

# Development and Implementation of Patient Information Leaflet on Hypertension and to Assess its Effectiveness

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**ABSTRACT:** A prospective study was aimed to develop and implement Patient Information Leaflets (PILs) on Hypertension, according to the standard formulas such as Flesch Reading Ease (FRE), Flesch-Kincaid Grade Level (FKGL) and to assess the effectiveness of Patient Information Leaflets after implementation. The study was conducted over a period of seven months in a multispecialty hospital, Coimbatore, Tamil Nadu, India. Questionnaire on hypertension was developed as a tool to assess the knowledge among the hypertensive patients. The questionnaire was initially developed in English and then translated into local languages such as Tamil and Malayalam. Data were collected from patients; accordingly PILs were implemented by using the formulae such as Flesch Reading Ease (FRE) and Flesch Kincaid Grade Level (FKGL). Lay out and design of leaflet was done according to Baker Able Leaflet Design (BALD). Among the 180 patients, 30 patients were excluded from the study due to lack of response. Data revealed the knowledge on hypertension based on the questionnaire scores. Present study showed that before education 92 (61.33%) of the study group were having below average knowledge 38(25.33%) were having average knowledge and 20 were having above average knowledge. After the educational intervention the knowledge on hypertension was improved which was evident by 82 (54.66%) in the above average group, 56(37.33%) in the average and only 12 (8%) were in the below average group, this confirms that education with patient information leaflet significantly improved their knowledge regarding hypertension. It may be concluded that the disease specific knowledge through patient information leaflets (PILs) are necessary to heighten patients' self-confidence in management of hypertension and to improve self management.

**Keywords:** Readability, FRE, FK-GL, BALD, Hypertension, Information leaflet.

## INTRODUCTION:

Hypertension is defined as a systolic pressure of 140mm Hg or more or a diastolic pressure of 90 mmHg or more. Hypertension continues to be one of the most significant risk factors for the development of stroke, coronary heart failure and renal disease. The appropriate treatment of hypertension has consistently proven to reduce both the morbidity and mortality associated with cardiovascular disease. The World Health Organization reports that the number of people with hypertension worldwide is estimated at 600 million, of whom 3 million will die annually as a result of hypertension.<sup>1</sup>

Patient Information Leaflets (PILs) are produced by either manufacturer or pharmacists for the benefit of the patients and are universally accepted as the most

important tool to educate the patient about their medications and disease<sup>2</sup>. Communication is a key process in health care provision. It not only provides the foundation for diagnosis and treatment, but is also closely associated with therapeutic outcomes. Patients can be left feeling unhappy with the amount of information they receive and the information that is given is often misunderstood or forgotten. Leaflets are cheap to produce and can save patients the embarrassment of asking questions directly of a professional. They can be used to reinforce what has been discussed and can be referred to by patients away from the stressful environment of the consultation room.<sup>3</sup>

Patient information leaflets are an important adjunct to verbal exchange between doctor and patient.<sup>4</sup>

Written information may complement verbal messages, thus enhancing concordance and encouraging behaviour change. Patients will vary in the quantity of information they want, and the professional has a duty to deliver it at an appropriate level for each patient, while the Patients Charter's also states that patients have a right to be as informed as they wish.<sup>5</sup> Information materials are no substitute for good verbal discussions, but consultations are usually short and plenty of evidence exists that patients do not receive the information they want and need. Leaflets and other materials can therefore play an important part in supplementing and reinforcing information provided by clinicians, but the information they contain must conform to the highest standards of scientific accuracy and must be tested for comprehensibility and relevance.<sup>6</sup>

