(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 661 216 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
21.11.2018 Bulletin 2018/47

(21) Application number: **12700299.6**

(22) Date of filing: **06.01.2012**

(51) Int Cl.:
A61B 5/02 (2006.01) ***A61B 5/021*** (2006.01)
A61B 5/00 (2006.01) ***A61B 5/103*** (2006.01)
A61B 5/0215 (2006.01) ***A61B 5/0285*** (2006.01)

(86) International application number:
PCT/GB2012/050024

(87) International publication number:
WO 2012/093266 (12.07.2012 Gazette 2012/28)

(54) APPARATUS AND METHOD OF ASSESSING A NARROWING IN A FLUID FILLED TUBE

VORRICHTUNG UND VERFAHREN ZUR BEURTEILUNG EINER VERENGUNG IN EINEM FLÜSSIGKEITSGEFÜLLTEN SCHLAUCH

APPAREIL ET PROCÉDÉ D'ÉVALUATION D'UN RÉTRÉCISSEMENT DANS UN TUBE REMPLI DE FLUIDE

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **06.01.2011 GB 201100137**

(43) Date of publication of application:
13.11.2013 Bulletin 2013/46

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EP 2 661 216 B1

Description

Field of the invention

[0001] This invention relates to an apparatus and method of assessing a narrowing in a fluid filled tube.

Background to the invention

[0002] A fluid filled tube or vessel formed with a constriction or narrowing can be analysed to measure the magnitude of the constriction or narrowing.

[0003] An example of a fluid filled tube or vessel formed with a constriction or narrowing is a blood vessel having a stenosis. Assessment or measurement of the constriction can result in a useful parameter to gauge the extent of the constriction.

[0004] A standard methodology for assessment of a constriction in a fluid filled tube such as a coronary stenosis is fractional flow reserve (FFR). This technique measures the drop in pressure at two points along a vessel; see Figure 1 of the accompanying drawings, under conditions of maximal achievable hyperaemia in a coronary environment. The Pd measurement comes from a pressure sensor on the wire and the Pa measurement comes from the catheter. A comparison is then made by expressing the mean distal pressure (*Pd*), as a proportion of mean proximal pressure (*Pa*), wherein the values are mean Pa and Pd over the entire cardiac cycle, taken over at least one complete cardiac cycle (but usually an average of 3 or more beats):

$$Fractional\ Flow\ Reserve\ (FFR) = \frac{P_d}{P_a}$$

[0005] Conditions of maximal hyperaemia are usually only achievable by administration of potent vasodilators such as adenosine or dipyridamole. Such vasodilators are necessary to minimise resistance from the distal vascular bed to accurately estimate the drop in pressure across a stenosis. It would be preferable not to have to use vasodilators.

[0006] Distal pressure arises from resistance of the microcirculation, in addition to active compression of small microcirculatory vessels which permeate the myocardium. When flow is measured simultaneously at different sites, it is possible to separate the pressure components arising from the distal myocardium (backward-originating pressure), from those arising from the proximal end (forward-originating pressure),

$$dP_+ = \frac{1}{2(dP + \rho c\ dU)}$$

$$dP_- = \frac{1}{2(dP - \rho c\ dU)}$$

where *dP* is the differential of pressure, ρ = density of blood, *c*=wave speed, and *dU* is the differential of flow velocity.

[0007] P_+ isolates forward originating pressure by removing the backward-originating component, and therefore negates the need for administration of vasoactive agents such as adenosine. Thus by comparing the ratio of P_+ on either side of a stenosis it is possible to estimate stenosis severity without requiring maximal hyperaemia to be achieved. The isolated forward pressure ratio is expressed as:

$$Forward\ pressure\ ratio = \frac{P_{+\ distal}}{P_{+\ proximal}}$$

[0008] Whilst the forward pressure ratio offers a considerable step forward as administration of vasodilator compounds are not required, it requires flow velocity to be measured in addition to pressure. This requires considerable extra skill, additional hardware and added expense.

[0009] US 2010/0234698 A1 describes an intravascular sensor delivery device for measuring a physiological parameter of a patient, such as blood pressure; within a vascular structure or passage. In some embodiments; the device can be used to measure the pressure gradient across a stenotic lesion or heart valve. For example; such a device may be used to measure fractional flow reserve (FFR) across a stenotic lesion in order to assess the severity of the lesion.

[0010] US 6,354,999 B1 describes a method and devices for detection, localization and characterization of occlusions, aneurysms, wall characteristics and vascular bed. An artificial pressure or flow excitation signal (a single signal or more) into the blood vessel (or in other tubular flowing fluid conduits), is introduced, and a measurement and analysis of the pressure and/or flow is performed. The invention discloses a method and devices for detection and characterization of partial or total occlusion or aneurysm in blood vessels or in other tubular flowing fluid conduits within a body, such as urine flow in the urethra.

[0011] EP 2298162 A1, a post-published European Patent Application, relates to an eavesdropping device for monitoring measured physiological variables of an individual, which eavesdropping device comprises a receiver and a communication interface. The eavesdropping device is typically applied in a system comprising a first sensor arranged to be disposed in or outside the body of the individual for measuring aortic blood pressure Pa, and a second sensor arranged for measuring distal blood pressure Pd. The signal representing the aortic blood pressure Pa is communicated to the receiver via a high-impedance connection at the communication interface, and the receiver of the eavesdropping device is further arranged to receive the signal representing the measured distal blood pressure Pd from the communication link. By means of the blood pressure signals of the respective sensor, FFR can be calculated.

