

CORRELATION OF THE OMNICARDIOGRAM WITH SELECTED
KNOWN RISK FACTORS OF HYPERTENSION
AND CORONARY HEART DISEASE

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We hereby recommend that the thesis prepared under
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DEDICATION

To my wife for her understanding
and love, and

To my son for being my son

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CHAPTER I

INTRODUCTION

Coronary heart disease is one of the largest single causes of sudden death in the United States (Cooper 1973, p. 135). The potential for developing coronary heart disease depends, to a large extent, on a number of risk factors which have been identified by epidemiologic investigations. These studies have shown that the more risk factors an individual has, the greater is the individual's chance of developing a significant cardiovascular manifestation of coronary heart disease (Werko 1976, pp. 87-96).

These epidemiologic studies have disclosed some highly specific cardiovascular risk factors, including family history of early coronary heart disease, hypertension, smoking, obesity, elevated serum cholesterol, glucose intolerance, and an abnormal electrocardiogram. With the possible exception of hypertension, it is not a single risk factor which predisposes an individual to coronary heart disease; rather, it is the degree of their inter-relationship which is ultimately pathogenic (Kannel 1976, p. 274).

The range of normal values for any one risk factor must be established with respect to its total epidemiologic

effect rather than to arbitrary and fixed limits. Thus, the risk factors for coronary heart disease should be viewed for their cumulative effect to evaluate their magnitude more precisely (Kannel 1976, p. 275).

At present, the only non-invasive method of detecting coronary heart disease is the electrocardiogram. Recently, a new method called the "omnicardiogram" has been developed in which

. . . various leads of the standard electrocardiogram are digitized and subjected to a nonlinear mathematical transformation so as to detect subtle degrees of abnormality not apparent in the standard electrocardiogram (Teichholz, Cohn and Gorlin 1975, p. 531).

The potential usefulness of the omnicardiogram as a screening procedure to identify high risk coronary heart disease subjects, alone and in combination with other risk factors, is very apparent. Therefore, a study was undertaken to determine if the omnicardiogram can be correlated with selected known risk factors of coronary heart disease.

Statement of the Problem

Does an abnormal omnicardiogram correlate with selected known risk factors of coronary heart disease?

Purposes of the Study

The purposes of the study were as follows:

1. To determine if there is any correlation between a group of early hypertensive patients, their risk factors, and the omnicardiogram which might be used as an early indication of coronary heart disease compared to a group of normotensive patients and their risk factors
2. To determine if there is any correlation between a group of long-standing or late hypertensive patients, their risk factors, and the omnicardiogram which might be useful as an early indication of coronary heart disease compared to a group of normotensive patients and their risk factors
3. To determine if there is any correlation between a group of early hypertensive patients and a group of late hypertensive patients, their risk factors, and the omnicardiogram which might be useful as an early indication of coronary heart disease compared to a group of normotensive patients

Background and Significance

Cardiovascular disease is the major cause of mortality in the United States and accounts for over one-half of the total number of annual deaths, causing a mortality of more than one million persons each year. The public generally views cardiovascular disease as "heart attack," but other

cardiovascular problems may be just as significant. Among them are hypertension and hypertensive heart disease (Cooper 1973, p. 135).

The majority of hypertensive patients are unaware they have a problem, and possibly only one-half of those who are aware of their hypertension are under treatment. A reasonable estimate is that about twenty-five million people have hypertension in this country alone (Kaplan 1977, p. 1).

The effects of hypertension may well be the leading cause of death in the United States. However:

. . . because of the manner in which causes of deaths are categorized and recorded, the statistics seldom reflect hypertensive disease as the cause of death. That is, a vast number of the people who die from cardiovascular causes as a result of their hypertension are listed under an 'arteriosclerotic heart disease' or a 'cerebrovascular disease' category, not under hypertensive disease category. The coronary patient who dies of a myocardial infarct, even if 'previous hypertension' is written on the death certificate, is coded as a coronary death. Consequently, the death rate data markedly underestimates the hypertension component although hypertension is present as a key contributing cause for at least a third of premature heart deaths, and an even higher proportion of premature stroke deaths.

(Stamler et al. 1974, p. 11)

Measurement of blood pressure is a major factor used in predicting life expectancy for the nation's life insurance companies. Actuarial charts are based on figures which show the effects of hypertension. As documented in Table 1, the higher the blood pressure at a given age, the shorter

the life expectancy (Time 1975, pp. 60, 64).

Table 1

EFFECTS OF HYPERTENSION ON LONGEVITY

Age	Blood Pressure Systolic/Diastolic	Added Life Expectancy	
		Men (Years)	Women (Years)
35	120/80	41 1/2	No data compiled.
	130/90	37 1/2	
	140/95	32 1/2	
	150/100	25	
45	120/80	32	37
	130/90	29	35 1/2
	140/95	26	32
	150/100	20 1/2	28 1/2
55	120/80	23 1/2	27 1/2
	130/90	22 1/2	27
	140/95	19 1/2	24 1/2
	150/100	17 1/2	23 1/2

(Time 1975, p. 69)

Information from the Society of Actuaries shows that for men aged 35 with a blood pressure of 142/90 mmHg, and without any risk factors, the mortality rate over age 20 years was 19.4 percent compared to only 11.0 percent for men of the same age who were considered normotensive. This degree of blood pressure is considered very mild, and is often viewed as insignificant. However, when one considers that there is a 76.4 percent higher death rate in middle age from this range of blood pressure, the importance of hyper-

tension alone as a risk factor becomes more significant (Lew 1967, p. 392).

Individuals at high risk for coronary heart disease may be identified so that the chain of events which result in a lethal cardiovascular episode may possibly be interrupted. It is difficult to state with certainty where normal ends and abnormal begins, thus, risk factors must be conceptualized. This provides a more relevant evaluation of risk than a mere categorical approach (Kannel 1976, p. 274).

The role of nursing is becoming increasingly more important in the control and prevention of hypertension and coronary heart disease. Traditionally, nurses have only dealt with these diseases and their effects in the hospital setting. As nursing expands its role into more areas of health care, it allows the profession to not only deal with disease, but more importantly, with health maintenance, wellness, disease prevention, and carrying out plans of care. This allows the nursing profession to participate in identifying high risk individuals for coronary disease.

The development of the clinical nurse specialist is an example of the nurse's expanded role. In this role, the nurse assumes certain responsibilities formerly held by physicians. As Bates has stated:

By expanding nursing knowledge and skills into medicine, and thereby acquiring some of that control, you can in fact expand into nursing. Less medicine, when mixed with more nursing, is probably better medicine or, to translate, better health care (Bates 1974, p. 698).

Medical research has pinpointed various factors which tend to predict the potential for coronary heart disease. The significance of these risk factors in helping to identify potential coronary patients is now apparent. The more risk factors which can be identified, the better the nursing and medical profession will be able to help their patients. And, the earlier these factors are identified, the more the patient can be helped. Therefore, this study will try to correlate selected known risk factors of coronary heart disease and a new method of electrocardiography, the omnicardiogram.

Hypotheses

1. There is no correlation between selected known risk factors for coronary heart disease in normotensive patients and an abnormal omnicardiogram
2. There is no correlation between selected known risk factors for coronary heart disease in early hypertensive patients and an abnormal omnicardiogram.
3. There is no correlation between selected known risk factors for coronary heart disease in late hypertensive patients and an abnormal omnicardiogram.

Definition of Terms

1. Omnicardiogram -

A new noninvasive technique in which various leads of the standard electrocardiogram are digitized and subjected to a nonlinear mathematical transformation so as to detect subtle degrees of abnormality not apparent in the original electrocardiogram (Teichholz, Cohn, and Gorlin 1975, p. 531).

2. Risk factors - An objective finding which has been shown by previous epidemiologic studies to contribute to coronary heart disease. For the purpose of this study, the following risk factors are considered: (a) age, (b) race, (c) sex, (d) family history of hypertension, coronary heart disease or diabetes mellitus, (e) personal history of hypertension, (f) smoking, (g) elevated serum cholesterol, (h) glucose intolerance, and (i) abnormal electrocardiogram (Kannel 1976, pp. 269-282).

3. Hypertension - High arterial blood pressure (Guyton 1971, p. 308).

4. Essential hypertension - Hypertension for which no recognizable cause can be found (Beeson, McDermott 1971, p. 1058).

Any person having an arterial pressure greater than 140/90 and who also have no obvious cause of hypertension is considered to have essential hypertension (Guyton 1971, p. 308).

5. Normotensive - Individuals who have been found by three-day blood pressure checks to have blood pressure on the average of less than 140/90 (Lew 1967, p. 392; Harvey et al. 1972, p. 318).

6. Early hypertension - Individuals with a documented medical diagnosis of essential hypertension for less than five years.

7. Late hypertension - Individuals with a documented medical diagnosis of essential hypertension for more than five years.

Limitations

The study is not longitudinal. A correlation with all potential coronary heart disease risk factors was not attempted.

Summary

Chapter I presents some of the important epidemiological studies which indicate the magnitude of coronary heart disease in this country. These epidemiologic investigations have shown that, in general, the more risk factors present, or the greater the degree of abnormality of any factor, the greater is the risk of coronary heart disease.

