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Percutaneous Coronary Interventions in Chronic Total Occlusion – Profile, Technique and Outcome –The Malabar Experience

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Abstract

Introduction: Percutaneous coronary intervention (PCI) of chronic total occlusion (CTO) remains a challenge. The reasons being that these procedures may be lengthy and complex, with elevated radiation exposure, increased contrast load, lower procedural success rate, and a higher risk of complication when compared with non-CTO elective PCI.

Clarifying the long-term clinical outcomes of CTO-PCI is very important to justify potential investments in training and technology. However, there is a paucity of data from Indian subcontinent. Hence we decided to report the outcomes from a real-life cohort of consecutive patients undergoing elective PCI for CTO at our institution.

Materials and methods: Single-center, prospective observational study. A total of 339 consecutive patients who underwent elective PCI for chronic total occlusion between Feb 2016 to Feb 2018 were included in the study. Procedural techniques, complications and clinical outcomes {all-cause death, cardiac death, major adverse cardiac events (MACE) and target vessel revascularization (TVR)} were assessed in our study population.

Results: 339 patients were prospectively followed up for a duration that ranged from 3 months to 36 months, with a median follow up of 24 months. Overall procedural success was achieved in 85.5% (n = 290) cases. No significant differences were noted in In-Hospital adverse events (5.5% vs. 4.1%; p 0.998). MACE rate was significantly higher in unsuccessful CTO group (36.7% vs. 8.9%, p 0.001) and was predominantly driven by Ischemia Driven (ID) - Revascularization (16.3% vs. 3.1%, p < 0.001). Cardiac death and All-cause death was not significantly different between the groups. Residual angina (26.5% vs. 10%, p 0.003) and residual dyspnoea (34.7% vs. 12.4%, p < 0.001) were significantly worse in unsuccessful CTO group.

Conclusions: Procedural success in the present drug-eluting stent (DES) era is more than 80% and newer techniques and hardwares have improved the procedural success rate, especially in younger age groups. MACE rates were significantly higher in the unsuccessful CTO group. Residual angina and dyspnoea were significantly worse in the unsuccessful CTO group.

Keywords: CTO-PCI, Successful CTO-PCI, Microcatheter, MACE, ID-Revascularization

1. Introduction

P ercutaneous coronary intervention (PCI) has improved outcomes dramatically in coronary artery disease (CAD) management. But despite being commonly encountered in patients undergoing coronary angiography, percutaneous treatment of chronic total occlusion (CTO) remains a challenge [1,2]. Recanalization of a CTO is attempted in only 10%–15% of patients undergoing percutaneous coronary intervention (PCI) [3]. The reasons being that the CTO PCI procedures may be lengthy and complex, with elevated radiation exposure, increased contrast load, lower procedural success rate, and a higher risk of complication when compared with non-CTO

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elective PCI [4,5]. One other reason is the uncertainty of the prognostic impact of percutaneous CTO revascularization.

Patients with a chronically occluded single-vessel disease (SVD) are often managed medically regardless of the severity of symptoms and extent of ischemia, as the anatomy is deemed to be stable. Whereas, those with multivessel disease (MVD) involving a CTO may be referred for coronary artery bypass graft (CABG) surgery even if other lesions are suitable for PCI [1,6].

Some studies indicate that successful CTO PCI may improve left ventricular function and survival when compared with failed CTO PCI [7-9]. But some studies do not show the benefit [10,11]. Clarifying the longterm clinical outcomes of CTO-PCI is very important to justify potential investments in training and technology, and the potential risks involved. Recently there have been a few studies in DES era which have shown long term benefits on clinical outcomes. However, there is a paucity of data from Indian subcontinent. Hence we decided to report the outcomes from a reallife cohort of consecutive patients undergoing elective PCI for CTO at our institution. This is the first CTO PCI study from northern Kerala traditionally called as Malabar region, after the provincial name of erst while British madras presidency.

2. Materials and Methods

2.1. Study design

A prospective observational study.

2.2. Study setting

Single centre – department of cardiology, Medical College Hospital (MCH), Kozhikode, Kerala, India.

2.3. Study population

A total of 339 consecutive patients who underwent elective PCI for chronic total occlusion between February 2016 to February 2018 were included in the study.

