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Influence of newly designed monorail pressure sensor catheter on coronary diagnostic parameters: An in vitro study

Rupak K. Banerjee *, Srikara V. Peelukhana, Ishan Goswami

Mechanical and Materials Engineering Department, University of Cincinnati, 593, Rhodes Hall, ML 0072, Cincinnati, OH 45221, United States

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ABSTRACT

The decision to perform intervention on a patient with coronary stenosis is often based on functional diagnostic parameters obtained from pressure and flow measurements using sensor-tipped guidewire at maximal vasodilation (hyperemia). Recently, a rapid exchange Monorail Pressure Sensor catheter of 0.022″ diameter (MPS22), with pressure sensor at distal end has been developed for improved assessment of stenosis severity. The hollow shaft of the MPS22 is designed to slide over any standard 0.014″ guidewire (G14). Hence, influence of MPS22 diameter on coronary diagnostic parameters needs investigation. An in vitro experiment was conducted to replicate physiologic flows in three representative area stenosis (AS): mild (64% AS), intermediate (80% AS), and severe (90% AS), for two arterial diameters, 3 mm (N2; more common) and 2.5 mm (N1). Influence of MPS22 on diagnostic parameters: fractional flow reserve (FFR) and pressure drop coefficient (CDP) was evaluated both at hyperemic and basal conditions, while comparing it with G14. The FFR values decreased for the MPS22 in comparison to G14, (Mild: 0.87 vs 0.88, Intermediate: 0.68 vs 0.73, Severe: 0.48 vs 0.56) and CDP values increased (Mild: 16 vs 14, Intermediate: 75 vs 56, Severe: 370 vs 182) for N2. Similar trend was observed in the case of N1. The FFR values were found to be well above (mild) and below (intermediate and severe) the diagnostic cut-off of 0.75. Therefore, *MPS22 catheter can be used as a possible alternative to G14*. Further, irrespective of the MPS22 or G14, basal FFR (FFR_b) had overlapping ranges in close proximity for clinically relevant mild and intermediate stenoses that will lead to diagnostic uncertainty under both N1 and N2. However, CDP_b had distinct ranges for different stenosis severities and could be a potential diagnostic parameter under basal conditions.

1. Introduction

Functional (hemodynamic) diagnostic parameters, along with angiography, are used to determine severity of a stenosed artery. For the evaluation of functional stenosis severity, patients are administered with a drug to induce maximal vasodilation (hyperemia). A sensor-tipped guidewire is inserted into the coronary artery to measure flow and pressure. From these measured hemodynamic information, coronary diagnostic parameters such as fractional flow reserve (FFR), coronary flow reserve (CFR) (de Bruyne et al., 1996), hyperemic stenosis resistance index (HSR; Meuwissen et al., 2002) and pressure drop coefficient (CDP) are calculated (Banerjee et al., 2008).

Recently, a 0.022″ diameter rapid exchange intravascular catheter, called Monorail Pressure Sensor catheter (MPS22), with a pressure sensor at its distal end of the shaft has been developed for improved assessment of stenotic severity (Fig. 1A–C). MPS22 is designed to slide over any standard 0.014″ guidewire. Therefore, it obviates the need to remove the standard 0.014″ guidewire for inserting a 0.014″ integrated sensor-tipped pressure wire (G14). This allows rapid deployment of the sensor-tipped MPS22 over a 0.014″ standard guidewire while minimizing sensor damage and reduced residence time within the vessel. In contrast, an integrated sensor-tipped G14 is widely used in the catheterization lab as a sensor for functional diagnosis of coronary disease. Sensor damage caused by torqueing motion during the deployment and increased residency time in target vessel are common problems while using a G14 sensor-tipped diagnostic wire. Additionally, pressure–velocity relations can be measured using a 0.014″ Combowire, which has both the pressure and flow sensors (Banerjee et al., 2009; Siebes et al., 2004). The introduction of the MPS22 over a guidewire creates an additional blockage, which leads to reduced flow and increased pressure drop across the stenosis (Ashtekar, 2007; Roy et al., 2005). Hence, the diameter effect of the MPS22 on coronary diagnostic parameters needs investigation, especially for intermediate stenosis (see below) where angiography alone cannot determine severity (Kern et al., 2006).

An in vitro experiment was used to replicate pathophysiologic flows for three representative AS (mild: ~64% AS; intermediate:

* Corresponding author. Tel.: +513 556 2124; fax: +513 556 3390.
E-mail address: rupak.banerjee@uc.edu (R.K. Banerjee).

