Recruitable collateral blood flow index predicts coronary instent restenosis after percutaneous coronary intervention

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Aims Collateral flow may influence long-term results after percutaneous coronary intervention (PCI) because of haemodynamic forces compete with the antegrade flow through the dilated lesion. The aim of the study was to assess the influence of recruitable collateral blood flow on restenosis in patients undergoing PCI with bare metal stents and using optimal antithrombotic treatment.

Methods and results In 95 patients, 95 de novo lesions were treated with PCI and a bare metal stent. Fractional flow reserve (FFR) at maximum hyperaemia induced by intravenous adenosine was determined. The pressure-derived collateral flow index (CFI) was determined as \( \frac{(P_w - P_{cvp})}{(P_a - P_{cvp})} \), where \( P_w \) represents coronary wedge pressure, \( P_{cvp} \) central venous pressure, and \( P_a \) mean aortic blood pressure. Both were measured during transient coronary occlusion by a balloon inflation of 30 s. Pre-interventional FFR (0.65 ± 0.20) correlated inversely with the CFI (0.18 ± 0.11), \( r = -0.356, P < 0.001 \). After 9 months, binary angiographic restenosis (>50% diameter stenosis) was seen in 29.1%. Compared to patients with poorly developed collaterals (CFI < 0.25), patients with well-developed collaterals (CFI ≥ 0.25) had a lower pre-interventional FFR (0.50 ± 0.14 vs. 0.72 ± 0.18, \( P < 0.001 \)), a higher CFI (0.33 ± 0.08 vs. 0.13 ± 0.07, \( P < 0.001 \)), and a higher binary restenosis rate (54.2% vs. 19.4, \( P = 0.003 \)). CFI*100 was an independent predictor of restenosis after 9 months (odds ratio 1.07, 95% CI 1.02–1.12, \( P = 0.016 \)).

Conclusion Recruitable collateral blood flow measured during balloon inflation predicts angiographic instent restenosis in PCI patients treated with bare metal stents.

KEYWORDS
Collaterals; Restenosis; Stent; Fractional flow reserve

Introduction
The coronary collateral circulation is a complementary source of blood supply to myocardium jeopardized by stenosis of a coronary vessel. Several studies have documented that collateral blood flow is sufficient to prevent ischaemia when fractional collateral flow, calculated from mean aortic pressure derived collateral blood flow index (CFI) is determined from simultaneous measurements of mean aortic pressure, coronary wedge pressure, and central venous pressure, and has been validated by myocardial perfusion scintigraphy and after angiogenic therapy.12 The aim of this study was to assess the influence of recruitable collateral blood flow with an intracoronary pressure-derived CFI on angiographic restenosis in patients undergoing PCI with bare metal stents and optimal antithrombotic treatment.

growth factors and stimuli to endothelial proliferation, thus favouring a restenotic milieu and later progression of disease. Progression of native coronary artery disease after surgical coronary grafting is well documented and has also been attributed to decreased flow proximal to the implanted graft.

Intracoronary pressure measurements can be used to determine collateral flow,1,9,10 as perfusion pressure distal to an occluded stenosis originate from collaterals. The pressure derived collateral blood flow index (CFI) is determined from simultaneous measurements of mean aortic pressure, coronary wedge pressure, and central venous pressure, and has been validated by myocardial perfusion scintigraphy and after angiogenic therapy.12 The aim of this study was to assess the influence of recruitable collateral blood flow with an intracoronary pressure-derived CFI on angiographic restenosis in patients undergoing PCI with bare metal stents and optimal antithrombotic treatment.

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Methods

Patient population

From October 2002–December 2004, 95 patients with a single lesion in a native coronary artery were enrolled in three centres; Odense University Hospital, Aarhus University Hospital, Skåby Sygehus, and Rigshospitalet, Copenhagen, Denmark. Patients with acute myocardial infarction, vein grafts, and chronic total occlusions were excluded. All patients were on aspirin (75 mg a day) and clopidogrel (loading dose 300 mg 24 h before PCI and continued with 75 mg/day for 12 months). Out of 95 patients, 86 patients had 9 months angiographic follow-up (91%). The study population was divided into a group with well developed (CFI ≥ 0.25) and poorly developed collaterals (CFI < 0.25). The patients provided written, informed consent, and the local institutional review board (The Scientific Ethics Committee for the Counties of Vejle and Funen, Denmark) approved the protocol (case no. 20020045).