2.4. Inclusion criteria

- 1. Patients undergoing elective PCI for CTOs in Dept. of cardiology, MCH, Kozhikode.
- 2. Age ${\geq}18$ years and willing to give written informed consent

2.5. Exclusion criteria

1. Patients with an estimated duration of total occlusion less than 3 months

Abbreviations used:

СТО	chronic total occlusion
PCI	percutaneous coronary interventions
MACE	major adverse cardiac events
TVR	target vessel revascularization
ID	ischemia driven
DES	drug eluting stent
sCTO	successful chronic total occlusion intervention
uCTO	unsuccessful chronic total occlusion intervention
ACS	acute coronary syndrome
UA	unstable angina
NSTEMI	non ST elevation myocardial infarction
STEMI	ST elevation myocardial infarction
CABG	coronary artery bypass grafting
CIN	contrast induced nephropathy
LVEF	left ventricular ejection fraction
HTN	hypertension
DM	diabetes mellitus
DLP	dyslipidemia
CKD	chronic kidney disease
PAD	peripheral artery disease
SVD	single vessel disease
DVD	double vessel disease
TVD	triple vessel disease
LM	left main
EA	effort angina
AWMI	anterior wall myocardial infarction
IWMI	inferior wall myocardial infarction
LWMI	lateral wall myocardial infarction
DAPT	dual anti platelet therapy

- 2. Patients with contraindications for dual antiplatelet therapy (DAPT)
- 3. Patients with second or third failed attempt of CTO-PCI
- 4. Patients with end-stage renal disease (ESRD) with eGFR less than 15 ml/kg/m2
- 5. Patients with incomplete data entry
- 6. Patients not willing for the study

2.6. End points

- 1. All cause death
- 2. Cardiac death
- 3. Target vessel revascularization (TVR)
- 4. MACE (composite of non-fatal MI, cardiac death, stroke and need for TVR)

2.7. Follow up

Patients were followed up during the outpatient department (OPD) visits or by a telephonic interview with a minimum follow up of 3 months.

2.8. Statistical analysis

Categorical variables were analyzed using the Pearsons chi-square test when appropriate (expected frequency >5). Otherwise, the Fisher's exact test was used.

Continuous variables were expressed as mean with standard deviation and compared using the independent student t-test.

Time was measured from the first admission for a procedure to an outcome (all-cause mortality).

Significance was inferred at p-value < 0.05.

All the statistical analysis were made using SPSS software (version 10.2, IBM).

2.9. Ethical clearance

The study was approved by the institutional ethical committee (IEC) at government medical college, Kozhikode.

3. Methodology

All the procedures were performed by a single operator.

All patients were pre-treated with aspirin (325 mg) and clopidogrel (300–600 mg).

Only drug-eluting stents were deployed.

The use of Gp IIb/IIIa inhibitors was at the discretion of the operator.

Preference of access site, approach to CTO-PCI, use of microcatheter/penetration catheter/cutting balloon and other special techniques was at the discretion of the operator.

After the procedure, all the patients were maintained on DAPT for as long as possible with a minimum of 6 months.

Patient outcomes were stratified according to successful (sCTO) or unsuccessful (uCTO) CTO recanalization.

Patients undergoing an initial unsuccessful procedure but undergoing a subsequent successful attempt were classified as successful.

Data were prospectively entered into a clinical database at the time of the PCI by the performing physician.

Following data was collected:

Patient Characteristics: age, sex, previous acute coronary syndrome (ACS)/PCI/coronary artery bypass grafting (CABG), hypertension, diabetes mellitus, dyslipidemia, peripheral vascular disease, new york heart association (NYHA) functional class, smoking status, chronic renal failure [eGFR between 15 and 90 ml/kg/m2or on renal replacement therapy], left ventricular function.

Procedure-Related Data: access site, target vessel, number of diseased vessels, approach to CTO-PCI, flouro time, heparin dose, contrast volume and number of stents deployed.

Procedural Complication Data: access site complications, no/slow flow, side branch occlusion, need for emergency CABG, the incidence of CIN.

Clinical Outcome Data: MACE, cardiac death, allcause death, need for TVR, residual angina/ dyspnoea.

