

Gensini Score as a Predictor for in-Stent Restenosis in Patients with Coronary Artery Disease (CAD)

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Research

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Abstract

Background: Despite Drug-eluting stent (DES) have considerably reduced the rates of in-stent restenosis (ISR). ISR is still the most common limitation of percutaneous coronary intervention (PCI). The aim of this study was to investigate potential predictors on ISR in patients with DES implantation for Coronary heart disease (CAD).

Methods: A retrospective case-control study was conducted. A total of 916 patients who underwent DESs implantations and angiography follow-up within one year at the First Affiliated hospital of Xinjiang medical University, between September, 2013, and September, 2016, were included. The subjects were divided into 2 groups, ISR (n=315) and non-ISR (n=601), ISR was defined as a diameter stenosis of $\geq 50\%$ located within a coronary stent or up to 5 mm beyond the stent edges. Clinical data and angiographic characteristics were collected. CAD severity was evaluated by calculating the Gensini score. The logistic regression and ROC analysis were performed to screen out efficient predictors.

Results: Comparison between the ISR group and the non-ISR group, Gensini Score, diastolic pressure, waist, blood glucose, left ventricular end diastolic diameter (LVED), left ventricular end systolic diameter (LVES) levels were higher in ISR group, and ApoA1, ejection fraction (EF%), and incidence of myocardial infarction (MI) were lower in the ISR group. Comparison of angiographic characteristics between the groups, the results showed the occurrence of stenosis in vessels of left main coronary artery (LM), left anterior descending artery (LAD), or right coronary artery (RCA) have more vulnerability to ISR. Patients in the ISR group have been implanted more stents. In univariate regression analysis, diastolic pressure, waist, history of MI, ApoA1, number of implanted stents, and Gensini Score were associated with ISR. After multiple logistic regression analysis, Gensini score was screen out to be an independent risk factor of ISR. Receiver operating characteristic curve analysis identified that the Gensini score was a reliable predictor for ISR, area under curve (AUC): 0.80 (0.78-0.83), Sensitivity and specificity were 73.33% and 72.33%, respectively.

Conclusions: Gensini score was independently associated with ISR, and was a good predictor for ISR in patients with DES implantation.

Introduction

For patients with coronary heart disease (CAD), percutaneous coronary intervention (PCI) was the most effective method to therapy and prevent acute myocardial infarction (AMI), which could improve survival rate and prognosis. Drug-eluting stent (DES) reduced the probability of repeat revascularization, compared with bare-metal stent (BMS) [1]. However, despite the use of DES and other novel medication at large, In-stent restenosis (ISR) remains the most common complication after PCI, approximately 10% occurred in stents implanted patients [2, 3]. Several studies showed that laboratory serological parameters or microRNAs which detected before the coronary stenting procedure could predict ISR [4–7]. However, there is not yet an efficient predictor which based on CAD severity survey.

The pathophysiological process of ISR has distinguishing mechanisms from that of natural coronary atherosclerosis, and its main mechanisms including vascular inflammation, vascular remodeling, and excessive proliferation and migration of vascular smooth muscle cells [8]. and dysfunction of these processes may lead to adverse arterial remodeling, neointimal hyperplasia, and restenosis [9].

Gensini score is one of the most widely used angiographic scoring system for quantifying the severity of CAD [10] and it is more likely to describe the complexity of CAD, since it involved multiple influence factors, as severity of lesion, cumulative effects of multiple obstructions, importance of their location, and importance of collateral changes affecting the size and mass of the distal vessels, as well as functional status of the myocardium [11]. There were studies shown that higher Gensini scores are associated with higher cardiac mortality in patients with heart failure after PCI, which suggesting that residual coronary atherosclerotic burden may contribute to a higher risk of cardiac events, such as blockages of coronary artery [12, 13]. While, as an important indicator of stenosis degree and predictor of cardiovascular disease (CVD), the values of Gensini score on ISR are still less evaluated.

