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QUALITY OF LIFE IN HYPERTENSION

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INTRODUCTION

Hypertension is the term used to describe high blood pressure. Blood pressure is a measurement of the force against the walls of your arteries as the heart pumps blood through the body. Blood pressure readings are measured in millimeters of mercury (mmHg) and usually given as two numbers -- for example, 120 over 80 (written as 120/80 mmHg). One or both of these numbers can be too high.

The top number is your systolic pressure.

- It is considered high if it is over 140 most of the time.
- It is considered normal if it is below 120 most of the time.

The bottom number is your diastolic pressure.

- It is considered high if it is over 90 most of the time.
- It is considered normal if it is below 80 most of the time.

Symptoms

High blood pressure usually causes no symptoms and high blood pressure often is labeled "the silent killer." People who have high blood pressure typically don't know it until their blood pressure is measured.

Sometimes people with markedly elevated blood pressure may develop

- headache,
- dizziness,
- blurred vision
- nausea and vomiting
- chest pain and shortness of breath.

People often do not seek medical care until they have symptoms arising from the organ damage caused by chronic (ongoing, long-term) high blood pressure. The following types of organ damage are commonly seen in chronic high blood pressure:

- Heart attack
- Heart failure
- Stroke or transient ischemic attack (TIA)
- Kidney failure
- Eye damage with progressive vision loss
- Peripheral arterial disease causing leg pain with walking (claudication)
- Outpouchings of the aorta, called aneurysms.

About 1% of people with high blood pressure do not seek medical care until the high blood pressure is very severe, a condition known as malignant hypertension.

- In malignant hypertension, the diastolic blood pressure (the lower number) often exceeds 140 mm Hg.
- Malignant hypertension may be associated with headache, lightheadedness, nausea, vomiting, and stroke like symptoms
- Malignant hypertension requires emergency intervention and lowering of blood pressure to prevent brain hemorrhage or stroke.

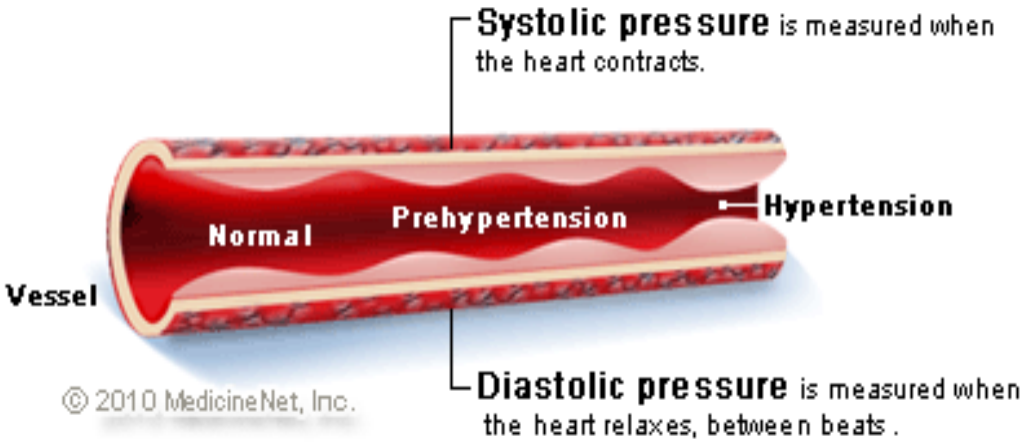


Fig 1.1: Showing Systolic Pressure and Diastolic Pressure.

Prevalence of hypertension

Hypertension affects about 1 billion individuals worldwide. In the United States the National Health and Nutrition Examination Survey (NHANES1988-2000) reported that hypertension prevalence was 31.3% with an estimates of 65 million American having hypertension (Fields et al. 2004). Of hypertensive subjects 68.9% were found to be aware of their condition, 58.4% were on treatment and 31% had controlled their hypertension (Hajjar and Kotchen, 2003). In Malaysia, The National Health and Morbidity survey of 21,391 individuals over the age of 30 in 1996 showed a high prevalence of high blood pressure with 33% of adults having hypertension. Among hypertensive individuals, 33% were aware of their hypertension, 23% were on treatment while only 6% had controlled their hypertension (Lim et al, 2004). In China, the prevalence of hypertension was found to be 27.2% in the adult population aged between 35 to 74 years of these 44.7% were aware of their condition, 28.2% were on treatment while only 8.1% had their blood pressure under control (Gu et al, 2002). In a survey of rural Filipinos (age 30 and more), the prevalence of hypertension was found to be 23%, 42% were diagnosed, 47% were on treatment, while blood pressure was controlled in 35% of the treated patients and in 17% of all hypertensive patients (Reyes-Gibby and Aday 2000). Awareness of hypertension is important to control blood pressure. Many patients are not aware of their condition leading to a low rate of hypertension control. In some communities about half of the patients were not aware of their condition. For instance, among the Parsi community of India, the prevalence of 3 hypertension was 36.4% of which 48.5% were not aware of their condition. Among those who were aware, 36.4% were not compliant and only 13.6% had controlled their hypertension (Bharucha and Kuruvilla 2003). Hypertension is a leading cause of morbidity and mortality with microvascular and macrovascular complication which includes coronary artery diseases, nephropathy, retinopathy, and neuropathy. Hypertension is rarely present without other accompanying risk factors. There is a strong association between hypertension and diabetes mellitus, as many studies have reported a high prevalence of diabetes mellitus among hypertensive patients (Ghannem and Hadj, 1997, Gavalda et al, 1993, Mafauzy et al, 2003).

