

A STUDY OF SOME OF THE FACTORS AFFECTING DRUG
COMPLIANCE IN THE HYPERTENSIVE PATIENT

A Thesis
Presented to
the Faculty of the College of Pharmacy
The University of Houston

In Partial Fulfillment
of the Requirements for the Degree
Master of Science in Pharmacy

by
John L. Lowery
August, 1975

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ABSTRACT

Hypertension is a major public health problem in the United States today. It is one of the most important afflictions producing illness, disability and premature death in our adult population. Hypertension is a disease that may not exhibit any symptoms, for which there is probably no cure, and the treatment of which may temporarily make the patient feel worse. The patient must be convinced, therefore, that the treatment of hypertension, if maintained, has the demonstrated potential of providing additional years of productive living. The present study was conducted to compare some of the factors which may affect drug compliance in the hypertensive patient. The factors which were studied included age of the patient, race of the patient, number of drugs prescribed per patient day, number of doses prescribed per patient day, and pharmacy counseling. Blood pressure readings were recorded to note the effect of drug compliance on blood pressure. In order to measure drug compliance, the patient was visited twice at his home where a medication count and an average of three blood pressure readings were recorded. These two visits consisted of a first home visit which was 14 ± 3 days after the clinic visit and a second home visit which was 28 ± 3 days after the clinic visit.

The patients for this study were selected from a hypertensive clinic for outpatients at a large, general hospital. The criteria the study patients had to meet for selection for this study were: they had to be new male patients accepted by the clinic; they had to have a primary diagnosis of essential hypertension; and they had to be on a prescribed drug regimen.

A total of 104 study patients were selected from the patients entering the clinic. Due to study patient attrition, data were collected for 87 of the 104 selected study patients. Of this 87 patient sample, two groups of patients were studied. For patients number 1 through 87 data were collected from the clinic and first home visit only. For 40 of these 87 patients data were collected from the clinic, first home visit and second home visit. The research design included an experimental group and a control group. The experimental group received pharmacy counseling at the clinic and at the first home visit. The control group did not receive pharmacy counseling at the clinic but did receive pharmacy counseling at the first home visit.

Of the factors studied, age, race, number of drugs prescribed per patient day, number of doses prescribed per patient day and pharmacy counseling, the only factor which was found to significantly affect patient drug compliance was pharmacy counseling. A further investigation showed that pharmacy counseling along with improved drug compliance

significantly reduced blood pressure. This study showed, therefore, that the pharmacy counseling service provided by the pharmacist investigator to hypertensive patients was effective in improving drug compliance and suggests that pharmacy counseling along with improved drug compliance may result in a greater reduction in blood pressure.

TABLE OF CONTENTS

	Page
LIST OF TABLES	ix
LIST OF FIGURES	x
INTRODUCTION AND LITERATURE SURVEY	1
Incidence of Hypertension	1
Race and Hypertension	4
Family History and Hypertension	5
Effect of Hypertension on Morbidity and Mortality	6
Value of Hypertensive Therapy	9
Non-compliance or Misuse of Drugs	11
Statement of Problem	17
METHODOLOGY	20
RESULTS AND DISCUSSION	29
SUMMARY AND CONCLUSIONS	47
BIBLIOGRAPHY	52

LIST OF TABLES

Table	Page
1. Summary of the Number of Study Patients	30
2. Frequency Distribution of Study Patients by Sex, Race and Age	32
3. Results of the Effect of Age, Number of Drugs Prescribed Per Patient Day and Number of Doses Prescribed Per Patient Day on Drug Compliance for Patients Number 1 Through 87 . .	33
4. Results of the Effect of Pharmacy Counseling on Drug Compliance at the First Home Visit for Patients Number 1 Though 87	35
5. Results of the Effect of Pharmacy Counseling on Drug Compliance in the Experimental Group and the Control Group for Patients Number 1 Through 40	37
6. Results of the Effect of Pharmacy Counseling on Drug Compliance at the Second Home Visit for Patients Number 1 Through 40	39
7. Results of the Effect of Pharmacy Counseling and Drug Compliance on Blood Pressure for the Experimental Group Patients Number 1 Through 40	41
8. Results of the Effect of Pharmacy Counseling and Drug Compliance on Blood Pressure for the Control Group Patients Number 1 Through 40	43
9. Results of the Effect of Pharmacy Counseling and Drug Compliance on Blood Pressure for the Experimental Group and the Control Group Patients Number 1 Through 87	44

LIST OF FIGURES

Figure	Page
1. Data Collection Form Used to Record Information Collected at the Clinic, First Home Visit and Second Home Visit	23
2. Research Design of the Study Illustrating When Pharmacy Counseling Was Provided for the Experimental Group and the Control Group	26

INTRODUCTION AND LITERATURE SURVEY

Incidence of Hypertension

Hypertension represents one of the major health challenges in the United States today. It is the leading cause of strokes and heart failure and is a contributing factor in heart attacks and kidney failure. Studies have indicated that more than 23 million people in the United States have hypertension. It is estimated that approximately 50 percent of these 23 million people are undiagnosed as hypertensives and less than 10 percent of the 50 percent who have been diagnosed are under effective treatment. (1, 2, 3)

In the United States high blood pressure is listed by the American Heart Association as the primary cause of only 600,000 deaths a year. This is partially due to the fact that hypertension is rarely listed as the cause of death on a death certificate; however, hypertension is probably the underlying cause of hundreds of thousands of deaths each year. The American Heart Association has estimated that heart disease will afflict approximately 600,000 Americans in 1975. Strokes will afflict an estimated 2 million Americans and be responsible for the death of some 200,000 in 1975. Kidney disease in the same year may account for as many as 60,000 deaths. Hypertension is considered to be

the major contributor to each of these diseases. This is emphasized by the American Heart Association's estimate that an untreated hypertensive is four times as likely to have a heart attack or a stroke and twice as likely to develop kidney disease as someone with normal blood pressure. (4)

The most recent National Health Survey (5) conducted in 1960-1962 by the Division of Health Examination Statistics defined "definite hypertension" as blood pressure in excess of 160 mm Hg systolic and/or 95 mm Hg diastolic. With this criteria for classification of hypertension, the National Health Survey statistically determined that in the United States one-seventh of all men and one-sixth of all women between 18 and 79 years of age have definite hypertension. This survey also showed that the frequency of hypertension increases with advancing age and is greater in men than in women. After the age of 50, however, the reverse is true, that is, the frequency of hypertension is greater in women than in men.

In dealing with statistics concerning the incidence of hypertension, "borderline hypertension" must also be considered. The National Health Survey defined the blood pressure range of borderline hypertension to be from 140 to 160 mm Hg systolic and/or 90 to 95 mm Hg diastolic. Establishing this range of blood pressure for borderline hypertension, the National Health Survey reported that approximately 15 percent of the United States population between

the ages of 18 and 79 have borderline hypertension. At age 55 and older this percentage increases to over 25 percent.

(5)

Another factor that has increased the incidence of hypertension is the oral contraceptive, the "pill". In 1967, Laragh (6) reported a "link" between oral contraceptives and high blood pressure. He estimated that 25 percent of all women who use oral contraceptives develop high blood pressure. Studies conducted in the birth control clinic at The Georgetown University Medical Division have also found an incidence of hypertension in women on oral contraceptives. This clinic reported that out of 100 patients, seventy-six were found to have arterial pressure of 140/90 mm Hg or higher (7).

It has been reported in the United States that there is a correlation between body build and blood pressure. Borhani (8), in his Alameda County blood pressure study concluded that the heavier the individual, the greater is the probability of hypertension. The Framingham Study (9) also showed a relationship between obesity and hypertension and revealed that subjects who lost weight showed a significant reduction in blood pressure. Considering that the United States and other affluent countries have been reported to have the highest incidence of obesity, it is reasonable to assume that obesity is one more factor contributing to the incidence of hypertension in the United States.

Race and Hypertension

In 1975, the American Heart Association reported that hypertension is the major cause of death in blacks in the United States (4). There is also evidence from several studies that high blood pressure is more prevalent among American blacks than American whites. The National Health Survey (5) reported that approximately 8 percent of the 97 million American adult whites was hypertensive. This survey also reported that the proportion of black men aged 45 to 64 with distinctly elevated systolic or diastolic blood pressures was double that of white men in the same age group. In black women aged 45 to 54, the proportion with distinctly elevated blood pressures was about two and one-half times that among white women of the same age group. Among black women and white women aged 55 to 64, however, the proportion of black women with elevated blood pressure was only about one-third higher than white women. It was also reported in this study that hypertension in blacks as compared to whites in the United States not only occurred at a younger age but the pathological state was more severe.