Investigation of risk factors and predictors for ISR may contribute to make strategies of CAD therapy and risk stratification for patients with CAD with stents implantation. This study was set out to explore an efficient predictor for ISR in CAD implanted with DES.

Methods And Materials

Ethnic approval

The Ethics Committee of the First Affiliated Hospital of Xinjiang Medical University has approved this study. All procedures were executed in accord with the standards of the Declaration of Helsinki.

Study population

This was a retrospective, single-center study. We enrolled 916 patients who were successfully treated with DES implantation for symptomatic CAD in the First Affiliated hospital of Xinjiang medical University from September 2013 to September 2016, and who had an angiographic follow-up more than 1 year. Patients who had infectious diseases, coronary artery bypass surgery, acute or chronic heart failure, coronary artery dissection, severe liver or kidney disease, and malignant tumors were rule out.

Data collection

Baseline parameters were collected, including gender, age, medical history as hypertension, diabetes, and, life style likesmoking status, alcohol intake, medical examine contains echocardiographic data and angiography results, laboratory detected results, On the basis of angiography, the degree and severity of CAD were expressed as Gensini score.

Angiographic data, such as target vessel, stent length, number of implanted stents were also recorded by experienced interventional cardiologists at baseline and follow-up for coronary angiography analysis. ISR

is defined as 50% luminal diameter narrowing of the stented or peri-stent segment (defined as a length of 5 mm proximal and distal to the stent edge) at follow-up angiography analysis, whereas non-ISR was defined as stenosis degree < 50% or no stenosis [14].

We evaluated the degree of coronary atherosclerosis according to the Gensini score. The Gensini score is calculated by scoring the severity of each coronary artery stenosis according to the degree of stenosis and the importance of the stenosis location. A reduction in the lumen diameter, and the angiographic appearance of concentric lesions and eccentric plaques were quantitatively evaluated. More specifically, reductions of 25%, 50%, 75%, 90%, 99% and complete occlusion were given Gensini score of 1, 2, 4, 8, 16 and 32, respectively [15].

Hypertension was defined as a systolic pressure ≥ 140 mmHg and/or diastolic pressure ≥ 90 mmHg, or currently taking antihypertensive medications [16]. Diabetes mellitus (DM) was defined as fasting blood glucose (FBG) ≥ 7.0 mmol/L and/or random glucose level ≥ 11.1 mmol/L or previously diagnosed DM treated with medicine [17].

Statistical analyses

Statistical tests were performed using SPSS for Windows, Version 23.0 statistical package (SPSS Inc., Chicago, IL, USA). Distributions were analysed via the Kolmogorov–Smirnov test to determine if the distribution of continuous variables was normal or not. Data are presented as numbers and frequencies for categorical variables and as means \pm SD for continuous variables. To compare groups, the χ^2 test (or Fisher's exact test, when any expected cell count was < 5 for a 2×2 table) was used for categorical variables, and an unpaired Student's t-test or one-way analysis of variance was applied for continuous variables. Univariate and multivariate logistic regression analyses were used to evaluate associations between the baseline clinical characteristics and risk of ISR. Based on receiver operating characteristic (ROC) curves, the optimal cut-off values for the Gensini score that could predict ISR risk were determined. The statistical tests were two sided and a P-value < 0.05 was considered statistically significant.

Results

Baseline character of ISR and Non-ISR group

A total of 916 patients were enrolled in this study, Of these 916 patients, 727 (79%) were male. The mean age of the study population was 58.40 ± 12.52 years. The baseline characteristic, clinical data of the participants are presented in Table 1. The status of diastolic pressure, waist, blood glucose, ApoA1, diastolic pressure, waist, LVED, LVES level were significantly different between the 2 groups. The mean Gensini score was significantly higher in patients with ISR than it was in those with no restenosis (50.68 ± 38.4 vs. 18.27 ± 24.41 ; $p < 0.001$).