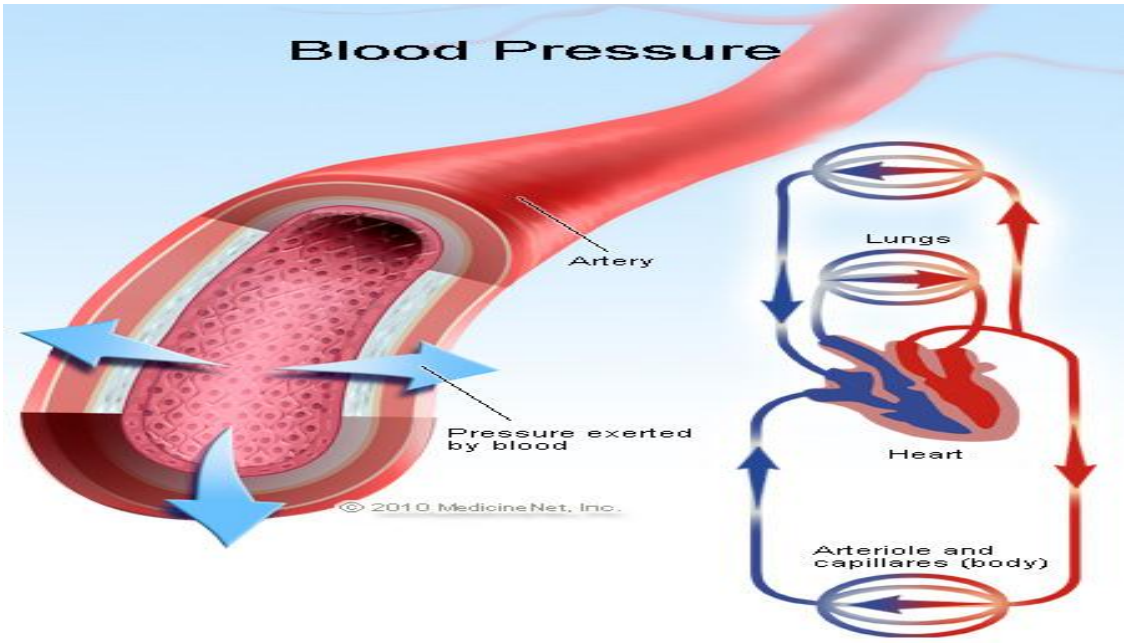


Figure 1.2: Showing Blood Pressure.

Classification

- There are two main types of hypertension, and there are four types of hypertension that are less common.
- Depending on the type of hypertension, the cause could be known or unknown.
- It is suspected that hypertension results from a combination of factors related to genetics, diet, and lifestyle.
- The Types are:

✓ Primary or essential hypertension, that has no known cause, is diagnosed in the majority of people.

✓ Secondary hypertension is often caused by reversible factors, and is sometimes curable.

- The other includes:

✓ Malignant Hypertension

✓ Isolated Systolic Hypertension

✓ White Coat Hypertension

✓ Resistant Hypertension

Primary or essential hypertension

- This type is also called essential hypertension.
- Primary hypertension is the most common type of hypertension and accounts for 95% of cases.

- It is a complex disorder with no isolated cause.
- Many factors can put you at risk for primary hypertension including obesity, diet, environment, stress, and sedentary lifestyle.
- High sodium and family history of hypertension can also put you at risk for this condition.
- Even though there is no single identifiable cause, a variety of factors can trigger the condition.
- Generally, primary hypertension runs in the family.
- If your parents or grandparents had it, then you are likely to develop the condition as well. For this reason, it is important that you undergo regular screenings to treat hypertension before it becomes serious and causes life-threatening complications.
- Doctors will treat primary hypertension by encouraging you to undergo certain lifestyle modifications.
- You may need to lose weight, adjust your diet, or adopt a regular fitness routine to keep your symptoms under control.
- If these lifestyle modifications are unsuccessful, then you may need to start taking medication on a daily basis to keep your symptoms under control.

Secondary Hypertension

- Secondary hypertension accounts for a small number of hypertension causes, and without other symptoms, the doctor may not be aware that another condition is causing your symptoms.
- This may be caused by:

✓ Kidney damage or impaired function (This accounts for most secondary forms of hypertension.)
✓ Tumours or overactivity of the adrenal gland
✓ Thyroid dysfunction
✓ Coarctation of the aorta
✓ Pregnancy-related conditions
✓ Sleep Apnea Syndrome
✓ Medication, recreational drugs, drinks & food

Malignant Hypertension

- This, the most severe form of hypertension, is severe and progressive.
- It rapidly leads to organ damage. Unless properly treated, it is fatal within five years for the majority of patients.
- Death usually comes from heart failure, kidney damage or brain haemorrhage.
- However, aggressive treatment can reverse the condition, and prevent its' complications.
- Malignant hypertension is becoming relatively rare, and is not caused by cancer or malignancy.
- Malignant hypertension is very rare and affects both children and adults. Pregnant women are also at risk. Heart damage is a possibility with this type of hypertension.
- A person might experience numbness in the body as well as vision problems, extreme fatigue, confusion, anxiety, and seizures.

Isolated Systolic Hypertension

- The arteries become stiff, resulting in a high systolic number with a normal diastolic number. Isolated systolic hypertension does not have an identifiable cause.
- This may occur in older people, and results from the age-related stiffening of the arteries.
- The loss of elasticity in arteries, like the aorta, is mostly due to arteriosclerosis.
- Risk factors include old age, obesity, using tobacco products, and having diabetes.
- Caucasian and black men are the groups that are highest at risk for developing this type of hypertension.

White Coat Hypertension

- Also called anxiety-induced hypertension
- This type of hypertension occurs only when blood pressure is taken in a clinical setting.
- Outside of a doctor's office, blood pressure is normal.
- It is believed that these patients feel extremely stressed when they visit a clinic or doctor's office. You might want to try checking your blood pressure in other locations such as your home.
- Lifestyle changes like more exercise, less salt and alcohol, no nicotine and weight loss, would be wise. A low fat, high fibre diet, with increased fruit and vegetable intake, will be beneficial

Resistant Hypertension

- This type of hypertension is unresponsive to strong medications.
- In any case, treatments for resistant hypertension have been developed to keep the condition under control.
- Hypertension is called resistant if three medications fail to successfully treat the condition.
- At least four medications may be necessary to treat resistant hypertension.

