

**ASSESSMENT OF QUALITY OF LIFE OF PATIENTS WITH HYPERTENSION AND PHARMACIST INTERVENTION IN A TERTIARY CARE HOSPITAL**

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**ABSTRACT**

**Back ground:** Hypertension is a major public health challenge because of the associated morbidity and mortality to society. The majority of the patients on antihypertensive medication fail to achieve their recommended target BP and it can lead to adverse impact on quality of life. Hypertensive patients can achieve definite outcome and improve quality of life through pharmaceutical care. **Objective:** The purpose of the study was to assess the quality of life of hypertensive patients and influence of pharmaceutical care on it. **Materials and Methodology:** A prospective observational study was carried out for a period of 9 months in the General Medicine Department of the hospital. A total of 106 patients were enrolled, 53 each were randomly allocated to the control and intervention groups. HRQoL of hypertensive patients were assessed using 36-item short form Health Survey (SF-36 Health Survey) and hypertension specific Minichal Questionnaire. These questionnaires were provided to the patients, at the time of admission and during review. At the time of admission the intervention group was provided with counseling for hypertension and with patient information leaflets on the disease and in control group they received general care provided by physician. All statistical analyses were performed with SPSS for Windows, version 19.0. For descriptive statistics, means, standard deviations and frequencies were calculated. **Results:** The major patient population were under 61-80 age group, the mean Age of control and Interventional groups were 64.36 and 66.20 respectively. About 58.49% of the patients were men and 41.50% female. In intervention group, physical functioning P =0.0143, general health P=0.0037, energy P=0.0005, social functioning P=0.0001, emotional wellbeing P=0.0001, role of limitation due to physical health P=0.0001, role of limitation due to emotional P=0.0001. In control group physical health P=0.0181, general health P=0.0239, energy P=0.0330, pain P=0.0239, social functioning P=0.0169, emotional wellbeing P=0.0014, role of limitation due to physical health P=0.1593, role of limitation due to emotional P=0.1593 (P value is less than 0.05, showed statistical significance and P value less than 0.0001 showed extremely significant). According to Minichal questionnaire, in intervention P=0.0001 for mental domain and P=0.0001 for somatic manifestation. In control group P=0.045 for mental health and P=0.0010 for somatic manifestations. **Conclusion:** The study showed that patient counseling had an important role in improving quality of life of hypertensive patients as there was significant improvement in mean score of the intervention groups after counseling was given. Study concluded that compared with control group, the intervention group in which the pharmaceutical care program delivered by clinical pharmacist, significantly improved mean systolic blood pressure and diastolic blood pressure and quality of life of hypertensive patients.

**KEYWORDS:** Quality of Life, Control Group, Intervention Group.**INTRODUCTION**

Hypertension, also known as high or raised blood pressure, is a condition in which the blood vessels have persistently raised pressure. According to National Heart, Lung and Blood Institute of the USA, a sustained diastolic pressure in greater than 89 mmHg, or a sustained systolic pressure in excess of 139 mmHg, are associated with a measurably increased risk of atherosclerosis, and are therefore felt to represent clinically significant hypertension. Both the systolic and diastolic blood pressure is important in determining

cardiovascular risk. 25% of individuals in the general population are hypertensive.<sup>[1]</sup>

**WHO Estimation**

World Health Organization estimates that over 140 million people are believed to be suffering from raised Blood pressure in our country and number expected to cross over 214 million by 2030. In developed world, about 330 million people have Hypertension, around 640 million in the developing world. The WHO rates hypertension as one of the most important causes of premature death (7.5million deaths, i.e. 12.8% of all

deaths) worldwide and the problem is growing. In 2025 it is estimated there will be 156 billion adults living with hypertension.<sup>[2]</sup>

### Epidemiological studies in India

Hypertension is a major public health problem in India and elsewhere<sup>4</sup>. As per the World Health Statistics 2012, of the estimated 57 million global deaths in 2008, 36 million (63%) were due to non-communicable disease (NCDs). Hypertension is reported to be the fourth contributor to premature death in developed countries and the seventh in developing countries. Prevalence of hypertension in the last six decades has increased from 2% to 25% among urban residents and from 2% to 15% among rural residents in India.<sup>[3]</sup> According to Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, the overall prevalence of hypertension in India will be 159.46/1000 population.

