National Taiwan University Hospital Letter

Address: No. ٧ Chung-Shan S. Road, Taipei City ١٠٠٠٢
Contact: C.Y. Wu
Tel.: ٠٢-٣٣٦٦-٨٢٤٢
Fax: ٠٢-٣٣٦٦-٨٢٤٣
Email: tywu@ntuh.gov.tw

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١٣F, No. ١٨٩, Kang Chien Road Niehu District, Taipei City

To: Rossmax InnoTek Corp.
Issuing date: March ٥, ٢٠١٥
Doc. No.: NTUH No. ١٠٤٦٧٠٠٨٠
Class: General
Confidentiality: General
Attachment: Clinical Trial Protocol & Contract

Subject: Clinical Trial Protocol & Contract

Explanations:

١. Rossmax InnoTek Corp. contracts National Taiwan University Hospital to conduct the "Clinical Validation of SB٢٠٠ Finger-tip APG (Acceleration PlethysmoGram) Pulse Oixmeter as a marker of atherosclerotic disease" (Ethics Committee Case No. ٢٠١٤١١٠٢٤RSA) by Dr. Da-Chen Su of the Department of Cardiology. The application was reviewed by the A Research Committee of National Taiwan University Hospital and approved for filing; also, the case was recognized in the ٦١st Committee meeting on December ٢٦, ٢٠١٤.

٢. The signed original clinical trial protocol and contract is delivered to the clinical trial consigner, National Taiwan University Hospital, and Principal Investigator as evidence.

Original: Rossmax InnoTek Corp., National Taiwan University Hospital, and Dr. Da-Chen Su of the Department of Cardiology.

Copy: Department of Account and Statistics, Ethics Committee, and Department of Medical Research, Clinical Research Group

院長 黃冠棠

Dean K.T. Huang

Clinical Validation of SB٢٠٠ Finger-tip APG (Acceleration PlethysmoGram) Pulse Oixmeter as a marker of atherosclerotic disease"

Clinical test performed by National Taiwan University Hospital
Principal Investigator: Dr. Da-Chen Su
Target enrollment: ٣٠٠ patients
Clinical trial period: January ١, ٢٠١٥ – September ٣٠, ٢٠١٥ (an extension must be with the consent of both parties)

Ethics Committee Case No.: ٢٠١٤١١٠٢٤RS
Date: ١٠/٣١/٢٠١٤

National Taiwan University Hospital
Clinical Test Protocol
1 The Protocol must be with a cover page "Clinical Test Summary" attached
☐ Drug ☐ Medical equipment ☐ Medical technology ■ Others _____

I. Project title:
Clinical validation of SB٢٠٠ Finger-tip APG (Acceleration PlethysmoGram) Pulse Oximeter as a marker of atherosclerotic disease

II. Principal Investigator: Dr. Da-Chen Su

III. Co-investigator: None

IV. Test theme:
Finger-tip APG Pulse Oximeter as a marker of atherosclerotic disease

V. Test purpose and background (including theoretical basis and related literature reports):

Research purpose:
Compare the arteriosclerosis status of test subjects to the APG measurement results derived from SB٢٠٠ to verify the correlation of the two results.

١. Verify the arteriosclerosis status derived from the mathematical formulas of SB٢٠٠ SpO٢ comparing to the arteriosclerosis severity in clinical practice in order to determine whether the SB٢٠٠ SpO٢ index can be used clinically.

٢. Verify whether the risk factors of coronary heart diseases and eating and living habits are correlated with SB٢٠٠ SpO٢ arteriosclerosis measurement.

Research background:

Economic development and change in lifestyle, busy schedule, change in dietary towards fast food, dinning-out, and high-grease, high-sugar, and high-calories eating habit; also, the risk factors of smoking young, diabetes, high blood pressure, high cholesterol cause the frequent occurrence of arteriosclerotic diseases. Therefore, early diagnosis, prevention, and early treatment are most important under the circumstance.

Arteriosclerotic diseases could occur in every part of the human body with a health threat of myocardial ischemia, high blood pressure, kidney failure, peripheral vascular ischemia and tissue necrosis, abdominal organ ischemia, etc., including the complication of acute myocardial infarction, stroke, or any other fatal diseases that should not be taken lightly. The atherosclerosis of peripheral vascular ischemia, coronary heart diseases, and cerebrovascular diseases is the main reason for the death or handicap of patients over fifty years old, in general.

The cardiovascular diseases are commonly seen in the aging population along with medicine advances and medical internationalization. The number of patients with leg stroke is increasing dramatically; also, leg stroke is a peripheral arterial occlusion. A peripheral arterial occlusion is mostly caused by arteriosclerosis or acute embolism, coagulation dysfunction, and vascular diseases. In general, patients with low limb arterial obstruction are most likely suffering from the complication of other arterial obstruction, such as, diseases;

coronary artery disease, cerebral vascular, and renal artery

therefore, they occurrence of myocardial infarction, stroke, or nephropathy is highly possible. Clinically, cardiovascular artery occlusion patients should receive other vascular system check-up.