Table 1
Baseline character of ISR and Non-ISR group

	ISR group(n = 315)	Non-ISR group(n = 601)	p values
Demographic findings			
Age(years)	60.09 ± 9.85	60.30 ± 10.88	0.778
male,n(%)	253(80.3)	474(79.1)	0.559
Systolic pressure(mmHg)	150.46 ± 31.19	144.01 ± 32.98	0.019
Diastolic pressure(mmHg)	93.74 ± 21.64	88.64 ± 22.24	0.007
Hypertension,n(%)	191(60.6)	343(57.2)	0.324
Diabetes,n(%)	80(25.4)	137(22.8)	0.414
Current smoking,n(%)	175(78.8)	351(80.3)	0.682
Alcohol intake,n(%)	42(19.4)	73(17.1)	0.455
Waist(cm)	95.19 ± 13.16	91.91 ± 13.0	0.002
BMI(kg/m ²)	26.58 ± 3.38	26.35 ± 3.41	0.348
Medical history			
MI,n(%)	46(14.6)	56(9.3)	0.020
Arrhythmial,n(%)	17(5.4)	38(6.3)	0.661
Atrial fibrillationI,n(%)	6(1.9)	8(1.3)	0.573
Laboratory data			
TC(mmol/L)	4.24 ± 2.32	4.04 ± 2.05	0.212
TG(mmol/L)	2.77 ± 4.73	2.90 ± 5.2	0.728
HDL(mmol/L)	3.51 ± 14.73	3.62 ± 15.51	0.922
LDL(mmol/L)	2.92 ± 7.82	3.86 ± 16.47	0.356
Blood glucose(mmol/L)	6.84 ± 3.88	6.14 ± 3.03	0.007
Glycated serum protein(mmol/L)	4.24 ± 10.93	4.63 ± 11.9	0.628
Creatine (μmol/L)	79.28 ± 31.11	79.55 ± 37.78	0.915
ApoA1(g/L)	1.13 ± 0.23	1.19 ± 0.27	0.006
Uric acid (μmol/L)	320.15 ± 110.47	310.57 ± 112.45	0.227
Echocardiographic data			

	ISR group(n = 315)	Non-ISR group(n = 601)	p values
LVED	50.74 ± 6.35	48.89 ± 6.54	0.001
LVES	34.74 ± 6.98	32.65 ± 5.74	0.000
EF	59.44 ± 8.32	61.09 ± 8.95	0.024
Gensini Score	50.68 ± 38.4	18.27 ± 24.41	0.000

Comparison between the angiographic characteristics

Comparison between the angiographic characteristics, the incidence of stenosis in the LM, LAD or RCA have a more chance of ISR. Patients in the ISR group had implanted more stents. (Table 2)

Table 2
Compered between the angiographic characteristics

	ISR group(n = 315)	Non-ISR group(n = 601)	p values
Target vessel LM,n(%)	28(8.9)	11(1.8)	0.000
Target vessel LAD,n(%)	31(9.8)	26(4.3)	0.001
Target vessel LCX,n(%)	15(4.8)	27(4.5)	0.869
Target vessel RCA,n(%)	45(14.3)	49(8.2)	0.006
Number of implanted stents(n)	1.03 ± 0.54	0.82 ± 0.82	0.003
Stent length (mm)	35 ± 18.67	38.7 ± 23.89	0.276

Univariate logistic regression analysis and multiple logistic regression analysis results

In the univariate logistic regression analysis, diastolic pressure, waist, history of MI, ApoA1, number of implanted stents and the Gensini Score were associated with ISR. According to multiple logistic regression analysis, we adjusted diastolic pressure, waist, blood glucose, ApoA1, waist, LVED, LVES, EF, WBC, LY, NE, number of implanted stents, MI, Gensini score were still independently associated with ISR (OR 1.029; 95% CI 1.013– 1.046) (Table 3).