The chapter also includes a brief description of the omnicardiogram and also presents the statement of the problem, purposes of the study, hypotheses, definition of terms and limitations.

Overview

The remaining chapters will be described briefly. Chapter II includes a review of current literature with respect to coronary heart disease. The review will cover the classic epidemiological studies, risk factors, and their effects, and finally, studies of the omnicardiogram will be reviewed.

Chapter III describes the setting and population. A description of how the omnicardiogram is used and interpreted is then included. Data collection is presented, and finally, treatment of data is discussed.

Chapter IV presents the analysis of the data collection, and Chapter V includes the summary, conclusions, and recommendations for further study.

CHAPTER II

REVIEW OF LITERATURE

Introduction

Within the last two decades, increasing attention has been focused on various risk factors for coronary heart disease. Their significance and the studies which postulated the risk-factor concept will be discussed in this chapter.

First, a review of nursing literature in regard to health maintenance will be presented. Then a discussion of the more important epidemiological studies which have identified risk factors of coronary heart disease will be reviewed. Next, selected risk factors will be reviewed in the following order: (a) age, (b) race, (c) sex, (d) family history of hypertension, coronary heart disease, and diabetes mellitus, (e) hypertension, (f) smoking, (g) elevated serum cholesterol, (h) glucose intolerance, and (i) abnormal electrocardiogram. Finally, those studies that have previously been done with the omniscardiogram will be discussed.

Nursing in Health Maintenance

The profession of nursing is expanding more into primary care. Though the definition for primary care may differ, two important factors are identified: (1) the first contact with a patient, and (2) continuity of care. The nurses who provide this primary care are oriented toward health maintenance, wellness, prevention of disease, and comprehensive care (Judge 1974, p. 31).

Unfortunately, there is not total agreement on, or acceptance of, this new role. It has been said that the nurse in this role will be dissolved when the doctor shortage is remedied, and that the nurses who are functioning in this role are only physicians' assistants. The definition of this expanded role is just as ambiguous when the different functions of nurses are reviewed. Thus, the expanded nursing role is cursed with the same problem which the nursing profession in general has, i.e., no clear role definition. To complicate the problem, various titles have been applied to the nurse functioning in the primary setting. Titles such as "nurse practitioner," "nurse clinician," and "clinical nurse specialist" apply to nurses performing the same function but in different settings (Judge 1974, pp. 30-36).

Stevens (1977, p. 79) suggests many of the problems of the nurse extender revolve around accountability. She says:

The major difficulty is that the clinical specialist (nurse extender) role was not designed to fit into the bureaucratic, hierarchial management system typical of health care institutions. Her accountability depends upon the authority of her particular position and the responsibilities inherent in her defined role (Stevens 1977, p. 79).

Several articles have reviewed the use of the nurse in the expanded role. One of the more important was "The Burlington Randomized Trial of the Nurse Practitioner." The purpose of this study was to see if qualified nurses with skills in physical assessment, history taking, and problem-solving could provide both safe and effective primary care. The results demonstrated that a qualified nurse performing in this role could safely and effectively arrive at a logical medical conclusion, as well as identifying nursing implications, and thereby provide primary clinical care. Patient satisfaction with the nurse was as great as with the physician (Spitzer 1974, p. 255).

Other articles have demonstrated that nurses functioning in the expanded role can care for patients with only minimal medical supervision and still provide quality health care. They have also shown that proper health teachings increase self-care and compliance to treatment. It has also been suggested that nurses in this role may not be highly prone to malpractice suits because of good communication between the nurse and the patient (Crate 1965, pp. 72-76; Judge 1974,

p. 36; and Schulman 1972, pp. 1453-1461).

Epidemiological Studies of Coronary Heart Disease

The Framingham study was begun in 1949 with a population sample of 5,209 men and women ranging from 30 to 62 years of age. This population has been followed biannually to determine the relationship of specific variables to the development of cardiovascular disease. This study has established that the risk of coronary heart disease increases in proportion to the degree and extent of specific factors. In this respect, the most important data of the Framingham study have been the relationship of cholesterol, hypertension, and cigarette smoking to the development of coronary heart disease (Werko 1976, p. 9). Kannel (1976, pp. 270, 277) states that "The Framingham data has provided a clearer picture of the total spectrum of the disease, the identity of those especially vulnerable, its precursor, and clues to pathogenesis."

The National Pooling Project was devised in an attempt to arrive at conclusions based on a larger population. Several prospective studies of males were pooled to achieve this end. The National Pooling Project was thus produced through collaboration between the Framingham, Albany, Chicago, and the Western collaborative studies and combines the data on approximately 7,000 men. This study came to the same conclusion as did Framingham, and that is, the importance of

high serum cholesterol, hypertension, and cigarette smoking (Werko 1976, pp. 89-92).

The third major epidemiologic study is the Veterans Administration Cooperative Study Group on Antihypertensive Agents (1972, p. 1003). This study demonstrated that treatment of hypertension can reduce the risk of associated cardiovascular complications. The evidence became so clear-cut that termination of the control group taking placebos was necessitated.

Risk Factors

Age

The American Heart Association (1976) has shown that with increasing age there is a related increase in cardiovascular disease. The age range from 35 - 44 years old represents 27 percent of all cardiovascular deaths, while the age range of 65 - 74 represents 56 percent of all cardiovascular deaths. Thus, the risk of cardiovascular disease increases with age.

Race

From age 25 to 35, it was found that only 3.6 percent of white males had hypertension, while black males of the same age group had hypertension at a rate of 12.5 percent.

The overall prevalence rate indicates that black males are affected by hypertension at a 2:1 ratio over white males. Not only are black males subject to hypertension at any age, but the complication in the black male tends to be more severe (Stamler 1974, p. 4).

Sex

It has been shown that women have a relative immunity from coronary heart disease until after menopause. However, it has been noted at autopsy that women have the same frequency of arteriosclerosis as men of the same age. The reason for this phenomenon is unclear (Doyle 1966, p. 84).

An exception occurs when oral contraceptives are used. The risk of fatal myocardial infarction is greater in women using oral contraceptives, especially in the older age groups (Mann 1975, p. 245). Another important side effect of oral contraceptive therapy is hypertension. Therefore, it has been suggested the most logical clinical application is not to advise oral contraceptives to any female who has hypertension (Wood 1972, p. 40).

Family History

It has been assumed that family history is an important indicator of potential disease. However, there is all too often a question of reliability. Taken by itself, a

family history of coronary heart disease in a parent or sibling, especially when it occurs in the early fifties or before, is certainly a warning signal for a careful assessment of risk-factor status in the individual concerned, and, indeed, also in his own offspring (Epstein 1971, pp. 331-332).

Hypertension

Essential hypertension represents 89 - 90 percent of all reported hypertension (Kaplin 1976, p. 6). Lack of a more specific diagnosis implies that other causes of hypertension have been investigated, and none was found. Causes of secondary hypertension include pheochromocytoma, renal arterial disease, and primary aldosteronism. Essential hypertension is then a diagnosis of exclusion (Duston 1976, p. 97).

A number of theories as to the cause of essential hypertension have been proposed. The principal one concerns abnormalities of the renin-angiotensin-aldosterone axis. This theory proposes that the renin-angiotensin-aldosterone axis has the central physiologic control over hypertension. Aldosterone stimulates the renal retention of sodium at the distal tubule. The continued presence of aldosterone induces chronic sodium retention and causes a volume overload which, over a period of time, ultimately leads to hypertension

(Hurst, Logue 1974, p. 297; and Oglesby 1974, p. 100).

It has been generally held during the last decade that an elevated diastolic blood pressure is responsible for the major consequences of coronary heart disease. However, actuarial studies have now demonstrated that an elevated systolic blood pressure is as accurate a prognosticator as diastolic blood pressure for major cardiovascular problems (Kannel 1976, p. 273).

In terms of blood pressure levels, the systolic pressure is more closely related to cardiac involvement. The physiologic basis of their relationship is as follows: cardiac work is determined by mean systolic pressure--the pressure developed by contraction--by heart rate, and by stroke volume. Therefore, in terms of oxygen consumption myocardial pressure work is much more costly to the heart than similar work due only to increased output (Tarazi 1976, p. 3).

A significant question which appears throughout the literature is "What level hypertension should be treated?" In patients with a diastolic pressure greater than 140 mmHg, it has been shown that decreasing the blood pressure decreases morbidity and mortality. As documented in the Veterans Administration Cooperative Study, the lower the initial diastolic pressure, the longer it takes for morbid events to occur (Sheps, Kirkpatrick 1975, p. 710).

According to the Pooling Project:

When hypertension coexists with other major risk factors (e.g., cigarette smoking, hypercholesterolemia) the risks are additive. Thus, the men originally age 30 - 59 with hypertension as the only risk factor experienced twice as high a death rate over the next ten years as men with no risk factors. But when hypertension coexisted with cigarette smoking or hypercholesterolemia (either one of these two), the risk of dying was more than tripled. And, when hypertension was present along with both these other factors, the death rate was five times higher (Stamler 1960, p. 6).

Thus, there is general agreement that hypertension increases the risk of coronary heart disease. When hypertension is combined with other risk factors, the risk is multiplied rather than being purely additive.

