

Theoretical Basis of Epicardial Resistance Index, a New Physiological Parameter of Lesion Severity, Obtained from Intracoronary Pressure Measurement

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To assess functional severity of the coronary stenotic lesion, we introduce a novel lesion-specific parameter, the epicardial resistance index (ERI), and describe its concept and theoretical basis. The ERI is defined as the ratio of the resistance of an epicardial coronary stenosis to that of downstream myocardium under hyperemic condition. The ERI is calculated as the trans-lesional pressure gradient divided by (Pd-Pv) at maximum hyperemia, where Pd represents the mean distal coronary pressure in the absence of any stenosis and Pv represents the central venous pressure. Based on theoretical conversion of fractional flow reserve (FFR) to ERI, the reported FFR cut-off value of 0.75 for inducible ischemia corresponds to an ERI of 0.33. This new parameter allows the resistance of the each coronary stenosis to be assessed separately even in the presence of multiple lesions in a coronary artery tree. Using the 170 measurements performed in the 90 lesions, the correlation of ERI with the anatomical parameters obtained from QCA was analyzed. By polynomial regression analysis, the ERI showed a significant positive correlation with the QCA-derived %DS ($r=0.67$, $p<0.001$). ERI may have wide application in routine clinical practice especially in the setting of complex catheter-based coronary intervention.

Key words: coronary stenosis, vascular resistance, fractional flow reserve

Introduction

Assessment of the functional severity of stenotic lesion is crucial to determine whether the lesion should be intervened or not in the setting of coronary revascularization procedure^{1)~4)}. We introduce the epicardial resistance index (ERI), a simple, lesion-specific index for the assessment of functional severity of stenosis. The ERI is defined as the ratio of the resistance of the lesion to that of the corresponding downstream myocardium under hyperemic condition¹⁾. The unique feature of ERI is that this new parameter allows the resistance of the each coronary stenosis to be assessed separately, even in the presence of multiple lesions in a coronary artery tree. We describe the concept and theoretical basis of ERI and consider possible clinical applications of this unique physiological index that indicates lesion severity.

Part 1. Concept and Calculation of ERI

Calculations of FFR and ERI (Fig. 1)

Fractional flow reserve (FFR) has been proposed as a value indicating functional severity of a coronary artery stenosis in a simple situation, one stenosis in one coronary tree⁴⁾.

When the pressure proximal to the stenosis (P_{prox}) drops to P_{dist} , distal to the stenosis, this results in a flow reduction from QN to Q , where QN represents the hypothetical blood flow without any stenosis. QN is described as follows:

$$QN = \frac{P_{prox} - Pv}{R} \dots\dots\dots (1)$$

where R represents the resistance of downstream myocardium, and Pv represents venous pressure.

Likewise, the reduced flow Q in the presence of a stenosis is described as follows:

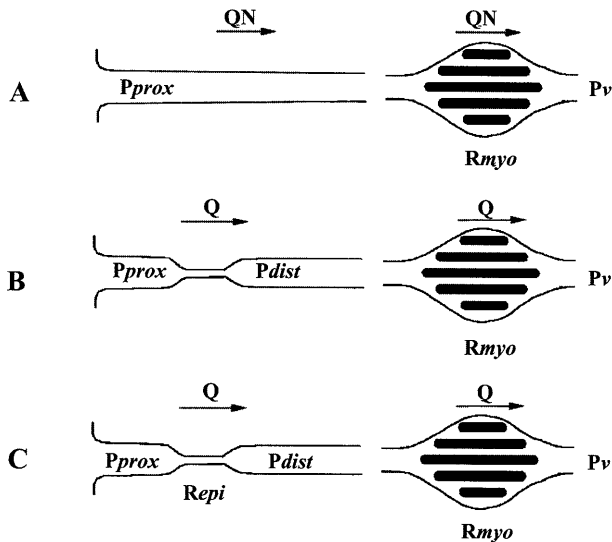


Fig. 1 Calculation of FFR and ERI

ERI = epicardial resistance index, FFR = fractional flow reserve.

