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Procedural, In-Hospital and One Year Follow-Up Outcome of Success versus Failure Percutaneous Coronary Intervention in Chronic Total Occlusions

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Abstract: ***Introduction: Percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) lesions are the most technically challenging for the interventional cardiologist with lower procedural success rates and higher complications. However, there are controversy in short-term and long-term results. Aims and Objectives: The purpose of this study was to know the procedural success rate, in-hospital and 1 year follow-up outcome of successful versus failure PCI in CTO. Material and Methods: This single center, observational study was conducted at KLEs Dr Prabhakar Kore Hospital & MRC, Belgaum, Karnataka, India, from January 2013 to September 2014. A total of 101 consecutive CTO patients in whom PCI was attempted were included in the study. Detailed clinical, angiographic, procedural, in-hospital and 1 year follow-up outcome data were collected and compared success versus failed procedures. Results: Procedural success rate was seen in 79 patients (78.21%). Patients with failed CTO-PCI compared to success group had a higher incidence of diabetes mellitus (72.73% vs. 54.43%; p=0.14), smoking (54.55% vs. 41.77%; p=0.33), prior myocardial infarction (MI) (68.18% vs. 41.77% ;p=0.03) and multivessel involvement (13.6% vs. 8.86%; p=0.53). In-hospital major adverse cardiac events (MACE) rate was significantly higher in failed CTO-PCI (31.82 % vs.0%;p=0.00) patients. When followed-up for 1 year, failed CTO-PCI was significantly associated with higher rate of 1 year MACE (57.14% vs. 18.99%;p=0.00), especially revascularization (33.33% vs. 12.66%;p=0.04). Conclusion: A successful PCI of CTOs was associated with better one year follow-up outcome with lower incidence of death, MI and need of CABG compared to failed CTO-PCI***

Keywords: Percutaneous coronary intervention (PCI), chronic total occlusion (CTO), major adverse cardiac events (MACE), myocardial infarction (MI), coronary artery bypass grafting (CABG).

1. Introduction

Coronary Chronic total occlusion's (CTO) are commonly encountered complex lesions identified in 15% to 30 % of all patients referred for coronary angiography (CAG)[1,2]and attempted only in 10% of patients undergoing percutaneous coronary intervention (PCI).[3-5] These lesions are the most technically challenging for the interventional cardiologist with lower procedural success rates and higher complications. Because of these reasons, CTO's are commonly referred for coronary artery bypass grafting (CABG) or managed medically. Although the duration of occlusion is difficult to determine on clinical grounds, a total occlusion must be present for atleast 3 months to be considered a true CTO.[6]

The technical and procedural success rates of CTO-PCI have steadily increased over last 15 years because of greater operator experience, improvement in equipment and procedural Techniques.[7,8] However, there is limited data on procedural and in-hospital outcome after PCI of CTO. Several previous studies have shown procedural success rates and outcomes after CTO-PCI, but they have included patients with occlusion of 4 weeks duration.[9,10,11] The present study was undertaken to know the procedural, in-hospital and 1 year follow-up outcome of successful versus failure PCI in true CTO's.

2. Material And Methods

Study design: This single center, retrospective, observational clinical study was conducted at KLEs Dr Prabhakar Kore Hospital & MRC, Belgaum, Karnataka, India, from January 2013 to September 2014. A total of 101 consecutive CTO patients in whom PCI was attempted were included in the study. The study was approved by the institutional ethics committee.

Patients with acute myocardial infarction (AMI) or occlusion of culprit vessel < 30 days, severe hepatic dysfunction or contraindications to antiplatelets were excluded from the study.

CTO was defined as a lesion with TIMI (Thrombolysis in myocardial infarction) 0 or 1 flow with a total duration of >3months.[6] Estimation of occlusion duration was based on a history of first onset of angina, a history of MI in the target vessel territory or comparision with a previous angiogram.

A technical success was defined as the ability to cross the occluded segment with both a wire and balloon and successfully open the artery with a < 40% residual stenosis in all views. Procedural success was defined an a technical success with no in-hospital major adverse cardiac events (MACE) with TIMI 3 flow. A CTO success was defined as a technical success .