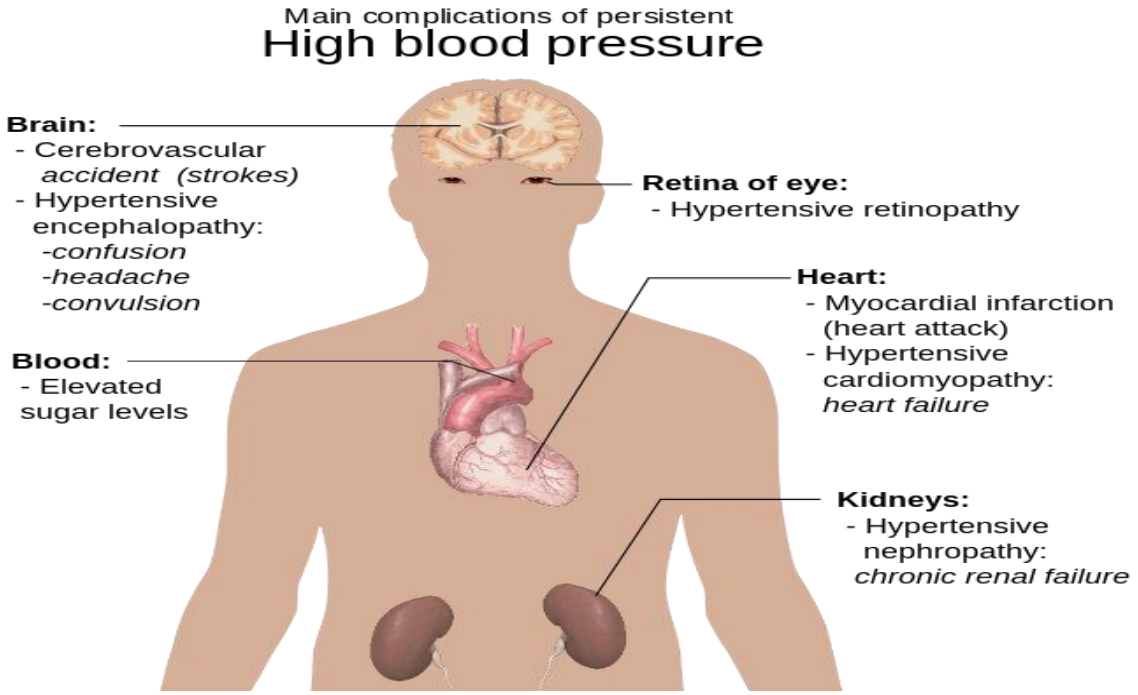


Figure-1.3: Showing main Complications of persistent High Blood Pressure.

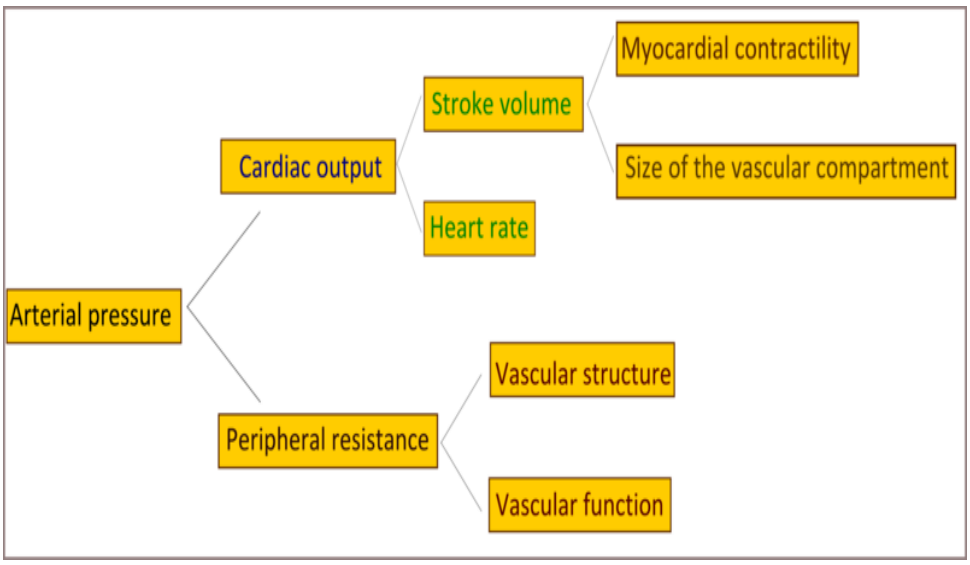


Figure 1.4: Pathophysiology Of Hypertension:

- In most people with established essential (primary) hypertension, increased resistance to blood flow (total peripheral resistance) accounting for the high pressure while cardiac output remains normal.

- **Cardiac Output**

✓ It is the volume of blood pumped by the heart per minute (ml blood/min).
✓ Cardiac output is a function of heart rate and stroke volume.
✓ The heart rate is simply the number of heart beats per minute.
✓ The stroke volume is the volume of blood, in milliliters (mL), pumped out of the heart with each beat. Increasing either heart rate or stroke volume increases cardiac output.
✓ So Cardiac Output:

Cardiac Output in mL/min = heart rate (beats/min) X stroke volume (mL/beat)

✓ An average person has a resting heart rate of 70 beats/minute and a resting stroke volume of 70 mL/beat. The cardiac output for this person at rest is.

Cardiac Output = 70 (beats/min) X 70 (mL/beat) = 4900 mL/minute.

Risk Factor of Hypertension

❖ ***Aging*** - Blood pressure tends to rise with age. For a male older than 45 (for female 55), the risk for Hypertensive is higher. Example Isolated systolic hypertension (ISH). It does not mean high blood pressure is routine part of aging, take steps to keep the blood pressure at a normal level.
❖ ***Overweight or obesity*** contributes for the cause of pre-hypertension or hypertensive so plan to reduce weigh to reduce the risk of developing high blood pressure.
❖ ***Unhealthy lifestyle*** is by taking too much of sodium salt & alcohol, and not getting enough potassium & physical activity.
❖ ***Smoking***-Too much and long lasting ***stress***.
❖ ***Family history*** of high blood pressure,
❖ Already diagnosed as ***pre-hypertension***