[0012] US 2008/139951 A1 describes a system for detecting stenosis in a patient. The system includes an implantable sensing unit having a turbulence sensor and a communication device for transmitting a signal from the turbulence sensor. The system also includes a cardiac sensor for generating a signal corresponding to cardiac activity and a processing device configured to receive signals from the sensing unit and from the cardiac sensor. The processing device is configured to determine a time window corresponding to cardiac activity, to determine a turbulence level from the turbulence signal within the time window, and to detect the presence of stenosis from the turbulence level.

[0013] It is an object of the invention to provide an apparatus of assessing a narrowing in a fluid filled tube which does not require a measurement of flow velocity, fluid flow rate, in addition to pressure measurement.

[0014] The object is solved according to the invention with an apparatus as defined in claim 1. Advantageously embodiments can be derived from the subclaims. One aspect provides a method of assessing a narrowing in a fluid filled tube having a fluid flow pressure wave having a backward-originating pressure component and a forward-originating pressure component without taking a flow velocity measurement, comprising: taking pressure measurements in the tube; separating the pressure components into the backward-originating pressure component and the forward-originating pressure component; identifying a time window when the differential of flow velocity (*dU*) is minimal or absent; and deriving the backward and forward pressure components for pressure measurements taken in at least the time window.

[0015] Another aspect of the present invention provides an apparatus to assess a narrowing in a fluid filled tube having a fluid flow pressure wave having a backward-originating pressure component and a forward-originating pressure component without taking a flow velocity measurement, the apparatus comprising: a pressure measurement device operable to take pressure measurements in the tube; and a processor operable to separate the pressure components into the backward-originating pressure component and the forward-originating pressure component; identify a time window when the differential of flow velocity (*dU*) is minimal or absent; and to derive the backward and forward pressure components for pressure measurements taken in at least the time window.

[0016] A further aspect provides a processor configured to assess a narrowing in a fluid filled tube having a fluid flow pressure wave having a backward-originating pressure component and a forward-originating pressure component without taking a flow velocity measurement, the processor: analysing pressure measurements taken in a tube; separating the pressure components into the backward-originating pressure component and the forward-originating pressure component; identifying a time window when the differential of flow velocity (*dU*) is minimal or absent; and deriving the backward and forward pressure components for pressure measurements taken in at least the time window.

[0017] A yet further aspect provides a data storage medium carrying a computer program to assess a narrowing in a fluid filled tube having a fluid flow pressure wave having a backward-originating pressure component and a forward-originating pressure component without taking a flow velocity measurement, the program: analysing pressure measurements taken in a tube; separating the pressure components into the backward-originating pressure component and the forward-originating pressure component; identifying a time window when the differential of flow velocity (*dU*) is minimal or absent; and deriving the backward and forward pressure components for pressure measurements taken in at least the time window.

Brief description of the drawings

[0018] In order that the present invention may be more readily understood, embodiments of the invention will now be described with reference to the accompanying drawings, in which:

FIGURE 1 is a schematic diagram of a tube formed with a constriction with proximal (Pa) and distal (Pd) pressure measurement sites;

FIGURE 2 is a schematic not-to-scale diagram of an apparatus embodying the present invention;

FIGURE 3 is a flow diagram illustrating a method embodying the present disclosure;

FIGURE 4 shows an example of a free wave period in a cardiac environment, which free wave period is used in an apparatus and method embodying the present invention.

Description

[0019] This invention provides an apparatus and method of assessing a narrowing in a fluid filled tube by measuring the pressure in the tube and does not require a measurement of flow velocity, fluid flow rate, in addition to the pressure measurement.

[0020] In a fluid flow system, the separated pressures are given as:

$$dP_+ = \frac{1}{2(dP + \rho c\, dU)}$$

$$dP_- = \frac{1}{2(dP - \rho c\, dU)}$$

where dP is the differential of pressure, ρ= density of blood, c=wave speed, and dU is the differential of flow velocity. The isolated pressure ratio, comparing the ratio of P_+ or P_- on either side of a constriction provides a measure, estimate or indication of the severity of the constriction.

[0021] The isolated forward pressure ratio using separated pressures is thus:

$$\frac{P_{+\,distal}}{P_{+\,proximal}}$$

[0022] Or isolated backward pressure ratio,

$$\frac{P_{-\,distal}}{P_{-\,proximal}}$$

[0023] Calculating the isolated pressure ratio using this technique gives a pressure only assessment of the severity of the constriction.

[0024] Referring to Figure 2, an apparatus 1 embodying the invention comprises a probe 2 such as an intra-arterial pressure wire (WaveWire or Combowire (Volcano Corp.) or Radi pressure wire (St Jude Medical) with a pressure measurement transducer 3 - i.e. a device measuring pressure (P), and a processor 4 to analyse and operate on the pressure measurements. A signal line 5 relays the pressure measurement signal from the transducer 3 to the processor 4. The signal line 5 is illustrated both as a wired connection 5 and as a wireless connection 5' - either configuration is available.

[0025] The processor 4 operates on the pressure measurements received from the transducer 3 in accordance with a number of algorithms which are discussed in greater detail below. The apparatus 1 may be provided in the following configurations or combination of configurations, but these are not an exhaustive list of configurations:

i) a stand-alone device incorporating a probe with pressure measurement capacity in wired connection with a processor to provide on-device analysis;
ii) a device incorporating a probe with pressure measurement capacity in wireless connection with a processor to provide analysis at the processor;
iii) a stand-alone device incorporating a probe with pressure measurement capacity and a data storage device operable to record measurement data for real time or subsequent communication to a processor to provide analysis at the processor (real time and/or off-line); and
iv) a device incorporating a probe with pressure measurement capacity in wireless connection with a data storage device operable to record measurement data for real time or subsequent communication to a processor to provide analysis at the processor (real time and/or off-line).

