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(54) Ultrasonic apparatus and method for indicating risk of coronary heart disease

Ultraschall-Gerät und Verfahren zum Angeben des Risikos einer koronaren Herzkrankheit

Dispositif à ultrasons et procédé pour indiquer le risque de coronaropathie

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Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to ultrasonic medical equipment, and in particular, to a method employable with such equipment to assess risk of coronary heart disease (CHD).

[0002] A key challenge in healthcare is identifying individuals who are at high risk for CHD and who thus would be candidates for intensive medical intervention either in the form of additional diagnostic testing or the initiation of proven therapeutic strategies.

[0003] One method of assessing risk of coronary heart disease is the Framingham Global CHD Risk Assessment (henceforth the "Framingham Assessment"). See, "Prediction of Coronary Heart Disease Using Risk Factor Categories", Circulation 1998; 97: 1837-1847 Wilson et al.

[0004] The Framingham Assessment, based on a long-term study of a population of individuals, relates age, cigarette smoking, blood pressure, total cholesterol and high-density lipoprotein (HDL) cholesterol, and diabetes to a quantitative risk of CHD typically expressed in a percent chance of having a CHD event (heart attack or cardiac death) in ten years. A drawback to the Framingham Assessment is that age dominates all other risk factors even though the risks of coronary heart disease between individuals of the same can differ substantially. The explanation for the relationship between age and CHD events most likely is increasing coronary plaque burden that occurs with advancing age. For this reason, it is generally recognized that a measure of coronary plaque burden might provide a better indicator of the probability of developing coronary heart disease for an individual than age alone.

[0005] There are a number of methods of measuring coronary plaque burden, including measurement of carotid intima-medial thickness (CIMT) with B mode ultrasound sonography. Such measurements provide a non-invasive and highly reproducible technique for quantifying sub-clinical atherosclerosis.

[0006] Measurement of CIMT is currently not used widely as a clinical tool, however. In part, this is because there is no established relationship between various patient factors, CIMT, and quantitative risk of cardiac heart disease. Ideally, the Framingham study would be repeated, but the age replaced by a CIMT measurement. Unfortunately, such studies take many years to complete and the future study is hampered by ethical concerns resulting from our understanding of the significance of some of the risk factors. For example, given the knowledge of the relationship between CHD and CIMT, long-term monitoring without treatment of patients with high CIMT may not be possible.

EP 0 958 784 A1 discloses an apparatus for measuring an intima-media thickness of a blood vessel. The apparatus includes: an ultrasound device for outputting digital image data representing an image of the blood vessel produced by scanning the blood vessel with ultrasound; and a data analyzing device for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. The digital image data includes a plurality of luminance values each corresponding to respective one of a plurality of pixels of the image. The data analyzing device includes: a setting device for setting a base position between a center of the blood vessel and a position in a vicinity of an inner intima wall of the blood vessel on the image, on the basis of a moving average of the luminance values; and a calculation device for detecting a maximum value and a minimum value from among the luminance values respectively corresponding to a predetermined number of the pixels arranged from the base position toward a position of an outer adventitial wall on the image, and calculating the intima-media thickness on the basis of the maximum value.

BRIEF SUMMARY OF THE INVENTION

[0007] The present inventors have recognized that a quantitatively rigorous relationship between CIMT and risk of CHD may be derived from the existing Framingham Assessment data by converting CIMT into an equivalent "vascular age" and substituting this "vascular age" for the chronological age used in the Framingham Assessment. The conversion of CIMT to vascular age can be done using studies that relate increase in CIMT to age in a standard population. One such study is the ARIC study described in "High Resolution B Mode Ultrasound Scanning Methods in the Arteriosclerosis Risk in Community Study (ARIC) J. Neuroimaging, 1991; 1: 68-73, Bond et al.

[0008] These latter studies generally show a range of CIMT values for individuals of a given age within the population and thus cannot be used to relate
CIMT to actual chronological age. Nevertheless, vascular age may be equated to the age of the study population at which the given individual's CIMT equals the population's mean or other statistical center value. The concept of vascular age allows connection between these two disparate studies, for example, that of the Framingham Assessment and ARIC, to provide a quantitative relationship between CIMT and risk of coronary heart disease.

[0009] Specifically then, the present invention provides an ultrasonic diagnostic machine having an ultrasonic transducer that is positionable near the carotid artery to obtain echo signals from the carotid artery. A processing circuit communicating with the ultrasound transducer operates to process the echo signal to review the carotid intima-medial thickness (CIMT) and to apply the revealed CIMT to stored data relating CIMT of a population to a quantified risk of coronary heart disease (CHD). This quantified risk of heart disease is then output.

[0010] Thus, it is one object of the invention to provide the quantitative relationship between CIMT and risk of

CHD such as may guide selection of treatment regimens.

[0011] The stored data used by the ultrasound machine may combine first data relating the CIMT to a vascular age and second data relating vascular age to quantified risk of CHD. The first data may be the ARIC data and the second data may be the data of the Framingham Assessment.

[0012] Thus, it is another object of the invention to establish a relationship between CIMT and risk of CHD using pre-existing studies.