Other differences have been found in another comparative study of hypertension and race. One of these differences was increased frequency of cerebrovascular accidents in blacks when compared to whites. Another was that renovascular hypertension was seen less in blacks than in whites. (10)

Finnerty (11) reported that an increased incidence of hypertension in blacks was found in the Social Security

Administration data which showed more disability benefits for hypertension before age 65 in blacks than in whites. He further stated that hypertension develops earlier in blacks, is more severe, and results in a higher mortality at a younger age. This data was collected from the District of Columbia inner city population which is 75 percent black. He reported that 75 percent of the 645 deaths attributed to hypertension in 1965 occurred in blacks and that 88 percent of these hypertensive deaths occurred before the age of 60.

Another study of race and mortality reported by Howard and Holman in 1970, compared various occupations and income levels. This study indicated that the higher blood pressure found in blacks was not related to lower socioeconomic status. They concluded that the mortality from hypertensive disease was higher in non-whites regardless of occupation or socioeconomic class. (12)

Family History and Hypertension

It has been recognized that hypertension occurs more frequently in families with a history of hypertension than in families without a history of hypertension (13). This familial hypertension is due to genetic rather than environmental influences. This was indicated by observations of identical twins with hypertension. Although identical twins lived apart for many years, similar elevations in blood pressure were generally found in both members of each pair. Platt (14) described one pair of identical twins who

developed malignant hypertension within eighteen months of each other. This close similarity of blood pressure levels was seen in monozygotic twins. In dizygotic twins the blood pressure differed to the same degree as in non-twins. Platt further reported that a history of relatively early death from a hypertensive complication in a parent or sibling increased the probability that the patient with borderline or mild hypertension will progress to a more severe stage. He estimated that compared to a person selected at random, a middle-aged sibling of a patient with severe hypertension has about an eight times greater chance of having a diastolic pressure of 100 mm Hg or higher.

On the basis of studies of blood pressure of East African inhabitants, Shaper (15) suggested that the higher blood pressure noted among blacks in the United States may reflect a genetic factor. His suggestion was based on observations that the hypertension common in East African tribes resembles the hypertension in blacks in the United States.

Effect of Hypertension on Morbidity and Mortality

It has been demonstrated repeatedly that morbidity and mortality in hypertension are quantitatively related to the level of blood pressure. The higher the blood pressure, the poorer is the prognosis. (16-18)

Gordon et al. (9) conducted a multivariate analysis of the sixteen year follow-up of the Framingham Study. They concluded that high blood pressure was the most significant

of the factors causing coronary heart disease and atherothrombotic brain infarction. Further evidence of slight rise in arterial pressure and its association with atherosclerotic cardiovascular and cerebral disease has been documented in clinical studies in whites, as well as in blacks (19, 20). Even though good data are not yet available on patients with mild hypertension, the Framingham report concluded that the control of hypertension, labile or fixed, systolic or diastolic, at any age, in either sex, appears to be the primary factor in the prevention of atherothrombotic brain infarction (21).

Sokolow (22) reported that morning occipital headaches, cerebral vascular atherosclerosis, transient ischemic attacks and even a fourth heart sound were associated with severe hypertension. This fourth heart sound was commonly heard in hypertensive patients. Sokolow stated that "this heart sound probably reflects decreased compliance of the left ventricle wall which in turn may be due to left ventricle hypertrophy" (22). He also stated that the presence of a third heart sound or "diastolic gallop" can be associated with hypertension and may alert the physician to the presence of left ventricular failure.

Studies have shown that the mortality rate over a five year period in people with untreated hypertension is directly related to the extent of the cardiovascular disease present (22, 23). Even minimal damage in either the optic fundi, heart, or kidneys is associated with some increase in mor-

tality. In the Veterans Administration Cooperative Study (24) the untreated patients with initial diastolic blood pressures between 90 and 114 mm Hg were subdivided into two groups: patients who exhibited cardiac, central nervous system or renal abnormality prior to becoming a patient in the study and those who did not. Over an average follow-up of 3.3 years, the incidence of major complications was two and one-half times higher in the patients with evidence of end-organ damage prior to becoming a patient in the study.

The conclusion reached by the National Cooperative Pooling Project supports the findings of the Veterans Administration Cooperative Study. This former study concluded that white men aged 30 to 59 years who entered the study with diastolic pressures of 105 mm Hg and higher were clearly associated with a higher incidence of first major coronary events. It was estimated in this study that white males with diastolic pressures of 105 mm Hg and higher had an incidence of first major coronary events about four times that of men with diastolic pressure under 75 mm Hg. (25)

Some earlier studies showed that mortality was lowest among persons with blood pressures below average (26, 27). Other studies corroborated this evidence and have established a limit at which the excessive blood pressure adversely affects mortality. All of these studies reported that the groups of patients with blood pressures in excess of 140/90 mm Hg had significantly more deaths than the groups with blood pressures below 140/90 mm Hg (28, 29).

Another study concerning mortality and hypertension was conducted by Bolt et al. (30) on 3,300 life insurance applicants. These applicants had blood pressure levels high enough to either cause refusal of insurance coverage or acceptance only at substantial extra premium rates. These 2,500 men and 800 women were followed from 1946 to 1950 through 1956, and it was found that men with systolic pressures of 178 mm Hg or higher, in combination with diastolic pressures of 108 mm Hg or higher, showed a mortality rate about 600 percent higher than that of men within the normal blood pressure range. Studies have also shown that the morbidity and mortality rates due to hypertension are about twice as high in men as in women (31, 32). From the results of these studies which investigated the effect of hypertension on morbidity and mortality, it has been shown that at any given age, sex, or race, the higher the blood pressure the shorter would be the life expectancy.

Value of Hypertensive Therapy

In a study of hypertensive patients with diastolic blood pressures in excess of 120 mm Hg, Leishman (33) reported a comparison of the survival record of a treated group of patients with that of a control group of patients. Mortality was found to be lower in the treated group. In the treated group of patients, death rates from cerebral hemorrhage and renal complications were lower than the control group of patients.

In a study reported by Mayer and Brest (34), 301 patients with benign hypertension were followed over a five year period. They reported that, in patients with diastolic pressures of 100 to 119 mm Hg, the mortality rate was approximately twice as high for the untreated group as for the treated group. The patients with diastolic pressures of 120 mm Hg or above had a mortality rate about three times higher for the untreated group as for the treated group.

A study of 316 patients with moderately severe and malignant hypertension was conducted by Perry (35). These patients had diastolic pressures of 110 mm Hg or higher and were treated for periods varying from seven to twelve years. This study indicated that regardless of the severity of the hypertension or the presence of complications, continued treatment reduced the level of diastolic pressure and brought the patients' blood pressures under control in nearly two out of three cases.

To date the most convincing study concerning the value of therapy was conducted by the Veterans Administration Cooperative Group on anti-hypertensive agents. This study involved 143 male hypertensive veterans whose initial diastolic pressures ranged from 115 to 129 mm Hg. Seventy-three patients received treatment under carefully controlled conditions. These patients had reductions in blood pressure averaging 43 mm Hg systolic and 30 mm Hg diastolic. The untreated control group showed no significant changes in blood pressure during the observation period. In the treated

group there were no deaths and only two reported non-fatal complications, while in the untreated control group, there were four deaths and twenty-three cases of major cardiovascular or renal complications. From these results, it was concluded that the risk of developing morbid events in hypertensive patients with treatment was reduced by a ratio of more than three to one. (36)

Non-Compliance or Misuse of Drugs

The development of effective drug therapies for many illnesses and the evolution of the general hospital as predominantly an acute treatment facility, have been two primary factors resulting in increased patient responsibility for his care at home. As a result, health practitioners have become increasingly concerned about the extent of patient compliance with their drug therapy regimens. (37) Non-compliance or misuse of drugs is generally accepted as taking medication in a manner other than that prescribed by a physician. In dealing with the problem of non-compliance, hypertension is a disease of major importance because hypertensive patients are long-term ambulatory patients who are responsible for self-administration of their drug therapy.