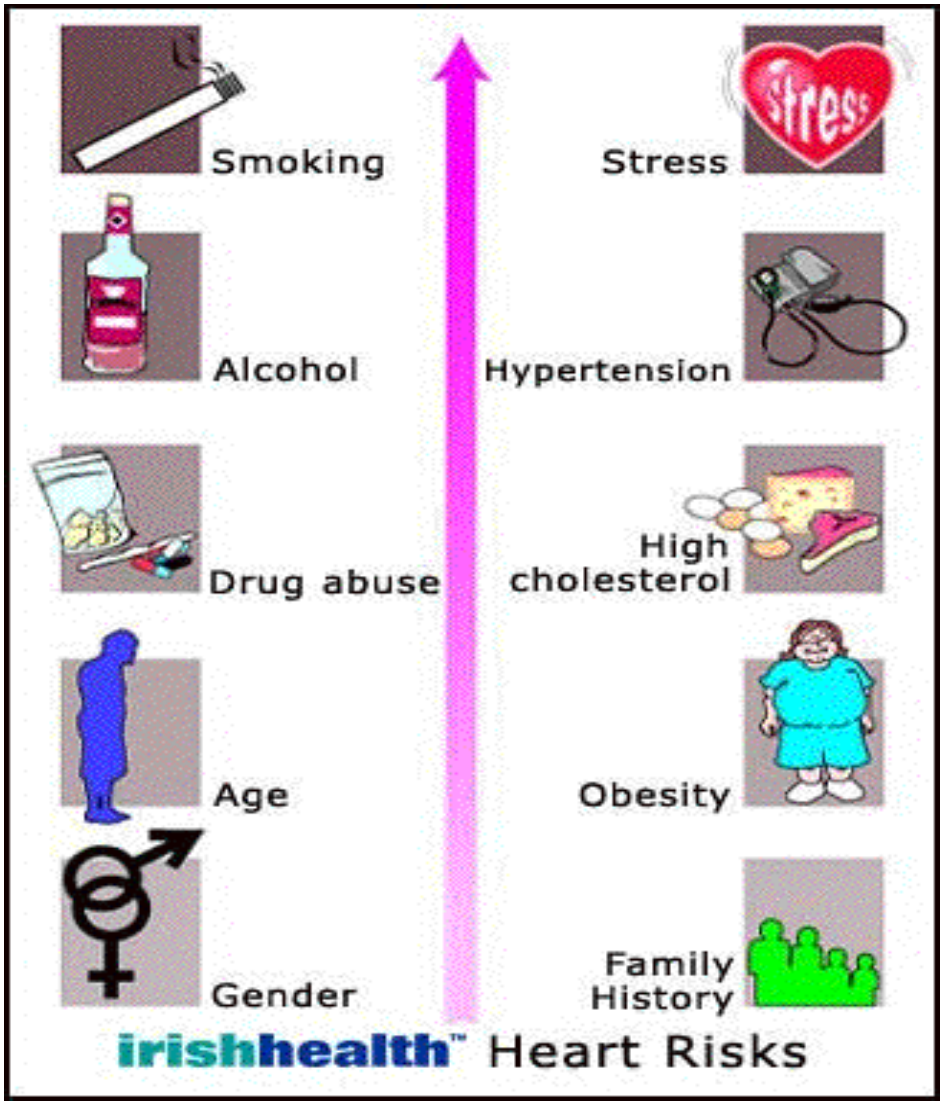


Figure 1.5: Showing Risk Factor Involve for Hypertension.

Types of Medication For Hypertension

There are several categories of hypertension medications. The main categories of medications for hypertension include.

- **Alpha Blocker.**

✓ Prazosin,

✓ Terazosin

- **Beta Blocker.**

✓ Propanolol,

✓ Metoprolol

✓ Atenolol

- **Alpha-beta blockers.**

✓ Carvedilol

- ✓ labetalol

- **Diuretics.**

- ✓ Spironolactone
- ✓ Triamterene
- ✓ Hydrochlorothaizide

- **ACE inhibitors.**

- ✓ captopril,
- ✓ enalapril
- ✓ ramipril

- **Angiotensin II receptor blockers (ARBs).**

- ✓ Telmesartan
- ✓ Olmesartan
- ✓ Valsartan
- ✓ Losartan

- **Calcium Channel Blockers.**

- ✓ Amlodipine
- ✓ Verapamil
- ✓ Diltiazem
- ✓ Nifedipine

- **Nervous system inhibitors.**

- ✓ Clonidine
- ✓ Methyldopa

- **Vasodilators.**

- ✓ Isosorbide mononitrate
- ✓ Hydralazine
- ✓ Isosorbide Dinitrate

Clinical Research

- Clinical research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use.
- These trials can take place only after satisfactory information has been gathered on the quality of the non-clinical safety, and Health Authority/Ethics Committee approval is granted in the country where the trial is taking place.

Types

The U.S.National institute of health (NIH) organizes trials into five (5) different types.

- **Prevention trials:** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
- **Screening trials**: test the best way to detect certain diseases or health conditions.
- **Diagnostic trials:** conducted to find better tests or procedures for diagnosing a particular disease or condition.
- **Treatment trials**: test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Quality of life trials:** explore ways to improve comfort and the quality of life for individuals with a chronic illness (a.k.a. Supportive Care trials).
- **Compassionate use trials**: provide partially tested, unapproved therapeutics prior to a small number of patients that have no other realistic options. Usually, this involves a disease for which no effective therapy exists, or a patient that has already attempted and failed all other standard treatments and whose health is so poor that he does not qualify for participation in randomized clinical trials. Usually, case by case approval must be granted by both the FDA and the pharmaceutical company for such exceptions.

Phase

- Clinical trials involving new drugs are commonly classified into four phases.

✓ **Phase 0**

✓ **Phase I**

✓ **Phase-II**

✓ **Phase-III**

✓ **Phase-IV**

- Before pharmaceutical companies start clinical trials on a drug, they conduct extensive Preclinical study.

Pre-Clinical Study

- Pre-clinical studies involve invitro (test tube) and in vivo (animal or cell culture) experiments using wide-ranging doses of the study drug to obtain preliminary efficacy, toxicity and Pharmacokinetic information.

- Such tests assist pharmaceutical companies to decide whether a drug candidate has scientific merit for further development as an investigational new drug.

Phase-0

- Phase 0 is a recent designation for exploratory, first in human trial conducted in accordance with the United States Food Drug Administration's (FDA) 2006 Guidance on Exploratory Investigational New Drug(IND) Studies.
- Phase 0 trials are also known as human micro dosing studies and are designed to speed up the development of promising drugs or imaging agent by establishing very early on whether the drug or agent behaves in human subjects as was expected from preclinical studies.
- Distinctive features of Phase 0 trials include the administration of single sub therapeutic doses of the study drug to a small number of subjects (10 to 15) to gather preliminary data on the agent's Pharmacokinetic (how the body processes the drug) and Pharmacodynamic (how the drug works in the body).
- A Phase 0 study gives no data on safety or efficacy, being by definition a dose too low to cause any therapeutic effect. Drug development companies carry out Phase 0 studies to rank drug candidates in order to decide which has the best pharmacokinetic parameters in humans to take forward into further development. They enable go/no-go decisions to be based on relevant human models instead of relying on sometimes inconsistent animal data.
- Questions have been raised by experts about whether Phase 0 trials are useful, ethically acceptable, feasible, speed up the drug development process or save money, and whether there is room for improvement.

Phase-I

- Phase I trials are the first stage of testing in human subjects. Normally, a small (20-100) group of healthy volunteers will be selected.
- This phase includes trials designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of a drug.
- Phase I trials also normally include dose ranging also called dose escalation, studies so that the appropriate dose for therapeutic use can be found.
- I trials most often include healthy volunteers

- There are some circumstances when real patients are used, such as patients who have cancer or HIV and lack other treatment options.
- There are different kinds of Phase I trials:

➢ **SAD**

- Single Ascending Dose studies are those in which small groups of subjects are given a single dose of the drug while they are observed and tested for a period of time. If they do not exhibit any adverse side effects, and the pharmacokinetic data is roughly in line with predicted safe values, the dose is escalated, and a new group of subjects is then given a higher dose. This is continued until pre-calculated pharmacokinetic safety levels are reached, or intolerable side effects start showing up (at which point the drug is said to have reached the Maximum tolerated dose (MTD).