$$Q = \frac{P_{dist} - P_v}{R} \dots\dots\dots (2)$$

The fraction of the reduced flow Q to the reserved flow QN , defined as FFR, is calculated by pressure data as follows;

$$\frac{Q}{QN} = \frac{P_{dist} - P_v}{P_{prox} - P_v} \approx \frac{P_{dist}}{P_{prox}} = FFR \dots\dots\dots (3)$$

FFR has been validated for the assessment of severity of coronary stenosis. However, the value of the FFR is influenced when one or more stenoses exist distal to the stenosis of interest, because the pressure distal to the first lesion is affected by the presence of other lesions. To overcome this limitation, we rather focused on the resistance of each individual stenosis. Based on the resistance of the epicardial stenosis ($Repi$) as well as that of the downstream myocardium ($Rmyo$), and assuming that flow (Q) at the lesion and downstream is equal, the following equations can be derived.

$$Q = \frac{P_{prox} - P_{dist}}{Repi} = \frac{P_{dist} - P_v}{Rmyo} \dots\dots\dots (4)$$

$Repi/Rmyo$, the ratio of the resistance at the stenosis to that of downstream myocardium during hyperemia, is termed the epicardial resistance index (ERI). The ERI can be calculated if Q is deleted from equation (4) as follows;

$$ERI = \frac{Repi}{Rmyo} = \frac{P_{prox} - P_{dist}}{P_{dist} - P_v} \approx \frac{P_{prox} - P_{dist}}{P_{dist}} \dots\dots\dots (5)$$

Thus, ERI is the relative resistance of a stenosis under hyperemic condition and ranges from 0 to ∞ . As the stenosis becomes more severe, the ERI increases. By intracoronary pressure measurements, ERI can be calculated for each stenosis individually by simply determining the trans-lesional pressure gradient (ΔPG) and the pressure distal to all stenoses.

Convertibility of ERI to FFR (Fig. 2)

The ERI and FFR are convertible in one specific situation; that is, when only one stenosis exists in a coronary artery tree. The distal pressure can be calculated from ERI and the proximal pressure by deforming equation (5).

$$P_{dist} = \frac{1}{1 + ERI} \cdot P_{prox} + \frac{ERI}{1 + ERI} \cdot P_v \approx \frac{1}{1 + ERI} \cdot P_{prox} \dots\dots\dots (6)$$

When the equation for FFR is substituted by equation (6), FFR can be described in terms of ERI using equation (6) as follows:

$$\begin{aligned} FFR &= \frac{Q}{QN} \\ &= \frac{P_{dist} - P_v}{P_{prox} - P_v} \\ &= \left(\frac{1}{1 + ERI} \cdot P_{prox} + \frac{ERI}{1 + ERI} \cdot P_v - P_v \right) / (P_{prox} - P_v) \\ &\approx \frac{1}{1 + ERI} \end{aligned}$$

On the other hand, ERI can be also described in terms of FFR as follows:

$$\begin{aligned} ERI &= \frac{P_{prox} - P_{dist}}{P_{dist} - P_v} \\ &= \frac{(P_{prox} - P_v)/Rmyo - (P_{dist} - P_v)/Rmyo}{(P_{dist} - P_v)/Rmyo} \\ &= \frac{QN - Q}{Q} \\ &= \frac{1 - Q/QN}{Q/QN} \\ &= \frac{1 - FFR}{FFR} \end{aligned}$$

Theoretically, if the stenosis of interest is the only stenosis existing in a coronary artery tree, ERI can be described as $ERI=(1-FFR)/FFR$, and the reported

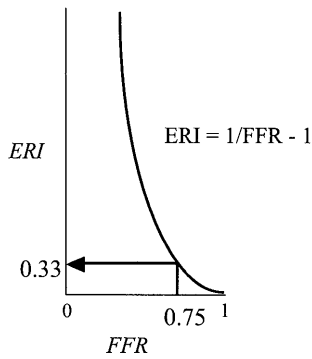


Fig. 2 Convertibility of ERI to FFR

ERI = epicardial resistance index, FFR = fractional flow reserve.