### Classification of BP for adults<sup>[4,5]</sup> Table 1.

BP Classification	SBP	DBP
Normal	<120	<80
Pre-hypertension	120-139	80-89
Stage 1 hypertension	140-159	90-99
Stage 2 hypertension	≥160	≥100

Hypertensive crises are clinical situations where BP values are very elevated, typically greater than 180/120mm Hg. They are categorized as either hypertensive emergency or hypertensive urgency. Hypertensive emergencies are extreme elevation in BP that is accompanied by acute or progressing target-organ damage.<sup>[6]</sup>

### Aetiology

Hypertension is an extremely complex interplay of multiple influences from within and outside of the human body. Hypertension can be divided into two basic etiologic categories: unknown aetiology and specific known etiology<sup>7</sup>. In most patients, hypertension results from unknown pathophysiological aetiology (essential or primary hypertension). This form of hypertension cannot be cured, but it can be controlled. A small percentage of patients have specific cause of their hypertension (secondary hypertension). There are many potential secondary cause causes that either are concurrent medical conditions or are endogenously induced.<sup>[7]</sup>

### Pathophysiology

Multiple factors that control BP are potential contributing components in the development of essential hypertension. These include malfunctions in either humoral (the rennin –angiotensin aldosterone system) or vasopressor mechanisms, abnormal neuronal mechanisms, defects in peripheral auto regulation and disturbances in sodium, calcium and natriuretic hormone. Many these factors are cumulatively affected by the multifaceted RAAS, which ultimately regulates arterial

BP. It is probable that no one factor is solely responsible for essential hypertension.<sup>[8]</sup>

### Causes of hypertension<sup>[9]</sup>

- Behavioural risk factors
  - Food containing too much salt and fat, and not eating enough fruits and vegetables.
  - Harmful levels of alcohol use
  - Physical inactivity and lack of exercise
  - Poor stress management

- Socioeconomic factors
  - Unemployment or fear, tobacco use etc.

- Other factors
  - Genetic factors

### Complications of hypertension

- Stroke
- Heart attack
- Heart failure
- Kidney damage
- Eye damage
- Peripheral artery disease

### Treatment

The ultimate goal in treatment of the hypertensive patients is to achieve the maximum reduction in the long-term total risk of cardiovascular morbidity and mortality. There are several strategies for achieving therapeutic goals: life style modifications, pharmacological modifications and general strategies for hypertensive therapy.

### Lifestyle modification<sup>[10]</sup>

- DASH diet (rich in fruits, vegetables, low fat dairy products, potassium and calcium).
- Regular physical aerobic activity such as walking at least 30 minutes/day.
- limit alcohol consumption.
- Salt reduction.
- Reduction of weight to BMI of 25kg/m<sup>2</sup>.
- Smoking cessation.

### Quality of Life

Quality of life (QOL) is a broad term that includes attributes such as environment, income, living standards, etc. besides health status. The aim of measuring QOL is to provide information about the wellbeing of the population at large. WHO has defined QOL as ‘an individual’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.<sup>[11]</sup>

Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life

expectancy and causes of death and focuses on the impact health status has on quality of life. Information about the impact of pharmacotherapy on HRQOL can provide additional data for making decisions regarding medication use. In HRQOL research, the quality of the data collection tool is the major determinant of the overall quality of the result. Generic instruments cover the complete spectrum of function, disability and distress of the patient and are applicable to a variety of population and conditions. Specific instruments are focused on disease or treatment issue particularly relevant to the disease or condition of interest. General health profiles offer a number of advantages to the clinical investigator. Their reproducibility and validity have been established often in a variety of populations. When using them for discriminative purposes, one can examine and establish areas of dysfunction affecting a particular population. Identification of these areas of dysfunction may guide investigators who are constructing disease-specific instruments to potentially target areas with the greatest impact on the quality of life. Three widely used instruments are the quality of well-being scale, the health index, Euroqol (EQ5), Short Form 36 Health Survey (SF-36).

