

Evaluation of long-term outcomes of percutaneous coronary intervention in patients with moderate to severe calcified coronary artery lesions

Mahmoud Ebrahimi¹ | Vahid Reza Askari^{2,3}  | Shima Sharifi¹ |
Seyed Mohammad Tabatabaei⁴ | Majid Rahmani¹ | Vafa Baradaran Rahimi¹ 

¹Department of Cardiovascular Diseases, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

²International UNESCO Center for Health-Related Basic Sciences and Human Nutrition, Mashhad University of Medical Sciences, Mashhad, Iran

³Applied Biomedical Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

⁴Department of Medical Informatics, Mashhad University of Medical Sciences, Mashhad, Iran

Correspondence

Majid Rahmani and Vafa Baradaran Rahimi, Department of Cardiovascular Diseases, Faculty of Medicine, Mashhad University of Medical Sciences, Azadi Sq., Vakil Abad Hwy, Mashhad, Iran.

Email: Rahmanimj961@mums.ac.ir, baradaranrv@mums.ac.ir, and vafa_br@yahoo.com

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Abstract

Background and Aims: Coronary artery calcification reduces elasticity and can cause hemodynamic disturbances, increasing the risk of cardiovascular complications. Furthermore, coronary calcifications make cardiovascular interventions difficult. The present study aimed to study the cardiovascular outcomes of the coronary intervention of calcified lesions in the Iranian population.

Methods: The present cross-sectional study evaluated patients with moderate to severe calcified coronary artery lesions on angiography who were candidates for percutaneous coronary intervention (PCI). Demographic, echocardiographic, and angiographic data of the patients were recorded. In addition, clinical outcomes, including mortality, myocardial infarction, stroke, and stent thrombosis, were also measured 1 year after the procedure.

Results: A total of 125 participants (65% male and 35% female) with a median age of 69 (13.0) years old were enrolled. The most common calcification degree was 270° (43.5%), followed by 360° (35.5%) and 180° (21.0%). Most patients had thrombolysis in myocardial infarction (TIMI) score of 3 (47.6%). A more than 10% residual coronary minimum lumen diameter was seen in 25.8% of patients. Puncture site hemorrhage and contrast-induced nephropathy were observed in 2 (1.6%) and 1 (0.8%) patients, respectively. Following 1 year after PCI, no cases of mortality, cerebrovascular accident, myocardial infarction, and stent thrombosis were reported. Furthermore, we observed one case of heart failure (0.8%) and target lesion revascularization (0.8%). In addition, we revealed a significant relationship between calcification degree and TIMI ($p < 0.001$) and body mass index ($p = 0.049$).

Conclusion: Percutaneous management of calcified lesions with noncompliant balloon and one or two guidewires was associated with a good success rate and few complications.

KEYWORDS

angiography, coronary artery calcification, percutaneous coronary artery intervention

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1 | INTRODUCTION

The prevalence of coronary artery calcification (CAC) mainly depends on age and sex. Approximately 90% of men and 67% of women over 70 years of age have such vascular disorders.¹ Numerous factors have been suggested as predisposing factors for coronary calcification, including aging, diabetes, hyperphosphatemia, increased blood pressure, dyslipidemia, and male gender.²

Calcium deposit accumulation in the vascular system is a dynamic process in which various factors, including vascular smooth muscle cell disorders, cellular apoptosis, and disorders resulting in the expression of mineralization inhibitors, are involved.³ Although CAC does not usually have specific clinical manifestations, this asymptomatic phenomenon can lead to several complications and is considered a prognostic factor for major cardiac events.⁴ The early detection of CAC can be performed by computed tomography (CT) scan. The American College of Cardiology/American Heart Association gives class IIa for indication of CT scan for diagnosing asymptomatic patients with intermediate-risk based on Framingham risk score or asymptomatic patients 40 years and older with diabetes. However, a CT scan is not recommended for patients with low or high Framingham risk score.⁵

