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SETTING A MANAGEMENT PROGRAM OF CORONARY ARTERY CHRONIC TOTAL OCCLUSION (CTO) IN AN INTERVENTIONAL CARDIOLOGY CENTER: MONOCENTRIC RETROSPECTIVE STUDY.

Cardiology

Sanoussi Hamza* M.D. Cardiology Department, Antibes Hospital, Antibes, France. *Corresponding Author

Bitton Nathaniel Cardiology Department, Antibes Hospital, Antibes, France.

Meyer Pierre Cardiology Department, Institute. Arnault Tzanck, Saint Laurent du Var, France.

Drogoul Laurent Cardiology department, Institute. Arnault tzanck, Saint Laurent du Var, France.

ABSTRACT

OBJETIVES: The aim of this work is to expose a successful hybrid management program of CTO lesions, in a high volume interventional cardiology center.

BACKGROUND: The benefit of successful recanalization of CTO on prognosis remains uncertain.

METHODS: From January 2015 to March 2016, a retrospective recruitment of 81 patients undergoing PCI for CTO at the Arnault Tzanck Institute, Saint Laurent du Var, France.

RESULTS: During 1 year follow up, The mean age was 65 +/- 10,5 years with male predominance. The average J-CTO score was 2 +/- 1.2.The antegrade technique has been used as first-line therapy in 97% of patients and we performed retrograde technique in 23%. Procedure success rate was 75.6%. DES implantation rate in recanalized lesions was 100%. all cause mortality rate was 0%.We have identified four predictors of recanalization failure: The presence of moderate to severe calcification, OR = 0.33 with 95% CI [0.11-0.96], p = 0.05.The occlusion segment length> 20 mm, OR = 0.19 with 95% CI [0.04-0.88], p = 0.034. The J CTO score> 2, OR = 0.21 with 95% CI [0.07-0.63], p = 0.005. Antegrade-retrograde technique switch, OR = 0.2 with 95% CI [0.06-0.66], p = 0.008.

CONCLUSIONS: CTO program using hybrid strategy improves recanalization success rate despite the complexity of the lesions, with a very low intra hospital events rate.

KEYWORDS

chronic total occlusion; drug-eluting stent; proctoring

INTRODUCTION

Angioplasty of chronic coronary occlusions (CTO) is associated with high doses of contrast use, radiation exposure and the possibility of severe complications especially by using inappropriate devices and techniques. In the past, these lesions were managed with "caution" therapeutic strategies: Patients with monotroncular lesion, even in case of clinical angina and / or proved ischemia, were managed with medical treatment and those presenting with bi-troncular or tri-troncular lesions were referred to surgical revascularization [1,2].

The procedural success rates of CTO-PCI have improved in recent years due to the development of dedicated devices and improved operator experience and techniques. The prognosis has changed, now we can affirm that successful CTO PCI using DESs can reduce long-term all-cause mortality and the risks of myocardial infarction, MACEs, and CABG [3].

The aim of this work is to expose a successful hybrid management program of CTO lesions, in a high volume interventional cardiology center.

MATERIAL AND METHODS

The interventional cardiology department of the Arnault Tzanck Institute (ATI) has an overall activity of 1200 angioplasties per year. The center is composed of 3 catheterization rooms including a hybrid room; there is a structure of cardiac surgery in situ.

The CTO registry database, involving the retrospective recruitment of patients undergoing PCI for CTO at the ATI, was used for the current study from January 2015 to March 2016. The hybrid approach is based on using all known techniques to treat CTO lesions, depending on anatomic characteristics.

The procedural success rates in the hybrid approach strongly depends on a learning curve so we ask for a proctor help (very high volume operator) in order to have a better chance of successful procedures.

CTO was defined as complete obstruction of the coronary artery with a Thrombolysis In Myocardial Infarction (TIMI) flow 0. The duration of the occlusion was estimated to be more than 3 months, judged by the interventional cardiologist, usually in a previous coronary angiography or clinical presentation. In the absence of clinical evidence suggestive of the duration of the occlusion, the diagnosis was based on angiographic (collateral developments, degree of calcification, and nontapered stump).

The success of the procedure was defined by residual stenosis <30% with a TIMI grade 3 with complete revascularization by percutaneous angioplasty on the main epicardial arteries. The failure of the procedure was defined by the impossibility of crossing the obstruction or reducing the occlusion by less than 50%.

The patients had either symptomatic angina, a positive myocardial perfusion imaging or functional stress test. All patients received pre-treatment with aspirin (loading dose, 200 mg) and clopidogrel (loading dose, 300 or 600 mg). All procedures were performed under effective intravenous heparin anticoagulation according to standard regimens. Patients consentment was obtained prior to the procedure.