[0013] The first data may relate multiple CIMT values to a given age but may be used to provide a single vascular age from a single CIMT value by a mathematical or statistical curve fitting process.

[0014] Thus, it is another object of the invention to employ existing studies describing CIMT as a function of age to create a virtual study relating CIMT values to vascular age.

[0015] The processing circuit may provide for input of patient data selected from the group consisting of: chronological age, gender, race, and body size. At least one of these patient data may also be applied to at least one of the first and second data sets.

[0016] Thus, it is another object of the invention to take advantage of the other patient input factors that may be used along with CIMT to establish quantified risk of CHD.

[0017] In one embodiment of the invention, the output from the ultrasound diagnostic machine may be vascular age.

[0018] Thus, it is another object of the invention to provide a simple unit for assessing CIMT data that can be readily understood by physicians and patients.

[0019] These particular objects and advantages may apply to only some embodiments falling within the claims and thus do not define the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] Fig. 1 is a perspective view of a patient's head showing the carotid artery and the proper positioning of an ultrasonic transducer for the measurements used in the present invention;

[0021] Fig. 2 is a fragmentary enlarged view of a bifurcation of the carotid artery used to locate positions for measurement of CIMT;

[0022] Fig. 3 is a graph showing in simplified representation the ARIC data such as provides a range of CIMT values for different age groups within the ARIC population and showing a curve fitted to this data to deduce a vascular age from CIMT;

[0023] Fig. 4 is a data flow diagram showing collection of CIMT data obtained from an ultrasound machine together with other patient data and conversion of this data to vascular age by use of a surface derived from the ARIC data of Fig. 3; and the further use of the vascular age, both as direct output to the physician and as an input to the Framingham Assessment to provide a quantitative measurement of risk of CHD;

[0024] Fig. 5 is a flow chart showing the steps of Fig. 4;

[0025] Fig. 6 is a graph showing treatment options that may depend on a quantifiable risk of heart disease and showing uncertainty in the Framingham study for an individual as may be reduced by the present invention;

[0026] Fig. 7 is a cross-sectional view of the artery of Fig. 2 showing an alternative measurement of CIMT possible with 3-D ultrasound machines; and

[0027] Fig. 8 is a figure showing a display of a B mode ultrasound image of the artery of Fig. 2 together with display of a region of interest and cursor ruler lines for automatic CIMT measurement.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0028] Referring now to Fig. 1, an ultrasound probe 10 may be directed toward the common carotid artery 12 of a patient 14 near the branching or bifurcation 16 of the carotid artery 12 into internal carotid artery 18 and exterior carotid artery 20. The ultrasound transducer may, for example, be an 8-megahertz linear array vascular ultrasound transducer (8L5) sold by Acuson of Mountain View, California for use with the Acuson Sequoia ultrasound machine, or a similar transducer made by another vendor.

[0029] As shown in Fig. 2, the ultrasound probe 10 may be directed to transmit a generally planar beam 22, defining a coplanar image plane, that is perpendicular to the lumen of the carotid artery 12 to provide a generally ring-shaped cross-sectional image 24 of a single lumen before the bifurcation 16. The planar beam 22 is established to be essentially perpendicular to the axis of the lumen by adjusting the angle to increase the sharpness of the walls of the cross sectional image 24.

[0030] The ultrasound probe 10 may then be moved in a superior direction 26 past the general enlargement of the carotid artery into a bulb 28, shown in cross sectional image 24', to continue to the carotid bifurcation 16 characterized by the presence of a flow divider 30 and two lumens as indicated by cross sectional image 24". At this time, the ultrasound probe 10 may be rotated about its axis ninety degrees producing planar beam 22' to provide a cross section parallel to the lumen encompassing three locations along a distal wall of the carotid artery 12.

[0031] The three locations include a common segment 31 defined as the distal one centimeter of the carotid artery 12 immediately proximal to the onset of increased spatial separation of the walls of the common carotid artery (i.e., immediately before the origin of the bulb 28), the bifurcation segment 33 defined as the distal one centimeter of the bulb 28 characterized by the presence of the flow divider 30 between the interior carotid arteries 18 and exterior carotid arteries 20 and the internal segment 35 defined as the proximal one centimeter of the internal carotid artery 18 starting immediately beyond the flow divider 30. At each of these segments 31, 33, and 35, the thickness of the intimal and medial layers of the

distal walls is measured. Alternatively, images of the far wall (or near wall if normative values are available) can be obtained at multiple, predefined, protocol-specified interrogation angles.

[0032] The combined thickness of the intimal and medial layers can be measured using, for example, software commercially available from Freeland Systems of Indianapolis, Indiana, under the trade name Access Point 2000, or similar software such as that available from Camtronics, Inc., Hartland, Wisconsin. A composite CIMT value may then be calculated as a mean of the averages or means of each of these segments according to the standardized protocol from the ARIC study.

[0033] Referring now to Fig. 3, the ARIC study established a relationship between CIMT and age (and gender and race) indicated by scatter plots points 34 reflecting the fact that in the populations studied in the ARIC study individuals of the same given age had different CIMT values varying over a substantial range. Generally, therefore, a given CIMT value cannot be mapped to a particular age using the ARIC data.

