

Impact of Clinical Pharmacist Mediated Patient Counselling on Health Related Quality of Life in Hypertensive Patients

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ABSTRACT

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Hypertension is a major risk factor to many diseases like myocardial infarction, stroke, heart failure, renal failure, and retinopathy which is a leading cause of death. Only two-thirds of patients with hypertension are aware of their status, which means that a large segment of the population has hypertension that is unrecognized and untreated. This study aims to provide patient counseling regarding risk factors, life style modifications and pharmacological therapy by orally and through patient information leaflet which will improve KAP and Health related quality of life in hypertension. At baseline there was no significant difference between the mean blood pressure, HRQoL score and KAP of the test and control groups. At final follow up test group patients had significantly ($p=0.021$) higher QoL scores than at baseline. Patient in the test group had very significant improvement in the KAP score. At the end of the study the patients in the test group had better blood pressure control values and better scores in all six subscales of the SF-36v2 health survey questionnaire. These patients also showed improved KAP scores at the final follow up. Our study concludes that clinical pharmacist can play an important role in improving the treatment outcomes and quality of life of patients with hypertension.

Keywords: hypertension; health related quality of life; counseling.

INTRODUCTION

Hypertension is not a disease but it is an important risk factor for cardiovascular complications. It can be defined as a condition where blood pressure is elevated to an extent where clinical benefit is obtained from blood pressure lowering. Hypertension has become a significant problem in developing countries which is associated with aging of the population, urbanization, socio economic changes favoring sedentary habits, obesity, alcohol consumption, and salt intake etc¹.

The most common and important cardiovascular complications associated with hypertension are stroke and myocardial infarction. In health care research quality of life has become ever more important since the world health organization defined health as being not only the absence of disease and infirmity but also the presence of physical, mental & social well-being. Quality of life represents a broad range of human experiences related to one's overall wellbeing and may be influenced by a multitude of nonmedical factors such as financial status, individual freedom and one's own personal environments. Hypertension care includes knowledge in symptom recognition, diets & life style modifications like routine exercise, adherence to medications, detection & management of signs & symptoms of hypertension².

The most effective therapy prescribed by clinician will control the patient's hypertension only if the patients are motivated to be compliance with their condition and management strategies. Motivation improves when patients have positive experiences with their treatment and trust their health care providers.³

The primary goal of the treatment of a hypertensive patient is the reduction of the long-term risk of cardiovascular morbidity and mortality. Health-related quality of life (HRQoL) in clinical medicine is defined as 'the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient'. A recent systematic review and meta-analysis of observational studies of HRQoL in hypertensive patients concluded that hypertension reduces HRQoL, but the magnitude is small⁴.

Quality of life is widely perceived to be an important end point in therapeutic assessment. QoL endpoints that are related to health are increasingly being used to adjust measures of effectiveness for clinical decision making, resource allocation and evaluation of drugs in various diseases conditions⁵

The major risk factors for developing hypertension include age, diabetes mellitus, family history, dyslipidemia, excessive alcohol intake, cigarette smoking, obesity, sedentary life style, renal diseases⁶.

The management of hypertension involves long term treatment & life style modification which will have greater impact on HRQoL. This study aims to give patient counseling

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regarding risk factors, life style modifications, pharmacological therapy & medication adherence in hypertension which in turn improves HRQoL.

The pharmacist is in an ideal position to assist with patient education and monitoring to improve medication and life style adherence⁷

Poor medication adherence and lack of knowledge and awareness on hypertension are the major reasons for poor BP control which is largely related to deterioration in a patient's quality of life⁸.

Patient counseling is an essential component of clinical pharmacy practice in hospitals and in community pharmacy settings. Counselling enhances the patient understanding of their illness and its treatment, and may improve adherence and therapeutic outcome. It allows pharmacists to gain first-hand knowledge of medication use from patient's perspective.⁹

The treatment of hypertension is usually long term, and its success will depend on the effects of the drug regimen on the patient's quality of life¹⁰.

METHODOLOGY

The study was carried out after obtaining ethical permission from institutional review board of Raghavendra Institute of Pharmaceutical Education and Research (RIPER-IRB-007-2012). This was prospective interventional study which was conducted over a period of 9 months from June 2012-February-2013 in RDT Hospital, Bathalapalli located in Anantapur district.