➢ **MAD**

- Multiple Ascending Dose studies are conducted to better understand the pharmacokinetics & pharmacodynamics of multiple doses of the drug. In these studies, a group of patients receives multiple low doses of the drug, while samples (of blood, and other fluids) are collected at various time points and analyzed to understand how the drug is processed within the body. The dose is subsequently escalated for further groups, up to a predetermined level.

Phase-II

- Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300)
- When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects.
- Phase II studies are sometimes divided into :

✓ Phase IIA

✓ Phase IIB.

PhaseIIA

- IIA is specifically designed to assess dosing requirements (how much drug should be given).

PhaseIIB

- IIB is specifically designed to study efficacy (how well the drug works at the prescribed dose(s)).

Phase-III

- Phase III studies are randomized controlled Multicenter trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied).
- The aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for Chronic medical conditions.
- Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency.
- This allows patients to continue to receive possibly lifesaving drugs until the drug can be obtained by purchase.
- Phase III clinical trials can be marketed under FDA norms with proper recommendations and guidelines, but in case of any adverse effects being reported anywhere, the drugs need to be recalled immediately from the market.

Phase-IV

- Phase IV trial is also known as Post Marketing Surveillance Trial.
- Phase IV trials involve the safety surveillance(Surveillance) and ongoing technical support of a drug after it receives permission to be sold.
- The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I-III clinical trials.
- Harmful effects discovered by Phase IV trials may result in a drug being no longer sold, or restricted to certain uses.

Inform Consent Process

- Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate.
- It is also a continuing process throughout the study to provide information for participants.

- To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.
- For Conducting Clinical Trial the inform consent form should be approved by the ethics committee.
- Inform consent form available in different language.
- If the participant's native language is not English, translation assistance can be provided. Then the research team provides an inform consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document.
- The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Quality Of Life

Quality of life is not a new concept. Many sciences such as sociology, psychology and economics have used it. In health care research and practice, quality of life has become ever more important since the World Health Organization defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being.

The terms "quality of life" and more specifically **"Health Related Quality Of Life" (HRQOL)** refer to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions. Individuals' perceptions of their quality of life may be affected not only by their illness but also by their therapy. This is the case with individuals who have hypertension. Many patients with mild to moderate hypertension have no symptoms.

Nevertheless, antihypertensive drug therapies are frequently associated with unpleasant side effects that may have an impact on many aspects pertaining to quality of life.

Many components of quality of life cannot be observed directly. They are usually evaluated according to classical principles of item measurement theory. This theory proposes that there is a true quality of life value, which may be measured indirectly by asking a series of questions known as "items."

Many instruments are currently available to measure HRQOL. These instruments are sometimes too long for use in research or clinical practice, for example, the Health Insurance Experiment health scales includes 108 items and requires around 45 minutes to be completed.

The length of most available instruments has prompted investigators to develop shorter instruments.

The **36-item Short Form Health Survey (SF-36)**, ***See Appendix 1,*** has been frequently used to measure quality of life.

The SF-36 is a short form instrument. It has been put together by selecting 36 items from a large series of health status instruments including 245 items employed in the Medical Outcomes Study.

The SF-36 consists of 36 items with one item used to measure health transition and the remaining 35 items, which may be grouped into scales, used to assess eight domains.

These are

1. Physical Functioning;
2. Role-Physical;
3. Bodily Pain;
4. General Health;
5. Vitality;
6. Social Functioning;
7. Role-Emotional; And
8. Mental Health.

These eight domains may be further aggregated into two summary measures: the physical component summary measure and the mental component summary measure.

The physical component summary measure includes physical functioning, role-physical, bodily pain and general health scales while the mental component summary measure includes vitality, social functioning, role-emotional and mental health scales.

QUALITY OF LIFE IN HYPERTENSION

Back Ground

Patients with hypertension frequently report symptoms that are similar to those reported by patients without the diagnosis.[1] Although hypertension is often thought to be asymptomatic, cognitive changes, mood alterations, and general symptoms, such as dizziness and headache attributable to hypertension, have been described.[2-7] Drugs used for the treatment of hypertension also may cause symptoms, some of which are specific to a particular drug, whereas others are similar to symptoms described or attributed to the disease of hypertension.

Quality of life is not a new concept. Many sciences such as sociology, psychology and economics have used it.

In health care research and practice, quality of life has become ever more important since the World Health Organization[1] defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being. The terms "quality of life". and more specifically "health related quality of life" (HRQOL) refer to the **physical**, **psychological**, and **social domains of health**, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions.[2]

Individuals' perceptions of their quality of life may be affected not only by their illness but also by their therapy. This is the case with individuals who have hypertension. Many patients with mild to moderate hypertension have no symptoms.[3] Nevertheless, antihypertensive drug therapies are frequently associated with unpleasant side effects that may have an impact on many aspects pertaining to quality of life.

OBJECTIVE

To determine the relationship between symptoms and health-related quality of life (HRQOL) in patients receiving drug therapy for hypertension.

MATERIAL AND METHODS

Retrospective analysis of 20-30 outpatients records with an established diagnosis of hypertension in outpatient.

Inclusion Criteria

- Patient Age between 18-80 yrs either male or female.

- Patient suffering from hypertension
- Willing to give signature in inform consent form(ICF)
- ability to read and respond to the self-administered questionnaire

Exclusion Criteria

- Pregnant women or nursing mothers
- Those patients with acute illnesses or having a definite psychiatric diagnosis.
- Symptomatic chronic disease states, such as pulmonary disease (asthma or chronic obstructive pulmonary diseases), inflammatory rheumatic diseases.

❖ **Data were collected by self-administered questionnaires.**

AIM AND OBJECTIVE

- Patients with hypertension frequently report symptoms that are similar to those reported by patients without the diagnosis.
- Although hypertension is often thought to be asymptomatic, cognitive changes, mood alterations, and general symptoms, such as dizziness and headache attributable to hypertension
- Drugs used for the treatment of hypertension also may cause symptoms, some of which are specific to a particular drug, whereas others are similar to symptoms described or attributed to the disease of hypertension.
- Quality of life is not a new concept. Many sciences such as sociology, psychology and economics have used it. In health care research and practice, quality of life has become ever more important since the World Health Organization defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being. The terms “quality of life”. and more specifically “health related quality of life” (HRQOL) refer to the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person’s experiences, beliefs, expectations, and perceptions.
- Individuals’ perceptions of their quality of life may be affected not only by their illness but also by their therapy. This is the case with individuals who have hypertension. Many patients with mild to moderate hypertension have no symptoms.[3] Nevertheless, antihypertensive drug therapies are frequently associated with unpleasant side effects that may have an impact on many aspects pertaining to quality of life.