4. Results

CENTRAL ILLUSTRATION :



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BASELINE CHARACTERISTICS	sCTO	uCTO	TOTAL $n = 339$ (%)	P-value
	n = 290 (%)	n = 49 (%)		
AGE (mean + S.D.)	57.45 ± 9.09	57.95 ± 7.57	57.35 ± 9.17	0.716
Male SEX, n (%)	246 (84.8)	48 (97.9)	294 (86.7)	0.01
HTN, n (%)	161 (55.5)	21 (42.8)	182 (53.7)	0.121
DM, n (%)	144 (49.7)	24 (48.9)	168 (49.5)	0.998
DLP, n (%)	60 (20.7)	9 (18.4)	69 (20.3)	0.848
SMOKING, n (%)	78 (26.9)	16 (32.7)	31 (9.1)	0.087
CKD, n (%)	18 (6.2)	4 (8.2)	22 (6.5)	0.539
OBESITY, n (%)	34 (11.7)	5 (10.2)	39 (11.5)	0.998
PAD, n (%)	11 (3.8)	4 (8.2)	15 (4.4)	0.247
EA III/IV, n (%)	102 (35.2)	24 (48.9)	126 (37.2)	0.078
Previous MI, n (%)	93 (32.1)	19 (38.8)	112 (33.0)	0.411
AWMI	50 (17.2)	06 (12.2)	56 (16.5)	0.532
IWMI	42 (14.5)	13 (26.5)	55 (16.2)	0.056
LWMI	01 (0.34)	0	01 (0.29)	_
Previous ACS, n (%)	129 (44.5)	20 (40.8)	149 (43.9)	0.755
UA	4 (1.4)	0	4 (1.2)	_
NSTEMI	32 (11.0)	1 (2.0)	33 (9.7)	0.064
STEMI	93 (32.1)	19 (38.8)	112 (33.0)	0.411
Previous PCI, n (%)	6 (5.5)	0	6 (4.7)	_
Previous CABG, n (%)	1 (0.9)	0	1 (0.8)	_
LVEF < 50, n (%)	44 (15.2)	3 (6.1)	47 (13.9)	0.116

Table 1. Baseline Characteristics

4.1. Demographics

A total of 339 patients were followed up for a duration that ranged from a minimum of 3 months to a maximum of 36 months. The median follow-up was 24 months in our study population.

The baseline characteristics of both groups were comparable. The baseline characteristics of our study population are shown in Table 1.

The mean age of our study population was 57.35 ± 9.17 overall. The mean age in sCTO group was 57.45 ± 9.09 and it was 57.95 ± 7.57 in the uCTO group. There was no significant difference between the mean age in both these groups.

However, when we compared different age groups, unsuccessful CTO-PCI was more common in the elderly age group as shown in Table 2 And Fig. 1.

We had more number of males overall in our study group 86.7% (n = 294) compared to females 13.3% (n = 45). Male sex was 84.8% (n = 290) and 97.9% (n = 49) in sCTO and uCTO groups respectively. Though it was statistically significant in uCTO group, it was skewed data since we had very less female patients in our study group.

Table 2. Age Wise Distribution Of Procedural Success.

	SUCCESS	FAILURE	TOTAL
<50	52 (91.2)	05 (8.8)	57
50 - 59	106 (85.5)	18 (14.5)	124
60 - 69	113 (84.3)	21 (15.7)	134
≥70	19 (79.1)	05 (21.9)	24

Both groups were comparable with respect to other baseline demographics.

Patients having effort angina class III-IV were numerically more in uCTO group, but were not statistically significant.

Most of the patients included in our study were having a good baseline LV ejection function. Patients with LV dysfunction (EF < 50%) were numerically more in sCTO group but was not statistically significant.

4.2. Procedural data

Overall successful CTO-PCI was achieved in 85.5% (n = 290) and unsuccessful CTO-PCI was seen in 14.5% (n = 49). Table 3 shows the procedural data of our study population.



Fig. 1. Age Wise Distribution Of Procedural Success.