Patient information leaflets are widely used by diverse health organizations and professionals as part of patient education or health promotion efforts, in support of preventive, treatment and compliance objectives.<sup>7</sup> Booklet helps patients in their self management decisions to provide information about self management and guidance about when it was important to see the doctor.<sup>8</sup> Illiteracy remains a pervasive problem that compromises quality health care, limits understanding of health information, and potentially leads to poor health outcomes.<sup>9</sup> The use of pictorial aids enhances patients understanding of how they should take their medications, particularly when pictures are used in combination with written or oral instructions.<sup>10</sup> Quality client education requires use of either educational materials appropriate for the measured reading level of clients or alternatives to written material.<sup>9</sup>The aim of our patient education intervention was to encourage behavioural changes in patients, including increased medication adherence, which could help bring about better blood pressure control.<sup>11</sup>

## METHODOLOGY

### Development of Questionnaire

Questionnaire on hypertension was developed as a tool to assess the knowledge among the hypertensive patients. The questionnaire was initially developed in English and then translated into languages such as Tamil and Malayalam. The questionnaire consists of 25 questions to assess the patients' knowledge on hypertension such as signs and symptoms, awareness on complications, medication and treatment plan. Each question was designed to score between two and one. For correct answer marked as two and for incorrect answer marked as one. The questionnaires were then given to the patients who met the inclusion criteria and their knowledge about hypertension was assessed. According to the awareness patient information leaflets (PILs) were prepared, developed and implemented by using the formulae such as Flesch Reading Ease (FRE) and Flesch Kincaid Grade Level (FK-GL). Lay out and design of leaflet was done according to Baker Able Leaflet Design (BALD). After the distribution of leaflets same

questionnaires were again given to the same category of patients and their knowledge was measured; thereby effectiveness of patient information leaflets was measured.

### Readability Scores:

Readability scores assess the reading level of a document. Each readability score bases its rating on the average number of syllables per word and the average number of words per sentence. For better accuracy, the computation requires a sample of at least 200 words. Readability scores are part of what are more generally called readability statistics.

### Flesch Reading Ease Readability Score (FRE)<sup>12</sup>

In the Flesch Reading Ease test, higher scores indicate material that is easier to read; lower numbers mark passages that are more difficult to read. The formula for the Flesch Reading Ease Score (FRES) test is

$$\text{FRE} = 206.835 - (1.015 \times \text{ASL}) - (84.6 \times \text{ASW})$$

ASL: average sentence length in words or average number of words in sentence (number of words divided by the number of sentences)

ASW: average syllables per word (the number of syllables divided by the number of words)

Scores can be interpreted as shown in the table below.

Score	Notes
90.0–100.0	Easily understandable by an average 11-year old student
60.0–70.0	Easily understandable by 13- to 15-year old students
0.0–30.0	Best understood by college graduates

The Flesch Reading Ease formula has been developed by Rudolf Flesch<sup>13</sup> in 1948 and it is based on school text covering grade 3-12. It is wide spread, especially in USA, because of good results and simple computation. The Flesch Reading Ease readability score formula rates text on a 100-point scale based on the average number of syllables per word and words per sentence. The higher the Flesch Reading Ease score, the easier it is to understand the document. For most standard

documents, aim for a Flesch Reading Ease score of approximately 60 to 70. The formula to compute the Flesch Reading Ease score is one of the best-known and most popular readability indicators.

### Flesch-Kincaid Grade Level (FK-GL)<sup>13</sup>

The Flesch-Kincaid Grade Level formula is used by the US Government Department of Defense as a standard test. The test allowing computing this score was created by Rudolf Flesch in the 1940's, and later enhanced by John P. Kincaid.

The Flesch-Kincaid Grade Level readability score analyzes and rates text on a U.S. grade-school level based on the average number of syllables per word and