- To determine the relationship between symptoms and health-related quality of life (HRQOL) in patients receiving drug therapy for hypertension.

MATERIAL AND METHODS

Study population and data collection

A study assessing a pharmacy-based health intervention program targeting individuals treated for hypertension, served as background for the present study.

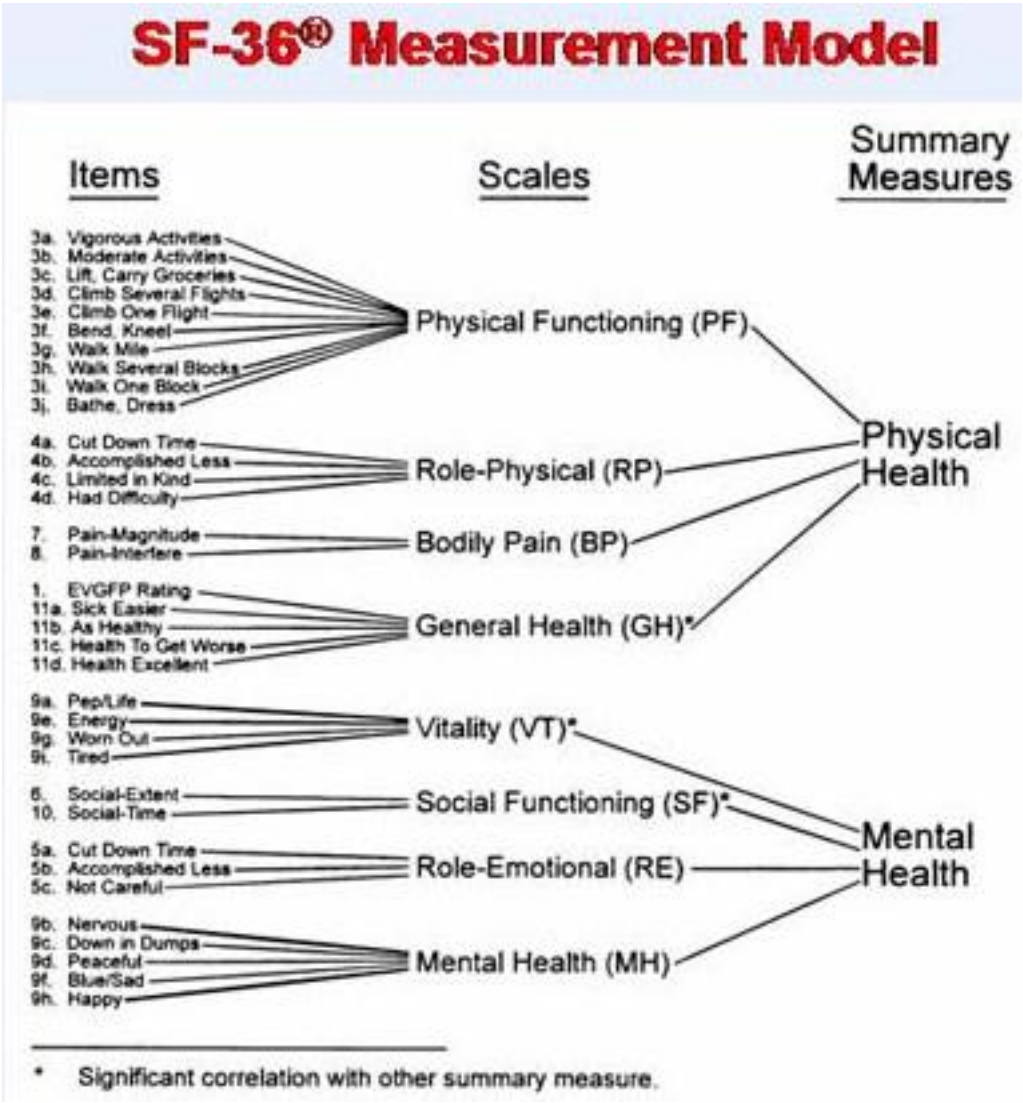
- To be eligible, patients had to be between 18 and 80 years of age and be taking at least one antihypertensive drug dispensed as a 30-day regimen.
- No modification to the antihypertensive drug therapy should have been recorded in the patient file for a 2-month period prior to study enrollment.
- Pharmacists sent the names of those who accepted to participate in the study to the coordinating center.
- A research assistant later met the participants at their home.
- During this first in home interview, the research assistant obtained a written informed consent from the participant and administered a computer-assisted structured questionnaire so as to obtain personal and health information.
- Throughout these interviews, quality of life was measured using the English version of the SF-36, embedded in a long questionnaire.
- The questionnaire was designed to collect socio-demographic information such as age, gender, educational status and employment status.
- Participants were asked about the presence or absence of comorbid conditions including diabetes, heart disease and stroke.
- This information was later validated with their medical records.
- Respondents were divided into 3 groups: participants with hypertension, participants with hypertension and cardiovascular co-morbidities, participants with both hypertension and diabetes mellitus.
- Cardiovascular comorbidities were defined as self-reported history of angina, myocardial infarction, heart insufficiency or stroke.
- HRQOL was assessed by SF-36, the medical outcome study short-form health survey (Ware and Sherbourne, 1992).
- The SF-36 consists of 36 items with one item used to measure health transition and the remaining 35 items, which may be grouped into scales, used to assess eight domains.

These are

- physical functioning;
- role-physical;
- bodily pain;
- general health;
- vitality;
- social functioning;
- role-emotional;
- mental health.

These eight domains may be further aggregated into two summary measures: the physical component summary measure and the mental component summary measure.
Scores range from 0 (poorest health) to 100 (optimal health).

Score also can be done electronically by using following link.
http://www.sf-36.org/demos/SF-36.html



Reference Population

The reference group consists of a random sample (n = 600), aged 18 to 87 years which was representative of the general Indian population.

INFORMED CONSENT FORM

CENTER NUMBER: …….

PATIENT'S INITIAL ……..…

PATIENT'S ID …….

TITLE OF THE PROJECT

NAME OF THE INVESTIGATOR:…….