Table 3.	Procedural	Data	1.
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Procedural Data:	sCTO	uCTO	TOTAL n = 339 (%)	P-value
	n = 290 (%)	n = 49 (%)		
ACCESS SITE, n (%)				0.608
Femoral	84 (28.9)	12 (24.5)	96 (28.3)	
Dual Femoral	206 (71.1)	37 (75.5)	243 (71.7)	
APPROACH				0.998
Antegrade	277 (95.5)	47 (95.9)	324 (95.6)	
Retrograde	13 (4.5)	2 (4.1)	15 (4.4)	
VESSELS INVOLVED				
SVD	145 (50.0)	24 (49.0)	169 (49.9)	0.99
DVD	98 (33.8)	16 (32.7)	114 (33.6)	0.870
TVD	44 (13.8)	8 (16.3)	52 (15.3)	0.831
LM + SVD	1 (0.3)	0	1 (0.3)	-
LM + DVD	1 (0.3)	0	1 (0.3)	_
LM + TVD	2 (0.7)	1 (2.0)	3 (0.9)	0.373
CTO VESSEL				
LAD	125 (43.1)	15 (30.6)	140 (41.3)	0.117
LCX	24 (8.3)	7 (14.3)	31 (9.1)	0.182
RCA	117 (40.3)	24 (49.0)	141 (41.6)	0.275
DIAGONAL	2 (0.7)	0	2 (0.6)	_
OM	3 (1.0)	0	3 (0.9)	-
PDA/PLV	3 (1.0)	0	3 (0.9)	-
LAD + LCX	5 (0.9)	0	5 (1.5)	_
LAD + RCA	7 (1.8)	0	7 (2.0)	_
LCX + RCA	6 (1.8)	3 (6.1)	9 (2.6)	0.126
MICROCATHETER USE				
Fine cross	170 (58.6)	30 (61.2)	200 (58.9)	0.756
Corsair	8 (2.8)	3 (6.1)	11 (3.2)	0.202
Crusade	2 (0.7)	1 (2.0)	3 (0.9)	0.373
Caravel	17 (5.8)	4 (8.2)	21 (6.2)	0.522
CUTTING BALLOON USE	2 (0.7)	0	2 (0.6)	-
ANCHORING BALLOON USE	10 (3.4)		10 (2.9)	—
BALLOON EMBEDDING IN SIDE BRANCH	13 (4.5)	0	13 (3.8)	-

All the study patients underwent viability testing with cardiac magnetic resonance (CMR) imaging, and only patients with significant viable myocardium were included in the study.

All the patients underwent PCI through the femoral route. The majority of the cases needed a dual femoral access. However, there was no statistically significant difference in the outcome based on the access used.

Most of the CTO-PCI was performed through the anterograde approach. Only a few were performed through a retrograde approach. Anterograde loose tissue tracking (ALTT) with serial wire escalation was the most common technique used. Anterograde sub-intimal tracking and reentry (ASTR) was used in a few cases. For a retrograde approach, subintimal tissue tracking was employed. However, there was no statistically significant difference in relation to the outcome.

Since the serial wire escalation strategy was used, only a few (17%) lesions could be crossed with intermediate wires, and most (83%) lesions required stiff wires. J-CTO score was calculated to assess the complexity of lesions in all our patients. Mean J-CTO score was 2.05 ± 1.22 in sCTO group & 2.63 ± 1.56 in uCTO group. uCTO group had a higher proportion of patients with worse scores, as depicted in Fig. 2.

In our study, the success rate was higher in the left anterior descending artery (LAD) territory followed by the right coronary artery (RCA) territory. It was lowest in the left circumflex artery (LCX) territory, as shown in Fig. 3. However, the outcomes were not significantly related.

Though procedural success was higher in LAD territory, there were no significant differences in outcome. Fig. 4 shows the success rate in LAD in comparison to other territories.

Special hardware like microcatheter, penetration catheter and cutting balloons were used in most of the cases at operator's discretion. In the remaining cases, only monorail balloon were used. Fig. 5 shows the different hardware used in our study population. However, their use was not statistically significant.



Fluoroscopy time, heparin dose and contrast volume used in our population are tabulated in Table 4. No statistically significant difference was noted between our study groups.

