

Percutaneous Revascularization of Chronic Total Occlusion of Diabetic Patients at Iraqi Center for Heart Diseases, A Single Center Experience 2012.

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Abstract

I want to evaluate the influence of (DM) on the results of (PCI) of patents with (CTO) and to compare that with the results in non diabetic patients.

We had prospectively studied 150 consecutive cases of (CTO) who had (PCI) at Iraqi center for heart diseases-Baghdad/Iraq for the period January –December 2012. All patients were symptomatic. We recorded patients baseline characteristics, which coronary artery involved, the segment/s involved, and whether the patient diabetic or not and impact of these parameters on the hospital outcome of the intervention. We also looked at influence of (HTN), (HLP), (SM), and (PFH) for ischemic heart diseases, on the outcome of the intervention as well.

Success of revascularization of chronic total occlusion by percutaneous coronary intervention was similar in both sexes (male 69.4% female 72.4%). Intervention was successful in 40 out of 55 patients with diabetes mellitus (72.7%) which was identical to those without diabetes mellitus (66 patients out of 95 patients (69.47%).The success in diabetic and non diabetic groups in the absence of other risk factors was 64.2 % and 62% while in the presence of these risk factors it was 73.1% and 71.2 % respectively.

In 11 out of the 15 patients with diabetes failed intervention was attributed to inability to pass the wire (73.3 %) compared to 23 out of the 29 nondiabetic patients (79.3%). While failure to pass the balloon was identical in both groups (13.3% compared 13.7 and failure to pass a stent while it was not reported compared to 3.4% in both diabetic and non-diabetic patients respectively.

As far as failure of procedure, passing the wire into a false lumen occurred in one patient (6.6%) of diabetic group and not reported in the non diabetics while creation of perforation had occurred in one patient (6.6%) in diabetics and also in one patient (3.45) in non diabetic patient.

Successful revascularization has led to a prompt relieve of symptoms; angina and improved exercise tolerance as well as enhanced left ventricular function equally in both groups.

Regarding CTO-PCI, there was no much difference between success in diabetic and non diabetic patients. The beneficial effect of successful recanalization of CTO on overall survival free of major adverse events was clearly apparent to be irrespective of diabetic status. Presence of additional risk factors other than diabetes mellitus has no additional burden on the

results of such interventions. CTO-PCI should be done in all patients with prognostically significant ischemia or heart failure with significant viability.

Keywords : diabetes mellitus (DM), percutaneous coronary intervention (PCI), chronic total occlusion (CTO), hypertension (HTN), hyperlipidemia (HLP), smoking (SM), positive family history (PFH)

Introduction

A CTO was defined as a lesion exhibiting Thrombolysis in Myocardial Infarction flow grade 0–1 of a native coronary artery. 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 as a technical success with no in-hospital major adverse cardiac event (MACE). A CTO success was defined as a technical success. A MACE was defined as the occurrence of death, Q-wave MI or urgent revascularization. Urgent revascularization was classified by operators caring for patients and required repeat PCI of target vessel during the same admission or coronary artery bypass graft surgery (CABG) including bypass of the target vessel. Repeat percutaneous transluminal coronary angioplasty (PTCA) was defined as a subsequent procedure in the occluded vessel.

(1)

These data highlight a striking survival advantage among patients with a successfully opened occluded artery versus those whose procedure was unsuccessful. Work supports the concept of a time-independent benefit of reperfusion. Results elucidate the importance of revascularization of a CTO, and they represent long-term follow-up on the largest reported series of treated chronic coronary occlusions. Although success rates have continued to improve over time, attempted revascularization does not come without complications. The MACE rates, although constant, were found to be 3.8% overall. With proper training and by carefully selecting the lesions attempted, aggressive intervention of a CTO is justified.