[0026] In the cardiac environment where the apparatus 1 is configured as part of haemodynamic equipment, the apparatus is configured using the processor 4 in the haemodynamic equipment, such as in McKesson equipment - Horizon Cardiology™, a cardiovascular information system (CVIS). Such configurations are particularly effective for the equipment processor to perform off-line analysis of the pressure data.

[0027] The apparatus 1 (and in particular the probe 2) can be used in combination with other haemodynamic equipment, medical imaging equipment and/or in-patient marker location equipment.

[0028] In a cyclic fluid flow system, there are time windows in which the rate of change of the fluid flow velocity tends to zero - i.e. dU tends to zero. At these times, termed here "wave free periods", it is possible to separate the wave pressure in the fluid at a measurement site into forward and backward pressures using the pressure waveform alone. This negates the need for measurement of flow velocity.

[0029] In a specific example of a cardiac cycle, at any point in the cardiac cycle dP+ is determined by dP + ρc dU. dU is large during parts of the cardiac cycle when significant proportions of wave energy are present (i.e. during left ventricular contraction). However, there are times in the cardiac cycle when dU tends to zero. This can be a single moment or sample in time, or a multiple moments or samples in time. At such times, the dU term can be cancelled and dP_+ or dP- estimated using the dP term alone.

[0030] In accordance with this example of the invention, pressure samples are taken at or over the wave free period when dU tends to zero. Precise adherence to pressure sampling at or over the wave free period is not essential but pressure sampling does need to take place when the influence of dU is minimised and preferably when tending to zero.

[0031] At or over the wave free period when the influence of dU is minimised or negated entirely, the dU side is cancelled from the separated pressures so:

dP_+ is calculated as

$$dP_+ = \frac{1}{2(dP + \rho c\, dU)}$$

and dP_- is calculated as

$$dP_- = \frac{1}{2(dP - \rho c\, dU)}$$

[0032] With the *dU* term cancelled) the separated pressures are calculated as:

$$dP_+ = \frac{1}{2}dP$$

and

$$dP_- = \frac{1}{2}dP$$

[0033] When *dU* tends to zero, the *dU* side is cancelled from the solution and dP_+ is calculated as:

$$dP_+ = \frac{1}{2}dP$$

and dP_- as,

$$dP_- = \frac{1}{2}dP$$

[0034] The apparatus and method provide for the separation of the wave pressure in the fluid at a measurement site into forward and backward pressures using the pressure waveform alone dispensing with the need for any measurement of flow velocity. This advance allows use of technically simplified equipment which does not need to measure fluid flow velocity.

[0035] In the apparatus and method embodying the invention, the pressure measurements are made at baseline during the free wave period and not during hyperaemia. This is contrary to the teaching of FFR measurement in combined flow rate and pressure measurement apparatus where measurements are specifically taken at hyperaemia. This is because examples of the invention extract the forward pressure component, rather than (as in conventional FFR) having to minimise the contribution of backward pressure from the measured pressure by administration of vasodilators. If measurements are made during vasodilator hyperaemia, then measurements will not be reliable as *dU* increases significantly at this time.

[0036] Figure 4 shows an example of *dU* fluctuating over a cycle. There is an identifiable window where *dU* tends to zero (marked at 580ms through to 770ms in this example). The window is identified for example by being: heuristically learnt by the processor; linked to characteristics of the pressure waveform; or a certain time window after another event in the waveform e.g. starting at a predetermined time (250ms) after event of dU_{max} and lasting for a predetermined period (150ms) - note dU_{max} can be reliably observed from pressure measurements of the waveform. The wave free period is identifiable using online analysis in real time or can be identified using offline analysis.

[0037] For example, in a cardiac environment, detecting minimised dU (wave free period) from pressure measurements can be carried out as follows:

identify peak pressure time (t_{Pmax})
identify end of pressure waveform time (t_{Pend})
sample pressure measurements from t_{Pmax} to t_{Pend}
analyse pressure measurements from (t_{Pmax}+150ms) through to (t_{Pend}-50ms) = wave free period.

[0038] Another example for identifying the wave free period is to base its identification on characteristics of the pressure waveform. This is advantageous because identification is not tied to fixed time points. In this specific example:

calculate the isolated forward (or backward) pressure ratio;
calculate standard deviation of isolated forward (or backward) pressure ratio
select the time period (free wave period) after peak pressure time point where the standard deviation is in the lowest 5% and if no points are identified, select the time period where the standard deviation is in the lowest 10% and so on.

[0039] The measurements are continuous within the identified free wave period and/or for a period of at least ~=100ms.

[0040] Another example for identifying the free wave period is:

identify the peak pressure time point;
identify the end of the pressure waveform time point; and
specifying the free wave period as a predetermined portion mid-window between these two time points. Preferably, the free wave period is identified as the mid 3/5 window between these two time points.

[0041] In the cardiac environment, reliable measurements can be taken in the window where *dU* varies less than +/- $2x10^{-4}$ from the zero crossing, where dU_{max} is $3x10^{-3}$, where *dU* is 20% or less of dU_{max}, preferably 10% or less, most preferably 5% or less. *dU* oscillates around the mean over the wave free period so its net contribution to separated pressures (i.e. P_+) is minimised as the -ve contributions cancel the +ve contributions. The oscillations about the mean during the wave free period (the time window) in a cardiac environment are due to limitations in the measurement equipment which will not detect small changes accurately.