Decreased vascular elasticity is regarded as the most important complication of calcium deposition in vessels resulting in abnormal circulation.² In this regard, calcium deposition in the body's large arteries, including the aorta, will disrupt vascular hemodynamics, prevent the transmission of effective contractile force along this artery, and cause heart failure.⁶ Similarly, calcium plaques in coronary arteries lead to vasomotor response disorders as well as abnormal oxygenation to myocytes. Extensive coronary calcification results in irregular lumen and reduced luminal flexibility, thus complicating the percutaneous coronary intervention (PCI). It may cause challenges in delivering guidewires, balloons, and stents during the PCI procedure.⁷ The rigidity of the calcified coronary lesions may make them "undilatable" and resistant to balloon expansion pressure. Thus, complete stent expansion in these calcified lesions requires higher balloon inflation pressure.⁸ In this case, stent delivery and complete stent expansion can be achieved through atherectomy of the calcified lesion.⁷

Calcified stenotic lesions can be managed by various methods, including Balloon angioplasty and using different stents, rotational atherectomy, laser coronary atherectomy, orbital atherectomy, and coronary artery bypass graft surgery.⁴ While the percutaneous management of coronary artery lesions, especially those with a higher rate of calcification, is directly related to the operator's experience and the chosen management instruments, the success rate and adverse clinical outcomes of management of such lesions vary across different centers. According to a study by Tan et al.,⁹ the success rate of balloon angioplasty in calcified lesions was 74% compared to 94% in noncalcified lesions.

Regarding the lack of clinical data about the outcomes of calcified coronary artery lesion management in our country, we decided to conduct a study on patients receiving percutaneous management of calcified coronary lesions and evaluate the major cardiovascular outcomes of interventions.

2 | MATERIAL AND METHODS

2.1 | Ethics

The present cross-sectional study was approved by The Ethics Committee of the Mashhad University of Medical Sciences (IR.-MUMS.MEDICAL.REC.1398.340). All participants received and signed written informed consent.

2.2 | Study design

This cross-sectional study was conducted on patients referred to the Imam Reza Hospital affiliated with Mashhad University of Medical Sciences for PCI. Patients with moderate and severe calcified coronary artery lesions on angiography were included in the present study. The exclusion criteria were pregnancy, age less than 20 years, kidney failure, previous myocardial infarction (MI), taking calcium supplements, and calcium metabolism disorders such as hyperthyroidism.

In this study, the criterion of the severity of calcification was based on the study by Nishida et al. reporting the presence of density-absorbing X-ray beams within as (1) no calcification, (2) mild calcification, (3) moderate calcifications as only densities in cardiac cycles following contrast injection, and (4) severe as the presence of densities over the two sides of the coronary artery wall before contrast injection (11). The present study only included patients with moderate and severe calcified lesions based on the mentioned classification criteria.

PCI was performed by one interventional cardiologist using two wires. The PCI of the calcified lesion was mainly used by one guidewire in most patients, and the noncompliant (NC) balloon for pre-dilation and inflation of the balloon was up to 28 mmHg, depending on the calcified lesion.¹⁰

2.3 | Evaluation of outcome

Demographic information and cardiovascular risk factors, including age, sex, body mass index (BMI), smoking, diabetes, hypertension, clinical laboratory tests, and ejection fraction (EF), were recorded. Patients' angiographic findings were noted, including type of vessel and number of involved vessels, the initial thrombolysis in myocardial infarction (TIMI) grade, calcification degree, hemorrhage, and contrast-induced nephropathy (CIN). The residual coronary minimum lumen diameter (MLD) is determined as the ratio of the remaining stenosis compared to

the normal state of the vessel after angioplasty. The CIN is defined as 0.5 mg/dL or a 25% increase in serum creatinine from baseline.¹¹

2.4 | Follow-up

After discharge, the patients were evaluated regularly every 3 months at the clinic or over a phone call for at least 1 year after PCI. The measured clinical outcomes were death due to cardiovascular problems, MI, cerebrovascular accident (CVA), stent thrombosis, vascular access problems (bleeding or pseudo aneurysm), and target lesion revascularization (TLR).

2.5 | Statistical analysis

The statistical package for social sciences (SPSS) software version 26 was used for data analysis. The Kolmogorov–Smirnov test was used to evaluate the normality of continuous variables. Mean and standard deviation were used to report normally distributed variables, while median and interquartile range were used to show nonnormally distributed variables. Frequency and percentage were used to declare categorical variables. Linear logistic regression was used to evaluate the relationship between stent length and width and study variables. Binary logistic regression was used to assess the relationship between abnormal echocardiographic findings and study variables using the backward elimination method. The level of statistical significance was set as $p < 0.05$.

