Direct read-out of coronary flow velocity by a new thermal transit time guidewire

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A new system for measuring the velocity of blood in the coronary artery is presented in this study. The system comprises a guidewire adapted for coupling with conventional coronary intervention devices and including two or more temperature sensors mounted at equally spaced intervals along its distal segment. With the guidewire positioned at a point of interest in the artery, a steady infusion of a room-temperature saline solution is injected into the blood stream at a coronary ostium, lowering the local blood temperature slightly. The warmer pulsatile flow from the aorta mixes with this steady room temperature infusion, producing phasic temperature oscillations that are detected in sequence by the gidewire's serially mounted temperature sensors. The lapse of time between the detected phase shifts indicates the velocity of the flowing blood. An external monitoring system connected to the guidewire provides instant read-outs of this value, which may be secured before, during and after intervention procedures, or after induced coronary hyperemia to determine coronary reserve. Experimental findings from a steady flow infusion of room temperature saline at 22 °C in a pulsatile water circulation at 37 °C through latex tubing, simulating that of a coronary artery, yielded values of peak flow velocity and volume flow rate that were very close to those collected in a measuring cylinder during the procedure. Recently this guidewire system has been applied successfully during angiography and values of coronary average peak velocity were determined.

نظام جديد لقياس سرعة تدفق الدم في الشريان التاجي يتكون من سلك إرشادي مماثل في صفاته للسلك الإرشادي العادي المستعمل أثناء العمليات الداخلية، ومجهز بحساستين للحرارة بينهما مسافة بالقرب من الطرف الآقصي للسلك الارشادى٠ وتتصل كل من هاتين الحساستين بمكبر خاص بها ، وكمبيوتر مبرمج لتسجيل أي تغييرات في درجه الحرارة٠ بعد إدخال هذا السلك الإرشادي إلى الشريان المطلوب دراسته، يبدأ حقن بطئ ومستقر من محلول الملح البارد في درجة حرارة الحجرة (٢٢°م) عن طريق فوهة الشريان التاجي من الأورطى لإحداث انخفاض بسيط في درجة الحرارة لا يتعدى جزء بسيط من الدرجة المئوية ٠ ولما كانت سرعة تدفق الدم في الشريان التاجي تتغير مع مراحل نبضات القلب فإن إدخال محلول الملح البارد بطريقة مستقرة و اختلاطه بالدم المتدفق على هيئة نبضات في الشريان التاجي يحدث موجات متكررة في درجة الحرارة تسجلها بالتوالي كل من الحساستين، حسب وضعها على السلك الإرشادي وتتناسب المسافة بين هذه الموجات المتتالية تناسبا عكسيا مع سرعة تدفق الدم في الجزء المطلوب دراسته في الشريان التاجي ٠ ويتم قياس هذه المسافات الزمنية وحساب سرعة تدفق الدم بشكل فوري ، عن طريق كمبيوتر مبرمج لقياس هذه القيم٠

Keywords: Guidewire, Thermodilution, Coronary flow velocity

1. Introduction

Measurements of coronary flow velocity and coronary flow reserve have gained wide acceptance as physiological diagnostic values in decision- making process during coronary angiography and before coronary intervention procedures.

Following rapid progress in Quantitative Coronary Angiography (QCA), it was assumed that anatomic information alone, enhanced by digital techniques, would become so comprehensive, that there would be no further need for physiological information of angiographic data.

Today, however, QCA has not fulfilled its promise to predict the physiological significance of coronary artery stenosis or to quantify increases in coronary flow following angioplasty.

At present these values are often determined by especially insertable coronary

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devices such as the Doppler guidewire [1,2] or the Pressure gradient guidewire [3,4]. While these methods have achieved reasonable degrees of accuracy, they pose certain limitations whether in terms of cost or speed of obtaining results.

The present work represents a promising new thermal method for measurement of coronary artery flow velocity and reserve. This system consists of a potentially cost effective guidewire of a size suitable for “over the wires” placement of intervention devices (0.035 mm outside diameter) that is capable of rapidly and accurately measuring these parameters throughout the intervention procedures.