In the United States, ١٢٪ of the adults (around ١٠ million persons) are most likely with a peripheral arterial occlusion; also, ٢٠٪ of the adults over ٧٠ years old are most likely with such disease due to the aging population [١].

The prevailing arteriosclerosis is becoming the heaviest medical burden in a developed or developing nation worldwide. Therefore, early diagnosis and early treatment is the one and only way of disease prevention control.

Most arteriosclerosis diagnosis equipment is heavy, massive, immobile, and expensive; also, it must be operated by professionals; therefore, the early diagnosis for patients with high risk is not easy, the early treatment is not possible, and the opportunity to control cardiovascular risk factors is slim.

The correlation of APG (Acceleration PlethysmoGram) and arteriosclerosis has been developed from the study of PPG (Photoplethysmography) [٢ & ٣].

APG (Acceleration PlethysmoGram) is applied to demonstrate the blood vessel flexibility waveform formed from blood flow acceleration. In other words, APG (Acceleration PlethysmoGram) is medical equipment applied to analyze blood flow acceleration and blood vessel flexibility of blood flow. Literally, acceleration pulse wave refers to applying non-invasive light modulation technology to irradiate on the skin tissue where vascular intensive – such as, fingers, earlobes, etc. The changes in transmittance intensity will cause a modulation change in hemoglobin level, then, collect the signals of changes in hemoglobin level and utilize photoelectric conversion technology to collect electrical signals, added with microprocessor programming and quadratic differential formula to compute APG (Acceleration PlethysmoGram). Analyze Acceleration PlethysmoGram) to derive several frequently seen characteristic figures ٣، ٤، & ٥. Coordinate such characteristic figures to the coronary diseases of the patients with known severity of arteriosclerosis, from symptom free to minor, from minor to major, in order to achieve the purpose of the clinical trial.

There are several APG equipment made and launched in market currently; however, they are big in size and not portable; therefore, they are mainly for hospital use. The SB٢٠٠ APG of Rossmax InnoTek Corp. is to provide APG analysis when measuring hemoglobin level at the same time for the entire process completed in one minute, improving the time-consuming arteriosclerosis level measurement with large equipment and enhancing the willingness of users to take the measurement in order to improve the possibility of early discovery and control of cardiovascular risk factors.

Literature reference:

١. Criqui MH, Fronek A, Barrett-Connor E, Klauber MR, Gabriel S, Goodman D. The prevalence of peripheral arterial disease in a defined population. Circulation ١٩٨٥; ٧١(٣): ٥١٠–٥١٥.

٢. Alnaeb M, Alobaid N, Seifalian A, Mikhailidis D, Hamilton G. Optical techniques in the assessment of peripheral arterial disease. Curr Vasc Pharmacol ٢٠٠٧; ٥: ٥٣–٩.

٣. Mohamed Elgendi. ON the analysis of fingertip photoplethysmogram signals. Current Cardiology Reviews ٢٠١٢; ٨: ١٤–٢٥.

٤. Homma S, Ito S, Koto T, Ikegami H. Relationship between accelerated pletysmography, blood pressure and arterial elasticity. Elasticity Science ١٩٩٢; ٤١: ٩٨–١٠٧.

٥. Fujimoto K, Sano Y, Watanabe E. Application of accelerated

plethysmography for measuring pulse wave velocity. Human Engineering ۲۰۱۲؛ ٤٨: ۲۸٥–۲۹٤.

VI. Test methods:

(I) Patient eligibility:

The Department of Cardiology and the Department of Cardiac Surgery of National Taiwan University Hospital invite ۱٥۰ coronary patients as test subjects، including ٥۰ patients with coronary artery bypass graft (CABG)، ٥۰ patients with percutaneous occlusive balloon angioplasty stinting (POBAS)، and ٥۰ patients with mild coronary heart disease؛ also، collect ۱٥۰ outpatients without any coronary heart disease as age control group. Both groups are tested completely for cardiovascular risk factors and blood biochemistry، including a non-invasive cardiovascular artery check-up.

(II) Clinical trial design and procedures (related to clinical test):

Starting from December ۲۰۱٤، invited patients with known coronary cardiac catheterization with their full knowledge of and their consent to the intended purpose to participate in this non-invasive cardiovascular check-up and arteriosclerosis level study. The arteriosclerosis level of each test subject is known to us (such as: ۱، ۲، or ۳ coronary artery occluded). Fifty (٥۰) patients with severe arteriosclerosis (CABG or with more than ۳-artery occlusion)، one hundred (۱۰۰) patients with mild coronary heart disease and intermediate level of arteriosclerosis (۱-artery or ۲-artery coronary occlusion)؛ also، one hundred and fifty (۱٥۰) outpatients without any coronary heart disease (without any noticeable artery occlusion) as the control group for a total of three hundred (۳۰۰) test subjects.

