

## CLINICAL SCIENCE

## HEALTH-RELATED QUALITY OF LIFE AND BLOOD PRESSURE CONTROL IN HYPERTENSIVE PATIENTS WITH AND WITHOUT COMPLICATIONS

Josiane Lima de Gusmão,<sup>I,II</sup> Decio Mion Jr.,<sup>I</sup> Angela Maria Geraldo Pierin<sup>II</sup>

doi: 10.1590/S1807-59322009000700003

Gusmão JL, Mion Jr. D, Pierin AMG. Health-related quality of life and blood pressure control in hypertensive patients with and without complications. Clinics. 2009;64(7):619-28.

**INTRODUCTION:** The goal of antihypertensive treatment is to reduce blood pressure without interfering in health-related quality of life (HRQL)

**OBJECTIVE:** This study aimed to assess the influence of hypertension control upon HRQL in hypertensive patients with and without complications.

**MATERIALS AND METHODS:** Seventy-seven hypertensive outpatients (71% women, 58% white, 60% with elementary school level education, average age  $54 \pm 8$  years) were observed during a 12-month special care program (phase 1: clinical visits every two months, donation of all antihypertensive medications, meetings with a multidisciplinary team, and active telephone calls) and three years of standard care (phase 2: clinical visits every four months, medication provided by the drugstore of the hospital with a two-hour wait and a possible lack of medication, no meetings with a multidisciplinary team or active telephone calls). The patient HRQL was assessed using Bulpitt and Fletcher's Specific Questionnaire, as well as the SF-36 scores. Hypertensive patients were divided into "with complications" ( $n=37$ , diastolic blood pressure great than 110 mm Hg for patients with or without treatment, with clinically evident target-organ or other associated illness) and "without complications" ( $n=40$ ). The variables studied were quality of life, blood pressure control, hypertension gravity, and demographic characteristics.

**RESULTS:** In hypertensive patients with and without complications, both the systolic and diastolic blood pressure were significantly higher ( $p<0.05$ ) in phase 2 of observation ( $143 \pm 18/ 84 \pm 11$  and  $144 \pm 21/ 93 \pm 11$  mm Hg for patients with and without complications, respectively) relative to phase 1 ( $128 \pm 17/ 75 \pm 13$  and  $128 \pm 15/ 83 \pm 11$  mmHg). The proportion of patients with controlled blood pressure (defined as a blood pressure less than 140/90 mm Hg) decreased from 70% to 49% in the "with complications" group and from 78% to 50% in the "without complications" group during phase 2 of observation. The patients with complications showed a decrease in bodily pain, vitality, and mental health component summary scores in both phases. In phase 2, the patients without complications had significantly better HRQL scores compared to complicated patients using both the Bulpitt and Fletcher's Questionnaire and the SF-36 assessment of physical capacity, bodily pain, and vitality domain summary scores. With regards to hypertension control, there was a significant decrease from phase 1 to phase 2 in the vitality component summary scores and an increase in the emotional aspect component summary scores assessed by the SF-36, whereas Bulpitt and Fletcher's Questionnaire showed no differences in these scores.

**CONCLUSION:** Special care programs with multidisciplinary activities, individualized and personalized assistance, easy access to pharmacological treatment, frequent meetings, and active telephone calls for hypertensive patients significantly increase blood pressure control but do not interfere with the HRQL.

**KEYWORDS:** Health-related quality of life; Hypertension; Blood pressure control; Treatment; Educational.

<sup>I</sup> Hypertension Unit, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo - São Paulo/SP, Brazil.

<sup>II</sup> School of Nursing, Universidade de São Paulo - São Paulo/SP, Brazil.

E-mail: josi@usp.br

Tel / Fax: 55 11 3069.7686

Received for publication on December 11, 2008

Accepted for publication on April 03, 2009

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>) which permits unrestricted noncommercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

## INTRODUCTION

Hypertension is a highly prevalent disease. In most countries, 15% to 30% of the adult population and more than 50% of the elderly population suffer from high blood pressure, making it a clear general public health problem. As

with smoking, diabetes, and dyslipidemia, hypertension is an important risk factor for cardiovascular diseases, which are responsible for roughly 30% of deaths worldwide.<sup>1-6</sup>

There is evidence that antihypertensive treatment significantly decreases cardiovascular morbidity and mortality.<sup>7,8</sup> Despite this evidence, it has been observed that the proportion of hypertensive patients in which blood pressure is adequately controlled is relatively low. In the United States, data from the National Health and Nutrition Examination Survey (NHANES) showed that 70% of hypertensive patients were aware of having the disease, 59% were under treatment, but only 34% had their hypertension under control.<sup>9</sup> Studies carried out in other countries revealed a similar low rate of blood pressure control: 25% in Belgium,<sup>10</sup> 21% in the Czech Republic,<sup>11</sup> 13.6% in India,<sup>12</sup> 15% in Hungary,<sup>13</sup> 10% in Austria,<sup>13</sup> 38% in England,<sup>14</sup> 8% in Egypt,<sup>13</sup> 5% in Slovakia,<sup>14</sup> less than 5% in China,<sup>15</sup> and 2.2% in Northern Greece.<sup>16</sup> Brazil is no exception, as multiple studies have demonstrated that approximately 30% of Brazilian hypertensive patients have adequate blood pressure control.<sup>17,18</sup> For example, Strelec et al. studied 130 hypertensive patients and found that only 35% of this cohort had good blood pressure control.<sup>19</sup>

