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IMPACT OF CLINICAL PHARMACIST-LED EDUCATION ON HYPERTENSION KNOWLEDGE IN HYPERTENSIVE PATIENTS AT A TERTIARY CARE HOSPITAL, INDIA: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: The prevalence of hypertension in India has been increasing recently. In response, the Ministry of Health and Family Welfare Government of India has issued guidelines for the prevention of hypertension and its complications. It is known that reducing blood pressure in hypertensive patients and improving their knowledge about hypertension can decrease the rate of cardiovascular disease and stroke complications.

Methods: A prospective observational study was conducted over six months at a tertiary care hospital, enrolling 250 participants based on predefined selection criteria. The study aimed to determine the influence of leaflets and education provided by clinical pharmacists on hypertension knowledge. Participants' knowledge of hypertension was assessed using the Hypertension Knowledge Level Scale (HK-LS). Categorical data were analyzed by Chi-square test, while quantitative variables were analyzed using paired t-test.

Results: The study highlighted the positive impact of leaflets and educational interventions on hypertension knowledge, increasing from 25.2% to 77.2%. Participants with low knowledge decreased from 74.2% to 22.8% post-distribution of the Patient Information Leaflet (PIL), with the most significant improvement in the "complications" domain. Socio-demographic comparisons showed males had more knowledge than females, likely due to social and cultural factors such as employment status and a higher prevalence of hypertension among males. Education level was positively correlated with hypertension knowledge (P-value < 0.005).

Conclusion: Our study highlights the need for educational guidance in disease management. Clinical pharmacists can improve patient knowledge and adherence through counselling and medication reviews, thereby reducing hypertension-related complications**.**

Keywords: Awareness, Hypertension, Hypertension knowledge level scale, Knowledge, Patient Information Leaflet

INTRODUCTION

According to World Health Organization (WHO) health statistics 2023, the highest disease burden worldwide is caused by Non-Communicable Diseases (NCDs). The influence of Non-Communicable Diseases (NCDs) has been rising since 2000 and causing 74% of global deaths in 20191.Genetics, physiology, environmental and behavioural factors impact on the development of Non-Communicable Diseases (NCDs). Major risk factors of Non-Communicable Diseases (NCD) include alcohol consumption, tobacco use, obesity and hypertension.[1]

An estimated 1.28 billion adults aged 30-79 years; around the globe have hypertension in which 46% of adults with hypertension are unaware of being hypertensive.[2] The epidemiology of hypertension in India is complex and influenced by numerous factors. Studies indicate that the prevalence of hypertension in India ranges from 11.0% to 13.0%, with higher rates observed in urban areas compared to rural regions.[3,4] Undiagnosed hypertension is a significant concern, affecting around 8.14% to 13.56% of individuals, with a higher prevalence among males.[4] It is referred to as a "silent killer" as it often manifests without noticeable warning sign[5] so it is necessary to assess the knowledge regarding hypertension in various age groups [6].

Previously published studies suggested that individuals with hypertension possess limited knowledge about the normal values of blood pressure and necessary lifestyle modifications during the process of treatment.[6] Hence, consequently evaluating knowledge levels becomes pivotal in assessing awareness of hypertension within the hypertensive population and implementing preventive measures to mitigate hypertension-related complications.[7] Several instruments have been developed to assess knowledge about hypertension, such as the Hypertension Knowledge Level Scale (HK-LS) and Hypertension Knowledge Test (HKT). The Hypertension Knowledge Level Scale (HK-LS) has been employed to assess the knowledge about hypertension as it is appropriate in the Indian context.[8] HK-LS was developed in 2012 and has high satisfactory reliability and validity with Cronbach's alpha quotient of 0.82 and test-retest validity of r= 0.79. [8,9]

Awareness and treatment are crucial for controlling hypertension and reducing morbidity and mortality, particularly among the elderly. In India, the factors influencing hypertension awareness are not well understood. Leaflet media is used as an educational tool to enhance awareness of hypertension and its complications, which aids in effective management[10,11] . The study aimed to determine the influence of leaflets and education provided by clinical pharmacists on hypertension knowledge and to assess the level of knowledge about risk factors, definition, complications, compliance, diet, and lifestyle modifications

MATERIALS AND METHODS

Study design

This prospective observational study was conducted over 6 months among 250 patients at SSIMS and RC, Davanagere, Karnataka aimed to assess the knowledge regarding hypertension among hypertensive individuals and to evaluate the rationality of prescribed antihypertensive medications. Ethical approval was obtained from the Institutional Ethics Committee before the initiation of the study (BPC/IEC No.91/2022-23).