FFR cut-off value of 0.75 for inducible ischemia^{2,4)} corresponds to an ERI of 0.33 $[(1-0.75)/0.75]$ (Fig. 2).

ERI in multiple stenoses (Fig. 3)

If there are two stenoses in a coronary artery tree, and intracoronary pressure drops from P_{prox} (proximal to stenosis) to finally P_{dist} (distal to all stenoses), FFR can be calculated for the total stenoses but cannot describe the severity of each stenosis individually (Fig. 3A).

$$QN = \frac{P_{prox} - P_v}{R_{myo}}$$

$$Q = \frac{P_{prox} - P_{mid}}{R_{epi1}} = \frac{P_{mid} - P_{dist}}{R_{epi2}} = \frac{P_{dist} - P_{dist}}{R_{myo}}$$

$$FFR_{total} = \frac{Q}{QN} = \frac{P_{dist} - P_v}{P_{prox} - P_d} \approx \frac{P_{dist}}{P_{prox}}$$

When the sum of resistance of all stenoses is described as R_{total} , ERI for all stenoses is described as follows:

$$ERI = \frac{R_{total}}{R_{myo}}$$

$$= \frac{P_{prox} - P_{dist}}{P_{dist} - P_v} = \frac{1 - FFR}{FFR}$$

The unique feature of ERI is that ERI allows separate assessment of the resistance of each coronary stenosis, even in the presence of multiple lesions in a coronary artery tree. ERI for each stenosis can be calculated separately as follows:

$$Q = \frac{P_{prox} - P_{mid}}{R_{epi1}}$$

$$Q = \frac{P_{mid} - P_{dist}}{R_{epi2}}$$

$$ERI_{prox} = \frac{R_{epi1}}{R_{myo}}$$

$$ERI_{dist} = \frac{R_{epi2}}{R_{myo}}$$

$$ERI_{prox} = \frac{P_{prox} - P_{mid}}{P_{dist} - P_v} \approx \frac{P_{prox} - P_{mid}}{P_{dist}}$$

$$ERI_{dist} = \frac{P_{mid} - P_{dist}}{P_{dist} - P_v} \approx \frac{P_{mid} - P_{dist}}{P_{dist}}$$

$$ERI = \frac{R_{epi}}{R_{myo}} = \frac{P_{prox} - P_{dist}}{P_{dist} - P_v} \approx \frac{P_{prox} - P_{dist}}{P_{dist}}$$

Moreover, ERI for each lesion can be simply summed.

$$ERI_{total} = \frac{P_{epitotal} - P_{dist}}{R_{myo}}$$

$$= \frac{P_{prox} - P_{dist}}{P_{dist} - P_v}$$

$$= \frac{P_{prox} - P_{mid}}{P_{dist} - P_v} + \frac{P_{mid} - P_{dist}}{P_{dist} - P_v}$$

$$= ERI_{prox} + ERI_{dist}$$

Thus, ERI is especially useful in the presence of multiple stenoses in a coronary tree. The following equation describes the generalized situation (Fig. 3B).

$$ERI_n = \frac{R_n}{R_{myo}}$$

$$ERI_n = \frac{P_n - P_{(n+1)}}{P_{dist} - P_v} \approx \frac{P_n - P_{(n+1)}}{P_{dist}}$$

$$ERI_{total} = \sum_n ERI_n = \frac{1 - FFR}{FFR}$$

Example of ERI Calculation (Fig. 4)

Calculation of ERI in a circumstance where two stenosis (stenosis a: proximal lesion; stenosis b: second (distal) lesion) exist in a coronary artery tree is demonstrated. Intracoronary pressure data obtained for each portion are shown in Fig. 4.