(1) CTOs are a continuum of atherosclerotic progression leading to plaque rupture with thrombus formation. Over time, this thrombus tissue will be converted to fibrous tissue composed mainly of collagen and, in the later phase, calcium. Histopathologically, CTOs are characterized by inflammation, neovascularization, and the extent of calcification. The plaque that forms a CTO is also categorized as soft, hard, or mixed. Soft plaque is primarily composed of cholesterol-laden cells and foam cells that are generally more amenable to wire passage. The hard plaques are composed of dense, fibrous tissue with fibrocalcific regions that are more resistant to wire passage. (2)

PCI of chronic total occlusion represents 10%- 20% of all angioplasty procedures and poses a management, dilemma for the interventional cardiologist (3).

A CTO was defined as obstruction of a native coronary artery with no luminal continuity and Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 or 1. The duration of occlusion had to be more than 3 months, estimated from clinical events such as myocardial infarction, sudden onset or worsening of symptoms or proven by previous angiography. Technical success was defined as restoration of TIMI flow grade 2 or 3 with residual stenosis <15 %.
(in stented lesion) (3).

Patients with diabetes mellitus (DM) constitute patient group with a high prevalence of multivessel disease (MVD) and high mortality after ST elevation myocardial infarction (STEMI). Approximately 35- 45% of non-diabetic STEMI patients have MVD compared with 60 -70% of patients with DM. The higher mortality of STEMI patients with DM has been suggested to be at least partly due to the greater extent of coronary artery disease. Recently, the presence of a chronic total occlusion (CTO) in a non-infarct-related artery (non-IRA) and not MVD alone was reported to be an independent predictor of mortality after STEMI. Given the greater extent of coronary artery disease in diabetic patients with STEMI, it was hypothesized that the prevalence of a CTO in a non-IRA would be higher in this high-risk subgroup. Moreover, the prognostic impact of a CTO in a non-IRA in diabetic patients with STEMI is currently unknown. (4)

Two retrospective studies from the 1990s suggested that the prevalence of CTO in patients with coronary artery disease (CAD) on coronary angiograms ranged from 33% to 52 %.(5)The true prevalence of CTO in the general population is unknown as a certain proportion of patients with CTO are asymptomatic or minimally symptomatic. (5)

Successful CTO PCI is associated with improved survival out to 5 years. Adoption of techniques and technologies to improve procedural success may have an impact on prognosis. (6)

Pre-selected variables for CTO-PCI were age, gender, diabetes mellitus, hypertension, and hypercholesterolaemia, presence of multivessel disease, impaired left ventricular function, prior AMI, prior PCI, and prior CABG, use of a glycoprotein IIb/IIIa inhibitor, target vessel, successful procedure, and use of a stent. (7)

Coronary chronic total occlusions (CTOs) are commonly encountered complex lesions identified in 15% of all patients referred for coronary angiography. Chronic total occlusion remains the most powerful predictor of referral for coronary bypass surgery. The benefits of CTO percutaneous coronary intervention (PCI) include symptom relief, improved left ventricular function, and potentially a survival advantage associated with success when compared with failed CTO-PCI.(8)

Recent advances in CTO-PCI techniques that have broadened PCI indications and improved success rates can be categorized into ante grade and retrograde techniques. (8)

No consensus exists for selecting an initial approach to a CTO (ante grade vs. retrograde). The most common reason to use retrograde techniques among experienced CTO operators is failure to succeed using the ante grade approach. If failure with the ante grade approach is imminent and fluoroscopy time is <30 min, the change can be made ad hoc. In the event that greater time has been used, the patient should be brought back for a staged attempt at least 48 h after the first attempt. Certain subsets of patients, including those with long lesions (>20 mm), ostial occlusions, extreme tortuosity, severe calcification, and small or poorly visualized distal vessels may also be selected for a primary retrograde approach. (8)