[0034] In order to overcome this problem, a curve 36 is fit to these scatter plot points 34 to provide a best fit. A number of different best-fit criteria are possible, with a linear regression being used in the preferred embodiment.

[0035] Vascular age can be determined by linear regression modeling using published nomograms of CIMT percentiles (5^{th}, 10^{th}, 25^{th}, 50^{th}, 75^{th}, 90^{th}, and 95^{th}) according to chronological age, sex, and race. Linear regression models are first constructed for each of the CIMT percentile functions for each carotid arterial segment 31, 33, and 35: by sex (male and female), race (white and black), and age (5-year increments from 45-65 years old). Composite CIMT values can then be used to determine the vascular age defined as the age at which the composite CIMT value for an individual of a given race and sex would represent the median value . (50^{th} percentile).

[0036] Specifically, the linear 50^{th} percentile function by chronological age, sex, and race can be used to assign a vascular age to the subject having a given composite CIMT value such that if each of the subject's segmental scores were at the 50^{th} percentile for their chronological age, sex, and race, then their composite CIMT would be at the 50^{th} percentile and their vascular age would be equal to their chronological age. For example, a 45-year black female with a composite CIMT of 0.593 mm would have a CIMT percentile of 50% and a vascular age of 50 years; however, a 45-year black female with a composite CIMT of 0.678 mm would have a CIMT percentile of 71% and a vascular age of 55 years, representing the age at which a composite CIMT value of 0.678 mm represents the 50^{th} percentile.

[0037] Using this modeling, a given CIMT value may be mapped to a unique vascular age. It should be noted that vascular age will generally not match the chronological age of the patient 14 but will be a statistical construction in which the vascular age of the patient 14 is an age of ARIC data at which the patient's CIMT is near the middle of the range of the scatter plot points 34.

[0038] Referring now to Fig. 4, the linear regression curve 36 as extended across other patient variables of the ARIC study such as age, gender, and race and potentially across new variables such as body size creates a multidimensional surface 38 mapping values of the patient variables to a unique vascular age 40. As a practical matter, the surface 38 may be stored as one or more data table and vascular age may be determined by interpolation between data table values as is well understood in the art.

[0039] Referring now to Fig. 5, a first step of the present invention indicated by process block 42 collects the patient data described above including, for example, age, gender, race and body size. This information may be entered into an ultrasound machine 46 by means of a keyboard 50 or the data may be directly imported from the ultrasound machine into a software program and displayed on a display 52 according to techniques well known in the art.

[0040] At process block 54, the above-described CIMT measurement is performed using the ultrasound probe 10.

[0041] The CIMT data 56 and the patient data 58 form arguments that are applied to the N-dimensional surface 38 to produce a vascular age 40 as indicated by process block 60. This determination of vascular age of process block 60 may be performed by processing circuitry contained in the ultrasound machine 46, however, it is also contemplated that the vascular age may be computed by a separate computing device.

[0042] The vascular age 40 may then be output to the display 52 of the ultrasound machine 46 to provide an intuitive measure of CIMT. Generally, the patient will compare his or her vascular age to his or her actual chronological age to get a sense of his or her risk of coronary heart disease.

[0043] The ultrasound machine 46 or the separate computing device may store the Framingham Assessment data 62 providing inputs for chronological age as well as inputs for cholesterol, HDL cholesterol, smoking, total cholesterol and diabetes. As represented by process block 66, these latter five inputs 64 are then applied to the Framingham Assessment data 62 with the vascular age 40 being substituted for the chronological age expected from the Framingham analysis. This application of data generally involves finding a row in the Framingham Assessment data 62 matching each of the characteristics or most closely matching each of inputs 64 and vascular age 40.

[0044] The Framingham Assessment data then yields a percent risk of CHD according to this well-known study. This risk is output as indicated by process block 68.

[0045] The present invention thus allows the inputting of the CIMT as well as other information such as age, gender, and race data into the Framingham study

through the use of the concept of vascular age.

[0046] Referring now to Fig. 6, although the Framingham Assessment accurately reflects risk of CHD for a population, or an individual, it will provide an uncertainty 70 measurable in a range of percent risk of CHD. This uncertainty may span ranges of risk 72A, 72B and 72C associated with different treatment options. It is expected that use of the present invention will reduce the uncertainty as indicated by 70'thereby clarifying treatment options. This expected improvement may be established by obtaining additional information from the ARIC study indicating whether individuals in that study had a clinical manifestation of coronary heart disease in the period following their measurement. The results obtained by the present invention would then be compared to actual outcomes of the ARIC population to confirm clinical significance.

[0047] Referring now to Fig. 7, the present invention is not limited to two dimensional ultrasound machines but may find application in three dimensional ultrasound machines which collect a volume of ultrasonic data and can display a cross-sectional image of the carotid artery 12. In this case, the intima-medial separation 67 may be measured, for example, in a ring extending circumferentially around the carotid artery in a plane perpendicular to the lumen of the artery rather than in a line segment along the distal portion of the lumen as described above. The measurements taken in the ring can be averaged together and substituted for the measurements described with respect to Fig. 2. Three rings may be measured intersecting the common section 31, the bifurcation segment 33, and the internal segment 35.