Table 3
Univariate and multivariate analyses demonstrating the Predictors related to of ISR

	Univariate			Multivariate		
	OR	95% CI	P values	OR	95% CI	P values
Diastolic pressure	1.010	1.003–1.018	0.007	1.000	0.979–1.022	0.996
Waist	1.021	1.007–1.034	0.002	1.024	0.990–1.060	0.168
History of MI	1.661	1.096–2.519	0.017	0.854	0.150–4.868	0.859
Blood glucose	1.063	1.017–1.111	0.006	1.216	0.966–1.530	0.095
ApoA1	0.427	0.230–0.791	0.007	1.282	0.184–8.919	0.802
Number of implanted stents	1.498	1.121–2.002	0.006	1.370	0.710–2.642	0.348
Gensini Score	1.034	1.028–1.040	0.000	1.029	1.013–1.046	0.000

ROC

Receiver operating characteristic curve analysis was used to explore the relationship between Gensini score and ISR. The area under curve (AUC) of Gensini score was 0.804 (95% CI 0.78–0.83), for diagnosis of ISR, and its optimal cut off value of Gensini score in the prediction ISR is 21.50 with sensitivity of 73.33% and specificity of 72.33%. It is related to the degree of coronary stenosis and effective in diagnosing ISR (Fig. 1).

Discussion

In our study, the main finding is that the Gensini score is positively associated with an increased risk of ISR in CAD patients who underwent DES implantation. The optimal cut off value of Gensini score in the prediction ISR is 21.50, with a good sensitivity and specificity. Compared to other factors that predict ISR, the Gensini score is a reliable and easily calculated scoring tool and may be applied in practice to predict ISR.

At present, CAD is one of the leading causes of morbidity and mortality in the world [18, 19]. PCI is currently the most effective treatment for coronary artery stenosis. Drug-eluting stents (DES) have a higher efficacy and safety profile than bare metal stents (BMS), and international guidelines recommend

their use as first-line treatment [20]. Although stent technology has made great progress in recent years, the incidence of ISR has not improved significantly and has become one of the major clinical challenges in the treatment of CAD [21]. Chronic inflammation and/or endothelial dysfunction may induce late de novo neoatherosclerosis inside. So, neoatherosclerosis has become the prime suspect in the pathogenesis of late stent failure [22]. However, there was no reliable tools to evaluate the neoatherosclerosis progress and predict stent failure. Some clinical symptom-based scoring systems such as CHA2DS2-VASc Score have been used to predict ISR [23]. At the same time, some coronary angiographic variables, such as minimum lumen diameter and stent dilation rate, have been shown to be associated with stent restenosis after PCI [24]. However, a scoring system based on angiography itself has not been established to identify patients at high risk for ISR.

The SYNTAX score is also used to evaluate coronary angiography, but it is mainly used for the left main coronary artery disease and/or three-vessel coronary artery disease. It is used to quantitatively evaluate the complexity of coronary artery disease according to the anatomical characteristics such as bifurcation calcification and the severity of the lesion location rather than the degree of CAD [25]. So we're stick with Gensini score.

In contrast to other available ISR risk stratification tools, the Gensini score is a reliable and easily calculated scoring tool and therefore may be applied in daily practice to predict ISR with DES. The Gensini score was originally intended to quantify the severity of CAD, Razi et al. [26] found a significant positive correlation between Gensini score and the duration of diabetes. However, subsequent studies have shown that it is able to identify patients at high risk of adverse events treated with PCI [27, 28]. The Gensini score has also been reported to predict short-term major adverse cardiovascular events following PCI in patients with acute myocardial infarction [29].

The current study shows that patients with higher Gensini scores have an increased risk of developing ISR, independent of other clinical variables. This is the first report on the relationship between Gensini score and ISR in patients with DES implantation.

Study limitations

Our study has some inherit limitations. First and foremost, it has a retrospective and single-center design. Patients with a history of CABG, previous PCI, or STEMI and reperfusion with thrombolytic drug administration were excluded. Thus, the results of this study may not be extrapolated to all patients. Additionally, the study did not use intravascular ultrasound or optical computed tomography to assess the degree of in-stent re-narrowing. Despite these limitations, we believe that our results indicate a valuable predictor for ISR.

