Results of percutaneous coronary intervention for chronic total occlusions of coronary arteries: a single center report

Kronik tam tıkanmalı damarlara yapılan perkütan koroner girişimin sonuçları: Tek merkez raporu

Mustafa Çetin, M.D., Kayıhan Karaman, M.D.,[#] Cemil Zencir, M.D.,[#] Ünal Öztürk, M.D.,[#] Emrah Yıldız, M.D.,[#] Sami Özgül, M.D.

Department of Cardiology, Adıyaman University Faculty of Medicine, Adıyaman;
[#]Department of Cardiology, Kahramanmaraş Necip Fazil State Hospital, Kahramanmaraş

ABSTRACT

Objectives: Percutaneous coronary intervention (PCI) for chronic total occlusions (CTOs) is associated with lower rates of procedural success and higher complication rates compared with PCIs in non-CTO lesions. The purpose of this study was to analyze the relationship between lesion characteristics and procedural success rates and in-hospital outcomes after PCI for CTO with novel equipment.

Study design: We evaluated the prospectively entered data of 63 consecutive patients undergoing PCI for CTO at our institute between August 2009 and June 2012.

Results: A total of 63 patients (mean age: 64±11, 71% male) with one CTO lesion each underwent PCI. There were 46 patients (mean age: 63±10, 70% male) in the CTO success group and 17 patients (mean age: 65±13, 76.5% male) in the CTO failure group. Successful revascularization was achieved in 73% of patients. We used antegrade approach in 61 cases and retrograde approach in 2 cases. Our predominant strategy was single-wire technique, which was used in 54 cases (85.7%), followed by parallel-wire technique in 7 cases (11.1%). Moderate-to-severe tortuosity (odds ratio [OR]: 9.732, 95% confidence interval [CI]: 1.783-53.115, p=0.009) and occlusion duration (OR: 1.536, 95% CI: 1.178-2.001, p=0.002) were independent predictors of procedural failure in the multivariate analysis. No in-hospital major cardiac events occurred.

Conclusion: We have reported a study with a relatively high success rate of PCI with very low procedural and in-hospital complications. Moderate-to-severe tortuosity was observed as the most challenging problem despite the utilisation of novel equipment and techniques for CTO recanalization.

ÖZET

Amaç: Kronik tam tıkanma (KTT) bulunan damarlara yapılan perkütan koroner girişimler (PKG), KTT içermeyen lezyonlara uygulanan PKG ile kıyaslandığında daha düşük işlem başarısı ve daha yüksek komplikasyon oranlarına sahiptir. Bu çalışmada, yeni donanımlar ile KTT'ye uygulanan PKG sonrası, lezyon özellikleri ve işlem başarı oranları arasındaki ilişki ve hastane içi sonuçlar incelendi.

Çalışma planı: Ağustos 2009 ile Haziran 2012 arasında merkezimizde KTT'ye PKG yapılan 63 hastanın kaydedilen verileri ileriye dönük olarak değerlendirildi.

Bulgular: Tümünde birer KTT saptanan 63 hastanın (ortalama yaş 64±11; %71 erkek) herbiri PKG için alındı. PKG'nin başarılı olduğu grupta 46 (ort. yaş 63±10, %70 erkek) ve başarısız grupta 17 hasta (ort. yaş 65±13, %76.5 erkek) vardı. Başarılı revaskülarizasyon yapılan hasta oranı %73 idi. Olguların 61'inde öne doğru girişim, iki olguda arkaya doğru girişim yapıldı. Esas strateji 54 olguda (%85.7) kullanılan tek tel tekniği idi. Bunu takiben yedi olguda (%11.1) paralel tel tekniği kullanıldı. Çok değişkenli analizde, orta-ciddi tortiyozite (odds oranı [OO]: 9.732, %95 Güven Aralığı [GA]: 1.783-53.115, p=0.009) ve tıkanma süresi (OO: 1.536, %95 GA: 1.178-2.001, p=0.002) işlem başarısızlığının bağımsız öngördürücüleri olarak bulundu. Hastane içi majör kardiyak olay hiç görülmedi.

Sonuç: Çalışmamızda kısmen yüksek PKG başarı oranı ile çok düşük işlem ve hastane içi komplikasyon oranı saptadık. Orta-ciddi tortiyozite, KTT'lerin yeni donanım ve tekniklere rağmen PKG ile açılmasının önündeki en önemli problem olarak gözlendi.