Dr. Edward Freis stated the problems concerning the non-compliance of the hypertensive patient (38). He concluded that the greatest obstacle to successful long-term treatment of hypertension may be in administering the anti-hypertensive agents. He also found that no matter how expert

the physician was in administering these agents, he failed in successfully treating the patient if the patient did not comply with instructions. Studies that Freis conducted concerning the reasons for non-compliance in the hypertensive patient indicated the following:

- "1. that the patient failed to understand directions;
2. that the patient's regimen was overly complicated;
3. that the patient did not understand the nature of his illness and the need for his continued treatment;
4. that the patient was seen by too many different therapists (often the case in outpatient clinics);
5. that the patient failed to comply due to occurrence and frequency of side effects."

Another study which involved patients from a mental health outpatient clinic also found problems with overly complicated regimens. Ivey (39) found that non-compliance increased with longer duration of treatment, number of concurrent medications and total number of daily doses.

Other studies have been conducted in the last decade which emphasize the problems of medication errors and drug misuse by the patient. These studies (40, 41) have revealed that the incidence of medication errors made by outpatients (patients treated outside an institutional setting under a physician's care) ranged from 30 percent to 43 percent, i.e. number of doses not taken compared to the total number of doses prescribed.

Stewart and Cluff (42) reviewed numerous institutional studies of medication errors and non-compliance in ambulant outpatients. They reported that between 25 percent and 59 percent of the patients in the various studies made errors in the self-administration of prescribed medications. Lack of compliance was reported in 20 percent to 82 percent of the patients studied.

M. S. Davis (43), in a study on compliance, estimated that 35 percent of patients did not follow their physician's medical recommendations. In reviewing the literature relating specifically to compliance with prescription drug regimens, Mikeal and Sharpe (37) concluded that less than six out of ten patients consume their medications as prescribed. There is also evidence that a higher incidence of non-compliance is found in lower-socioeconomic groups (44). The National Center for Health Statistics supports this conclusion by reporting that an inverse correlation was found between level of education and hypertension with the lowest average blood pressure being found in the more highly educated population group (45).

Latiolais and Berry (46) concluded that 33.3 percent of the patient errors committed in their study was due to a misunderstanding of directions. Another study by Hermann (47) in 1973, suggested that ambulatory patients were generally incapable of establishing an appropriate schedule for medication administration given twice daily, three times a day, or four times a day as contrasted with directions specifying a

given hourly interval. Hermann's findings indicated that for 15.5 percent of the directions given in which the patient had to establish the timing of self-administration, patients were completely unable to interpret the implied drug schedule.

Once the patient is in the clinic, another problem of non-compliance is patient management. Freis (38) in his study of the management of the hypertensive patient, found that one problem with compliance was that the patient was made to feel like a "second class citizen". This was due to prolonged waiting time and the over-all impersonal, busy atmosphere created by an over-crowded clinic. This conclusion by Freis was further supported by Finnerty (48) in a study of drop-outs in a hypertensive clinic. His study showed that patients dropped out of the clinic not because they were uneducated, did not care about their health, or could not afford medication, but because they were "treated like cattle". They were moved from one room to another, and made to wait many hours to be examined by a different doctor on each visit. This study revealed that the hypertensive patients' major complaints centered around the amount of time they had to expend to receive medical care and the lack of a doctor-patient relationship. Finnerty reported that the average waiting time at the clinic was 1.8 hours. Since most of the patients used public transportation, the time spent in getting to the clinic was considered one more element adding to the problem of patient management and compli-

ance. In contrast to the long waiting time before and after the patient was examined by a doctor, Finnerty found that the average time spent with the doctor was 7.5 minutes. This gave the patient no time to have his questions answered, no time to receive an adequate explanation of his symptoms and no time for the development of a doctor-patient relationship.

Schoenberger et al. (49) stated that the "cavalier attitude" that many physicians take regarding patients with mild and moderately severe hypertension further adds to hypertensive patients' problems. This study revealed that 55 percent of the newly diagnosed hypertensive patients in the offices of the cardiologists and internists studied were not given a second appointment. This study indicated that a smaller percentage of hypertensives are being treated today than several years ago.

Boyd et al. (50) pointed out in a study of drug defaulting that the fundamental prerequisite to compliance in the use of prescription medications was the thorough understanding of the directions for use. Initial comprehension must be maintained throughout the duration of therapy. From a review of the literature on compliance, Marston (51) concluded that "it is clear . . . that the problem of non-compliance with medical recommendations is a substantial one, and there is much we need to learn concerning the factors involved in helping people to take care of their health when they are not under the direct surveillance of professional caretakers,

such as physicians and nurses."

Since the doctor is not easily accessible to the patient and more time should be spent with the patient, Finnerty (48) strongly suggested that physicians in private practice and hospitals utilize paramedical personnel to manage the long-term hypertensive patient. Once the hypertensive patient has been evaluated, placed on therapy and had his blood pressure stabilized, he could be followed up by properly trained paramedical personnel. After three years experience in working with the hypertensive, Finnerty (48) found that the long-term care of the hypertensive patient can ideally be carried out by specially trained paramedical personnel. This latter study supports this contention since drop-outs decreased from 42 percent in 1966, without the use of paramedical personnel, to 8 percent in 1970 and 1971, with the use of paramedical personnel. In another study by Finnerty (52), it was reported that this paramedical directed operation has improved the over-crowded conditions of the clinic and has relieved the pressure on the physician in examining every patient when he returns. Considering the roughly 8 to 1 cost ratio of physicians to paramedical personnel, this arrangement can also represent substantial economic savings.

There have been many studies which have concluded that the pharmacist, as a member of the health care team, is in a prime position to offer his professional services to the physician and patient which may enhance future compliance on the part of the patient (46-50, 53). One study conducted by

McKenney et al. (54) evaluated pharmacy services extended to essential hypertensive patients. The authors studied the effect of clinical services provided by a pharmacist on twenty-five study patients with essential hypertension compared with that of twenty-five control hypertensive patients not receiving these services. The results of this study showed a significant improvement in patient drug compliance and in the patient's knowledge of his disease state which was attributed to counseling by a pharmacist. This study also reported a significant increase in the number of study patients whose blood pressures were kept within the normal range during the study period. It was concluded by McKenney et al. that clinical pharmacy services are beneficial and that pharmacists should become more involved in the long-term care given the hypertensive patient.

Statement of Problem

From a review of the literature on hypertension, it is evident that hypertension presents a unique set of challenges. The patient must be informed that he has a disease that may not exhibit any symptoms, for which there is probably no cure, and the treatment of which may temporarily make him feel worse. The patient must also be convinced that the treatment, if maintained, has the demonstrated potential of providing additional years of productive living. From a review of the literature on compliance, it is also evident that many patients do not adhere to the drug regimens that physicians

prescribe for them. Since one of the fundamental prerequisites for compliance seems to be comprehension and recall of the directions for use, the pharmacist, as the provider of the medication, has the opportunity to attempt to directly affect both comprehension and recall on the part of the patient. The pharmacist may be able to improve drug compliance by counseling the patient on the correct utilization of his medications. This counseling should involve answering any questions the patient may have concerning his medications and his disease state.

The purpose of this research was to study the effects, if any, of some factors which may affect compliance in the hypertensive patient. The factors which were studied included age, race, number of drugs prescribed per patient day, number of doses prescribed per patient day, and pharmacy counseling. Blood pressure readings were recorded in order to note the combined affect of pharmacy counseling and compliance on blood pressure. The hypotheses for this study were as follows:

H_1 : Age of patient does affect drug compliance of the hypertensive patient.

H_0 : Age of patient does not affect drug compliance of the hypertensive patient.

H_2 : Race of patient does affect drug compliance of the hypertensive patient.

H_0 : Race of patient does not affect drug

compliance of the hypertensive patient.

H_3 : Number of drugs prescribed per patient day does affect drug compliance of the hypertensive patient.

H_0 : Number of drugs prescribed per patient day does not affect drug compliance of the hypertensive patient.

H_4 : Number of doses prescribed per patient day does affect drug compliance of the hypertensive patient.

H_0 : Number of doses prescribed per patient day does not affect drug compliance of the hypertensive patient.

H_5 : Pharmacy counseling does affect drug compliance of the hypertensive patient.

H_0 : Pharmacy counseling does not affect drug compliance of the hypertensive patient.

H_6 : Pharmacy counseling and drug compliance do affect blood pressure in the hypertensive patient.