Selection criteria

Our study included participants with age greater than or equal to 18 years of either gender, patients who are previously or newly diagnosed with hypertension, type 2 diabetes mellitus, thyroid disorders (hypothyroidism /hyperthyroidism), renal diseases (chronic kidney diseases, acute renal injury, diabetic nephropathy, etc.).

Pregnant and lactating women, patients diagnosed with aphasia and dementia, neuropsychiatric disorders like depression, bipolar disorder, Alzheimer's disease, Parkinson's disease, and

schizophrenia, and patients who were not willing to give informed consent were excluded from our study

Sample size calculation:

With the reference to the literature, we assumed prevalence of hypertension to be 20%,[12] then, P= 0.020, d= precision (if the precision is 5% , then d=0.05) and Z statistic for a level of confidence is 1.96. Cochran's formula initially suggested a sample size of 246 participants but ultimately enrolled 250 participants in our study.

Data collection:

Development and validation of data collection form and patient information leaflet:

A well-constructed data collection form was developed in English and Kannada (a native language of Karnataka) and the study included participants who signed informed consent forms approved by the ethical committee and answered the questionnaire face to face. An average time of 15-20 minutes was taken to complete the questionnaire. The data collection form consists of 4 main components such as demographics and clinical status, anthropometric measurements, medication chart, and Hypertension knowledge level scale (HK-LS)

- **Sociodemographic details:** where the participants were asked about gender (male vs female), age, marital status (married, unmarried, widow, divorced), and education level (no formal education, primary, secondary, higher secondary, graduated and post-graduated), residential area (urban or rural).
- **Social habits:** where the participants were asked about their social habits like smoking, alcohol consumption, tobacco chewing, and both smoking and alcohol consumption
- **Medical condition and history:** the participants were asked about the present medical condition, other past co-morbidities and past medication history

Hypertension Knowledge Level Scale

The assessment of hypertension knowledge is done using the hypertension knowledge level scale (HK-LS). It is a 22-questionnaire scale, developed by Erkoc et al. It consists of 6 sub-divisions: Definition (2 items), Medical treatment (4 items), Drug compliance (4 items), Diet (2 items), Lifestyle (5 items) and Complications (5 items).

ASSESSMENT OF HYPERTENSION KNOWLEDGE:

1. The patients' pre-test knowledge score on hypertension was evaluated using the HKLS.
2. A well-constructed Patient Information Leaflet (PIL) containing concise information about the disease, its complications, risk factors, signs and symptoms, and potential lifestyle modifications were distributed to the patients which were developed and validated with Flesch Reading Ease score of 81.7% and Flesch- Kincaid Grade level was 3
3. Following the distribution of the PIL, patients were further encouraged to contact them in case of any queries about the disease. The knowledge of hypertension was reassessed in a post-test.
4. The scores obtained in the post-test were calculated and analyzed to determine whether the distributed PIL had a positive impact on increasing patients' knowledge levels of hypertension.

Scoring:

Patients' responses were categorized as either correct, incorrect or "don't know". Correct responses were assigned a score of one, while both incorrect and "don't know" responses received a score of zero. The maximum score for the entire scale is 22 and the minimum score across the entire scale, as well as within each sub-dimension, was zero

The HKLS scores were used to categorize patients into low and high-knowledge groups regarding hypertension. Patients with scores of 17 or below were classified as having low knowledge, while

those with scores ranging from 18 to 22 were categorized as having high knowledge concerning hypertension.
Patients were further encouraged to contact us in case of any queries about disease condition

Statistical analysis:
The statistical analysis was Performed by using SPSS software. All values are expressed in form of percentage proportions and mean. Statistical significance was set at $P \leq 0.05$. Categorical data were analyzed using the Chi-square test, while quantitative variables were analyzed using the paired t-test. Significant correlations were assessed using the Chi-square and Fisher's exact tests.