Arranged test subjects to receive non-invasive check-up. The arteriosclerosis level of each test subject is measured with the use of SB۲۰۰ SpO۲؛ also، the designated research therapists are not aware of the arteriosclerosis severity of each test subject. The comparison of correlation with coronary arteriosclerosis includes:

۱. SB۲۰۰ SpO۲ (Fingertip Pulse Oximeter): Arteriosclerosis status derived from the mathematical formulas of SB۲۰۰ SpO۲ is classified as SB۲۰۰ score ۱ ~ score ٦. Test subject may not smoke a cigarette، exercise، drink coffee، tea، or wine prior to the clinical trial؛ also، must stay in a quiet room for ۱۰ minutes calmly and then clap the Fingertip Pulse Oximeter (SB۲۰۰ SpO۲) on the index finger or middle finger of right hand or left hand، from left to right، from index

finger to middle finger for a standardized measurement. One finger per minute and the entire process takes about ٢٠ minutes per patient.

٢. Collect the most recent cardiac catheterization result and arteriosclerosis level of each test subject; also, the occurrence and frequency of cardiovascular event of each test subject, and other related cardiovascular risk factors in clinical, eating habit, and lifestyle data, including equipment test, medical records, or questionnaires.

(III) Clinical test period and progress:

١٢/٣١/٢٠١٤ ~ ١٢/٣١/٢٠١٥ (an extension must be agreed upon by both parties)

(IV) Medicines or medical equipment needed (name and quantity):

No medicine is used for this clinical trial. Six units of SB٢٠٠ SpO٢ (Fingertip Pulse Oximeter) are used.

(V) Medical record format:

Medical records forms are not used.

(VI) Data collection, process, evaluation, and statistical analysis method:

MS Excel for data storage and SAS statistical software for analysis.

VII. Test subjects introduction and consent forms:

See attachment

VIII. Data reference from prior clinical trial:

This clinical trial does not involve medicine clinical trial.

IX. Free Sales Certificate photocopy of the nation of the manufacturer and the highest health department of the marketing nation:

This clinical trial does not involve medicine clinical trial.

X. For the new medicines or new medical equipment in research and development stage, please describe the status and progress with the clinical trial certificate photocopy of the manufacturing nation or marketing nation enclosed:

XI. This clinical trial does not involve medicine clinical trial.

XII. The risk and potential physical and spiritual benefit:

None

XIII. The risk and potential financial gains:

None

XIV. Conflict of interest:

None

XV. Other data:

None

Clinical Validation Report of SB۲۰۰ Finger-tip APG (Acceleration PlethysmoGram) Pulse Oixmeter as a marker of atherosclerotic disease"

Dr. Da-Chen Su

Project title:

Clinical validation of SB۲۰۰ Finger-tip APG (Acceleration PlethysmoGram) Pulse Oximeter as a marker of atherosclerotic disease

Research purpose

Compare the arteriosclerosis status of test subjects to the APG measurement results derived from SB۲۰۰ to verify the correlation of the two results.

۱. Verify the arteriosclerosis status derived from the mathematical formulas of SB۲۰۰ SpO۲ comparing to the arteriosclerosis severity in clinical practice in order to determine whether the SB۲۰۰ SpO۲ index can be used clinically.

۲. Verify whether the risk factors of coronary heart diseases and eating and living habits are correlated with SB۲۰۰ SpO۲ arteriosclerosis measurement.

Research background:

Economic development and change in lifestyle, busy schedule, change in dietary towards fast food, dinning-out, and high-grease, high-sugar, and high-calories eating habit; also, the risk factors of smoking young, diabetes, high blood pressure, high cholesterol cause the frequent occurrence of arteriosclerotic diseases. Therefore, early diagnosis, prevention, and early treatment are most important under the circumstance.

Arteriosclerotic diseases could occur in every part of the human body with a health threat of myocardial ischemia, high blood pressure, kidney failure, peripheral vascular ischemia and tissue necrosis, abdominal organ ischemia, etc., including the complication of acute myocardial infarction, stroke, or any other fatal diseases that should not be taken lightly. The atherosclerosis of peripheral vascular ischemia, coronary heart diseases, and cerebrovascular diseases is the main reason for the death or handicap of patients over fifty years old in general.

