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INFLUENCE OF VARIABLE NATIVE ARTERIAL DIAMETER ON FRACTIONAL FLOW RESERVE: AN IN-VITRO STUDY

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ABSTRACT

Fractional flow reserve (FFR), the ratio of the pressures distal (P_d) and proximal (P_a) to a stenosis, and coronary flow reserve (CFR), the ratio of flows at maximal vasodilation to the resting condition, are widely used for determining the functional severity of a coronary artery stenosis. However, the diameter of the native artery might influence the FFR values. Therefore, using an *in-vitro* experimental study, we tested the variation of FFR for two arterial diameters, 2.5 mm (N1) and 3 mm (N2). We *hypothesize* that FFR is not influenced by native arterial diameter. For both N1 and N2, vasodilation-distal perfusion pressure (CFR-P_{rh}) curves were obtained using a 0.35 mm guidewire by simulating physiologic flows under different blockage conditions: mild (64% area stenosis (AS)), intermediate (80% AS) and severe (90% AS). The FFR values for the two arterial models differed insignificantly, within 3%, for mild and intermediate stenoses but differed appreciably for severe stenosis (~25%). This significant difference in FFR values for severe stenosis can be attributed to relatively larger difference in guidewire obstruction effect at the stenotic throat region of the two native arterial models. These findings confirm that FFR will not differ for the clinically relevant cases of mild and intermediate stenosis for different arterial diameters.

INTRODUCTION

The severity of a coronary artery stenosis is measured by introducing a guidewire to evaluate functional parameters such as FFR and CFR. Guidewires are usually used for assessing functional severity of intermediate to severe stenosis where a cut-off value between 0.75 and 0.8 is used to decide on intervention. Lower FFR values (<0.75) typically leads to intervention. Lower native diameter typically results in higher pressure drops due to increased wall shear stress. In contrast, the hyperemic flow values are likely to be lower for a smaller native artery diameter, which in turn, reduces the pressure drop. Considering these scenarios, FFR and CFR values need assessment for different native diameters.

Therefore, in this study, we *hypothesize* that FFR is *not* influenced by native arterial diameter. This hypothesis was tested using two native diameters of 2.5 mm (N1) and 3 mm (N2), using an *in-vitro* experimental set up. Pressure and simultaneous flow readings were obtained in three representative blockages (64% AS – mild, 80% AS – intermediate and 90% AS – severe) with a 0.35 mm or 0.014" (G014) guidewire.

METHODOLOGY

Experimental Procedure. The detailed explanation of the experimental procedure may be found in Banerjee *et al.* [1]. Linear vasodilation-distal perfusion curves (CFR-P_{rh}) were obtained experimentally in both native arteries with the guidewire. To keep the models *physiologically* comparable, the zero flow mean pressures (P_{zf}) were kept constant at ~ 20 mmHg for both native diameters. Measured pressure drops at hyperemic flow rates were used to calculate FFR in the three representative stenoses.

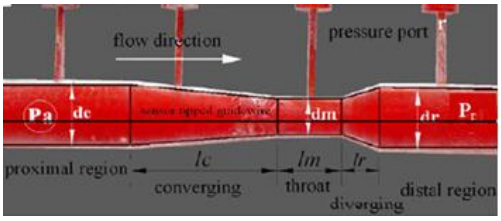

Figure 1: Test section of a 64% area stenosis

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Assumptions. A typical geometry for the stenosis models used is shown in Figure 1. The geometry for N2 was based on the angiographic evidence by Wilson *et al*. [3]. *Geometric similarity* was used to obtain the values for N1 case. The dimensions of stenotic sections used are tabulated in Table 1. A basal flow rate of 50 ml/min for N2 was based on the study by Hundley *et al.* [2]. For N1, a basal flow of 42 ml/min was obtained based on *Reynolds similarity*. CFR values for pathophysiological conditions were used based on the results from 32 patient group reported by Wilson *et al*. [3]. Proximal pressures were considered to be 84 mmHg (mild), 86 mmHg (intermediate) and 89 mmHg (severe) based on Wilson *et al*. [3]. Any microvascular dysfunction was ignored.

Experimental Measurements. The schematic of the experimental setup and details of experimental measurements can be found in Banerjee et al [1]. A typical input flow and pressure pulse is shown in Figure 2.

Table 1: Dimensions of the stenotic geometries used.