2. System description and procedure

A system for measuring the velocity of blood in the coronary artery comprising a guidewire adapted for coupling with conventional coronary intervention devices and has at least two temperature sensors such as copper constantan thermocouples mounted sequentially at a predetermined interval of 10 or 20 mm along its distal segment. Copper constantan thermocouples are commonly used as thermal sensors that convert heat energy into thermoelectric voltage at the rate of 42 μV/ °C.

Two insulated electrical paths of the same materials as those of the thermal junctions extend from each thermocouple in a helical winding along the length of the guidewire shaft to its proximal end, where each electrical path is joined to one of four separate sleeve electrodes of the same materials. The shaft and its added components are sheathed by a protective thin layer of medical grade flexible epoxy or polyurethane and a very thin smooth hydrophilic coating suitable for easy introduction in a human vessel (fig. 1).

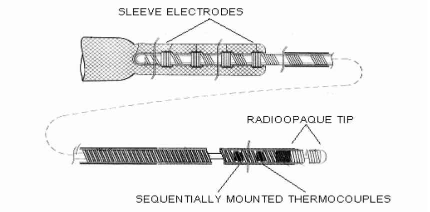

Fig. 1. Side view of the guidewire showing serially mounted thermal sensors on radiopaque markers, a spring radiopaque tip at distal segment and four sleeve electrodes on proximal segment.

Each of the four sleeve electrodes located on the guidewire proximal segment is electrically connectable to external cables through a cylindrical connector that allows steering and maneuvering of the guidewire in the coronary artery and its branches (fig. 2). These cables lead to respective reference junction and amplifiers (fig. 3).

This thermal guidewire**,** which is introduced into a guiding catheter, is positioned at the Ostium of the coronary artery. When this thermal guidewire is positioned at the point of interest of the coronary artery, a steady infusion of the saline at 22 °C is injected into the blood stream at the coronary Ostium for 30-60 seconds, lowering the local blood temperature a fraction of degree Centigrade. Warmer pulsatile flow from the aorta mixes with this saline inflow, producing phasic temperature oscillation that is detected in sequence by the guidewires temperature sensors. The degree of thermodilution varies during each phase of the cardiac cycle creating periodic oscillations of temperature gradient that simulate rectified sine waves (fig. 4).

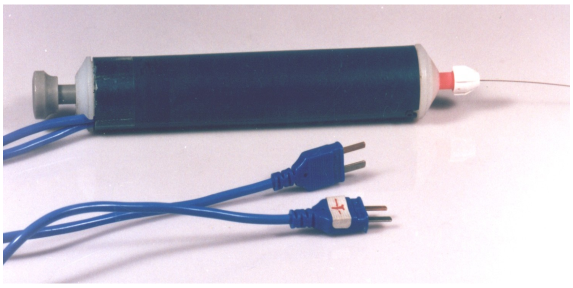

Fig. 2. Cylindrical connector and external cables connecting four sleeve electrodes of the guidewire to the respective reference junctions and amplifiers.

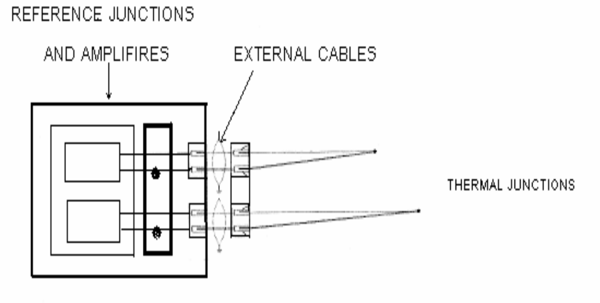

Fig. 3. Schematic circuit diagram of two thermal sensors showing their successive position, their respective sleeve electrodes, two thermocouple connectors, external cables, reference junctions and thermocouples amplifiers.

