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Current practice of percutaneous coronary intervention on patients with acute coronary syndrome in Iran: A prospective observational study

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Abstract

Background: Frequent Percutaneous Coronary Intervention (PCI) procedures are being performed on a daily basis in Iran. However, no study has been reported on the current PCI practice in patients with acute coronary syndrome (ACS) in Iran. We aimed to describe the clinical characteristics and treatment patterns in Iranian ACS patients treated with PCI.

Methods: Between February 2017 and July 2017, ACS patients presented to 5 referral hospitals in two major cities of Iran (Tehran and Shiraz) were included in this observational study if aged > 18 years and underwent PCI for ACS during hospitalization; and their clinical and procedural characteristics were collected. All data were entered into SPSS v.21 and descriptive statistics were performed.

Results: Of a total of 314 patients, 228 (73%) were males, 162 (52%) were diagnosed with ST-elevation myocardial infarction and 152 (48%) with Unstable angina/ Non-ST elevation myocardial infarction. Trans-femoral approach was more often (64%) used for PCI procedures. Stent placement was the most frequent (98%) treatment strategy on PCI, with drug-eluting stent selected in the majority of subjects (98%). The overall rate of PCI success was 95%, with 4.1% PCI-related complications, and 1.6% post-PCI bleeding events. The vast majority of the study patients (99%) were discharged with dual anti-platelet therapy.

Conclusion: In this study, we observed a high level of adherence to the currently accepted guidelines in the current PCI practice on ACS patients in Iran. Also we found our practice is highly in line with the global reduction trend in the PCI-related complications.

Keywords: Percutaneous coronary intervention, Acute coronary syndrome, Iran

Conflicts of Interest: Pejman Golbidi and Marzieh Pourjafari are Sanofi employees. None declared for other authors.
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Introduction

Cardiovascular diseases (CVD) are the leading cause of death worldwide (1). Ischemic heart disease, including acute coronary syndrome (ACS), accounts for nearly half of the CVD-related mortalities (2). Despite significant developments in the management of patients with unstable angina (UA), non-ST elevation myocardial infarction (NSTEMI) and ST-elevation myocardial infarction (STEMI), ACS remains a major global healthcare problem. In this context, Middle East countries are among the most concerning regions throughout the world; because of

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↑What is "already known" in this topic:
The current practice of Iranian physicians for in-hospital "medical management" of patients with acute coronary syndrome (ACS) has already been known.

→What this article adds:
The present study is the first to describe the current practice of "percutaneous coronary intervention" on patients with ACS in Iran.

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the overall younger average age of deaths due to CVD which represents greater national and financial burdens (3).

Among different modalities for managing ACS patients, percutaneous coronary intervention (PCI) has undergone tremendous growth in recent years. Along with developments in clinical approach and pharmacology, more complex ACS cases are now successfully treated with PCI that substantially improves their clinical outcomes (4). For a better implementation of evidence-based PCI recommendations into clinical practice, commitment to guidelines of well-regarded authorities has been strongly emphasized (5-8). Although several large registries have evaluated PCI practice in developed societies (9-11), little is known about PCI in developing countries. In addition, it has been noted that there are wide variations in ACS management and PCI utilization among different countries (12, 13). Therefore, local registries are needed for developing countries in order to find possible gaps between their actual clinical practice and international guidelines.

Numerous ACS patients undergo PCI on a daily basis in different cities of Iran. However, very limited nationwide data regarding the current PCI practice in Iran is available. Hence, the purpose of this investigation was to gain insights into the clinical characteristics, treatment patterns (adherence to guidelines) and in-hospital outcome in Iranian ACS patients treated with PCI.

Methods

Study Participants

Between February 2017 and July 2017, study subjects were prospectively recruited from ACS patients consecutively presented to the 5 referral hospitals in two major cities of Iran (Tehran, the capital of the country; and Shiraz, the main referral city in the south of Iran), among which 2 hospitals were in the 24/7 dedicated primary PCI centers. The patients were included if confirmedly diagnosed with ACS (STEMI, NSTEMI, or UA), and underwent PCI for ACS during the hospitalization, and signed informed consent. Considering the proposed rate of procedural success as about 72% [based on the information in a referenced Iranian study (14)], for finding a difference of 0.05, we needed to enroll 323 cases. The sample size distribution among the study sites was based on the number of the patients and number of beds in each hospital. Seven independent physicians were asked to recruit patients from the study centers. Each physician consecutively recruited patients until the targeted number of patient in his/her center was reached.