Pressure-derived collateral flow index and fractional flow reserve

Prior to the pressure measurements and intervention, 200 μg nitroglycerin intracoronary and heparin 5–10.000 U intravenously were administered. A 0.014 in pressure guidewire (PressureWire, Radi Medical Systems, Uppsala, Sweden or WaweWire, JoMed, Helsinborg, Sweden) was passed through the target lesion with the lumen tip as distal in the coronary artery as possible. Fractional flow reserve (FFR) at maximum hyperaemia induced by intravenous adenosine (140 μg/kg per min) was determined by the ratio $P_d/P_s$, where $P_d$ represents mean hyperaemic coronary pressure distal to the stenosis measured by the pressure wire, and $P_s$ represents mean aortic pressure measured by the guiding catheter (Figure 1). The pressure-derived collateral flow index (CFI) was determined as $(P_w - P_{cvp})/(P_s - P_{cvp})$, where $P_w$ represents coronary wedge pressure and $P_{cvp}$ represent the central venous pressure obtained from a 6F multipurpose catheter introduced via the femoral vein to the right atrium. CFI was measured by simultaneous recordings of all pressures during transient coronary occlusion by balloon inflation of 30 s (Figure 2). CFI was calculated for the first and last balloon inflation to evaluate if CFI was influenced by repeated ischaemic episodes during balloon inflation.

Quantitative coronary angiography

When the patients were referred to PCI, the diameter stenosis was based on visual estimates by the operator using the guiding catheter and reference points on the guidewire as reference according to normal clinical practise at the three participating hospitals. Angiographic studies performed at baseline, post-procedurally, and at follow-up were sent to assessment to the Angiographic Core Laboratory (Catheterization Laboratory, Odense University Hospital, Odense, Denmark). The computer-based ACOM.PC V3.1 (Siemens Medical Systems, Inc.) was used for QCA analysis. Quantitative analysis was performed offline by experienced personnel unaware of the pressure measurements. The same projections were used at all time points. The following angiographic measurements were measured: reference diameter of the vessel, minimal luminal diameter (MLD), percent diameter stenosis $[1- (MLD/reference segment diameter)] \times 100$, and late lumen loss (difference between MLD at the end of the procedure and MLD at follow-up).

Study endpoint and definitions

The primary endpoint of the study was binary angiographic restenosis (BAR) > 50% after 9 months.

Statistical analysis

The statistical analysis was carried out using SPSS 14.0. Categorical data were presented as counts and percentages and compared by the Pearson χ² test or the Fisher exact test. Continuous data were expressed as mean ± SD and compared by t-test. All statistical tests were two-tailed. Separate logistic regression analyses were performed to identify univariate predictors of BAR, and a subsequent stepwise (forward conditional) regression analysis was performed with entry and removal criteria of 0.05 and 0.10, respectively. Logistic regression analyses were presented as odds ratio with 95% confidence intervals (OR, 95% CI). For continuous variables in the regression analysis, the linearity assumption was assessed by categorizing the continuous variable before the variables were included in the analysis. CFI (the variable of interest) has been multiplied by 100. For CFI=100, the linearity has been assessed by investigating different power functions of CFI, and CFI=100 supported the assumption of linearity. A Bland-Altman plot is provided. This plot depicts the relationship between the average value between CFI calculated with central venous pressure and CFI calculated without central venous pressure and the absolute difference between CFI with and without central venous pressure, the relationship between the average value between CFI during the first balloon inflation and CFI during the last balloon inflation and the absolute difference between CFI during the first and last balloon inflation. Repeated measurements with CFI (first and last balloon inflation) were compared with a paired t-test.

Figure 1 Study design.

Figure 2 Simultaneous recording of arterial ($P_a$), central venous ($P_{cvp}$), and coronary wedge pressure ($P_w$) during balloon inflation.
Anticipating a mean BAR (50%) rate of 25% within 9 months, 166 patients enrolled provided a 80% power and a 5% alpha to detect a difference of 20% (event rate of 15 and 35%, respectively). A P-value < 0.05 (two-sided) was considered statistically significant.

### Results

#### Baseline characteristics and procedural results

Out of the included 95 patients, 86 patients had 9 months angiographic follow-up (91%). The baseline characteristics of the nine non-completers were very similar to those of the 86 completers and CFI did not differ significantly between completers (CFI = 0.18 ± 0.11) and non-completers (CFI = 0.16 ± 0.10), P = 0.511. One of the non-completers had a CFI ≥ 0.25 and eight of the non-completers had a CFI < 0.25.

The clinical features at baseline for the 86 completers are shown in Table 1. Age and risk factors did not differ significantly between the two groups with well (CFI ≥ 0.25, n = 24) and poorly (CFI < 0.25, n = 62) developed collateral vessels.