INTIAL THE BOXES(Y/N)

1	I Confirm That I Have Read And Understood The Patient Information Sheet Dated _____ For The Above Study.
2	I Confirm That The Investigator Has Given Me Detail Information About The Sudy And Explained To Me The Trial Related Procedures And Processes.
3	I Confirm That I Have Had The Opportunity To Ask Questions And Am Fully Satisfied With Answers And Explanations Given.
4	I Confirm That I Was Given Oportunity And Enough Time To Carefully Read The Patient Information Sheet And Discuss With Others Before My Decision For Participation.
5	I Understand That My Participation In The Study Is Voluntary And That I Am Free To Withdraw At Any Time, Without Giving Any Reason, Without My Medical Care Or Legal Rights Being Affected.
6	I Understand That The Sponsor Of The Clinical Trial, Others Working On The Sponsor's Behalf, The Ethics Committee And The Reulatory Authorities Will Not Need My Permission To Look At My Health Records Both In Respect Of The Study And Any Further Research That May Be Conducted In Relation To It, Even If I Withdraw From The Trial.I Agree To This Access. However, I Understand That My Identity Will Not Be Revealed In Any Information Released To Third Parties Or Publication.
7	I Agree Not To Restict The Use Of Any Data Or Results That Arise From This Study.
8	I Agree To Take Part In The Above Study.

SIGANATURE (OR THUMB IMPRESSION) OF THE SUBJECT/LEGALLY ACCEPTABLE

REPRESENTATIVE:…….

DATE: ……./……./……...

NAME OF PATIENT ……..

DATE: ……./……./……...

SIGNATURE …….

NAME OF PERSON TAKING CONSENT……

SIGNATURE …….

DATE: ……./……./……...

NAME OF THE INVESTIGATOR……

SIGNATURE…… DA

RESULTS

Table 1 shows the characteristics of respondents. A total of 300 patients were included in this study. Their average age was 60 years. Of the sampled patients, 61.8% were telugu, 25.8% were kannad and 12.4% were others. A majority of the respondents were married (74.5%)

and unemployed (72.7%). Almost half of respondents had graduated from secondary school. There were 110 participants with hypertension, 120 participants with hypertension and diabetes mellitus and 70 participants with hypertension and cardiovascular comorbidities (Table 1).

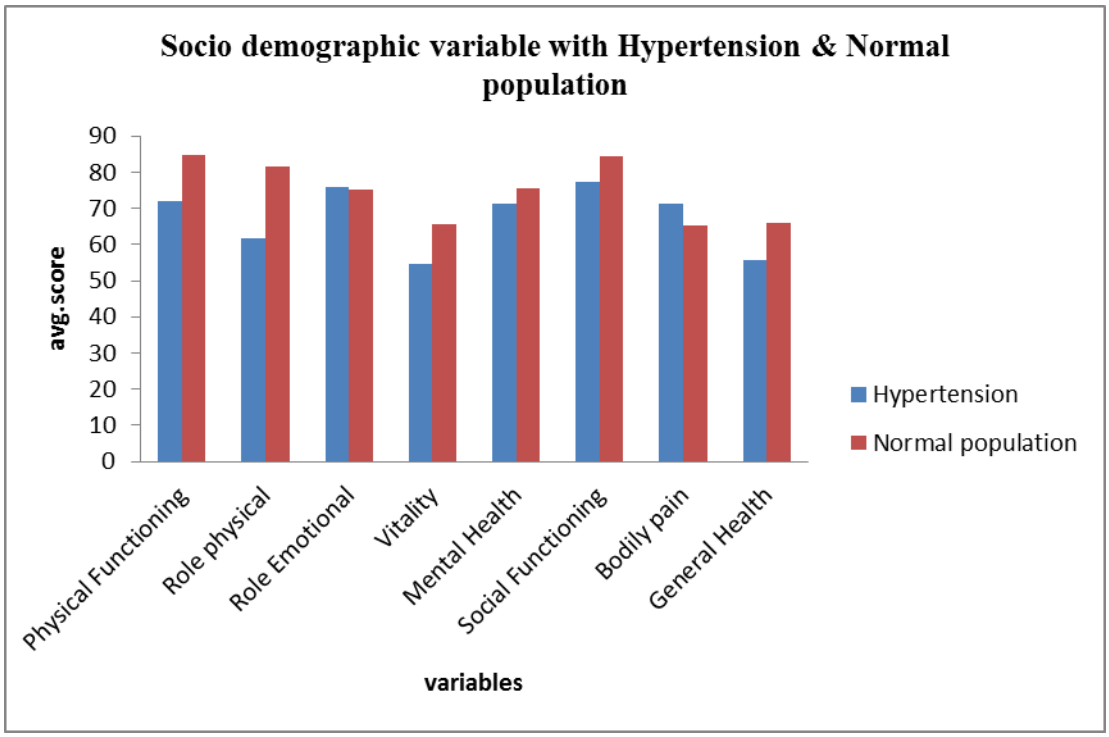
Table 1: Characteristics of Respondents.

Characteristics	N	%
Gender		
Male	120	40
Female	180	60
Age(Mean±SD)	59.72±12.46	
Ethnicity(Indian)	300	100
Marital status		
Single	26	8.6
Married	200	66.66
Divorced/Widowed	74	24.66
Working Status		
Employed	95	31.66
Unemployed	205	68.33
Educational Level		
No formal education	57	19
Primary school	120	40
Secondary school	80	26.66
University or higher	43	14.33
Comorbidities		
Hypertention only	130	43.33
Hypetention +DM	125	41.66
Hypertention+CVS	45	15

The mean SF-36 scale scores for the 300 adults with hypertension were significantly lower than the Indian norms for physical functioning, role limitations due to physical problems, vitality, mental health, social functioning and general health (Table 2). However, the scores for role limitations due to emotional problems and bodily pain were consistent with general population norms.

Table 2: Socio demographic variable with Hypertension & Normal population.

SF-36 domains	Hypertension	Normal population	Mean Difference	P-value
Physical Functioning	72.15± 25.58	84.63 ±16.95	-13.54	<0.001
Role physical	61.69 ±38.23	81.65 ±30.25	-18.45	<0.001
Role Emotional	75.82 ±32.25	75.25 ±38.65	-3.41	0.186
Vitality	54.48± 20.63	65.74 ±14.95	-7.45	<0.001
Mental Health	71.25 ±18.42	75.64± 15.95	-4.15	<0.001
Social Functioning	77.35 ±25.15	84.25± 18.35	-5.32	<0.001
Bodily pain	71.25 ±25.32	65.25 ±17.54	3.21	0.121
General Health	55.84 ±20.47	65.96 ±18.95	-8.95	<0.001



