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Assessment of Proportion of Resistant Hypertension and Quality of Life Among Patients with Chronic Kidney Disease: A Prospective Study in A Tertiary Care Centre Kerala

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Abstract

Aim and Objectives: Aim is to assess the proportion of resistant hypertension by analyzing the prescribing pattern of antihypertensive and quality of life in patients with chronic kidney disease. **Methods:** This is a prospective observational study with a minimum sample size of 100. Data was collected from those who met the inclusion criteria after obtaining a written informed consent. BP readings and list of antihypertensive prescribed was recorded and the patients were assessed for their blood pressure control. A proper counseling on diet and lifestyle modification was given to each patients and they were assessed for quality of life with KDQOL questionnaire. The statistical analysis was done with SPSS software program and Chi-square tests showed the level of significance with a P value of <0.05. Results-Out of 93 CKD patients selected, 40 (43%) patients were having poly therapy, means that majority of the patients required multiple drug therapy to control their blood pressure at the targeted level. The percentage distribution of drugs was showed that Diuretics were the most prescribed class of drugs comprises 86%. The least prescribed one was ARBS and none of the ACE inhibitors were prescribed. 73.1% of the total population was identified as having resistant hypertension, among which 52 patients with uncontrolled blood pressure. The 10 domain analysis showed that the quality of life among CKD patients improved. General health was one among the significantly affected domains of the KDQOL and increased to an average score of 62.5±14.59% (p=0.0015). An average score of 43.87±24.03% was observed for emotional wellbeing and was found to be better than the General Health and it was statistically significant (p<0.018). Issues related to kidney disease had an average score of 74.02±8.35, which indicates the better QOL after counseling. **Conclusion:** As resistant hypertension is a phenomenon which remains easily undiagnosed due to under presentation and because the symptoms are not very specific, it is important to consider this disorder in patients with CKD. For patients with CKD, health education focusing on disease and need for long term treatment, also the diet and life style

changes provided by the clinical pharmacist plays an important role in improving the ability to cope up with illness and health status. Pharmacists are in an ideal position to provide patient education and optimize patient care. Greater understanding about the illness and a change of diet and lifestyle would in turn results in a better therapeutic outcome.

Keywords
Resistant Hypertension, Antihypertensive, Chronic Kidney Disease, Quality of Life.

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INTRODUCTION

Resistant hypertension is defined as a condition in which blood pressure remains above 140/90 mm Hg despite the use of 3 antihypertensive (including a diuretic), or a controlled BP by the use of greater than or equal to 4 antihypertensive (including a diuretic).

A scientific statement from the American Heart Association (AHA) has recently highlighted the need to improve awareness and knowledge of resistant hypertension, which remains limited despite the presumed high cardiovascular (CV) risk associated with this condition. In this context, evaluation of CKD patients is highly relevant for two reasons. First, the prevalence of renal disease is rapidly rising worldwide with approximately 10% of the adult population currently affected. Notably, 65–95% of CKD patients develop hypertension as the glomerular filtration rate (GFR) declines from 85 to 15 ml/min and hypertension constitutes a major risk factor for the progression of renal disease, as well as to the high CV risk observed from the early stages of CKD. Second, the burden and importance of resistant hypertension in CKD is currently unknown.

Hypertension is a chronic disease that affects 10-15% of adult population in India. One third of who are unaware of their condition. It is a significant risk for cardiovascular morbidity and mortality and may also leads to stroke, myocardial infarction, blindness and renal failure. Concerning hypertension control in CKD, BP is controlled in less than 20% of patients with CKD in many countries. With this projected increase in prevalence rates of HTN associated with CKD, the prescription volume of antihypertensive drugs is expected to assume an upward trend especially in India where health care services are sub-optimal for the rapidly expanding population.

The prevalence and incidence of resistant hypertension among CKD patients are high, but resistant hypertension is often underdiagnosed and undertreated in these patients. Inadequate treatment for resistant hypertension leads to insufficient care, poor quality of life, and premature death. Several risk factors are well known to predict resistant hypertension in CKD patients: BMI, age, gender, diabetes, smoking, dyslipidemia, and poor quality of life [1]. If the link between resistant hypertension and commonly used drug pattern becomes clear, physicians could respond by screening such patients for improved clinical care to limit the complications. This would increase the rate of diagnosis and adequate treatment of resistant hypertension [2].