The strategy of recanalization and the device's choice were left at the operator's discretion. Several parameters were collected for each procedure including the antegrade or retrograde procedure: wire characteristics, the number and length of stents implanted, the fluoroscopy time and the contrast use. A biological assessment is performed 6 hours and / or 12 hours after angioplasty (CPK cardiac enzymes, Troponin , hemmogram and renal function).

The primary efficacy endpoint was target vessel revascularization (TVR) represented by TIMI 3, and drug eluting stent (DES) implantation .

The primary safety endpoint was: all-cause mortality.

Periprocedural and in-hospital complications described as: tamponade, stroke, stent thrombosis, vascular complication at the point of puncture, acute renal failure (defined by an increase in serum creatinine greater than 25% of basal value in the first 48 hours following angioplasty), bleeding with a need to transfusion (at least two red blood cells) and skin lesions secondary to irradiation were also assessed as secondary endpoints.

RESULTS

1.Clinical characteristics:

The overall clinical characteristics of the 81 patients are summarized in (***Table 1)***. The mean age was 65 +/- 10,5 years and more than 85% of the population were male. There mean number of cardiovascular risk factors was greater than 2, smoking and hypercholesterolemia were the main factors. 45% of patients had prior PCI. The left ventricular ejection fraction (LVEF) was severely impaired in 8.6% of patients. In the majority of patients, clinical presentation was dominated by stable

angina in 70 % of cases. Positive ischemic test was observed in 92% of patients. All patients received pre-treatment with aspirin and 70% received clopidogrel . All procedures were performed under effective intravenous heparin anticoagulation. Beta blockers and angiotensin converting enzyme(ACE) inhibitors were given respectively in 90% and 60% of patients, and 95% were under statin therapy.

Table 1: Patients Clinical characteristics.

Characteristics	Number(81)	Value
Age (years)	65,5	±10,5
Male	71	87.6%
Hypertension	30	37%
Diabetis mellitus	22	27,2%
Hypercholesterolemia	42	51,8%
Current smoker	44	54,3%
Body mass index (Kg/m2)	27	± 4,3
Clinical diagnosis at presentation		
Stable Angina	57	70.4%
STEMI	2	2.4%
NSTEMI	10	12.3%
Antecedent		
Prior PCI	37	45.7%
Prior CABG	9	11,1%
Prior STEMI	20	24,7%
Prior NSTEMI	11	13,5%
Chronic lung disease	3	3.7%
Peripheral vascular disease	10	12,3%
LVEF		
<35%	7	8,6%
35-50%	16	19,7%
>50%	58	71,6%
Clearence (ml/min)	87,3	±39,1
Ischemic test		
Positif	75	92,5%
Incertain	6	7,4%

Values are mean SD or n (%).
CABG: coronary artery bypass grafting, PCI: percutaneous coronary intervention, LVEF: Left ventricle ejection fraction NSTEMI: Non ST elevation myocardial infarction, STEMI: ST elevation myocardial infarction

2 Angiographic characteristics of lesions

The angiographic features are summarized in (Table 2). CTO was located in the right coronary artery (RCA) in more than 60%. The average diameter of the treated arteries was 2.71 +/- 0.25 mm. The duration of occlusion remains undetermined in 40% of cases. For remaining lesions, the average duration of the occlusion was 22 +/- 41 months. 10% of CTO were intra stent. The average length of the occlusion was estimated at 30.5 +/- 14.3 mm. The criteria of technical difficulties (bending> 45 ° and moderate to severe calcifications) were present for more than 30% of the occlusions. The absence of a proximal cap was found in 23% of cases. The average J-CTO score was 2 +/- 1.2.

Table 2 : Angiographic characteristics

Characteristics	Nb(81)	Value
CTO located artery		
LAD	17	21%
LCX	14	17,3%
RCA	50	61,7%
CTO located segment		
Ostium	16	19,7%
Proximal	24	29,6%
Middle	37	58%
Distal	4	5%
Intra stent localisation	8	10%
Bending > 45°	26	32,1%
Moderate to sever calcification	25	30,9%
Absence of proximal cap	19	23,5%
Occlusion length (mm)	30,5	± 14,3
J CTO score	2	± 1,2
Collaterals		
Ipsilateral	22	27,1%
Contralateral	35	43,2%
Ipsi and contralatral	20	24,7%
Bifurcation	18	22,2%
Average artery diameter (mm)	2,72	± 0,25
Average duration of occlusion(months)	22	±41

Values are n (%) or mean SD.
CTO: Chronic total occlusion, J CTO score: Japan CTO score, LAD: Left anterior descending artery LCX: Left circumflex artery, RCA: Right coronary artery.