Smoking

The risk of myocardial infarction in middle-aged men has been shown to be three to five times greater for those men smoking twenty or more cigarettes daily than for the nonsmoker.

The mechanism whereby cigarette smoking predisposes coronary heart disease is unknown, but an acute effect on the coagulation system, perhaps an increase in platelet stickiness, seems a plausible although unproved possibility. Nicotine energetically mobilizes endogenous catecholamines. These, in turn, cause a rapid rise in free fatty acids that may affect clotting factors or unfavorably affect the endothelium (Doyle 1966, p. 85).

Individuals who stop smoking have only half the risk of those who continue. The benefit is not only substantial but occurs rather promptly (Kannel 1977, p. 83).

Cholesterol

There are several methods of determining blood lipids or lipoprotein patterns, but the most reliable method remains a random serum cholesterol for assessing the risk potential. The total serum cholesterol concentration has been the sole indicator of hyperlipidemia in most epidemiologic studies to date.

Cholesterol is generally esterified with a fatty acid in the serum which makes it an incomplete indicator of a specific lipid characteristic in humans. However, very elaborate chemical and physical analyses have been unable to show specific lipids or serum fractions with greater predictive powers than the total serum cholesterol concentration in population studies (Epstein, Ostrander 1971, p. 325).

There seems to be little question as to the importance the American dietary habits play in enhancing lipid elevation. The Inter-Society Commission for Heart Disease has recommended that a long-term national policy for changes in diet to prevent or control hyperlipidemia be adopted (Stamler et al. 1974, pp. 24-25).

By using data from the Framingham study, it is possible to demonstrate the significance of elevated serum cholesterol. The incidence of new events of coronary heart disease was five times greater among those with serum cholesterol concentrations of 260mg/100ml. or higher than among those whose concentrations were less than 200mg/100ml. (Epstein, Ostrander 1971, p. 325).

There is little evidence at present which documents that treatment for hyperlipidemia decreases or slows atherogenesis in men. However, the treatment will help slow, and possibly produce some regression of moderately advanced lesions (Kannel 1977, p. 181).

Carbohydrate Intolerance

Diabetes has been proven to be a metabolic inducer of coronary heart disease. Hyperglycemia is now viewed as a continuous variable like serum cholesterol and blood pressure. However, there is still inadequate data to determine the degree to which hyperglycemia adds predictive weight above and beyond that already provided by other risk factors (Ostrander et al. 1965, p. 1188).

Impaired carbohydrate tolerance at least doubles the risk of cardiovascular disease and virtually obliterates the relative immunity of women to cardiovascular mortality or morbidity. Diabetes with or without coronary heart disease

or coexisting atherogenic traits, is associated with an increased risk of development of heart failure, particularly in patients requiring insulin (Hjortland, Kannel 1974, p. 30).

Electrocardiogram

In the sixty years of its existence, electrocardiography has become established as a relatively inexpensive, and extremely useful technique for gaining information about the heart. According to Hurst (1974, p. 297):

In spite of its age and utility, the art is still on a somewhat insecure theoretical basis. The surface electrocardiogram is assumed to be a complex mathematic summation of electrical activity of the heart, but in spite of the fundamental nature of this relationship, it is not possible to predict the configuration of the action potential of the heart, nor is it possible to predict the details of the surface electrocardiogram from the sequence of activities (Hurst, Logue 1974, p. 297).

Despite this limitation, there is much information which can be gained from the electrocardiogram. There are certain findings which suggest a possible indication to or precursor of coronary heart disease.

Various studies have shown that ventricular premature contraction in resting electrocardiogram of apparently healthy individuals is of questionable significance. However, ventricular beats such as bigeminy, coupling, or multiformity may possibly be predictive of impaired longevity (Doyle 1975, p. 176).

The depression of the ST segment and T wave inversions are signs which are associated with an increased incidence of coronary heart disease. Not all ST segment depression or T wave inversions are diagnostic of abnormalities, but generally they are significant (Epstein 1971, p. 336).

Left ventricular hypertrophy by electrocardiographic criteria is generally an ominous sign. Fully 44 percent of deaths due to cardiovascular disease are preceded by left ventricular hypertrophy. Half of the patients with this finding are dead within eight years (Kannel 1976, p. 274).

Omnicardiogram

At present, there have been only three reported studies using the omnicardiogram. The first reported use of the omnicardiogram in March 1975 concerned the ability of the omnicardiogram to detect latent coronary heart disease in an asymptomatic population. Two-hundred normal electrocardiograms from the Framingham study cohort were analyzed by this technique. One-half of the electrocardiograms consisted of the last normal electrocardiogram prior to development of clinical coronary heart disease. The omnicardiogram proved to be more sensitive than the electrocardiogram in predicting subsequent morbid events resulting from coronary heart disease. This demonstrated the individuals of this group were at a

higher risk for myocardial infarction. However, the low specificity for the omnicardiogram, a 54 percent false positives, implied that the omnicardiogram may not be totally diagnostic of coronary heart disease in asymptomatic persons with normal electrocardiograms. However, the report added that this method may be useful as a screening procedure to identify high risk coronary subjects. The authors felt that an abnormal omnicardiogram is probably associated with an increased probability of myocardial infarction (estimated at twofold), but whether this is independent of other risk factors, elevated blood pressure in particular, was not stated and further studies were encouraged (Nay et al. 1975, pp. 462-466).

The second study in April 1975 concerned 121 male patients with a normal resting twelve-lead electrocardiogram who underwent selective coronary cineangiography because of a chest pain syndrome. In normotensive patients with a normal resting electrocardiogram, an abnormal omnicardiogram was recorded in 81 percent of those patients with three-vessel disease, 67 percent of those individuals with two-vessel disease, and 41 percent of those subjects with one-vessel disease. The omnicardiogram was abnormal in 81 percent of patients with hypertension, whether or not coronary artery disease was present. A double master exercise test was performed by 109 of the 121 patients studied. In normotensive

patients, the Masters test was positive in 67 percent of those with three-vessel disease, 31 percent of those with two-vessel disease, and 14 percent of those with one-vessel disease. There was a 4 percent false positive rate. Thus, in this study, the omnicardiogram appeared to be superior to the Masters test for predicting coronary artery disease, and it appeared to provide a useful new approach to the detection of coronary artery disease in male patients with a normal resting electrocardiogram (Teichholz, Cohn, Gorlin 1975, pp. 531-536).

The third study examined 72 male patients over age 35 who had normal resting twelve-lead electrocardiograms. All patients were studied with cardiac catheterization, coronary arteriography, and a left ventricular angiograph. All patients had been referred because of chest pain with a presumed diagnosis of coronary artery obstruction and myocardial ischemia.

Of the 72 patients studied, 21 were free from coronary artery disease. Of these free of coronary artery disease 14 percent had abnormal omnicardiograms while 7 percent had a normal omnicardiogram reading indicating an incidence of 66 percent false positive abnormal omnicardiogram.

Fifty-one of the 72 patients had coronary artery disease. Nineteen (38 percent) of the 51 patients having coronary artery disease had a normal omnicardiogram, giving an incidence of 38 percent of false negative diagnosis.

When the patients with coronary artery disease were classified as to single, double, or triple vessel coronary obstruction, it was apparent that the omnicardiogram did not separate patients with more extensive disease (Redy 1975, pp. 13-16).

Summary

Chapter II presents a review of nursing literature which considers the expanded role of the nurse in providing health maintenance and disease prevention. A review of literature over the last two decades strongly suggests that coronary heart disease can be predicted with a certain degree of accuracy. The chapter considers the major risk factors and their importance alone and in combination. Information was also given that if the number of deaths associated with coronary heart disease were to be decreased, a more effective measure to prevent or delay the occurrence of the disease must be found, and also methods by which new events of coronary heart disease can be anticipated earlier than at present must be developed. The studies of the omnicardiogram

were reviewed in light of their potential usefulness anticipating early signs of coronary heart disease.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

Introduction

Chapter III presents the methodology utilized in developing this study. First, setting and population are examined. Then, the tool, the omnicardiogram, is explained in more detail. The collection of data is next described in sequence of occurrence, and last, treatment of data is presented.

Setting

This study was conducted at a 285-bed federally-operated hospital located in Central Texas. The Internal Medicine Clinic of this hospital was used to identify participants for the study.

This clinic staff consisted of eight physicians: one cardiologist, one neurologist, and six general internal medicine physicians who provided a broad spectrum of medical care and one registered nurse. Ancillary personnel consisted of three nursing aids, a receptionist, and a secretary.

The clinic functioned on a five-day week, 7 A.M. to 4:30 P.M. and provided a physician on call twenty-four hours a day, including weekends. This system accommodates approximately 15,000 patient visits a year.

Population

The population served by the hospital is approximately 160,000. The study population was derived from males and females coming to the Internal Medicine Clinic for routine annual physical examinations or for follow-up treatment of essential hypertension. There were 106 patients chosen for the study. Informed written consent was received from each participant in the study (Appendix A).