[0042] Further this advance provides a measure of the severity of a constriction using the measure of isolated pressure ratio.

[0043] Further this advance negates the need in the cardiac environment for the administration of potent vasodilators.

[0044] There are particular needs in the cardiac environment for simplified equipment having the smallest possible footprint (or being the least invasive requiring the smallest possible entry site) so the provision of an isolated pressure ratio measurement device or probe which has only one measurement device mounted on or in the probe represents a significant technical advance in that field.

[0045] Further, such devices or probes in the cardiac field include signal lines from the probe which terminate either in a transmitter for relaying the measurement signal to a processor or a processor itself. If there is a flow sensor and a pressure sensor, then two different measurement devices are in/on the same probe and there are also two signal lines required to take the signal from the two distinct measurement devices. The loss, in examples of the invention, of the flow sensor from the system is extremely beneficial as it reduces the complexity of the device, can improve handling of the probe and can reduce the number of signal lines necessary to take the measurement signal(s) away from the measurement devices. In the case of examples of the invention, there is only one measurement device - that of pressure measurement and the need for a flow sensor in addition to one or more pressure sensors is obviated. A single pressure sensor wire can be more manoeuvrable than a wire with both pressure and flow sensors. Having a flow sensor in addition to the pressure sensor is sub-optimal for guide wire design.

[0046] Pressure-only measurements are taken relative to the constriction. Multiple measurements can be taken in preference to one measurement. The probe 2 can be moved relative to the constriction, in which case, multiple measurements would be taken.

[0047] There is a further sophistication to the above described apparatus and method which concerns the identification of wave free periods - those times in the cyclic flow when dU tends to zero. A person skilled in the art is able to calculate and identify wave free periods - occurring as they do during periods of the cardiac cycle when wave activity is minimised or absent.

[0048] For a given wave free period from time point tw_0 to time point tw_1:

with P_+ (during any wave free period tw_0 to tw_1) as,

$$P_+ = \int_{tw0}^{tw1} dP_+$$

and P_- as ,

$$P_- = \int_{tw0}^{tw1} dP_-$$

where $P_{+\ proximal}$ is defined as,

$$P_{+\ proximal} = \int_{tw0}^{tw1} dP_{+\ proximal}$$

and $P_{+\ distal}$ is defined as,

$$P_{+\ distal} = \int_{tw0}^{tw1} dP_{+\ distal}$$

and $P_{-\ proximal}$ is defined as,

$$P_{-\ proximal} = \int_{tw0}^{tw1} dP_{-\ proximal}$$

and $P_{-\ distal}$ is defined as,

$$P_{-\ distal} = \int_{tw0}^{tw1} dP_{-\ distal}$$

[0049] The isolated pressure ratio using separated pressures is thus isolated forward pressure:

$$\frac{P_{+\ distal}}{P_{+\ proximal}}$$

[0050] Or isolated backward pressure,

$$\frac{P_{-\ distal}}{P_{-\ proximal}}$$

[0051] Calculating the isolated pressure ratio using this technique over the wave free period gives a pressure-only assessment of the severity of the constriction, such as a stenosis. There is no need to provide flow velocity measurement equipment on the probe 2 in addition to the pressure measurement transducer 3 and there is no need to process any flow velocity measurement.

[0052] When used in this specification and claims, the terms "comprises" and "comprising" and variations thereof mean that the specified features, steps or integers are included. The terms are not to be interpreted to exclude the presence of other features, steps or components.

[0053] The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

Claims

1. An apparatus (1) for assessing a narrowing in a fluid filled tube being a blood vessel of a cyclic fluid flow system, in particular a cardiac environment, having a fluid flow pressure wave having a backward-originating pressure component (P_-) and a forward-originating pressure component (P_+), without taking a flow velocity measurement, the apparatus comprising:

   a pressure measurement device (3) configured to take pressure measurements (Pd, Pa) in the blood vessel, on each side of the narrowing; and a processor (4) configured to:

   receive the pressure measurements from the pressure measurement device;
   analyse the pressure measurements so as to identify a time window as a wave free period, wherein during the wave free period the differential of flow velocity (dU) being minimal or absent, such that no measurement of the flow velocity is necessary;
   derive the backward and/or forward pressure components separated using the pressure waveform alone from the pressure measurements (Pd, Pa) during the time window; and
   use the backward and/or forward pressure components taken in at least the time window to calculate a pressure ratio of pressures on either side of the narrowing so as to provide an assessment of the severity of the narrowing.

2. The apparatus of claim 1, further comprising a signal line (5, 5') between the pressure measurement device and the processor.

3. The apparatus of claim 2, wherein the signal line is a wired connection (5) between the pressure measurement device and the processor.

4. The apparatus of claim 2, wherein the signal line is a wireless connection (5') between the pressure measurement device and the processor.

5. The apparatus of any preceding claim, wherein the pressure measurement device relays the pressure measurements to a data storage device which stores the pressure measurements and is remote from the processor.

6. The apparatus of any of claims 1 to 5, wherein the time window is from time point tw_0 to time point tw_1 and the forward-originating pressure component (P_+) is:

$$P_+ = \int_{tw0}^{tw1} dP_+,$$

where dP_+ is a differential of the forward-originating pressure component, and wherein the pressure ratio is an isolated forward pressure ratio given by:

$$\frac{P_{+\,distal}}{P_{+\,proximal}}$$

where $P_{+\,distal}$ is a distal forward-originating pressure component and $P_{+\,proximal}$ is a proximal forward-originating pressure component.

7. The apparatus of claim 6, wherein the time window is a period in which the standard deviation of the isolated forward pressure ratio after a peak pressure time point is below a predetermined percentage.