4.3. Complications

Access site complications were the most common procedure-related complications overall. It was significantly more common in uCTO group (8.3% vs. 20.4%; *p* 0.017). Predominantly driven by TIMI major and minor bleeds.

Other complications like perforation, side branch occlusion, no flow/slow flow, cardiac tamponade, cardiac arrest, contrast-induced nephropathy and need for emergency CABG were seen in only a minority of patients and was not significantly related to the outcome. Table 5 lists the complications encountered in our study groups.



Fig. 3. Procedural success in various arterial territory.

4.4. Clinical outcomes

Our study population had very few in-hospital adverse events, predominantly driven by MACE as depicted in Table 6. However, they were not statistically significant.

All cause death and cardiac death were marginally higher in uCTO group but were not statistically significant as shown in Table 7.

New onset ACS was significantly higher in uCTO group (5.5% *vs.* 14%; *p* 0.033) which was predominantly driven by non ST-elevation ACS (NSTEACS). ST-elevation myocardial ischemia (STEMI) rates, however were not significantly related to outcomes.

MACE was significantly higher in uCTO group (36.7% vs. 8.9%, p 0.001) and was predominantly driven by Ischemia Driven Revascularization (16.3% vs. 3.1%, p < 0.001).

The need for CABG was significantly higher in uCTO group (16.3% vs. 0.7%, p < 0.001) and was the predominant means of revascularization in uCTO group.



Fig. 4. Procedural success in LAD vs non LAD territory.



Fig. 5. Hardwares use in our study.

Table 4. Procedural Data 2.

	Group	Ν	Mean	S.D.
Flouro Time (min)	sCTO	290	25.99	12.64
	uCTO	49	27.06	12.27
Heparin Dose (ml)	sCTO	290	7935.78	952.82
	uCTO	49	7631.58	573.53
Contrast Volume (ml)	sCTO	290	218.99	88.07
	uCTO	49	218.68	90.93

Residual angina (26.5% vs. 10%, p 0.003) and residual dyspnoea (34.7% vs. 12.4%, p < 0.001) were significantly worser in uCTO group.

DAPT was continued beyond 12 months in most of our patients. Only a few patients had discontinued them before 12 months. However, that was not significantly related to the outcomes. Details of the duration of dual antiplatelet therapy is as depicted in Table 8.

5. Discussion

Our study was a single centre, single operator experience in real life in south Indian population.

We had procedural success in 85.5% of patients. A meta-analysis by Patel et al. [13] of 65 studies with 18,061 patients and 18,941 target CTO vessels

Table 5.	Compi	lications.
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showed angiographic success in 77%. Few recent studies with the use of modern techniques have shown a procedural success of more than 80% [14,15]. Our results were consistent with these recent studies.

The mean age of our patients was 56.96 ± 9.17 . It was observed that procedural success declined as the age advanced (91.2% in <50yrs vs. 79.1% in >70yrs).

We had large male population (86.7%), similar to the extensive UK registry database (78.8% males of 13,443 CTO patients) [16].

Some of the previous studies [17,18] included more patients with older age, lower left ventricular ejection fraction, and previous MI in uCTO group, whereas we did not have any such discrepancy.

Patients with a previous history of revascularization did not have a worse outcome, unlike in previous studies [18].

Patients with worse J-CTO score had poorer outcomes as found in previous studies [15].

We observed that the success rate was 90.3% in LAD territory, whereas it was 81.2% in LCX territory and 84.3% in RCA territory.

Previous studies [19] have reported a significant benefit in survival after successful PCI of a CTO located in the LAD territory but not after successful PCI of a CTO located in the circumflex or right coronary arteries. However, in our study, though procedural success was higher in LAD territory, there was no significant differences in outcome.

Use of special hardwares like micro catheter, penetration catheter and cutting balloon was done in most of the cases and hence led to higher procedural success. However, they were not significantly different among our study groups.

We also noted that fluoroscopy time, heparin dose and contrast volume were marginally higher in uCTO group but was not significant.