Received: September 23, 2012 *Accepted:* May 07, 2013

Correspondence: Dr. Mustafa Çetin. Adıyaman Üniversitesi Tıp Fakültesi Hastanesi, 02000 Merkez, Adıyaman.
Tel: +90 312 - 306 11 34 / 1157 e-mail: drmcetin@gmail.com

Chronic total occlusions (CTOs) are complex lesions identified in 15-30% of all patients referred for coronary angiography.[1,2] However, percutaneous coronary intervention (PCI) rates for these lesions have been reported as only 10-15%,[3] and most of the patients are treated with either medical therapy or coronary artery bypass grafting (CABG). Several studies have shown that successful PCI for CTO reduces symptoms of angina, improves exercise capacity, improves left ventricular function, and reduces the need for subsequent CABG.[3-7] In addition, successful PCI for CTO has shown a long-term survival benefit and may increase tolerance of future cardiac events compared to patients with an unsuccessful PCI.[8-10] Although success rates are lower than with PCI for non-CTO lesions, they have been seen to improve with the advent of sophisticated materials specifically designed for these lesions.[3,11]

Despite the recent developments in the field of interventional cardiology, the data in Turkey about the results of PCI for CTO with novel equipment are insufficient. The purpose of this study was to analyze the relationship between lesion characteristics and procedural success rates and in-hospital outcomes in patients treated with PCI for CTO.

PATIENTS AND METHODS

Study design and patient population

In this single-center observational study, we evaluated the prospectively entered data of 63 consecutive patients undergoing PCI for CTO in 63 lesions at our institute between August 2009 and June 2012. The PCI indication for CTO was the presence of angina and the demonstration of viable myocardium or silent ischemia in the territory of the occluded artery. Procedures were performed by four experienced cardiologists in our hospital. Each operator has performed more than 150 PCIs (including primary and elective) per year.

A CTO was defined as proposed by the Euro CTO Club as a lesion with the presence of thrombolysis in myocardial infarction (TIMI) flow grade 0 within an occluded arterial segment of greater than three months' standing.[12] The duration of occlusion was estimated on the basis of either history of angina or previous MI in the same territory or as proven by previous angiography. Major adverse cardiac events (MACE) were defined as death, non-fatal MI, or urgent revascularization during the same admission. Urgent revascularization was defined as target vessel repeat PCI within 24 hours (h) or urgent CABG. Non-fatal MI was defined as recurrent chest pain and/or development of new electrocardiography (ECG) changes accompanied by a new rise ≥20% of cardiac biomarkers measured after the recurrent event.

Abbreviations:

CABG	*Coronary artery bypass grafting*
CART	*controlled anterograde and retrograde subintimal tracking*
CTOs	*Chronic total occlusions*
DES	*Drug-eluting stents*
IVUS	*Intravascular ultrasound*
LAD	*Left anterior descending*
MACE	*Major adverse cardiac events*
PCI	*Percutaneous coronary intervention*
RCA	*Right coronary artery*
TIMI	*Thrombolysis in myocardial infarction*

The lesion success was defined as restoration of TIMI flow grade 3 with a residual stenosis of <20% in the target CTO lesion after stent implantation. The procedural success was defined as restoration of TIMI flow grade 3 with a residual stenosis of <20% in the target CTO lesion after stent implantation without MACE. Informed consent was obtained from all patients, and the study was approved by the institutional ethics committee.

Definitions of lesion characteristics

Firstly, detailed qualitative angiographic assessments were made in all cases. Angiographic morphology of the entry point was classified as "tapered" if the occluded segment ended in a funnel-shaped form or "blunt stump" if it did not. Presence of calcification was assigned to two categories according to severity. "Moderate-severe calcification" was accepted as multiple persisting opacifications of the coronary wall visible in at least one projection surrounding the complete lumen of the coronary artery at the site of the lesion, or "mild calcification" if it did not. "Moderate-severe tortuosity" was defined as at least 1 bend of >45° assessed by angiography throughout the occluded segment.

Quantitative assessment including the variables of occlusion length, proximal vessel diameter, and distal vessel diameter was performed using a commercially available software package (CAAS II [Cardiovascular Angiography Analysis System Mark II] by Pie Medical, The Netherlands). "Occlusion length" was measured from the proximal occlusion to the distal retrograde filling from contralateral collaterals using

a dual injection technique, start of filling of bridging collaterals to the distal vessel reconstruction, or from the length of the lesion visible after the guidewire crossing.