8. The apparatus of any of claims 1 to 5, wherein the time window is from time point tw_0 to time point tw_1 and the backward-originating pressure component (P_-) is:

$$P_- = \int_{tw0}^{tw1} dP_-$$

where dP_- is a differential of the backward-originating pressure component, and wherein the pressure ratio is an isolated backward pressure ratio given by:

$$\frac{P_{-\,distal}}{P_{-\,proximal}}$$

where $P_{-distal}$ is a distal backward-originating pressure component and $P_{-proximal}$ is a proximal backward-originating pressure component.

9. The apparatus of claim 8, wherein the time window is a period in which the standard deviation of the isolated backward pressure ratio after a peak pressure time point is below a predetermined percentage.

10. The apparatus of claim 1, wherein the time window is identified as starting at a predetermined time after an identifiable event and lasting for: a predetermined period after the event; or a predetermined period before or after a further event.

11. The apparatus of claim 10, wherein the identifiable event is a peak pressure event and the further event is an end of the pressure wave.

12. The apparatus of any preceding claim, wherein *dU*

fluctuates around a zero crossing during the identified time period with the wave free period.

13. The apparatus of any preceding claim, wherein *dU* is 20% or less, 10% or less, or 5% or less of dU_{max} during the identified time period having the wave free period.

14. The apparatus of claim 1, wherein the time window is identified by:

identifying a peak pressure time point;
identifying the end of the pressure wave; and
specifying the time window as a predetermined portion mid-window between these two time points.

Patentansprüche

1. Gerät (1) zur Beurteilung einer Verengung in einem flüssigkeitsgefüllten Schlauch, bei dem es sich um ein Blutgefäß eines zyklischen Fluidströmungssystems, insbesondere eine kardiale Umgebung, mit einer Fluidströmungsdruckwelle mit einer rückwärts gerichtet entstehenden Druckkomponente (P-) und einer vorwärts gerichtet entstehenden Druckkomponente (P+) handelt, ohne Durchführung einer Strömungsgeschwindigkeitsmessung, wobei das Gerät Folgendes umfasst:

eine Druckmessungsvorrichtung (3), die konfiguriert ist, um Druckmessungen (Pd, Pa) in dem Blutgefäß auf jeder Seite der Verengung durchzuführen;
und
einen Prozessor (4), der konfiguriert ist zum:

Empfangen der Druckmessungen von der Druckmessungsvorrichtung;
Analysieren der Druckmessungen, um ein Zeitfenster als eine wellenfreie Periode zu identifizieren, wobei das Differential der Strömungsgeschwindigkeit (dU) während der wellenfreien Periode minimal oder nicht vorhanden ist, so dass keine Messung der Strömungsgeschwindigkeit notwendig ist;
Ableiten der Rückwärts- und/oder Vorwärts-Druckkomponenten separat unter Verwendung der Druckwellenform allein aus den Druckmessungen (Pd, Pa) während des Zeitfensters; und
Verwenden der in mindestens dem Zeitfenster aufgenommenen Rückwärts- und/oder Vorwärts-Druckkomponenten, um ein Druckverhältnis der Drücke auf beiden Seiten der Verengung zu berechnen und so eine Beurteilung des Schweregrads der Verengung bereitzustellen.

2. Gerät nach Anspruch 1, ferner umfassend eine Signalleitung (5, 5') zwischen der Druckmessungsvorrichtung und dem Prozessor.

3. Gerät nach Anspruch 2, wobei die Signalleitung eine verdrahtete Verbindung (5) zwischen der Druckmessungsvorrichtung und dem Prozessor ist.

4. Gerät nach Anspruch 2, wobei die Signalleitung eine drahtlose Verbindung (5') zwischen der Druckmessungsvorrichtung und dem Prozessor ist.

5. Gerät nach einem der vorhergehenden Ansprüche, wobei die Druckmessungsvorrichtung die Druckmessungen an eine Datenspeichervorrichtung weiterleitet, die die Druckmessungen speichert und von dem Prozessor abgesetzt ist.

6. Gerät nach einem der Ansprüche 1 bis 5, wobei das Zeitfenster von dem Zeitpunkt tw_0 bis zum Zeitpunkt tw_1 reicht und die vorwärts gerichtet entstehende Druckkomponente (P_+)

$$P_+ = \int_{tw0}^{tw1} dP_+ \text{ ist,}$$

wobei dP_+ ein Differential der vorwärts gerichtet entstehenden Druckkomponente ist, und wobei das Druckverhältnis ein isoliertes Vorwärts-Druckverhältnis gegeben ist durch

$$\frac{P_{+\,distal}}{P_{+\,proximal}},$$

wobei $P_{+\,distal}$ eine distale vorwärts gerichtet entstehende Druckkomponente ist und $P_{+\,proximal}$ eine proximale vorwärts gerichtet entstehende Druckkomponente ist.

7. Gerät nach Anspruch 6, wobei das Zeitfenster eine Periode ist, in der die Standardabweichung des isolierten Vorwärts-Druckverhältnisses nach einem Spitzendruck-Zeitpunkt unter einem vorgegebenen Prozentsatz liegt.

8. Gerät nach einem der Ansprüche 1 bis 5, wobei das das Zeitfenster von dem Zeitpunkt tw_0 bis zum Zeitpunkt tw_1 reicht und die rückwärts gerichtet entstehende Druckkomponente (P_-)

$$P_- = \int_{tw0}^{tw1} dP_- \text{ ist,}$$

wobei dP_- ein Differential der rückwärts gerichtet entstehenden Druckkomponente ist, und wobei das

Druckverhältnis ein isoliertes Vorwärts-Druckverhältnis gegeben ist durch

$$\frac{P_{-\,distal}}{P_{-\,proximal}},$$

wobei $P_{-\,distal}$ eine distale rückwärts gerichtet entstehende Druckkomponente ist und $P_{-proximal}$ eine proximale rückwärts gerichtet entstehende Druckkomponente ist.