ERI for each stenosis (a and b) is calculated as follows:

$$ERI_a = \frac{100 - 80}{40} = 0.5 (>0.33)$$

$$ERI_b = \frac{80 - 40}{40} = 1 (>0.33)$$

If the ratios of distal pressure to proximal pressure (trans-lesion pressure gradient) for the two stenoses are calculated as shown below, unlike FFR in single stenosis, they do not represent severity of

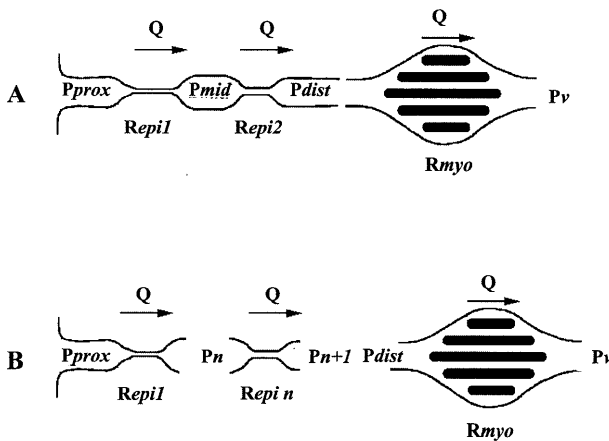


Fig. 3 ERI in multiple stenoses

stenosis.

$$\frac{P_{mid}}{P_{prox}} = \frac{80}{100} = 0.8 (>0.75)$$

$$\frac{P_{dist}}{P_{mid}} = \frac{40}{80} = 0.5 (<0.75)$$

This can be verified as follows. If the ERI value for each stenosis is obtained, the expected pressure following complete dilatation of distal lesion ($Repi2=0$, $P_{mid}=P_{dist}$) can be calculated using the concept of ERI as follows:

$$Repi1 \cdot Q = P_{prox} - P_{dist}$$

$$Rmyo \cdot Q = P_{dist} - P_v$$

$$\therefore \frac{Repi1}{Rmyo} = \frac{P_{prox} - P_{dist}}{P_{dist} - P_v}$$

$$(P_{dist} - P_v) \cdot \frac{Repi1}{Rmyo} = P_{prox} - P_{dist}$$

$$P_{dist} \cdot \left(\frac{Repi1}{Rmyo} + 1 \right) = P_{prox} + P_v \cdot \frac{Repi1}{Rmyo} \approx P_{prox}$$

$$P_{dist} = \frac{P_{prox}}{\left(\frac{Repi1}{Rmyo} + 1 \right)}$$

$$P_{dist} = \frac{P_{prox}}{ERIa + 1}$$

As $ERIa = 0.5$ and $P_{prox} = 100 \text{ mmHg}$,

$$P_{dist} = \frac{100}{0.5 + 1} = 66.66\dots$$

Obviously, ERI does not change.

$$ERIa = \frac{P_{prox} - P_{dist}}{P_{dist}} = \frac{100 - 66.66\dots}{66.66\dots} = 0.5$$

The ratio of distal pressure to proximal pressure

changes.

$$FFR = \frac{P_{dist}}{P_{prox}} = \frac{66.66\dots}{100} \approx 0.67 \neq 0.80$$

Part 2. ERI in Clinical Setting

Methods

Study patients

Seventy-five patients underwent coronary angiography and intracoronary pressure measurements at the time of diagnostic catheterization or before and after percutaneous coronary intervention (PCI). Written informed consent for all procedures was obtained from each patient, and the Investigational Review Board of Tokyo Women's Medical University Hospital approved the study protocol.