A MACE was defined as the occurrence of death, Myocardial Infarction (MI) or urgent revascularization during the same admission.[12] Stent thrombosis was defined according to academic research consortium.[12]

All patients underwent antegrade approach via femoral route.

Dual injection was performed through selective coronary angiography (CAG) for the CTO-PCI target vessel and through another vessel (the contralateral coronay artey or a

bypass graft) that provides collaterals to the distal vessel and determining the lesion length. The guidewire strategies used were single wire and parallel wire technique. Angioplasty was performed using standard over the wire technique and coronary guide wires with progressive wire tip stiffness were used.

All patients were pretreated with aspirin (325 mg) and clopidogrel (a loading dose of 300 mg at least 6 hours before procedure). After the procedure , all patients were given aspirin 150 mg OD indefinitely and clopidogrel 75 mg twice daily for first 24 months followed by 75 mg indefinitely after implantation of stents.[13,14] Glycoprotein II b/ IIIa inhibitors were given at the discretion of the operator. Unfractionated heparin (100 U/kg bolus) with additional administration if necessary to achieve an ACT ≥ 250 seconds .

Patients were divided into two groups with regard to the success or failure to achieve revascularization of the occluded artery.

All patients baseline demographic, clinical, procedural characteristics and in-hospital outcomes were recorded. Clinical follow up was performed in all patients at 1, 3, 9 & 12 months post procedure. All patients post procedural ECG were routinely assessed for presence of new Q waves.

Patients who had angina underwent treadmill test (TMT). Follow up CAG was done in patients with positive TMT or patients who complained of recurrent chest pain . Study end points were MACE including death, MI, revascularization (TVR and TLR) and stent thrombosis .

Statistical analysis: Continuous data are presented as mean±SD and differences are compared using student *t* test. Discrete variables are expressed as counts and percentages. In two-by-two tables, differences were assessed by Fisher exact test. In two-by-three and two by four tables, differences were assessed by Chi-square test. All statistical tests were two-tailed. All statistical calculations were performed with minitab 15 and SPSS version 17 statistical software. A p value of 0.05 or less was considered significant.

3. Results

Between January 2013 to September 2014, a total of 101 patients underwent attempted PCI of CTOs. In 79 patients (78.21%), procedural success was achieved and 22 patients (21.78%) remained unsuccessful. Baseline demographics for both CTO success and failure group are shown in Table 1.

Table 1: Baseline Demographics

Variable	Total (n = 101)	CTO Success (n =79)	CTO Failure (n =22)	P Value
Age(years)	57.06 ± 8.69	56.63 ± 9.11	58.59 ± 6.99	0.353^{NS}
Male gender	80(79.21)	64(81.01)	16(72.73)	0.397^{NS}
Angina	90(89.11)	69(87.34)	21(95.45)	0.448^{NS}
Ejection Fraction (%)	45.39 ± 3.44	45.69 ± 3..81	44.67 ± 2.29	0.336^{NS}
Diabetes Mellitus	59(58.42)	43(54.43)	16(72.73)	0.147^{NS}
Hypertension	66(65.35)	53(67.09)	13(59.09)	0.613^{NS}
Dyslipidemia	63(62.38)	50(63.29)	13(59.09)	0.805^{NS}
Obesity	31(30.69)	26(32.91)	5(22.73)	0.440^{NS}
Smoking	45(44.55)	33(41.77)	12(54.55)	0.337^{NS}
Family History Of CAD	27(26.73)	24(30.38)	3(13.64)	0.296^{NS}
CVA	7(6.93)	7(8.86)	0(0.00)	0.342^{NS}
PVD	3(2.97)	3(3.80)	0(0.00)	1.000^{NS}
Prior MI	48(47.52)	33(41.77)	15(68.18)	0.033*
Prior PCI	17(16.83)	17(21.52)	0(0.00)	0.020*
Prior CABG	3(2.97)	2(2.53)	1(4.55)	0.525^{NS}

Data listed as number of patients (percent of group), mean±SD.