3 Technical characteristics of the procedures

The technical characteristics of the procedures are summarized in ***(Table 3)***. Radial access was performed in 65% of cases. A simultaneous contralateral injection was performed in 67%. A microcatheter has been used in 96% of the procedures. The antegrade technique has been used as first-line therapy in 97% of patients and we performed retrograde technique in 23% of our patients; Indeed we performed the retrograde technique after failed antegrade technique in 20% of cases, but we tried it as first line treatment in only two patients in whom CTO was located in ostial RCA with severe calcifications.

The antegrade approach was successful in 70%. The techniques we used to perform the antegrade recanalization were: A simple guide wire technique in 60% of cases, the dual guide wire technique in 2.5% of cases, dissection and reentry in 6.3% of cases.

The retrograde approach was successful in 47.3% of the cases. The most successful technique was the "wire crossing technique" in 26.3% of cases, and a REVERSE CART tecnique in 21% of patients.

An average of 2.7 +/- 1.7 guides were used per procedure. DES implantation was successful in every recanalized CTO (100 % of cases)

The average duration of the procedure was 85 +/- 45 min. Average use of contrast was 235 +/- 94 ml. The average radiation dosimetry of patients was 1920 +/- 6788 mGy.

Table 3: Procedure characteristics.

Procedure characteristics	Nb	Value
Radial access	53	65,4%
Antegrade technique	79	97%
Successfull antegrade technique	55	70%
Single wire antegrade technique	48	60,7%
Dual wire antegrade technique	2	2.5%
Antegrade dissection and reentry	5	6.3%
Retrograde Teccnique	19	23.4%
Successfull retrograde technique	9	47,3%
Wire crossing	5	26.3%
Reverse CART	4	21%
Switch antegrade to retrograde technique	17	20%
Contralateral injection	54	67%
Number of wires	2,7	± 1,7
Polymer coated wire	33	41%
Non polymer coated wire	48	59%
Microcatheter	78	96.3%
Rotablator	1	1,2%
Anchor balloon technique	4	5%
Guide extension catheter (Guidezilla)	8	9.9%
Number of balloons used	1,8	1,3
DES	81	100%
Number of DES per procedure	1,6	± 1,3
Stent length (mm)	47	± 35,5
Procedure duration (min)	85,6	± 45,5
Fluoroscopie duration (min)	36,6	± 26
Contrast volume (ml)	235	± 94
Radiation dosimetry (mGy)	1920	± 6788

4. Primary safety endpoints

Over the study period, 62 (75.6%) CTOs were successfully recanalized. DES implantation rate in recanalized lesions was 100%. ***(Table 4)***

Table 4: Primary efficacy endpoint

Primary efficacy endpoint (81)	**Nb**	**Value**
Successfull procedures	62	75,6%
Residual stenosis (%)		
90-100	19	23,4%
20-30	4	5%
<10	58	71,6%

Final TIMI		
TIMI 3	67	82,7%
TIMI0/1	14	17,2%

5. Primary and secondary safety endpoints:

After one year follow up, all cause mortality rate was 0%. We reported one case of coronary artery perforation with tomponade managed successfully by using pericardial drainage and a covered stent. One patient underwent urgent angioplasty for a non-occlusive traumatic dissection of the left main coronary.

We didn't observe any case of stroke or dermatological complications secondary to irradiation. The systematic post procedure control of creatinin didn't find any case of renal failure. None of our patients had a major bleeding or a vascular complication. ***(Table 6)***

Table 5: Primary and secondary safety endpoints

Primary and secondary safety endpoints	Nb	Value
Death	0	0%
Myocardial infarction	0	0%
restenosis and re-target lesion revascularisation (TLR)	0	
Coronary perforation	1	1,2%
Tomponade	1	1,2%
Contralateral coronary artery dissection	1	1,2%
Vascular complications	0	0%
Major bleeding	0	0%
Stroke	0	0%
Renal failure	0	0%

6. Predictors of procedure failure

In order to be able to evaluate the predictive factors of procedural success, we compared in a multivariate and univariate analysis the clinical and angiographic characteristics of patients after successful and failed procedure. ***(Table 6)***

In univariate analysis, we identified four predictors of recanalization failure:

- The presence of moderate to severe calcification, OR = 0.33 with 95% CI [0.11-0.96], p = 0.05.
- The occlusion segment length> 20 mm, OR = 0.19 with 95% CI [0.04-0.88], p = 0.034
- The J CTO score> 2, OR = 0.21 with 95% CI [0.07-0.63], p = 0.005.
- Antegrade-retrograde technique switch, OR = 0.2 with 95% CI [0.06-0.66], p = 0.008.