As resistant hypertension is a clinical condition which remains easily undiagnosed due to under presentation and because the symptoms are not very specific, it is important to consider this condition in patients with CKD. Understanding the nature of blood pressure control and treating them is important for improving a patient's quality of life, maximizing healthcare utilization and treatment out comes [3].

There is an increased risk of re hospitalizations in patients with resistant uncontrolled blood pressure. In emergency department patients, the presence of resistant uncontrolled blood pressure is associated with significantly higher admission and relapse rates [4].

Given the significant burden associated with presence of uncontrolled blood pressure in patients with CKD, screening and early treatment of resistant hypertension despite of uncontrolled or uncontrolled BP is considered to be important [5].

The above mentioned issues motivated us to undertake the present study which is aimed at determining the proportion of resistant hypertension and prescribing pattern of antihypertensive in patients with Chronic Kidney Disease.

PATIENTS AND METHOD

Study duration: The study was conducted for a period of 6 months from (December 2018 to May 2019)

Study setting: The study was conducted at Nephrology department of Cosmopolitan Hospital, a tertiary care Centre.

Inclusion Criteria

a) Age above 18 years.

b) Patients with CKD, receiving antihypertensives.

Exclusion Criteria

a) Pregnant women

b) Patients with other psychiatric disorders.
c) Inpatients with CKD.
d) Patients who are not willing to participate in the study.

STUDY PROCEDURE

A written informed consent was taken in prescribed format from the patients diagnosed with CKD satisfying the inclusion and exclusion criteria. All information relevant to study was collected from case records and direct interview with patients, which was documented in the proforma. The blood pressure readings were recorded on each visit during study period. The patients were reviewed for four follow ups. By observing the prescription of each patient, the number of patients with resistant hypertension is identified based on the criteria. The prescribed drug regimen was analyzed based on JNC-8 recommendations for BP control in CKD and we categorized them as OPTIMAL and SUB OPTIMAL REGIMEN. Optimal regimen includes the treatment with any of the classes of antihypertensives except ACE inhibitors and ARBs. The suboptimal regimen includes either single therapy or combination therapy with ACE inhibitors and ARBs. A structured interview with patient or care giver was conducted by using questionnaire to elicit information about their life style and dietary habit. Also we assessed the impact of kidney disease in their daily life using KDQOL-SFTMv1.3 questionnaires. Proper counseling about drugs and diet was given to the patients, especially those with uncontrolled blood pressure by using validated Patient Information Leaflet. The counseling was provided at each visit at OPD and the changes in the score was recorded. The outputs were statistically plotted.

The KDQOL-SFTM v1.3 questionnaires we are using is a validated questionnaire that contains 36 item health survey.

STATISTICAL ANALYSIS

All the data were represented as frequency and percentage distribution. The association between qualitative study variables was assessed by Chi-square test (if the cell frequency is <5, then appropriate continuity correction was made). A calculated P value <0.05 is considered to be statistically significant. All the analysis was done using SPSS, version 22.0.

RESULTS

There are total of 100 patients who visit the outpatient department of Nephrology Unit enrolled in the study. But out of this 100, there were 6 drop out, due to lost follow up and one death. Hence the final sample size from which the result obtained was 93. The collected data were analyzed and different outputs were obtained.

The results on gender characterization among 93 CKD patients revealed that out of 93 patients 62 (66.7%) patients were males and 31 (33.3%) were females. It suggests that majority of patients were males compared to females. Majority of patients were in the age group between 61-80 years that is 64 patients (68.8%) and the least were in the age group of 20-40 years that is 3 patients (3.2%). The patients in the age group of 41-60 years were 19 (20.4%) and the patients in the age group of greater than 80 years were 7 (7.5%).

The personal history analysis was as follows- out of 93 patients 25 (26.9%) patients were either current or past smokers and 68 (73.1%) patients were non-smokers. This suggests that the percentage of non-smokers is greater when compared to smokers. Also the percentage distribution of sample according to the status of alcohol consumption showed that 37 (39.8%) patients had the habit. It also includes the number of ex-alcoholics also. 56 (60.2%) patients were not having the habit. While analyzing the dietary style among the study participants, we found that 6 (6.5%) patients were vegetarians, 69 (74.2%) patients were having mixed diet status, and 18 (19.4%) patients were having non-vegetarian diet pattern. Hence it was understood that majority of patients had mixed diet routine than single routine.