[0048] While one embodiment of the present invention contemplates that the measurement of CIMT will be performed manually, in an alternative embodiment the measurements of CIMT may be performed automatically by the ultrasound machine 36 which may also perform the averaging necessary for the software described. Such automatic measuring is known in the art and is described, for example, in U. S. Patent 6,132, 373 issued October 17,2000.

[0049] Referring to Fig. 8, alternatively a combination of manual and automatic measurement techniques may be used in which an operator of the ultrasound machine 46 locates a region of interest cursor 90 being generally a rectangle over the image of the carotid artery 12 displayed on the display 52. The region of interest cursor 90 allows the operator to identify the appropriate regions (common section 31, the bifurcation segment 33, and the internal segment 35.). Once the region of interest cursor is located, defining the length along the wall of the carotid artery 12, thickness cursors 92 may be placed on either side of the intimal and medial layers of the distal wall at a particular location. The CIMT value may then be automatically computed based on starting points of the thickness cursors 92 extrapolated by computer analyses of the image data using region extraction algorithms well known in the art.

[0050] It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein, but include modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims.

Claims

1. A diagnostic ultrasound machine (46) comprising:

an ultrasound transducer (10) positionable near the carotid artery (12) to obtain echo signals from the carotid artery (12);
a processing circuit able to communicate with the ultrasonic transducer (10) and configured to:

(i) process the echo signal to reveal carotid intima-medial thickness (CIMT); and
(ii) apply the revealed CIMT to first stored data (38) relating the CIMT to vascular age (40) to determine vascular age (40), wherein:

the first data (38) is derived from data relating age to CIMT in a study population, and the vascular age (40) is a statistically derived age of an individual having the revealed CIMT in the study population; **characterised in that** the processing circuit is further configured to:

(iii) apply the determined vascular age (40) to stored second data relating chronological age to the quantified risk of heart disease, and
(iv) output a quantitative estimate of the risk of heart disease, wherein:

the second data is data relating chronological age to quantified risk of heart disease, wherein the first and second data are combined by taking vascular age (40) deduced from the first data set (38) and inputting it as chronological age into the second data set.

2. The diagnostic ultrasonic machine (46) of claim 1 wherein the second data is Framingham data.

3. The diagnostic ultrasonic machine (46) of claim 1 wherein the processing circuit further provides for input of patient data selected from the group consisting of: chronological age, gender, race and body size and wherein at least one of these patient data are also applied to at least one of the first and second data sets.

4. The diagnostic ultrasound machine (46) of claim 1

wherein the measure of risk of heart disease is expressed in percent chance of heart disease within ten years.

5. The diagnostic ultrasound machine (46) of claim 1 wherein the measure of CIMT is an average of carotid intima-medial thickness over a predetermined region (31, 33, 35) of the carotid artery (12).

6. The diagnostic ultrasonic machine (46) of claim 5 wherein the predetermined region is near the carotid bifurcation (16).

7. The diagnostic ultrasonic machine (46) of claim 5 wherein the predetermined region is an axial line along the carotid artery (12).

8. The diagnostic ultrasonic machine (46) of claim 1 wherein the processing circuitry collects a three-dimensional image set of the carotid artery (12) and wherein the predetermined region is a circumferential ring of the carotid artery (12).

9. The diagnostic ultrasound machine (46) of claim 1 wherein the processing circuitry provides automatic measurement of the CIMT.

10. The diagnostic ultrasonic machine (46) of claim 1 wherein the processing circuitry further output an image of the carotid artery (12) and accepts user input locating points on the image for the automatic measurement.

11. A diagnostic ultrasound machine (46) of claim 1 wherein the processing circuit is configured further to:

(v) output the vascular age (40).

12. The diagnostic ultrasound machine (46) of claim 1 wherein the data relating age to CIMT is ARIC data.

13. The diagnostic ultrasonic machine (46) of claim 1 wherein multiple CIMT values related to a single age are combined by curve fitting to yield a single vascular age (40) for a single CIMT value.

14. The diagnostic ultrasonic machine (46) of claim 1 wherein the processing circuit further provides for input of patient data selected from the group consisting of: chronological age, gender, race and body size and wherein at least one of these patient data are also applied to the first stored data (38).

15. A method of analyzing data about an individual having a given chronological age and a given carotid intima-medial thickness (CIMT) comprising the steps of:

(a) deducing a vascular age (40) of the individual differing from the given chronological age such as would place the individual's given CIMT in a median of CIMT for that vascular age (40) for a standard population; **characterised by**:
(b) using the vascular age (40) as an input for chronological age in a Framingham model of heart disease to provide a quantitative estimate of the risk of heart disease; and
(c) providing the individual with the vascular age (40) and the quantitative estimate of the risk of heart disease.