H_0 : Pharmacy counseling and drug compliance do not affect blood pressure in the hypertensive patient.

METHODOLOGY

The patients for this study were selected from a hypertensive clinic for outpatients at a large, general, acute medical and surgical hospital. This clinic treats walk-in patients and patients that are assigned to the clinic on an outpatient basis by disease state. At the time of the study, the patients attending this clinic were predominantly male, black and from a low socioeconomic population.

The criteria the patients had to meet for selection for this study were:

1. They had to be new patients accepted by the clinic;
2. They had to be males;
3. They had to have a diagnosis of essential hypertension for their primary disease state; and
4. They had to be on a prescribed drug regimen.

The definition of essential hypertension used for this study was: a disease of unknown etiology causing high blood pressure for which a specific endocrine, renal, or organic cause cannot be found (55). The diagnosis of essential hypertension was the criteria for the primary disease state, however, the patient could also have had related hypertensive diseases, i.e. congestive heart failure, cardiovascular disease and cerebral vascular disease.

One hundred and four patients were selected from the patients entering the clinic. To assure that all new patients entering the clinic had an equal opportunity of being selected for this study, a coin was tossed by the investigator to either select the patient as a member of the study group or to reject him. Another toss was made to assign the selected patient to either of two groups, experimental or control.

The patients in the experimental group received pharmacy counseling at the hypertensive clinic and again 14 ± 3 days later at their homes. The patients in the control group received no pharmacy counseling at the clinic; however, 14 ± 3 days later they received pharmacy counseling at their homes.

After being selected for this study, the patient's regular clinical routine was not altered. The pharmacist investigator was called back to the clinic after the patient had completed all of his "clinic work-up". At this point, the patient's prescription(s) was (were) filled. In order to insure that the initial number of doses in each container was correct, the investigating pharmacist counted and placed the medication in the dispensing container and another pharmacist verified the accuracy by a second count of the medication. In order to prevent variation in the prescription label, the labeling of the prescription(s) for both the experimental group and the control group was identical and was performed by the investigator.

After the patient was given his medication, the inves-

tigator took the patient's blood pressure. Three blood pressure readings were taken in a sitting or in a standing position for the patients in both groups, experimental and control. The average of these readings for each patient was recorded on a data collection form (Figure 1). Other information recorded on this form included the name of the patient, race, age, the medication(s) prescribed for him and the date the patient was told to return to the clinic. The form also contained space for pulse, respiration, blood pressure, observations and reported side effects (S.E.).

Up to this point at the clinic, the control group and experimental group patients were exposed to the same conditions. The control group patients received their medication(s), had their blood pressure taken and left the clinic. The experimental group patients also received their medication(s) and had their blood pressure taken, however, before they left the clinic they were counseled by the pharmacist investigator. This counseling included an explanation of their disease state, essential hypertension, and the drug therapy prescribed for them by the physician. In order to establish uniformity, the following guidelines were used when counseling the patient:

1. explanation of disease state, hypertension, in general terms;
2. description of drug(s) prescribed, i.e. the drug name (generic), the trade name of the drug and the appearance of the drug;
3. explanation of why the patient was taking the drug(s), i.e. relationship between taking

NAME: _____	EXP _____
ADDRESS: _____	CONT _____
PHONE: _____	DATE IN CLINIC _____
ID NO.: _____	CLINIC B/P: _____
AGE: _____	PULSE: _____
RACE: _____	RESP: _____
MEDICATION: _____	PROBLEM LIST: _____
_____	_____
_____	_____

1st Home Visit	2nd Home Visit
Date: _____	Date: _____
B/P: _____	B/P: _____
Pulse: _____	Pulse: _____
Resp: _____	Resp: _____
Medication: _____	Medication: _____
Observations: _____	Observations: _____
S. E.: _____	S. E.: _____
Date of Return: _____	Date of Return: _____

Figure 1

Data Collection Form Used to Record
Information Collected at the Clinic, First
Home Visit and Second Home Visit

- medication(s) and reduction of blood pressure;
4. length of therapy;
 5. refill instructions;
 6. special instructions, e.g. "this drug may make you dizzy if you stand up too fast from a sitting or lying position";
 7. common side effects;
 8. how and when to take the dose(s) of prescribed drug(s);
 9. what to do if a dose of a prescribed drug was missed;
 10. common allergic or adverse reactions;
 11. non-prescription drugs to avoid while taking the prescribed drug(s);
 12. foods to avoid while taking the prescribed drug(s); and
 13. how to properly store the prescribed drug(s).

In order to test the hypotheses of this study, the investigator visited the patients at their homes and collected the data on compliance and blood pressure shown in the first home visit column of Figure 1. Each patient, therefore, was visited at his home 14 ± 3 days after the clinic visit. The patient's only prior knowledge of the investigator's visit was a telephone call to his home about two hours before the visit. The patient was asked if he would be home for the remainder of the evening so that a "routine check" could be made concerning his health. At the patient's home an actual medication count was made and three blood pressure readings were taken. The average of the three blood pressure readings was recorded. Any information about side effects or

complaints concerning the drug therapy were also recorded on the data collection form (Figure 1) in the column labeled "1st home visit".

To further test the hypotheses, a second visit was made to both the experimental group and the control group patients' homes 28 ± 3 days after the clinic visit. During this second home visit a medication count and three blood pressure readings were taken and recorded. This second home visit was made so that the investigator could determine the effect of pharmacy counseling on the control group patients who received no pharmacy counseling at the clinic but did receive pharmacy counseling at the first home visit. The investigator also made this second home visit to determine whether there would be a difference in the compliance of the experimental group compared to the control group after the control group received pharmacy counseling.

Figure 2 illustrates the research design of this study and the manipulation of the independent variable, pharmacy counseling, on the two groups of patients. As illustrated in Figure 2, there were two groups of patients, the experimental group and the control group. The encircled cross designates when the patient received pharmacy counseling.

The medication count taken at the patients' homes was one of the measurements of the dependent variable, patient drug compliance. The formula used to convert the medication count into percent compliance was:

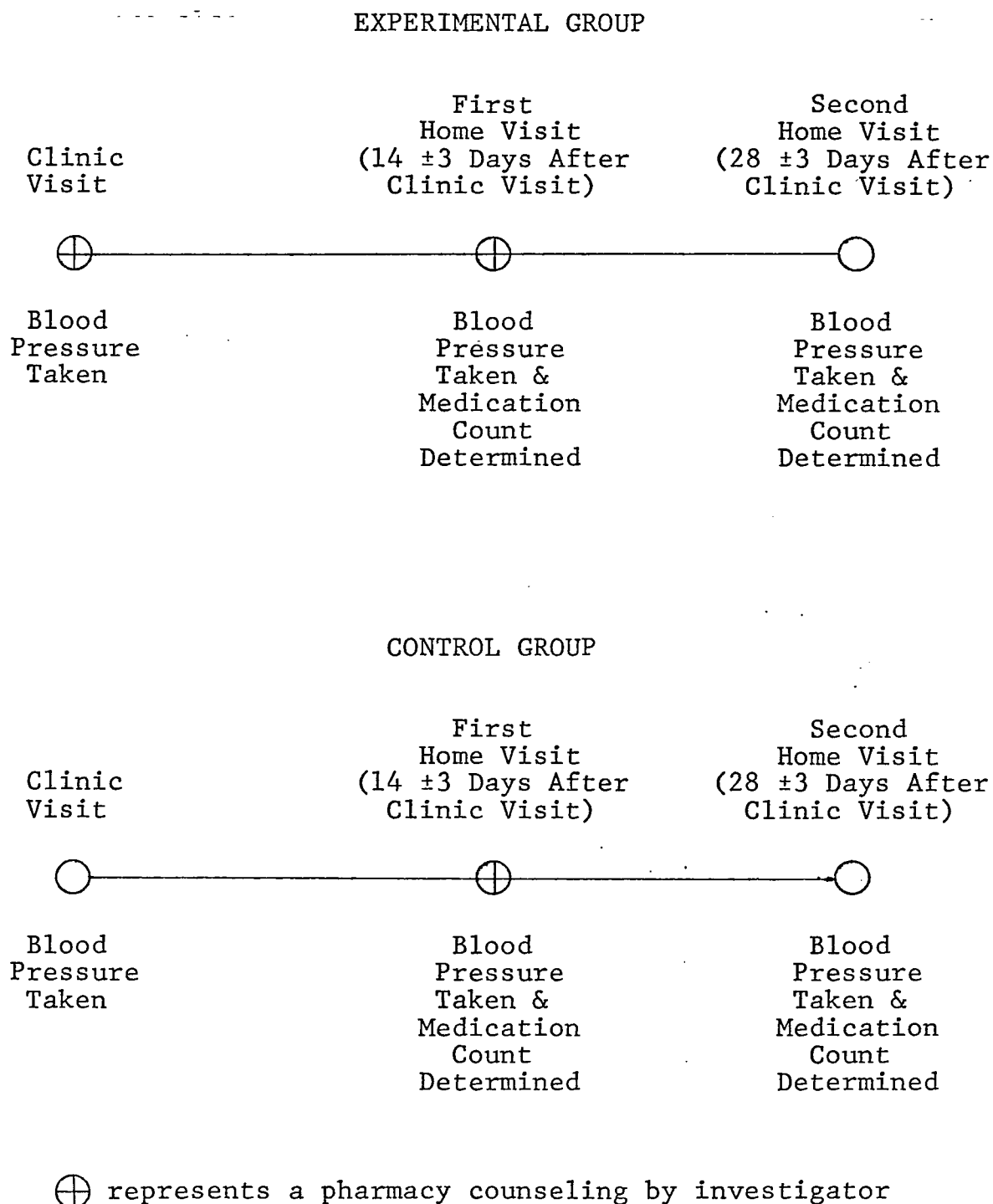


Figure 2

Research Design of the Study Illustrating
When Pharmacy Counseling Was Provided
for the Experimental Group and the Control Group

$$\% C = \frac{A}{T} \times 100$$

where, C = Compliance

A = Actual number of
doses consumed

T = Theoretical number
of doses consumed
if 100% compliance
by patient

The method of measurement of drug compliance by medication count is reliable to the extent that the subject did not lose or destroy some of his medications. The actual medication count relies on the assumption that the patient did take the medication that was not in the prescription bottle. A medication count, however, was deemed to be the best measurement for compliance for this study since urine and blood samples are considered too time consuming and cumbersome for use in the patient's home. Information obtained by patient interview might be misleading because some patients might have a tendency to prevaricate or to try to please the investigator and as a result the investigator could be biased in recording the data.

It has been documented that blood pressure is a function of compliance, i.e. patients who correctly comply with their drug regimen reportedly show reduction in blood pressure. Blood pressure readings were taken at the clinic and at the patients' homes 14 $\pm$ 3 days and 28 $\pm$ 3 days later. The formula used to convert the blood pressure readings into mean arterial pressure was:

$MAP = DP + 1/3 (SP-DP)$ where, MAP = Mean Arterial Pressure

DP = Diastolic Pressure

SP = Systolic Pressure

The aforementioned hypotheses were tested using the F-statistic by an IBM 370 computer.¹ The "multivariate general linear hypothesis"² was used to compare the sets of data. The mean, standard deviation and standard error of the mean were calculated for each of the variables.

¹International Business Machines, New York, N. Y.

²Health Sciences Computing Facility, Program BMDX63
(Revised April 14, 1969), U.C.L.A., Los Angeles, California.

RESULTS AND DISCUSSION

Study Patient Attrition

For this study data were collected on one hundred and four new male patients (Table 1). Some problems were encountered which prevented complete accumulation of data for some of these patients. For 17 of the patients, data were collected at the clinic visit only, and no data were collected from home visits because:

1. some patients were not home at the time established for the first home visit which was 14 ± 3 days after the clinic visit, or
2. some patients evidently did not give their correct home address at the clinic or they moved before the investigator could contact them at the time established for the first home visit.

Data were collected on 47 of the patients from the clinic and from the first home visit, but no data were collected from the second home visit because:

1. forty-one patients were not home at the time established for the second home visit which was 28 ± 3 days after the clinic visit,
2. four patients were readmitted to the hospital as inpatients between the 14 ± 3 days and the 28 ± 3 days after the clinic visit, and
3. two patients deceased after the first home visit.

At the conclusion of the study, there were basically two sets of data. One set included 87 patients (patients

Table 1
SUMMARY OF THE NUMBER OF STUDY PATIENTS

Data Obtained	Number of Patients		
	Experimental Group	Control Group	Total
at the clinic only	54	50	104
at the clinic and at the first home visit	44	43	87
at the clinic, first home visit and second home visit	20	20	40

number 1 through 87) for whom data were collected from the clinic and the first home visit. The other set of data included 40 patients (patients number 1 through 40) for whom data were collected from the clinic and two home visits. The first set of data, 87 patients, includes the second set of data, 40 patients (see Table 1).

Descriptive Statistics

The frequency distribution of patients in the two sets of data are shown in Table 2. This distribution includes the percentage of patients according to sex, race and age in the first group, patients 1 through 40, and in the second group, patients 1 through 87.

Statistical Methods

The statistical method used in comparing the sets of data was the multivariate general linear hypothesis. The F-statistic was used to test for significance between each of the variables. All of these statistical tests were run on an IBM 370 computer using a correlated matrix to test for each hypothesis.

Effect of Age, Race, Number of Drugs and Number of Doses on Drug Compliance

The F-statistics comparing age, number of drugs prescribed per patient day and number of doses prescribed per patient day to drug compliance, showed that these factors were not significant in affecting drug compliance in the hypertensive patient (see Table 3). The F-statistic com-

Table 2
FREQUENCY DISTRIBUTION OF STUDY PATIENTS
BY SEX, RACE AND AGE

		Patients Number 1-40 (Percent)		Patients Number 1-87 (Percent)	
		Experimental Group	Control Group	Experimental Group	Control Group
Sex	Male	100.0	100.0	100.0	100.0
Race	Black	65.0	75.0	65.9	69.8
	Non-Black	35.0	25.0	34.1	30.2
Age Range in Years	20-29	5.0	0.0	6.8	2.3
	30-39	0.0	0.0	2.3	9.3
	40-49	30.0	40.0	34.1	30.2
	50-59	50.0	25.0	47.7	34.9
	60-69	15.0	30.0	9.1	21.0
	70-79	0.0	5.0	0.0	2.3

Table 3

RESULTS OF THE EFFECT OF AGE, NUMBER OF DRUGS
 PRESCRIBED PER PATIENT DAY AND NUMBER OF DOSES
 PRESCRIBED PER PATIENT DAY ON DRUG COMPLIANCE FOR
 PATIENTS NUMBER 1 THROUGH 87

	Experimental Group ¹ (n = 44)	Control Group ² (n = 43)	Level of Significance
Mean Age	49.50	50.98	NS ³
Standard Error	1.42	1.77	
Range	21-64	18-70	
Mean Number of Drugs per Patient Day	1.84	1.86	NS
Standard Error	0.11	0.09	
Range	1-4	1-3	
Mean Number of Doses per Patient Day	4.64	5.44	NS
Standard Error	0.53	0.52	
Range	1-17	1-16	

¹pharmacy counseling at the clinic

²no pharmacy counseling at the clinic

³p > 0.05

paring the race of the patient to drug compliance was also found not to significantly affect drug compliance in the hypertensive patient. Therefore, the following null hypotheses were not rejected:

H_0 : Age of patient does not affect the drug compliance of the hypertensive patient.

H_0 : Race of patient does not affect the drug compliance of the hypertensive patient.

H_0 : Number of drugs prescribed per patient day does not affect the drug compliance of the hypertensive patient.

H_0 : Number of doses prescribed per patient day does not affect the drug compliance of the hypertensive patient.

Comparison of Pharmacy Counseling with Drug Compliance

From the results of the F-statistic calculated after the first home visit, comparing the experimental group with pharmacy counseling at the clinic to the control group without pharmacy counseling at the clinic, a significant difference ($p < 0.01$) in the drug compliance of the two groups was found (see Table 4). This difference can be attributed to the independent variable, pharmacy counseling, given at the clinic. This effect of pharmacy counseling can be seen in the means of the percent compliance of the two groups calculated after the first home visit. In Table 4, patients 1

Table 4

RESULTS OF THE EFFECT OF PHARMACY COUNSELING
ON DRUG COMPLIANCE AT THE FIRST HOME VISIT
FOR PATIENTS NUMBER 1 THROUGH 87

	Experimental Group ¹ (n = 44)	Control Group ² (n = 43)	Level of Significance
Mean Percent Compliance	79.48	53.65	p < 0.01
Standard Error	3.67	4.53	
Range	0-100	0-100	

¹pharmacy counseling at the clinic

²no pharmacy counseling at the clinic

through 87, the experimental group mean percent compliance at the first home visit was 79.48 and the control group mean percent compliance at the first home visit was 53.65. These statistics support the hypothesis that pharmacy counseling does affect patient drug compliance by showing that the group with pharmacy counseling at the clinic (experimental group) had a significantly higher percent compliance than the group without pharmacy counseling at the clinic (control group).