3 | RESULTS

3.1 | Baseline characteristics

The participants' demographic, medical history, and laboratory findings are presented in Table 1. A total of 125 participants (65% male and 35% female) were evaluated in this study. The median age of the participants was 69 (13.0) years old. The most common underlying condition was hypertension (70, 56.0%), followed by diabetes (60, 48.0%), dyslipidemia (54, 44.0%), and smoking (34, 27.0%). The mean EF of the studied patients was 41.24 ± 11.55 , and 35 (28.2%) patients had abnormal EF (Table 1).

3.2 | Procedural characteristics

The procedural characteristics of the participants are illustrated in Table 2. The most common calcification degree was 270° (43.5%), followed by 360° (35.5%) and 180° (21.0%). Most patients had a TIMI score of 3 (47.6%). A more than 10% residual coronary MLD was seen in 25.8% of patients. Puncture site hemorrhage and CIN were observed in 2 (1.6%) and 1 (0.8%) patients, respectively. The median stent length and width were 3.00 (0.62) and 22.00 (13.00) mm, respectively (Table 2).

TABLE 1 Demographic, medical history, and laboratory findings of the participants.

Variable	N = 125	
Age (year)	69.00 (13.00) ^a	
Gender (N, %)	Female	44 (35%)
	Male	81 (65%)
Weight (kg)	72.00 \pm 13.00 ^b	
Length (cm)	164.00 (13.00) ^a	
BMI (kg/m ²)	25.00 (7.00) ^a	
DM (N, %)	No	65 (52%)
	Yes	60 (48%)
HTN (N, %)	No	55 (44%)
	Yes	70 (56%)
Dyslipidemia (N, %)	No	71 (56.%)
	Yes	54 (44%)
Smoker (N, %)	No	91 (73%)
	Yes	34 (27%)
Cardiac medication (N, %)	No	77 (62%)
	Yes	48 (38%)
EF (%)	41.24 \pm 11.55 ^b	
EF	$\geq 50\%$	89 (71.8%)
	$< 50\%$	35 (28.2%)
FBS (mg/dL)	145.00 (71.00) ^a	
LDL (mg/dL)	86.00 (34.00) ^a	
HDL (mg/dL)	46.00 \pm 11.0 ^b	
TG (mg/dL)	171.00 (71.00) ^a	
Total cholesterol (mg/dL)	174.00 (51.00) ^a	

Abbreviations: BMI, body mass index; DM, diabetes mellitus; EF, ejection fraction; FBS, fasting blood sugar; HDL, high-density lipoprotein cholesterol; HTN, hypertension; LDL, low-density lipoprotein cholesterol; SD, standard deviation; TG, triglyceride.

^aMedian (Interquartile range) was used to describe the variables.

^bMean \pm SD was used to describe the variables.

The most common involved vessel was LAD (61, 48.8%), followed by LCX (39, 31.2%), RCA (34, 27.2%), OM (11, 8.8%), LM (8, 6.4%), and diagonal artery (15, 0.8%) (Figure 1).

3.3 | One-year outcomes

The results of follow-up 1 year after PCI are summarized in Table 3. No mortality, CVA, MI, and stent thrombosis cases were reported. Furthermore, we observed one case of HF (0.8%) and TLR (0.8%). One patient who experienced HF received medical treatment, and one patient with TLR underwent second PCI with a drug-coated balloon, which was successful.

TABLE 2 Procedural characteristics of the participants.

Variable	N = 125	
Calcification degree	180°	27 (21.0%)
	270°	54 (43.5%)
	360°	44 (35.5%)
TIMI	0.0	32 (25.8%)
	1.0	13 (9.7%)
	2.0	21 (16.9%)
	3.0	59 (47.6%)
Residual coronary MLD (%)	>10%	32 (25.8%)
Hemorrhage	No	122 (98.4%)
	Yes	2 (1.6%)
CIN	No	124 (99%)
	Yes	1 (0.8%)
Stent width (mm)	3.00 (0.62) ^a	
Stent length (mm)	22.00 (13.00) ^a	
Number of involved vessels	1 (0) ^a	
Number of guidewires	1 (1) ^a	

Abbreviations: CIN, contrast-induced nephropathy; MLD, minimum lumen diameter; TIMI, thrombolysis in myocardial infarction.