The family history analysis showed that 19 (20.4%) patients were having history of HTN, 25(26.9%) patients were having history of DM, and 33 (35.5%) patients were having both HTN and DM. There were 6 (6.5%) number of patients having history of CKD itself and the data analysis showed that 9 (9.7%) patients were devoid of family history of any of the diseases. Interestingly one patient had the history of all the three diseases. Hence the analysis showed that there exists a family history of lifestyle diseases for majority of the patients. The figure 1 represents the percentage distribution of sample according to antihypertensive drug therapy pattern. The pattern of antihypertensive drug therapy was classified as Mono therapy uses only one drug, Dual therapy use two drugs, Triple therapy and Poly therapy which uses three antihypertensives and more than three respectively to achieve the goal BP. Out of 93 CKD patients selected, 2 (2.2%) patients were found to mono therapy distribution, 15 (16.1%) patients were having dual therapy, 36 (38.7%) patients were having triple therapy, and 40 (43%) patients were having poly therapy. From this data it is evident that majority of the patients required multiple drug

therapy to control their blood pressure at the targeted level.

The figure 2 describes the various classes of antihypertensives prescribed in the management of hypertension. The different class of anti hypertensives used in the management of hypertension in CKD were Diuretics, Calcium channel blockers, α Blockers, β Blockers, Direct vasodilators and Centrally acting sympathomimetics.

The percentage distribution of these classes of drugs was showed that Diuretics were the most prescribed class of drugs comprises 86%. Calcium channel blockers were prescribed at a frequency of 81.8%, followed by α Blockers 63.4%, β Blockers 37.65, Direct vasodilators 11.8%, and α+β blockers 10.8%. The least prescribed one was ARBS and none of the ACE inhibitors were prescribed. The above mentioned agents are beneficial in controlling the blood pressure in CKD. The following graph shows the prescribing pattern.

The main objective of the study was to find out the prescribing pattern of anti hypertensives and to find out the proportion of resistant hypertension. In figure 3 explains that 73.1% of the total population was identified as having resistant hypertension. This makes the number of 68 out of 93 populations. 26.9% of the population was without resistant hypertension.

Hence the proportion of resistant hypertension in chronic kidney disease was found to be 73.1%. It was found that the result was statistically significant (P 0.002).

Among the patients treated with mono therapy 100% (2out of 2) were found to have controlled BP. In the patients managed with duel therapy the distribution was equal (50% each). Among those patients who were treated with triple therapy, 35.1% of patients were having controlled BP and 64.9% of patients were having uncontrolled BP. When observing those patients who were managed with polytherapy 10.5% of patients were found to be having controlled BP and 89.5% of patients with uncontrolled BP. It can be assed that even though the patients are receiving polytherapy majority of the patients had uncontrolled BP. Figure 4 represents the association of blood pressure control and the mode of drug therapy.

73% patients were found to have resistant hypertension among with16 patients were diagnosed with controlled blood pressure and 52 patients with uncontrolled blood pressure. 27% patients were detected to have non-resistant hypertension. From that patients, 11 were diagnosed to have controlled blood pressure while 14 patients with uncontrolled blood pressure (table 2).

The association of diet and blood pressure control was analyzed using statistical method. It showed that there was an association between diet and BP control which is statistically significant (p 0.005*). The figure 4 describes the relationship as majority of the patients (53 patients) with uncontrolled blood pressure was having mixed diet. Also in vegetarians and non-vegetarians the number of patients with uncontrolled BP was found to be 4 and 9 respectively.

Proper counseling about drug and diet was given to the patients at each visit and the effect on patient quality of life was recorded on KDQOL. The 10 domain analysis showed that the quality of life among CKD patients improved. The output was taken at an interval of one month. At the end of the follow up of each patient, preferably after 4 months 70 patients showed improved quality of life. The percentage distribution is illustrated in the figure 5.