The following categories of patients, who visited the study sites, were enrolled in to the study. Hypertensive patients of either sex above 18 years of age with or without comorbidities and Patient willing to give their informed consent to participate in the study. Pregnant women and Pediatric patients were excluded from the study.

Study Procedure

Patient enrollment and collection of data:

Patients who are satisfying the inclusion criteria were enrolled in this study. The nature of study was explained to study participants and their informed consent was obtained. Patient details were collected through the suitably designed data collection form, patient interview, prescriptions and / or medication strips.

Measuring QoL and Blood pressure:

Quality of Life scores were assessed based on their response to the SF-36v2 Health survey questionnaire by patient interview. It contains 11 questions focusing on General, Functional status, Psychological, Social/family, Positive

Wellbeing and Physical activity. To determine the effect of education on patient's Quality of life, the questionnaire was administered by the study Pharmacist at base line, First follow up, Second follow up and Final follow up. At base line and at each of the three follow-ups the patient's BP was recorded.

Measuring Knowledge Attitude & Practice:

To assess Knowledge, attitude and practice towards hypertension a self-designed questionnaire was prepared and validated by pilot study. Then KAP questionnaire was administered in study participants at baseline and at final follow up, to evaluate the impact of education on patients KAP towards hypertension.

Preparation of Patient information Leaflet:

A patient Information Leaflet was prepared. The leaflet contains information about high blood pressure, its risk factors, symptoms, hypertensive complications, dietary and life style modifications that hypertensive patients need to be followed.

Follow up:

Patients were asked to come back for follow up once a month. The clinical pharmacist educate patients belonged to test group regarding their disease, medication and life style modifications they would need to make. Patients in the control group were given basic information regarding correct ways to take their medicines. Detailed patient education, similar to the test group was provided to the control group patients after the study was completed.

Statistical Analysis:

Student's't' test was used to analyze and compare the study data. A P value <0.005 was considered as statistically significant.

RESULTS

A total 130 patients were enrolled in to the study. 15 patients were lost to during follow up visit. There was no significant difference ($P > 0.005$) seen between the baseline values of the two groups with respect to Gender, Age, Social history, Comorbidities like diabetes mellitus, stroke, CCF and others were shown in (Table 1). Out of 115 patients 67 patients were in the control group and 48 patients were in the test group.

Changes in the blood pressure of Patients before and after intervention:

At baseline mean systolic B.P was 153.3 ± 8.93 mm Hg and mean diastolic B.P was 88.11 ± 5.94 mm Hg in test group. After 9 months of intervention, the mean systolic B.P was 128.50 ± 7.86 mm Hg and mean diastolic B.P was 81.23 ± 5.23 mm Hg in test group. (Table 2)

| | Control Number (%) | Test number (%) |
|-----------------------|---------------------------|------------------------|
| Gender | | |
| Males | 33 (49.2) | 22 (45) |
| Females | 34 (50.7) | 26 (54.1) |
| Age in years | | |
| 30-40 | 10 (14.9) | 13 (27.1) |
| 40-50 | 13 (19.4) | 19 (39.5) |
| 50-65 | 21 (31.3) | 27 (56.2) |
| >65 | 04 (5.9) | 05 (10.4) |
| Social history | | |
| Alcohol | 13 (19.4) | 11 (22.7) |
| Smoking | 19 (28.3) | 14 (29.8) |
| Both | 10 (13.6) | 05 (10.9) |
| None | 25 (38.7) | 18 (36.6) |
| Co-morbidities | | |
| Diabetes mellitus | 27 (40) | 19 (40) |
| CCF | 19 (27) | 16 (33) |
| Stroke | 11 (17) | 08 (17) |
| Others | 10 (16) | 05 (10) |

Comparison of blood pressure values at Base line and Final follow up:

Control versus Test group:

At baseline there was no any significant difference (P>0.005) between the systolic and diastolic blood pressure of test and control group.

