

Pharmacist's Contribution to Blood Pressure Outcome and Quality of Life of Hypertensive Patients

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ABSTRACT

Blood pressure (BP) control, BP reduction and the quality of life (QOL) of hypertensive patients monitored by a pharmacist in three primary care settings in Mahasarakham Province, Thailand were evaluated. Patients were randomly assigned into the treatment and the control groups. The treatment group received their usual care plus the attention of a pharmacist every month to monitor BP and provide pharmaceutical care and counseling. The control group just received their usual care. QOL was measured at the pretest and after six and 12 months. BP was compared between that obtained at the pretest and after 12 months. The results after 12 months from 235 patients, 118 treatment and 117 control, showed that the proportion of BP control was significantly higher in the treatment group, 92 of 118, than in the control group, 76 of 117, $p < 0.05$. BP reduction was significantly greater in the treatment group, 26.72 ± 19.36 for systolic and 13.53 ± 11.21 for diastolic, than in the control group, 12.32 ± 21.55 for systolic and 9.75 ± 11.23 for diastolic, $p < 0.05$. There were significant differences between the groups in physical functioning and role of physical scales. A significant interaction in role emotional scales, and a significant difference between groups after 12 months were noted. Our results indicate that a pharmacist's care of hypertensive patients in the primary care setting can increase BP control, BP reduction and patients' QOL.

Key words: Pharmacist, Hypertension, Pharmaceutical care, Primary care setting

INTRODUCTION

Hypertension remains a major risk factor for cardiovascular disease and is an important health problem in Thailand. The death rate from hypertension and cerebrovascular disease has increased between 1999 and 2003 from 15.6 to 26.8 people per 100,000 of the population and it was ranked third of the major causes of death in 2003 (Health Information Division, Bureau of Health Policy and Plan, 2004). Blood pressure (BP) reduction, especially systolic BP, has been shown to be beneficial in decreasing morbidity and mortality from strokes and coronary events (Klungel et al., 2000; Perry et al., 2000; Staessen et al., 2000, 2001; Blood Pressure Lowering Treatment Trialists' Collaboration, 2003).

Pharmaceutical care is defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Hepler and Strand, 1990). Health related quality of life (HRQOL) is a more specific term with regard to

health and is a very useful and important indicator of patients' health perceptions resulting from their treatment. A strong association has been found between respondents' judgments of their health in general and choices of excellent, very good, fair or poor, with mortality over a 12 year follow-up period (Idler and Angel, 1990). There is an increasing awareness of the importance of HRQOL and both researchers and clinicians are paying more attention to evaluating HRQOL as a substantial outcome to be measured routinely in clinical care (Guyatt et al., 1997). In chronic conditions, where prevention or cure is not possible, the provision of pharmaceutical care can have the aim of improving HRQOL as a realistic outcome (Kheir et al., 2004).

Pharmacist's involvement in the care of hypertensive patients, as a normal practice in primary care units, is quite unusual in Thailand. Therefore, our study aimed to evaluate whether the involvement of a pharmacist in monitoring hypertensive patients over a 12 month period could improve BP outcomes and HRQOL issues.

MATERIALS AND METHODS

This study was approved by the Ethics Review Committee, the Faculty of Pharmacy, Chiang Mai University, on 9 September 2002.

There were a total of 235 patients with hypertension who entered the study. These were from three primary care units, one in Mahasarakham Hospital and in each of Takornyang and Kharmrieng districts, between October 2002 and February 2004. The patients were assigned into two groups, one group received a pharmacist's monitoring and intervention as an extra to their usual care and the other group received only the usual care. The method of patient selection, assignment and of the pharmacist's monitoring and intervention have been reported elsewhere (Sookaneknun et al., 2004).

The Medical Outcomes Study 36-Item Short-Form General Health Survey, SF-36 Thai version, which was validated in the Thai population, was selected for use in this study. The SF-36 Thai Version contains eight domains: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. There is also one question used to assess the patients' current health compared with their health in the previous year.