#### Collateral flow index, angiographic data, and fractional flow reserve

In the group with good collaterals, CFI was 0.33 ± 0.08, and 0.13 ± 0.07 in the group with poor collaterals. The occurrence of three vessel coronary artery diseases and the distribution of the coronary arteries undergoing PCI were similar in the two groups. Patients with poor collaterals had significantly less severe diameter stenoses than those with good collaterals (66.2 ± 13.9 vs. 73.1 ± 10.6, P = 0.033). Vessel size, lesion type, and length did not differ between the two groups (Table 2). Pre-interventional FFR was significantly decreased in the group with CFI ≥ 0.25 compared to the group with CFI < 0.25 (0.50 ± 0.14 vs. 0.72 ± 0.18, P < 0.001). FFR pre-intervention correlated to the angiographic diameter stenosis (r = 0.504, P < 0.001), Figure 3, and CFI during transient coronary occlusion by balloon inflation of 30 s correlated weakly to the angiographic diameter stenosis (r = 0.246, P = 0.024, Figure 3). FFR after PCI did not differ between the two groups (0.96 ± 0.09 vs. 0.95 ± 0.07, P = 0.735).

#### Central venous pressure

Mean right atrial pressure was 6.12 ± 3.13, and did not change between the first and last balloon inflation 6.07 ± 3.13 vs. 6.18 ± 3.25 mmHg, P = 0.993. Calculating CFI with central venous pressure [CFI = (P_w – P_cvp) / (P_a – P_cvp)] compared to CFI where the central venous pressure was ignored [CFI = (P_w / P_a)] demonstrated a significantly higher mean CFI when the central venous pressure was ignored: 0.18 ± 0.11 vs. 0.24 ± 0.11, P < 0.001. Thirteen patients (21%) with a CFI < 0.25 had a CFI ≥ 0.25 when the venous central pressure was ignored (P < 0.001). Correspondingly, the CFI for patients with angiographic restenosis would have been higher 0.23 ± 0.13 vs. 0.29 ± 0.12, P < 0.001. CFI (ignoring central venous pressure) correlated significantly to CFI (including central venous pressure) r = 0.968, P < 0.001.

The Bland–Altman plot (Figure 4) shows the trend for measuring lower values of CFI when the CVP is not included in the calculation, especially in the lower range of values.

#### Repeated collateral flow index measurements

In 49 patients (57%), more than one transient coronary occlusion by balloon inflation of 30 s was performed.
Neither the CFI (0.20 ± 0.13 vs. 0.21 ± 0.13, P = 0.765) nor the mean coronary wedge pressure (Pw) (24.9 ± 14.9 vs. 25.8 ± 13.0 mmHg, P = 0.345) changed significantly between the first and last inflation. CFI during the first balloon inflation for 30 s correlated significantly with the CFI during the last balloon inflation, r = 0.882, P < 0.001. The Bland–Altman plot (Figure 5) shows that CFI did not differ between the first and last balloon inflation, neither at all nor in the lower or higher range of values.

Angiographic follow-up and event rate
At nine months follow-up, 29.7% of the patients were not free from angina pectoris [18 patients (28.8%) in the group with CFI < 0.25 and eight patients (33.3%) in the group with CFI ≥ 0.25, P = 0.228], 29.1% had a BAR, and 25.6% had target lesion revascularization (Table 3). The BAR rate was 21.1% (n = 8) for RCA lesions, 30.4% (n = 7) for LAD lesions, and 37.5% (n = 9) for LCX lesions. Six patients (7.0%) had PCI and two patients (2.3%) had coronary artery bypass grafting of other lesions than the study lesion. In patients with CFI ≥ 0.25, 54.2% had angiographic restenosis compared to the group with CFI < 0.25 where angiographic restenosis was seen in 19.4%, P = 0.003. In patients with angiographic restenosis, the mean CFI at the time of index PCI was 0.23 ± 0.13 compared to patients without significant restenosis 0.17 ± 0.10, P = 0.012 (Figure 6). In lesions with BAR mean CFI at the time of index PCI was RCA: 0.25 ± 0.14; LAD 0.20 ± 0.11; and LCX 0.27 ± 0.13. During the 9 months follow-up, no stent thrombosis was seen and none of the patients died or suffered an acute myocardial infarction.

Predictors of BAR
Logistic regression was used to assess the independent predictors of BAR at 9 months. The parameters examined using univariate logistic regression analysis is shown in Table 4. CFI*100 (OR 1.05, 95% CI 1.01–1.10; P = 0.017) and reference vessel diameter (OR 0.16, 95% CI 0.05–0.50; P = 0.002) were significantly associated with a reduced BAR.