Mean age and gender frequency were similar in both groups. Anginal chest pain was the predominant presenting symptom in both groups. The CTO failure group had higher incidence of diabetes (DM) (72.73%), smoking (54.55%) and prior MI (68.18%) and CTO success group had higher incidence of prior PCI. Baseline angiographic characteristics for both groups are shown in Table 2.

Table 2: Baseline Angiographic Characteristics

Variable	*Total (n = 101)*	*CTO Success (n =79)*	*CTO Failure (n =22)*	*P Value*
No. Of Diseased Vessels				
SVD	64(63.37)	49(62.03)	15(68.18)	0.530^{NS}
DVD	27(26.73)	23(29.11)	4(18.18)	
TVD	10(9.90)	7(8.86)	3(13.64)	
CTO-Location				
LM	0(0.00)	0(0.00)	0(0.00)	0.219^{NS}
LAD	53(52.48)	45(56.96)	8(36.36)	
RCA	39(38.61)	28(35.44)	11(50.0)	
LCX	9(8.91)	6(7.59)	3(13.64)	
Collateral Filling				
Bridge Collaterals	30(29.70)	22(27.85)	8(36.36)	0.439^{NS}
Retrograde Filling	71(70.30)	57(72.15)	14(63.64)	
TIMI Flow				
Grade 0	79(78.22)	61(77.22)	18(81.82)	0.644^{NS}
Grade 1	22(21.78)	18(22.78)	4(18.18)	

Data listed as number of patients (percent of group).

The CTO failure group had higher incidence of triple vessel disease (TVD), bridging collaterals and TIMI grade 0 flow.

The CTO was located predominantly in left anterior descending (LAD) coronary artery (52.48%), followed by right coronary artery (RCA)(38.61%) and left circumflex coronary artery (LCX)(8.91%). The CTO was located predominantly in the RCA (50%) in CTO failure group and LAD (56.96%) in success group. The overall technical and procedural success rates were 79.20% and 78.21% for the total CTO cohort. Among the failed procedures, inability to cross the lesion with a guide wire and perforation were the main reasons for failure in 81.82%(18) and 18.18%(4) of cases.(Figure 1)

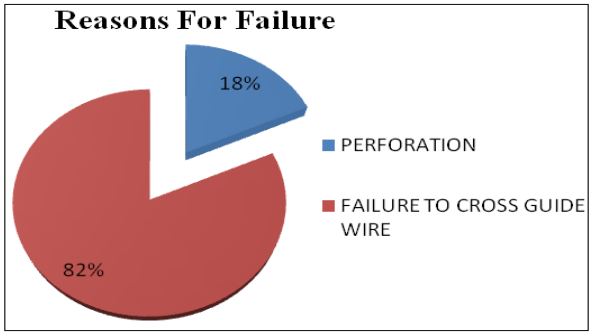

Figure 1: Reasons for failure

Guide wires and guide support used are shown in Table 3.

Table 3: Procedural Characteristics- Guide wires and Guide Support

Variable	*Total (n = 101)*	*CTO Success (n =79)*	*CTO Failure (n =22)*	*P Value*
Procedure Success	101(100.00)	79(78.21)	22(21.78)	0.042*
Guide Wires				
Miracle 6	17(16.83)	9(11.39)	8(36.36)	NA
Conquest Pro	17(16.83)	15(18.99)	2(9.09)	
Whisper	19(18.81)	16(20.25)	3(13.64)	
Fielder XT	32(31.68)	27(34.18)	5(22.73)	
Fielder Fc	3(2.97)	3(3.80)	0(0.00)	
Cross It 100 XT	13(12.87)	9(11.39)	4(18.18)	
Guide Support				
Microcatheter	61(60.40)	43(54.43)	18(81.82)	0.005**
Balloon Support	33(32.67)	32(40.51)	1(4.55)	
Tornus	7(6.93)	4(5.06)	3(13.64)	

Data listed as number of patients (percent of group).

Fielder XT guide wire (34.18%) was the most successful guide wire in crossing the CTO followed by whisper wire (20.25%) and conquest Pro wire (18.99%) supported by microcatheter (54.43%) and balloon (40.51%). Stent used are shown in Table 4.