9. Gerät nach Anspruch 8, wobei das Zeitfenster eine Periode ist, in der die Standardabweichung des isolierten Rückwärts-Druckverhältnisses nach einem Spitzendruck-Zeitpunkt unter einem vorgegebenen Prozentsatz liegt.

10. Gerät nach Anspruch 1, wobei das Zeitfenster identifiziert wird als beginnend zu einem vorgegebenen Zeitpunkt nach einem identifizierbaren Ereignis und andauernd über: eine vorgegebene Periode nach dem Ereignis; oder eine vorgegebene Periode vor oder nach einem weiteren Ereignis.

11. Gerät nach Anspruch 10, wobei das identifizierbare Ereignis ein Spitzendruck-Ereignis ist und das weitere Ereignis ein Ende der Druckwelle ist.

12. Gerät nach einem der vorhergehenden Ansprüche, wobei *dU* während der identifizierten Zeitperiode mit der wellenfreien Periode um einen Nulldurchgang herum schwankt.

13. Gerät nach einem der vorhergehenden Ansprüche, wobei *dU* 20 % oder weniger, 10 % oder weniger, oder 5 % oder weniger von dU_{max} während der identifizierten Zeitperiode mit der wellenfreien Periode ist.

14. Gerät nach Anspruch 1, wobei das Zeitfenster identifiziert wird durch:

Identifizieren eines Spitzendruck-Zeitpunkts;
Identifizieren des Endes der Druckwelle; und
Spezifizieren des Zeitfensters als einen vorgegebenen Abschnitt in der Mitte des Fensters zwischen diesen beiden Zeitpunkten.

Revendications

1. Appareil (1) pour évaluer un rétrécissement dans un tube rempli de fluide qui est un vaisseau sanguin d'un système à écoulement de fluide cyclique, en particulier un environnement cardiaque, ayant une onde de pression d'écoulement de fluide ayant une composante de pression (P_-) d'origine arrière et une composante de pression d'origine avant (P_+), sans effectuer de mesure de vitesse d'écoulement, l'appareil comprenant :

un dispositif de mesure de pression (3) configuré pour prendre des mesures de pression (Pd, Pa) dans le vaisseau sanguin, de chaque côté du rétrécissement ; et
un processeur (4) configuré pour :

recevoir les mesures de pression en provenance du dispositif de mesure de pression ;
analyser les mesures de pression de manière à identifier une fenêtre temporelle en tant que période exempte d'onde, le différentiel de vitesse d'écoulement (dU) étant minimal ou absent pendant la période exempte d'onde, de sorte qu'aucune mesure de la vitesse d'écoulement n'est nécessaire ;
dériver les composantes de pression arrière et/ou avant séparées en utilisant la seule forme d'onde de pression à partir des mesures de pression (Pd, Pa) pendant la fenêtre temporelle ; et
utiliser les composantes de pression arrière et/ou avant prises au moins dans la fenêtre temporelle pour calculer un rapport de pression des pressions de chaque côté du rétrécissement afin de fournir une évaluation de la gravité du rétrécissement.

2. Appareil selon la revendication 1, comprenant en outre une ligne de signal (5, 5') entre le dispositif de mesure de pression et le processeur.

3. Appareil selon la revendication 2, dans lequel la ligne de signal est une connexion câblée (5) entre le dispositif de mesure de pression et le processeur.

4. Appareil selon la revendication 2, dans lequel la ligne de signal est une connexion sans fil (5') entre le dispositif de mesure de pression et le processeur.

5. Appareil selon l'une quelconque des revendications précédentes, dans lequel le dispositif de mesure de pression relaie les mesures de pression à un dispositif de stockage de données qui stocke les mesures de pression et est distant du processeur.

6. Appareil selon l'une quelconque des revendications 1 à 5, dans lequel la fenêtre temporelle s'étend du point temporel tw_0 au point temporel tw_1 et la composante de pression d'origine avant (P_+) est :

$$P_+ = \int_{two}^{tw1} dP_+,$$

où dP_+ est un différentiel de la composante de pression d'origine avant, et dans lequel le rapport de pression est un rapport de pression avant isolée donné par

$$\frac{P_{+distal}}{P_{+proximal}}$$

où $P_{+\text{distal}}$ est une composante de pression distale d'origine avant et $P_{+\text{proximal}}$ est une composante de pression proximale d'origine avant.

7. Appareil selon la revendication 6, dans lequel la fenêtre temporelle est une période dans laquelle l'écart-type du rapport de pression avant isolée après un point temporel de pression crête est inférieur à un pourcentage prédéterminé.

8. Appareil selon l'une quelconque des revendications 1 à 5, dans lequel la fenêtre temporelle s'étend du point temporel tw_0 au point temporel tw_1 et la composante de pression d'origine arrière (P_-) est :

$$P_- = \int_{two}^{tw1} dP_-,$$

où dP_- est un différentiel de la composante de pression d'origine arrière, et dans lequel le rapport de pression est un rapport de pression arrière isolée donné par :

$$\frac{\mathrm{P}_{-\mathrm{distal}}}{\mathrm{P}_{-\mathrm{proximal}}}$$

où $P_{-\text{distal}}$ est une composante de pression distale d'origine arrière et $P_{-\text{proximal}}$ est une composante de pression proximale d'origine arrière.