Technology continues to grow in the field of interventional cardiology. The evolution of newer wires, stents, support catheters, and forward-looking devices, such as the Safe-Cross, will continue to improve success rates in treating CTOs. Success, however, will improve only in the appropriately selected patient. The question of routine intervention for CTOs was

effectively answered by the Occluded Artery Trial (OAT) investigators, who demonstrated no reduction in death, reinfarction, or heart failure with routine intervention to persistently occluded arteries after myocardial infarction. The ideal patient is one who has persistent angina with suitable lesion anatomy consisting of a tapered occlusion, angulation $<45^\circ$, a single lesion, and lesion length <15 mm. The appropriately selected patient can now look forward to increased successful recanalization and safety during treatment of CTOs using the Safe-Cross System, which is unique in its ability to assess the intraluminal tissue in real time.

(9)

Among all patients who undergo coronary arteriography, CTO is present in at least 30% of cases. Coronary CTO remains one of the most challenging lesion subsets in interventional cardiology, even with the development of medical devices and operator expertise, although the long term outcome of PCI for CTO is currently unknown. There is a benefit of cardiac magnetic resonance (CMR), a safe, noninvasive technology, for the follow-up and assessment of the efficacy of a complex PCI procedure like CTO. (10)

Methods:

I had studied 150 cases of CTO who had undergone PCI at Iraqi center for heart diseases regarding the base line characteristics. Then I classified the patients according to arterial and then segmental involvement. So also I verified the causes of failure and number of attempts of PCI in both diabetic and non diabetic groups. After that I studied the success of CTO-PCI in both diabetic and non diabetic patients when diabetes was the only risk factor and also the success in the presence of other risk factors for ischemic heart diseases in both groups. Then I studied both groups according to age groups, sex with relation to success and failure.

Chi-square test was used to analyze the statistical association between the various selected variables. Statistical significance was accepted for $P \leq 0.05$ (significant). and $P > 0.05$ (insignificant).

Results:

Regarding the base line characteristics our results demonstrated in table (1), age groups as in table (2)

Table (2), procedure related characteristics as in table (3), arterial segment in the 150 patients studied as in table (4), success, failure in diabetic and non-diabetic patients, causes of failure and number of failed attempts as in table (5), diabetic and non diabetic groups and whether DM was the only risk or in the presence of other risk factors as in table (6), gender related CTO-PCI in diabetics as in table (7)

Discussion

Regarding baseline characteristics we studied our 150 CTO-PCI patient according to gender, diabetic status, hypertension, smoking, obesity, prior PCI, prior CABG, prior MI and multivessel diseases. There was a similar study which used the same parameters (3) while in another study (7) the pre-selected variables were age, gender, diabetes mellitus, hypertension,

hypercholesterolemia, presence of multivessel disease, impaired left ventricular function, prior AMI, prior PCI. Prior CABG, use of a glycoprotein II b/ III an inhibitor, target vessel, successful procedure and use of a stent and our results are nearly comparable. While in another study no differences were found in baseline clinical and procedural variables between patients with (n=34) and without diabetes (n=129), unless for hypertension (p=0.03). Hospitalization period after PCI in diabetics (3.26±0.61 days) and non-diabetics (2.86±0.52 days) was similar. In-hospital MACE occurred in 8 (23.5%) individuals of diabetics and 10 (7.8%) individuals of non-diabetics (p=0.02), among them revascularization was significantly higher in diabetics (20.6% vs. 7%, p=0.04). Follow-up events in diabetic and non-diabetic groups were 12 (35.3%) and 37 (28.5%), respectively (p was not significant). In patients undergoing successful PCI on CTO, diabetes is associated with higher in-hospital adverse events; however diabetes does not affect long term outcomes in these patients. (11)

Regarding the arterial involvement my results were a little bit similar to another study (6) which showed that CTO PCI was performed on the left anterior descending coronary artery (LAD) in 232 (35.1%), left circumflex coronary artery in 112 (16.9%), and right coronary artery in 298 (45.1%) patients. Patients in the successful group were more likely to have undergone LAD intervention, whereas those in the unsuccessful group were more likely to have undergone intervention to the right coronary artery.