The cardiovascular diseases are commonly seen in the aging population along with medicine advances and medical internationalization. The number of patients with leg stroke is increasing dramatically; also, leg stroke is a peripheral arterial occlusion. A peripheral arterial occlusion is mostly caused by arteriosclerosis or acute embolism,

coagulation dysfunction، and vascular diseases. In general، patients with low limb arterial obstruction are most likely suffering from the complication of other arterial obstruction، such as، coronary artery disease، cerebral vascular and renal artery diseases؛ therefore، the occurrence of myocardial infarction، stroke، or nephropathy is highly possible. Clinically، cardiovascular artery occlusion patients should receive other vascular system check up.

In the United States، ١٢٪ of the adults (around ١٠ million persons) are most likely with a peripheral arterial occlusion؛ also، ٢٠٪ of the adults over ٧٠ years old are most likely with such disease due to the aging population ﷺ١. The prevailing arteriosclerosis is becoming the heaviest medical burden in a developed or developing nation worldwide. Therefore، early diagnosis and early treatment is the one and only way of disease prevention control. Most arteriosclerosis diagnosis equipment is heavy، massive، immobile، and expensive؛ also، it must be operated by professionals؛ therefore، the early diagnosis for patients with high risk is not easy، the early treatment is not possible، and the opportunity to control cardiovascular risk factors is slim.

The correlation of APG (Acceleration PlethysmoGram) and arteriosclerosis has been developed from the study of PPG (Photoplethysmography) ﷺ٢ & ٣. APG (Acceleration PlethysmoGram) is applied to demonstrate the blood vessel flexibility waveform formed from blood flow acceleration. In other words، APG (Acceleration PlethysmoGram) is medical equipment applied to analyze blood flow acceleration and blood vessel flexibility of blood flow.

Literally، acceleration pulse wave refers to applying non-invasive light modulation technology to irradiate on the skin tissue where vascular intensive – such as، fingers، earlobes، etc. The changes in transmittance intensity will cause a modulation change in hemoglobin level، then، collect the signals of changes in hemoglobin level and utilize photoelectric conversion technology to collect electrical signals، added with microprocessor programming and quadratic differential formula to compute APG (Acceleration PlethysmoGram). Analyze (Acceleration PlethysmoGram) to derive several frequently seen characteristic figures ﷺ٣، ٤، & ٥. Coordinate such characteristic figures to the coronary diseases of the patients with known severity of

arteriosclerosis، from symptom free to minor، from minor to major، in order to achieve the purpose of the clinical trial.

There are several APG equipment made and launched in market currently؛ however، they are big in size and not portable؛ therefore، they are mainly for hospital use. The SB٢٠٠ APG of Rossmax InnoTek Corp. is to provide APG analysis when measuring hemoglobin level at the same time for the entire process completed in one minute، improving the time-consuming arteriosclerosis level measurement with large equipment and enhancing the willingness of users to take the measurement in order to improve the possibility of early discovery and control of cardiovascular risk factors.

Test methods:

Patient eligibility

The Department of Cardiology and the Department of Cardiac Surgery of National Taiwan University Hospital invite ١٥٠ coronary patients as test subjects، including ٥٠ patients with coronary artery bypass graft (CABG)، ٥٠ patients with percutaneous occlusive balloon angioplasty stinting (POBAS)، and ٥٠ patients with mild coronary heart disease؛ also، collect ١٥٠ outpatients without any coronary heart disease as age control group. Both groups are tested completely for cardiovascular risk factors and blood biochemistry، including a non-invasive cardiovascular artery check-up.

Clinical trial design and procedures (related to clinical test)

Starting from December ٢٠١٤، invited patients with known coronary cardiac catheterization with their full knowledge of and their consent to the intended purpose to participate in this non-invasive cardiovascular check-up and arteriosclerosis level study. The arteriosclerosis level of each test subject is known to us (such as: ١، ٢، or ٣ coronary artery occluded). Fifty (٥٠) patients with severe arteriosclerosis (CABG or with more than ٣-artery occlusion)، one hundred (١٠٠) patients with mild coronary heart disease and intermediate level of arteriosclerosis (١-artery or ٢-artery coronary occlusion)؛ also، one hundred and fifty (١٥٠) outpatients without any coronary heart disease (without any noticeable artery occlusion) as the control group for a total of three hundred (٣٠٠) test subjects.

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١. SB٢٠٠ SpO٢ (Fingertip Pulse Oximeter): Arteriosclerosis status derived from the mathematical formulas of SB٢٠٠ SpO٢ is classified as SB٢٠٠ score ١ ~ score ٦. Test subject may not smoke a cigarette، exercise، drink coffee، tea، or wine prior to the clinical trial؛ also، must stay in a quiet room for ١٠ minutes calmly and then clap the Fingertip Pulse Oximeter (SB٢٠٠ SpO٢) on the index finger or middle finger of right hand or left hand، from left to right، from index finger to middle finger for a standardized measurement. One finger per minute and the entire process takes about ٢٠ minutes per patient.