The SF-36 Thai version was administered by face-to-face interview because some patients could not read or understand the questions by themselves. Six interviewers interviewed each patient a total of three times, i.e., at the pre test, after six months and after 12 months. The interviewers consisted of two nurses and four Mahasarakham University Pharm.D. students who were all trained to help the patients understand the meaning of each of the questions used, based on the method described by Guenzel and colleagues (1983). The interviewers were subsequently tested to ensure a consistency of interviewing technique between interviewers. Some interviews were conducted outside the primary care units but most were carried out at the patients' houses.

We did not specifically calculate the sample size for the study from the variance of the questionnaire but used the existing 235 patients who had already been enrolled in the study of the effect of pharmacist's involvement on the treatment outcomes of hypertensive patients (Sookaneknun et al., 2004). This was because we also wished to investigate the effects of a

pharmacist's interventions on the same patients' quality of life.

Statistical analysis was performed using SPSS 10.0. Continuous variables were analyzed using multiple linear regression with the pre test as a covariate, the proportion comparison between groups were analyzed by multiple logistic regression, with the pre test as a covariate, and also by using the chi square test. Where variables violated normal distributions, nonparametric analyses were used, that is the Mann-Whitney U test and the Wilcoxon signed-rank test. Multiple comparisons between times and groups were made using analysis of variance and the Post hoc test. Internal consistency of the scales was determined using Cronbach's alpha.

RESULTS

Patient Characteristics

Patient characteristics at the pre test were the same between the treatment and the control group as shown in Table 1. At the pre test, 235 patients entered the study but after six months, seven patients dropped out of the study because of death (two), disablement (two), refusing to enter the study (two) and refusing to respond to the questions (one). After 12 months, there were an additional six patients who dropped out of the study because of death (three), disablement (one) and refusing to continue to the end of the study (two). However, the response rate remained quite high over the one year period. Percentages of gender over one year were quite stable in both genders. The percentage having illnesses and the mean ages also remained quite similar over the one year period.

Table 1. Homogeneity of demographic variables between groups at the pre test, after six and 12 months.

Treatment	Pre test		After 6 months		After 12 months	
	Control gr.	Treatment gr.	Control gr.	Treatment gr.	Control gr.	Treatment gr.
Number of patients	118	117	112	116	109	113
Response rate	100.00%		97.02%		94.47%	
Gender						
Men, no. (%)	42 (35.59%)	33 (28.21%)	39 (34.82%)	33 (28.45%)	39 (35.78%)	31 (27.43%)
Women, no. (%)	76 (64.41%)	84 (71.79%)	73 (65.18%)	83 (71.55%)	70 (64.22%)	82 (72.57%)
Age, mean + SD	63.20±9.33	63.23±9.25	62.92±8.94	63.23±9.29	62.86±9.05	63.37±9.17
Disease						
HTN	57 (48.31%)	54 (46.15%)	55 (49.11%)	51 (43.97%)	54 (49.54%)	51 (45.13%)
HTN +DM	39 (33.05%)	45 (38.46%)	38 (33.93%)	45 (38.79%)	36 (33.03%)	43 (38.05%)
HTN + TOD *	13 (11.02%)	7 (5.98%)	11 (9.82%)	9 (7.76%)	11 (10.09%)	8 (7.08%)
HTN + DM + TOD	9 (7.63%)	11 (9.40%)	8 (7.14%)	11 (9.48%)	8 (7.34%)	11 (9.73%)

*Target organ damage = previous stroke, myocardial infarction, left ventricular hypertrophy, angina pain, congestive heart failure, transient ischemic attack, renal failure

Note: p values were checked between groups, the results showed no significant difference between groups in any time, $p > 0.05$.

BLOOD PRESSURE OUTCOMES

Table 2 shows the proportion of patients who had their BP controlled. At the pre test, there were 27 of 118 patients in the treatment group who had controlled BP and these did not significantly differ from the patients in the control group, 21 of 117 patients, $p > 0.05$. After

12 months, the proportion of patients who achieved controlled BP was significantly higher in the treatment group, 92 of 118, than in the control group, 76 of 117, $p < 0.05$.