Table 6: Predictors of procedure failure

Parameters	OR	CI	p
Coronary Artery			
LAD	1,7	[0,48-5,83]	0,42
LCX	1,6	[0,41-6,18]	0,49
RCA	1,5	[0,38-4,25]	0,35
CTO located			
Ostium	1,8	[0,15-21,5]	0,65
Proximal	0,6	[0,05-7,35]	0,69
Mid	0,83	[0,07-9,15]	0,88
Intra stent CTO	0,91	[0,17-4,94]	0,91
Bifurcation	0,74	[0,23-2,44]	0,62
Artery diameter	3,62	[0,46-28,3]	0,22
Absence of proximal cap	1,22	[0,38-3,9]	0,74
Moderate to severe calcification	0,33	[0,11-0,96]	0,05
Prior recanalization	0,7	[0,2-2,3]	0,55
Occlusion length>20 mm	**0,19**	**[0,04-0,88]**	**0,034**
Bending >45°	0,56	[0,2-1,63]	0,29
J CTO score > 2	**0,21**	**[0,07-0,63]**	**0,005**
Switch antegrade-retrograde technique	**0,2**	**[0,06-0,66]**	**0,008**

DISCUSSION

The angioplasty of CTOs remains one of the most complex procedure. Previous observational studies demonstrated that successful CTO recanalization increases survival and reduces cardiac events [4-9]. This study proved that CTO angioplasty is an effective and low-risk technique. Our procedure success rate was 75.6% despite the complexity of our CTO lesions with an average J CTO score of 2 +/- 1.2 and over 30% of lesions with a J CTO score> 2, this success rate remains comparable to the most recent studies [10,11].

We used to manage our CTO lesions by antegrade technique as first-line strategy in 97% of patients with a success rate of 70%. The retrograde technique was privileged in second intention after antegrade approach failure in 20% of our patients.

Although we showed that the retrograde- antegrade switch in the same procedure is a predictor of recanalization failure, we can therefore expect that after gaining more experience in the retrograde technique we can achieve higher success rates.

Our complication rate was very low less than 3% and no case of death was observed during one year follow up, which is comparable to results reported in non-CTO angioplasty series.

We reported a case of coronary perforation with secondary tamponade leading to pericardial drainage in emergency. The coronary perforation may be due to wire crossing or balloon inflation. This type of complication has become rare with systematic contralateral injection allowing wire positionning and it can be managed be managed by prolonged balloon inflation, heparin antagonism, and covered stent implantation.

Renal failure secondary to contrast injection can be avoided by optimal hydratation and limiting contrast use (the risk appears from 4 times the clearance level and increases considerably beyond 8 times) [12]. No case of renal failure was reported in our study.

We didn't report any case of restenosis and re-target lesion revascularisation (TLR) , we can explain it mainly by the use of the latest generation drug eluting stent, as it is recommended in CTOs [12]. The predictive factors of CTO recanalization failure have changed in the last decade due to improvement of operator technique and specialized devices. Previous studies has described calcifications, proximal bending to occlusion, the downstream of the arterial bed, the circumflex artery as a target vessel, the small size of the artery, the ostial occlusion, the length of the occlusion and the age of the CTO as predictive factors of recanalization failure [13]. Japanese experts described calcifications and upstream bending appear as predictors of independent failure [14]. In our study we found that the presence of significant calcification and an occlusion length> 20 mm are predictive factors of recanalization failure. (Intravascular ultrasound) IVUS will allow us to increase our success rate [11].

Setting up a CTO program in a center requires the selection of operators with a large experience. Proctoring is an essential step; Sharma et al [15] published an article including 587 patients on the interest of proctoring in success rate of CTO's recanalization . They retrospectively compared 2 groups: A group of 232 procedures without initial proctoring and a group of 355 procedures with proctoring, The study shows that proctoring improves the procedure success rate: 77,5% versus 62,1%. (OR = 0.44, p <0.001, CI [0.33-0.67]). This difference is even more important when it comes to complex procedure with a J CTO score> 2 (70.7% vs. 49.5%, p = 0.0003).

In our center proctoring was a fundamental step in setting up the CTO program.

CONCLUSION

Setting up a CTO program using hybrid strategy can lead to recanalization success rates despite the complexity of the lesions, with a very low intra hospital events rate, proctoring in the first year remains fundamental.

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