The SF-36 questionnaire consists of 36 items and is divided into eight domains. For each domain, the items were coded and transformed into a scale from zero (worst QoL) to 100 (best QoL), according to the standardization in the manual. SF-36 can also be categorized into two grouped components. The physical component (physical component summary-PCS), which consists of the grouping of the functional capacity, physical aspects, pain and general health status domains; and the mental component (mental component summary -MCS), which consists of the grouping of the vitality, social aspects, emotional aspect, and mental health domains. A single item is also included that identifies perceived change in health, making the SF-36 a useful indicator for change in QoL over time and treatment.

### Specific Instruments

An alternative approach to HRQL measurement is to focus on aspect of health status that are specific to the area of primary interest, MINICHAL was developed in Spain in 2001 and it contains multiple choice 16-question. Questionnaires organized in 2 factors: Mental Status and Somatic manifestations and 1 question to assess the patient's perception of how hypertension and its treatment have influenced his/her quality of life. The patient should answer the questions considering the 7 perceiving days. The domain mental state includes questions 1-9 and has a maximum score of 27 points. The domain somatic manifestations include questions 10 to 16, with a maximum score of 21 points.<sup>[13]</sup>

### AIM AND OBJECTIVE

Aim of the study is to assess the impact of Quality of Life of hypertensive patients. Objectives are.

- To assess the quality of life of hypertensive patients.
- To assess the role of pharmaceutical care in improving quality of life among hypertensive patients.
- Assessing the various risk factors for hypertension.

### METHODOLOGY

#### Study Location

The study was carried out in the General Medicine Department of a 500-bedded tertiary care hospital attached with drug information centre.

#### Study duration

The study was carried out for a period of 9 months.

#### Study Criteria

Inclusion Criteria: Patients within the age group of 18years and above both men and women Exclusion Criteria: Bed-ridden patients, Gestational hypertension.

#### Literature Survey

An extensive literature survey was carried out regarding assessment of hypertension related quality of life using SF-36 health Survey and Specific Minichal questionnaire. The literatures were collected from various sources including journals.

**Health Related Quality of Life (HRQoL)** was assessed using SF-36 Health Survey Questionnaire and Specific Minichal questionnaire. SF-36 questionnaire are categorized into 8 domains: Physical functioning, General health, Limitation due to emotional, Limitation due to Physical health, Energy, Social functioning, Pain, Emotional wellbeing. Minichal questionnaire categorized into two domains: Mental domain and Somatic manifestations.

#### Data Collection

Screening of the patient done based on the inclusion and exclusion criteria. 106 patients are included and categorized into 2 groups: 53 patients are under Intervention group and 53 under control group. They were randomly assigned to control group and the interventional group. The patients' data filled on a data entry form.

#### Statistical analysis

Statistical Analysis was done using SPSS 19.0 Version. Categorical variables were described by frequencies and percentages. Paired- t test were used to compare Baseline and follow up in intervention and usual groups. Student t-test (between study groups) was used to compare and Mean values at 95% confidence intervals were also estimated. P-Value <0.05 was considered as Statistically Significant.

### RESULTS AND DISCUSSIONS

The study was carried out in a 500-bedded tertiary care hospital. A total number of 112 patients approached for screening who met the inclusion criteria. Among them 6

were not interested. Informed Consent and Baseline characteristics were obtained from 106 patients. They were assessed for Quality of Life using SF-36 health survey and Minichal questionnaire. Randomization was done and 53 patients were allocated to control group and 53 to interventional group. Intervention group received patient education with Patient Information Leaflet (PIL) through pharmacists in addition to general Health Care.

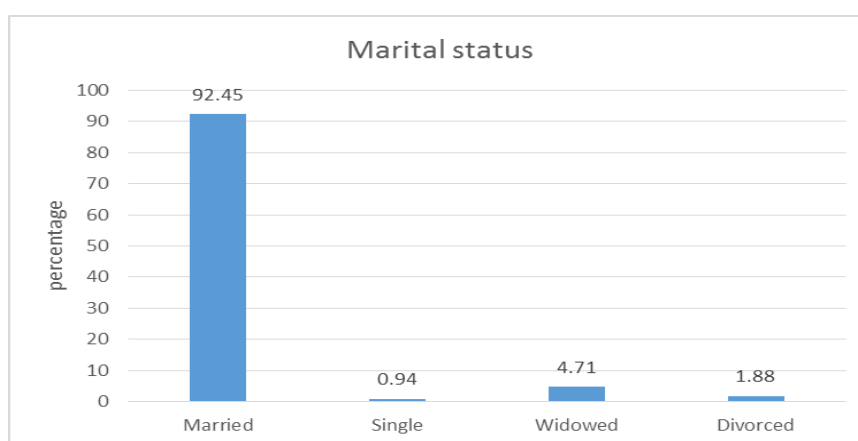
The demographics details of the patients are as follows.