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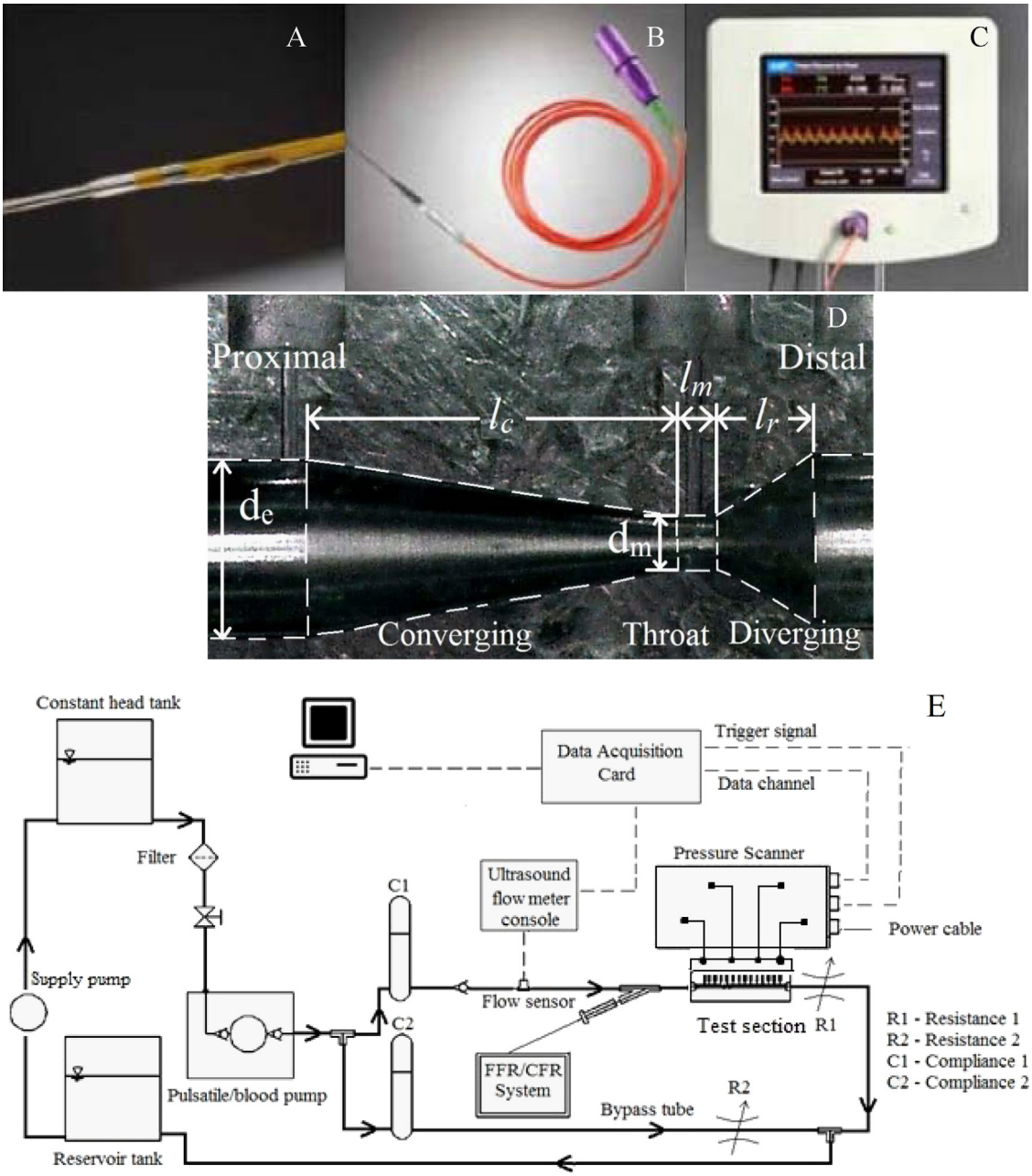

Fig. 1. The new rapid exchange catheter with Monorail Pressure Sensor is shown in (A). The pressure sensor is integrated into the distal tip (position indicated by the radiopaque marker band). The system is attached through a connector (B) to the console (C). The geometry of a typical stenotic test section is shown in (D). Subscripts e, c, m and r denote proximal, converging, throat, and distal, respectively for diameter (d) and lengths (l). The schematic of the experimental flow loop is shown in (E).

~80% AS; severe: ~90% AS) in two native arterial diameters (N1: 2.5 mm; N2: 3 mm). Statistically, the N2 arterial diameter is more commonly found in the human coronary arteries in comparison to N1. Stenosis levels of 64% and 90% AS represent pre- and post-angioplasty cases respectively, based on 32 patient clinical data by (Wilson et al., 1988), and were used in our previous studies (Banerjee et al., 2000, 2003b). The 80% AS represents an intermediate stenosis case, for which visual determination using angiography is often difficult and thus, is generally recommended for further functional assessment (Back and Denton, 1992). This geometry was validated with clinical data in several of our past studies (Ashtekar, 2007; Banerjee et al., 2008; Konala et al., 2011; Roy et al., 2005). *In this study, the FFR and CDP values obtained with the newly designed MPS22 and a conventional G14 guidewire are compared for the first time.* Further, due to some recent interest in diagnosis of stenosis severity at basal condition (Sen et al., 2012; van de Hoef et al., 2012a), we have also assessed the effect of MPS22 catheter on basal FFR and CDP. Details about basal analysis are provided in the Appendix.

2. Methodology

While a brief summary of experimental procedure is provided below, a detailed explanation may be found in our previous publications (Ashtekar et al., 2007; Banerjee et al., 2008; Goswami et al., 2013). The flow loop consists of an inlet from a pulsatile flow pump (*Harvard apparatus*) bifurcating into two: the main line representative of the coronary flow and the by-pass line. In order to obtain the necessary diastolic dominant flow pulse in the coronary loop, the compliance chambers C1 and C2 along with the resistances R1 and R2 were used (Ashtekar et al., 2007; Banerjee et al., 2008). Test-sections (Fig. 1D), mimicking stenosed artery, were assembled one at a time into the representative coronary flow loop