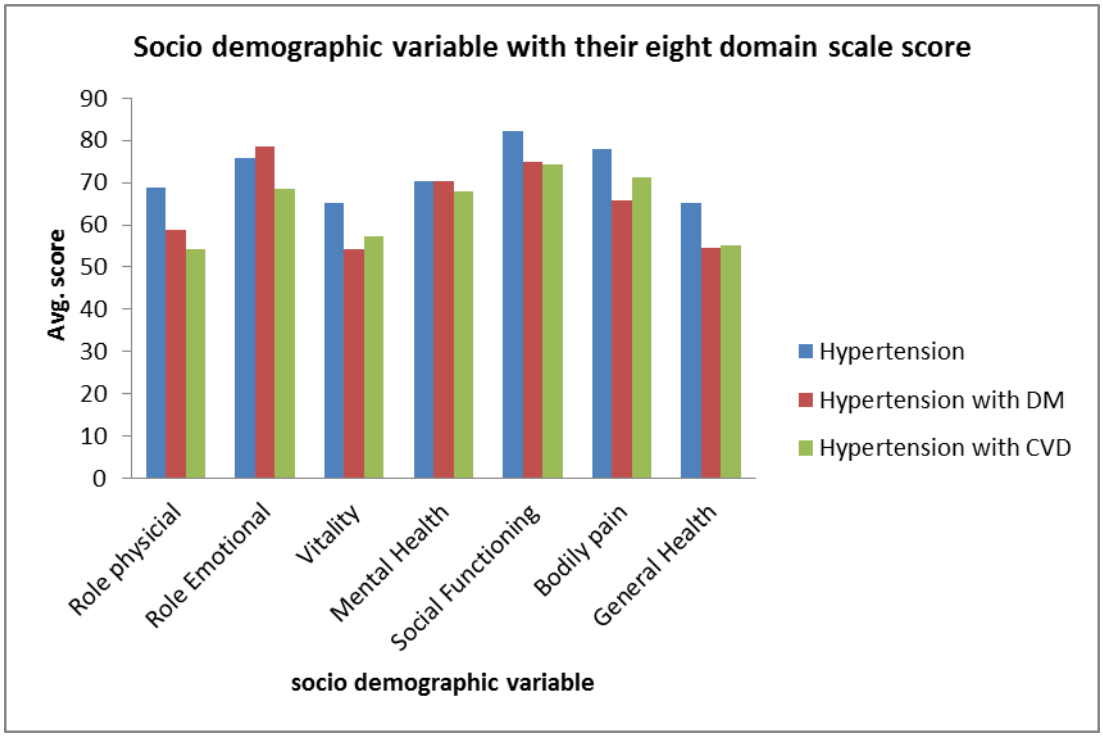
Graph 1: Socio demographic variable with Hypertension & Normal population.

Adjusted mean differences for the eight-domain scales are presented in Table 3. After adjusting for socio-demographic variables (age, gender, education and employment), patients with cardiovascular comorbidities had lower scores than hypertensive patients on all scales except mental health and bodily pain.

Patients with hypertension and diabetes mellitus had lower health-related quality of life (HRQOL) scores than patients with hypertension on the physical function scale. There were no significant differences between hypertensive patients with diabetes mellitus and cardiovascular comorbidities in all SF-36 scales except for the role-emotional domain.

Table 3: Socio demographic variable with their eight domain scale score.

SF-36 scale scores	Hypertension	Hypertension with DM	Hypertension with CVD	P-Value
Role physicial	68.75	58.95	54.25	0.043
Role Emotional	75.95	78.65	68.64	0.045
Vitality	65.32	54.32	57.25	0.045
Mental Health	70.25	70.25	67.95	0.58
Social Functioning	82.24	74.85	74.21	0.032
Bodily pain	78.05	65.95	71.26	0.148
General Health	65.32	54.58	55.2	0.031



Graph 2: Socio demographic variable with their eight domain scale score.

DISCUSSION

Hypertensive patients had lower scores on all domains in the SF-36 instrument-scale than the Indian norms except for bodily pain and role emotional. These results suggest that the burden of disease, as indicated by HRQOL, is primarily in the physical dimensions of health.

Hypertension was related to significantly lower physical scales, including physical functioning, role physical and general health scales, when compared to comparable measures in the Indian normal population (the norm). The differences in scores in domains related to mental health were smaller than those in domains related to physical function.

Cardiovascular comorbidities affected most of the domains in HRQOL negatively. It has an impact on both physical and mental domains. Results of this study are consistent with the findings of studies on hypertensive patients with angina, myocardial infarction and stroke which reported lower physical and psychological well-being. These findings agree with another study which showed that **cardiovascular disease** can cause physical disability and psychological stress, thus, affect the HRQOL assessment.

In the present study, about half of hypertensive patients did have diabetes mellitus. They reported more impairment in physical domains than mental domains, in agreement with previous studies.

We found no statistically significant differences between hypertensive patients with cardiovascular comorbidities and those with diabetes mellitus. There are probably at least two reasons for these findings. First, we did not assess the biomedical severity of the chronic conditions. Second, in this study patients were recruited from hospital-based and therefore tend to have more severe illness than subjects from the general population. It is not known whether cardiovascular comorbidities and diabetes mellitus impact similarly on quality of life of hypertensive patients.

The SF-36 scale is a generic instrument, is available in many languages and had been used to assess quality of life in many chronic conditions.

The findings should also be interpreted in the perspectives of convenience sampling and reliance on patient recall especially for comorbidities. Subjects were recruited from one hospital, hence this disproportionate representation limits the generalizability and interpretation of findings to other groups such as those of other racial origin, cultural backgrounds or younger patients. Moreover, we cannot definitively exclude that the possible arthritis and/or obstructive lung conditions were more severe and acted as cofounders. These probably lead to an overestimation of the reduction in HRQOL in our measurement.

STATISTICAL ANALYSIS

All statistical analyses were performed using SAS. Descriptive analysis included calculations of means, standard deviations and frequencies of categorical variables. To estimate the HRQOL of hypertension, we computed the mean of SF-36 scale scores for the 300 hypertensive patients of this study.

We compared the mean scores reported by the study patients to general population scores by using t-test.

Separate ANOVAs were used to estimate the individual scales on which the group differed significantly, when socio-demographic variables such as age, gender, educational level and employment status were controlled. Post hoc analyses were performed to determine which groups contribute to the significant differences ($p<0.05$).

CONCLUSION

Hypertensive patients presented a lower HRQOL scores in SF-36 than the general population. These measured deteriorations of the physical health domains were most apparent.

A similar finding concerns the HRQOL of hypertensive patients with cardiovascular comorbidities and diabetes mellitus. Moreover, these two groups had poorer HRQOL when compared with patients with hypertension.

This study provides an insight on HRQOL in hypertensive patients with and without the presence of comorbidities. Hence, effective health interventions should ensure maintenance of desirable HRQOL as well as controlling of **blood pressure**, in order to prevent or reduce comorbidities of hypertension.

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