٢. Collect the most recent cardiac catheterization result and arteriosclerosis level of each test subject؛ also، the occurrence and frequency of cardiovascular event of each test subject، and other related cardiovascular risk factors in clinical، eating habit، and lifestyle data، including equipment test، medical records، or questionnaires.

Research result:

We invited a total of ١٥٠ patients with coronary heart disease from National Taiwan University Hospital Cardiology and Surgery in the period of March – November، ٢٠١٥، of which، ٦٩ patients with severe coronary artery disease and ٨١ patients with mild coronary heart disease patients. Also، another ١٥٠ individuals without coronary heart disease were invited as the control group for this study. Male patients with coronary heart disease were accounted for ٨٥.٣٣٪ while the male patients without coronary heart disease accounted for ٨٣.٣٣٪. The coronary heart disease patients with high blood pressure were accounted for ٦٨٪. The patients in both groups who were smokers were insignificant، of which، the patient with coronary heart disease group was ١٠.٦٧٪ and the patient without coronary heart disease group was ١٢.٦٧٪. No significant difference was found between these two groups in the regard of diabetes، hyperlipidemia، smoking and drinking habits، or obesity index (body mass index).

According to the APG arterogenic index measurement results، we found that the APG index of the patients with coronary heart disease group (٢.٤٦±٠.٨٣ and ٢.٤٩±٠.٧٣) was significantly higher than the patients without coronary heart disease group (٢.٢١±٠.٧١ and ٢.٢٩±٠.٦٩) was significant and it was mainly in the left middle finger and in left hand in average، which was significant statistically. The significant difference persisted even after the blood pressure and age adjustment made. The APG index on the left middle finger was ٢.٤٤ ± ٠.٠٦ for the patient with coronary heart disease group and it was higher than the ٢.٢٣ ± ٠.٠٧ for the patient without coronary heart disease group. The APG index of the left hand in average was ٢.٤٨ ± ٠.٠٦ for the patient with coronary heart disease group and it was higher than the ٢.٣١ ± ٠.٠٦ for the patient without coronary heart disease group. As for the APG index right of the

right hand، no significant difference was found between these two groups. The average APG index of both right hand and left hand was found slightly higher in the patient with coronary heart disease group than in the patient without coronary heart disease group. There was no difference in SpO٢ found in these two groups. The patient with coronary heart disease group is found with lower heart rate in the right hand but without significant difference found in the average index by the severity of coronary artery disease، the patients in the group with severe coronary artery disease are mostly diabetic and most of them do not smoke. The patients in both groups are mostly with hyperlipidemia، ٧٠.٢٧٪ for the patients with coronary heart disease group and ٧٧.٣٠٪ for the patients without coronary heart disease group. For the three groups with severe، moderate، and none-coronary heart disease، the APG arteriosclerosis index on the left middle finger and left hand in average is found indeed higher in the patients with coronary heart disease group that the patients without coronary heart disease group؛ also، the difference is minimized after adjusting the factors of blood pressure and the age difference. The APG index on the right hand is without significant differences found in all three groups. No difference in oxygen saturation and heart rate is found in all three groups.

Discussion:

The incidence and prevalence of cardiovascular diseases around the world remain high، and the hypertension، high cholesterol، diabetes، and cardiovascular disease (mainly heart disease and stroke) important health issues for people، not only the major causes of death، ranked the second and third of the top-١٠ causes of death، but also a big burden on the national economy. Regarding the high risk factors for cardiovascular disease، including hypertension، high cholesterol، diabetes، obesity، and metabolic syndrome، according to the study، the risk of cardiovascular diseases occurs usually to individuals over ٤٥ years old؛ however، due to the prevalence of childhood obesity in recent years، the metabolic syndrome and cardiovascular disease may occur to individuals at their early age. In addition to changing eating habits and lifestyle، the prevention and treatment of hypertension، high cholesterol، diabetes، and obesity is definitely the key. However، in the early assessment of atherosclerosis، there is lack of a simple and fast diagnostic instrument to provide early indicators for prompt treatment. The study found that the finger-tip PPG provides a simple and fast APG index، providing clinicians with a reference in the extent of atherosclerosis in patients. This study found that coronary heart disease patients do have a higher index of APG، mainly on the left middle finger and left hand in average. After adjusting the blood pressure and age، coronary heart

disease patients do have a higher index of APG. The clinical research results indicate that the oxygen concentration meter in the measurement of oxygen with the acceleration pulse wave graph of finger microcirculation recorded; also, the derived APG index is valuable in clinical applications. When coronary heart disease patients were divided into three groups, the said correlation is weaken after having the blood pressure and age factor adjusted. It indicates that the acceleration pulse wave graph of microcirculation cannot significantly have the seriousness of coronary heart disease distinguished, in other words, coronary heart disease is a macrovascular disease ﷺ that requires a further test and diagnosis. Therefore, a further study is recommended to have severe, moderate, and

In conclusion, this study indicates that the APG index of the APG finger-tip graphics acceleration pulse oximeter is relevant to the coronary heart disease in the sense of artery clog and thickness, especially the measurement reading from the left hand, that is, on the left middle finger and left hand in average.