RESULTS

The study included 250 participants, comprising 148 (59.20%) males and 102 (40.8%) females, as indicated in the table. These participants were divided into three age groups, with the majority (n=153, 61.2%) falling into the >60 years category. Among them, 214 (85.60%) were married, 34 (13.60%) were widows, and 2 (0.80%) were single. A total of 124 (49.60%) participants resided in urban areas, while the remaining 126 (50.40%) were from rural areas. Regarding education, 50 (20%) were illiterate, 72 (28.80%) had primary education, 95 (38.00%) had secondary education, and 33 (13.20%) had completed graduation. Additionally, 163 (65.2%) participants had comorbidities, with Type 2 Diabetes Mellitus (T2DM) being the most common, affecting 105 (64.42%) participants. Furthermore, 212 (84.80%) participants had a prior history of antihypertensive drug usage and compliance, while 38 (15.20%) were not on any antihypertensives.

COMPARISON OF KNOWLEDGE OF HYPERTENSION AMONG HYPERTENSIVE PATIENTS USING HK-LS, BEFORE AND AFTER DISTRIBUTION OF PATIENT INFORMATION LEAFLET (PIL)

In our study, **Table 2** shows that a high level of knowledge about hypertension was present only among 25.2% of the hypertensive patients before the distribution of PIL, which was improved to 77.2% in the post-test; whereas 74.8% of participants had a Low level of Knowledge which gradually decreased to 22.8% after distribution of PIL
Table 3 interprets that the p-value is less than 0.001, indicating a highly significant difference in knowledge scores between the pre-test and post-test and it suggests that the change in knowledge scores from the pre-test to the post-test. The significant increase in knowledge score from the pre-test to the post-test (mean change of 3.97) indicates that the distribution of the patient information leaflet was associated with an improvement in knowledge.

Table 1-Socio-demographics of study participants

VARIABLE	FREQUENCY(n=250)	PERCENTAGE (%)
Age		
Adults (25 years to 35 years)	6	2.40
Middle age (36 years to 60 years)	91	36.4
Geriatrics (> 60 years)	153	61.2
Gender		
Males	148	59.2
Females	102	40.8
Residential area		
Urban	124	49.60
Rural	126	50.4
Education level		
Illiterates	50	20.0
Primary	72	28.80
Secondary	95	38.0

Graduates	33	13.20
Comorbid conditions		
Type 2 diabetes mellitus	105	64.42
Type 2 diabetes mellitus and chronic kidney disease	27	16.56
Chronic kidney disease	11	6.75
Acute kidney injury and Type 2 diabetes mellitus	8	4.90
Asthma	6	3.68
Chronic obstructive pulmonary disease	3	1.84
Acute kidney injury	3	1.84
History of antihypertensive drug usage		
No	38	15.20
Yes	212	84.80

Table 2: Percentage comparison of knowledge of hypertension among hypertensive patients using HK-LS before and after distribution of PIL

Level of Knowledge	Before (pre-test)		After (post-test)	
	Frequency	%	Frequency	%
High	63	25.2%	193	77.2%
Low	187	74.8%	57	22.8%

Table 3: Mean, S.D., and t-value to compare Pre-test and Post-test knowledge (HK-LS)

Domains	Test	Mean	SD	Mean change	*T*	*df*	*p-value*
Definition	Pre	0.88	0.89	0.45	10.13	249	*p<0.001*
	Post	1.33	0.81				
Medical treatment	Pre-	3.55	0.86	0.37	7.17	249	*p<0.001*
	Post	3.92	0.36				
Drug compliance	Pre-Post	2.69	0.73	0.20	4.42	249	*p<0.001*
		2.89	0.46				
Diet	Pre	4.25	1.05	0.59	9.61	249	*p<0.001*
	Post	4.84	1.01				
Life style	Pre	1.05	0.97	0.43	8.01	249	*p<0.001*
	Post	1.48	0.86				
Complications	Pre	2.29	1.92	1.78	15.54	249	*p<0.001*
	Post	4.07	1.25				