Control group: Systolic blood pressure:

At base line 25 patients had their systolic blood pressure in the range of 120-139 mmHg (Pre

Hypertension), 27 patients are having stage I hypertension, and 15 patients are having >160 mm

Hg (Stage II) categorized according to JNC VII. (Table 3)

Test group: Systolic blood pressure:

At baseline, 20 patients were having stage I hypertension, 13 were having stage II hypertension, while 15 patients were having pre hypertension (120-139) mm of Hg. At final follow up, 05 patients were having stage I diastolic blood pressure, 03 were having stage II, while 20 are having pre-hypertension of diastolic blood pressure. (Table 3)

Control group: diastolic blood pressure:

At baseline 20 patients had JNC VII stage I and 16 patients had JNC VII stage II diastolic blood pressure. In addition 4 patients had normal diastolic blood pressure and 27 had diastolic blood pressure in pre hypertension stage. At the final follow up 34 patients had stage I, 8 patients of stage II. While 2 patients were having normal hypertension and 23 were having pre-hypertension. (Table 4)

Test group: diastolic blood pressure:

At baseline 12 patients had JNC 7 stage I and 10 patients had JNC 7 stage II, while 8 patients are having normal hypertension and 18 patients are having pre-hypertension. At

| Systolic Blood Pressure in mmHg | | | | | |
|--|---------|-----------------------|--------------------|------------------------|--------------------|
| B.P Classification | | Baseline | | Final follow up | |
| | | Control Number | Test Number | Control Number | Test Number |
| Normal | <120 | - | - | - | - |
| Pre Hypertension | 120-139 | 25 | 15 | 23 | 20 |
| Stage I | 140-159 | 27 | 20 | 38 | 25 |
| Stage II | >160 | 15 | 13 | 06 | 03 |
| P value | | 0.60 | | 0.046 | |
| Total | | 67 | 48 | 67 | 48 |

| Diastolic Blood Pressure in mmHg | | | | | |
|---|-------|-----------------------|--------------------|------------------------|--------------------|
| B.P Classification | | Baseline | | Final follow up | |
| | | Control Number | Test Number | Control Number | Test Number |
| Normal | <80 | 04 | 08 | 02 | 03 |
| Pre Hypertension | 80-89 | 27 | 18 | 23 | 26 |
| Stage I | 90-99 | 20 | 12 | 34 | 17 |
| Stage II | >100 | 16 | 10 | 08 | 02 |
| P value | | 0.27 | | 0.014 | |
| Total | | 67 | 48 | 67 | 48 |

Table 2: Changes in blood pressure of Patients before and after interventions in TEST group

| Blood Pressure in | Before Pharmacist intervention | After Pharmacist intervention |
|-------------------|--------------------------------|-------------------------------|
| mm Hg | | |
| Systolic B.P | 153.3± 8.93 | 128.50±7.86 |
| Diastolic B.P | 88.11±5.94 | 81.23±5.23 |

final follow up 17 had stage I and 02 are having stage II diastolic blood pressure, while 26 patients are having pre-hypertension of diastolic blood pressure and 03 are having normal hypertension of diastolic blood pressure (Table 4)

Quality of life (QoL) scores of study patients:

The quality of life was assessed using a SF-36v2 health survey questionnaire. An increase in QoL score indicates an improvement in QoL. At baseline there was no significant difference between the scores of control and test groups. However, at the final follow up the test group patients had significant improvement in QoL scores with a P value of 0.001.

Comparison of total QoL scores at each follow up: control versus test

Quality of life scores at base line: There was slight significant difference between test and control group with a P value of 0.027.

Quality of life scores at final follow up: There were increased QoL scores in control group during follow up visits but this was not significant. However compared to control group, there was a significant increase in QoL scores seen in the test group patients. (Figure 1)

Comparison of Quality of life scores with respect to the individual sub scales of the SF-36v2 Health survey

The SF-36v2 survey has six subscales like general, functional, psychological, social/family, positive wellbeing and physical. In the test group at second and third follow up, there was a significant increase in the scores of all the subscales of SF-36v2TM health survey when compared to base line. In the control group there was no significant change observed in the scores of individual subscales. (Figure 2)

Comparison of mean change in the score of individual subscales: Control versus Test (Table 5)

Change in the score of General health sub scale seen across the follow-ups

Control group: The general health scores of the control group patients did not change significantly ($P>0.005$) from baseline to final follow up.