From the figure 5 it is clear that all domains in the QOL assessing scale were largely affected. Considering the symptoms, it is clear that the patients QOL is very much low and the symptoms are making greatly bad effects on patient's health. The lower score of effect of kidney disease on patient's health related quality of life indicates that there is need to correct the symptoms and the emotional burdens. Overall the general health status is decreased. The baseline score level was suggestive of the role of patient counseling in patients with CKD to improve their physical and emotional wellbeing. The descriptive statistics was obtained from the SAS programme. After providing proper counseling about drugs, diet and life style modifications the above mentioned scores was obtained. In KDQOL-SF-36 assessment the highest scores indicate better quality of life, which means 100 indicates free of disease (perfect health) and zero indicates death. In our study none of the patient attained perfect health, but majority of the patients improved their health status. General health was one among the significantly affected domain and an average score was increased to be 62.5±SD (=14.59) % (p=0.0015). An average score of emotional wellbeing also increased and was found to be better than the General Health and it was statistically significant (p<0.018). Issues related to kidney disease had an average score of 74.02±SD (= 8.35) which indicates the better drug, diet and lifestyles management offered to the patient.

The present study has revealed that there is significant correlation between physical health, Mental health and kidney function, whenever there is problem in kidney Physical and Mental health get affected. Hence it is being showed that, even though

the mental and physical health is affected by the kidney disease, effective counseling on diet and lifestyle changes can improve the patient health related quality of life.

In our study 75% of the population showed improved quality of life after receiving the counseling on each at the OPD visit. From our study it is showed that there is a need for proper counseling on diet and life style changes to improve the patient health related quality of life.

DISCUSSION

This prospective study of CKD patients in the nephrology department provided the knowledge of proportion and risks of resistant hypertension among patients with CKD. Even many patients have appreciable knowledge about their condition and the necessary lifestyle changes that have to be adopted; there were some with misconcepts and views about their lifestyle including diet, water intake etc. This misunderstanding may be one of the probable cause of delayed improvement or even worsening of health in CKD patients.

In our study, baseline characteristics like age and gender didn't' show any significant association with the occurrence of resistant hypertension. In a study done by AM Makiusidi et.al, where prevalence of resistant hypertension has been assessed rather than the proportion, 82% patients were found to have resistant hypertension with 18% patients achieving target BP goal [6]. In this study, resistant hypertension was common in males (73%) compared to females (63%), which is in contrast to our study where there are no such common trends. When it is compared to our results, there were 73% patients with resistant hypertension; out if which 23.5% of patients were achieving BP control also in this study the most commonly used drug class combinations were that of ARBs, ACEIs, CCBs and diuretics. But in our study, drug class combinations including ACEIs/ ARBs are prescribed for nobody and multiple anti hypertensives used to manage a CKD patient mostly included a diuretic, a CCB or a beta blocker or a calcium channel blocker, or a centrally acting sympathomimetic agent. The rate of drug compliance was 53% and resistant hypertension was found to be more common among manual workers (71%) followed by students (68%) and traders (66%). In our study, we couldn't find such relations and also, medication compliance couldn't be assessed.

When we assessed the association of personnel habits like smoking and alcoholism in CKD, it was showed to have no association. The majority of our study population was non-smokers and non-alcoholics. Our finding was contrast to the study carries out by Pan CS, et al in 2018. In their retrospective cohort study through database analysis, they concluded that Alcohol Use disorder was associated with an increased incidence of CKD by nearly two folds [7].

Among the study population of CKD patients, 73.1% patients were having resistant hypertension who met the criteria for resistant hypertension, as per JNC 8 guidelines (i.e. those who remain above the goal BP of 140/90mmHg for those without proteinuria and 130/80mmHg for those with proteinuria, despite the use of ≥3 antihypertensive medications among which one is a diuretic). Despite increased awareness about hypertension, CKD and its complications, the status of BP control was disappointing. 29% patients had controlled blood pressure while 71% patients had uncontrolled BP. A study in which patients are classified based on their 24-hour ambulatory blood pressure monitoring and absence or presence of resistant hypertension have shown a true resistance of 23% or sustained hypertension without resistant hypertension of 43% among CKD patients [26]. But in this study, the criteria used to define resistant hypertension was an office BP≥130/80 mmHg on 3 or more full dose drugs including a diuretic agent or any office BP if the patient is on 4 or more drugs and prescribing pattern of antihypertensive was not assessed in this study. In our study, ambulatory BP monitoring couldn't be performed.