Complications	sCTO	uCTO	TOTAL $n = 339$	P-Value
1	n = 290	n = 49		
ACCESS SITE COMPLICATIONS, n (%)	24 (8.3)	10 (20.4)	34 (10.0)	0.017
TIMI Minor Bleed	16 (5.5)	6 (12.3)	22 (6.4)	0.108
TIMI Major Bleed	5 (1.7)	3 (6.1)	8 (2.4)	0.093
Peudoaneurysm	3 (1.0)	1 (2.0)	4 (1.2)	0.466
Perforation, n (%)	6 (2.0)	3 (6.1)	9 (2.7)	0.126
Minor	4 (1.3)	2 (4.1)	6 (1.8)	0.209
Major	2 (0.7)	1 (2.0)	3 (0.9)	0.373
Side Branch Occlusion, n (%)	4 (1.3)	0	4 (1.2)	—
No Flow/Slow Flow, n (%)	5 (1.7)	0	5 (1.5)	—
Tamponade, n (%)	2 (0.7)	1 (2.0)	3 (0.6)	0.373
Cardiac Arrest, n (%)	1 (0.3)	0	1 (0.3)	—
Emergency CABG	1 (0.3)	0	1 (0.3)	_
CIN, n (%)	9 (3.1)	2 (4.1)	11 (3.3)	0.663

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ladie 6. in-Hospital Adverse Events.							
In–Hospital	sCTO	uCTO	TOTAL $n = 339$	P-Value			
Adverse Events	n = 290	n = 49					
Cardiac Death, n (%)	0	0	0	_			
MACE, n (%)	16 (5.5)	2 (4.1)	18 (5.3)	0.998			
STEMI, n (%)	1 (0.3)	0	1 (0.3)	_			
Target vessel Re-PCI, n (%)	1 (0.3)	0 (0)	1 (0.3)	-			

Table 6. In-Hospital Adverse Events.

Table 7. Long term clinical outcomes.

Outcomes	sCTO	uCTO	TOTAL $n = 339$	P-Value
	n = 290	n = 49		
All Cause Death, n (%)	9 (3.1)	3 (6.1)	12 (3.5)	0.391
Cardiac Death, n (%)	6 (2.1)	2 (4.1)	8 (2.4)	0.333
MACE, n (%)	26 (8.9)	13 (36.7)	39 (11.5)	0.001
NEW ACS, n (%)	16 (5.5)	7 (14.3)	23 (6.8)	0.033
UA	5 (1.7)	2 (4.1)	7 (2.1)	0.267
NSTEMI	9 (3.1)	4 (8.2)	13 (3.8)	0.102
STEMI	2 (0.7)	1 (2.0)	3 (0.9)	0.373
STEMI, n (%)	2 (0.7)	1 (2.0)	3 (0.9)	0.373
ID-Target Vessel	9 (3.1)	8 (16.3)	17 (5.0)	< 0.001
Revascularization, n (%)				
Re - PCI, n (%)	7 (2.4) '	0	7 (2.1)	_
CABG, n (%)	2 (0.7)	8 (16.3)	10 (2.9)	< 0.001
Residual Angina, n (%)	29 (10.0)	13 (26.5)	42 (12.4)	0.003
Residual Dyspnoea, n (%)	36 (12.4)	17 (34.7)	53 (15.6)	< 0.001

Previous studies had postulated that the complications of CTO-PCI might have some influence on the mortality after PCI.

Japanese CTO registry showed a coronary perforation rate of 7.2% [15]. Mehran et al. [12] reported the rate of coronary perforation and residual dissection rate of 7.4% and 9.4%, respectively in an unsuccessful CTO group.

In our study, we had a perforation rate of 6.1% in uCTO group though it was not statistically significantly related to outcomes.

Access site complications were the most common complication encountered (20.4 vs. 8.3%; p 0.017) and was predominantly driven by TIMI major and minor bleeds.

Severe complications such as cardiac tamponade, cardiac arrest or need for emergency CABG were not significantly different in our study groups. In contrast, they were more frequent in the failed PCI group in previous studies. Olivari et al. [8] reported that 2.3% of patients in the failed CTO-PCI group underwent emergent CABG, but we had none in our study.

Suero et al. [20] reported that the incidence of inhospital major adverse cardiac events was significantly high in the failed CTO-PCI group but our study did not show any such difference.

Successful CTO-PCI was not associated with a lesser risk for all-cause death and cardiac death over a follow up of 3 yrs unlike previous studies [12].