Test group: The general health subscale score of the test group

Table 5: Mean scores in various QoL subscales seen at different follow ups

| | Base line Mean±S.D | 1 st follow up Mean±S.D | P value | 2 nd follow up Mean±S.D | P value | Final follow up Mean±S.D | P value |
|----------------------------|-----------------------|---------------------------------------|---------|---------------------------------------|---------|-----------------------------|---------|
| Total score | | | | | | | |
| Control | 88.86±11.16 | 89.62±9.42 | 0.027 | 90.03±10.9 | 0.029 | 91.12±11.6 | 0.098 |
| Test | 93.24±11.28 | 105.6±10.07 | 0.06 | 115.2±7.64 | 0.031 | 123.4±6.47 | 0.021 |
| General Health | | | | | | | |
| Control | 4.16±1.14 | 4.29±1.21 | 0.0003 | 4.40±1.06 | 0.041 | 4.52±1.02 | 0.051 |
| Test | 4.72±1.33 | 5.89±1.47 | 0.042 | 6.58±1.28 | <0.0001 | 7.10±1.17 | <0.0001 |
| Functional | | | | | | | |
| Control | 17.68±2.23 | 17.05±1.72 | 0.08 | 17.17±2.25 | 0.06 | 17.28±2.72 | 0.061 |
| Test | 17.79±2.324 | 19.33±1.894 | 0.07 | 20.56±1.457 | <0.0001 | 23.52±1.280 | 0.0005 |
| Psychological | | | | | | | |
| Control | 44.82±1.91 | 45.05±2.21 | 0.0011 | 45.22±2.76 | 0.0003 | 45.40±3.08 | 0.0002 |
| Test | 46.37 ±2.038 | 49.72±1.830 | 0.033 | 51.66±1.826 | 0.0027 | 53.62±1.248 | <0.0001 |
| Social/Family | | | | | | | |
| Control | 4.23±1.07 | 4.35±1.28 | 0.083 | 4.46±1.32 | 0.072 | 4.61±1.7 | 0.063 |
| Test | 4.79±1.38 | 6.29±1.23 | 0.004 | 7.16±0.88 | 0.023 | 7.68±0.46 | <0.0001 |
| Positive Well Being | | | | | | | |
| Control | 8.89±2.60 | 9±1.15 | 0.075 | 9.04±1.42 | 0.033 | 9.17±1.07 | 0.06 |
| Test | 9.70±2.23 | 11.66±2.05 | 0.061 | 14.56±1.23 | <0.0001 | 15.35±1.12 | <0.0001 |
| Physical | | | | | | | |
| Control | 9.82±2.23 | 9.88±1.85 | 0.077 | 10.01±2.09 | 0.068 | 10.14±1.93 | 0.061 |
| Test | 9.87±1.99 | 12.27±1.60 | 0.062 | 14.72±0.98 | 0.028 | 16.14±1.20 | <0.0001 |

patients improved significantly from baseline to second follow up (P=0.042) and base line to final follow up (P=<0.001)

Change in the score of Functional sub scale seen across the follow ups:

Control group: The functional scores of the control group patients did not change significantly (P>0.005) from baseline to final follow up

Test group: The functional subscale score of the test group patients improved significantly from baseline to second follow up(P=0.07) and base line to final follow up(P=0.0005)

Change in the score of Psychological sub scale seen across the follow ups:

Control group: The Psychological subscale score of the test group patients improved significantly from baseline to second follow up(P= 0.0003) and base line to final follow up(P=0.0002)

Test group: The Psychological subscale score of the test group patients improved significantly from baseline to second follow up(P=0.027) and base line to final follow up(P=<0.001).

Change in the score of social/family sub scale seen across the follow ups:

Control group: The social/family scores of the control group patients did not change significantly (P>0.005) from baseline to final follow up.

Test group: The social/family subscale score of the test group patients improved slight significantly from baseline to final follow up(P=<0.001).

Change in the score of Positive wellbeing sub scale seen across the follow ups:

Control group: The Positive wellbeing subscale score of the test group patients improved significantly from baseline to second follow up (P=0.033) and base line to final follow up (P=<0.001).

Test group: The positive wellbeing subscale score of the test group patients improved slight significantly from baseline to final follow up (P=<0.001).

Change in the score of Physical sub scale seen across the follow ups:

Control group: The Physical subscale score of the Control group patients improved significantly from baseline to second follow up (P=0.07) and base line to final follow up (P=<0.006).

Test group: The Physical subscale score of the test group patients improved significantly from baseline to final follow up (P=<0.001).

