary artery bypass graft surgery of the target lesion that includes 5 mm proximal and distal to the stented vessel segment.

⑧ A procedure is considered retrograde if an attempt is made to cross the lesion through a collateral vessel supplying the target vessel distal to the lesion. Complex lesions with unclear location of the proximal cap or with poor distal target are initially attempted by the retrograde approach. In those cases, after positioning of a microcatheter at the distal CTO cap, a true-to-true retrograde lumen crossing technique is first attempted for shorter lesions (<20 mm). When entering in the subintimal space or with longer lesions, knuckled wires are used to reach the proximal cap, followed most often by reverse-controlled anterograde and retrograde re-entry techniques.

⑨ A procedure is considered antegrade if no retrograde crossing attempts are made. An anterograde approach is initially attempted for short lesions (<20 mm) with clear proximal cap location and good distal vessel target using a wiring strategy. Anterograde dissection/re-entry using dedicated devices (CrossBoss and Stingray catheters) is, however, preferred for longer lesions with an optimal distal re-entry zone, without significant side branches that could be occluded by the technique, or when an initial wire escalationstrategy failed. Wire-based anterograde dissection/re-entry was also used successfully when an initial attempt at crossing from a “true-to-true” approach failed. Such a strategy involves the use of a microcatheter delivered on a knuckled polymer-jacketed wire advanced into the subintimal dissection plane, with subsequent re-entry into the true distal lumen using a stiff tapered guidewire or a knuckled guidewire. A Stingray system will be used to cross from the false lumen to the true lumen, the so-called hybrid procedure, rapidly switching from one approach to another when the initial strategy attempted is failing.

For the main analysis, the investigators consider that the lesion is crossed with dissection/re-entry when (1) a wire-based anterograde dissection was performed followed by re-entry into the true distal lumen with a straight or knuckled wire/CrossBoss, (2) A Stingray system was used to cross from the false lumen to the true lumen, and (3) when a reverse-controlled anterograde and retrograde re-entry technique is used to cross the CTO segment. Other CTO crossing techniques were considered "intraplaque," "true-to-true," or wire escelation techniques**(as figure 1**).

3. Intervention Procedures

① All patients receive optimal intravenous hydration the days before and after PCI.

② Patients receive an initial bolus of intravenous unfractioned heparin (100 IU/kg). The activated clotting time is monitored every 30 min to determine if an additional bolus of unfractioned heparin is necessary to maintain an activated clotting time >250s. Upstream use of glycoprotein IIb/IIIa inhibitor therapy or bivalirudinis avoided.

③ All procedures are performed via the radial or/and femoral route, with double coronary cannulation and contralateral selective injection. Seven-French guiding catheters are used in most cases.

④ All operators have received proctoring in AWE, antegrade dissection re-entry (ADR), retrograde wire escalation (RWE) and retrograde dissection re-entry (RDR) approaches used in the hybrid algorithm. And operators have performed a career minimum of 300 CTO cases.

⑤To adjust the patients number in intimal stents group and subintimal stents group with either the antegrade or the retrograde approach,wire escalation technique was made as the first choice in all patients, if failed, to choose which CTO revascularization strategy is left to the operator's discretion (Fig 1).The selection of the optimal initial CTO crossing strategy is dependent on the anatomy of the coronary vessels. Four angiographic characteristics are used to make the decision (Fig. 1): (a) lesion length (lesions ≥20 mm in length tend to have lower success rates and longer procedure times using standard antegrade wire escalation); (b) proximal cap location and morphology; (c) size, quality (i.e. vessel size and presence of luminal stenoses

and/or calcification) and presence of side branches of the target coronary vessel at the distal cap; and (d) size and suitability of collateral circulation for the retrograde technique. Several guidewire strategies are used, including the single-wire technique, the parallel-wires technique, the intravascular ultrasound–guided wiring technique, and retrograde wiring through collateral vessels, such as simple retrograde wiring, kissing wires, the knuckle technique, and the CART and reverse CART techniques, as previously described.

⑥ The number and type of approaches (AWE/ADR/RDR/RWE) required to cross the CTO segment are recorded. Wire crossing time is from insertion of the guidewire into either the target vessel or retrograde donor vessel to when the wire successfully crossed the CTO segment and re-entered the true lumen.

⑦ The occluded segment is stented with second generation DESs(XIENCE, Abbott) (if no contraindication for prolonged dual antiplatelet therapy) and post-dilation performed to optimize stent expansion and apposition as needed.