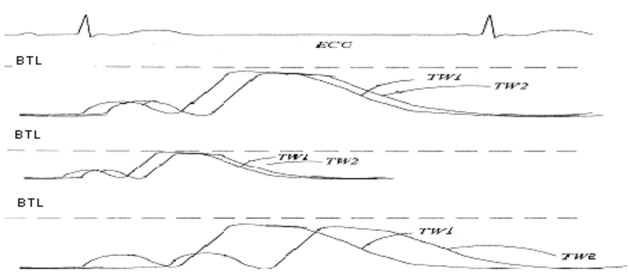

Fig. 4. Graph of an ECG above three predicted ranges of biphasic temperature wave shifts *(TW1, 2: temperature wave phase shift detected sequentially)—(BTL: base temperature line).

In normal coronary flow each temperature oscillation is detected by the two serially mounted thermal sensors as two consecutive rectified sine waves with phase shifts between them. The degree of phase shift between the consecutive waves is an expression of the transit time of blood flow between the thermal sensors.

This value which is inversely related to the phasic velocity, is directly determined by an online computer programmed to calculate the average peak flow velocity from the shortest group of transit time between successive phase shifts. An online color-coded monitor with adjustable sweep velocity also displays these successive oscillations during the infusion time.

When this thermal transit time guidewire is applied to patients with a narrow pulse pressure in the coronary segment of interest due to coronary pathology such as ischemic heart disease, post-stenotic turbulent flow or dilated cardiomyopathology, the steady saline infusion may be replaced by pulsatile time-adjusted infusion utilizing an ECG triggered pump in order to accentuate the thermal waves induced by the saline infusion. In such cases these phase shifts between accentuated thermal waves would provide accurate measures of the transit time between successive waves and a more precise value of coronary flow velocity.

2.1. Determination of the average peak velocity

Current knowledge suggests that as coronary blood flows into branch points, that part of the vessel has non-laminar, non- steady flow [5].

The viscous behavior of blood, which is a suspension of cells in plasma, affects the shape of the velocity profile. The velocity gradient is gradually increased near the wall while the parabola is blunted in the center region, allowing more room in the center to measure peak velocity [6].

The degree of phase shift between recorded waves is an expression of the transit time of the average peak velocity of coronary flow at time of measurement as follows:

$$V = \frac{\Delta S}{\Delta T}.$$

Where V is the average peak velocity, ΔS is the distance between the two thermal, sensors and ΔT is the transit time.

Using this formula, the online computer would compute the peak flow velocity during a single cardiac cycle. Since room temperature saline infusion extends over a predetermined measuring time of 30-60 seconds covering several cardiac cycles, the average peak flow velocity during the measuring procedure would also be determined.

Values of volume flow may be calculated when the angiographiycally determined vessel diameter is supplied to the online programmed computer according to the following equation:

$$Q_D = \frac{\pi D^2}{4}(0.5xAPV).$$

Where Q_D is the volume flow rate, D is the vessel diameter and APV is Average Peak Velocity.

The thermal time constant of the fast response thermal sensors in a running fluid medium such as the bloodstream is less than 20 milliseconds. This thermal time- constant affects all the consecutive oscillations equally and therefore has no effect on the transit time between phase shifts.

Thorough mixing of the infused saline with the coronary flow is not essential since it is the transit time between identical phases and not the degree of temperature gradient which is of crucial importance.

Similarly, insignificant thermal conduction through the arterial walls does not affect the transit time of temperature changes.

2.2. Coronary flow reserve

Determination of coronary flow reserve may be carried out by repeating room temperature saline infusion after increasing the rate of coronary flow by means of pharmacologically induced hyperemia of the coronary arteries. Under basal conditions nomal coronary flow velocity induces a standard range of transit time between consecutive waves. During measurements of coronary flow reserve, the increased flow velocity produces narrow phase shifts between short transit times.