In order to further test the hypothesis that pharmacy counseling does affect drug compliance, the investigator provided pharmacy counseling to the control group patients at their homes at the first home visit. A comparison was made at the second home visit of these patients before pharmacy counseling and after pharmacy counseling in order to determine if the drug compliance of these patients would improve after they had received pharmacy counseling at the first home visit. In this comparison of the first home visit mean percent compliance with the second home visit mean percent compliance, there was an increase from 51.10 to 93.05 (Table 5). This was a significant increase ($p < 0.01$) in drug compliance which again can be attributed to pharmacy counseling. The only difference in the pharmacy counseling provided was that this (first) pharmacy counseling was given at the patients' homes instead of at the clinic.

Another comparison was made in order to determine the

Table 5

RESULTS OF THE EFFECT OF PHARMACY COUNSELING ON
 DRUG COMPLIANCE IN THE EXPERIMENTAL GROUP¹ AND THE
 CONTROL GROUP² FOR PATIENTS NUMBER 1 THROUGH 40

	First Home Visit	Second Home Visit	Level of Significance
Experimental Group: (n = 20)			
Mean Percent Compliance	77.75	85.35	NS ³
Standard Error	6.70	5.81	
Range	0-100	25-100	
Control Group: (n = 20)			
Mean Percent Compliance	51.10	93.05	p < 0.01
Standard Error	7.59	1.78	
Range	0-100	73-100	

¹pharmacy counseling at the clinic and at the first home visit

²pharmacy counseling at the first home visit only

³p > 0.05

effect of pharmacy counseling on drug compliance, however, in this case the experimental group mean percent compliance was compared to the control group mean percent compliance at the second home visit. This was done in order to determine whether there would remain a difference in drug compliance between the two groups after they had both received pharmacy counseling. The investigator provided pharmacy counseling to both groups at the first home visit and compared the percent compliance of these two groups at the second home visit. The results of this comparison at the second home visit in drug compliance showed that there was not a significant difference between the two groups (Table 6).

The data in Table 5 show that mean percent compliance determined at the time of the first home visit (14 ± 3 days after the clinic visit) in the experimental group after their first counseling at the clinic was 77.75 percent. The mean percent compliance determined at the time of the second home visit (28 ± 3 days after the clinic visit) in the control group after their first counseling at the first home visit (14 ± 3 days after the clinic visit) was 93.05 percent. No statistical difference was tested on this data due to the possible effect of the difference in the length of time the patients had been on their prescribed drug regimen. The higher mean percent compliance in the control group after counseling, however, would appear to indicate that counseling in the home might have been more effective than

Table 6

RESULTS OF THE EFFECT OF PHARMACY COUNSELING ON
 DRUG COMPLIANCE AT THE SECOND HOME VISIT
 FOR PATIENTS NUMBER 1 THROUGH 40

	Experimental Group ¹ (n = 20)	Control Group ² (n = 20)	Level of Significance
Mean Percent Compliance	85.35	93.05	NS ³
Standard Error	5.81	1.78	
Range	25-100	73-100	

¹pharmacy counseling at the clinic and at the first home visit

²pharmacy counseling at the first home visit only

³p > 0.05

counseling in the study clinic.

There was no significant difference in percent compliance after both groups had been counseled but there was a significant difference in percent compliance when one group was counseled and one was not. This further indicates that the independent variable, pharmacy counseling, was the factor that caused the percent drug compliance to increase in the counseled group. This adds to the support of the hypothesis that with pharmacy counseling, drug compliance was significantly higher than without pharmacy counseling. Therefore, the following hypothesis was not rejected:

H_5 : Pharmacy counseling does affect the drug compliance of the hypertensive patient.

Comparison of Pharmacy Counseling and Compliance with Blood Pressure

It has been documented that blood pressure is a function of drug compliance, i.e. the higher the drug compliance, the greater the reduction in blood pressure (33-36). As shown in Tables 4 and 5, the means of the percent compliance were significantly higher at the first home visit for the experimental group with pharmacy counseling. Table 7 shows that in the experimental group (patients number 1 through 40), with pharmacy counseling, the mean of the mean arterial pressures (MAP) dropped 8.45 mm Hg from the clinic visit to the first home visit. Table 9 shows that in the experimental group (patients number 1 through 87), the mean of the MAP dropped 9.91 mm Hg from the clinic visit to the first

Table 7

RESULTS OF THE EFFECT OF PHARMACY COUNSELING AND DRUG COMPLIANCE ON BLOOD PRESSURE FOR THE EXPERIMENTAL GROUP¹
PATIENTS NUMBER 1 THROUGH 40

Experimental Group: (n = 20)	Clinic Visit mm Hg	First Home Visit mm Hg	Second Home Visit mm Hg	Level of Significance
Mean of the MAP ²	113.55	105.10		p < 0.01
Standard Error	2.97	3.74		
Range	83-127	89-168		
Mean of the MAP	113.55		99.25	p < 0.01
Standard Error	2.97		1.90	
Range	83-127		83-112	
Mean of the MAP		105.10	99.25	NS ³
Standard Error		3.74	1.90	
Range		89-168	83-112	

¹pharmacy counseling at the clinic and at the first home visit

²Mean Arterial Pressure

³p > 0.05

home visit. These reductions in blood pressures in both of these experimental groups were shown to be significant ($p < 0.01$). This indicates that with the increase in the percent compliance in these experimental groups with pharmacy counseling, there were significant reductions in blood pressure. As previously mentioned, these groups showed a significantly higher percent compliance (see Table 5). This adds further to the hypothesis that pharmacy counseling does affect drug compliance and also supports the hypothesis that pharmacy counseling along with improved drug compliance affects blood pressure.

The results of the effect of no pharmacy counseling and drug compliance on blood pressure in the control group (patients number 1 through 40) are shown in Table 8. From the clinic visit to the first home visit, the mean of the mean arterial pressures actually increased 1.10 mm Hg. Table 9 shows that in the control group (patients number 1 through 87), the mean of the mean arterial pressures decreased only 1.59 mm Hg during this same study period. These differences in the means of the mean arterial pressures in the above two control group samples, were not shown to be significant. This can be attributed to the fact that in these control groups ($n=20$ and $n=43$), the mean percent compliance was low (see Table 4 and 5). Since drug compliance was low in these groups without pharmacy counseling, the blood pressure did not improve significantly. This again further supports the hypothesis that pharmacy counseling does affect

Table 8

RESULTS OF THE EFFECT OF PHARMACY COUNSELING AND
 DRUG COMPLIANCE ON BLOOD PRESSURE FOR THE CONTROL GROUP¹
 PATIENTS NUMBER 1 THROUGH 40

Control Group (n = 20)	Clinic Visit mm Hg	First Home Visit mm Hg	Second Home Visit mm Hg	Level of Significance
Mean of the MAP ²	110.65	111.75		NS ³
Standard Error	3.50	3.51		
Range	90-153	87-142		
Mean of the MAP	110.65		99.45	p < 0.01
Standard Error	3.50		2.99	
Range	90-153		76-123	
Mean of the MAP		111.75	99.45	p < 0.01
Standard Error		3.51	2.99	
Range		87-142	76-123	

¹no pharmacy counseling at the clinic but with pharmacy counseling at the first home visit

²Mean Arterial Pressure

³p > 0.05

Table 9

RESULTS OF THE EFFECT OF PHARMACY COUNSELING AND DRUG COMPLIANCE ON BLOOD PRESSURE FOR THE EXPERIMENTAL GROUP¹ AND THE CONTROL GROUP² PATIENTS NUMBER 1 THROUGH 87

	Clinic Visit mm Hg	First Home Visit mm Hg	Level of Significance
Experimental Group: (n = 44)			
Mean of the MAP ³	117.57	107.66	p < 0.01
Standard Error	2.46	2.21	
Range	83-151	87-168	
Control Group: (n = 43)			
Mean of the MAP	113.26	111.67	NS ⁴
Standard Error	2.63	2.00	
Range	82-173	87-142	

¹pharmacy counseling at the clinic

²no pharmacy counseling at the clinic

³Mean Arterial Pressure

⁴p > 0.05

drug compliance and also, that pharmacy counseling along with improved drug compliance affects blood pressure.