Study Protocol

Study protocol was prepared in detail with eligibility criteria, logistics, and exact definition of all items. It was then reviewed and approved by all investigators from each collaborating site before the study was started. A detailed paper Case Report Form (CRF) was developed for recording data from recruited patients which included data on demographics, presenting symptom, medical history (CVD risk factors, etc.), First Medical Contact (FMC) time, FMC-to-PCI time, subtype of ACS, prescribed medications, procedural details on PCI, and PCI-related complications (if any). The data was collected and filled in the paper CRF by the responsible physician in each center.

Successful PCI was defined as post-PCI flow restoration with < 10% residual stenosis and no early stent thrombosis, nor emergent need for coronary artery bypass graft (CABG) surgery (8). Based on some well-accepted guidelines, other items were defined as follows:

- ACS (5): A suspected coronary event that is subcategorized as STEMI, NSTEMI, or UA.
- STEMI (6): Presence of positive cardiac biomarkers and presumably new left bundle branch block or presumably new ischemic ST elevation of > 1mm in two adjacent leads (except V2, V3 for which > 2mm [men] or > 1.5mm [women] are considered).
- NSTEMI (5): Presence of positive cardiac biomarkers without other STEMI criteria
- UA (5): Presence of ischemic chest discomfort (angina or its equivalents) with negative cardiac biomarkers and no ST elevation as previously described for STEMI.
- FMC time (6): The time point at which the STEMI patient was seen by medical personnel. For those patients who arrived at the first facility by emergency medical service (EMS), the time of EMS arrival to the patient was considered as FMC. For those with self- or family-transport, the time of arrival to the first facility was considered as FMC.
- FMC-to-PCI time (6): The time from FMC to the time of the beginning of PCI (i.e., wire insertion).
- PCI-related Complication (8): Occurrence of one of the followings during or after PCI (when not considered as a complication of the ACS itself): stent thrombosis (reinfarction), cardiogenic shock, new atrial fibrillation, ventricular tachycardia, ventricular fibrillation or cardiac arrest, suspected bleeding event (any bleeding diagnosed by the operating interventional cardiologist [at access site, retroperitoneal, gastrointestinal, genitourinary, etc.], whether it needs surgical/endoscopic intervention, packed cell transfusion or not), stroke, mechanical ventilatory support, emergency CABG, or PCI-related death.

Statistical analysis

All of the study data were entered into SPSS for Windows version 21.0. Descriptive statistics were performed, and results were expressed as frequency and percent, mean with standard deviation (SD), or median with interquartile range (IQR) where applicable. Some clinical subgroups of special interest were identified and baseline, angiographic and procedural characteristics and complications were compared between those subgroups. For continuous data, differences were calculated using the Student's t-test (or Mann–Whitney U test, Chi-square test, and Fisher's exact test); and for proportions, the Chi-square test and correlation coefficient were used. All statistical tests were two-tailed with a 0.05 significance level.

Results

Baseline Characteristics

During the 5-month course of this study, 317 patients were recruited. After excluding 3 cases with incomplete

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Table 1. Baseline Characteristics of the Study Participants