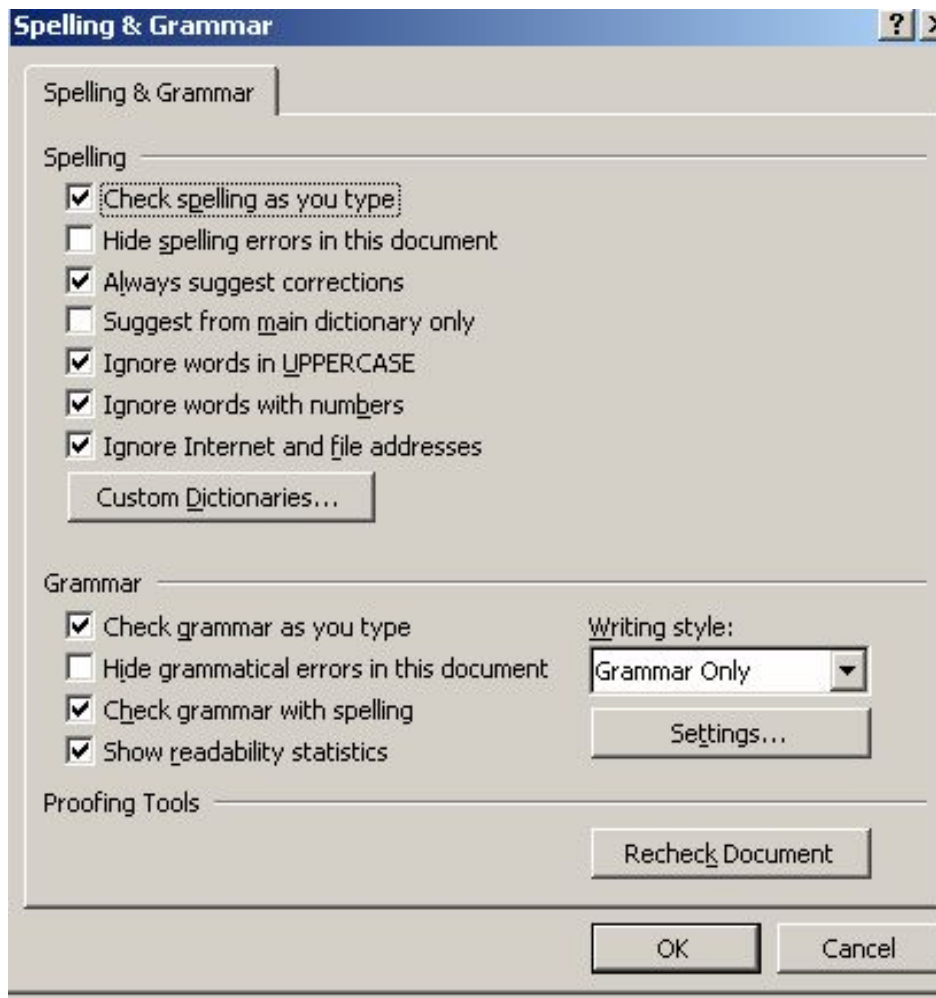
words per sentence. For example, a score of 8.0 means that an eighth grader would understand the text. Given standard writing averages seventh to eighth grade, aim for a Flesch-Kincaid score between 7.0 and 8.0.

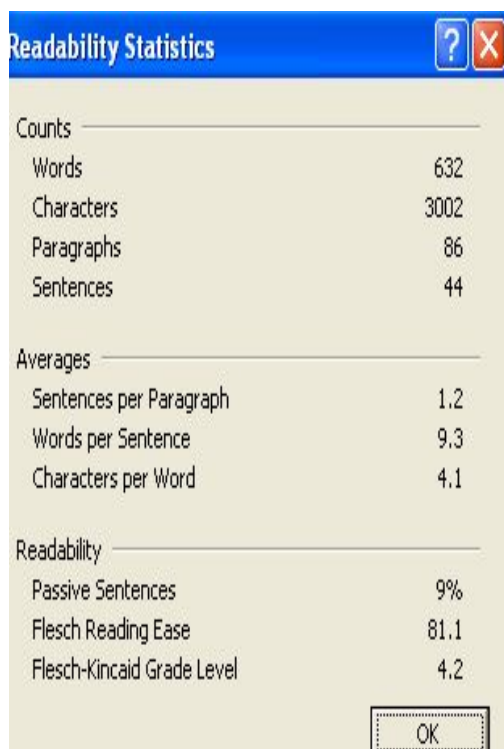
The Flesch-Kincaid Grade Level readability score formula is:

$$FKRS = (0.39 \times ASL) + (11.8 \times ASW) - 15.59$$

FKRS: Flesch-Kincaid Readability Score

The message box showing the FRE and FK-GL scores from Computer Software





**Interpretation of Flesch Reading Ease Score**

Reading Ease	Description of Style
90-100	Very easy
80-90	Easy
70-80	Fairly easy
60-70	Standard
50-60	Fairly difficult
30-50	Difficult
0-30	Very difficult