Interventional procedure

Aspirin and loading dose of clopidogrel were given to all patients before the procedure, and dual antiplatelet therapy was prescribed for 12 months after discharge. A bolus of 60-100 U/kg unfractionated heparin was given before the procedure and followed by intravenous infusion to achieve an activated clotting time >250 seconds (s) during the procedure. All PCI procedures were performed via the femoral route. Guiding catheters were selected according to operator preference. 7-8 French (F) Launcher (Medtronic, USA) guiding catheters were used. Bilateral coronary injections were performed when retrograde collateral flow was present.

We performed anterograde approach in 61 patients and retrograde approach in two patients. In anterograde approach, single-wire and parallel-wire techniques were used. Parallel-wire technique was defined as follows: after a wire passes into the subintimal space, it is left in position to encourage a second wire, in parallel to the first, which is manipulated to find an alternative path into the distal true lumen.

In one of the two patients who underwent retrograde approach via septal collaterals, we used "retrograde wire technique" to the right coronary artery (RCA) ostial lesion, and in the other patient with a mid-left anterior descending (LAD) lesion, we used "kissing wire technique". Retrograde wiring was defined as a technique that involves manipulating and advancing the guidewire through microcatheters via collaterals into the CTO retrogradely to reach the proximal true lumen and achieve successful recanalization. The kissing wire technique combines the simultaneous use of antegrade and retrograde approaches. The retrograde wire serves either as a marker of the distal CTO location or creates an intraluminal channel in the distal CTO portion. This facilitates the passage of a second intraluminal wire in an antegrade direction until they meet ('kiss') each other.

Dedicated guidewires were used, such as soft or moderate polymeric wires, including tapered Fielder XT (used when crossing the CTO lesions via microchannels of the plaques) and non-tapered Fielder FC (Asahi Intecc, Aichi, Japan), and stiff flat spring guidewires such as Miracle 3-12 (Asahi Intecc) and stiff tapered guidewires such as Confienza Family 9-12 (Asahi Intecc). In all patients, we used microcatheters such as Corsair (Asahi Intecc) and/or 1.0 x 10 mm Falcon CTO low-profile over-the-wire balloon (Invatec, Italy) in order to facilitate guidewire manipulation and lesion crossing. We also used the Tornus Device (Asahi Intecc) to cross intense calcific lesions. The selection of these wiring techniques and the guidewires was based on the operator's discretion and the patient's coronary anatomy. The anterograde approach was started initially, and a step-up to different wiring strategies or stiffer wires was done when necessary.

Statistical analysis

Continuous variables were expressed as mean±standard deviation; categorical variables were defined as percentages. Categorical data were assessed by chi-square test. If one of the cells had an expected count of less than 5, we used Fisher's exact test instead of the chi-square test. Continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test. While the mean differences between groups were compared by Student's t test, Mann-Whitney U-test was applied for comparisons of the median values. The association of different variables with unsuccessful CTO procedure was calculated in the univariate analysis. The variables for which p value was <0.25 in the univariate logistic regression analysis were identified as potential risk markers and included in the full multivariate model as covariates. Forward elimination multivariate logistic regression analysis using likelihood ratio test was utilized to eliminate variables. A p value <0.05 was considered as significant. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 15.0 (SPSS, Inc., Chicago, IL).

RESULTS

A total of 63 patients (mean age: 64±11; 71% male) underwent PCI for CTO. All patients had only one CTO lesion. There were 46 patients (mean age: 63±10; 70% male) in the CTO success group and 17 patients (mean age: 65±13; 76.5% male) in the CTO failure group. Baseline characteristics are shown in Table 1. The mean age, gender frequency, and risk