Quantitative coronary angiography

Quantitative coronary angiography (QCA) was performed by an independent analyst who was blinded to the results of coronary pressure measurements. It was done using a computer-assisted, automated edge-detection algorithm (AWOS, Siemens, Erlangen, Germany). The external diameter of the contrast-filled catheter was employed for calibration. The minimum luminal diameter (MLD), the reference segment diameter, and the percent diameter stenosis (%DS) at end-diastole were measured from the worst view trace. Lesion length was measured as the distance between the proximal and distal shoulder in the projection demonstrating the stenosis with the least foreshortening.

Intracoronary pressure measurement and ERI calculation

A 0.014-inch pressure wire (Pressure Guide™, Radi Medical System, Uppsala, Sweden) was advanced to the tip of the guide catheter and the observer confirmed that equal pressures were recorded at that position. After intracoronary injection of papaverine (10 mg in the right and 12 mg in the left coronary artery), care was taken to disengage the guide catheter from the coronary ostium to preclude any wedging in the vessel that could reduce maximum hyperemic perfusion. During maximum hyperemia, the pressure wire was pulled back slowly from the distal coronary artery across all of the stenoses until it reached the proximal stenosis-free segment. After checking the site of the pres-

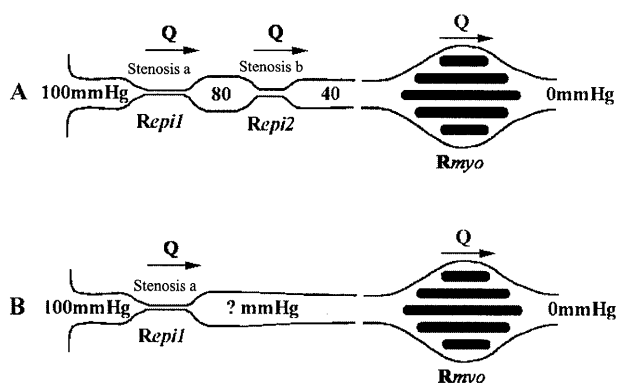


Fig. 4 ERI in Tandem lesions (A) and Estimation of distal pressure after PCI for multiple stenoses using ERI (B)

sure wire tip by coronary angiogram, the coronary pressure was recorded continuously during the pull-back, thus providing the pressure in the distal stenosis-free segment, the pressure gradient of each lesion, and the pressure proximal to all stenoses. Then the ERI for each stenosis was calculated as the trans-lesional pressure gradient divided by the pressure in the distal stenosis-free segment, as described above. When PCI was performed, pressure measurement was repeated at the end of the intervention to calculate the post-procedural ERI.

Statistical analysis

Statistical analysis was performed with SPSS 10.0 software (SPSS Inc., Chicago, Illinois). The relationship between ERI values and QCA parameters was assessed by regression analysis. For analysis, $p < 0.05$ was considered to indicate significance.

Results

Correlation of ERI with anatomical parameters (Fig. 5)

One hundred and seventy measurements of intracoronary pressure and QCA were performed in 90 lesions of 75 patients. Of these 90 lesions, 60 were angiographically isolated lesions and no other pressure gradient was observed except for the lesion. The other 30 lesions (33%) had additional lesions with significant pressure gradients in the same coronary artery. The mean % DS (including pre- and post-PCI) was $45 \pm 21\%$ (range: 3 to 87%). The mean MLD evaluated by QCA was 1.67 ± 0.70 mm (range: 0.35 to 3.56 mm), and the mean reference diameter was 2.93 ± 0.54 mm. In 55 PCI procedures

(55 lesions in 55 patients), a stent was used in 45% of the patients. The QCA-derived minimal luminal diameter (MLD) was 0.90 ± 0.28 mm at baseline (pre-PCI) and increased to 2.29 ± 0.53 mm after the PCI procedure, while %DS was $70 \pm 11\%$ at baseline and decreased to $25 \pm 11\%$ following the procedure. Changes of all the anatomical parameters were statistically significant, except for the slight increase in reference diameter after the procedure. Similarly, the MLA evaluated by IVUS was 2.0 ± 0.4 mm² at baseline and increased to 5.5 ± 1.6 mm² after the procedure. In all the subjects, the coronary pressure was successfully measured without serious complications. The mean ERI was 0.85 ± 0.51 before PCI and decreased significantly to 0.14 ± 0.09 at the end of the intervention.