Knowledge, Attitude, and Practice of the study patients:

A self designed KAP Questionnaire was used to assess the Knowledge, attitude and practice of the study patients towards their disease and its management. The questionnaire contains yes or No options. (Figure 3, 4, 5, 6)

Fig. 1: Mean total QoL score seen at different follow ups: control versus test group

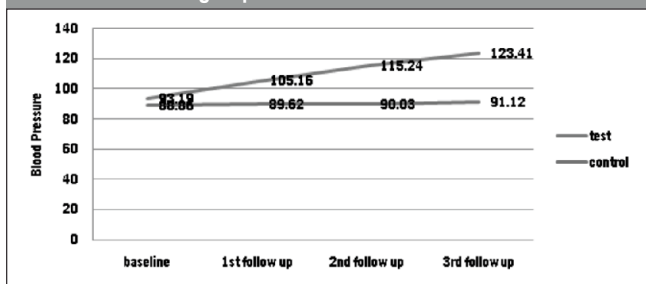


Fig. 2: Comparison of Quality of life scores with respect to the individual sub scales of the SF-36v2 Health survey

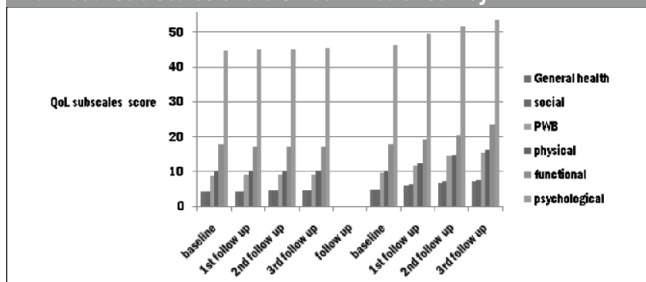


Fig. 3: KAP measurement at Base line level in control patients:

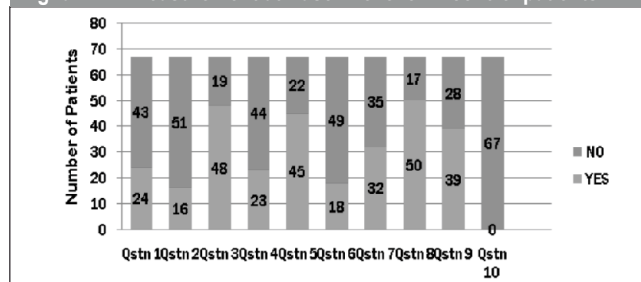
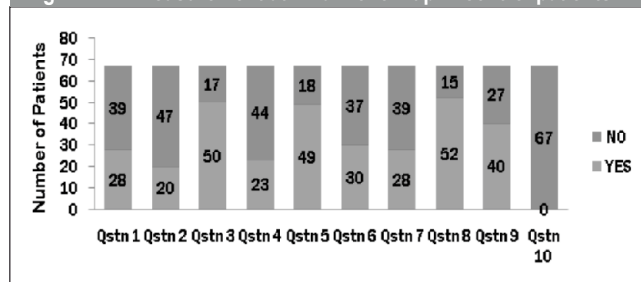


Fig. 4: KAP measurement at Final Follow up in control patients:



The mean KAP scores for the control and test group, at baseline and final follow up are presented in the figure 7. The test group patients showed a significant improvement in KAP scores at final follow up visit compared to Control group. (Figure 7)

DISCUSSION

Hypertensive patients require better patient counseling and treatment to achieve adequate blood pressure control, to improve health related quality of life. In health care sector, Pharmacists are in a position to provide patient counselling as an intervention for the purpose of achieving definite outcomes which will improves Patient health related quality of life. This study provides how pharmacist mediated patient counselling improves definite outcomes like knowledge regarding disease, control of blood pressure and HRQoL in hypertensive patients. A total number 130 eligible consenting patients participated in study. 15 patients dropped out during