Tool

The omnicardiogram has recently been developed to detect abnormalities in the normal standard twelve-lead electrocardiogram, not identified by ordinary means of interpretation. The omnicardiogram mathematically transforms the usually linear form of the electrocardiogram into an electronically-produced template which is roughly Florida-shaped. The resulting signal is then mechanically superimposed on a previously determined normal template. The template represents the normal boundaries for the transformed electrocardiogram (Nay 1975, p. 463).

The normal template boundaries have been produced from normal electrocardiograms done on patients who were documented to have totally normal coronary artery circulation at cardiac catheterization. The normal omnicardiogram is one in which the transformed complex from the electrocardiogram falls totally within a "Florda-shaped" template.

When the omnicardiogram is performed, two cardiac cycles are selected at random from leads I, II, V₄, V₅, and V₆ of the electrocardiogram. These tracings are enlarged, digitized, and programmed through a computer which then converts them into the nonlinear form. The omnicardiogram is then drawn automatically and superimposed on the normal template. Therefore, there is an omnicardiogram tracing for each cardiac cycle of the five electrocardiogram leads used (Nay 1975, pp. 463-464). In each of the five leads used, the omnicardiogram template varies slightly as shown in Figure 1.

Each omnicardiogram is read as either "IN" (normal) or "OUT" (abnormal) based on whether the tracing is inside or outside the lines of the template. Rarely, the omnicardiogram falls on the border of the template, and in this case, the "borderline" is scored as "out." The three studies on the omnicardiogram present no consensus on exactly how many "outs" constitute an abnormal omnicardiogram. Teichholz uses four or more, while Nay uses three and five or more "outs",

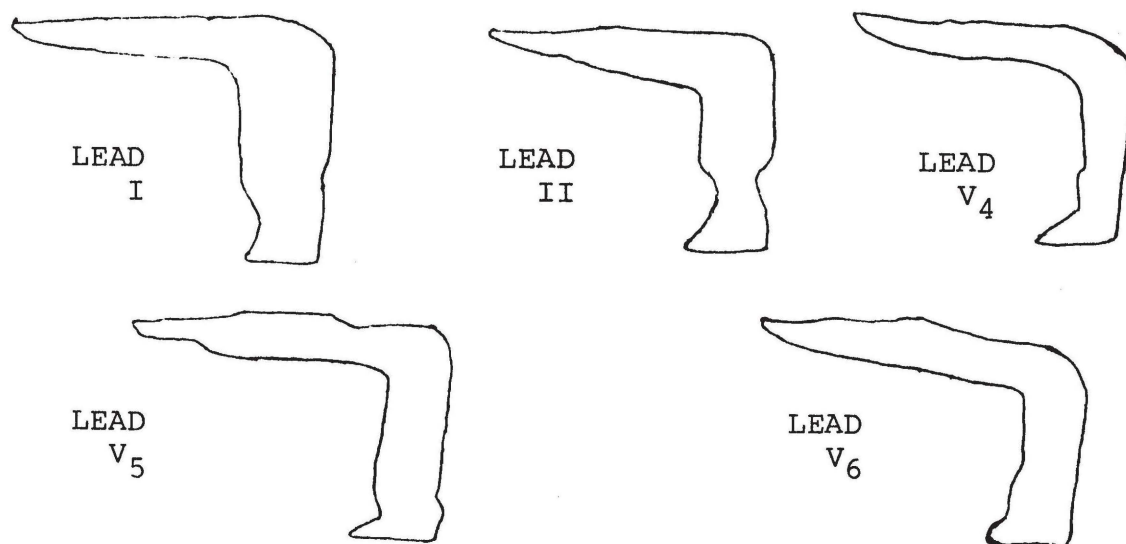


Figure 1. Normal Templates for Each Electrocardiogram Lead Used

and also applied a more rigid criteria of 100 percent "in," or 100 percent "out" for normal and abnormal, and Redy does not define in his article what his criteria for normal and abnormal omnicardiograms are (Teichholz, Cohn, Gorlin 1975, p. 53; Nay et al. 1975, pp. 463-464; and Redy et al. 1975, pp. 13-16). Therefore, for the purpose of this study, computer analysis was used to define this problem more clearly.

In performing the omnicardiogram, a three-channel Hewlett-Packard 1514A electrocardiograph was used. The

omnicardiogram was attached to the electrocardiograph with the appropriate connections. The patient was connected to the electrocardiogram with the four standard limb leads and standard chest leads. The lead to be analyzed was then selected on the electrocardiogram and omnicardiogram simultaneously.

An oscilloscope on the omnicardiogram produced four separate signals: (a) the electrocardiogram, (b) a baseline, (c) template, and (d) an omnicardiogram pattern. For the omnicardiogram to compute, it was essential that the isoelectric line of the electrocardiogram fall exactly on the baseline as shown in Figure 2.

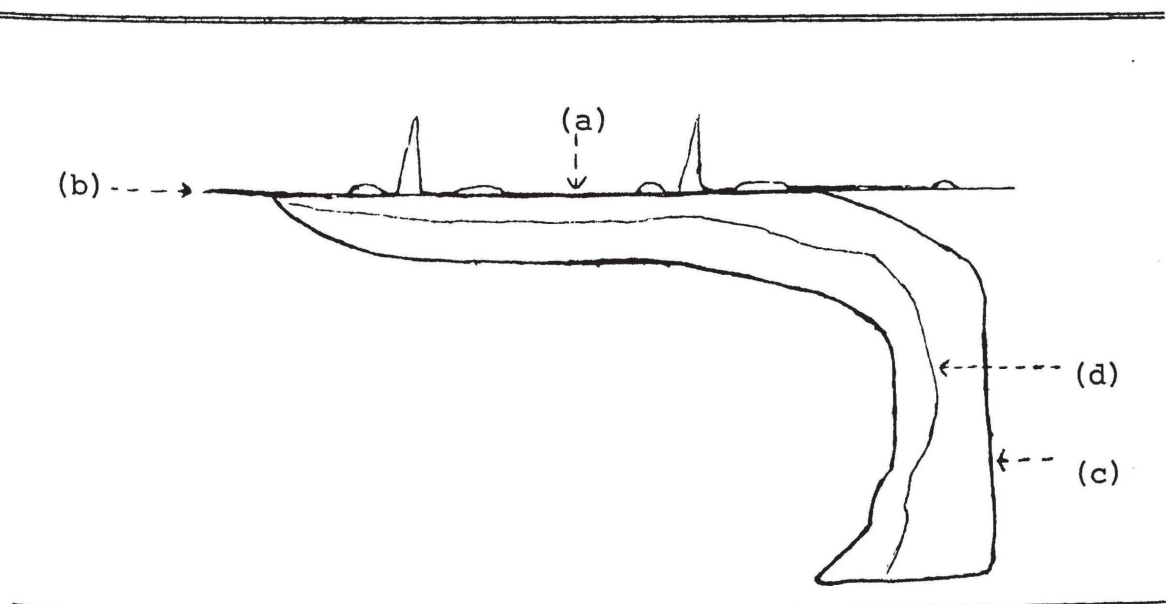


Figure 2. A Normal Omnicardiogram Pattern of Lead V_4

Note the omnicardiogram pattern (D) remains entirely within the template (C). If at anytime it had fallen outside the template, it would have been abnormal. Also note the isoelectric line of the electrocardiogram (A) falls exactly on the baseline (B).

A random cardiac cycle is chosen for analysis and "frozen" on the oscilloscope. If the electrocardiographic signal is not on the baseline, the omnicardiogram will not compute, and the oscilloscope picture is distorted. If the omnicardiogram computes, it is then recorded by an MEF X-Y plotter.

After each cardiac cycle is computed and recorded, they are then scored as previously mentioned. The information is then transferred to a variable flow sheet (Appendix B) and ultimately to computer cards for final analysis.

Data Collection

Prior to the period of data collection, permission from the federally-operated hospital and the Human Research Committee from Texas Woman's University was obtained (Appendix A). The study was conducted over a period of time from January 3, 1977 to March 15, 1977. One hundred and six patients who were derived from the Internal Medicine Clinic participated in the study.

Each physician was informed of the study by a verbal description. They were asked to refer patients whom they

considered to be basically healthy and normotensive, and patients who had a documented medical history of essential hypertension to the cardiac laboratory where the procedure and study was explained in detail by the investigator. If the individual chose to participate, informed written consent was obtained (Appendix B).

The physician, at this point, filled out the medical history and physical examination form (Appendix B). The patient was given forms for objective laboratory tests. These tests consisted of chest x-ray, urinalysis, blood test for fasting blood sugar and cholesterol to be obtained prior to their scheduled electrocardiogram and omnicardiogram.

Prior to the omnicardiogram, the information from the history, physical examination, and other objective data was transferred to the variable flow sheet. At the time of the omnicardiogram, the patient's consent form was placed in a file separate from their other information. The patients were then assigned a coded number to insure confidentiality.

The electrocardiogram and omnicardiogram were then performed by the investigator. A sitting blood pressure was obtained using the Korotkoff sounds as the criteria for systolic (Phase 1) and diastolic blood pressure (Phase 5) (Maxwell 1974, pp. 48-51). The information received at this time was transferred to the variable flow sheet (Appendix B).