^aMedian (Interquartile range) was used to describe the variables.

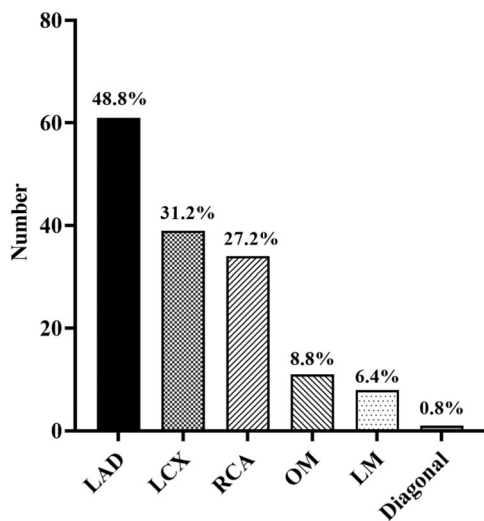


FIGURE 1 The frequency of involved vessels in studied patients. LAD, left anterior descending artery; LCX, left circumflex coronary artery; LM, left-main; OM, obtuse marginal artery; RCA, right coronary artery.

3.4 | Relationship between calcification degree and abnormal EF and selected study variables

Table 4 reports the relationship between calcification degree and other study variables. There was a significant relationship

TABLE 3 One-year outcomes of studied patients.

Variable	N (%)	
Mortality	No	125 (100.0%)
	Yes	0 (0.0%)
CVA	No	125 (100.0%)
	Yes	0 (0.0%)
MI	No	125 (100.0%)
	Yes	0 (0.0%)
HF	No	124 (99%)
	Yes	1 (0.8%)
TLR	No	124 (99%)
	Yes	1 (0.8%)
Stent thrombosis	No	125 (100.0%)
	Yes	0 (0.0%)

Abbreviations: CVA, cerebrovascular accident; HF, heart failure; MI, myocardial infarction; TLR, target lesion revascularization.

between calcification degree and TIMI ($p < 0.001$) and BMI ($p = 0.049$).

The relationship between abnormal EF and study variables is presented in Table 5. We found no significant relationship between abnormal EF and study variables ($p > 0.05$).

4 | DISCUSSION

CAC can be studied in several ways, including computed tomography coronary angiography, intravascular ultrasound, and optical coherence tomography (OCT).⁴ However, coronary computed tomography angiography is more accurate in diagnosing CAC with a negative predictive value exceeding 90%.^{12,13} Angiography is currently among the most important and definitive diagnostic methods in evaluating cardiovascular diseases, but calcification reduces its efficacy.¹⁴ PCI has always been associated with increased risks, technical challenges, and reduced success rates in patients with calcified vessels due to reduced luminal diameter in calcified vessels.^{15,16} However, expanding the use of drug-eluting stents (DES) has reduced re-stenosis risk by delaying neointimal hyperplasia.

The present study evaluated 125 participants with moderate and severe calcified coronary lesions. Coronary artery intervention outcomes mainly depend on the complexity of the coronary lesion, and calcified atheroma is an indicator of an advanced atherosclerotic lesion.¹⁷ According to a study by Tan et al.,⁹ the success rate of balloon angioplasty in calcified lesions was 74% compared to 94% in noncalcified lesions. Also, the percentage of major adverse cardiovascular events (MACE) in patients with calcification was 14% versus 2.5% in patients with non-calcification.⁹ In the present study, a residual MLD of more than 10% was observed in 32 (25.8%) participants after the coronary intervention. There was no stent

TABLE 4 Relationship between calcification degree and selected study variables.