Literatures:

ﷺ Criqui MH, Fronek A, Barrett-Connor E, Klauber MR, Gabriel S, Goodman D. The prevalence of peripheral arterial disease in a defined population. Circulation ١٩٨٥; ٧١: ٥١٠–٥١٥.

ﷺ Alnaeb M, Alobaid N, Seifalian A, Mikhailidis D, Hamilton G. Optical techniques in the assessment of peripheral arterial disease. Curr Vasc Pharmacol ٢٠٠٧; ٥: ٥٣–٩.

ﷺ Mohamed Elgendi. On the analysis of fingertip photoplethysmogram signals. Current Cardiology Reviews ٢٠١٢; ٨: ١٤–٢٥.

ﷺ Homma S, Ito S, Koto T, Ikegami H. Relationship between accelerated pletysmography, blood pressure and arterial elasticity. 体力科學 (CiNii Articles) ١٩٩٢; ٤١: ٩٨–١٠٧.

ﷺ Fujimoto K, Sano Y, Watanabe E. Application of accelerated plethysmography for measuring pulse wave velocity. 人間工学 (Human Factors and Ergonomics) ٢٠١٢; ٤٨: ٢٨٥–٢٩٤.

ﷺ Libby P, Theroux P. Pathophysiology of coronary artery disease. Circulation. ٢٠٠٥; ١١١(٢٥): ٣٤٨١–٨. Review

Table ١ Characteristics of patients with and without coronary heart disease

Characteristics	Without coronary heart disease (١٥٠ test subjects)	With coronary heart disease (١٥٠ test subjects)	P value
Age Male (٪)	٦٣.٣٦±١٢.٨٢	٦٥.٣٩±١٢.٢٦	٠.١٦٩٥
Weight and height (kg /m٢)	٨٣.٣٣	٨٥.٣٣	٠.٦٣٣٧
	٢٥.٨٨±٣.٥٤	٢٥.٩٨±٣.٥٢	٠.٧٩٥٦
High blood pressure (٪)	٥٦.١٦	٦٨.٠٠	٠.٠٣٥٨
Diabetic (٪)	٢٤.٤٩	٣٢.٠٠	٠.١٥٠٨
Hyperlipidemia (٪)	٧٧.٣٠	٧٠.٢٧	٠.١٧٤٥
Smoker (٪)	١٢.٦٧	١٠.٦٧	٠.٥٨٩٥
Drinker (٪)	١٢.٠٠	١٥.٣٣	٠.٤٠٠٧

Table ٢ Rossmax SB٢٠٠ APG value of patients with and without coronary heart disease comparison

Characteristics	Without coronary heart disease (١٥٠ test subjects)	With coronary heart disease (١٥٠ test subjects)	P value
APG index			
Left index finger	٢.٣٧±٠.٨٢	٢.٥٣±٠.٩٣	٠.١١٤٨
Adjusted	٢.٣٩±٠.٠٧	٢.٥١±٠.٠٧	٠.٢٢٦٨
Left middle finger	٢.٢١±٠.٧١	٢.٤٦±٠.٨٣	٠.٠٠٨٩
Adjusted	٢.٢٣±٠.٠٧	٢.٤٤±٠.٠٦	٠.٠٢٠٥
Left hand average value	٢.٢٩±٠.٦٩	٢.٤٩±٠.٧٣	٠.٠١٤٦
Adjusted	٢.٣١±٠.٠٦	٢.٤٨±٠.٠٦	٠.٠٤٢٩
Right index finger	٢.٣٥±٠.٨٠	٢.٣٦±٠.٨١	٠.٩٢٢٧
Adjusted	٢.٣٨±٠.٠٦	٢.٣٤±٠.٠٦	٠.٦٥٢٧
Right middle finger	٢.٢٣±٠.٦٧	٢.٣١±٠.٧٣	٠.٣٤٥١
Adjusted	٢.٢٥±٠.٠٦	٢.٢٩±٠.٠٦	٠.٥٩٥١
Right hand average value	٢.٢٨±٠.٦٣	٢.٣٣±٠.٦٦	٠.٥١١٩
Adjusted	٢.٣٠±٠.٠٥	٢.٣٢±٠.٠٥	٠.٨٠٣٣
Average value of both hands	٢.٢٩±٠.٥٩	٢.٤٢±٠.٦٢	٠.٠٦٣٨
Adjusted	٢.٣١±٠.٠٥	٢.٤٠±٠.٠٥	٠.١٩٧٢