**a) Distribution of patients with respect to gender (N=106) Table 2.**

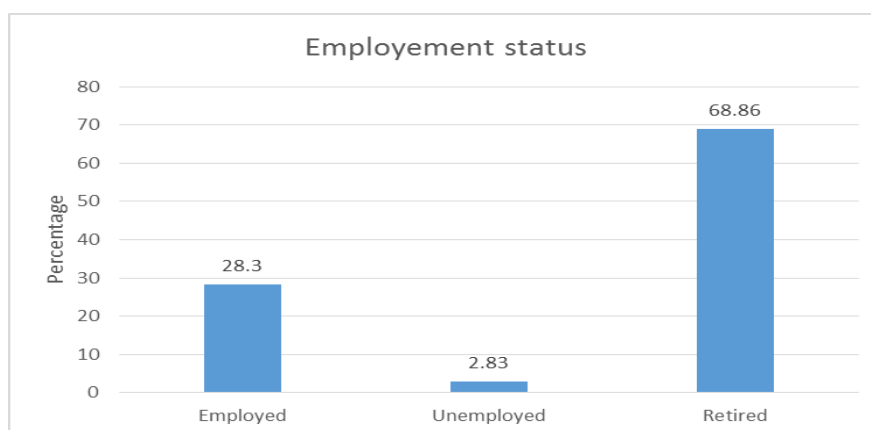
GENDER	NO. OF PATIENTS	PERCENTAGE (%)
MALE	62	58.49
FEMALE	44	41.51
TOTAL	106	100

**B) Distribution of patients with respect to age (N=106) Table 3.**

AGE (YEARS)	NUMBER OF PATIENTS	PERCENTAGE (%)
0-20	0	0
21-40	21	88
41-60	27	25.47
61-80	77	72.64
TOTAL	106	100



**c) MARITAL STATUS (Fig 1)**



**d) EMPLOYEMENT STATUS (Fig 2)**

**CHARACTERISTICS OF STUDY PARTICIPANTS**

The major patient population were under 61-80 age group, the mean Age of 64.36. About 58.49% of the patients were men and 41.50% female. Among 106 patients 14.29% were having family history of hypertension, 18.09% are obese, 17.14% were taking high fatty food, 20.00% were taking salty food, 4.76% having hypertension due to stress, 8.57% due to lack of physical activity, 12.38% of the patient were smokers,

9.52% were alcoholic and 28.57% were having other diseases.

92.48% were married, 0.94% single, 4.7% widowed and 1.88% divorced. Population with employment status 28.30% were employed, 2.83% unemployed and 68.86% retired.

**PRE-AND POST SF-36 HEALTH SURVEY OF HEALTH-RELATED QUALITY OF LIFE (Intervention Group) (Table 4).**

Health Related Quality of Life	Mean	SD	P value
Physical functioning			
Baseline	476.41	121.53	0.0143
Follow up	500.94	79.95	
General health			
Baseline	179.24	42.10	0.0037
Follow up	196.69	51.19	
Energy			
Baseline	192.45	83.77	0.0005
Follow up	215.84	77.09	
Pain			
Baseline	105.37	15.46	0.0023
Follow up	120.28	18.56	
Social functioning			
Baseline	97.16	41.21	0.0001
Follow up	123.20	41.12	
Emotional well being			
Baseline	158.11	30.95	0.0001
Follow up	180.37	37.51	
Role of limitation due to Physical health			
Baseline	109.43	92.53	0.0001
Follow up	124.52	82.98	
Role of limitation due to Emotional			
Baseline	84.90	74.41	0.0001
Follow up	98.11	60.41	