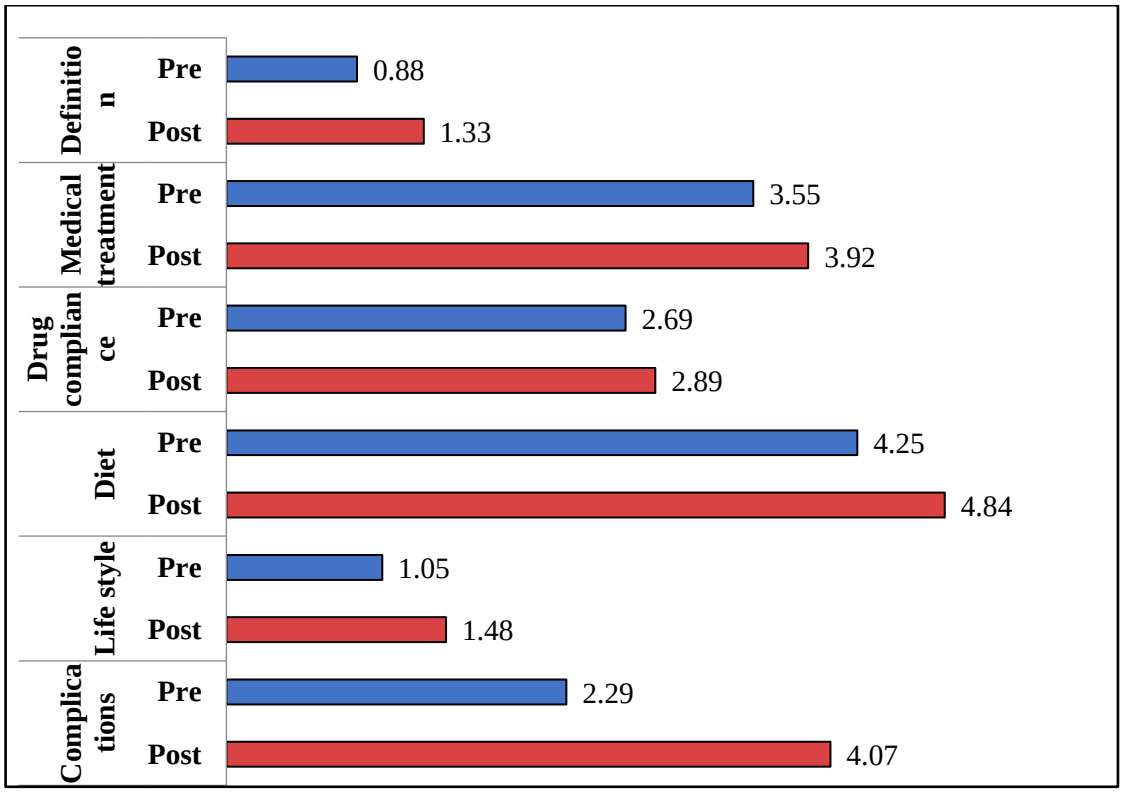
COMPARISON OF PRE-TEST AND POST-TEST OF HK-LS DOMAINS

Table 4 shows that, since the value of *p* is *< 0.001,* there is a highly significant difference between the pre-test and post-test scores among individuals in their respective domains of HK-LS. The mean score has significantly increased in the post-test. This proves the effect of PIL (Patient information leaflet) among hypertensive patients and the Mean analysis of pre and post-test scores in HK-LS domains were shown in **Figure:1**

Table 4: Comparison of pre-test and post-test of HK-LS:

Test	Mean	SD	Mean change	n	*t*	*df*	*p-value*
Pre-test	14.74	3.73	3.97	250	22.352	49	*p < 0.001*
Post-test	18.71	2.37					

FIG 1: Mean analysis of pre and post-test scores in HK-LS domains: impact of patient information leaflet distribution



COMPARISON OF SOCIO-DEMOGRAPHICS WITH KNOWLEDGE LEVEL (HK-LS QUESTIONNAIRE)

