Is it feasible to perform coronary chronic total occlusion intervention with conventional angioplasty equipment?

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ABSTRACT

الأهداف: التحقق من جدوى استخدام أجهزة العلاج التقليدية من أجل التحكم بمشكلة الانسداد الكلي المزمن للشرايين.

الطريقة: أُجريت هذه الدراسة في مستشفى إسطنبول الطبي، إسطنبول، تركيا وذلك خلال الفترة من يناير 2007م إلى يونيو 2011م. شملت هذه الدراسة الاسترجاعية 95 مريض مصاب بالانسداد الكلي المزمن للشرايين، ولقد قمنا برأب الأوعية، واستخدام الأنابيب، والقسطرة بالبالون وذلك من أجل علاج المرضى الذين تنطبق عليهم مواصفات الدخول في هذا البحث. وتمت أيضاً مناقشة نسبة نجاح العملية وذلك اعتماداً على الصفات السريرية والديموغرافية للمرضى، بالإضافة إلى صفات الأجهزة المستخدمة للعلاج.

النتائج: لقد وصلت نسبة نجاح إعادة التوعي للمرضى إلى 80%، كما خرج كافة المرضى من المستشفى بعد العلمية الجراحية بيوم واحد من دون مضاعفات. وقلت نسبة النجاح إلى 60% لدى المرضى الذين وصلت مدة إصابتهم بالانسداد إلى أكثر من عام، ووصلت تقريباً إلى 90% لدى المرضى الذين وصلت إصابتهم بالمرض إلى أقل من هذه المدة. وتمت زراعة الدعامة لدى 82.9% من المرضى حيث وصل متوسط طول الدعامة 42.7±21.4 ملم. لقد كانت مدة الانسداد من أكثر المؤشرات الدالة على نجاح العلمية في تحليل الانحدار (p=0.01).

خاتمة: أظهرت الدراسة بأن علاج الانسداد الكلي المزمن للشرايين باستخدام وسائل العلاج التقليدية يعد منطقياً عند عدم تجاوز مدة المرض لأكثر من عام واحد. كما يجب تحويل المرضى الذين تزيد مدة إصابتهم بالمرض عن عام واحد إلى مركز متخصص ومجهز بالأجهزة الطبية والأطباء الذين يعرفون كيفية التعامل مع هذا المرض.

Objectives: To demonstrate feasibility of coronary chronic total occlusion (CTO) procedures with conventional interventional equipment.

Methods: Ninety-five subsequent CTO patients were analyzed retrospectively. Patients who met the inclusion criteria were intervented with standard angioplasty catheters, guidewires, and balloon catheters. The procedural success rate of the interventions was discussed according to clinical and demographic characteristics of patients and equipment used for intervention. This study was carried out in Istanbul Medicine Hospital, Istanbul, Turkey between January 2007 and June 2011.

Results: Successful revascularization was achieved in 80% of patients, and all patients were discharged on the day after the procedure without complication. The success rate decreased to 60% in the CTOs of more than one year and approximately 90% in the shorter duration. Stent implantation was carried out in 82.9% of patients with a mean stent length of 42.7±21.4 mm. Occlusion duration was the major predictor of successful procedure on regression analysis (p=0.01).

Conclusion: Coronary intervention for CTO with conventional equipment is still reasonable in the CTOs of short duration. Duration of coronary CTO over a year should be referred to a reference center where skilled operators and specialized equipment for CTOs are widely available.

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Chronic total occlusion (CTO) of coronary arteries commonly found on diagnostic angiography and it constitutes one third of coronary arteries' lesion. Revascularization of CTO lesion leads to improvement in left ventricular function, which benefits the long-term survival rates.[1-3] Chronic total occlusion intervention is still a challenge for interventional cardiologist and the success rate of intervention differs according to operator experience and availability of specialized equipment.[4] Chronic total occlusion intervention has recently became essential in Turkey. In addition, no reported large series of CTO in Turkey. In this study, we aimed to show the feasibility of CTO intervention with conventional methods. The benefit of CTO interventions had already demonstrated with numerous CTO series. In addition, CTO procedures are gaining more popularity with definition of new techniques, and introduction of new equipment. Beside these improvements, most of the cities, even countries are lack of the specialized referral centers for CTO intervention. It is not uncommon to face with CTO lesions in regular coronary angiography, and it is still challenge for most cardiologists to approach CTO lesions. In fact, in the recent developments in the CTO intervention era, there is no clear standard use of antegrade approach for CTO lesion with conventional equipment. Herein, we discussed the feasibility of conventional approach to CTO lesions.