⑧ In this study, by evaluating CTO lesions in the pre-stenting and post-PCI period, the investigators seek to identify the predictors of ISR. The standard restenosis scores (R-scores) related six factors including: A: the number of stent (n＜2 0score; 2＞n＜4 1score; n＞4 2score); B: stent length (＜35mm 0score; 36-70mm 1score; ＞71mm 2 score); C: lumen dissection length (＜20mm 0score; 21-30mm 1score; ＞31mm 2score) ; D: calcification (mild 1score; severe 2score; E: lumen area (＜5mm^2 3score; 5-7$mm^2$2score; ＞7mm^2 1score) and F: angulation slight (>45°single bend 1score), moderate (2 bends >45° or 1 bend >90° 2 score) or severe (2bends >90° or 1bend >120° 3score). Additionally, the investigators will utilize IVUS as a tool to evaluate predictor factors to obtain in-depth analyses of the lesions.

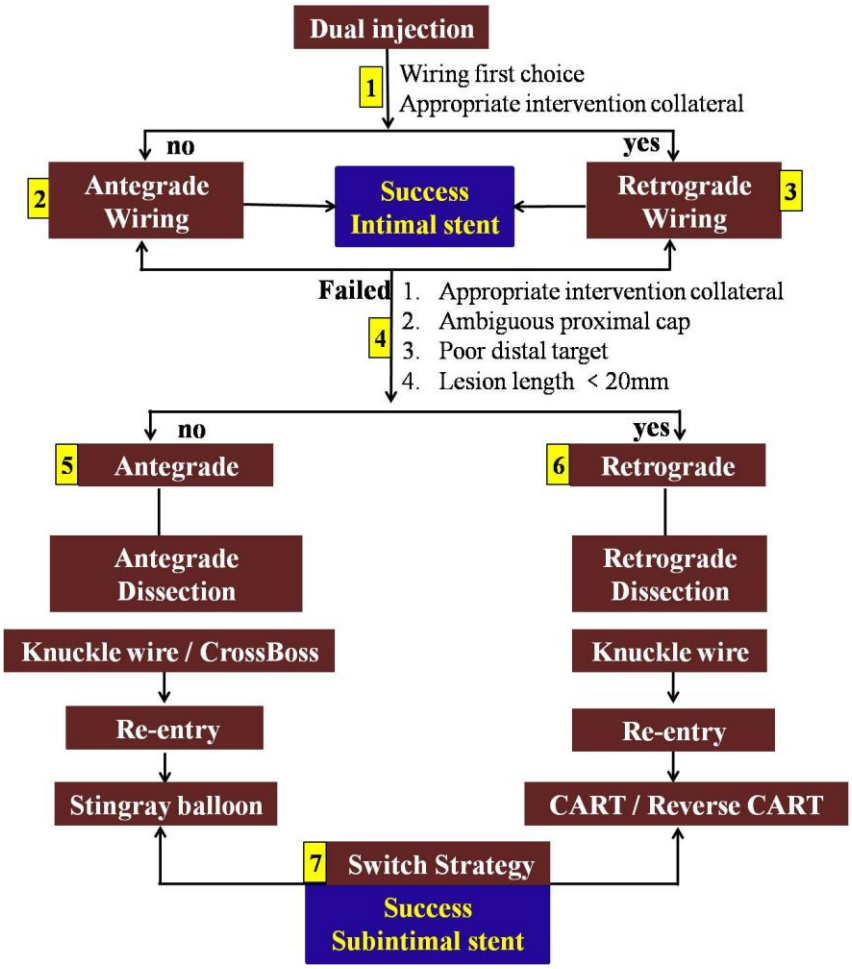

Figure 1: CTO PCI techniques in trial

4. Statistical analysis

Discrete data are summarized as frequencies and continuous data as mean±SD or median and interquartile range. Chi-square test or Fisher exact test analyses were used for comparison of categorical variables. The multivariable analysis to evaluate the independent contribution of clinical, angiographic, and procedural variables to re-occlusion and in-segment restenosis was performed by forward stepwise logistic regression analysis.Cumulative survival analyses were performed using the Kaplan-Meier method, and the difference between curves was assessed by log-rank test. A multivariable analysis by forward stepwise Cox proportional hazards model was performed to evaluate the independent predictors of death, myocardial infarction, and target CTO vessel revascularization. Odds ratios (ORs), hazards ratios (HRs), and their 95% confidence intervals (CIs) were calculated.

All tests were 2-tailed. A p value <0.05 was considered significant. Analyses

were performed using the software package SPSS (version 11.5, SPSS Inc., Chicago, Illinois).

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