In this study, the p-value for gender is less than 0.005 for both before-knowledge and after-knowledge (both having a chi-square p-value of 0.003). The Fisher's Exact Test applied to the data indicates a p-value of 0.005 before the intervention and 0.004 after the intervention, demonstrating a significant influence on knowledge levels. Similarly, for education level, the p-value is 0.000 before the intervention and 0.003 after the intervention, both less than 0.005, indicating significant differences in knowledge levels influenced by education, which is given in **Table -5.**

Table-5: Comparison of socio-demographics with knowledge level (HK-LS questionnaire)

	BEFORE KNOWLEDGE		**Chi-square**	**AFTER KNOWLEDGE**		**Chi-square**
	LOW	HIGH	P-VALUE	LOW	HIGH	P-VALUE
GENDER						
Male	101(54.0%)	47(74.6%)	0.004	24(42.1%)	124(64.2%)	0.003
Female	86(46.0%)	16(25.4%)		33(57.9%)	69(35.8%)	
AGE						
Adults (25-35Y)	3(1.6%)	3(4.8%)		1(1.8%)	5(2.6%)	
Middle age(36-60Y)	63(33.7%)	28(44.4%)	0.084	19(33.3%)	72(37.3%)	0.78
Geriatrics(>60y)	121(64.7%)	32(50.8%)		37(64.9%)	116(60.1%)	
EDUCATION						
Illiterate	47(29.6%)	3(4.8%)		19(35.6%)	31(16.1%)	
Primary	58(31.0%)	14(22.2%)	0.000	18(31.6%)	54(28.0%)	0.003
Secondary	67(35.8%)	28(44.4%)		18(31.6%)	77(39.9%)	
Graduation	15(8%)	18(28.6%)		2(3.5%)	31(16.1%)	
MARITAL STATUS						

Married	157(84.0%)	57(90.5%)		46(80.7%)	168(87.0%)	
Single	1(0.5%)	1(1.6%)	0.23	0(0%)	2(1.0%)	0.27
Widow	29(15.5%)	5(7.9%)		11(19.3%)	23(11.9%)	

DISCUSSION:

Inadequately managed or untreated hypertension can result in progressive and irreversible damage to organs, culminating in life-threatening complications or death. Effectively addressing hypertension includes ongoing medication use, alongside lifestyle adjustments and adherence to a comprehensive set of therapeutic guidelines. Limited understanding and education regarding treatment adherence significantly impact patient awareness and behaviour, posing a substantial challenge in maintaining optimal hypertension control.

Our study comprised a total 250 participants, categories into three distinct age groups. Notably, the majority of the participants fell within age group of > 60 years, accounting to 153 (61.2%). This study aligns with findings of research conducted by Ajani K et al.[13] and Bashyal.[14]. Increased age affects the increasing prevalence of hypertension.[15]Breaking down the gender distribution, out of 250 participants, 148(59.2%) were males, while 102 (40.80%) were females, which coincides with the outcomes of research conducted by Bakhsh L A et al.[16] and Suriyakala P. [17]

In our study, only 25.2% of hypertensive patients demonstrated a high level of knowledge (HK-LS $\leq$ 17) about hypertension before receiving patient information leaflet (PIL) The pre-test results of our study revealed a low level of knowledge, mirroring the findings in a study conducted by Polanska B J et al.[7] After the distribution of the PIL, this figure increased significantly to 77.2%, while the percentage of participants with low knowledge dropped from 74.8% to 22.8%. These results clearly indicate the effectiveness of the informational intervention in enhancing knowledge levels among hypertensive patients. Similarly, in a study conducted by Ernawati I et al., there was a notable increase of 49.49% in the percentage of patients with high knowledge levels after the leaflet intervention, further supporting our study.[15]

The evaluation of the six different domains on the hypertension knowledge level scale in the pre-test showed varying mean values: definition (0.88), medical treatment (3.55), drug compliance (2.69), diet (4.25), lifestyle (1.05), and complications (2.29). Following the distribution of patient information leaflets, there was a notable improvement, with the post-test means indicating enhanced knowledge: definition (1.33), medical treatment (3.92), drug compliance (2.90), diet (4.84), lifestyle (1.48), and complications (4.07). This suggests an overall positive impact on participants' understanding after receiving the PIL