More tests for significance were made of pharmacy counseling and drug compliance and their effect on blood pressure. There were two comparisons made at the second home visit, one in the experimental group and one in the control group. The experimental group was given a second pharmacy counseling at the first home visit. At a second home visit, a medication count and three blood pressure readings were taken. As shown in Table 5, the increase in the mean percent compliance from the first home visit to the second home visit in the experimental group patients was not significant. During the same study period these same patients' blood pressures decreased from 105.10 mm Hg to 99.25 mm Hg (Table 7). When this reduction was tested for significance, it was also not significant.

The control group (patients number 1-40) was also given a pharmacy counseling at the first home visit. Table 5 shows that the mean percent compliance from the first home visit to the second home visit in the control group patients increased from 51.10 to 93.05 which was a significant increase ($p < 0.01$). Table 8, also shows that with the significant increase in percent compliance, there was a drop in mean arterial pressure from 111.75 mm Hg to 99.45 mm Hg in this same study period and same patients. When this reduction in blood pressure was tested, it was found to be significant ($p < 0.01$).

It can be seen from the above comparisons that pharmacy counseling and drug compliance did lower blood pressure significantly. Therefore, the following hypothesis was not rejected:

H_6 : Pharmacy counseling and drug compliance do affect blood pressure in the hypertensive patient.

SUMMARY AND CONCLUSIONS

Of the factors tested in this study, age, race, number of drugs prescribed per patient day, number of doses prescribed per patient day and pharmacy counseling, the only factor which was found to significantly affect patient drug compliance was pharmacy counseling. This study has shown that the counseling service provided by the pharmacist investigator to hypertensive patients was effective in improving percent compliance. This service apparently resolved some of the problems of the hypertensive patient.

There were three main problems that were observed in the study patients which pharmacy counseling attempted to correct. First, some study patients were found to know very little about hypertension and their drug therapy. The pharmacy counseling in this study was designed to include information concerning the patient's disease state and prescribed drug therapy. Second, some study patients were also found to know very little about blood pressure, its significance, and its relation to drug therapy. During each counseling session the patient was told his blood pressure reading and was told in general terms what a blood pressure reading meant. This was done in order to help the patient realize that blood pressure values were related to drug compliance,

i.e. the higher the drug compliance, the more probable the reduction in blood pressure. Third, some study patients admitted that they were reluctant or afraid to talk freely with physicians. Since this is one of the obstacles in establishing a doctor-patient relationship, it was the purpose of this investigator to actively participate in the management of each patient, and modify this relationship to fit the patient's individual needs.

In the process of obtaining data from study patients, many observations were made by this investigator. One such observation revealed that home counseling by the pharmacist appeared to be more effective in improving drug compliance than clinic counseling by the pharmacist. This was supported by the data collected on mean percent compliance (Table 5). These data revealed that with pharmacy counseling at the home, the mean percent compliance was higher than the mean percent compliance with pharmacy counseling at the clinic. It is the opinion of this investigator that clinic counseling did not result in as high a mean percent compliance as home counseling due to the conditions to which the study patients were subjected at the clinic. Some of the conditions at the clinic which this investigator found which may have adversely affected drug compliance were:

1. the general over-crowded conditions at the clinic and at the main pharmacy,
2. the prolonged waiting time at the clinic and at the main pharmacy, and
3. the busy, over-crowded conditions where the study patient was counseled.

Due to the above existing conditions, the study patient was confused and intimidated and by the time he was counseled by the pharmacist, he was neither attentive nor interested.

Since the above conditions at the clinic did not exist at the study patient's home, this investigator observed that the study patient, in his home environment, was more alert, attentive and interested in what the pharmacist investigator had to tell him. For counseling to be as effective at the clinic as it appeared to be at the home, the following criteria should be met:

1. expansion of the hypertensive clinic to relieve the over-crowded conditions.
2. enlargement of clinic staff in order to decrease patient waiting time,
3. establishment of separate satellite pharmacies to relieve the over-crowded conditions at the main pharmacy and subsequently reduce patient waiting time, and
4. establishment of patient education and counseling programs.

This investigator also observed another factor that appeared to contribute to the effectiveness of counseling in this study. This was the utilization of the pharmacist as the counselor. The pharmacist, as the provider of the medication, was well received by the study patients as a counselor in giving instruction on medications and their use. It appeared that the study patients actually expected to receive some sort of explanation concerning the medication(s) that the pharmacist was giving him. The study patients, therefore, were generally found to be co-operative

and even anxious to listen to the pharmacist investigator.

This investigator encountered many problems in completing this study. The main problem was the difficulty in locating the study patients' homes. Many addresses given to this investigator were actually addresses of the landlord and not that of the patient. The patient many times would be located in an unmarked tenement house behind the landlord's home with numerous other families living in the same tenement house. Therefore, this investigator would have to contact each family in order to find the study patient. This problem often resulted in the inability to visit the required study patients for that day.

Another problem encountered by this investigator was the interference of the mother in the family. This was due to the strong influence exhibited by the mother as characterized by a matriarchal society which has been found to exist in the black population. The success of this study was contingent upon the co-operation of the study patient. In the case of a matriarchal society, the success of this study was also contingent upon the co-operation of the mother. The mother, therefore, had to be consulted concerning the health of anyone in her family. In some cases, the mother insisted that the entire family have their blood pressure taken. This at times included up to fifteen people in one home. Only after the investigator satisfied the needs and demands of the mother, could he concentrate on the study patient.

These difficulties in dealing with the mother of the

study patient's family and in locating the patients' homes, were found to be very time consuming. These problems should be considered by any investigator in proposing a research study which would necessitate visiting the patient at his home.

With the results indicated in this study, the pharmacist was successful in assuming an increased responsibility for the long-term health care of the hypertensive patient. Due to the need for more manpower to help relieve the overcrowded conditions that exist at the clinic, this study suggests that the pharmacist is in a prime position to offer his professional services in the form of pharmacy counseling to the patient. It is concluded that pharmacy counseling is beneficial and that the extension of this professional service should be continued in order to contribute to the maintenance and care of the long-term health care patient.

BIBLIOGRAPHY

1. Report of Inter-Society Commission for Heart Disease Resources: Guidelines for the Detection, Diagnosis, and Management of Hypertensive Populations. Circulation, 44:A237, 1971.
2. Wilber, J. A. and Barrow, J. G.: Hypertension--a Community Problem. Amer. J. Med., 52:653-663, 1972.
3. Finnerty, F., Jr.: Untreated Hypertension--the Shame of Modern Medicine. Drug Therapy, 4:129, May, 1974.
4. 1974 Heart Facts. American Heart Association, New York, N. Y., pp. 1-28, 1974.
5. Hypertension and Hypertensive Heart Diseases in Adults, United States 1960-62. National Center for Health Statistics, Series II, no. 13, U.S. Department of Health, Education and Welfare. Public Health Service, Washington, D.C., 1966.
6. Laragh, J. H.: Oral Contraceptive Hypertension. Postgrad. Med., 52:98-105, Sept., 1972.
7. Hypertensive Affects of Many Young Black Women, Medical News, J. Amer. Med. Assoc., 215:876, 1971.
8. Borhani, N. O. and Barkman, T. S.: The Alameda County Blood Pressure Study. Berkeley, State of California Department of Public Health, 1968.
9. Gordon, T., Sorlie, G. and Kannel, W. B.: Coronary Heart Disease, Atherothrombotic Brain Infarction, Intermittent Claudication--A Multivariate Analysis of Some Factors Related to Their Incidence: Framingham Study, 16-Year Follow Up. The Framingham Study. sect. 27, pp. 23-24, May, 1971.
10. Mroczek, W. J., Finnerty, F., Jr., and Catt, K. J.: Lack of Association Between Plasma Renin and History of Heart Attack or Stroke in Patients with Essential Hypertension. Lancet, 2:464, 1973.
11. Finnerty, F., Jr.: Hypertension is Different in Blacks. J. Amer. Med. Assoc., 216:1634-1635, June, 1971.