**The FRE can be converted to an appropriate grade using this table**

Grade level	FRE
5 <sup>th</sup> grade	90-100
6 <sup>th</sup> grade	80-90
7 <sup>th</sup> grade	70-80
8 <sup>th</sup> to 9 <sup>th</sup> grade	60-70
10 to 12 <sup>th</sup> grade (high school)	50-60
13 <sup>th</sup> to 16 <sup>th</sup> grade (college level)	30-50
College graduate	0-30

**RESULTS:**

Out of 150 subjects, 82 (54.66%) had family history of hypertension whereas 68 (45.33%) did not have any family history of similar illness; this data confirms that most of the subjects have genetic predisposition of hypertension. Most of the patients had co-morbidities, 25(16.66%) had diabetes mellitus, 58 (38.66%) had heart disease, 22(14.66%) had renal diseases and 45(30%) had hypercholesterolemia. This data reveals that most of the subjects suffered from heart disease, which is the commonest complication of hypertension.

Out of 150 patients 24 (16%) had eye problem, 28(18.66%) had renal failure, 22 (14.66%) had stroke, 42 (28%) had heart problems and remaining 34 (22.66%) reported more than one complications. Among the study group, out of 150, 85 of them were smokers, in that 10 patients were taking <5 cigarettes, 50 were taking 5 to 10 cigarettes and 25 were taking more than 10 cigarettes before education. After education patients who were taking more than 10 cigarettes were reduced from 25 to 15 and those who were taking 5 to 10 cigarettes were reduced from 50 to 30 and among those who were taking <5 was increased from 10 to 40. This showed that education programme was effective in tapering the number of cigarettes among smokers (Fig 1).

Regarding the nature of exercises followed by patients with hypertension it was found that, before education, 32 (21.33%) of patients regularly walked, 24 (16%) ran, 26 (17.33%) swam as part of their daily exercises. Out of 150 subjects 28 (18.66%) had practiced yoga & meditation and 40 (26.66%) did not follow any exercises. Following education, 21.33% of subjects who practiced walking increased to 31.33%, 18.66% ran, 14.66% swam while 30 (20%) of them practiced yoga & meditation. After education patients who did not follow any exercise, were decreased from 26.66% to 15.33%. Since the majority of patients practiced walking, the data confirms that walking is the suitable exercise for patients with hypertension.

Frequency of checking blood pressure was determined from the data. It was noted that 60 (40%) had check-up once in six months, 50 (33.33%) had once in two months, 30 (20%) had once in a month and 10 (6.66%) checked pressure daily before education. Data revealed that most of the patients checked their blood pressure after six months of interval. So they were not particular about their frequency of checking blood pressure. After education the percentage of patients who checked their BP once in a month increased from 20 to 60% which showed that the study subjects recognised the need for regular BP check-up (Fig 2).

Data revealed the knowledge on hypertension based on the questionnaire scores. Present study showed

that before education 92 (61.33%) of the study group were having below average knowledge 38(25.33%) were having average knowledge and 20 were having above average knowledge. After the educational intervention the knowledge on hypertension was improved which was evident by 82 (54.66%) in the above average group, 56(37.33%) in the average and only 12 (8%) were in the below average group, this confirms that education with patient information leaflet significantly improved their knowledge regarding hypertension.

The difference in mean score knowledge on hypertension before and after education was tested by paired't' test. The observed't' value is 13.32 at 149 df at 1% level of significance which is greater than the critical value of 2.58. Since the observed't' value is greater than the critical value, it shows that the patient information leaflet significantly improved the knowledge about disease condition among patients with hypertension (Fig 3).