**Comparison of impact of hypertension on individuals before and after providing pharmaceutical care using SF-36 questionnaire (Intervention Group)**

**Pre and Post Sf-36 Health Survey of Health Related Quality of Life(Control Group) (Table 5).**

Health Related Quality of Life	Mean	SD	P value
Physical functioning	478.30	128.41	0.018
Baseline	484.90	121.12	0.018
Follow up			
General health	180.66	40.02	0.0239
Baseline	183.01	39.45	
Follow up			
Energy	190.56	78.01	0.0330
Baseline	192.83	76.57	
Follow up			
Pain	102.26	15.67	0.0239
Baseline	104.15	14.50	
Follow up			
Social functioning	98.11	39.48	0.0169
Baseline	102.83	38.18	
Follow up			
Emotional well being	152.07	32.18	0.0014
Baseline	159.62	29.21	
Follow up			
Role of limitation due to Physical health		54.27	0.1593
Baseline	111.32	49.59	
Follow up	115.09		
Role of limitation due to Emotional			
Baseline	90.56	74.06	0.1593
Follow up	94.33	71.83	

**Comparison of impact of hypertension on individuals before and after the treatment without providing pharmaceutical care using SF-36 Questionnaire (Control group)**

Quality of Life for Hypertensive patients (SF-36 health survey) showed Statistical significance for 8 domains in intervention and control group. In intervention group, physical functioning  $P=0.0143$ , general health  $P=0.0037$ , energy  $P=0.0005$ , social functioning  $P=0.0001$ , emotional wellbeing  $P=0.0001$ , role of limitation due to physical health  $P=0.0001$ , role of limitation due to emotional  $P=0.0001$ . In control group physical health  $P=0.0181$ , General health  $P=0.0239$ , energy  $P=0.0330$ , pain  $P=0.0239$ , social functioning  $P=0.0169$ , emotional wellbeing  $P=0.0014$ , role of limitation due to physical health  $P=0.1593$ , role of limitation due to emotional  $P=0.1593$  ( $P$  value is less than 0.05, showed statistical significance and  $P$  value less than 0.0001 showed extremely significant).

#### PRE-AND POST SURVEY USING MINICAL QUESTIONNAIRE (Intervention Group) (Table 6)

Health related quality of Life	Mean	SD	P value
Mental domain	15.81	2.96	0.0001
Baseline			
Follow up	9.66	3.06	
Somatic domain			
Baseline	12.94	2.96	
Follow up	6.20	3.06	0.0001

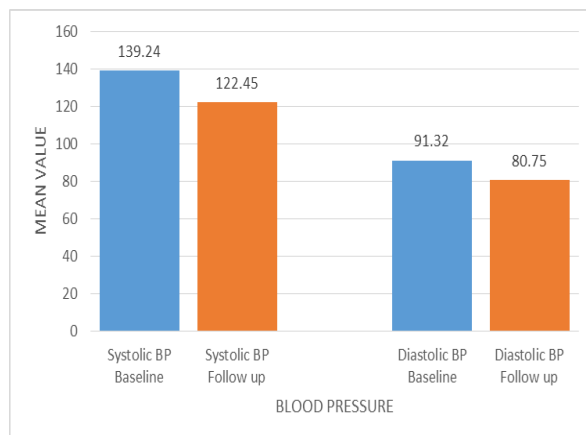
#### Comparison of impact of hypertension on individuals before and after the treatment providing pharmaceutical care using Hypertension Specific Minical questionnaire (Intervention Group)

#### Pre and Post Survey Using Minical Questionnaire (Control Group) (Table 7)

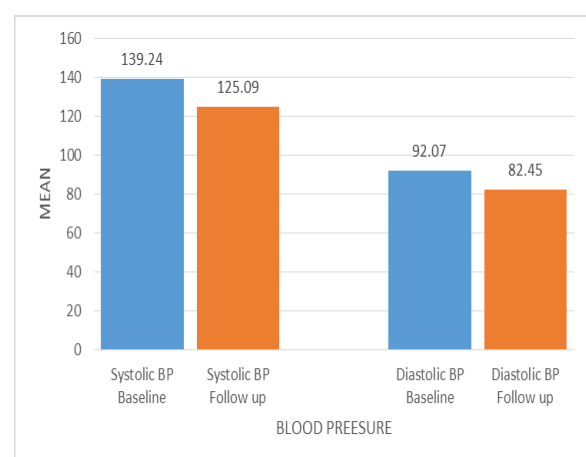
Health related quality of Life	Mean	SD	P value
Mental domain	15.49	4.05	0.045
Baseline			
Follow up	14.66	3.93	
Somatic domain			
Baseline	12.79	3.06	0.0001
Follow up	10.86	2.28	