In another study the following results had been established; 57 patients with chronic total occlusions underwent PCI out of them 31.58% are female and 68.42% are male. There was no periprocedural or in hospital complications. 49.1% patients had multivessel disease. 33.33%.left anterior descending artery lesion, 29.82% right coronary lesion, 24.56% circumflex lesion and 12.28%.obtuse marginal lesion. Predilation was done in all cases using various size balloons. Various wires were used and in most cases more than one wire were used. Cypher, Taxus and driver stents were used for stenting.75.4% are successful while 24.6% were unsuccessful. (3)

I also verified the segmental involvement of CTO lesions in our 150 patients (table 4), and I compared my findings with what had been accounted in another study (5) whereas it was stated that the distribution of solitary CTOs showed 47% were in the right coronary artery (RCA). Whereas only 20% had a solitary CTO in the left anterior descending artery. And 16% in the left circumflex branch. Chronic occlusion in >1 coronary artery were observed in 17%. The CTO location was in the proximal or middle portion of the coronary arteries in 78% of cases (distribution of proximal or midvessel occlusion per vessel: left anterior descending artery 84%; left circumflex branch 63% and our results were nearly comparable.

Out of our 150 cases studied, there were 55 patients having DM and success of PCI trial was reported in 40 (72.7%) of cases. While the non diabetic cases were 95 and the success of CTO-PCI was reported in 66 patients (69.4%), and in comparison with our results one study (5) showed that the success rate (70%) and is consistent with that of many previous registries (3), although more recent studies from CTO specialized centers have reported success rates >80% and all these results were a little bit comparable to my findings.

According to our study, out of the 15 (27.2%) failed attempts the causes of failure were as follow: 11 cases (73.3%) were due to failure to pass a wire, 2 cases (13.3%) were due to

failure to pass a balloon, 1 case (6.6%) was due to a passage in a false lumen and 1 (6.6%) case was due to a creation of a perforation. While in the non diabetic 29 (30.5%). failed attempts the causes of failure were as follow:23 (79.3%) cases were due to a failure to pass a wire, 4 cases (13.7%) were due to a failure to pass a balloon, 1 case (3.4%) was due to a failure to pass a stent and in 1 case (3.4%) was due to creation of a perforation while as a comparison it was reported in one study (3) that technical and procedural success was obtained in 75.4% of patients. Among failed procedures, inability to cross the lesion with a guide wire, inability to cross with a balloon and inability to dilate were the reasons of failure in 57.14%, 28.57% and 12.28% respectively.

In our diabetic failed 15 attempts, 13 (86.6%) cases were reported as a single failed attempt and in 2 (13.3%) of the cases there was more than a single failed attempt. While regarding the 29 failed attempts in non diabetic patients we reported 26 (89.6%) as a single and in 3 (10.3%) the matter was due to multiple attempts.

Regarding the race, all our cases were of the white race and during the review of literature I had not found anything related to this aspect for a comparison.

I classified our 150 cases according to age groups and their success and failure, and in relation to diabetic and non diabetic status I compared our results with what had been seen in other studies. One of these accounted that mean age of patients was 56.19 +/- 10.19 years showing that disease occur earlier and it is more serious. (3) in another study it was stated that the mean age of CTO was 66±11 years and 81% were male. (5)

Also I studied gender related CTO-PCI results in diabetics and non diabetics as demonstrated in table 7 and our results were comparable with what had been accounted in the above reference (5).