Table 2. Blood pressures at pre test and after 12 months in the treatment and the control groups

	Treatment group (N=118)		Control group (N=117)		Exp (B) (B)	95% CI	P value*
	BP controlled	BP uncontrolled	BP controlled	BP uncontrolled			
Pre test	27	91	21	96	1.36	0.72–2.57	0.349
After 12 months	92	26	76	41	1.85	1.03–3.34	0.040

*Multiple logistic regression was performed to evaluate a difference between groups which used pre test time results as a covariate.

Interactions which did not show a significant difference were excluded from the model.

Table 3 shows the results of BP reductions after 12 months. Systolic and diastolic BPs at the baseline did not significantly differ between groups, $p > 0.05$. After 12 months, there were significant differences between groups in both the mean of systolic and diastolic BPs, $p < 0.05$. This meant that both systolic and diastolic BPs in the treatment group were significantly lower than both BPs in the control group. No significant interaction between baseline SBP or baseline DBP and patient group was found. Within group comparison by paired t test showed that both the treatment and the control groups had significant reduction in both SBP and DBP after 12 months, $p < 0.05$.

Table 3. Mean blood pressure and paired differences for all patients (235) compared between the pre test and after 12 months.

Variable	Treatment group (n=118) Mean±SD	Control group (n=117) Mean±SD	p value
Pre test between groups			
Systolic mmHg	144.76±19.69	142.41±19.81	0.600
Diastolic mmHg	85.72±13.56	85.96±12.94	0.889
After 12 months between groups			
Systolic mmHg	118.03±13.67	130.08 ±20.63	<0.001
Diastolic mmHg	72.19±10.68	76.22 ±10.61	0.001
Paired differences within groups			
Systolic mmHg	26.72±19.36	12.32±21.55	<0.001
Diastolic mmHg	13.53±11.21	9.75±11.23	<0.001

RELIABILITY TEST

Table 4 shows the internal consistency (Cronbach's alpha) in each domain at each time interval. At the pre test, Cronbach's alpha ranged between 0.33–0.84. After six months, it ranged between 0.42–0.86 and after 12 months it ranged between 0.32–0.86. There were three domains which had values higher than the recommended value for indicating consistency of 0.7 (Leurmarnkul and Meetam, 2000) at all three measurement times, that is, physical functioning, role physical and role emotional scales, and at one time in bodily pain and mental health scales after 12 months.

Table 4. Comparisons of mean scores between the treatment and control groups across three measurement times analyzed by ANOVA.

SF-36 scales	No. of items	Times	Mean $\pm$ SD		Cronbach's alpha	p value (gr.)	p value (time)		p value (Inter)
			Treatment gr.	Control gr.			Treat gr.	Con gr.	
Physical function	10	Pre test	63.36 $\pm$ 21.16	63.36 $\pm$ 22.42	0.84	0.034	0.236	0.590	0.197
		After 6 mo.	66.92 $\pm$ 20.35	62.97 $\pm$ 24.17	0.86				
		After 12 mo.	67.86 $\pm$ 22.00	60.58 $\pm$ 24.39	0.86				
Role physical	4	Pre test	50.21 $\pm$ 36.76	47.01 $\pm$ 36.28	0.72	0.019	0.283	0.703	0.236
		After 6 mo.	49.33 $\pm$ 39.49	45.91 $\pm$ 40.24	0.82				
		After 12 mo.	56.88 $\pm$ 39.51	42.92 $\pm$ 37.72	0.79				
Bodily pain	2	Pre test	52.29 $\pm$ 17.77 ¹	52.86 $\pm$ 20.65	0.69	0.124	0.004	0.695	0.147
		After 6 mo.	56.03 $\pm$ 15.07	54.87 $\pm$ 16.02	0.55				
		After 12 mo.	60.16 $\pm$ 20.41 ¹	54.27 $\pm$ 18.61	0.74				
General health	5	Pre test	43.56 $\pm$ 17.14	47.59 $\pm$ 17.76	0.46	0.406	0.858	0.476	0.458
		After 6 mo.	47.63 $\pm$ 16.50	45.03 $\pm$ 14.84	0.42				
		After 12 mo.	47.56 $\pm$ 15.42	45.89 $\pm$ 17.74	0.43				
Vitality	4	Pre test	56.44 $\pm$ 16.40	55.98 $\pm$ 15.05	0.33	0.156	0.140	0.464	0.851
		After 6 mo.	58.97 $\pm$ 17.02	56.42 $\pm$ 16.74	0.44				
		After 12 mo.	60.92 $\pm$ 17.68	58.50 $\pm$ 17.24	0.32				
Social function	2	Pre test	74.77 $\pm$ 19.20	71.47 $\pm$ 19.20	0.41	0.015	0.643	0.713	0.940
		After 6 mo.	72.54 $\pm$ 18.90	69.61 $\pm$ 19.31	0.59				
		After 12 mo.	74.08 $\pm$ 19.37	69.91 $\pm$ 16.92	0.63				
Role emotional	3	Pre test	36.49 $\pm$ 41.57	42.17 $\pm$ 42.07	0.82	0.273	0.065	0.447	0.038
		After 6 mo.	41.96 $\pm$ 43.09	39.94 $\pm$ 41.29	0.82				
		After 12 mo.	49.54 $\pm$ 40.98 ²	35.40 $\pm$ 39.91 ²	0.78				
Mental health	5	Pre test	63.39 $\pm$ 16.81	63.11 $\pm$ 16.91	0.61	0.578	0.597	0.795	0.955
		After 6 mo.	63.14 $\pm$ 16.16	62.52 $\pm$ 15.23	0.61				
		After 12 mo.	65.21 $\pm$ 16.56	64.00 $\pm$ 17.74	0.74				