The patient population was categorized into one of three groups:

- Group I: Normotensive
- Group II: Early hypertensive
- Group III: Late hypertensive

The purpose of dividing the population into groups related to hypertension was:

1. Hypertension has been shown to be one of the major risk factors contributing to coronary heart disease (Kannel 1976, pp. 269-282)
2. Of all the risk factors, hypertension is probably the most reliable to document and categorize
3. The division of hypertension into early and late hypertension was selected because it has been suggested that after approximately five years of even mild to moderate hypertension there is a possibility of some organ change (Joffe 1977).

The following criteria were used to categorized a patient into one of three groups:

Group I

1. Normal physical examination
2. Negative history of hypertension
3. Normal electrocardiogram
4. Normal blood pressure (average below 140/90)

Group II

1. Medical documentation of essential hypertension
2. Hypertension for no longer than five years

Group III

1. Medical documentation of essential hypertension
2. Hypertension for longer than five years

Treatment of Data

Due to the amount of data and the desired results, a statistical and computer analyst was consulted. The data will be presented in the following manner:

1. Measures of Central Tendency with Standard Deviation and Variance will be considered first to present a clearer picture of the relationships of risk factors, groups, and the omnicardiogram (Jaworski 1977)

2. Spearman Rank Correlation Coefficient will be used because while originally analyzing the omnicardiogram scores, it was clear there were no normal distribution patterns. Therefore, a nonparametric form of statistics was chosen. Kerlinger (1973, p. 286) says of the Spearman Correlation Coefficient:

This form of nonparametric statistics is particularly free of assumptions about the characteristics or the form of the distributions of the populations of research samples. . . . A nonparametric statistical test is a test where model does not specify conditions about the parameters of the population from which the sample was drawn.

3. Factor Analysis will be the last method analyzed.

This method essentially examines a number of variables and tries to discover underlying factors to explain all the variables. The "factors" produced are mathematical abstract concepts or dimensions, that sometimes explain reality (Kerlinger 1973, p. 685).

Summary

Chapter III presents an overview of the setting and population studied. The tool, the omnicardiogram, was then discussed with a full explanation of its operation. Data collection was then described in the sequence it occurred. Finally, treatment of data was explained in the order it will be presented in Chapter IV.

CHAPTER IV

ANALYSIS OF DATA

Introduction

Epidemiological studies have demonstrated the importance of several risk factors which contribute to coronary heart disease. It has also been demonstrated that a new form of electrocardiography, the omnicardiogram, may possibly be able to detect abnormalities not apparent in the standard electrocardiogram. If this can be demonstrated, then the omnicardiogram represents an important new, early, indicator of coronary heart disease. Thus, the purpose of this study was to see if the omnicardiogram correlates with selected known risk factors of coronary heart disease.

For the purpose of this study several risk factors were identified. They were (a) age, (b) race, (c) sex, (d) family history of hypertension, coronary heart disease, cerebral vascular accident, and diabetes mellitus, (e) personal history of hypertension, (f) smoking, (g) elevated serum cholesterol, (h) glucose intolerance, and (i) abnormal electrocardiogram.

The data will be presented in the following manner:

1. Statement on the studied population
2. Information and breakdown on race and sex
3. Measures of Central Tendency with Standard Deviation and Variance. Each risk factor will be analyzed in relationship to group and the omnicardiogram
4. Spearman Rank Correlation Coefficient will be used to analyze the relationship of risk factors of the three groups to the omnicardiogram
5. Factor Analysis considers six risk factors and the omnicardiogram. Factor analysis of Group I, the normotensive patients, will be examined and then compared to a composite of Groups II and III together
6. Discussion of results

Population Studied

A total of 106 subjects were studied. Fifty were in Group I, 35 were in Group II, while 21 were in Group III. To determine approximately what percent of the population served by the hospital had hypertension, 180 charts were selected at random and reviewed for hypertension. The charts were selected from patients coming to the Acute Minor Illness Clinic over a two-day period of time.

It was found that 12.2 percent of the charts reviewed had some degree of hypertension. This correlates well with the current estimate of hypertension in the United States which is 12.5 percent.

Race and Sex

As Table 2 demonstrates, there was a very high percentage of white males involved in the study compared to the rest of the studied population. The American Heart Association (1976, p. 2) estimates that 13 percent of white males, and 17 percent of white females have hypertension, as compared to 26 percent black males and 28 percent black females.

Measures of Central Tendencies for Selected Risk Factors

Age

The age distribution of those studied was from age 20 to 68. This represented a mean age of 40.3 years. Table 3 demonstrates the mean age increased with length of hypertension. In each of the three groups, when two or less abnormal omnicardiograms are compared with seven to ten abnormal omnicardiograms, there is again an increase of the mean age.

Table 2

Race and Sex Characteristics of Sample Population

GROUP	WHITE				BLACK				ORIENTAL		Total	
	Males		Females		Males		Females		Females			
	No.	Percent	No.	Percent	No.	Percent	No.	Percent	No.	Percent	No.	Percent
I	36	(33.96)	9	(8.50)	4	(3.77)	1	(0.95)	0	(0)	50	(47.6)
II	21	(19.81)	8	(7.54)	3	(2.83)	2	(1.88)	1	(0.95)	35	(32.4)
III	10	(9.43)	6	(5.66)	4	(3.77)	0	(0)	1	(0.95)	21	(20.0)
Total	66	(63.20)	23	(21.70)	11	(10.37)	3	(2.83)	2	(1.90)	106	(100.0)

Table 3

Comparison of Age in Years by Blood Pressure Group and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	40.14	11.60	134.69	106
NORMOTENSIVE	35.58	9.90	98.08	50
A.	33.78	10.39	108.04	32
B.	43.12	9.86	97.26	8
C.	35.30	4.90	27.01	10
EARLY HYPERTENSIVE	40.45	11.74	138.02	35
A.	37.76	138.40	179.69	13
B.	40.69	9.80	96.23	13
C.	44.00	12.11	146.75	9
LATE HYPERTENSIVE	50.46	8.23	67.86	21
A.	45.00	7.16	51.33	4
B.	53.00	6.58	43.33	4
C.	51.38	8.74	76.42	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Age and elevated blood pressure are known risk factors which contribute to coronary heart disease. As Table 3 demonstrates, the omnicardiogram scores increase with both variables, thus, there appears to be some correlation between age, duration of hypertension, and the omnicardiogram.

Family History

Family history of hypertension (Table 4) demonstrates a rise with groups, but no pattern with the omnicardiogram. Family history of coronary heart disease (Table 5) shows slight increase in the mean with Group III, but no pattern with the omnicardiogram scores.

In relation to family history of cerebral vascular accident (Table 6), again, an increase of groups is noted, but no pattern with the omnicardiogram scores. Family history of diabetes (Table 7) also has a rise in relationship to groups, but the omnicardiogram scores continue to be unrelated. Since family is a very difficult variable to measure, the reliability of this risk factor can be questioned.

Table 4

Comparison of High Blood Pressure in Family by Blood Pressure Group
and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	.4660	.5013	.2513	103
NORMOTENSIVE	.3878	.4923	.2423	49
A.	.4194	.5016	.2516	31
B.	.3750	.5175	.2697	8
C.	.3000	.4830	.2333	10
EARLY HYPERTENSIVE	.4706	.5066	.2567	34
A.	.5385	.5189	.2692	13
B.	.5000	.5222	.2727	12
C.	.3333	.5000	.2500	9
LATE HYPERTENSIVE	.6500	.4894	.2395	20
A.	.5000	.5774	.3333	4
B.	.7500	.5000	.2500	4
C.	.6667	.4924	.2424	12

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 5

Comparison of Coronary Heart Disease in Family by Blood Pressure Group and
Omniscardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	.3235	.4701	.2210	103
NORMOTENSIVE	.3265	.4738	.2245	49
A.	.3000	.4661	.2172	31
B.	.1111	.3333	.1111	8
C.	.6000	.5164	.2667	10
EARLY HYPERTENSIVE	.2424	.4352	.1894	34
A.	.2500	.4523	.2045	12
B.	.2500	.4523	.2045	12
C.	.2222	.4410	.1944	9
LATE HYPERTENSIVE	.4500	.5104	.2605	20
A.	.2500	.5000	.2500	4
B.	.6667	.5774	.3333	3
C.	.4615	.5189	.2692	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 6

Comparison of Cerebral Vascular Accident in Family By Blood Pressure Group
and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	.1845	.3898	.1519	103
NORMOTENSIVE	.1020	.3058	.0935	49
A.	.0323	.1796	.0353	31
B.	.3750	.5175	.2679	8
C.	.1000	.3162	.1000	10
EARLY HYPERTENSIVE	.2059	.4104	.1684	34
A.	.1538	.3755	.1410	13
B.	.1667	.3892	.1515	12
C.	.3333	.5000	.2500	9
LATE HYPERTENSIVE	.3500	.4894	.2395	20
A.	.0000	.0000	.0000	4
B.	.5000	.5774	.3333	4
C.	.4167	.5149	.2652	12

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 7

Comparison of Diabetes in Family by Blood Pressure Group
and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	.2330	.4248	.1805	103
NORMOTENSIVE	.2041	.4072	.1658	49
A.	.1935	.4016	.1613	31
B.	.1250	.3536	.1250	8
C.	.3000	.4830	.2333	10
EARLY HYPERTENSIVE	.2059	.4104	.1684	34
A.	.2308	.4385	.1923	13
B.	.2500	.4523	.2045	12
C.	.1111	.3333	.1111	9
LATE HYPERTENSIVE	.3500	.4894	.2395	20
A.	.5000	.5774	.3333	4
B.	.2500	.5000	.2500	4
C.	.3333	.4924	.2424	12

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Blood Pressure

The mean systolic blood pressure was 134.88 for the entire population. There is a steady rise related to groups. There is a very significant rise of systolic blood pressure noted between Group I and the mean of the hypertensive groups. With higher systolic blood pressure, higher abnormal omnicardiogram scores are noted (Table 8).