Variable*	All (N=314)	STEMI (N=162)	UA/NSTEMI (N=152)	P
Age: mean (SD)	62 (12)	61 (12)	63 (11)	0.380
Male gender	228 (73)	121 (75)	107 (70)	0.394
Body weight: mean (SD)	77 (12)	76 (11)	78 (14)	0.399
Body mass index: mean (SD)	26.9 (4.0)	26.8 (3.9)	27.2 (4.3)	0.411
Living area				0.044
Urban	293 (93)	156 (96)	137 (90)	
Rural	21 (7)	6 (4)	15 (10)	
Education Level				0.001
Illiterate	40 (13)	25 (15)	15 (10)	
Primary	77 (25)	50 (31)	27 (18)	
Secondary	105 (33)	54 (33)	51 (34)	
University/Higher	92 (29)	33 (21)	59 (39)	
Background/Risk Factors				
Hypertension	183 (58)	106 (65)	77 (51)	<0.001
Hypercholesterolemia	150 (48)	63 (39)	87 (57)	0.001
Diabetes mellitus	73 (23)	32 (20)	41 (27)	0.130
Current smoker	46 (15)	25 (15)	20 (13)	0.566
Chronic kidney disease	17 (5)	8 (5)	9 (6)	0.701
Cerebrovascular disease	7 (2)	2 (1)	5 (3)	0.270
Peripheral arterial disease	4 (1)	2 (1)	2 (1)	1.000
Prior myocardial infarction	32 (10)	10 (6)	22 (14)	0.013
Prior heart failure	13 (4)	11 (7)	2 (1)	0.015
Prior PCI	56 (18)	12 (7)	44 (29)	<0.001
Prior CABG	35 (11)	7 (4)	28 (18)	<0.001
Prosthetic heart valve	2 (1)	1 (0.6)	1 (0.7)	1.000
Atrial fibrillation/flutter	5 (2)	1 (0.6)	4 (3)	0.202

*Values are No. (%) except otherwise specified; STEMI: ST Elevation MI; UA/NSTEMI: Unstable Angina/Non-ST Elevation MI; SD: Standard Deviation; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft

CRF, a total of 314 patients were analyzed with a mean (SD) age of 62 (12) years. The majority of participants (73%) were males and from urban areas (93%). Other baseline characteristics are summarized in Table 1. As seen, the most frequent CVD risk factor was hypertension (58%) followed by dyslipidemia (48%) and diabetes mellitus (23%). In addition, 91 subjects (29%) had prior coronary revascularization, either PCI (18%) or CABG (11%).

Clinical and Procedural Characteristics

ACS patients in this study included 162 (52%) STEMI and 152 (48%) UA/NSTEMI patients (Table 2). Among STEMI subjects, the FMC-to-PCI time ranged from 15 to

Table 2. Clinical and procedural characteristics of the study participants

Variable*	All (N=314)	STEMI (N=162)	UA/NSTEMI (N=152)	P
Vital signs at presentation**				
Systolic blood pressure	133 (20)	131 (20)	135 (19)	0.041
Diastolic blood pressure	79 (11)	79 (11)	79 (11)	0.709
Heart rate	76 (11)	79 (12)	74 (10)	<0.001
Chest pain at presentation	296 (94)	158 (98)	138 (91)	0.006
Transportation mean				
By EMS	-	92 (57)	-	-
By Family/Self	-	52 (32)	-	-
Unknown	-	18 (11)	-	-
FMC-to-PCI time (minutes)***	-	65 (45-110)	-	-
PCI approach site				0.222
Femoral artery	199 (64)	110 (68)	89 (58)	
Radial artery	110 (35)	50 (31)	60 (39)	
Brachial artery	5 (1)	2 (1)	3 (2)	
PCI indication				NA
Primary PCI for STEMI	149 (47)	149 (92)	NA	
Rescue PCI for STEMI	9 (3)	9 (6)	NA	
PCI after successful thrombolysis for STEMI	4 (1)	4 (2)	NA	
PCI for UA/NSTEMI	152 (48)	NA	152 (100)	
Disease extent				0.493
1 vessel disease	109 (35)	52 (32)	57 (38)	
2 vessel disease	105 (33)	58 (36)	47 (31)	
3 vessel disease	100 (32)	52 (32)	48 (31)	
Lesion location				
LAD	175 (56)	105 (65)	70 (46)	0.001
RCA	134 (42)	82 (51)	52 (34)	0.003
LCX	77 (24)	48 (30)	29 (19)	0.030
OM	39 (12)	29 (18)	10 (7)	0.002
Diagonal	25 (8)	13 (8)	12 (8)	0.966
Left main	8 (3)	5 (3)	3 (2)	0.532