Using the 170 measurements performed in the 90 lesions, the correlation of ERI with the anatomical parameters obtained from QCA was analyzed. By polynomial regression analysis, the ERI showed a significant positive correlation with the QCA-derived %DS ($r=0.67$, $p<0.001$) (Fig. 5).

Discussion

Evaluation of the functional severity of each coronary stenosis in the presence of multiple lesions in a coronary tree to determine whether or not the lesion is responsible for myocardial ischemia is crucial, especially in the setting of complex percutaneous coronary intervention (PCI)⁵⁻⁸. As we describe in the present article, one can distinguish which lesion (s) is responsible for ischemia when multiple lesions exist in one coronary vascular tree by using ERI. In routine practice, distinction of the culprit lesion from multiple insignificant lesions is still performed on the basis of anatomical severity judged by coronary angiography⁷. Objective quantification of the functional significance of multiple stenoses with undetermined severity at angiography may be useful to avoid unnecessary interventional procedure.

We focused on the resistance of the lesion in assessing functional severity. The resistance of a particular stenosis is truly lesion-specific, and therefore may be more suitable for assessing the physiological severity of each stenosis. Because the absolute

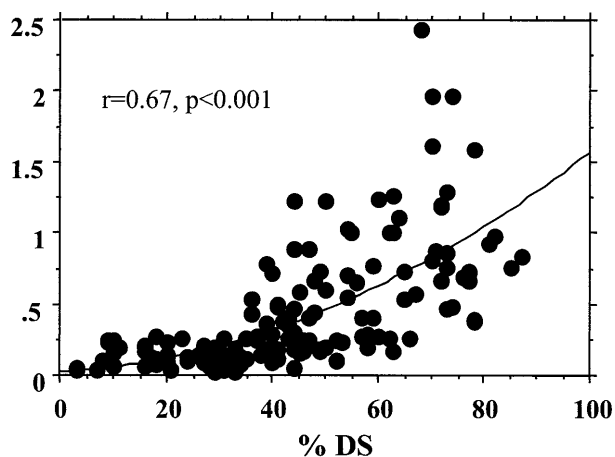
ERI

Fig. 5 Correlation of ERI to QCA-derived % diameter stenosis

$$Y = .024 + .002 * X + 1.347E-4 * X^2; R^2 = .452$$

resistance cannot be calculated unless both the trans-lesional pressure gradient and volumetric flow are available, the ERI is calculated as a ratio of the lesion resistance to the corresponding myocardial resistance, which can be determined from the intracoronary pressures alone. The ERI has some advantages over conventional indexes such as the FFR and coronary flow reserve (CFR). First, the ERI is theoretically designed to assess the hemodynamic significance of individual stenosis in the case of multiple stenoses within the same artery. Even when multiple lesions exist in one coronary artery tree, the ERI for each lesion can be calculated individually. Second, calculation of the ERI is simple and easy, since it is the trans-lesion pressure gradient divided by the distal coronary pressure during hyperemia. Recently, Pijls et al⁵⁾ and De Bruyne et al⁹⁾ have proposed a theoretical basis and provided clinical validation of equations predicting the FFR for sequential stenoses. However, in contrast to the simple calculation of the FFR for a single stenosis, determination for sequential stenoses is complex and requires coronary wedge pressure measurement. On the other hand, the trans-lesional pressure gradient has been utilized for evaluation of lesion severity in previous studies¹⁰⁾⁻¹³⁾. It should be noted, however, that the pressure gradient varies depending on systemic hemodynamics. Furthermore, the pressure distal to the lesion is affected by other dis-

tal lesions that exist in the same artery, therefore lesion severity may be underestimated in the presence of another distal lesion (s) when using the pressure gradient for assessment. In addition, pressure gradient measurement under resting condition also depends on the autoregulation of downstream resistance vessels even in the absence of distal epicardial stenosis.