❖Adjusted age and hypertension

Table ٣ Rossmax SB٢٠٠ APG value of patients with and without coronary heart disease SpO٢ and Heart Rate comparison

Characteristics	Without coronary heart disease (١٥٠ test subjects)	With coronary heart disease (١٥٠ test subjects)	P value
SpO٢			
Left index finger	٩٧.٢٧±١.٧٦	٩٧.٣٧±١.٦٤	٠.٦٠٣١
Left middle finger	٩٧.٠٨±٢.٦٩	٩٧.٥٧±١.٣١	٠.٠٥٧٠
Left hand average value	٩٧.١٩±١.٩٥	٩٧.٤٧±١.٣٤	٠.١٥٣٠
Right index finger	٩٧.٠٨±٢.٥٠	٩٧.٤٤±١.٥٤	٠.١٣١٦
Right middle finger	٩٧.١٩±٢.٦٣	٩٧.١٦±٧.٥٤	٠.٩٦١٨
Right hand average value	٩٧.١٥±٢.٤٢	٩٧.٣٠±٣.٩٥	٠.٦٨٩١
Average value of both hands	٩٧.١٧±٢.١٤	٩٧.٣٨±٢.٢٥	٠.٤٠٤٤
Heart rate			
Left index finger	٧٢.٥١±١٢.٦٣	٧٢.١٦±١٣.٤٩	٠.٨١٩٢
Left middle finger	٧٢.٧٢±١٢.٦٨	٧٠.٠٥±١١.٩٣	٠.٠٦٨٤
Left hand average value	٧٢.٤٣±١٢.١٧	٧١.١٠±١١.٩٣	٠.٣٤٠٩
Right index finger	٧٢.٧٨±١١.٨١	٧١.١٦±١٢.٤٩	٠.٢٥٠٣
Right middle finger	٧٣.١٥±١٢.٩٥	٧٠.١٨±١١.٨٢	٠.٠٤٤٤
Right hand average value	٧٢.٨٣±١١.٧٥	٧٠.٦٧±١١.٥٢	٠.١٠٩٣
Average value of both hands	٧٢.٦٣±١١.٦٨	٧٠.٩٢±١١.٤٦	٠.١٩٩٤

Table ٤ Characteristics of patients with severe، moderate، and none-coronary heart disease

Characteristics	Without coronary heart disease (١٥٠ test subjects)	With moderate coronary heart disease (٨١ test subjects)	With severe coronary heart disease (٦٩ test subjects)	P value
Age Male (٪)	٦٣.٣٦±١٢.٨٢	٦٥.٥٤±١٢.٤٢	٦٥.١٥±١٢.١٦	٠.٣٨٣٠
Weight and height (kg /m٢)	٨٣.٣٣	٨٢.٧٢	٨٨.٤١	٠.٥٦٥٥
Blood pressure (٪)	٢٥.٨٨±٣.٥٤	٢٦.٢٢±٣.٦٥	٢٥.٧٠±٣.٣٨	٠.٦٤٣٧
Diabetic (٪)	٥٦.١٦	٦٧.٩٠	٦٨.١٢	٠.١١٠٤
Hyperlipidemia (٪)	٢٤.٤٩	٢٣.٤٦	٤٢.٠٣	٠.٠١٥٠
Smoker (٪)	٧٧.٣٠	٦٩.١٤	٧١.٦٤	٠.٣٧٤٩
Drinker (٪)	١٢.٦٧	١٧.٢٨	٢.٩٠	٠.٠٢٠٥
	١٢.٠٠	١٧.٢٨	١٣.٠٤	٠.٥٢٨٨

Table ٥ Rossmax SB٢٠٠ APG value of patients with severe، moderate، and none-coronary heart disease SpO٢ comparison