entire study period and 115 patients were categorized in to test group (48) and control (67). Number of subjects was more in age group of 50-65 years when compared with other age groups. In this study 47.8% were males and 52.2% were females. Comorbidities distributed in the subjects are as follows Diabetes-40%, CCF-30%, Stroke-17% and other diseases-13%. At baseline mean systolic B.P was 153.3 ± 8.93 mm Hg and mean diastolic B.P subjects of Test group 88.11 ± 5.94 mm Hg. After 9 months of intervention, the mean systolic B.P was lowered by 24.8 mmHg and mean Diastolic B.P was lowered by 6.8 mmHg. In a similar study like Physician and Pharmacist collaboration to improve blood pressure control by Carter BL et al, which was prospective cluster randomized control clinical trial, a 6 months study whose mean systolic B.P was lowered by 20.7 mmHg and the mean diastolic BP was lowered by 9.7 mmHg. These Studies have demonstrated that blood pressure (BP) control can be improved when clinical pharmacists assist with patient management. Finally study results revealed Pharmacist mediated patient counselling resulted in significant reduction in systolic and diastolic B.P as in other studies. In SF 36-v2 health survey questionnaire scores of patients before and after interventions were compared using student t-test and report showed that statistically significant difference ($P < 0.05$) was found in scores of all domains of HRQoL after patient counselling. HRQoL scores before and after counselling in Test and Control group are shown in (Table 5). At base line of study all patients receiving usual care and SF-36 v2 health survey showed that there was a poor QoL in Test and Control groups. At the end of the study statistically significant improvement were found in SF-36 v2 HRQoL domains (General health, Functional, Psychological, Social/Family, positive Well Being, physical) after patient counselling. This study demonstrated that Pharmacist mediated patient counselling achieved a greater improvement in HRQoL of Patients. The results of a previous study by Lyra Jr DP et al also support these findings. The study shows that improvement in KAP towards hypertension and its management in test group comparing to control group. This helped patients to develop better knowledge of hypertension and determination in preventing hypertension.

Fig. 5: KAP measurement at Base line level in Test Patients:

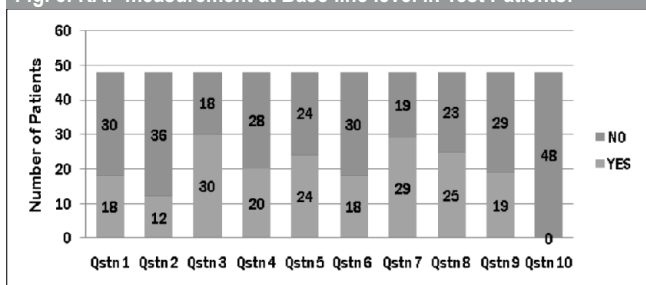


Fig. 6: KAP measurement at Final follows up in Test Patients:

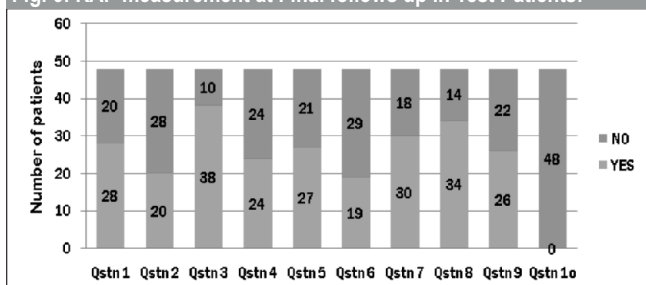
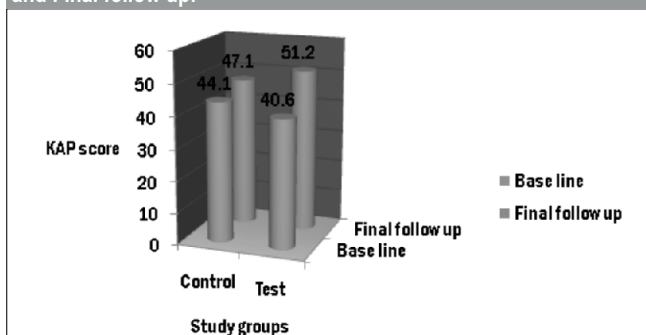


Fig. 7: Comparison of Mean KAP scores for each group at Base line and Final follow up:



CONCLUSION

The study concludes that hypertension affects the quality of life of patients and the education has a major role in improving the healthcare outcomes. This study demonstrates that pharmacist's interventions achieved significant reduction in mean systolic BP and diastolic BP and improvement in health related quality of life of hypertensive patients. Based on these findings, this study concludes that pharmacist's interventions can be effective in reducing BP and improving quality of life of hypertensive patients. Additional research should be conducted to evaluate the efficacy of pharmacist's interventions and the extent to which it is beneficial for the management of hypertension.

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