**Statistical Methods:**

The difference in mean score knowledge on hypertension before and after education was tested by paired't' test. The observed't' value is 13.32 at 149 df at 1% level of significance which is greater than the critical value of 2.58. Since the observed't' value is greater than the critical value, it shows that the patient information leaflet significantly improved the knowledge about disease condition among patients with hypertension (Fig 4).

**SUMMARY AND CONCLUSION:**

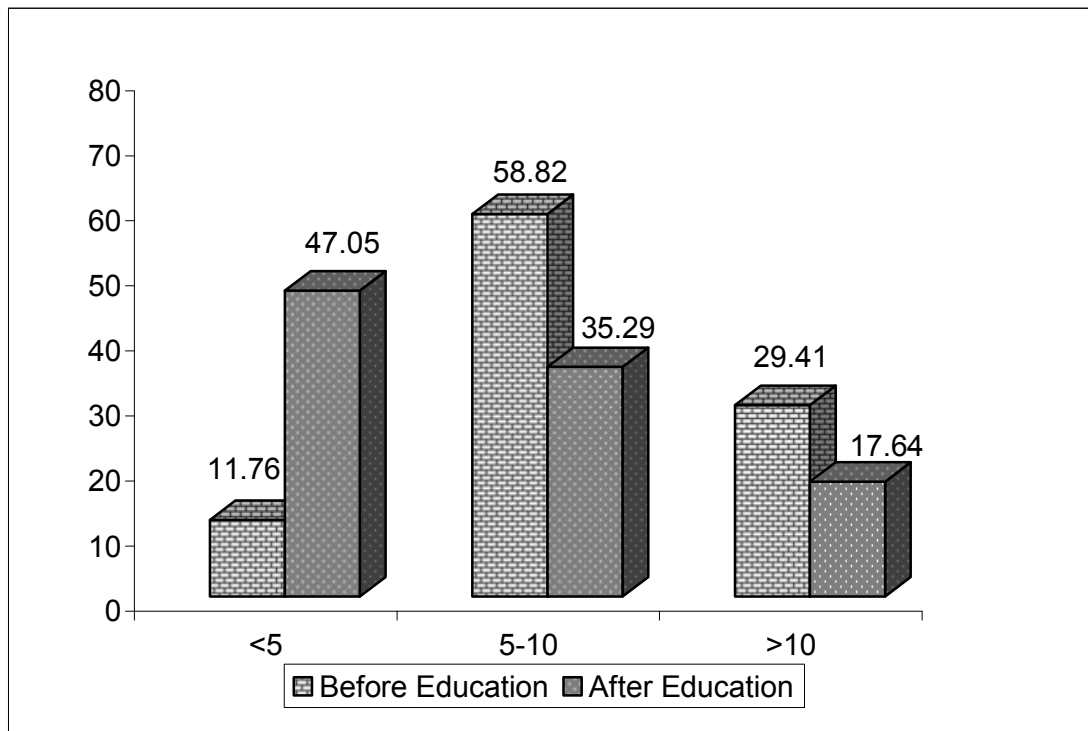
It was concluded that the disease specific knowledge through patient information leaflets (PILs) are necessary to heighten patients' self-confidence in management of hypertension and to improve self management. To enhance patients' care, self-efficacy and self management, providers need to promote patients' capacity to define the problems they are facing, make informed decision about their management on hypertension and set realistic goals and strategies to meet those goals.

Pharmacist should advocate reading the leaflet and promote it as a useful resource. The leaflet should not replace the pharmacist's obligation to provide verbal counselling. A brief educational intervention through PILs appeared effective in encouraging patients' toward better self management and more regular metabolic testing and to become more aware of their own test results.