Probable reasons being, firstly, Subsequent coronary revascularization in uCTO group might have attenuated the possible long-term mortality benefit of successful CTO-PCI. Secondly, the difference in the background characteristics of patients. Because of the relatively high initial success rate, the successful CTO-PCI group included many patients with complex clinical and procedural characteristics, who are deemed to have a poor long-term prognosis. We can postulate that many complex patients

Table 8	Duration	\cap	f Dual	Anti	nlatalat	Thoram
Table 8.	Duration	U	t Duai	Anti	viateiet	inerapu.

		sCTO	uCTO	Total	P - value
DURATION OF DAPT	LESS THAN 6 MONTHS	2	0	2	_
	6 - 12 MONTHS	9	1	10	0.998
	MORE THAN 12 MONTHS	279	48	329	0.998
Total		290	49	339	

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included in the sCTO group in our study could be included in the uCTO group in previous studies. Thirdly, a lesser number of procedural complications in uCTO group could have had better long term results.

MACE rate was significantly higher in uCTO group compared to sCTO group (36.7% vs. 8.9%, p 0.001) and was predominantly driven by Ischemia Driven Revascularization (16.3% vs. 3.1%, p < 0.001).

Valenti et al. [17] reported that the incidence of CABG at one year was 9.1% in the failed PCI group. Need for CABG in the uCTO group over a period of 3 yrs 16.3% and was the predominant mode of revascularization in uCTO group.

Successful CTO-PCI had significantly low residual angina(26.5% vs. 10%, p 0.003) and residual dyspnoea (34.7% vs. 12.4%, p < 0.001).

Most of the patients continued DAPT for more than 12 months. Except for 2 patients who had to discontinue it within 6 months owing to non-cardiac surgery and 10 patients discontinued between 6 and 12 months (6 due to excessive bleeding and 4 defaulters). However, it was not significantly related to outcomes.

There is no randomized controlled trial comparing PCI plus medical therapy with medical therapy alone in patients with CTO. Prospective randomized trials comparing PCI plus medical therapy with medical therapy alone in patients with CTO, adequately powered for evaluating long-term mortality, are absolutely required to define the indication of CTO-PCI.

5.1. Study limitations

Our study was an observational study. Prospective randomized control trials are required to compare PCI plus medical therapy with medical therapy alone to define indications for CTO-PCI. We had a variable duration of follow up, though the median follow up was 24 months. A longer duration of follow up might show better results. Our study was underpowered to evaluate mortality benefits in a successful CTO group. We did not have any angiographic follow up. We did not include a non CTO-PCI comparison group. Hence, we do not know how the outcomes of CTO-PCI group compares with the other non CTO-PCI groups. Unsuccessful CTO group used as a surrogate for medical therapy. A proper comparison with medical therapy alone will be more useful clinically.

6. Conclusions

- 1. Procedural success in the present drug-eluting stent era is more than 80%, and newer techniques and hardwares have improved the procedural success rates.
- 2. Successful CTO-PCI was not associated with a lesser risk for all-cause death and cardiac death over a follow up of up to 3 yrs.
- 3. MACE rates were significantly higher in the unsuccessful CTO-PCI group.
- 4. Ischemia Driven-Revascularization rates were significantly higher in patients with unsuccessful CTO-PCI.
- 5. The need for subsequent CABG was very high in the unsuccessful CTO-PCI group.
- 6. Residual angina and residual dyspnoea were significantly worse in the unsuccessful CTO-PCI group.

Author contribution

Desabandhu Vinayakumar, Mohanan K. S: Conceptualization of study, Intermittent review of data collected.

Desabandhu Vinayakumar, Raikar M. P., Mohanan K. S.: Study design and expected results, Critical review of article.

Raikar M. P.: Collection and tabulation of data.

Raikar M. P., Mohanan K. S.: Analysis of data, Review of past literature.

Desabandhu Vinayakumar, Raikar M. P.: Write up of the article.

Ethical Clearance

The study was approved by institutional ethical committee (IEC) at government medical college, Kozhikode.

Conflicts of Interest

All authors declared there is no conflicts of interest in this study and there is no grant and financial support to this study.

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