When analyzed the mode of drug therapy, 43% patients were managed with poly therapy followed by triple therapy where 38.7% patients were prescribed with 3 drugs concomitantly. Diuretics (86%), especially, loop diuretics were the mostly prescribed agents among the antihypertensive, followed by CCBs (81.8%), alpha blockers (63.4%), beta blockers (37.6%), centrally acting symapthomimetics (25.8%), direct vasodilators (11.8%), alpha and beta blockers (10.8%), ARBs (9.7%) and centrally acting sympathomimetic (25.8%). Elevated levels of aldosterone are common in resistant hypertension and excess fluid volume also plays a major role in the pathogenesis of resistant hypertension in Chronic Kidney Disease, hence patients with edema or any other signs of excess fluid should be treated with diuresis. Both diuretics and beta blockers may be required for patients with both edema and tachycardia. Elevated systemic vascular resistance may require an increased vasodilator dose. Also, evidences suggesting existence of a catecholamine excess in resistant hypertension require use of a beta blocker in CKD.

In our study, newer antihypertensive drugs such as Azilsartan, an ARB, Benidipine, a calcium channel

blocker and Moxonidin, a centrally acting sympathomimetic agent were used to achieve BP control in CKD patients. In patients with diabetic nephropathy, a new DPP4 inhibitor, Lina gliptin was used to achieve optimum blood sugar levels. But our study didn't focus to the parameter 'heart rate' which is needed to assess the rationale of prescribing beta blockers.

In a cross sectional study done by Markus P Schneider et.al to assess BP control in CKD patients where resistant hypertension is confirmed by the mean of the 3 blood pressure measurements ≥140 mmHg systolic, or ≥90mmHg diastolic, despite therapy with three different antihypertensive drugs, including a diuretic, 51% patients with uncontrolled blood pressure were found to have resistant hypertension [8]. In our study, 79% patients with uncontrolled hypertension met the criteria for resistant hypertension. In contrast to our study, RAS inhibitors including ACE inhibitors, ARBs or Renin inhibitors were prescribed for 82.9% hypertensive patients. In our study, only 9.7% patients were prescribed with ARBs and nobody prescribed with ACE inhibitors for the management of hypertension in CKD.

Being adherent to the recommendations, loop diuretics were mostly prescribed in our study than any other diuretics. In contrast to our study, a study by Michele R Hanselin et.al revealed the finding that ACEIs and/or ARBs (96.2%) were the most prescribed antihypertensive followed by diuretics and the most common subclass of diuretic was thiazide [9]. The most common β blockers were metoprolol and atenolol. But in our study, the mostly used diuretic was loop diuretics and bisoprolol was the β blocker. In contrast to our study, hydrochlorothiazide was highly used than chlorthalidone irrespective of the evidences that Chlorthalidone is more effective thiazide diuretic than hydrochlorothiazide. In our study, Chlorthalidone is the only prescribed thiazide like diuretic. Like our study, dihydropyridine CCBs were greatly used than non dihydropyridines. This study also uses the same criteria as our study to define resistant hypertension. Irrespective of the evidences and recommendations, Aldosterone antagonists were also had a lower rate of use in resistant hypertension.

Our study proved that there exists a strong association between diet and blood pressure control with a p value of <0.05. Also revealed the necessity of DASH like diet in CKD patients, who are hypertensive. In achieving the targeted BP goals, along with proper drug regimen dietary modifications are needed. This finding was supported by the research work carried out by Yang Liu et al. I n their study they concluded as, low accordance to a DASH- like diet was not associated with incident CKD, but was associated with higher risk of rapid decline in eGFR among those with hypertension [10].

Since non medication adherence may be considered as a cause of resistant hypertension, it's a limitation of the study that monitoring of medication adherence couldn't be performed. Truly resistant hypertension can actually be classified into four types, which is not mentioned in our study. Also, pseudo resistance and non- adherence are not properly assessed in our study. Our study didn't assess certain parameters such as heart rate, GFR, and the correlation with the certain laboratory parameters and the disease.

CONCLUSION

Antihypertensive treatment can slow the progression of CKD to renal failure; however, the treatment of hypertension can be challenging among CKD patients because of the bidirectional cause and effect relationship between hypertension and CKD. Additionally, hypertensive CKD patients often require treatment with multiple antihypertensive drugs.