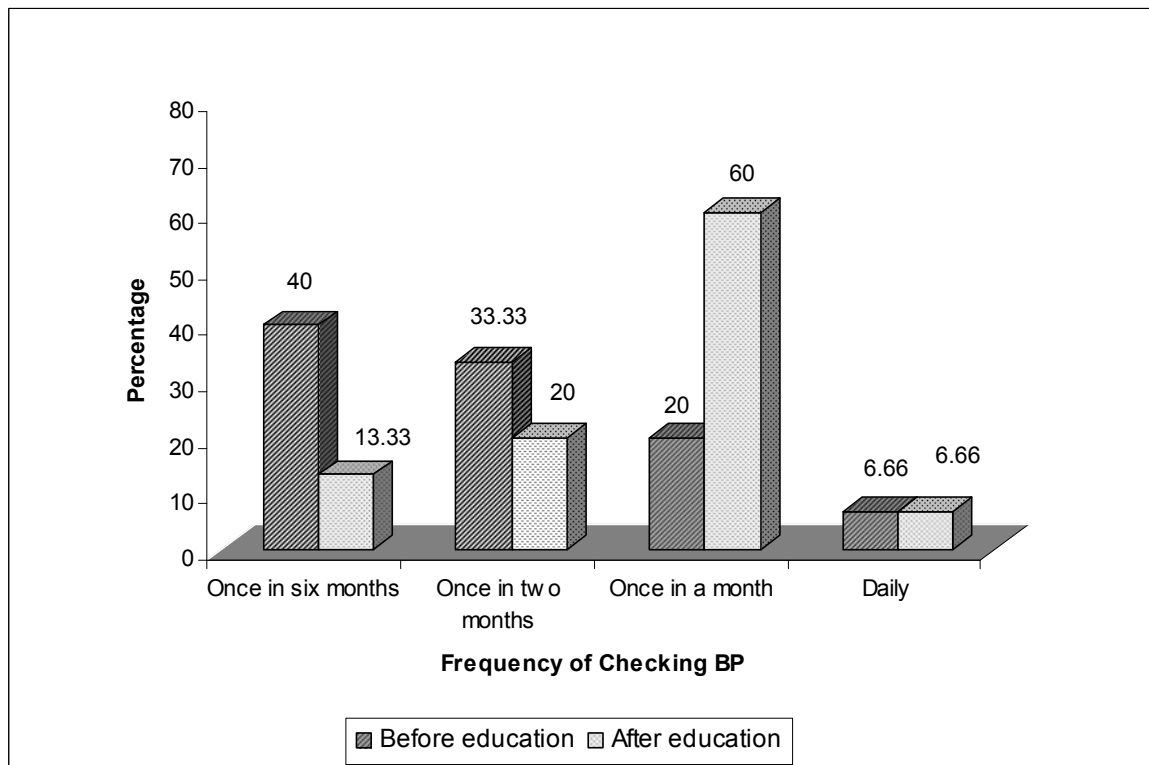
**ACKNOWLEDGEMENT:**

We acknowledge the financial assistance of the Kovai Medical Center and Hospital (KMCH), toward our printing costs.