Patentansprüche

1. Diagnostische Ultraschallmaschine (46), umfassend:

einen Ultraschallwandler (10), welcher nahe der Karotis (12) positionierbar ist, um Echosignale von der Karotis (12) zu erhalten;
einen Prozessorschaltkreis, welcher mit dem Ultraschallwandler (10) kommunizieren kann und konfiguriert ist:

(i) das Echosignal zu prozessieren, um eine Karotid-Intima-Medial-Thickness (CIMT) zu erkennen; und
(ii) die erkannte CIMT auf erste gespeicherte Daten (38) anzuwenden, welche die CIMT in Bezug zu Gefäßalter (40) setzen, um ein Gefäßalter (40) zu bestimmen, wobei:

die ersten Daten (38) aus Daten abgeleitet werden, welche in einer Studienpopulation Alter in Bezug zu CIMT setzen, und das Gefäßalter (40) ein statistisch abgeleitetes Alter eines Individuums mit der erkannten CIMT in der Studienpopulation ist; dadurch charakterisiert, dass der Prozessorschaltkreis weiterhin konfiguriert ist:

(iii) das bestimmte Gefäßalter (40) auf zweite gespeicherte Daten anzuwenden, welche chronologisches Alter in Bezug zu dem quantifizierten Risiko einer Herzkrankheit setzen, und
(iv) eine quantitative Abschätzung des Risikos einer Herzkrankheit auszugeben, wobei:

die zweiten Daten Daten sind, welche chronologisches Alter in Bezug zu quantifiziertem Risiko einer Herzkrankheit setzen, wobei die ersten und zweiten Daten dadurch kombiniert werden, dass von dem ersten Datensatz (38) hergeleitetes Gefäßalter (40) genommen wird und

es als chronologisches Alter in den zweien Datensatz eingegeben wird.

2. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei die zweiten Daten Framingham-Daten sind.

3. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis weiterhin die Eingabe von Patientendaten bereitstellt, welche aus der Gruppe ausgewählt werden, die besteht aus: chronologischem Alter, Geschlecht, Rasse und Körpergröße, und wobei mindestens eine dieser Patientendaten auch auf mindestens einen der ersten oder zweiten Datensätze angewendet werden.

4. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei das Risikomaß einer Herzkrankheit durch eine prozentuale Wahrscheinlichkeit einer Herzkrankheit innerhalb von zehn Jahren ausgedrückt wird.

5. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei das Maß der CIMT ein Mittelwert einer Karotid-Intima-Medial-Thickness innerhalb eines Vorbestimmten Abschnitts (31, 33, 35) der Karotis (12) ist.

6. Diagnostische Ultraschallmaschine (46) nach Anspruch 5, wobei der Vorbestimmte Abschnitt nahe der Karotisbifurkation (16) ist.

7. Diagnostische Ultraschallmaschine (46) nach Anspruch 5, wobei der Vorbestimmte Abschnitt eine axiale Linie entlang der Karotis (12) ist.

8. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis einen dreidimensionalen Bilddatensatz der Karotis (12) aufnimmt und wobei der Vorbestimmte Abschnitt ein peripherer Ring der Karotis (12) ist.

9. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis automatisches Messen des CIMT bereitstellt.

10. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis weiterhin ein Bild der Karotis (12) ausgibt und Benutzereingabe akzeptiert, die Punkte auf dem Bild für die automatische Messung lokalisiert.

11. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis weiterhin konfiguriert ist:

(v) das Gefäßalter (40) auszugeben.

12. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei die Daten, welche Alter zu CIMT in Bezug setzen, ARIC-Daten sind.

13. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei mehrere CIMT-Werte, welche in Bezug zu einem einzigen Alter stehen, mittels Kurvenanpassung kombiniert werden, um ein einzelnes Gefäßalter (40) für einen einzelnen CIMT-Wert zu erhalten.

14. Diagnostische Ultraschallmaschine (46) nach Anspruch 1, wobei der Prozessorschaltkreis weiterhin Eingabe von Patientendaten bereitstellt, welche aus der Gruppe ausgewählt werden, die besteht aus: chronologischem Alter, Geschlecht, Rasse und Körpergröße, und wobei mindestens eine dieser Patientendaten auch auf die ersten gespeicherten Daten (38) angewendet werden.

15. Verfahren zur Analyse von Daten über ein Individuum, welches ein vorgegebenes chronologisches Alter und eine vorgegebene Karotid-Intima-Medial-Thickness (CIMT) hat, die Schritte umfassend:

(a) Herleiten eines Gefäßalters (40) des Individuums, welches sich von dem vorgegebenen chronologischen Alter unterscheidet, so dass es den vorgegebenen CIMT des Individuums in einem Median von CIMT für dieses Gefäßalter (40) einer Standardpopulation platzieren würde; charakterisiert durch:
(b) Verwenden des Gefäßalters (40) als eine Eingabe für chronologisches Alter in ein Framingham-Modell der Herzkrankheit, um eine quantitative Abschätzung des Risikos einer Herzkrankheit bereitzustellen; und
(c) Bereitstellen des Gefäßalters (40) und der quantitativen Abschätzung des Risikos einer Herzkrankheit an das Individuum.