9. Appareil selon la revendication 8, dans lequel la fenêtre temporelle est une période dans laquelle l'écart type du rapport de pression arrière isolée après un point temporel de pression crête est inférieur à un pourcentage prédéterminé.

10. Appareil selon la revendication 1, dans lequel la fenêtre temporelle est identifiée comme commençant à un moment prédéterminé après un événement identifiable et se prolongeant pendant : une période prédéterminée après l'événement ; ou une période prédéterminée avant ou après un autre événement.

11. Appareil selon la revendication 10, dans lequel l'événement identifiable est un événement de pression crête et l'autre événement est une fin de l'onde de pression.

12. Appareil selon l'une quelconque des revendications précédentes, dans lequel *dU* fluctue autour d'un passage par zéro pendant la période de temps identifiée avec la période exempte d'onde.

13. Appareil selon l'une quelconque des revendications précédentes, dans lequel *dU* représente 20 % ou moins, 10 % ou moins, ou 5 % ou moins de dU_{max} pendant la période de temps identifiée ayant la période exempte d'onde.

14. Appareil selon la revendication 1, dans lequel la fenêtre temporelle est identifiée en :

identifiant un point temporel de pression crête ;
identifiant la fin de l'onde de pression ; et
spécifiant la fenêtre temporelle en tant que mi-fenêtre de partie prédéterminée entre ces deux points temporels.