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Table 2. Ctd

Variable*	All (N=314)	STEMI (N=162)	UA/NSTEMI (N=152)	P
Treatment strategy				
Stent placement	308 (98)	159 (98)	149 (98)	0.936
Pre-dilatation	211 (68)	144 (89)	67 (44)	<0.001
Post-dilatation	258 (82)	142 (88)	116 (76)	0.009
Thrombus aspiration	25 (8)	21 (13)	4 (3)	0.001
Stent type				0.956
Drug-eluting stent	309 (98)	161 (99)	148 (97)	
Bare-metal stent	2 (1)	1 (1)	1 (1)	
Successful PCI	298 (95)	148 (91)	150 (99)	0.479

*Values are No. (%) except otherwise specified; **Values are mean (standard deviation); ***Value is median (interquartile range); STEMI: ST Elevation MI; UA/NSTEMI: Unstable Angina/Non-ST Elevation MI; EMS: Emergency Medical Service; FMC: First Medical Contact; PCI: Percutaneous Coronary Intervention; LAD: Left Anterior Descending artery; RCA: Right Coronary Artery; LCX: Left Circumflex artery; OM: Obtuse Marginal artery.

Table 3. First medical contact (FMC)-to-PCI time for STEMI patients between subgroups

FMC-to-PCI time (minutes)	N (%)	Mean	Median (IQR)	Min	Max	P
Transportation mean						< 0.001
By Self/Family	52 (36)	258	130 (60-250)	30	1580	
By EMS	92 (64)	85	60 (40-80)	18	1185	
Gender						0.525
Male	107 (74)	140	65 (45-110)	15	1545	
Female	37 (26)	173	65 (50-120)	19	1580	
Education						0.073
Illiterate	22 (15)	168	66 (50-96)	26	1580	
Primary	44 (31)	110	65 (48-115)	15	1176	
Secondary	49 (34)	131	60 (45-110)	18	1185	
University / Higher	29 (20)	223	65 (40-115)	18	1545	

PCI: Percutaneous Coronary Intervention; STEMI: ST Elevation MI; IQR: Inter-Quartile Range; EMS: Emergency Medical Service

1580 minutes (min), with mean and median (IQR) of 149 and 65 (45-110) min, respectively. There was a statistically significant difference in FMC-to-PCI time between EMS transported STEMI patients and self/family-transported ones (median [IQR]: 60 [40-80] min vs. 130 [60-250] min, respectively; P < 0.001). No difference, however, was found in terms of gender, living area, or education level (Table 3).

Details on clinical features and procedural techniques of the study participants are seen in Table 2. Around two-third of procedures (64%) were performed via femoral artery access. Nearly two-thirds of patients (65%) had multivessel disease, whereas 35% had single-vessel involvement. The most frequently involved vessel was the left anterior descending artery (56%), followed by the right coronary artery (42%) and the left circumflex artery (24%).

The overall PCI success rate was 95%. Stent placement was performed in 98% of the total study subjects. Drug-eluting stent (DES) was placed in 98% of patients; balloon angioplasty without stent implementation was performed in 1%, and bare-metal stent (BMS) was placed in only 1% of patients.

Medications and Complications

Table 4 shows the prescribed medications to the study patients. COX inhibitor, P2Y12 inhibitor, and dual anti-platelet therapy (DAPT) were given to the most of the study subjects both at the emergency department (ED) (87%, 89%, and 87% respectively) and at discharge (98%, 99.7%, and 99% respectively). Glycoprotein IIb/IIIa inhibitors were used for near to one quarter (24%) of the total cases. Whereas the vast majority (99%) of patients received anticoagulation in hospital, only 2% were discharged with a vitamin K antagonist.

The overall rate of PCI-related complications was 4.1%, most of which (1.6%) related to the suspected bleeding events. No PCI-related mortality was reported in this study population (Table 5).