Methods. *Patient selection.* This is a retrospective analysis of the CTOs intervention from January 2007 to June 2011 in Istanbul Medicine Hospital, Istanbul, Turkey. A total of 95 consecutive patients with CTO lesions were included in the study. The inclusion criteria were as follows: patients with CTO and evidence of ischemia either approved with stress test or nuclear scintigraphy and/or presence of typical angina. The exclusion criteria was as follows: patients with acute coronary syndromes and/or decompensated heart failure, patients without evident of ischemia and/or typical angina, creatinine level >2 g/dl, left ventricular ejection fraction <30%, left ventricular end-diastolic pressure >20 mm Hg and patients who did not accept CTOs intervention. Procedures were performed by 2 experienced cardiologists in Istanbul Medicine Hospital, Istanbul, Turkey. Istanbul Medicine Hospital is a referred cardiac center in the region with >100 primary and >400 elective coronary intervention capacity per year. Our success rate in the primary coronary intervention was 97% in 2010. The Local Ethics Committee of our hospital approved the study. Before the angiography procedure, all patients were informed on the procedure and informed consent was obtained.

Chronic total occlusion was defined as a lesion showing thrombolysis in myocardial infarction (TIMI) grade 0 of 3 months or more in duration. Duration of occlusion was estimated on the basis of history of angina, previous myocardial infarction (MI) in the same territory, or proven by previous angiography.[1] Procedural success was defined as successful guidewire and balloon crossing with/without final stent implantation resulting <30% residual stenosis and antegrade TIMI 2-3 flow. Fluoroscopy time was calculated from introduction of guiding catheter to coronary osteum and restoration of distal TIMI 2-3 flow in the target vessel. Diabetes mellitus was defined according to patients' history, use of insulin or anti-diabetic agents, or a fasting glucose >126 mg/dl. Dyslipidemia was defined as either LDL cholesterol >100 mg/dl and/or triglycerides >150 mg/dl. Hypertension was defined as previous use of anti-hypertensive medications or systolic pressure >140 mm Hg or a diastolic pressure >90 mm Hg in at least 2 separate measurements. Previous coronary artery disease was defined as angiographically proved coronary artery stenosis previously and/or echocardiographic and electrocardiography evidence of coronary artery disease depart from final presentation. Smoking was defined as current regular use of cigarettes. Multi-vessel disease was defined by a stenosis of >50% of 2 major epicardial coronary arteries.

Procedure and protocol. Before the procedure, all patients treated with a loading dose of 600 mg clopidogrel and 300 mg of aspirin. At the start of the procedure, the patients received a single dose of unfractioned heparin (10.000 U). Femoral route was used in all patients and 6F launcher right and left judkins (90%) and left EBU catheters (10%) (Medtronic, Minneapolis USA) were also used as guiding catheter. The PT 2 (70% of cases), PT graphix (60%), choice intermediate-standard guidewires (30% and 20%) (Boston Scientific, Miami USA) and Floppy 2 (20%), Whisper guidewires (10%) (Abbot Vascular, Diegem, Belgium) were used for crossing lesions. Aside from standard antegrade guidewire crossing technique, parallel wire technique was used in 80% of cases, and subintimal tracking and re-entry technique was used in 30% of cases. After crossing the lesion, guidewire tips directed to possible side branch's lumen to differentiate true and false lumen. All lesions were predilated with 1.25*10-12-15 mm Sprinter Legend balloon catheter (Medtronic, Minneapolis USA). Driver Sprint (Medtronic, Minneapolis, USA) and Liberte Monorail (Boston Scientific, Miami, USA) were used as bare-metal stents (BMS) and endeavor resolute (Medtronic, Minneapolis, USA) was used as drug eluting stent (DES) in 31.3% of cases. For each

procedure, at least 2 guidewires and 2 balloon catheters were used (average 2.77 guidewires and 2.41 balloon catheters for each procedure). More than one stents were deployed in 50% of patients (average 1.55 stent for each procedure). After procedure, femoral sheath was removed 6 hours later and the patient were discharged the next day.