The diastolic blood pressure also increased from the normotensive group to the hypertensive groups. In regard to the omnicardiogram scores, there is only a slight increase of Groups II and III when two or less and seven to ten abnormal omnicardiograms are analyzed (Table 9).

Smoking

Groups I and II have similar means. In Group III, the mean increases for the group and for seven to ten abnormal omnicardiograms. This may only be related to an increased mean age for Group III. The relationship of the omnicardiogram with smoking is not significant (Table 10).

Cholesterol

There is a relationship between the means of the normotensive group (Group I) and the length of hypertension (Groups II and III). Significant increases of each group with two or less and seven to ten abnormal omnicardio-

grams are presented. There is a positive correlation between cholesterol, length of hypertension, and the omnicardiogram (Table 11).

Fasting Blood Sugar

Increase of group mean is seen, but no relationship with the omnicardiogram scores is found. There is a low correlation with fasting blood sugar and hypertension, but no apparent relationship with omnicardiogram readings (Table 12).

Electrocardiogram

The Romhilt point-score system for the electrocardiogram diagnosis of left ventricular hypertrophy was used (Appendix B). As noted in Table 13, there is a progressive increase of the mean Romhilt score in Groups I, II, and III. There is, however, no pattern related to the omnicardiogram scores. The tendency of the Romhilt index to increase with length of hypertension correlates it with hypertension as it would be expected to, but in relation to the omnicardiogram, there is no apparent relationship (Table 13).

Table 8

Comparison of Systolic Blood Pressure by Blood Pressure Group
and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	134.88	17.18	295.16	106
NORMOTENSIVE	124.72	12.72	161.79	50
A.	125.43	12.56	157.80	32
B.	124.75	13.81	190.791	8
C.	122.40	13.45	181.15	10
EARLY HYPERTENSIVE	142.62	17.63	311.12	35
A.	138.23	10.55	111.35	13
B.	144.53	26.48	701.26	13
C.	146.22	7.17	51.44	9
LATE HYPERTENSIVE	146.19	11.26	126.86	21
A.	143.75	9.46	89.58	4
B.	143.00	20.94	438.66	4
C.	147.92	8.41	701.74	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 9

Comparison of Diastolic Blood Pressure by Blood Pressure Group and
Omniscardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	85.98	9.00	81.10	106
NORMOTENSIVE	79.86	6.98	48.81	50
A.	79.50	6.42	41.29	32
B.	82.75	3.84	14.78	8
C.	78.70	10.13	102.67	10
EARLY HYPERTENSIVE	91.02	7.64	58.44	35
A.	91.84	7.85	61.64	13
B.	88.15	6.90	47.64	13
C.	94.00	7.74	60.00	9
LATE HYPERTENSIVE	91.71	5.84	34.11	21
A.	91.00	2.58	6.66	4
B.	91.00	8.40	70.66	4
C.	92.15	6.08	36.97	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 10

Comparison of Pack-Years Smoking by Blood Pressure Group and
Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	12.11	17.21	296.19	105
NORMOTENSIVE	11.62	15.28	233.57	49
A.	12.51	17.32	300.12	31
B.	8.62	13.08	171.12	8
C.	11.30	10.06	101.34	10
EARLY HYPERTENSIVE	10.51	15.81	250.25	35
A.	7.23	17.36	301.69	13
B.	13.00	14.10	199.00	13
C.	11.66	16.83	283.50	9
LATE HYPERTENSIVE	15.90	23.11	534.09	21
A.	16.00	18.54	344.00	4
B.	6.25	12.50	156.25	4
C.	18.84	26.91	724.64	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 11

Comparison of Cholesterol by Blood Pressure Group and Omnicardiographic
Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	228.66	40.64	1652.26	106
NORMOTENSIVE	213.92	37.24	1387.46	50
A.	209.93	41.77	1745.15	32
B.	207.00	27.69	766.85	8
C.	232.20	21.82	476.17	10
EARLY HYPERTENSIVE	241.97	38.87	1511.00	35
A.	231.23	24.88	619.19	13
B.	236.92	39.51	1561.74	13
C.	264.77	48.33	2336.69	9
LATE HYPERTENSIVE	241.61	40.94	1676.64	21
A.	219.00	62.32	3884.00	4
B.	299.00	25.93	672.66	4
C.	252.46	36.11	1304.26	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 12

Comparison of Fasting Blood Sugar by Blood Pressure Group and Omnicardiographic Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	109.21	11.33	128.38	106
NORMOTENSIVE	103.58	7.54	56.98	50
A.	103.09	7.98	63.76	32
B.	104.62	8.58	73.69	8
C.	104.30	5.55	30.90	10
EARLY HYPERTENSIVE	111.74	10.23	104.84	35
A.	112.15	11.19	125.25	13
B.	112.53	10.65	113.43	13
C.	110.00	9.09	82.75	9
LATE HYPERTENSIVE	118.42	13.28	176.45	21
A.	125.75	12.57	158.25	4
B.	126.25	20.02	400.91	4
C.	113.76	9.61	92.52	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Table 13

Comparison of Romhilt Index by Blood Pressure Group and Omnicardiographic
Diagnostic Break

	Mean	Standard Deviation	Variance	Number of Participants
ENTIRE POPULATION	.93	1.75	3.07	106
NORMOTENSIVE	.48	1.14	1.31	50
A.	.46	1.16	1.35	32
B.	.37	1.06	1.12	8
C.	.60	1.26	1.60	10
EARLY HYPERTENSIVE	.77	1.47	2.18	35
A.	.69	1.31	1.73	13
B.	.46	.96	.93	13
C.	1.33	2.17	4.75	9
LATE HYPERTENSIVE	2.28	2.59	6.71	21
A.	4.25	4.19	17.58	4
B.	1.50	1.73	3.00	4
C.	1.92	2.10	4.41	13

- A. Two or less abnormal omnicardiograms
 B. Three - six abnormal omnicardiograms
 C. Seven - ten abnormal omnicardiograms

Spearman Rank Correlation Coefficient

Table 14 presents the information in the following manner: Data on each group is presented in its respective column, with Groups II and III being combined. Each risk factor is correlated by a correlation coefficient score (A) and then calculated to give the significance level (B).

Table 14

Spearman Rank Correlation Coefficient

		GROUP I	GROUP II	GROUP III	GROUP II & III
Omnicardiogram with systolic blood pressure	(A) .0288	.2910	.3133	.3245	
	(B) .422	.042	.084	.008	
Omnicardiogram with diastolic blood pressure	(A) .2298	.0405	.1744	.0766	
	(B) .055	.409	.225	.288	
Omnicardiogram with cholesterol	(A) .2591	.3448	.2311	.3408	
	(B) .035	.022	.157	.006	
Omnicardiogram with Pack Years	(A) .023	.1264	.1239	.0370	
	(B) .436	.235	.297	.394	
Omnicardiogram with Fasting Blood Sugar	(A) .020	.1266	.3070	.0003	
	(B) .444	.235	.088	.499	

- (A) Represents coefficient correlation
 (B) Represents significant level

Systolic blood pressure has little relationship with Group I, but in Groups II and III a significant level exists. When the hypertensive groups are combined, a .008 significance level was obtained. In other words, there is a .8 percent chance there is no relationship with systolic blood pressure and the omnicardiogram, but a 99.2 percent chance that there is a relationship.

Diastolic blood pressure had a higher correlation in Group I than the hypertensive groups separately and combined. Since all the hypertensives in this study were on some form of treatment for their disease, this could explain the difference between systolic and diastolic blood pressure. Most hypertensive treatment effectively lowers the diastolic pressure more than the systolic (Joffe 1977).

The significance of cholesterol level in Group III increases sharply when compared to Groups I and II. When Groups II and III are combined, a level of significance is obtained. A 99.4 percent relationship that there is a correlation between cholesterol and the omnicardiogram exists.

Pack-years smoking shows no outstanding correlation. Fasting blood sugar has the highest correlation with the omnicardiogram in Group III. When Groups II and III are combined, the significance level decreases.

Factor Analysis

Five risk factors used previously with the Spearman Correlation Coefficient, and a sixth (obesity) are analyzed along with the omnicardiogram by factor analysis. Factor analysis of Group I is examined in Table 15. Factor 1 demonstrates an extremely close relationship between systolic and diastolic blood pressure and to a lesser extent, with fasting blood sugar.