Treat = Treatment group, Con = Control group, Inter = Interaction

¹Post hoc test showed value <0.05 compared within group between the pre test and after 12 months

²p values < 0.05 compared between groups by Mann-Whitney U test

HYPERTENSIVE PATIENTS' QUALITY OF LIFE

Table 4 presents the mean scores which were obtained using the SF-36 scales, and these are compared between the treatment and control groups across the three measurement times by ANOVA. Most of the mean scores in the treatment group were higher than those in the control group. Patients within the treatment group had the lowest mean scores in role limitation due to emotional problems and the highest mean scores in social functioning. Similarly, patients within the control group showed the lowest mean scores in role limitation due to emotional problems and the highest mean scores in social functioning. After 12 months, patients within the treatment group rated lowest in general health and had the highest mean scores in social functioning, while patients within the control group responded with lowest mean scores in role limitation due to emotional problems and highest mean scores in social functioning. However, the results after six months did not show any significant difference between groups. Comparisons within each group showed only one significant improvement, and that was in the treatment group in bodily pain.

The health transition scale at the pre test and after six and 12 months is shown in Table 5. At the pre test, patients in both groups largely felt that their health was somewhat better

than a year previously, 28.0%, followed by somewhat worse, 23.7%. There was no significant difference between groups, $p > 0.05$. After six months, patients in the treatment group mostly felt that their health was then somewhat better, 31.3%, and much better, 24.1%, than one year previously, while patients in the control group mostly felt that their health was somewhat worse, 27.6%, or about the same, 22.4%, than one year previously. These results indicated a significant difference between groups, $p = 0.048$, and meant that patients in the treatment group at six months tended to feel that their health was better than one year previously. After 12 months, most patients in the treatment group felt that their health was somewhat better, 32.1%, followed by feeling about the same, 25.7%, and feeling much better, 21.1%. Whereas most patients in the control group felt that their health was about the same, 31.0%, followed by somewhat better, 29.2%, and somewhat worse, 20.4%. Only 5.3% felt that their health was much better than one year previously. These results indicated a greater significant difference between groups after 12 months, $p = 0.001$, when compared with after six months, $p = 0.048$. This meant that more patients in the treatment group tended to feel that their health was better than one year previously when compared with the feelings of patients in the control group.

Table 5. Percentage responses in the health transition scale of each group at the pre test, after six and 12 months.