Statistical analysis. Statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA) software. Descriptive parameters were quoted as mean ± SD and 95% confidence intervals (95% CI). The unpaired t-test was used for continuous variables between the groups. Categorical variables were compared using the Chi-square and the Pearson tests for independent 2 samples. Comparison between intervention results with chi-square and Analysis of Variance tests were carried out. In addition, multivariate binary logistic regression analysis was performed to detect independent factors for successful CTO intervention. All *p*-values were 2-sided and *p*-values less than 0.05 were considered to be statistically significant.

Results. Baseline demographic and clinical characteristics of patients are summarized in **Table 1**. The mean age was 62.04±11.1 ranging from 35 to 80 years and 78 patients (82.1 %) were male. Most of the patients had hypertension (HT), dyslipidemia and previously diagnosed coronary heart disease (CHD) and 36.5% of patients had diabetes mellitus (DM). Eighteen percent of the patients were operated before and 9.5% of the patients had in-stents stenosis. Approximately, 50% of the patients had CTO of more than one year duration. Right coronary artery (RCA) was most common target vessel (54.7%) and more than 80% of the patients were possess multivessel disease. Success rate was 80% with a mean 58.1±17.8 minutes fluoroscopy time. Coronary angioplasty performed in 13 patients without stent implantation. In the 19.8% of the patients, 3 or >3 stents were implanted due to extensive luminal dissection. All patients were discharged the next day without any complication including MI and death. According to intervention results; there were no significant difference in terms of age (p=0.34), gender (p=0.34), presence of DM, HT, and dyslipidemia (p=0.28, p=0.87, p=0.89). Presence of multi-vessel disease, left ventricular ejection fraction, and target vessels did not show any significant impact on the successful intervention (p=0.65, p=0.35 and p=0.45). Occlusion period of CTO was prominently longer in the failure group (p<0.001). In the occlusion duration, in more than one year patients, the success rate was decreased to 60%, whereas, success rate was 90% in the CTO of 3 months and 1 year. Previous by-pass surgery and in-stent stenosis were more common in the failure group (p=0.12 and p=0.08, **Table 2**). In the multivariate binary logistic regression analysis, occlusion duration was the major independent predictor of successful CTO intervention (p=0.01, **Table 3**).

Discussion. Chronic total occlusion of a coronary artery is defined as complete obstruction with antegrade TIMI 0 flow lasting 3 months or more. Chronic total occlusions are reported in 20% of patients undergoing

Table 1 - Baseline demographic characteristics, clinical features, laboratory results and angiographic findings of the patients (N=95).

Demographic characteristics	N (%)	
Age (years) (mean±SD)	62.04 ± 11.1	
Range (years)	35-80	
Gender		
Male	78	(82.1)
Female	17	(17.9)
Presence of diabetes mellitus	35	(36.8)
Presence of hypertension	84	(88.4)
Dyslipidemia	79	(83.2)
Current smoking	53	(55.8)
Previously diagnosed CHD	67	(70.5)
Previous CABG	17	(17.9)
In-stent stenosis	9	(9.5)
Occlusion duration		
Unknown	29	(30.5)
3 months-1 year	26	(27.4)
>1 year	40	(42.1)
Ejection fraction (%)	52.8 ± 9.4	
Multi-vessel disease	80	(84.2)
Fluoroscopy time (minutes)	58.1 ± 17.8	
Success rate	76	(80.0)
Target vessel		
LAD	20	(21.1)
CX	21	(22.1)
RCA	52	(54.7)
Diagonal	2	(2.1)
Stents number		
PTCA	13	(17.1)
1	29	(38.2)
2	19	(25.0)
3	10	(13.2)
>3	5	(6.6)
DES	20	(31.3)
Stent's diameter		
2.5	14	(22.2)
2.75	35	(55.6)
3.0	9	(14.3)
>3.0	5	(8.0)
Mean stent length (mm)	42.7 ± 21.4	