Table 4: Procedural Characteristics - Stent Used

Variable	*Total (n = 101)*	*CTO Success (n =79)*	*CTO Failure (n =22)*
Stent Used			
Drug Eluting Stent (DES)	75(74.25)	75(94.93)	0(0.00)
Sirolimus (SES)	52(51.49)	52(65.82)	0(0.00)
Everolimus (EES)	18(17.82)	18(22.78)	0(0.00)
Zotarolimus (ZES)	5(4.95)	5(6.33)	0(0.00)
Baremetal Stent (BMS)	4(3.96)	4(5.06)	0(0.00)
No. Of Stents Per Lesion	1.16±0.80	1.48±0.57	0.00±0.00
Stent Length (mm)	22.14±13.16	28.30±6.74	0.00±0.00
Stent Diameter (mm)	2.41±1.31	3.09±0.29	0.00±0.00

Data listed as number of patients (percent of group), mean±SD.

Stents were implanted in all CTO success group with Drug eluting stent (DES) in 94.93 % [Sirolimus eluting stent (SES) – 65.82 %, Everolimus eluting stent (EES)– 22.38 % and zotarolimus eluting stent (ZES) - 6.33 %] and Baremetal stent (BMS) in 5.66 % of cases . Mean stent per lesion was 1.48±0.57mm with 28.30±6.74mm in length and 3.09±0.29mm in diameter. Procedure time (min) , fluoroscopy time (min) and contrast dose (ml) are shown in Figure 2.

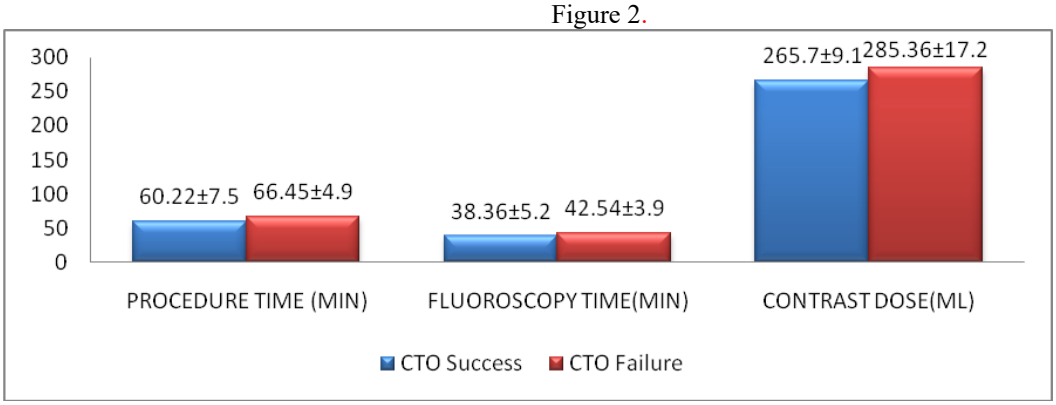

Figure 2: Procedural Characteristics - Procedure time, Fluoroscopy time and Contrast Used

The CTO failure group had higher mean procedural time, fluoroscopy time and higher amount of contrast used during procedure compared to success group. Intracoronary medications used during procedure are shown in Figure 3.

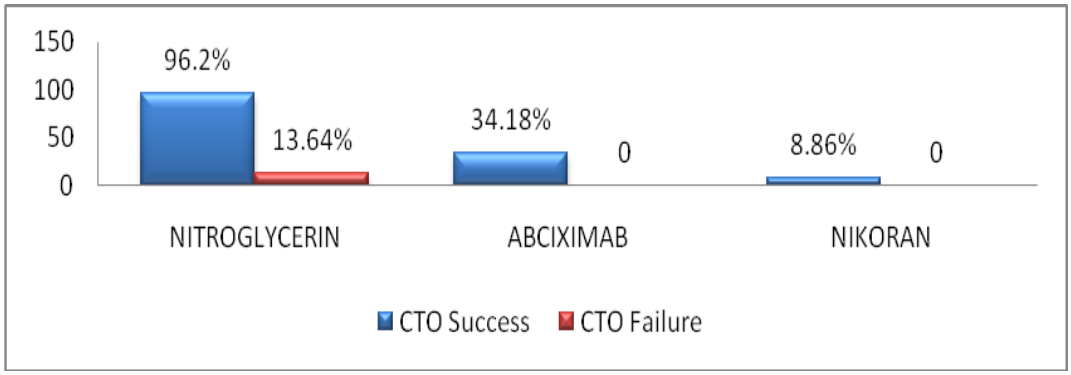

Figure 3: Procedural Characteristics – Intracoronary Medications Used

Glycoprotein II b / III a inhibitors (Abciximab) was used in 34.18 % of patients in CTO success group. The complications are shown in Figure 4.