In the present study, we sought to gain a more comprehensive understanding of antihypertensive drug prescribing patterns, BP control status, and the proportion of resistant hypertension among hypertensive patients with CKD. Initially we identified that there was no significant association between socio demographic factors and development of resistant hypertension, but is associated with diet and family history of the patient. Since hypertensive CKD patients are more likely to have resistant hypertension, these findings may assist clinicians to provide more targeted risk management and CKD stage specific antihypertensive treatment for patients at high risk of adverse outcomes.

In summary, we found that JNC 8 guideline-recommended ACEI/ ARB-based therapy was not prescribed large sum of patients with CKD. Although ACEI/ARBs based regimen is encouraging, there are still a substantial proportion of patients who are not being afforded the benefits of these Reno protective agents. Our findings may be especially useful for patients who need ≥3 drugs to control BP and ultimately reduce adverse outcomes. Among these patients, clinicians may select CCB + diuretic as add on to Adrenergic antagonists or Centrally acting agents or a direct vasodilator to better prevent the risk of cardiovascular and renal complications, including the progression of CKD. Furthermore, our

study findings may help fill knowledge gaps in the hypertension/ CKD treatment guidelines about optimal specific antihypertensive therapy for CKD patients.

Resistant hypertension is not a rare phenomenon, but the use of inadequate medical regimens for hypertension appears to be observed far more often than true resistance to a regimen that includes drug from three different classes. The group identified as resistant has many high-risk features, including a substantial burden of cardiovascular disease, stroke, diabetes mellitus, and underlying renal dysfunction. Special consideration may be needed to help mitigate these risks.

The association of resistant hypertension with adverse renal outcomes is compelling and has clinical implications for patients with CKD. Our findings underscore the need for early identification and systematic evaluation and management of patients with RH and CKD. In addition, these data support the need for novel therapeutic strategies and effective patient counseling on diet and lifestyle modifications to improve BP control in patients with CKD.

This study also points out the need of clinical pharmacist along with other healthcare professional for implementing adequate therapeutic strategies for management of hypertension in CKD patients for improving clinical outcomes and better QOL of patients. For patients with CKD, health education focusing on disease and need for long term treatment, also the diet and life style changes provided by the clinical pharmacist plays an important role in improving the ability to cope up with illness and health status. It is also effective in accomplishing certain treatment related goal like controlled blood pressure, optimal glycemic control etc. Pharmacists are in an ideal position to provide patient education and optimize patient care. Greater understanding about the illness and a change of diet and lifestyle would in turn results in a better therapeutic outcome.

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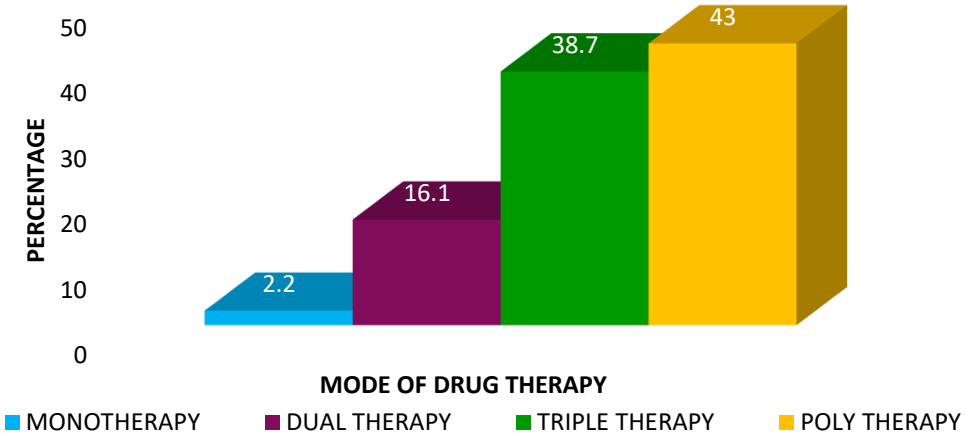
CONFLICT OF INTEREST - Nil