All our 150 cases of CTO-PCI were initially symptomatic whereas it was stated in one study that the true prevalence of CTO in the general population is unknown as a certain proportion of patients with CTO are asymptomatic or minimally symptomatic (5). It was added in the same study that only 11% to 15% undergoing PCI for CTO were asymptomatic. The same percentage was also reported in another study (9)

The success rate for percutaneous CTO recanalization have undoubtedly improved over the last 5 years, a major reason is the introduction of stiffer, more powerful and more supportive guidewires with greater torque response, tapered tip wires and wires with hydrophilic coatings.(3). According to the same study most of patients receive drug-eluting stents. Drug eluting stents produces favorable results as compared to bare metal stents.

Management of patients with CTO remains a challenge. It is clear that total occlusion portends a worse prognosis than a patent vessel in patients with acute myocardial infarction. With emerging evidence that successful; percutaneous recanalization of chronic coronary occlusions resulting improved survival, as well enhanced left ventricular function, reduction in angina, and improved exercise tolerance. PCI should be considered the preferred initial revascularization modality in patients in whom high procedural success rate may be anticipated. Fortunately with the tremendous progress in guide wire technology and introduction of dedicated devices for refractory occlusions has resulted in success rate of 80% to 90% in true CTO. Although success rates have continued to improve over time, attempted

revascularization does not come without complication. With proper training and by carefully selecting the lesion attempted, aggressive intervention of CTO is justified. (3)

According to our study, the beneficial effect of successful recanalization of CTO on overall survival free of major adverse events was clearly apparent to be irrespective of diabetic status and this was confirmed in a similar study (7).

In my study there was no much difference in the success rates in both diabetic and non diabetic patients, this was confirmed also in other two studies (12, 13) which accounted that diabetic and non diabetic patients have similar rates of initial angioplasty success but diabetic patients have higher restenosis rates after percutaneous transluminal coronary angioplasty (PTCA) and worse long term outcomes.

All our patients with successful CTO-PCI got remarkable improvement and this was witnessed by follow up in the outpatient clinic through enhanced left ventricular function , reduction of angina and improved exercise tolerance and our results were similar with what had been stated in another study (7) which accounted that the benefits of CTO percutaneous coronary intervention (PCI) include symptom relief, improved left ventricular function, and potentially a survival advantage associated with success when compared with failed CTO-PCI.” In addition, successful PCI of CTO is associated with improved quality of life and reduced ischemia, (7)

Conclusion

Regarding CTO-PCI results ,there was no much difference between success in diabetic and non diabetic patients , so also the presence of other risk factors has no an impact on the same results at the time of intervention . In both groups and in all patients the disease was symptomatic and those with successful attempts got many benefits from PCI so CTO-PCI should be done in all patients with prognostically significant ischaemia or heart failure with significant viability.

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Table (1)

	All CTO-PCI patients studied	CTO-PCI success	CTO-PCI failure	p-value
Male	121(81%)	84 (69.4%)	37 (30.5%)	0.7 N/S
Female	29(19%)	21 (72.4%)	8 (27.5%)	

Diabetic patients	55(36.6%)	40 (72.7%)	15 (27.2%)	0.6 N/S
Non diabetic patients	95(63.3%)	66 (69.47%)	29 (30.5%)	
HTN	72(48%)	52 (72.2%)	20 (27, 7%)	0.5 N/S
Hyperlipidemia	55(36.6%)	42 (76.36%)	13 (23.63%)	0.1 N/S
Smoking	48(32%)	37 (77%)	11 (22.9%)	0.1 N/S
Obesity	47(31.3%)	36 (76%)	11 (23.4%)	0.2 N/S
Prior MI	46(30.6%)	27(58.7%)	19(41.3%)	0.04 S
Prior CABG	7(4.6%)	5(71.4%)	2(28.5%)	0.9 N/S
Prior PCI	20(13.3%)	17(85%)	3(15%)	0.1 N/S
Multi-vessel disease	84(56%)	68(80.9%)	16(19%)	0.2 N/S

Table (2)