Factor 2 shows a relationship between cholesterol, the omnicardiogram, and obesity. Factor 3 relates pack-years smoking, cholesterol, and fasting blood sugar.

Table 15

Factor Analysis Risk Factors and Omnicardiogram--Group I

	Factor 1	Factor 2	Factor 3
Omnicardiogram	.069	.472	.082
Systolic blood pressure	.822	.103	.099
Diastolic blood pressure	.805	.172	.045
Cholesterol	.194	.608	.331
Pack-Years Smoking	.123	-.027	.710
Fasting blood sugar	.562	.184	.278
Obesity	.333	.328	.212

The hypertensive groups were combined as a final step in analysis. Using the same seven variables as used with Group I, four factors were produced (Table 16)

Factor 1 demonstrates an exceptionally high relationship between the omnicardiogram and cholesterol, and to a lesser extent, systolic blood pressure. Factor 2 demonstrates a correlation between systolic and diastolic blood pressure. In Factor 3, there is a relationship between pack-years, and a negative correlation with obesity. The correlations in Factor 4 are fasting blood sugar, systolic blood pressure, obesity, and a negative relationship with diastolic blood pressure.

Table 16

Factor Analysis Risk Factors
and
Omnicardiogram--Groups
II & III

	Factor 1	Factor 2	Factor 3	Factor 4
Omnicardiogram	.619	.149	.123	-.128
Systolic blood pressure	.279	.612	.075	.205
Diastolic blood pressure	-.074	.575	-.105	-.302
Cholesterol	.608	-.016	-.016	.100
Pack-Years Smoking	.058	.119	.560	.150
Fasting Blood Sugar	-.006	-.025	-.009	.498
Obesity	-.032	.220	-.609	.231

The purpose of factor analysis is to take a number of independent variables and mathematically produce as few factors or measures as possible to explain all the variables. Each factor is independent of the other, and in essence, represents one dimension of a patient.

"Does the abnormal omnicardiogram correlate with selected known risk factors of coronary heart disease?" Factor 2 of Group I shows a relationship between the omnicardiogram and cholesterol, and somewhat with obesity. Factor 1 of Groups II and III demonstrates a very high correlation between the omnicardiogram and cholesterol, and to a lesser extent, with systolic blood pressure.

Since factor analysis is an abstract mathematic concept, it might be proposed from findings of Factor 2, Group I, and Factor 2, Groups II and III, that there is a significant underlying relationship between the omnicardiogram and cholesterol. The exact mechanism is unclear.

Discussion of Results

By using measures of central tendency, the following known risk factors of coronary heart disease are demonstrated to have some correlation with the omnicardiogram: age, blood pressure (both systolic and diastolic), and cholesterol. Relationship with the following were non-conclusive: family history, smoking, fasting blood sugar,

electrocardiogram by Romhilt index.

The Spearman rank correlation coefficient demonstrated significant relationships with the combination of Groups II and III:

1. Cholesterol with a 99.4 percent correlation
2. Systolic blood pressure with a 99.2 percent correlation
3. Diastolic blood pressure with a 71.2 percent correlation

Factor analysis demonstrated a high correlation with the omniscardiogram and cholesterol. Systolic blood pressure was also proven to have significant correlation.

By using the three methods of statistical analysis, it can be said that there is a correlation between certain known risk factors of coronary heart disease and the omniscardiogram. Specifically, cholesterol, systolic blood pressure, diastolic blood pressure, fasting blood sugar, and age. An unclear relationship with family history and pack-years of smoking exists.

Summary

Chapter IV has analyzed the data collected by three methods:

1. Measure of central tendency
2. Spearman rank correlation coefficient
3. Factor analysis

The information from these methods was analyzed by computer, and the results indicate that there is a relationship between selected known risk factors of coronary heart disease and the omnicardiogram. To what extent the omnicardiogram relates to coronary heart disease has not been shown in this study.

CHAPTER V

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

Summary

A descriptive survey was conducted to determine if selected risk factors of coronary heart disease correlate with an abnormal omnicardiogram. Coronary heart disease is the largest single cause of sudden death in the United States. Epidemiological investigations have postulated the risk factor concept of coronary heart disease which says the more risk factors an individual has, the greater are his chances of developing a significant cardiovascular manifestation of coronary heart disease. When individuals with these risk factors are identified, it may be possible to intervene and possibly interrupt, the chain of events leading to overt coronary heart disease.

A new method of electrocardiography, the omnicardiogram, has been developed in which five leads of the standard electrocardiogram are used: Leads I, II, V₄, V₅, and V₆. These leads are subjected to a nonlinear mathematical transformation so as to distinguish subtle abnormalities not recognized in the normal electrocardiogram. The criteria for

the omnicardiogram templates used with each of the five leads were derived from information on patients who had normal electrocardiograms, and who had undergone cardiocatheterization for a chest pain syndrome. A technique of this type which could detect earlier cardiac changes before the development of coronary heart disease would be an important addition to the health care system.

Nurses in the expanded role are now helping to identify risk factors of potential coronary victims. Just as the electrocardiogram is used by nurses, so could the omnicardiogram be used.

The setting for this study was a 285-bed federally-operated hospital located in Central Texas. Participants for the study were identified through the internal medicine clinic. The population served by the hospital is approximately 160,000. There were 106 patients, both male and female, chosen for the study.

The patients were divided into three groups: Group I (normotensive), Group II (early essential hypertensive), and Group III (late essential hypertensive). Each patient was given a physical examination in conjunction with a medical history. Specific laboratory data were gathered to assess selected risk factors. The omnicardiogram was performed with the electrocardiogram. The data were placed on computer cards and analyzed.

Conclusions

The hypothesis has been rejected. The data clearly demonstrate that there is a correlation between the omnicardiogram and selected known risk factors of coronary heart disease for normotensive, early hypertensive, and late hypertensive patients.

1. A definite correlation between the omnicardiogram, cholesterol, and blood pressure (both systolic and diastolic) and, to a lesser extent, fasting blood sugar was demonstrated
2. The relationship between the omnicardiogram and the electrocardiogram was unclear
3. There was questionable correlation between smoking, family history, and the omnicardiogram
4. A relationship between cholesterol and the omnicardiogram was shown in all three methods of analysis used. Statistically, this relationship in Factor 1, Groups II and III of the factor analysis, was the most significant finding in the study
5. No single omnicardiogram score was derived. However, by comparing the means of the abnormal omnicardiogram scores of two or less and seven and ten, it can be seen that, generally, the

mean increases. From this it might be suggested that the more "outs" that are considered after seven, the less false positives will be found

6. At the present use of the omnicardiogram would not be a useful tool for nurses functioning in a primary care setting

Implications

If further research demonstrates the omnicardiogram may be an early indicator of coronary heart disease, a whole new concept toward diagnosing and treating cardiovascular disease may be developed. If this occurs, it may be necessary for nursing practice to change with it.

As the role of the nursing profession expands, professional education programs will need to expand to keep pace with technological advancements in order to prepare the nurse in incorporating these changes. Nursing education will need to adapt to these changes by promoting research into such areas as physiologic monitoring, role conceptualization and preventive health care delivery. The results of research in nursing need to be incorporated into nursing education at an increasing rate.

The implications of the omnicardiogram to the nurse providing primary care is important. If a tool of this type could be perfected, the nurse will have a very important tool at his disposal. Nurses providing primary care are in a unique type of position, both to apply and test predictive theories of health care, and inculcate research findings to their practice, leading to the ultimate goal of practice for prevention of disease and health maintenance.

Recommendations

1. Further research into exactly what the omnicardiogram measures and exactly what are the criteria for interpretation
2. A more in-depth study into the relationship between cholesterol, blood lipids, and the omnicardiogram should be investigated
3. Repeat of this study in a longitudinal manner examining all risk factors with a larger and more evenly distributed population
4. Further research by nurses into more areas of physiological research, role conceptualization, and methods of health care.

APPENDIX A

PERMISSION FOR THE STUDY

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
DENTON, TEXAS

DALLAS CENTER
1810 Inwood Road
Dallas, Texas 75235

HOUSTON CENTER
1130 M.D. Anderson Blvd.
Houston, Texas 77025

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE _____ (institution)

GRANTS TO _____ HARVEY O'NEAL STOWE

a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem:

The purpose of this proposed study will be to see if an abnormal omniscardiogram correlates with known risk factors of hypertensive and coronary heart disease.

The conditions mutually agreed upon are as follows:

1. The agency (~~may~~) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (~~may~~) (may not) be identified in the final report.
3. The agency (wants) (~~does not want~~) a conference with the student when the report is completed.
4. The agency is (willing) (~~unwilling~~) to allow the completed report to be circulated through interlibrary loan. (after proper approvals)
5. Other: _____

Date 20 October 76

(Signed by Chief of Prof. Serv.)
Signature of Agency Personnel

Harvey O'Neal Stowe
Signature of student

Mona M. Grant R.N., Ph.D.
Signature of Faculty Advisor

*Fill out and sign three copies to be distributed as follows: Original -- Student; first copy -- agency; second copy -- T.W.U. College of Nursing.