Table 1. Baseline characteristics of the study population

Variables	CTO success (n=46)		CTO failure (n=17)		*p*	Odds* ratio	95% Confidence Interval*
	n	%	n	%			
Age (years)	63.02±10.3		65.06±12.8		0.512	1.017	0.966-1.071
Male	32	69.6	13	76.5	0.757	1.422	0.394-5.138
Diabetes mellitus	16	34.8	6	35.3	0.970	1.023	0.319-3.279
Hypertension	24	52.2	9	52.9	0.957	1.031	0.338-3.143
Hyperlipidemia	20	43.5	7	41.2	0.870	0.910	0.295-2.812
Family history of CAD	12	26.1	3	17.6	0.740	0.607	0.148-2.487
Smoking	19	41.3	6	35.3	0.666	0.775	0.244-2.460
Previous MI	13	28.3	4	23.5	–	0.781	0.215-2.841
Previous CABG	4	8.7	0	0	0.567	–	–
Previous PCI	10	21.7	7	41.2	0.199	2.520	0.764-8.310
Vessel disease							
1-vessel	21	45.7	8	47.1	–	–	–
2-vessel	17	37	6	35.3	0.904	0.926	0.269-3.191
3-vessel	8	17.4	3	17.6	0.984	0.984	0.208-4.670
Target vessel							
LAD	16	34.8	7	41.2	0.640	1.313	0.419-4.107
RCA	23	50	10	58.8	0.534	1.429	0.464-4.403
LCx	7	15.2	0	0	0.175	–	–

CAD: Coronary artery disease; MI: Myocardial infarction; CABG: Coronary artery bypass surgery; PCI: Percutaneous coronary intervention; LAD: Left anterior descending artery; RCA: Right coronary artery; LCx: Left circumflex artery. p value comparison between CTO success and failure groups. *Values were obtained by the univariate logistic regression analysis.

factors were similar between the groups. The CTO failure group had a higher incidence of a history of previous PCI, but the difference was not statistically significant. The majority of patients had multivessel disease. The target vessel was RCA in 33 patients (52.4%), the LAD in 23 patients (36.5%) and the left circumflex artery (LCx) in 7 patients (11.1%). There were two patients with in-stent restenosis, and in one of them, the CTO lesion was successfully recanalized. The median occlusion duration of the CTO lesions was found as 8 (4-24) months. The lesion success rate was 73% (46/63); the remaining 27% (17/63) were unsuccessful. The procedural success rate was equal to the lesion success rate.

Angiographic and procedural characteristics

Angiographic and anatomical lesion characteristics are shown in Table 2. The incidences of moderate-to-severe calcification and moderate-to-severe tortuosity in the CTO failure group were significantly higher, and the mean lesion length and occlusion duration were significantly longer in the CTO failure group.

Table 3 summarizes the procedural characteristics. Our predominant strategy was single-wire technique. It was used in 54 (85.7%) cases, followed by parallel-wire technique in 7 (11.1%) cases. Retrograde approach was used in two cases, and in both cases, procedures were done successfully.

Contralateral injection at the beginning of the procedures by a second catheter was required in 36.5% of the cases. Several guidewires ranging from soft to stiff were used. Fielder XT guidewire, predominantly the first choice, was used in 93.7% of cases. Miracle series and Confienza Pro were used in 30.1% and 17.4% of cases, respectively. Wire manipulation was supported by over-the-wire balloons and microcatheters, which were used in 47.6% and 61.9%, respectively.

Table 2. Lesion characteristics

Variables	CTO success (n=46)		CTO failure (n=17)		*p*	Odds# ratio	95% Confidence Interval#
	n	%	n	%			
Calcification							
Moderate-to-severe	24	52.2	15	88.2	**0.009**	6.875	1.409-33.537
Ostial location	6	13.0	1	5.9	0.663	0.417	0.046-3.742
LAD	2	4.3	1	5.9			
RCA	3	6.5	0				
LCx	1	2.2	0				
Tortuosity							
Moderate-to-severe	7	15.2	13	76.5	**<0.001**	18.107	4.557-71.941
Blunt stump at occlusion	20	43.5	10	58.8	0.279	1.857	0.601-5.739
Bridge collateral	9	19.6	3	17.6	–	0.881	0.208-3.704
Side branch at occlusion	15	32.6	5	29.4	0.809	0.861	0.256-2.893
Length of occlusion, mm	24.7±7.9		32.1±8.2		**0.002**	1.130	1.039-1.230
Occlusion duration, months*	7	(4-12)*	15	(6-24)*	**<0.001**	1.659	1.269-2.170

Data are presented as mean±standard deviation and numbers/percentages. *Occlusion duration is presented as median (minimum-maximum value); p value comparison between the CTO success and failure groups. #Values were obtained by the univariate logistic regression analysis.