FIGURE 1

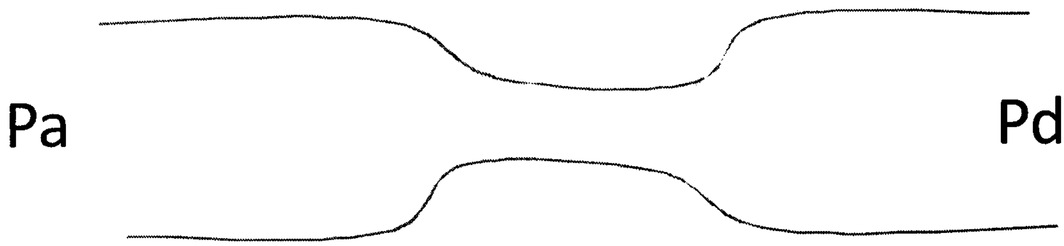


FIGURE 2

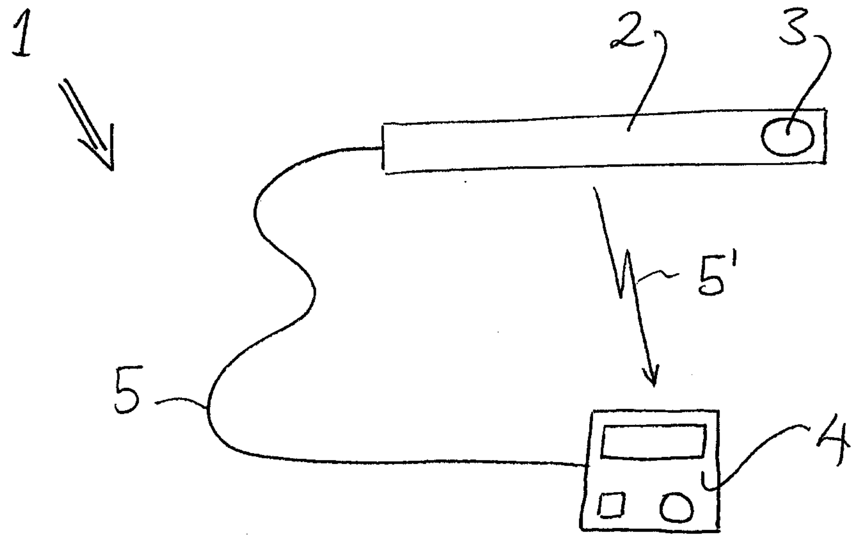


FIGURE 3

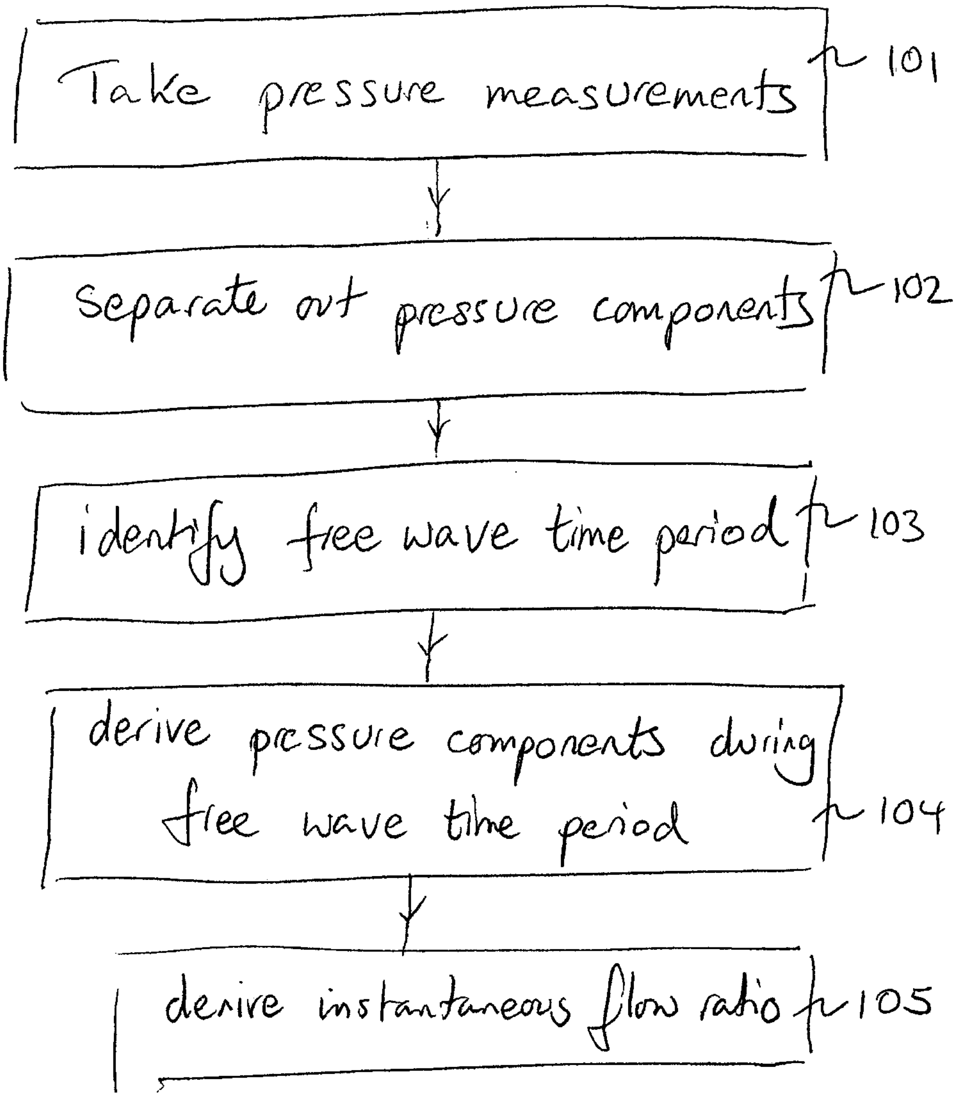
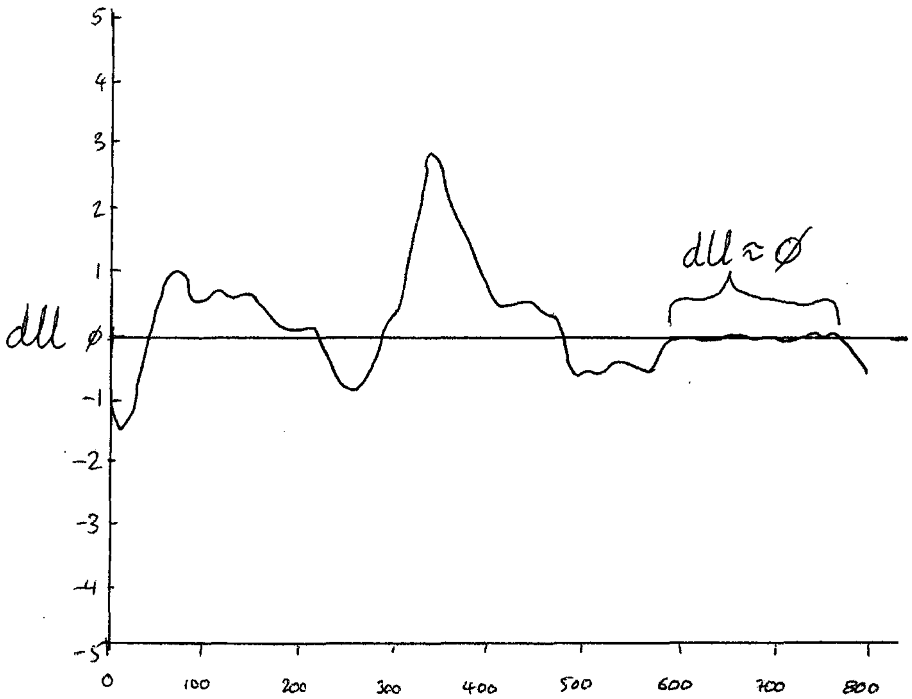

Take pressure measurements
101
separate out pressure components
102
identify free wave time period
103
derive pressure components during free wave time period
104
derive instantaneous flow ratio
105

FIGURE 4



REFERENCES CITED IN THE DESCRIPTION

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- EP 2298162 A1 **[0011]**
- US 2008139951 A1 **[0012]**

专利名称(译)	评估流体填充管中变窄的装置和方法		
公开(公告)号	EP2661216B1	公开(公告)日	2018-11-21
申请号	EP2012700299	申请日	2012-01-06
[标]申请(专利权)人(译)	麦德索维有限公司		
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IPC分类号	A61B5/02 A61B5/021 A61B5/00 A61B5/103 A61B5/0215 A61B5/0285		
CPC分类号	A61B5/02007 A61B5/0215 A61B5/103 A61B5/021 A61B5/02125 A61B5/0285 A61B5/7264 A61B5/7278		
代理机构(译)	德哈恩波尔ERIK		
优先权	2011000137 2011-01-06 GB		
其他公开文献	EP2661216A1		
外部链接	Espacenet		

摘要(译)

一种用于离线评估作为循环流体流动系统的血管，特别是心脏环境的流体填充管中的变窄的装置和方法，包括：从存储装置接收先前在血压计的任一侧进行的血压测量。缩小从纯压力测量中确定流速差（dU）最小或不存在时的时间窗口；导出用于时间窗口的压力测量的后向和前向压力分量，并通过使用后向和/或前向压力分量导出瞬时流量比作为变窄两侧的压力的压力比以便评估缩小的严重程度。

$$\text{Fractional Flow Reserve (FFR)} = \frac{P_d}{P_a}$$