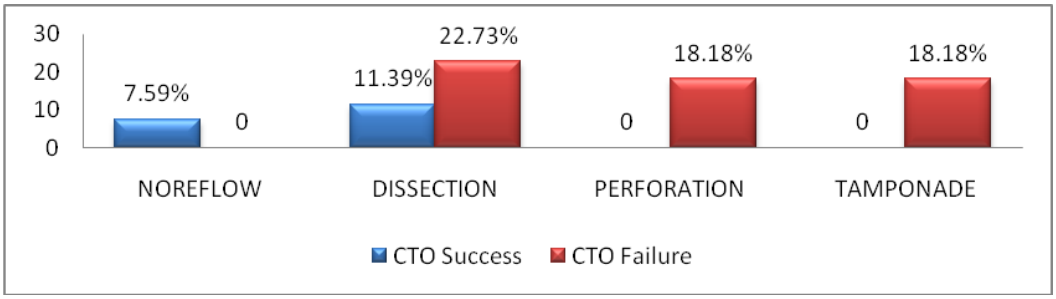

Figure 4: Procedural Characteristics – Complications

During the attempted PCI of CTOs, 5 patients (22.73%) had dissection of the arterial wall in CTO failure group and 9 patients (11.39%) in success group. In the CTO failure group, 4 patients (18.18%) had coronary perforation and the PCI attempts were halted and emergency pericardiocentesis was done for cardiac tamponade. One patient required emergency surgery for perforation but developed hypotension , bradycardia and cardiac arrest during surgery. During the post procedure phase, 6 patients (27.27%) in CTO failure group underwent CABG (3 required closure of peroration). No patient had stent thrombosis or MI in CTO success group. The in-hospital outcome for both CTO success and failure group are shown in Table 5.

Table 5: In hospital outcome

Variable	*Total (n = 101)*	*CTO Success (n =79)*	*CTO Failure (n =22)*	*P Value*
In-Hospital MACE	7(6.93)	0(0.00)	7(31.82)	0.000**
Cardiac Death	1(0.99)	0(0.00)	1(4.55)	0.218^{NS}
MI	0(0.00)	0(0.00)	0(0.00)	NA
In-Hospital Stent Thrombosis	0(0.00)	0(0.00)	0(0.00)	NA
Urgent Revascularization	6(5.94)	0(0.00)	6(27.27)	0.000**
TVR-PCI	0(0.00)	0(0.00)	0(0.00)	NA
TVR-CABG	6(5.94)	0(0.00)	6(27.27)	0.000**

Data listed as number of patients (percent of group).

The CTO failure group had significantly higher rate of in-hospital MACE compared to success group. The one year follow-up outcome for both CTO success and failure group are shown in Table 6.

Table 6: One Year Outcome

Variable	*Total (n = 100)*	*CTO Success (n =79)*	*CTO Failure (n =21)*	*P Value*
1 Year MACE	28(28.00)	15(18.99)	12(57.14)	0.000**
Cardiac Death	1(1.00)	0(0.00)	1(4.76)	0.2100^{NS}
Non cardiac Death	0(0.00)	0(0.00)	0(0.00)	NA
MI	9(9.00)	5(6.33)	4(19.05)	0.089^{NS}
Revascularization	17(17.00)	10(12.66)	7(33.33)	0.045*
TVR-PCI	3(3.00)	3(3.80)	0(0.00)	1.000^{NS}
TLR-PCI	5(5.00)	5(6.33)	0(0.00)	0.581^{NS}
TVR-CABG	9(9.00)	2(2.53)	7(33.33)	0.002**

Data listed as number of patients (percent of group).