![Figure 3](#) FFR vs. angiographic diameter stenosis (left) and CFI vs. angiographic diameter stenosis (right). FFR and CFI correlate to the angiographic diameter stenosis.

![Figure 4](#) Bland–Altman plot of the relationship between CFI calculated with and without central venous pressure (CVP). The x-axis depicts the average value between CFI with CVP and CFI without CVP, while the y-axis depicts the absolute difference between CFI with CVP and CFI without CVP.

![Figure 5](#) Bland–Altman plot of the relationship between CFI during the first and last balloon inflation. The x-axis depicts the average value between CFI during the first and last balloon inflation, while the y-axis depicts the absolute difference between CFI during the first and last balloon inflation. The limit of agreements is –0.13 to 0.11.
To adjust for differences in lesion factors, we performed a multiple logistic regression analysis including CFI*100 (as the variable of primary interest) and reference vessel diameter (as a well known factor influencing on BAR) by forced entry and parameters with a P-value, 0.20 (from the univariate analysis) in a forward stepwise procedure. Included in the forward procedure were lesion length, stent length, FFR pre PCI, and FFR post PCI. After these adjustment, CFI*100, reference vessel diameter and stent length were found to be independent predictors of BAR at 9 months (Table 5). Performing a backward stepwise procedure showed the same independent predictors of BAR. The final model classifies 81% correct using a cut off value for predicted probabilities of 0.5.

In patients without nine months angiographic follow-up, the mean CFI was 0.16 ± 0.10 and eight patients had a value < 0.25.

**Number of patients included**

According to the power calculation, 166 patients were expected to be included. However, during the enrolment period, the drug eluting stents were implemented for clinical use, and the study was stopped before enrolment of the 166 patients not to have a selective cohort with bare metal stents.

Calculating the power with (1) the 86 completers in the study: for a comparison of two independent binomial proportions using the likelihood ratio statistic with a *χ²* approximation with a two-sided significance level of 0.05, a total sample size of 86 assuming a balanced design has an approximate power of 0.581 when the proportions are 0.15 and 0.35.

Calculating the power with (2) the observed difference of 54.2% – 19.4% = 34.8% in the event rate with BAR: for a comparison of two independent binomial proportions using the likelihood ratio statistic with a *χ²* approximation with a two-sided significance level of 0.05, a total sample size of 86 assuming a balanced design has an approximate power of 0.925 when the proportions are 0.194 and 0.542.

**Discussion**

This study shows that CFI measured during PCI was a predictor of angiographic restenosis within 9 months in patients treated with bare metal stents. The higher the CFI, the higher the BAR. The degree of coronary artery stenosis correlated with CFI, which is in accordance with data showing that coronary artery stenosis severity is related to the
collateral circulation of the human heart. However, only CFI was a predictor of angiographic restenosis. Previous studies have shown that a high coronary wedge pressure or CFI is associated with a higher recurrence of stenosis after percutaneous coronary balloon angioplasty. Wahl et al. demonstrated that patients with restenosis after PCI had a more extended collateral supply to the recipient area than patients without restenosis. In Wahl et al.’s study, 43% of the patients were treated with stent. The patients did not have systematic angiographic follow-up, but individuals with signs or symptoms of myocardial ischaemia, or those scheduled for PCI of a second lesion underwent re-angiography. The patients with restenosis had a CFI of 0.26 ± 0.14 which is comparable to the results of the present study. Also, they did not measure the central venous pressure, but used a fixed value. While a highly developed collateral supply predicts restenosis, collaterals have a beneficial impact on the occurrence of other major ischaemic events. Thus, the collaterals seem to have different effects, as they may be both protective for cardiac events related to coronary artery occlusions and increase the risk of restenosis. Competing haemodynamic forces for antegrade flow in the stented lesion may alter shear stress, endothelial proliferation, and platelet activity, thus favouring a restenotic milieu and later progression of disease. Progression of disease may be accelerated by the retrograde development of collaterals and pressurization distal to the lesion that was already active. Similarly, progression of native coronary artery disease after surgical coronary grafting is well documented and has been attributed to the decreased trans-stenotic flow induced by the graft.

Repeated ischaemic episodes and recruitment of collaterals

In the present study, the CFI did not increase by repeated ischaemic episodes during balloon inflation. This is in contrast to a study by Billinger et al., who demonstrated that the myocardial tolerance to repetitive ischaemia was closely related to collateral recruitment in patients with few collaterals (CFI<0.13). They studied patients with a low CFI, and they had twice the balloon occlusion time of in the present study. According to our data, patients with CFI<0.25 had a higher CFI at the last balloon inflation than at the first balloon inflation, but the increase was not statistically significant.