Fig.1 Percentage Distribution of Antihypertensive Drug Therapy Distribution



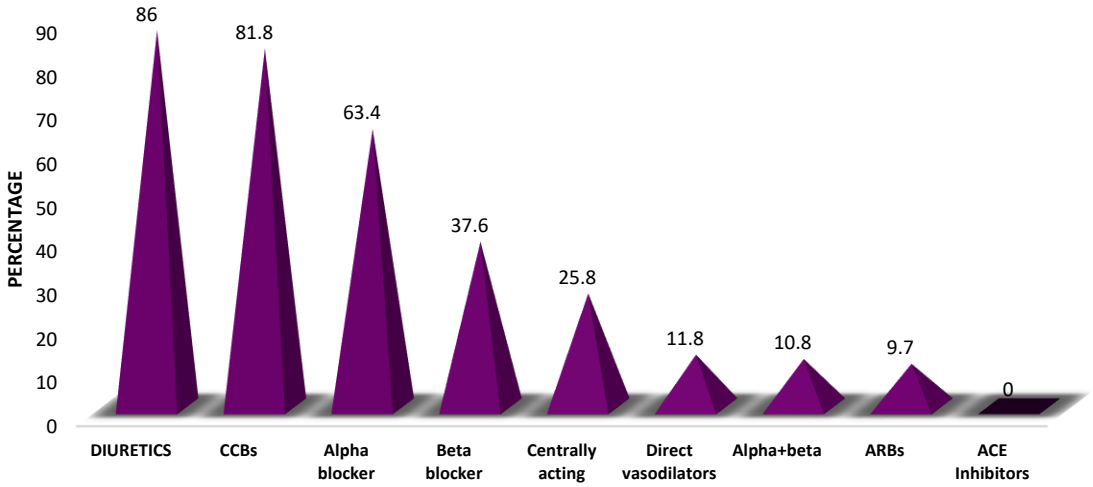


Figure 2: Percentage Distribution of Various Classes of Antihypertensives Prescribed