Characteristics	(人數=١٥٠) Without coronary heart disease (١٥٠ test subjects)	With moderate coronary heart disease (٨١ test subjects)	With severe coronary heart disease (٦٩ test subjects)	P value
APG Index				
Left index finger	٢.٣٧±٠.٨٢	٢.٥٩±٢.٤٥	٢.٤٥±٠.٨٧	٠.١٧٤٧
Adjusted	٢.٣٩±٠.٠٧	٢.٥٧±٠.٠٩	٢.٤٤±٠.١٠	٠.٣٠٣٢
Left middle finger	٢.٢١±٠.٧١	٢.٤٦±٠.٨٣	٢.٤٥±٠.٨٣	٠.٠٣٢٥
Adjusted	٢.٢٣±٠.٠٧	٢.٤٥±٠.٠٨	٢.٤٤±٠.٠٩	٠.٠٦٨٥
Left hand average value	٢.٢٩±٠.٦٩	٢.٥٣±٠.٧١	٢.٤٥±٠.٧٦	٠.٠٤٠٥
Adjusted	٢.٣١±٠.٠٥	٢.٥١±٠.٠٨	٢.٤٤±٠.٠٨	٠.١٠٦٤
Right index finger	٢.٣٥±٠.٨٠	٢.٤٠±٠.٨٧	٢.٣٠±٠.٧٣	٠.٧٦٦٤
Adjusted	٢.٣٨±٠.٠٦	٢.٣٨±٠.٠٩	٢.٢٩±٠.٠٩	٠.٧٠٤٨
Right middle finger	٢.٢٣±٠.٦٧	٢.٣١±٠.٧٦	٢.٣٠±٠.٧١	٠.٦٣٩٢
Adjusted	٢.٢٥±٠.٠٦	٢.٣٠±٠.٠٨	٢.٣٠±٠.٠٨	٠.٨٦٧٩
Right hand average value	٢.٢٨±٠.٦٣	٢.٣٠±٠.٥٧	٢.٣٦±٠.٧٣	٠.٧١٥٤
Adjusted	٢.٣١±٠.٠٥	٢.٣٤±٠.٠٧	٢.٢٩±٠.٠٧	٠.٨٩٦٣
Average value of both hands	٢.٢٩±٠.٥٩	٢.٤٥±٠.٦٥	٢.٣٨±٠.٥٨	٠.١٣٧٧
Adjusted	٢.٣١±٠.٠٥	٢.٤٣±٠.٠٦	٢.٣٦±٠.٠٧	٠.٣٣٩٥

❖Adjusted age and hypertension

Table ٦ Rossmax SB٢٠٠ APG value of patients with severe، moderate، and none-coronary heart disease SpO٢ and heart rate comparison

Characteristics	Without coronary heart disease (١٥٠ test subjects)	With moderate coronary heart disease (٨١ test subjects)	With severe coronary heart disease (٦٩ test subjects)	P value
SpO٢				
Left index finger	٩٧.٢٧±١.٧٦	٩٧.٤٠±١.٦٥	٩٧.٣٣±١.٦٤	٠.٨٤٩٣
Left middle finger	٩٧.٠٨±٢.٦٩	٩٧.٦١±١.٣٣	٩٧.٥٢±١.٢٩	٠.١٤٠٢
Left hand average value	٩٧.١٩±١.٩٥	٩٧.٥١±١.٣٨	٩٧.٤٣±١.٢٩	٠.٣٤٦٩
Right index finger	٩٧.٠٨±٢.٥٠	٩٧.٥٤±١.٤٥	٩٧.٣٣±١.٦٤	٠.٢٦٩٥
Right middle finger	٩٧.١٩±٢.٦٣	٩٧.٨٦±١.٢٥	٩٦.٣٦±١٠.٩٩	٠.٢٧٦٥
Right hand average value	٩٧.١٥±٢.٤٢	٩٧.٧٠±١.٢٦	٩٧.٨٤±٥.٦٤	٠.٢٥٧٧
Average value of both hands	٩٧.١٧±٢.١٤	٩٧.٦٠±١.٢٩	٩٧.١٣±٣.٠٠	٠.٣١٠٤
Heart rate				
Left index finger	٧٢.٥١±١٢.٦٣	٧١.٠٨±١٤.٠٢	٧٣.٤٢±١٢.٨٣	٠.٥٣٦٧
Left middle finger	٧٢.٧٢±١٢.٦٨	٦٩.١٥±١٢.٢٧	٧١.٠٩±١١.٥٢	٠.١٢٠٤
Left hand average value	٧٢.٤٣±١٢.١٧	٧٠.١١±١٢.٣١	٧٢.٢٥±١١.٤٥	٠.٣٥٤٥
Right index finger	٧٢.٧٨±١١.٨١	٦٩.٨١±١٢.٦٠	٧٢.٧٢±١٢.٢٦	٠.١٧٨٤

Right middle finger	٧٣.١٥±١٢.٩٥	٦٩.١٦±١١.٥٧	٧١.٣٦±١٢.٠٨	٠.٠٧٤١
Right hand average value	٧٢.٨٣±١١.٧٥	٦٩.٤٩±١١.٥٧	٧٢.٠٤±١١.٤٠	٠.١١٣٨
Average value of both hands	٧٢.٦٣±١١.٦٨	٦٩.٨٦±١١.٦١	٧٢.١٥±١١.٢٥	٠.٢١٢٨