Table 4. Medications during hospitalization and at discharge

Variable*	All (N=314)	STEMI (N=162)	UA/NSTEMI (N=152)	P
Drugs prescribed at ED/Cath lab				
COX inhibitor	274 (87)	160 (99)	114 (75)	< 0.001
P2Y12 inhibitor	280 (89)	160 (99)	120 (79)	< 0.001
DAPT	273 (87)	158 (98)	113 (74)	< 0.001
Anticoagulant	312 (99)	162 (100)	150 (99)	0.143
Vitamin K antagonist	0 (0)	0 (0)	0 (0)	1.000
Glycoprotein IIb/IIIa inhibitor	76 (24)	66 (41)	10 (7)	< 0.001
Drugs prescribed at discharge				
COX inhibitor	309 (98)	160 (99)	149 (98)	0.601
P2Y12 inhibitor	313 (99.7)	161 (99)	152 (100)	0.332
DAPT	311 (99)	159 (98)	149 (98)	0.938
Vitamin K antagonist	6 (2)	2 (1)	4 (3)	0.366

*Values are No. (%); ED: Emergency Department; STEMI: ST Elevation MI; UA/NSTEMI: Unstable Angina/Non-ST Elevation MI; COX: Cyclooxygenase; DAPT: Dual Anti-Platelet Therapy

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Table 5. PCI-related complications in study participants

Complication	Frequency (%)
Stent thrombosis (re-infarction)	2 (0.6)
Cardiogenic Shock	1 (0.3)
New Atrial Fibrillation	2 (0.6)
Ventricular Tachycardia	2 (0.6)
Ventricular Fibrillation / Cardiac Arrest	1 (0.3)
Suspected Bleeding Event	5 (1.6)
Stroke	0 (0.0)
Mechanical Ventilatory Support	0 (0.0)
Emergency CABG	0 (0.0)
Death	0 (0.0)
Total	13 (4.1)

PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft

Discussion

To the best knowledge of the authors, no specific registry for PCI practice has yet been performed by the countries in our region. Moreover, this is the first nationwide study in Iran that specifically focused on the characteristics of the current PCI practice in ACS patients. Our main results included a 52% rate of STEMI among ACS patients, a median (IQR) of 65 (45-110) min for FMC-to-PCI time, a 98% rate for selecting DES for PCI, a 64% rate of trans-femoral approach for PCI, a PCI success rate of 95% with 4.1% PCI-related complications, and a 99% rate for DAPT at discharge.

Nearly one-half (52%) of the ACS patients in the current study had STEMI, which is similar to the STEMI rates both reported in a study from Europe and Mediterranean basin (15) and many other studies from developing countries in our region (16-19). However, a significantly lower STEMI proportion was reported in a recent ACS registry from Iran, the IPACE2 (Iranian Project for Assessment of Coronary Events 2) Study (20). Although hypertension and male gender were more frequent in our study population compared to the IPACE2 Study (58% vs. 50%; and 73% vs. 65%, respectively), the notable difference in STEMI rate could be best attributed to the different study populations. We included those ACS patients who underwent PCI during hospitalization, but the IPACE2 investigators included all hospitalized ACS patients, either underwent PCI or did not.

According to the guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) (6) and the European Society of Cardiology (7), the "total ischemic time" is recommended not to exceed 120 min for STEMI patients. In this study, we found the median (IQR) of FMC-to-PCI time for STEMI patients is 65 (45-110) min which is an acceptable result overall. However, among STEMI patients, the FMC-to-PCI time for the subgroup of those with self- or family-transportation to ED (mean= 258 min; median= 130 min) was more than twice as late as those who transferred by EMS (mean=85 min; median= 60 min). Considering our definition of FMC ("the time of EMS arrival to the patient" for EMS-transported patients vs. "the time of arrival to the first facility" for those with self- or family-transportation), this finding supposes that, in real practice, when a given STEMI patient is presented to ED, the situation would be more seriously taken when he/she has been transferred by EMS than when transferred by his/her own family. This interesting issue could be targeted in future studies. Such issues as the method of transport among UA/NSTEMI patients and the onset of symptom-to-FMC time are also interesting for future investigations.