All lesions in the CTO success group were treated with stents after balloon angioplasty. Drug-eluting stents (DES) were used in 78.3% (36/46) of the CTO success group and bare metal stents were used in 24.4% (10/46). The mean stent length was 44.8±20.8 mm. The median contrast agent usage was 280 (140-450) ml, and it was statistically the same in both groups. The median fluoroscopy time and fluoroscopy dose were 70 (30-140) min and 8.1 (3.4-16.4) Gy, respectively.

Table 3. Procedural characteristics

Variables	Procedures (n=63)		
	n	%	Min-Max
Contralateral injection	23	36.5	
Single-wire technique	54	85.7	
Parallel-wire technique	7	11.1	
Retrograde approach	2	3.2	
Microcatheter	39	61.9	
Over-the-wire balloon	30	47.6	
Stiff wires	28	44.5	
Fluoroscopy time (min*)	70		30-140
Fluoroscopy dose (frontal) (Gy*)	8.1		3.4-16.4
Contrast medium (ml*)	280		140-450

Data are presented as mean±standard deviation and numbers/percentages. *Variables are presented as median (minimum-maximum value).

The odds ratio (OR) and 95% confidence interval (CI) values for each parameter using the univariate logistic regression model are listed in Tables 1 and 2. According to these results, occlusion duration, lesion length, moderate-to-severe tortuosity, and moderate-to-severe calcification were associated with procedural failure. Only moderate-to-severe tortuosity (OR: 9.732, 95% CI: 1.783-53.115, p=0.009) and occlusion duration (OR: 1.536, 95% CI: 1.178-2.001, p=0.002) were found as independent predictors of procedural failure in the multivariate analysis (Table 4).

Complications and in-hospital outcomes

There was no death, non-fatal MI or urgent revascularization in this series. No coronary perforation or cardiac tamponade occurred despite the high usage rate of hydrophilic wires and stiff wires. Catheter-induced aortic dissection was seen in one patient, and resolved with conservative treatment. Coronary dissection was the most common procedure-related complication, which was seen in 23.6% of all cases, and it was resolved successfully with stenting in all patients.

Table 4. Multivariate logistic regression result for unsuccessful procedures

	p	Odds ratio	95% CI for odds ratio	
			Lower	Upper
Step 1				
Occlusion duration	**<0.001**	1.659	1.269	2.170
Step 2 (final step)				
Occlusion duration	**0.002**	1.536	1.178	2.001
Moderate-severe tortuosity	**0.009**	9.732	1.783	53.115

Final steps of the logistic regression using Forward LR method were shown. Occlusion duration, moderate-severe tortuosity, moderate-severe calcification, length of occlusion and previous PCI were included in the analysis as covariates.

DISCUSSION

These are the first data from Turkey about the results of PCI for CTO lesions with novel equipment. The major findings of this study are as follows: 1) Our lesion success rate and procedural success rate were equal, at 73%. 2) Moderate-to-severe tortuosity and occlusion duration were independent predictors of procedural failure. 3) There was no in-hospital MACE. 4) No coronary perforation or cardiac tamponade occurred, but the incidence of coronary dissection was high, seen in about one-fourth of the cases.

Unlike the conventional PCI materials, novel equipment such as dedicated guidewires, microcatheters, and crossing devices are essential for CTO recanalization, because coronary CTO is characterized by heavy atherosclerotic burden, uncertain course of the vessel at the site of occlusion, and longer length of lesions within the artery. Despite the development of modern interventional devices, opening of CTO lesions has a lower success rate than that of non-CTO PCI.[4,13,14]

Procedural success rates

Olivari et al.[6] reported a procedural success rate of 73.3% in 2003, and Hoye et al.[3] reported a success rate of 65.1% in 2005. Prasad et al.[14] published a 25-year experience from the Mayo Clinic in 2007, and their success rate was 70%. Experience in the United States in 636 consecutive patients was reported by Thompson et al. in 2009.[15] In this trial, operators were divided into two groups according to their CTO volume, and the ability to perform retrograde approach. The overall technical success rate was 58.9% for non-retrograde operators and 75.2% for retrograde operators. Recently, Fefer et al.[16] published a CTO recanalization success rate of 70% in the Canadian Multicenter Chronic Total Occlusions Registry.