The CTO failure group had significantly higher rate of 1 year follow-up MACE, especially revascularization compared to success group. In the CTO failure group, 4 patients (19.05%) had Non Q AWMI , one patient died as patient presented with VT/VF and 7 patients (33.33%) underwent CABG. In the CTO success group, 5 patients (6.33%) had Non Q AWMI, 3 patients (3.8%) underwent TVR- PCI, 5 patients (6.33%) TLR-PCI and 2 patients (2.53%) CABG.

4. Discussion

In this study, we compared procedural, in-hospital and 1 year follow-up outcome in 79 successful and 22 failed CTO-

PCI patients. Patients with failed CTO-PCI compared to successful group had higher incidence of DM, history of prior MI, smoking, multivessel involvement, had higher procedural complications, in-hospital and 1 year MACE rates.

The clinical outcome was significantly improved with lower in-hospital and 1 year MACE rates with successful CTO recanalisation. The Need for revascularization at 1 year follow up was significantly higher in CTO failure group.

In our study, procedural success rate is 78.21 % which is higher than previous studies by Hoye et al.[9] and Olivari et al.[11] with rates of 65.1% and 73.3% respectively. Both these studies used 4 weeks duration to define CTO compared to >3 months duration in our study. The high success rate in our study is due to use of newer dedicated CTO guide wires, better back support (microcatheter and balloon support) and increased operators experience. The predominant reason for lower success rates is failure to cross the lesion with a guide wire. In our study, failure to cross the lesion (81.82%) and perforation (18.18%) were the main reasons for failure.

In our study, success rate was higher in LAD (56.96%) than RCA (35.44 %) and LCX (7.59 %). Safley et al.[15] reported higher success rate for LAD (77 %) than LCX (76%) and RCA(72 %). More recently, Hasegawa et al.[16] reported higher success rates in LCX (79.0%) than LAD (74.8) and RCA (71.8%).
Presence of bridging collaterals which reflect chronicity of the lesions are associated with lower success rates. In our study, 36.36 % of patients in CTO failure group had bridging collaterals. Han YL et al.[17] reported lower success rates with presence of bridging collaterals whereas Kinoshita et al.[18] reported modest adverse impact of bridging collaterals.

The Success of CTO-PCI has significantly improved with the use of dedicated CTO guide wires and guide support. In our study, fielder XT guide wire (34.18 %) was most successful in crossing the CTO followed by whisper (20.25%) and conquest pro wire (18.99 %) supported by microcatheter (54.43%) and balloon (40.51%). In our study, the mean procedure time, fluoroscopy time and the amount of contrast used was significantly higher in CTO failure group compared to success group. This could be due to higher complexity of CTO cases. Suzuki et al.[19] reported higher mean procedure and fluoroscopy times for CTO than non CTO-PCI.

In our study, overall in-hospital MACE rate in all CTO patients was 6.93 %, which was higher than previous studies by olivari et al.[11] Hoye et al. [9] and rathore et al.[20] with rates of 5.1%, 3.5% and 1.9 % respectively. The in-hospital MACE rate was significantly higher in CTO failure group compared to success group. Chen et al.[21]and Hoye et al.[9] reported higher MACE rates in the CTO failure group very similar to our study. During the 1 year follow-up, CTO failure group was associated with a significantly higher MACE rates especially revascularization. Olivari et al.[11] reported higher incidence of cardiac death , combined rate of cardiac death and MI and CABG in CTO failure group very similar to our study. This excess of cardiac death and MI in patients with failed CTO-PCI has been reported in the other studies but it has never been reported as early as at 1 year and these findings need to confirmed during longer follow-up. The CTO success group was associated with significantly lower MACE rates at 1 year follow up. Olivari et al.[11] reported reduced 12 month incidence of cardiac death or MI, a reduced need for CABG and freedom from angina in CTO success group very similar to our study.

Study limitations: It was single centre study. The results of this study could be influenced by selection criteria, operator experience and technique variation among operators. IVUS was not used due to in-availability at our centre during the study period.

5. Conclusion

A successful PCI of CTOs was associated with better one year follow-up outcome with lower incidence of death, MI and need of CABG compared to failed CTO-PCI.

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