Revendications

1. Machine de diagnostic à ultrasons (46) comprenant :

un transducteur d'ultrasons (10) pouvant être positionné près de l'artère carotide (12) pour obtenir des signaux d'écho venant de l'artère carotide (12) ;
un circuit de traitement pouvant communiquer avec le transducteur d'ultrasons (10) et configuré pour :

(i) traiter le signal d'écho pour révéler une épaisseur intima-média carotidienne (EIMC) ; et
(ii) appliquer l'EIMC révélée à des premiè-

res données stockées (38) concernant le rapport EIMC à âge vasculaire (40) pour déterminer l'âge vasculaire (40), dans lequel :

les premières données (38) sont dérivées des données concernant le rapport âge à EIMC dans une population étudiée, et l'âge vasculaire (40) est un âge statistiquement dérivé d'un individu ayant l'EIMC révélée dans la population étudiée ; **caractérisé en ce que** le circuit de traitement est en outre configuré pour :

(iii) appliquer l'âge vasculaire (40) déterminé à des secondes données stockées concernant le rapport de l'âge chronologique au risque quantifié de maladie cardiaque, et (iv) sortir une estimation quantitative du risque de maladie cardiaque, dans lequel :

les secondes données sont des données concernant le rapport de l'âge chronologique au risque quantifié de maladie cardiaque, dans lequel les premières et secondes données sont combinées en prenant l'âge vasculaire (40) déduit de la première série de données (38) et en l'entrant comme âge chronologique dans la seconde série de données.

2. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle les secondes données sont des données Framingham.

3. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement permet aussi l'entrée de données de patient sélectionnées dans le groupe consistant en : l'âge chronologique, le genre, la race et la taille corporelle et dans lequel au moins l'une de ces données de patient sont aussi appliquées à au moins l'une des premières et secondes séries de données.

4. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle la mesure du risque de maladie cardiaque est exprimée en pourcentage de chance de maladie cardiaque dans les dix années qui viennent.

5. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle la mesure de l'EIMC est une moyenne de l'épaisseur intima-média carotidienne sur une région prédéterminée (31, 33, 35) de l'artère carotide (12).

6. Machine de diagnostic par ultrasons (46) selon la revendication 5 dans laquelle la région prédéterminée est proche de la bifurcation carotidienne (16).

7. Machine de diagnostic par ultrasons (46) selon la revendication 5 dans laquelle la région prédéterminée est une ligne axiale le long de l'artère carotide (12).

8. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement collecte une série d'images en trois dimensions de l'artère carotide (12) et dans laquelle la région prédéterminée est un anneau circonférentiel de l'artère carotide (12).

9. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement fournit une mesure automatique de l'EIMC.

10. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement sort en outre une image de l'artère carotide (12) et accepte l'entrée par l'utilisateur de points de positionnement sur l'image pour la mesure automatique.

11. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement est configuré en outre pour :

(v) sortie l'âge vasculaire (40).

12. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle les données concernant le rapport d'âge à EIMC sont des données ARIC.

13. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle de multiples valeurs de l'EIMC concernant un seul âge sont combinées par une adaptation de courbe pour faire correspondre seul un âge vasculaire (40) à une seule valeur de EIMC.

14. Machine de diagnostic par ultrasons (46) selon la revendication 1 dans laquelle le circuit de traitement permet en outre l'entrée de données de patient sélectionnées dans le groupe consistant en : l'âge chronologique, le genre, la race et la taille corporelle et dans lequel au moins l'une de ces données de patient sont aussi appliquées aux première données stockées (38).

15. Procédé d'analyse de données au sujet d'un individu ayant un âge chronologique donné et une épaisseur intima-média carotidienne (EIMC) donnée comprenant les étapes consistant à :

(a) déduire un âge vasculaire (40) de l'individu différant de l'âge chronologique qui placerait l'EIMC de l'individu donné dans une moyenne de l'EIMC pour l'âge vasculaire (40) d'une population standard ; **caractérisé par** le fait :

(b) d'utiliser l'âge vasculaire (40) comme une entrée pour l'âge chronologique dans un modèle de Framingham de maladie cardiaque pour fournir une estimation quantitative du risque de maladie cardiaque ; et
(c) de fournir à l'individu l'âge vasculaire (40) et l'estimation quantitative du risque de maladie cardiaque.