Post stenotic reduction of flow velocity prolongs the transit time between successive waves and is expressed by widening of the phase shifts between them. Evaluation of the degree of coronary stenosis, which is a valuable parameter in decision-making, is determined by the degree of widening of the transit time at basal conditions or during measurements of coronary reserve. For optimal patient care, this procedure may be repeated to evaluate the immediate and late outcome of coronary intervention.

2.3. Reversed direction of blood flow from collateral vessels

When a color-coded monitor is used the forward direction of coronary flow is indicated by the order of colors shown on the color-coded monitor. The order of colors would be reversed or markedly disturbed in certain types of coronary stenosis with reversed flow from adjacent collateral vessels.

3. Experimental trials

We tried several transit time guidewires in a pulsatile water circulation flowing from a reservoir that was kept at 37 °C (fig. 5).

The Transit Time guidewire was introduced through a side branch and a steady flow of colder room temperature saline was introduced through another more distal side branch.

Mixing of the steady flow room temperature saline with the pulsatile warm water flow induced the expected oscillations of the baseline temperature. These oscillations were detected by each thermal sensor with a transit time between them that was dependant on flow velocity. The output flow was received in a measuring cylinder and its value is transformed to velocity by dividing the volume measured by the area of the 2.6 mm-diameter latex rubber tubing used. These values were compared with those recorded by the Transit Time (TT) guidewire as shown in table 1.

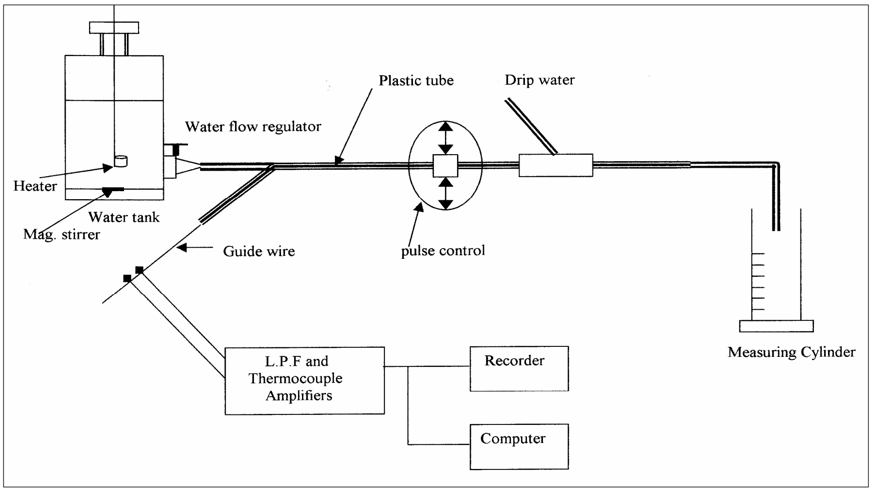

Fig. 5. Experimental trial of flow system simulating the coronary artery.

Table 1
Mean velocity values by measuring cylinder and by TT guidewire

	Mean velocity by measuring cylinder (cm./sec.)	Mean velocity By TT guidewire (cm./sec.)	% Difference
1	22.1	20.7	-6%
2	2.7	2.31	-14%
3	35.7	31.25	-12%

The introduction of Doppler guidewires has allowed the widespread use of Doppler technology for diagnostics and pathophysiological studies during coronary intervention. To produce reliable and reproducible flow velocity data, a spectral display with strong signals in the high velocity range and a sharply defined envelope are markers for good positioning of the Doppler wire [7]. With the proposed thermal guidewire, transit times expressed as narrow phase shifts between successive thermal waves from a single cardiac cycle are markers of good positioning of the thermal sensors on the guidewire during the measuring procedure.

Recently, after written informed consent, this guidewire was applied during coronary angiography to a patient over 50 years old with Rheumatic Heart disease, Mitral Stenosis and Atrial Fibrillation, to ensure normal coronary arteries before surgical intervention.

The guidewire was introduced into the distal segment of normal LAD. The baseline temperature level detected separately by each thermal sensor was first adjusted on the monitor and recorded using two channel jet recorder.