CHD - coronary heart disease, CABG - coronary artery by-pass graft surgery, DES - drug eluting stent, LAD - left anterior descending artery, CX - circumflex artery, RCA - right coronary arterym, PTCA - percutaneous transluminal coronary angioplasty

cardiac catheterization and most of them usually referred to bypass surgery.[2,5] It was shown that the opening of the totally occluded artery is beneficial if the vessel territory is viable. The revascularization of CTOs could lead to alleviation of angina, improvement in wall motion abnormalities and left ventricular function, increased exercise capacity, and ultimately, increased long-term survival.[2,3,6,7] Moreover, having an open artery may increase the tolerance to future acute coronary events, which may improve long-term prognosis. However, the procedures are still challenging for most cardiologist due to necessity of specialized instruments and advanced complex techniques also demanding on time and resources, with a lower success rate in revascularization and higher restenosis rate. The procedural success rate for CTO has improved over time with the development of medical device and operator expertise but is still low and is mainly due to the failure to cross the lesion with the guidewire.[2,4] Different strategies and specific devices and instruments for CTO have been introduced to invasive cardiology area to improve guidewire crossing and successful recanalization. The most popular recently announced techniques are subintimal tracking and re-entry, parallel wire technique, intravascular ultrasound guided wire crossing, retrograde approaches, controlled antegrade and retrograde tracking.[5,8,9] It was shown that, the success rate of CTO declines with long duration of occlusion, abrupt missing stump, bridging collaterals, longer occluded length, moderate to severe calcification, or tortuosity and ostial or distal location of CTO.[10,11] In our series, occlusion duration was the major predictor of successful intervention which compatible with literature. Occlusion duration longer than one year was

Table 2 - Distribution of clinical and demographic characteristics of patients according to success rate of intervention.

Variables/ intervention result	Successful		Failure		*P*-value*
Age (years)	62.6±11.0		59.7±11.5		0.34
Gender					0.34
Male	61	(80.3)	17	(89.5)	
Female	15	(19.7)	2	(10.5)	
Presence of diabetes mellitus	26	(34.2)	9	(47.4)	0.28
Presence of hypertension	67	(88.2)	17	(89.5)	0.87
Dyslipidemia	63	(82.9)	16	(84.2)	0.89
Current smoking	42	(55.3)	11	(57.9)	0.83
Previously diagnosed CHD	50	(65.8)	17	(89.5)	0.43
Previous CABG	11	(14.5)	6	(31.6)	0.08
In-stent stenosis	6	(7.9)	3	(15.8)	0.12
Occlusion duration					<0.001
Unknown	27	(35.5)	2	(10.5)	
3 months-1 year	25	(32.9)	1	(5.3)	
>1 year	24	(31.6)	16	(84.2)	
Ejection fraction (%)	53.2±9.2		50.8±10.2		0.35
Multivessel disease	64	(84.2)	16	(84.2)	0.65
Target vessel					0.45
LAD	18	(23.7)	2	(10.5)	
CX	16	(21.1)	5	(26.3)	
RCA	41	(53.9)	11	(57.9)	
Diagonal	1	(5.3)	1	(1.3)	
Fluoroscopy time (min)	56.5±18.0		64.2±16.0		0.04
Total	**76**	**(80.0)**	**20**	**(19.0)**	

CHD - coronary heart disease, CABG - coronary artery by-pass graft surgery, LAD - left anterior descending artery, CX - circumflex artery, RCA - right coronary artery. *p<0.05 (significant)

Table 3 - Binary logistic regression analysis for predicting successful intervention.

Dependant variables	Odds ratio	*P*-value
Age (years)	0.01	0.85
Gender (male/female)	-0.49	0.69
Presence of diabetes mellitus	-0.78	0.25
Presence of hypertension	1.11	0.38
Dyslipidemia	0.04	0.96
Current smoking	-0.35	0.63
Previously diagnosed CHD	-0.31	0.78
Previous CABG	0.14	0.87
In-stent stenosis	-1.70	0.08
Occclusion duration	-2.10	0.01
Ejection fraction (%)	0.03	0.38
Multivessel disease	-0.40	0.67
Target vessel	-0.55	0.23

CHD - coronary heart disease, CABG - coronary artery by-pass graft surgery, p<0.05 is indicated as significant

Table 4 - Success rate of chronic total occlusions intervention in the selected series comparing to results in this study.