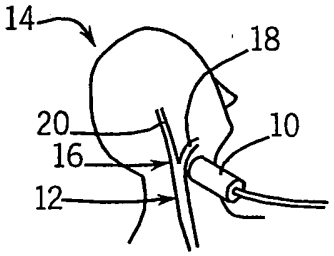


FIG. 1

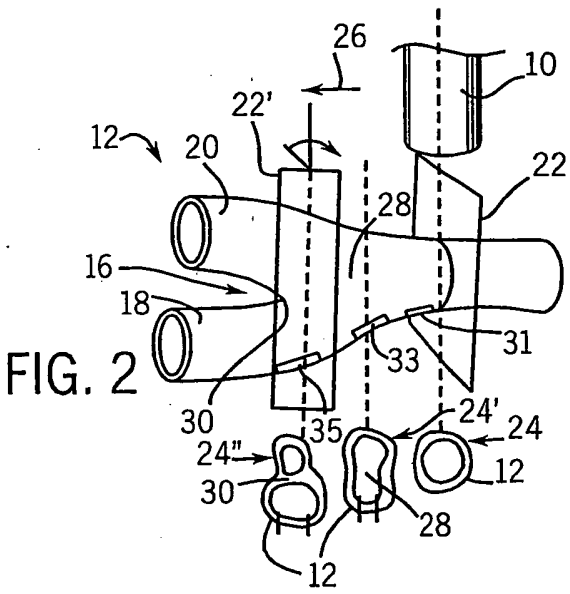


FIG. 2

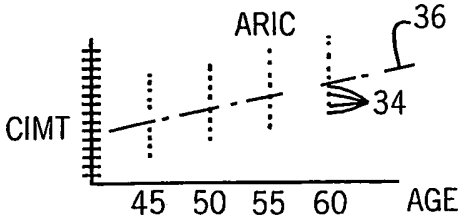


FIG. 3

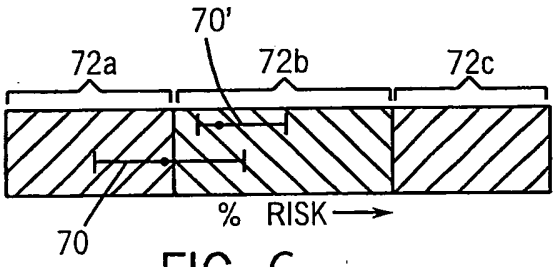


FIG. 6

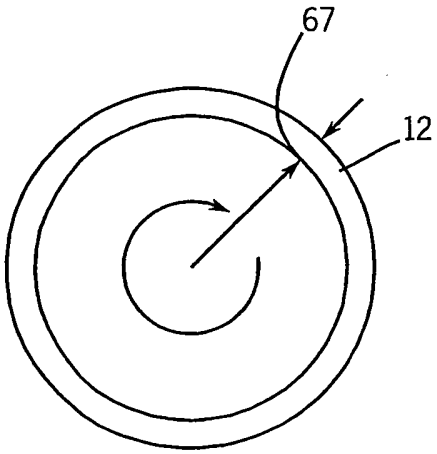


FIG. 7

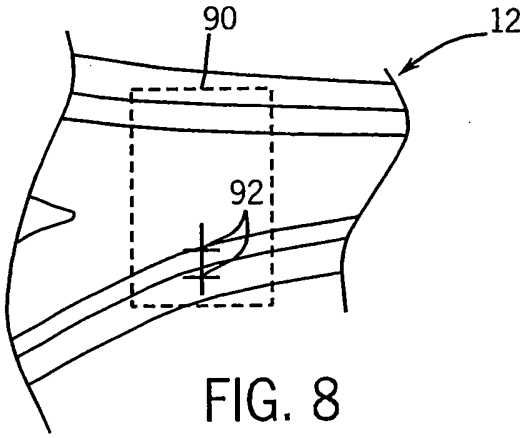
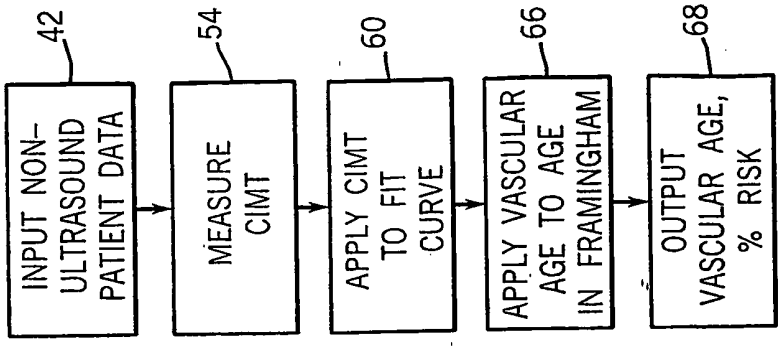


FIG. 8

FIG. 5


42
INPUT NON-ULTRASOUND PATIENT DATA
54
MEASURE CIMT
60
APPLY CIMT TO FIT CURVE
66
APPLY VASCULAR AGE TO AGE IN FRAMINGHAM
68
OUTPUT VASCULAR AGE, % RISK