#### Comparison of impact of hypertension on individuals before and after the treatment without providing pharmaceutical care using Hypertension Specific Minical questionnaire (Control Group)

According to Minical questionnaire, showed significance for 2 domains in both intervention group and control group. In intervention  $P=0.0001$  for mental domain and  $P=0.0001$  for somatic manifestation. In control group  $P=0.045$  for mental health and  $P=0.0010$  for somatic manifestations.



Comparison of systolic blood pressure and diastolic blood pressure before and after providing pharmaceutical care (Intervention Group) (Fig 3)



Comparison of systolic blood pressure and diastolic blood pressure before and after the treatment without providing pharmaceutical care (Control Group) Graph 4.

While comparing intervention group and control group, the study showed more statistically significance in intervention group than control group. At baseline, patients were at therapeutic goals of SBP, DBP. After 3 months of follow up intervention group showed statistically significant increase in the percentage of patients who achieved therapeutic goals in SBP and DBP when compared with control group. Control group also showed some statistically significant. Despite, evidence suggests that pharmacist intervention is beneficial for patients with hypertension.

#### CONCLUSION

The study showed significant clinical improvement of outcome through pharmacist based care in hypertensive patients. The pharmacist based education regarding the disease condition, medication and life style modification for individual patients depending their condition.

Study concluded that compared with control group, the intervention group in which the pharmaceutical care program delivered by clinical pharmacist, significantly

improved mean systolic blood pressure and diastolic blood pressure and quality of life of hypertensive patients.

#### REFERENCES

1. Kumar, Abbas, Fausto, Aster. Robbins, Cotran. Pathologic Basic of Disease. 8<sup>th</sup> edition; Page number, 492-495.
2. Fadela Chaib. New Data Highlight Increases in Hypertension, Diabetes Incidence [internet]. WHO New Release, 2012.
3. Rajeev Gupta and Soneil Guptha. Strategies for initial management of hypertension. Indian Journal of Medical Research, 2010; 132(5): 531-542.
4. Richard A Helms, David J Quan, Eric T Herfindal, Dick R Gourley. Text Book of Therapeutics Drug and Disease Management. 8<sup>th</sup> edition, 451-481.
5. Brunton, Chabner, Knollman. Goodman and Gilman's – The pharmacological Basics of therapeutics. 12<sup>th</sup> edition, 767.
6. Lippincott Williams and Wilkins. Kaplan NM: Kaplan's Clinical hypertension. 9<sup>th</sup> edition; Philadelphia, 2006; 1-518.
7. Joseph T Dipiro, Robert L Talbert, Gary C Yee, Gary R Matzke, Barbara G Wells, L. Michael Posey. Pharmacotherapy- A pathophysiologic approach. 8<sup>th</sup> edition, 102.
8. Babbette D Lamarca, Jeffery Gilbert, Joey P Granger. Recent Progress Toward the understanding of the pathophysiology of Hypertension During Preeclampsia; Hypertension, 2008; 51: 982-988.
9. National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. Fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. Pediatrics, 2004; 114(2): 555-576.
10. European Agency for the Evaluation of Medical Products (EMA), Committee for Proprietary Medicinal Products (CPMP). Reflection Paper on Health-Related Quality of Life in the Evaluation of Medicinal Products, 2006.
11. Brian L Strom, Stephen E Kimmel, Sean Hennessy. Pharmacoepidemiology. 5<sup>th</sup> edition, 709-7.
12. Badla C, Roca-Cusachs A, Dalto A, Gascon G, Abellan J, Lahoz R, et al. Validation of the short form of the Spanish hypertension quality of life Questionnaire (MINICHAL). Clin Ther, 2002; 24(12): 2137-54.