On starting the measurement procedure, a steady room temperature saline infusion (at 22° C) was started through the guiding catheter positioned at the ostium of the left main coronary artery. The infusion, which was maintained for two minuets, induced a blood temperature drop of a fraction of a degree Centigrade during the infusion time. This reduced temperature level showed the predicted thermal oscillations that were concomitant with cardiac diastoles as confirmed on the monitor. These thermal oscillations were detected separately by each thermal sensor with a phase shift between them, representing the transit time of blood flow over a distance of 25 mm between the thermal sensors (fig. 6 and fig.7).

It was noticed that the average peak velocity was 30 cm./s. during phases of slow heart rate (fig. 6), and dropped to 15 cm./s. during phases of fast heart rate of atrial fibrillation (fig. 7). This observation which demonstrates the adverse effect of fast heart rate on coronary flow velocity is recommended to be followed in the future studies.

4. Conclusions

A cost-effective thermal transit time guidewire that measures coronary flow velocity and reserve is described. A prototype of the new device was used in a pulsatile circulation model simulating the coronary circulation and the values of flow velocity determined were compared with those obtained from volumes collected in a measuring cylinder during the experiments.

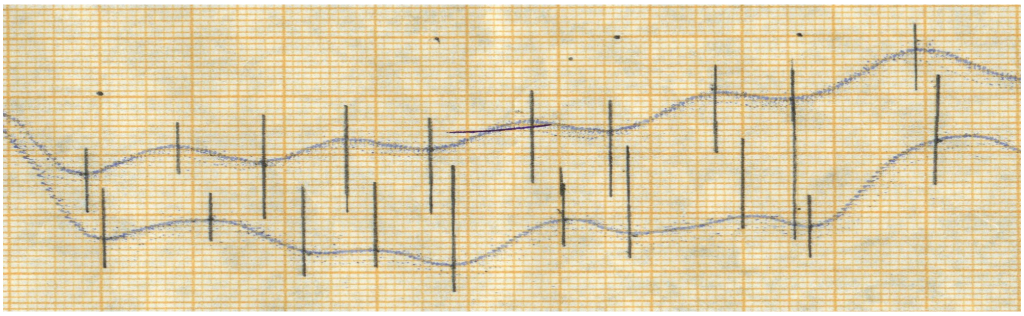

Fig. 6. Transit time measured from the phase shift between the two sequential thermocouples with slow phases of heart beats.

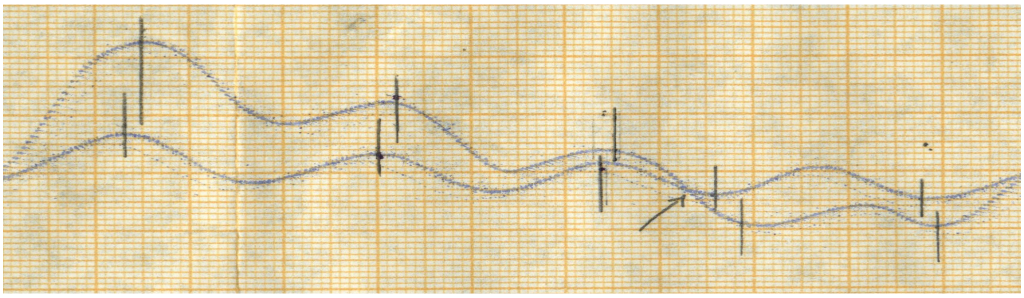

Fig. 7. Transit time measured from the phase shift between the two sequential thermocouples with rapid phases of heart beats.

Recently, this device was applied during angiography to a patient with Rheumatic Heart disease, Mitral Stenosis and Atrial Fibrillation. Average peak flow velocity and mean velocity were determined during the 30-second procedure. It was noticed that peak coronary flow velocity had a direct relation to the duration of diastoles of the irregular heartbeats of atrial fibrillation.

Direct read out of coronary flow velocity by the described thermal transit time guidewire may prove to be cost-effective, allowing this value to become a routine measurement during intervention procedures.

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