Variables	Unstandardized coefficients		Standardized coefficients β	p-Value
	B	Std. error		
Gender	0.015	0.089	0.009	0.871
DM	-0.005	0.083	-0.003	0.954
HTN	-0.099	0.083	-0.067	0.236
Dyslipidemia	0.062	0.081	0.042	0.448
Smoker	-0.034	0.098	-0.021	0.726
Cardiac medication	0.067	0.086	0.044	0.436
TIMI	-0.507	0.032	-0.866	<0.001*
Waste Percent	0.003	0.009	0.018	0.737
Stent length	0.038	0.087	0.023	0.664
Stent width	-0.008	0.078	-0.005	0.922
Age	-0.003	0.004	-0.035	0.499
Weight	-0.001	0.004	-0.017	0.749
Length	-0.034	0.021	-0.601	0.101
BMI	0.035	0.018	0.463	0.049*
FBS	0.089	0.056	0.658	0.113
LDL	0.001	0.001	0.038	0.488
HDL	-0.001	0.001	-0.022	0.689
TG	0.002	0.004	0.030	0.607
Cholesterol	0.001	0.001	0.048	0.384

Note: Linear regression was used for the analysis.

Abbreviations: BMI, body mass index; DM, diabetes mellitus; FBS, fasting blood sugar; HDL, high-density lipoprotein cholesterol; HTN, hypertension; LDL, low-density lipoprotein cholesterol; TG, triglyceride; TIMI, thrombolysis in myocardial infarction.

*Significant relationship.

thrombosis. Hemorrhage was observed in 1.6% of participants. The study by Tan et al.⁹ did not report a success rate based on MLD but reported that coronary calcification was associated with an increased risk for abrupt closure.

Similarly, Satish et al.¹⁷ evaluated 283 patients with calcified coronary lesions and 156 patients without calcified coronary lesions. They demonstrated that cardiovascular risk factors, including diabetes and hypertension, were not significantly different among these two groups of patients.¹⁷ The findings of the current study showed that underlying diseases were not significantly related to the calcification degree

The current study showed no significant relationship between calcification degree and stent length. These findings were in contrast

TABLE 5 Relationship between abnormal EF and study variables.

Variable	p-Value	Exp (B)	95% CI for EXP (B)	
			Lower	Upper
Gender (female)	0.725	0.832	0.298	2.319
HTN	0.436	0.669	0.243	1.842
Dyslipidemia	0.519	1.358	0.536	3.443
Smoker	0.912	0.938	0.300	2.928
Cardiac medication	0.194	0.515	0.189	1.401
Calcification degree	0.294	2.058	0.534	7.922
TIMI (1)	0.090	0.132	0.013	1.369
TIMI (2)	0.339	0.286	0.022	3.725
TIMI (3)	0.647	1.416	0.319	6.285
Waste	0.484	1.480	0.494	4.433
Hemorrhage	0.314	5.828	0.188	180.434
Weight	0.179	0.836	0.643	1.086
Length	0.383	1.106	0.882	1.386
BMI	0.196	1.597	0.786	3.244
FBS	0.408	0.996	0.988	1.005
HDL	0.424	0.981	0.936	1.028
TG	0.248	1.004	0.997	1.012

Note: The binary logistic regression was used for the analysis.

Abbreviations: BMI, body mass index; EF, ejection fraction; FBS, fasting blood sugar; HDL, high-density lipoprotein cholesterol; HTN, hypertension; TG, triglyceride; TIMI, thrombolysis in myocardial infarction.

to the findings of a previous study. Satish et al. reported that calcified lesions were significantly longer than noncalcified lesions and required longer stents.¹⁷ The reason for the difference between the current study's findings and the study by Satish et al.¹⁷ might be related to the difference in study design and sample size between the studies.

It has been reported that patients with calcified lesions had a significantly higher rate of complications, such as vascular site bleeding, and noncalcified lesions, such as pseudo-aneurysm, heart failure, and enzymatic infarctions.¹⁷ Similarly, our study on calcified lesions demonstrated that 1.6% of patients developed hemorrhage, and none of the patients developed re-stenosis. Fujimoto et al.¹⁸ study evaluated angiographic outcomes after 240 days and clinical outcomes after 1080 days after implementing a sirolimus-eluting stent (SES) in patients with or without calcified coronary artery lesions.¹⁸ They demonstrated that the rate of major cardiac events, re-stenosis, and target lesion revascularization was similar among nondialysis patients with and without coronary calcified lesions receiving sirolimus-eluting stent implantation.¹⁸ However, dialysis patients with calcified coronary lesions had a significantly higher rate of re-stenosis and target lesion revascularization.¹⁸