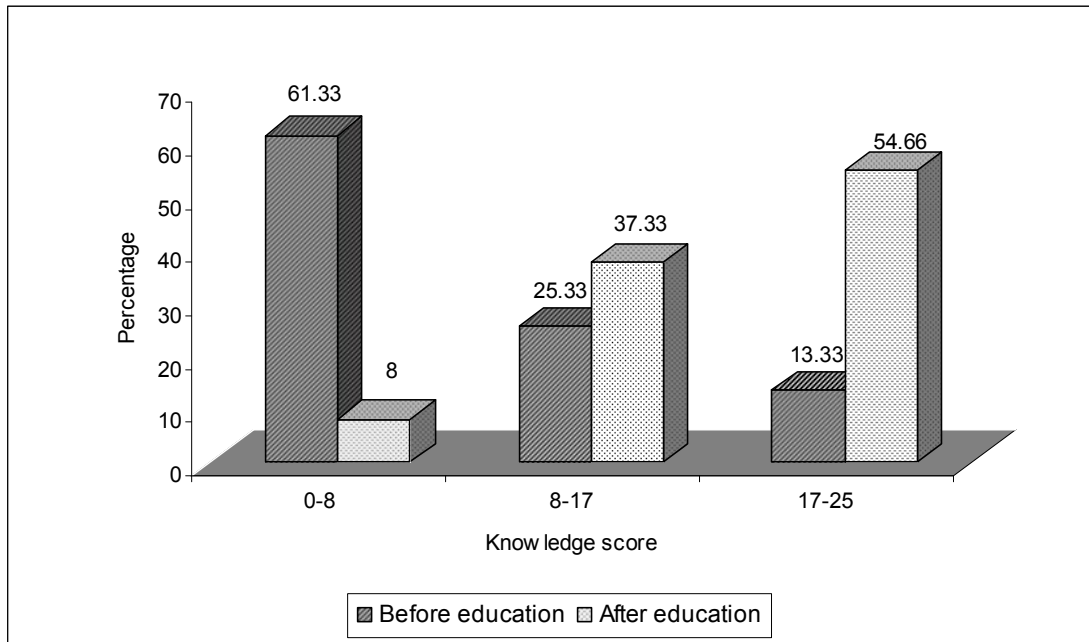
**Figure 1. Smoking habit before & after education among the study group**



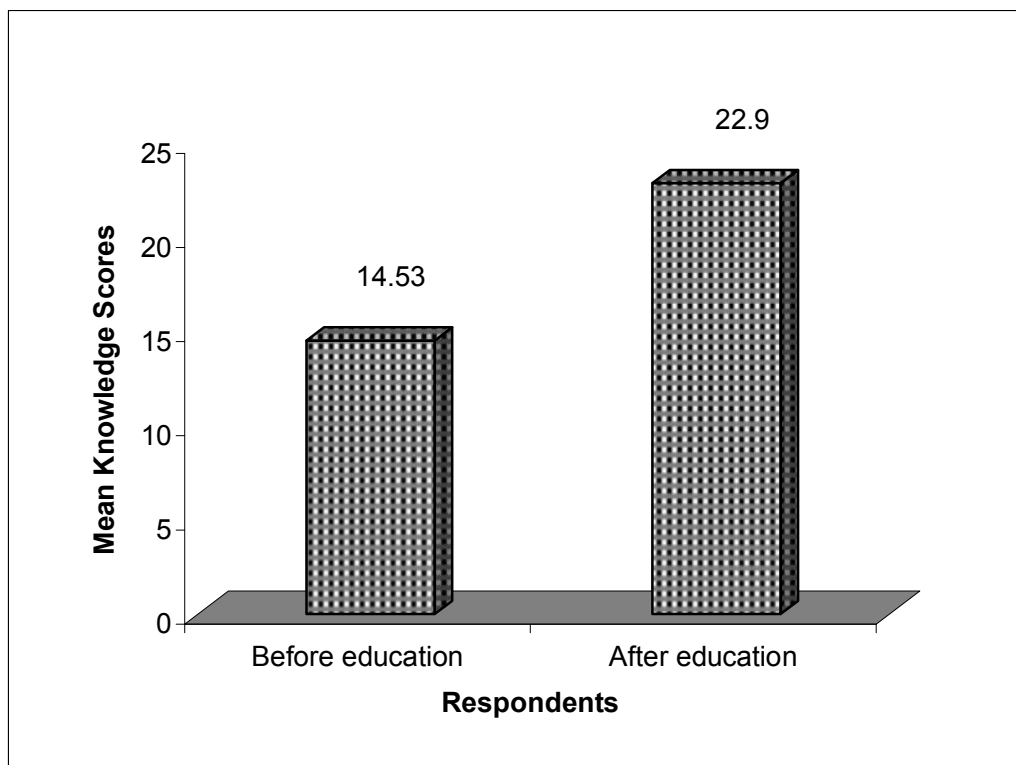
**Figure 2. Frequency of checking BP before & after education among the study group**



**Figure 3. Knowledge on hypertension before & after education among study group**



**Figure 4. Knowledge Scores related to hypertension before & after Education**



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