TEXAS WOMAN'S UNIVERSITY

DENTON, TEXAS 76204



DEPARTMENT OF PSYCHOLOGY
AND PHILOSOPHY
Box 24133, TWU STATION

2-21-77

Harvey O'neal Stowe
c/o L. L. Moore Counts
Texas Woman's Univ Dept
Temple Texas

Dear ~~MAX~~ Smith: Mr Stowe

The Human Research Review Committee has reviewed and
approved your program plan " Correlation of the ECG with Known
Factors of Hypertensive and Coronary Heart Disease "

Sincerely yours,

Calvin Janssen, Vice Chairman
Human Research Review Committee

cc: Dr. Eridges

APPENDIX B

INFORMED CONSENT

Omnicardiogram Study with Risk Factors
Being Conducted by
Harvey O. Stowe, Capt. A.N.C.
Graduate Student, Texas Woman's University

1. I voluntarily agree to participate in the research study of a new form of cardiography, the omnicardiogram. This is a new method developed to detect subtle degrees of abnormality not apparent in the electrocardiogram.
2. I agree to have a physical exam, with routine laboratory data, a chest x-ray, electrocardiogram, and omnicardiogram.
3. I understand the omnicardiogram is performed at the same time with the electrocardiogram. It is painless and requires only a few minutes to complete.
4. I understand that I may withdraw from the study at any time without prejudicing my treatment. My identity will remain confidential. All questions I have regarding the study have been answered to my satisfaction.

Date

Volunteer's Signature

Date

Investigator's Signature

APPENDIX B

MEDICAL HISTORY

Group_____ # _____

Age_____ Weight_____ Height_____ Sex_____ Race _____

1. Has any close relative (father, mother, brother, sister) ever had any of the following diseases:

Yes No Don't Know

Heart disease
Hypertension
Stroke
Diabetes

2. Personal History

Yes No Don't Know

Heart Disease
Hypertension
Stroke
Diabetes
Kidney Disease

3. Do you smoke?_____ If so, cigarettes, cigars, or a pipe?
(underline which)

How many years have you smoked? _____

How much, on the average, do you smoke a day?_____

4. Any comments pertaining to your medical history?

APPENDIX B

PHYSICAL EXAMINATION

Group _____ # _____

Age _____ Weight _____ Height _____ Sex _____ Race _____

B/P _____ R arm _____ L arm _____

Eyes, ears, nose, throat _____

Neck-thyroid _____

Abdomen _____

	Normal	Abnormal	Describe or Measure
--	--------	----------	---------------------------

FUNDI

Arteries			
Veins			
Retina			
Disc			

CHEST

Inspection			
Auscultation			
Percussion			

HEART

Precordium			
PMI			
Auscultation			
Jugular pulses			
Venous pulses			

PERIPHERAL VESSELS

Carotid R.L.			
Femorals R.L.			
Popliteals R.L.			
DP's R.L.			
DT's R.L.			

APPENDIX B

VARIABLE FLOW SHEET

____ Patient
 ____ Group #
 ____ Race & Sex
 ____ Age

Family History

____ Hypertension
 ____ Coronary Heart Disease
 ____ Cerebral Vascular
 Accident
 ____ Diabetes

Personal History

____ Hypertension
 ____ Cerebral Vascular
 Accident
 ____ Diabetes
 ____ Smoking
 ____ Pack-years

Examination

____ Height
 ____ Weight
 ____ Systolic blood
 pressure
 ____ Diastolic
 blood pressure
 ____ Fundi I-IV
 ____ Check, Normal,
 Rales

____ Heart, S3
 ____ Heart, #4
 ____ Heart, Systolic
 Murmur
 ____ Heart, Diastolic
 Murmur
 ____ Vessels, Bruits
 ____ Vessels, Pulsation
 ____ Cholesterol
 ____ Fasting blood
 sugar

Electrocardiogram

____ Amplitude
 ____ ST-T segment
 ____ L Atrial Involve-
 ment
 ____ L Axis Deviation
 ____ QRS Duration
 ____ Intrinsicoid
 Deflection

Omniscardiogram

____ Lead I
 ____ Lead II
 ____ Lead V4
 ____ Lead V5
 ____ Lead V6

APPENDIX B

CRITERIA FOR VARIABLES

The group, race, age, sex, family history, and personal history will be obtained by interview according to the Medical History Form (Appendix B).

The physical examination (Appendix B) will be general in nature, but will concentrate on four areas of the cardiovascular system. The physical will be performed by the referring physician.

The fundi will be graded on a scale from I - IV, with I being normal, II AV nicking and arterial narrowing, III old hemorrhage and/or old exudate, IV papilledema.

The chest examination will be considered abnormal if any pathologic or physiologic findings are noted, specifically, rales.

The heart will be considered abnormal if any palpable or auscultatory abnormalities are found such as enlarged heart, S3, S4, systolic or diastolic murmur.

Peripheral vessels will be abnormal if an auscultatory bruit or palpable decrease in pulsations is noted.

The objective laboratory data:

Serum cholesterol abnormal if above 250mg%
Fasting blood sugar abnormal if above 120mg%
Urinalysis abnormal if it contains protein

APPENDIX B

The chest x-ray will be considered abnormal if there is cardiomeglia, aortic calcification, or an abnormality with the shape of the aorta. The x-rays will be interpreted by a radiologist.

The electrocardiogram. If a patient's electrocardiogram showed evidence of an old myocardial infarction or a problem with conduction, they were deleted from this study. For the purpose of this study, two variations from normal were considered: ST-T wave segments, and left ventricular hypertrophy.

The Romhilt point-score system for the electrocardiogram diagnosis of left ventricular hypertrophy was selected for this study. This method was chosen because it is "more sensitive in the presence of combined hypertension and coronary artery disease than either alone" (Romhilt 1968, p. 758).

APPENDIX B

Point-Score System

- | | |
|----------------------------|----------|
| 1. Amplitude | 3 points |
| 2. ST-T segment | 3 points |
| 3. Left atrial involvement | 3 points |
| 4. Left axis deviation | 2 points |
| 5. QRS duration | 1 point |
| 6. Intrinsicoid deflection | 1 point |

Four points is read as probably left ventricular hypertrophy

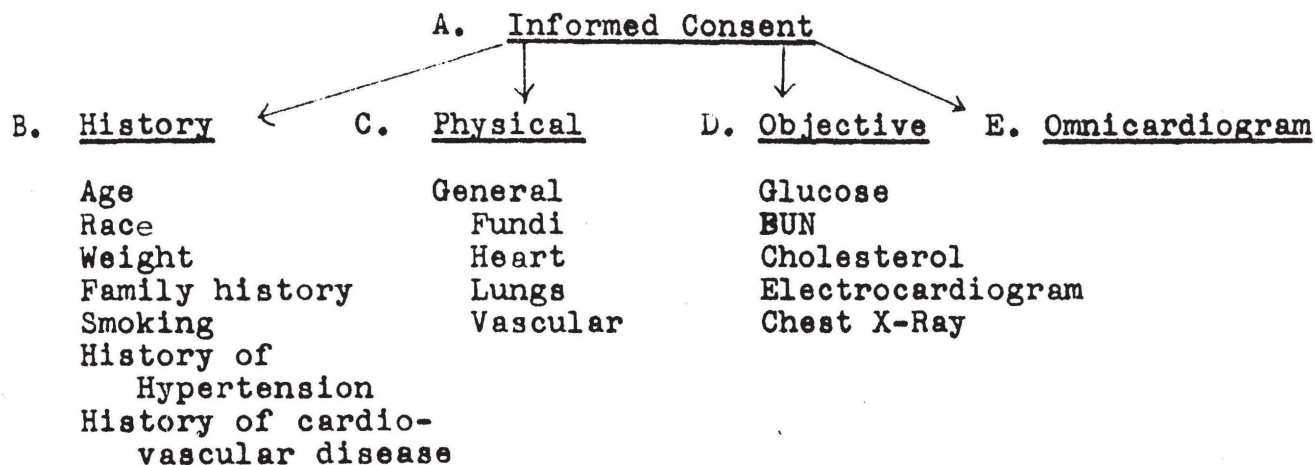
Five points is read as left ventricular hypertrophy

The omnicardiogram considers leads I, II, V₄, V₅, and V₆ of the electrocardiogram. The omnicardiogram scores will be considered in the following way:

1. Two or less abnormal omnicardiograms
2. Three to six abnormal omnicardiograms
3. Seven to ten abnormal omnicardiograms

APPENDIX B

DATA COLLECTION

STEP I

Group I
(Normotensive)

STEP II

Group II
(early hypertensive)

medical documentation
of elevated B/P for
less than five years

STEP III

Group III
(late hypertensive)

medical documentation
of elevated B/P for
more than five years

(B) (C) (D)

(E)

STEP IVSTEP VSTEP VISTEP VIISTEP VIIISTEP IX

Form (B) (C) (D) Known risk factors will be developed

Correlation of omnicardiogram to risk factors of Gr. I

Correlation of omnicardiogram to risk factors of Gr. II

Correlation of omnicardiogram to risk factors of Gr. III

Relationship of total study population to see if the abnormal omnicardiogram correlates with known risk factors of coronary heart disease

Treatment of data

Measures of central tendency
Spearman's correlation coefficients
Factor analysis

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