The rate of DES use in the current investigation was as high as 98%. After being approved by the USA Food and Drug Administration (FDA), the use of DES was rapidly increased by up to 84% of all stents placed during 2004-2006 (21-23). In 2006, however, the advisory statement by the FDA on the risk of late stent thrombosis after DES transiently declined its use to 59% during 2007-2008. Then again, the prevalence of DES use approximated 80% of all PCI procedures during 2012-2014, with an estimated annual increase over the recent years (21-23). When compared to BMS, the main advantage of DES is the lower rate of in-stent restenosis which is for the use of antiproliferative drug coatings. Although some concerns have been raised for DES about the risk of "very late" in-stent thrombosis among STEMI patients (24), data from recent literature supports the overall superiority of DES over BMS in terms of lower risk for target vessel MI and cardiac death as well as lower risk of in-stent thrombosis with DES than with BMS in STEMI cases (25). Nevertheless, when the risk of bleeding is a concern in a given patient, BMS might be selected over DES because it needs a shorter duration of DAPT after PCI. Practically, according to the current literature, when PCI is planned for a patient, DES should be selected as a routine choice of stent except when the patient cannot continue DAPT for at least 3 months after PCI (e.g., in case of planned noncardiac surgery) (26). Therefore, the extremely high rate of DES in Iranian PCI-capable centers in this study is seemingly in line with the current recommendations. However, it could raise the concern that the Iranian interventionists may overlook to consider the specific patients' characteristics (in terms of bleeding risk, planned surgery [if any], good or poor adherence to DAPT, etc.) before deciding for stent selection.

We found that the trans-femoral approach was more often (64%) used for PCI procedures among Iranian interventionists. Although lower net adverse events (esp. bleeding) have been reported in the trans-radial PCI approach for ACS (27), those benefits have been more observed in the high-volume radial PCI hospitals (> 80% of PCIs via radial artery access) (28). Also taking into consideration that the trans-radial approach makes more radiation exposure to the operator (29), it could be suggest-

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ed that for moderate to high-volume femoral PCI centers with low bleeding events, trying to change the practice to radial access might result in minimal marginal benefit. In this investigation with the rate of suspected bleeding events as low as 1.6%, perhaps there is no need to insist on changing the practice from femoral to radial approach.

The rate of post-PCI bleeding events (1.6%) and PCI-related complications (4.1%), as well as the overall procedural success rate of 95% in this study, are all similar to those rates reported by Western countries (30), and to some extent better than the results reported by some Eastern nations (31). It means that the real PCI practice in Iran is in line with the global reduction trend in the PCI-related complications (32).

Finally, the rate of DAPT at ED was acceptably high (87%) in this registry, and the total proportion of those patients who discharged with dual anti-platelet agents was as high as 99% which is significantly higher than the values reported from the previous Iranian ACS registry (IPACE2) (20) and many other registries from developing countries (33-36). After a specific focus on the current practice of other countries in our region, the rate of DAPT is found from as low as 6% (40) to the rates around 45 to 68% (16, 17), which proves our performance in DAPT for ACS patients as excellently higher. According to the literature, in spite of the ACC/AHA recommendations about the beneficial effects of DAPT for ACS patients (5, 6), underutilization of DAPT is a global trend (36-38). That trend has been reported to be more pronounced in those ACS patients who do not undergo PCI (15, 39); a fact that describes the observed rate difference in the use of DAPT in this study and the IPACE2 registry. After analyzing the subgroups separately, however, we found a significantly less proportion of the patients with UA/NSTEMI (74%) than those with STEMI (98%) received DAPT ($p<0.001$) in ED. A similar trend to less use of DAPT among UA/NSTEMI patients than STEMIs has also been reported in previous investigations (15, 16, 36, 38, 39). Given the weight of evidence supporting the use of DAPT in all ACS patients, more reinforcement on the appropriate use of DAPT in ED for UA/NSTEMI patients seems necessary in retraining programs for physicians.

The main limitation of this study is the undeniable bias in the selection of our sample. Although this was a multicenter study, patients and centers participating in this registry may not have been well representative of all Iranian PCI procedures on ACS patients. Not only the small number of the recruited patients (most of whom from urban areas) limits the generalizability of the results, but also the selected PCI centers from 2 main referral provinces might not reflect the current PCI practice in the other regions of the country.

Conclusion

In this observational prospective multicenter study on PCI practice in ACS patients in Iran, the results demonstrated good adherence of the Iranian interventionists to the ACC/AHA guidelines.

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Conflict of Interests

Pejman Golbidi and Marzieh Pourjafari are Sanofi employees. The Other authors declare that they have no competing interests.

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