Age group	DIABETIC PATIENTS			P-VALUE	NON-DIABETIC PATIENTS			P-VALUE
	Total	Success	Failure		Total	Success	Failure	
3039 year	-	-	-	0.2 N/S	5(5.2%)	5 (100%)	_____	0.03 S
4049 year	11(20%)	6(54.54%)	5(45.45%)		23(24.2%)	21 (91.3%)	2 (8.69%)	

5059 year	24(43.6%)	18(75%)	6(25%)		27(28.4%)	16 (59.2%)	11 (40.7%)	
6069 year	15(27.2%)	11(73.33%)	4 (26.66%)		35(36.8%)	21 (60%)	14 (40%)	
7080 year	5(9.09%)	5(100%)	-		5(5.2%)	3 (60%)	2 (40%)	

Table(3)

Artery	Total number	success	Failure	P-VALUE
LAD	62(41.3%)	45 (72.5%)	17 (27.4%)	0.5 N/S
LCX	9(6%)	8 (88.8%)	1 (11.1%)	0.3 N/S
RCA	67(44.6%)	43 (64.1%)	24 (35.8%)	0.1 N/S
OM	8(5.3%)	6 (75%)	2 (25%)	0.7 N/S
Diagonal	1(0.6%)	1 (100%)	—	0.9 N/S
PLV	1(0.6%)	1 (100%)	—	0.9 N/S
PDA	—	—	—	
Ramus	2(1.3%)	2 (100%)	—	0.9 N/S

Table (4)

Artery	Total number	Ostial	proximal	Mid	distal	success	failure	P-VALUE
			1					

LAD	62(41.3%))	4 (6.4%)	10 (16.1%))	44 (70.9%))	4 (6.4%)	45 (72.5%))	17 (27.4%))	0.5 N/S
LCX	9(6%)	—	1 (11.1%))	5 (55.5%))	3 (33.3%))	8 (88.8%))	1 (11.1%))	0.3 N/S
RCA	67(44.6%))	—	16 (23.8%))	37 (55.2%))	14 (20.8%))	43 (64.1%))	24 (35.8%))	0.1 N/S
OM	8(5.3%)	1 (12.5%))	4 (50%)	3 (37.5%))	—	6 (75%)	2 (25%)	0.7 N/S
Diagonal	1(0.6%)	—	1 (100%)	—	—	1 (100%)	—	0.9 N/S
PLV	1(0.6%)	1 (100%)	—	—	—	1 (100%)	—	0.9 N/S
PDA	—	—	—	—	—	—	—	
Ramus	2(1.3%)	1 (50%)	1 (50%)	—	—	2 (100)		0.9 N/S

	number	success	failure	Failure to pass a wire	Failure to pass a balloon	Failure to pass a stent	Passing wire in a false lumen	Creation of perforation	Single failed attempt	Multiple failed attempts

diabetic patients	55(36.6%)	40(72.7%)	15(27.2%)	11(73.3%)	2(13.3%)	-	1(6.6%)	1(6.6%)	13(86.6%)	2(13.3%)
Non-diabetics	95(63.3%)	66(69.4%)	29(30.5%)	23(79.3%)	4(13.7%)	1(3.4%)	-	1(3.4%)	26(89.6%)	3(10.3%)

Table (5)

Table 6:

	Total	Success	Failure	P-VALUE
Number of diabetic patients, DM as only risk factors	14(9.3%)	9 (64.2%)	5 (35.7%)	0.8 N/S
Number of diabetic patients, DM + other risk factors	41(27.3%)	30 (73.1%)	11 (26.8%)	0.6 N/S
Number of non diabetic patients with no other risk factors	29(19.3%)	18 (62%)	11 (37.9%)	0.3 N/S
Number of non diabetic patients with (+Ve) other risk factors	66(44%)	47 (71.2%)	19 (28.7%)	0.2 N/S

Table 7:

Type of patients	Sex	Total	Success	Failure	P-VALUE
	Male	43(78.1%)	30 (69.7%)	13 (30.2%)	0.9 N/S

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