	Pre test		After 6 months		After 12 months	
	Treatment gr.	Control gr.	Treatment gr.	Control gr.	Treatment gr.	Control gr.
1. Much better	15.3%	15.5%	24.1%	13.8%	21.1%	5.3%
2. Somewhat better	28.0%	27.6%	31.3%	21.6%	32.1%	29.2%
3. About the same	16.9%	19.0%	17.0%	22.4%	25.7%	31.0%
4. Somewhat worse	23.7%	22.4%	18.8%	27.6%	17.4%	20.4%
5. Much worse	16.1%	15.5%	8.9%	14.7%	3.7%	14.2%
p value*	0.996		0.048		0.001	

* p values were calculated by Chi square test

DISCUSSION AND CONCLUSION

During the study, JNC VI guidelines were used to define the target of BP goals and the protocol of the treatment (National High Blood Pressure Education Program, 1997). Only the target goal of BP for patients with diabetes, $<130/80$ mmHg, was used as in the later guidelines, JNC VII (National High Blood Pressure Education Program, 2003), which came into force after this study was started.

The results of BP difference and BP control after 12 months follow-up showed a significantly greater proportion of patients who had their BP controlled and who had bigger decreases in both systolic and diastolic BPs in the treatment group than in the control group. The results obtained at six months were similar and have already been reported (Sookaneknun et al., 2004). It was not expected that the control group would have such a large decrease in their BP, as previous studies had not shown this (Solomon et al., 1998; Garcao and Cabrita, 2002). This might be because of a major campaign by Mahasarakham hospital called 'Good Heart and Good Health'. This campaign encouraged patients to do exercise, gave information in controlling BP and attend group counseling. Nevertheless, the results reported here clearly show that having pharmacist involvement with patients on a monthly basis resulted in greater control of BP after six months and also that this greater control was maintained over

the 12 months period. This indicates that patients in the treatment group would receive more benefits in preventing morbidity and mortality than patients in the control group.

The SF-36 Thai version which was used in this study was validated in 569 normal Thai people, Cronbach's alpha coefficients ranged between 0.63-0.77 (Leurmarnkul and Meetam, 2000). However, the results obtained in our study ranged between 0.33-0.84 at the pre test, 0.42-0.86 after six months and 0.32-0.87 after 12 months. The coefficients were higher than 0.7 in only three scales; physical functioning, role physical and role emotional scales. Two studies have reported using two different Chinese SF-36 versions and both showed very low reliability in the social functioning scale. The respective coefficient alphas were 0.39 in 1,316 normal samples (Li et al., 2003) and 0.54 in 156 normal samples (Ren et al., 1998). Although the validation of the Thai version showed that the coefficient alpha was reasonable, the authors commented that the vitality scale scores were highly correlated to the mental health scale score. This could indicate that the SF-36 Thai version might need further cultural modification in order to more accurately measure Thai health status, especially in hypertensive patients in Northeastern Thai people.

Although there were quite low coefficient alphas in most of the domains, Cronbach's alpha < 0.7 , the reliability of the results obtained in this study was such that confidence can be placed in the significant differences between groups in the domains of the physical functioning, the role physical and the role emotion scales where Cronbach's alpha was > 0.7 . The results of ANOVA showed that patients in the treatment group had a better quality of life, especially in physical function, role limitation due to physical problems across the pre test, after six and 12 months and in role limitation due to emotional problems after 12 months. Moreover, mean scores in the treatment group increased in most of the domains, except in the social functioning. On the other hand, mean scores in the control group decreased in most of the domains except the bodily pain, the vitality and the mental health scales. This tended to indicate that a pharmacist's involvement had a positive influence in improving the patients' ability in physical, mental and social well-being at the one-year follow-up. Noticeably, the results after six months did not show any improvement or deterioration from the baseline and this is similar to other short-term studies (Erickson et al., 1997; Gourley et al., 1998; Krska et al., 2001). When the length of the study was greater, as in this study of 12 months, then the patients' quality of life in physical functioning, role limitation due to physical problems and social functioning scale showed significant improvements. This indicates that a sustained interaction in providing pharmaceutical care is probably necessary in order to have benefits on patient's quality of life (Kheir et al., 2004). Another possible explanation for producing a difference between groups was that a regular schedule of seeing patients was followed in order to provide pharmaceutical care. Thus there was a good relationship between patients and the pharmacist and good communication, which enabled the pharmacist to empathize with the patients' emotional difficulties (Foppe van Mil et al., 2004).

Our results indicate that personal involvement by a pharmacist with the treatment of hypertensive patients provided increased benefits in BP reduction and control together with an improvement in the patients' health-related quality of life.

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