References	Time period (years)	Sample size (n)	Success rate (%)
Suero et al[1]	1980-1999	2007	74.4
Hoye et al[2]	1992-2002	885	65.1
Han et al[3]	1995-2005	1625	88.9
Suttorp et al[4]	2003-2004	528	89.0
Mitsudo et al[5]	2003-2004	110	88.8
Barli et al[6]	2003-2006	202	82.7
Rathore et al[7]	2003-2008	157	85.0
Sianos et al[8]	2005-2007	175	83.4
Tomasello et al[9]	2005-2009	328	86.3
Wu et al[10]	2006-2010	85	87.1
Kimura et al[11]	2006-2008	224	92.4
Karabulut et al	2007-2011	95	80.0

associated with lower success rate (60%), which enhance the necessity of special equipment and techniques for CTOs of longer duration.

The standardization of guidewire technique was also proposed to increase successful CTOs intervention.[12,13] Beside introduction of enhanced guidewires and specialized catheters, specific devices using highly sophisticated technology such as laser guidewire, optical coherence reflectometry, and a blunt microdissection catheter were also proposed. The most novel approach is the biologic one, in which proteolytic enzymes that digest the CTO cap to facilitate mechanical passage.[8,9]

Normally, an anterograde approach was used to reach the occlusion. The introduction of enhanced guidewires combined with increasing operator experience and creative procedural techniques, such as the retrograde approach and re-entry subintimal tracking technique, have significantly reduced the number of unapproachable CTOs.[1,14-17] All new developments with skilled operators increased the success rate up to 90% in recent reported series especially, in which retrograde approach techniques effectively used.[17]

Exact CTOs approach in Turkey is still unknown due to the absence of large reported series. Because of uncovarage of insurance system for specific CTO's instruments, CTO interventions offer high cost, which could be performed, to selected patients only. Some centers perform CTOs with conventional equipment, but it is still not cost beneficial. The general public insurance systems cover once only guidewire, and balloon catheter for one patient and system pays the same amount for all interventions including type A lesion to CTOs. So, most of the cardiologists do not prefer CTOs intervention. Although, we had used conventional equipment, we did not limit the guidewires and balloon catheters and even we used more than 5 guidewires and balloon in a same patient. Our success rate was 80%, which was slightly below the recent results in literature (**Table** 4). However, it is not frustrating and results are better than reported first series. The major aggravation in our series was the longer length of stents (42.7±21.4 mm). In 44.8% of patients, more than one stents were implanted due to either diffuse diseases or more commonly luminal dissection which prone patients to higher risk of restenosis. On contrary, Choy et al[18] showed that length of stent is not associated with high rate restenosis in well-sized vessel (>3 mm). Approximately 50% of our patient received stents with a diameter of 2.75 mm or upper sized; thus, our restenosis rate could be lower than the expected value. It was already shown that DES usage was superior to BMS in the CTOs intervention.[19-22] In our series, 31.3% of patients had DES, which is incomparable to recent reported series. Thus, further follow-up will show the feasibility of our results.

Study imitations. The major limitation was the small number of patients from a single center. In addition, there was no control group to compare success rate due to unavailability of specialized CTO's material and CTO centers in Turkey. Thus, we compared our result with data reported in the literature. In addition, we presented only procedural success for CTOs intervention. Patient's follow-up and rate of restenosis or major cardiac adverse events should also be searched to assess exact CTOs intervention results. Finally, we reported one of the pilot CTO series from Turkey; thus, operators' experience could be debatable.

Clinical implications. Chronic total occlusion intervention is a special field in the interventional cardiology and most of the referral centers for CTOs intervention are located either in Japan, United States or certain countries of European Union. There is no well-known CTOs referral center in Turkey also same situation is present in the most developing countries. Herein, we clarified the necessity of CTOs referral centers institution. In addition, we showed that, CTOs of shorter duration could be intervented with conventional methods securely. We found that our results would be guided to cardiac centers with limited CTOs experience.

In conclusion, coronary CTO intervention with conventional equipment is still reasonable with a 80% success rate. However, success rate was prominently lower in the CTOs of long duration. Therefore, CTO approach with standard equipment should be preferred only in CTO of duration less than a year for having better results. Moreover, restriction of CTO procedures to certain reference centers where specialized materials for CTO is widely available could increase the success rate, furthermore. Chronic total occlusion procedure also should be performed by the skilled operators who could practice all the proposed techniques for CTOs.

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