12. Howard, J., and Holman, B. L.: The Effects of Race and Occupation in Hypertension Mortality. Milbank Memorial Fund Quarterly, 48:263, 1970.
13. Schweitzer, M. D., Clark, E. G., Gearing, F. R., and Perera, G. A.: Genetic Factors in Primary Hypertension and Coronary Disease. J. Chron. Dis., 45:1093, 1962.
14. Platt, R.: Heredity in Hypertension. Lancet, 1:899, 1963.
15. Shaper, A. G.: Blood Pressure Studies in East Africa, The Epidemiology of Hypertension. Grune and Stratton: New York, N. Y., p. 16, 1967.
16. Pickering, G.: Hypertension Definitions, Natural History and Consequences. Amer. J. Med., 52:570, 1972.
17. Society of Actuaries Build and Blood Pressure Study, vol. 1, Chicago Society of Actuaries: Chicago, Illinois, 1959.
18. Kannel, W. B.: Current Status of the Epidemiology of Brain Infarction Associated with Arterial Disease. Stroke, 2:295, 1971.
19. Kannel, W. B., Dauber, T. R., Cohen, M. E. and McNamara, P. M.: Vascular Disease of the Brain--Epidemiologic Aspects: The Framingham Study. Amer. J. Public Health, 55:1355-1366, 1965.
20. Chapman, J. M. and Massey, E. J.: The Interrelationships of Serum Cholesterol, Hypertension, Body Weight, and Risk of Coronary Disease. J. Chron. Dis., 17: 933-949, 1964.
21. Kannel, W. B., Wolf, P. A., Verter, J. and McNamara, P. M.: Epidemiologic Assessment of the Role of Blood Pressure in Stroke: The Framingham Study, J. Amer. Med. Assoc., 214:301-310, 1970.
22. Sokolow, M. and Perloff, D.: The Prognosis of Essential Hypertension Treated Conservatively. Circulation, 23:697, 1961.
23. Palmer, R. S. and Muench, H.: Course and Prognosis of Essential Hypertension. J. Amer. Med. Assoc., 153:1, 1953.
24. Veterans Administration Cooperative Study Group on Anti-Hypertensive Agents: Effects of Treatment on Morbidity, III, Influence of Age, Diastolic Blood Pressure, Prior Cardiovascular Disease. Further Analysis of Side Effects. Circulation, 45:991, 1974.

25. Stamler, J. and Epstein, F.: Coronary Heart Disease: Risk Factors as Guides to Prevent Action. Prev. Med., 1:27, 1972.
26. Robinson, S. C. and Brucer, M.: Range of Normal Blood Pressure. Arch. Inter. Med., 64:409, 1939.
27. Body Build and Blood Pressure Study: vol. II, Society of Actuaries: Chicago, Illinois, 1959.
28. Medical Impairment Study, 1929. Actuarial Society of America and Association of Life Insurance Medical Directors, New York: 1931.
29. Hunter, A.: Supplementary Note on Blood Pressure. Transactions, Society of Actuaries, 1:24, 1931.
30. Bolt, W., Bell, M. F. and Harnes, J. R.: A Study of Mortality in Moderate and Severe Hypertension. Trans. Ass. Life Ins. Med. Dir. Amer., 41:61, 1957.
31. Bechgaard, P.: The Natural History of Benign Hypertension, 1000 Patients Followed from 26 to 32 Years, Stamler, J., Stamler, R. and Pullman, T. N. (eds.) Grune and Stratton: New York, N. Y., pp. 357-363, 1967.
32. Lew, E. A.: Blood Pressure and Mortality, Life Insurance Experience. Stamler, J., Stamler, R. and Pullman, T. N. (eds.) Grune and Stratton: New York, N. Y., pp. 392-396, 1967.
33. Leishman, A. W. D.: Merits of Reducing High Blood Pressure. Lancet, 1:1284, 1963.
34. Mayer, J. M. and Brest, A. N.: The Changing Outlook for the Patient with Hypertension. Amer. J. Cardiol., 17:673, 1966.
35. Perry, H. M., Schroeder, H. A., Catanzaro, F. J., More-Jones, D. and Camel, G. H.: Studies on the Control of Hypertension. VIII. Mortality, Morbidity and Remission During Twelve Years of Intensive Therapy. Circulation, 33:958, 1966.
36. Veterans Administration Cooperative Study Group on Anti-Hypertensive Agents: Effects of Treatment on Morbidity and Mortality. Results in Patients with Diastolic Blood Pressures Averaging 115 Through 129 mm Hg. J. Amer. Med. Assoc., 1028, 1967.
37. Mikeal, R. L. and Sharpe, T. R.: Patient Compliance, A. T. Wertheimer and M. C. Smith (eds.) Pharmacy Practice--Social Behavior Aspects. University Park

Press: Baltimore, Maryland, pp. 28-36, 1974.

38. Freis, E. D.: The Modern Management of Hypertension, U.S. Government Printing Office: V. A. Hospital, Washington, D.C., (January), 1973.
39. Ivey, M.: The Pharmacist in the Care of the Ambulatory Mental Health Patient. Amer. J. Hosp. Pharm., 30:599-602, 1973.
40. Clinite, J. C. and Kabat, H. F.: Errors During Self-Administration. J. Amer. Pharmaceut. Ass., NS9:450-452, (January), 1971.
41. Cole, P. and Sister Emmanuel: Drug Consultation: Its Significance to the Discharged Hospital Patient and Its Relevance as a Role for the Pharmacist. Amer. J. Hosp. Pharm., 28:954-960, (January), 1971.
42. Stewart, R. B. and Cluff, L.: A Review of Medication Errors and Compliance in Ambulant Patients. Clin. Pharmacol. Ther., 13:463-468, 1972.
43. Davis, M. S.: Variations in Patients' Compliance With Doctors' Orders: Analysis of Congruence Between Survey Responses and Results of Empirical Investigations, J. Med. Educ., 41:1037-1048, (November), 1966.
44. Mohler, D. N., Wallin, D. G. and Dreyfus, E. G.: Studies in the Home Treatment of Streptococcal Disease. New Eng. J. Med., 252:1116-1118, 1955.
45. National Center for Health Statistics: Hypertension and Hypertensive Heart Disease in Adults. U.S. 1960-62, Washington, D.C., U.S. Dept. of HEW, Vital and Health Statistics, Series 11, no. 13, U.S. Government Printing Office, 1966.
46. Latiolais, C. J. and Berry, C. C.: Misuse of Prescription Medications by Outpatients. Drug Intel. Clin. Pharm., 3:270-277, 1969.
47. Hermann, F.: The Outpatient Prescription Label as a Source of Medication Errors. Amer. J. Hosp. Pharm., 30:155-159, 1973.
48. Finnerty, F. A., Mattie, E. C. and Finnerty, F., Jr.: Hypertension in the Inner City. I. Analysis of Clinic Dropouts, Circulation, 47:73-75, (January), 1973.
49. Schoenberger, J. A., Stamler, J., Shekelle, R. B. and Sltেকে, S.: Current Status of Hypertension Control in an Industrial Population. J. Amer. Med. Assoc., 222:559, 1972.

50. Boyd, J. R., Covington, T. R., Stanaszek, W. F. and Coussons, R. T.: Drug Defaulting: Part I, Determinants of Compliance, Amer. J. Hosp. Pharm., 31:362-367, 1974.
51. Marston, M.: Compliance with Medical Regimens: A Review of the Literature. Nurs. Res., 19:312-323, 1970.
52. Finnerty, F., Jr., Show, L. and Himmelsbach, K.: Hypertension in the Inner City. Part II. Detection and Follow Up. Circulation, 47:76-78, 1973.
53. Blackwell, B.: Patient Compliance. N. Eng. J. Med., 289:249-252, (August), 1973.
54. McKenney, J. M., Slining, J. M., Henderson, H. R., Devins, D. and Barr, M.: The Effect of Clinical Pharmacy Services on Patients With Essential Hypertension. Circulation, 48:1104-1111, 1973.
55. Wintrobe, M. M., Thorn, G. W., Adams, R. D., Bennet, F., Braumwold, E., Isselbacher, D. J. and Petersdorf, R. G. (eds.): Harrison's Principles of Internal Medicine, 6th ed., McGraw-Hill: New York, N. Y., pp. 1252-1262, 1970.