This aligns with the previous research showing that educational interventions, such as distributing leaflets or informative material, can effectively enhance the knowledge and awareness regarding hypertension. Such interventions can serve as a motivational tool and strategy for healthcare workers to improve adherence to blood pressure control.[15]

In our study, there is a similarity with the findings of Eshah N F et al, as both studies observed lower knowledge levels in the domains of "definition" and "complications." However, there is a difference in the "lifestyle" domain, where our study noted lower knowledge, whereas Eshah N F et al.[18] found higher knowledge. Conversely, our study identified higher knowledge in the "diet," "medical treatment," and "drug compliance" domains, while Eshah N F et al [18] observed higher knowledge in the "lifestyle" and "complications" domains. These comparisons highlight variations in knowledge distribution across different domains between the two studies. The domain with the most significant improvement in knowledge, based on the mean values, appears to be "complications." In the pre-test, the mean for complications was 2.29, and after the distribution of patient information leaflets, it increased notably to 4.07 in the post-test. This suggests a substantial enhancement in understanding regarding complications associated with hypertension after participants received the informational material.

In the present study, coincides with the study conducted by Bashyal S P et al., where a significant association was observed between hypertension knowledge and socio-demographic factors such as

gender (pre-test p=0.004 and post-test p=0.003) and level of education (pre-test p=0.00 and post –test p=0.003).[14]

Regarding educational status, in pre intervention test, majority of the participants with high knowledge were literate in which 22.2 % completed their primary education, 44.4 % of them have secondary education and 28.6 % of the participants were graduates. The results in our study align with the Bashyal SP[14] and Kilic M et al.[19]where majority of participants with high knowledge are literates. However, after the intervention, there is a significant increase in the number of individuals who demonstrated high knowledge about hypertension across all educational level. Hence, there is a significant association between educational status and hypertension knowledge, as the level of knowledge about hypertension increased proportionally with a higher degree of educational status. This suggests that literate individuals may be more aware about the hypertension and importance of the regular follow-up.[14]

There was a significant relationship between gender (pre-test, p= 0.004 & post-test p= 0.003) and knowledge of hypertension. In our study since prevalence of hypertension among males is more, they are more likely to have clearer understanding of condition, likely due to increased exposure to health information and teachings. They also have greater access to external knowledge through work had better awareness and perception of hypertension. In contrast, females often more engaged in household duties, had less time for interactive activities, which may have contributed to lower awareness and knowledge regarding hypertension

The impact of age on hypertension knowledge was not statistically significant (pre-test p=0.084), aligning with the finding of Kilic M[19]. There is no significant association between marital status and hypertension knowledge (p=0.23) as well.

Our study suggests a notable influence of Patient Information Leaflets (PIL) in enhancing patients' knowledge across various factors of hypertension. This improved understanding empowers individuals to potentially self-manage hypertension in the future, with potential positive effects on their quality of life by minimizing the risk of complications, in our study; the sample size included in this study is relatively small compared to the hypertensive population so results cannot be generalized. The sample recruitment was done from a single center; therefore, the study population may be relatively homogenous, and limited studies have been conducted and published regarding HK-LS in the Indian population.

CONCLUSION

Our research highlights the substantial impact that Patient Information Leaflets (PILs) have in enhancing patients' understanding of hypertension across various dimensions. This increased awareness empowers individuals to potentially self-manage their condition, offering the prospect of improving their quality of life by reducing the risk of complications. By providing these leaflets, we can significantly improve the health of patients and the public, ultimately helping to prevent complications related to hypertension.

ABBREVIATIONS

SI NO	ABBREVIATIONS	EXPANSIONS
1.	HK-LS	HYPERTENSION KNOWLEDGE-LEVEL SCALE
2.	PIL	PATIENT INFORMATION LEAFLET
3.	HKT	HYPERTENSION KNOWLEDGE TEST
4.	WHO	WORLD HEALTH ORGANISATION
6.	SD	STANDARD DEVIATION

DECLARATION:

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