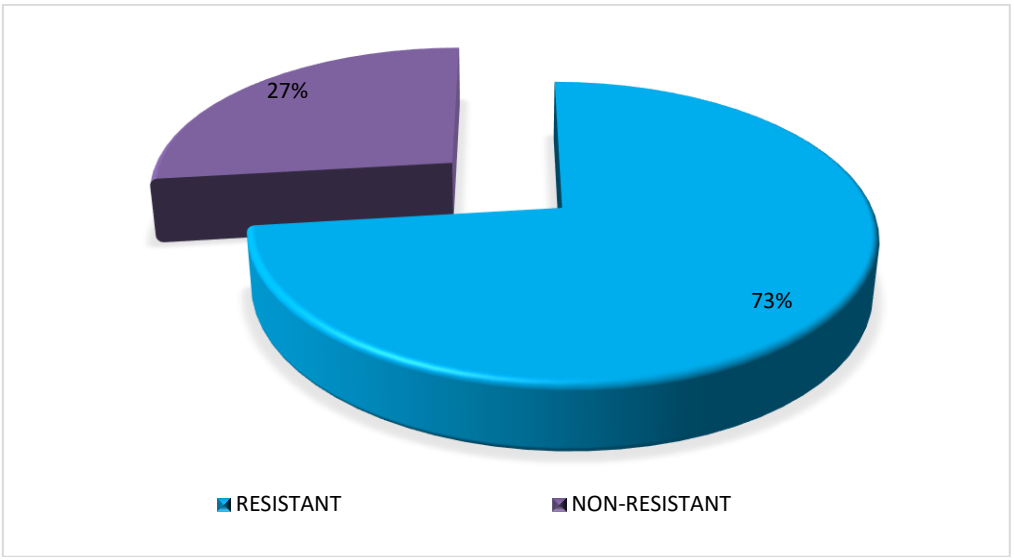


Fig. 3: Percentage Distribution of Status of Resistant Hypertension

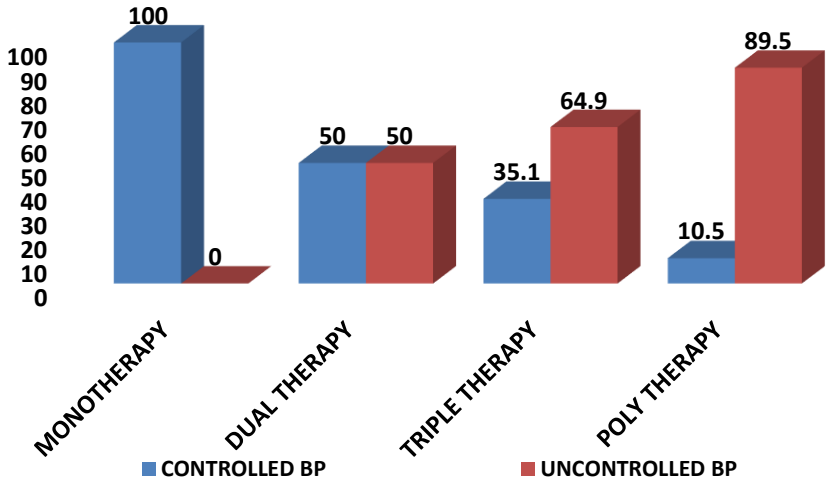


Figure 5: The Mean Of KDQOL-36 In 10 Domains Before and After Counselling

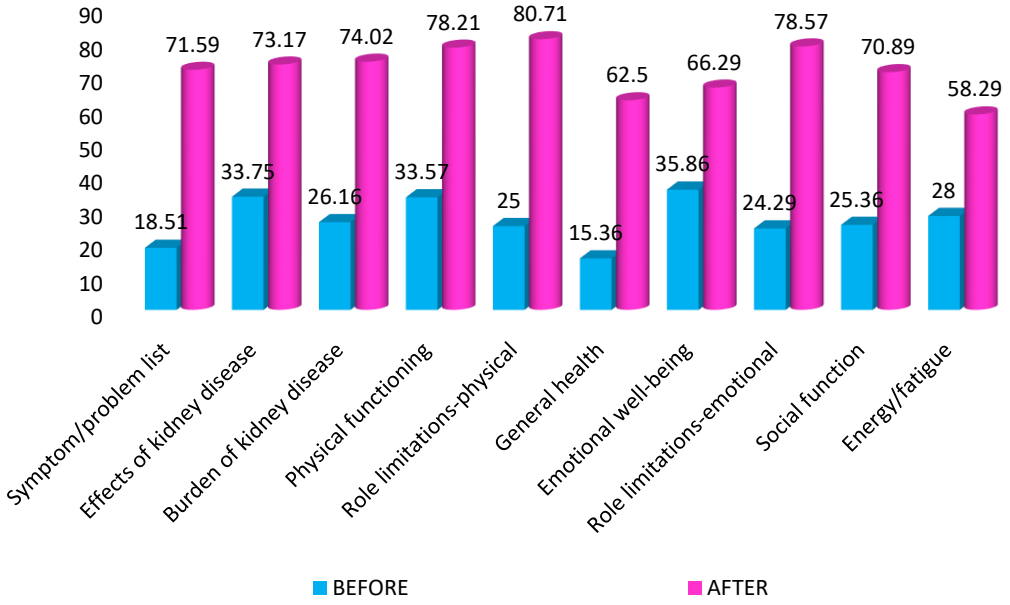


Table No 1 Socio Demographic Features

		FREQUENCY (n)	PERCENTAGE (%)
GENDER	MALE	62	66.7
	FEMALE	31	33.3
AGE	20-40	3	3.2
	41-60	19	20.4
	61-80	64	68.8
	>80	7	7.5
PERSONEL HISTORY	SMOKERS	25	26.9
	NON-SMOKERS	68	73.1
	ALCOHOLICS	37	39.8
	NON-ALCOHOLICS	56	60.2
DIET	VEG	6	6.5
	NON-VEG	18	19.4
	MIXED	69	74

Table No 2 Family History Of Diseases

	FREQUENCY (n)	PERCENTAGE (%)
HYPERTENSION	19	20.4
DIABETES MELLITUS	25	26.9
CKD	6	6.5
BOTH HTN & DM	33	35.5
ALL THREE	1	1.1
NO FAMILY HISTORY	9	9.7

Table No 3 Association Of Resistant Hypertension And Blood Pressure Control

	CONTROLLED BP		UNCONTROLLED BP		χ2	P
	n	%	n	%		
RESISTANT HTN	16	23.5	52	76.5	3.557	0.05
NON RESISTANT HTN	11	44	14	56		

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