However, in recent years, Japanese and European expert operators achieved higher success rates with specialized techniques (retrograde approach, controlled anterograde and retrograde subintimal tracking (CART) technique, reverse CART, and intravascular ultrasound (IVUS)-guided wiring). Rathore et al.[17] published a procedural success rate of 86.2% in a consecutive series of 904 CTO PCI procedures, performed at Toyohashi Heart Center, with use of 17.1% retrograde wiring and IVUS-guided techniques. In the J-CTO registry from 2010, 12 centers contributed 528 CTO PCIs; the procedural success rate was 88.6% and retrograde approach was used in 25% of the cases.[18] Galassi et al.[19] more recently published data from the ERCTO registry. The overall procedural success rate was 82.9% in 1,983 CTO lesions. Our study showed that our procedural success rate is similar or close to the current success rates in most centers, but lower than that of the Japanese and some European centers due to advances in specialized guidewire techniques and more experienced operators.

Factors influencing failure

Percutaneous coronary intervention (PCI) for CTO lesion is the most challenging procedure in interventional cardiology practice. Crossing a CTO with a guidewire is difficult and is the most common reason for failure of CTO PCI.[20] Conventionally, several predictors for failure in PCI for CTO lesions have been identified, including duration of occlusion,

length of occlusion, calcification, abrupt stump, presence of a side branch at the point of occlusion, presence of bridging collaterals, poorly visualized distal vessel, occlusion situated within a tortuous part of the vessel, ostial location, and previous failed attempt.[21] In our study, unlike these predictors, only moderate-to-severe tortuosity and occlusion duration were independent predictors of procedural failure. In our opinion, most of the predictors were eliminated by using the novel guidewires and techniques. The incidence of moderate-to-severe tortuosity in our CTO failure group was 76.5%. This ratio was very high compared to other studies. As reported in many studies, moderate-to-severe tortuosity is the difficult factor to overcome even with modern techniques and is the most common predictor for procedural failure.[6,17,22]

Plaques in CTO lesions are composed of dense fibrous tissue, loose fibrous tissue, cellular fibrous tissue, calcium, pultaceous debris, foam cells, and lymphocyte infiltration without foam cells.[23] The duration of occlusion is reflected in progression of the atherosclerotic process in the CTO lesion. The lesions with longer occlusion time are prone to be more calcific and more fibrotic. Thus, the occlusion duration is an important predictor of the ability to cross the lesions with guidewires and balloons.

In-hospital outcomes

In our study, there was no death, stroke or MI. This rate was low compared to large series of PCI for CTO.[17] Coronary perforation and cardiac tamponade were never seen, which is compatible with non-CTO PCI data.[24,25] Coronary dissection, which developed mainly due to subintimal progression of the guidewires, developed in one-fourth of the patients. It was also related to longer length of stents implanted in our study (44.2±20.1 mm). We used DES in 78.3% of the CTO success cases due to the general health insurance system, which pays only for DES with diameter of <3 mm and length of >15 mm. Thus, we implanted stents with a diameter of <3 mm and length of >15 mm. If possible, DES should be used in all CTO cases because of the lower restenosis rates.

Limitations

First, this study has a small number of patients from a single center. Second, for the purpose of comparison with our results, the published data from Turkey about PCI for CTO are insufficient. Third, PCI for CTO was performed by different operators. The operators' techniques and their material selection criteria may have affected the results of the study.

In conclusion, we have reported a study with a relatively high success rate of PCI, with very low procedural and in-hospital complications. We found that predictors of failure are moderate-to-severe tortuosity and the duration of occlusion. Unlike the conventional predictors of failure in PCI for CTO, moderate-to-severe tortuosity was observed as the most challenging problem related to the novel equipment and techniques for CTO recanalization. Therefore, we suggest that more attention should be paid when approaching a tortuous CTO lesion.

Finally, PCI for CTO still presents some difficulties for most interventional cardiologists because of the necessity of dedicated materials and sophisticated techniques, and it also demands more time in comparison to non-CTO PCI. In addition to the new sophisticated materials, careful selection of patients, advanced techniques and operator expertise are necessary to increase the success rates.

Conflict-of-interest issues regarding the authorship or article: None declared

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Key words: Angioplasty, balloon, coronary; chest pain / epidemiology; coronary angiography; coronary artery bypass; coronary occlusion; equipment and supplies; percutaneous coronary intervention; stents.

Anahtar sözcükler: Anjiyoplasti, balon, koroner; göğüs ağrısı / epidemiyoloji; koroner anjiyografi; koroner arter baypas; koroner oklüzyon; ekipman ve malzeme; perkütan koroner girişim; stentler.