Conclusion

By screening 916 patients with coronary angiography, we found that Gensini score was independently associated with ISR in patients with DES implantation, and was a good predictor for ISR in patients with

CAD and DES, which could provide an important tools for ISR prevention and risk stratification.

Declarations

Contribution of the Authors

The experiments were designed and conceived by SY who also wrote the draft of the experiment's manuscript; data collections as well as analyses inclined to the statistics were done by MG; the laboratory experiments were conducted by MMW while the critical comments that were pertained to the draft were given by YM who also took part in the writing of the manuscript. This study was under supervision and had its clinical assessments review done by MG, SY as well as BC. The final approval of the whole study was given by all the authors who had gone through whole of the study.

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Conflict of Interests

A declaration was made by the authors that this study has no competing interests.

Materials and data Availability

There will be no sharing of the obtained data since it will be required in another study.

Consent for publication

Not applicable.

Approval of Ethics and the participation consent

The hospital of Xinjiang medical University had their board (Ethical Review board of the institution first affiliate university) approve this study that also had the patients enroll the written informed consent.

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Figures

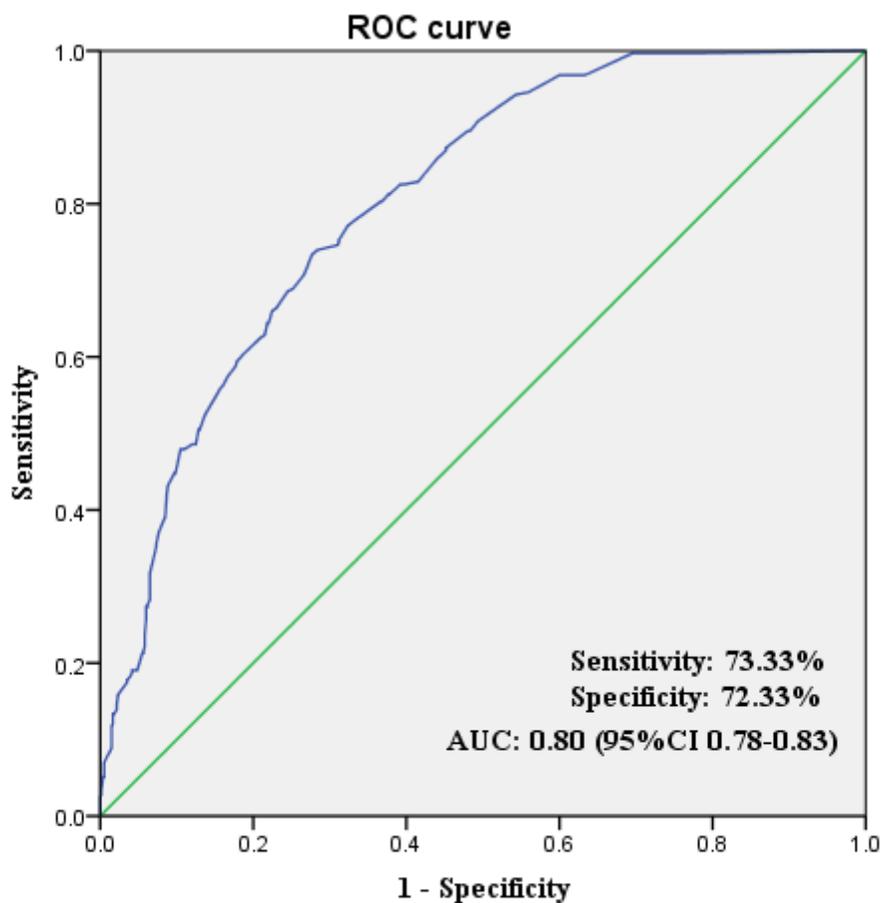


Figure 1

The receiver-operating characteristics (ROC) curve analysis of Gensini Score for predicting ISR.