Configuration	*lc (mm)*	*lm (mm)*	*lr (mm)*	*dm (mm)*
Case A - 3 mm				
90AS	6.28	0.39	1.59	0.98
80AS	6.35	0.95	1.62	1.32
64AS	6.96	3.15	1.79	1.75
Case B - 2.5 mm				
90AS	5.00	0.63	1.25	0.78
80AS	5.00	1.33	1.25	1.12
64AS	5.00	2.67	1.25	1.50

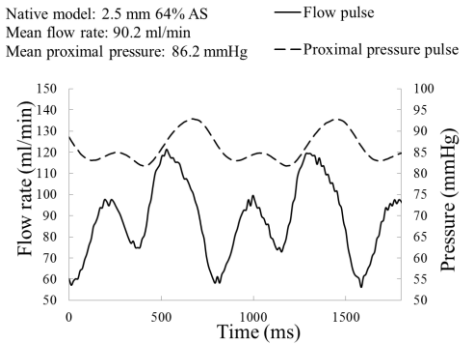

Figure 2: An example of flow and pressure pulse obtained.

RESULTS AND DISCUSSIONS

CFR-P_{rh} Curve. The relationship between CFR and mean distal pressure (P_{rh}) for the two native arteries using guidewire is shown in Figure 3. The distal pressures for mild, intermediate and severe stenosis for N1 were 73.84 mmHg, 62.95 mmHg and 38.94 mmHg, respectively. The CFR values for the corresponding cases were 3.18, 2.55 and 1.14. The distal pressures for mild, intermediate and severe stenosis for N2 were 75.34 mmHg, 64.45 mmHg and 52.21 mmHg, respectively. The CFR values for the corresponding cases were 3.25, 2.60 and 1.88.

The hyperemic flow rates, measured pressure drops, and calculated values of FFR for the two arterial models using G014 are summarized in Table 2.

Comparison of FFR. For guidewire, the hyperemic flow rates for N1 and N2 differed by 26.4 ml/min (mild), 22.9 ml/min (intermediate), and 46.1 ml/min (severe). While Reynolds similarity provides a reasonable (within 1%) estimate for the comparison of hyperemic flow rates in the two arteries for mild and intermediate stenosis, for severe stenosis, a reduced flow rate was obtained from the CFR-P_{rh}. This was necessitated from the fact that the guidewire obstruction was significant for severe stenosis. Reynolds similarity holds true when the guidewire obstruction effect was minimal when compared to the percentage area stenosis.

The corresponding FFR values (Table 2) for N1 and N2 were similar, within 3 %, for mild and intermediate cases but was appreciable in severe stenosis case (~25%). This significant difference in FFR values for severe stenosis can be attributed to relatively larger difference in guidewire obstruction effect at the stenotic throat region of the two native arterial models.

For a typical clinical setting, the severe stenosis is diagnosed by anatomical endpoints such as angiographic images and thus functional assessments are generally not required. On the other hand, for mild to intermediate stenosis, functional assessment such as FFR is obtained in addition to angiographic end points to determine the stenotic severity. Hence, we believe that variability of native diameter will not influence clinical treatment protocol for mild and intermediate stenosis.

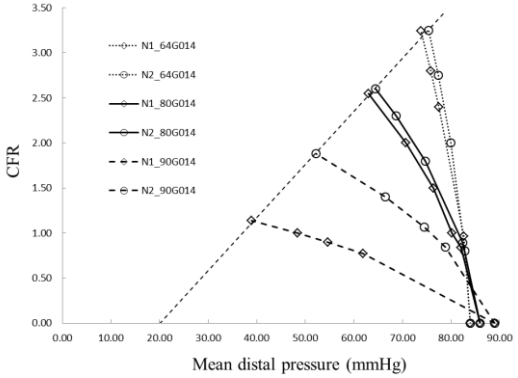

Figure 3: CFR-P_{rh} curve for both native arteries with G014.

Table 2: Table comparing the without and with guidewire cases for the two arterial models at 80%AS.

	Hyperemic flow (ml/min)		*Pressure drop (mm Hg)*		*FFR*		FFR % difference
	N1	N2	N1	N2	N1	N2	
Mild	136.10	162.50	10.22	8.66	0.88	0.90	2.22
Intermediate	107.10	130.00	23.05	21.55	0.73	0.75	2.67
Severe	47.88	94.00	50.06	36.79	0.44	0.59	25.42

Pa = 84 mmHg (mild), 86 mmHg (intermediate), 89 mmHg (severe)

CONCLUSIONS

With a 0.35 mm guidewire inserted, the FFR values were similar for the mild and intermediate stenosis (<3%) for the N1 and N2 artery diameters. However, there was variability between N1 and N2 for the severe case (~25%). These findings confirm that FFR will not differ for the clinically relevant cases of mild to intermediate stenosis for different arterial diameters and will not influence clinical protocol.

REFERENCES

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