Influence of central venous pressure on collateral flow index

The original validation of CFI relied on calculations, including coronary wedge pressure, aortic pressure, and central venous pressure. The latter is rarely measured in clinical practice and in several other studies, the central venous pressure is either ignored or assigned a fixed value (5 mmHg). During coronary occlusion, the coronary wedge pressure is relatively low, and the failure to include the central venous pressure may cause significantly errors. Ignoring the central venous pressure in the present study would have resulted in significant higher CFI. Also, CFI for patients with angiographic restenosis would have been significantly higher. Importantly, 21% of the patients with a true CFI < 0.25 would have been classified as having CFI ≥ 0.25 if the central venous pressure was ignored. Recently, the importance of measuring the central venous pressure was demonstrated by Vogel et al. They validated the concept of pressure-derived collateral-flow assessment to measurements of collateral-derived myocardial blood flow by contrast echocardiography and demonstrated that inclusion of central venous pressure was necessary to optimize the measurements.

All patients were treated with bare metal stents, as part of the routine at the time of recruitment of patients, and the mean FFR (≥0.95 in both groups) after coronary artery stenting was comparable in both groups. After treatment with bare metal stents, several studies have demonstrated that FFR predicts major cardiac events. However, even with optimal antithrombotic treatment (aspirin and clopidogrel for >9 months) and with acceptable FFR values, the overall angiographic instant restenoses rate was 29% which are comparable to the placebo group in drug eluting stent trials. In patients with well-developed collaterals and a CFI ≥ 0.25, the restenosis rate was even more than 50%.

Study limitations

Several limitations related to the study design should be taken into account: first, 86 out of 95 patients had 9 months angiographic follow-up (91%). The exclusion of patients based on data availability can introduce serious selection bias; however, the baseline characteristics of the nine non-completers were very similar to those of the 86 completers. One of the non-completers had a CFI > 0.25 and eight of the non-completers had a CFI < 0.25. Assuming that these patients were free from angina and free from BAR, as they by them self cancelled the angiographic follow-up, BAR in patients with CFI > 0.25 would have been 52.0% compared to the group with CFI < 0.25, where BAR would have been 17.1%, P = 0.001.

Secondly, all patients were treated with bare metal stents and the overall angiographic restenosis rate was 29%, which is comparable to the restenosis rates of the control group in drug eluting stent trials. The use of drug eluting stents has reduced restenosis rates dramatically, and our results cannot be extended to patients treated with drug eluting stents. In chronic total occlusions successful recanalization with PCI causes immediate attenuation of collateral function and a further regression during a follow-up of 5 months. It remains unknown, if this is also the case in subtotal coronary stenoses of the present investigation. However, CFI was not influence by repeated ischaemia episodes during balloon inflation.

Thirdly, the patients were referred to PCI for clinical and angiographic reasons. When the patients were referred to PCI, the lesion diameters were assessed visually by the operators as in normal clinical practise at the three centres participating in this study. By the following QCA analysis, seven patients had a diameter stenosis of <50%. It is well known that visual estimates normally are higher than QCA measurements. Eliminating these seven patients from the analysis, FFR pre-intervention still correlated to the angiographic diameter stenosis (r = −0.517 P < 0.001), whereas CFI during transient coronary occlusion by balloon inflation of 30 s no longer correlated to the angiographic diameter stenosis (r = 0.140, P = 0.208).

Fourthly, the expected 166 patients were not enrolled because of changes in clinical practise with use of drug...
eluting stents; however, the power of the study was more than 90% (92.5%) with the observed proportions.

Conclusion
The method used in this study to derive an index of collateral flow from simultaneous pressure recordings, is rapid and relatively simple to apply with standard equipment and may be a valid tool to predict lesions with high restenosis potential.

Conflict of interest: none declared.

Appendix

<table>
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<tr>
<th>Types of stent implanted</th>
<th>CFI ≥ 0.25</th>
<th>CFI &lt; 0.25</th>
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</thead>
<tbody>
<tr>
<td>Flexmaster, n (%)</td>
<td>5 (20.8)</td>
<td>18 (26.2)</td>
</tr>
<tr>
<td>BX Sonic, n (%)</td>
<td>6 (25.0)</td>
<td>14 (20.3)</td>
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<tr>
<td>Express, n (%)</td>
<td>6 (25.0)</td>
<td>23 (33.3)</td>
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<td>Motion, n (%)</td>
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<td>4 (5.8)</td>
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<td>Multilink Pixel, n (%)</td>
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References