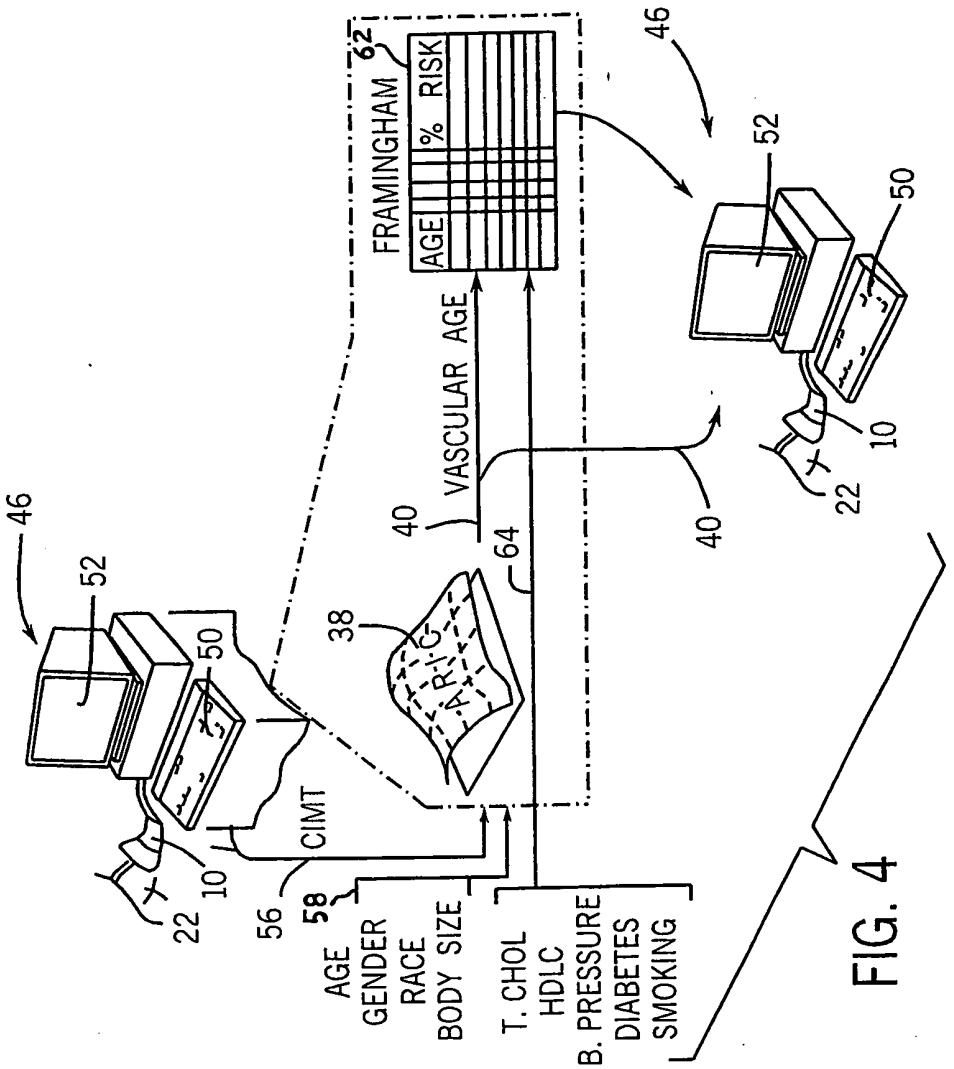

46
52
50
10
22
CIMT
56
58
AGE
GENDER
RACE
BODY SIZE
T. CHOL
HDLC
B. PRESSURE
DIABETES
SMOKING
38
64
40
VASCULAR AGE
62
FRAMINGHAM
AGE
% RISK
40
46
52
50
10
22

FIG. 4

REFERENCES CITED IN THE DESCRIPTION

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- EP 0958784 A1 **[0006]**
- US 6132373 A **[0048]**

Non-patent literature cited in the description

- **WILSON.** Prediction of Coronary Heart Disease Using Risk Factor Categories. *Circulation,* 1998, vol. 97, 1837-1847 **[0003]**
- **BOND.** High Resolution B Mode Ultrasound Scanning Methods in the Arteriosclerosis Risk in Community Study (ARIC. *J. Neuroimaging,* 1991, vol. 1, 68-73 **[0007]**

专利名称(译)	用于指示冠心病风险的超声设备和方法		
公开(公告)号	EP1531732B1	公开(公告)日	2011-12-28
申请号	EP2003741832	申请日	2003-05-29
[标]申请(专利权)人(译)	威斯康星校友研究基金会		
申请(专利权)人(译)	威斯康星校友研究基金会		
当前申请(专利权)人(译)	威斯康星校友研究基金会		
[标]发明人	STEIN JAMES H		
发明人	STEIN, JAMES, H.		
IPC分类号	A61B8/00 A61B8/08		
CPC分类号	A61B5/02007 A61B8/0858		
优先权	10/290421 2002-11-07 US 60/386905 2002-06-05 US		
其他公开文献	EP1531732A2		
外部链接	Espacenet		

摘要(译)

超声机测量冠状动脉内膜 - 内侧厚度并将其与统计学推导的血管年龄相关联。可以使用血管年龄来计算冠心病的定量风险，以在公开可用的风险评估数据中替代实足年龄。

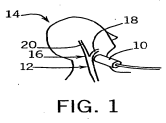


FIG. 1

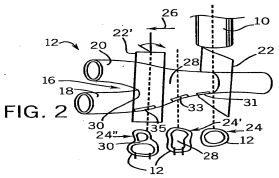


FIG. 2

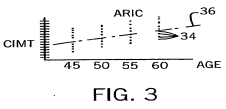


FIG. 3

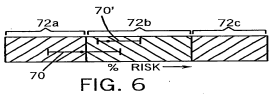
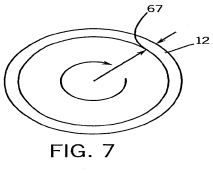


FIG. 6



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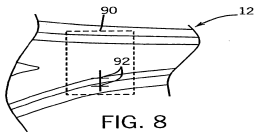

FIG. 8