Lesion assessment by ERI may have other clinical application. ERI can be used for the evaluation of post-procedural functional result of dilated segment. Along with the same line, the final result for a stented segment can be assessed using the concept of ERI even when two stents are employed separately for two lesions in one artery (non-overlapping). ERI value for each stent can be obtained separately by recording the pressure gradient along each stent, and such data may be useful for studies comparing the relationship between the final physiological stent result and the long-term outcome. Indeed, we recently reported in the clinical setting that the ERI value had a significant correlation with the anatomical parameters of the lesion obtained from quantitative coronary angiography or intravascular ultrasound¹⁾. In addition, the post-procedural resistance of the target lesion assessed by ERI was a reliable predictor of the late outcome of catheter based coronary intervention¹⁾. Thus, our new lesion-specific physiological parameter, ERI, seems to be a simple practical tool for making decisions in the catheterization laboratory.

Limitations of ERI

ERI has some limitations. First, if a large side branch exists between two stenoses, the ERI for each lesion cannot be calculated because changes in flow may modify the mutual hemodynamic influence of one stenosis on the other. Second, the influence of myocardial resistance on the ERI value is unclear. In the case of increased myocardial resistance due to diabetes, previous myocardial infarction, and other conditions, the ERI value might underestimate lesion severity. Finally, the ERI does not account for collateral circulation, which affects distal pressure. This is particularly important in patients with chronic coronary artery disease and

variable collateral development.

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冠動脈内圧測定により得られる病変重症度の新しい生理学的指標 Epicardial Resistance Index の基礎理論

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冠動脈狭窄性病変の機能的重症度を評価するため、我々は独自に、病変に特異的な新たな指標である epicardial resistance index (ERI) を考案した。本論文では ERI の概念および理論的基礎を論説する。

ERI は、薬物による最大充血状態 (hyperemia) 下において、心外膜に存在する冠動脈の狭窄性病変の血管抵抗と狭窄以下の末梢心筋部の抵抗の比で表される指標である。ERI は先端に圧センサーチップを有する圧測定ワイヤを用いて、狭窄病変前後の冠動脈内圧を測定することで得られる病変部の圧較差を、末梢部血管内圧-中心静脈圧（末梢部心筋での圧較差）で除することにより計算される。測定を最大充血状態で行うのは、冠動脈内圧の自己調整機構の影響を排除するためである。

冠動脈内圧の測定による狭窄病変の評価としては、従来 fractional flow reserve (FFR) が指標として用いられていたが、同一冠動脈内に複数の病変を有する場合、個々の病変の重症度を個別に評価することは不可能であった。今回我々が考案した新たな指標である ERI は、個々の病変の抵抗を表す指標であるため、病変特異的に重症度評価を行うことが可能となった。

単一病変において、虚血が生じえる病変の重症度の閾値は、FFR では cut-off 値 <0.75 と報告されている。我々は、数学的変換によりこの虚血閾値が ERI では、ERI 値 >0.33 であることを証明した。さらに FFR と異なり、同一血管に複数の病変がある場合もこの ERI 値が個々に計算可能で、重症度評価の指標となることを明らかにした。実臨床 90 病変において、PCI 前後で病変の ERI 測定および定量的冠動脈造影を比較した結果、ERI と血管造影上の狭窄度は $r=0.67$ と良好な正相関を示した。

我々の考案した ERI は、実際の臨床上問題となる複数の病変を有する複雑病変の治療に際し、どの病変を治療すれば虚血を解除することが可能か事前に判別することができ、不要な治療を避け、必要な病変のみ選択治療を施行できるという点で、特にカテーテルによる冠動脈治療上大きな意義があると考えられる。