Li et al.¹⁹ similarly evaluated the outcomes of using SES in 333 patients with calcified lesions. They demonstrated that in-stent restenosis and in-segment restenosis, target lesion revascularization, and overall thrombosis were not significantly different among patients with or without calcified lesions.¹⁹ On the other hand, Kawaguchi et al.²⁰ demonstrated that using SES in patients with severe or moderate calcified lesions had a significantly higher rate of re-stenosis and target lesion revascularization. Moreover, patients with severe and moderate calcified lesions had higher major adverse cardiac events. They demonstrated that the requirement of rotational atherectomy and hemodialysis were the predictors of target lesion revascularization.²⁰ Maclsaac et al.²¹ compared the outcomes of rotational atherectomy procedure results among 1078 patients with and 1083 patients without calcified lesions. Similar to our study, they demonstrated that the calcified lesions are longer and more complex. The procedural success, post-procedural residual stenosis, and major complications were not significantly different between the two groups.²¹

In addition, Guedeney et al.²² demonstrated that 31.3% of patients undergoing angiography have moderate or severe CAC. They showed that the patients with moderate to severe CAC had increased 5-year MI, death, or ischemia-driven target revascularization.²² Moreover, they demonstrated that using second-generation drug-eluting stents in contrast to first-generation drug-eluting stents is associated with a lower rate of complications in calcified lesions.²² Bangalore et al.¹⁵ evaluated the effects of PCI on moderate to severely calcified lesions among 884 patients who received Bare metal stent (BMS) and 653 patients who received DES. Patients managed by DES had a significantly lower risk of recurrent revascularization. This study showed that using DES in patients with moderate to severe calcification may be appropriate in reducing the need for vascularization without increasing mortality and MI.¹⁵

Ito et al.²³ evaluated the outcomes of using drug-coated balloons (DCB) for calcified coronary lesions. They demonstrated that the restenosis and late lumen loss were not significantly different in those with or without calcified lesions. Moreover, the survival rate and major cardiac events were not significantly different among the two study groups.²³ Rissanen et al.²⁴ evaluated the use of DCB with rotablation in 82 patients and demonstrated that major adverse cardiac events occurred in 20% of patients after 2 years of follow-up. Moreover, 9% of patients experienced significant hemorrhage after 1 year of follow-up.²⁴ It has been demonstrated that calcium fracture of severe calcified lesion is associated with better stent expansion. Ito et al.²⁵ demonstrated that cutting balloons generate 157,000 times more pressure in contrast to the plain balloons and, therefore, some studies, including Liu et al.²⁶ used cutting balloons for heavily calcified lesions reporting higher successful rate and better outcomes in contrast to using plain balloons.

These findings indicate that increased TIMI was related to reduced calcification degree, while increased BMI was associated with increased calcification degree. Finally, the present study had

some limitations. First, we performed a single-center study with a small sample size. The second limitation was the short follow-up period. Further studies with larger sample sizes and longer duration of follow-up are necessary.

5 | CONCLUSION

Our study demonstrated that percutaneous management of calcified lesions with NC-balloon and one or two guidewires was associated with a good success rate and few complications. In addition, calcification degree was significantly associated with TIMI and BMI.

AUTHOR CONTRIBUTIONS

Mahmoud Ebrahimi: Conceptualization; funding acquisition; methodology; supervision. **Vahid Reza Askari:** Formal analysis; writing—original draft; writing—review & editing. **Shima Sharifi:** Data curation; investigation. **Seyed Mohammad Tabatabaei:** Formal analysis; software. **Majid Rahmani:** Data curation; investigation; writing—original draft. **Vafa Baradaran Rahimi:** Formal analysis; investigation; writing—original draft; writing—review & editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest

DATA AVAILABILITY STATEMENT

Data is available from the corresponding author upon reasonable request.

TRANSPARENCY STATEMENT

The lead author Majid Rahmani, Vafa Baradaran Rahimi affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

ORCID

Vahid Reza Askari  <https://orcid.org/0000-0001-9268-6270>

Vafa Baradaran Rahimi  <https://orcid.org/0000-0003-2320-5095>

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