An important aspect in the treatment of hypertension that must be considered is that treatment should not interfere with patient's quality of life.<sup>20</sup> Adverse effects from treatment drugs, diseases associated with hypertension, and simply being diagnosed with the disease since it is related to increased mortality can all decrease patient quality of life.<sup>21</sup> As such, the interest in assessing the health-related quality of life (HRQL) has increased significantly in the past few decades. One example of this interest is the Dietary Approaches to Stop Hypertension Trial (DASH), which has analyzed how effective three diets were for lowering blood pressure and preserving the HRQL. The DASH Diet (rich in fruits, vegetables, and low-fat dairy products and reduced in saturated and total fat) decreased blood pressure significantly and increased the HRQL as assessed by the Medical Outcomes Study Short Form-36 (SF-36) questionnaire in all groups studied.<sup>22</sup> In studies such as TOHP (Trials of Hypertension Prevention)<sup>23</sup> and TOMHS (Treatment of Mild Hypertension),<sup>24</sup> the decreased in blood pressure decrease was followed by an improvement in the HRQL.

The domains of HRQL chosen for evaluation in most studies involving hypertension are those that reflect the potential adverse effects of the treatment on work performance, sexual function, and humor.<sup>25</sup> Aydemir et al.<sup>26</sup> showed that hypertensive patients have a statistically significant decrease in all HRQL domains as assessed by the SF-36 when compared to normotensive patients. This study also showed that hypertensive patients with target-organ

damage are those with the lowest emotional and physical aspect, vitality, and mental health component summary scores.

Most studies on HRQL and hypertension do not refer to patients with severe hypertension or complications but are restricted to patients with moderate or mild hypertension. Severe or complicated hypertension is defined as a diastolic blood pressure  $\geq 110$  mm Hg for patients regardless of treatment status, with clinically evident target-organ damage (e.g., acute myocardial infarction, stroke, retinopathy) or other associated pathologies (e.g., diabetes, heart failure, renal diseases).

The present study is aimed at assessing the influence of blood pressure control on the HRQL of hypertensive patients with and without complications.

## MATERIALS AND METHODS

Seventy-seven hypertensive patients seen at an ambulatory service of the General Hospital of São Paulo, Brazil were selected (71% women, 58% white, 60% with elementary school level,  $54 \pm 8$  years) and enrolled in a 12-month special care program for hypertensive patients (phase 1). After the special program was completed, the patients were called back three years later for the second phase of the study. The criteria for patients to be enrolled in the special care program included: a male or female adult between 18 to 60 years old, primary hypertension, a body mass index lower than 40 kg/m<sup>2</sup>, and must have been attending the special care program for hypertensive patients for six months. The hypertensive patients were classified into two groups: "with complications" and "without complications".

### *Group 1. Hypertensive patients without complications*

The following criteria were used to define patients without complications: systolic blood pressure  $\geq 140$  mm Hg and/or diastolic blood pressure  $< 110$  mm Hg and  $\geq 90$  mm Hg, either undergoing or not undergoing treatment, and no clinically evident target-organ damage.

### *Group 2. Hypertensive patients with complications*

Patients with complications met the following criteria: diastolic blood pressure  $\geq 110$  mm Hg either undergoing treatment or not, with clinically evident target-organ.

## Study design

Hypertensive patients who were included in the study were assessed at two different points, in phase 1 (Special Care) and after three years in phase 2 (Usual Care).

Patients filled out an identification questionnaire and had their HRQL assessed using two questionnaires. In addition, anthropometric and blood pressure measurements were taken. All data were gathered on at the same appointment in both phases. The HRQL assessment was performed after the blood pressure measurements were taken.

#### *Phase 1 – Special Care*

In phase 1, patients attended a 12-month special care program for hypertensive patients. During this period, patients had to come to the hospital every two months to be seen by the same physician. The antihypertensive medications required by the patients were donated by the service itself. The patients also attended meetings held by the multidisciplinary team to talk about the disease, treatment, and life style. The patients also received active telephone calls from appropriately trained operators, as well as magazines with health-related information that were sent periodically by mail. In this phase, at the visit day, the patients were invited to take part in the present study and after providing written, informed consent, they followed the routine described.

#### *Phase 2 – Usual Care*

After the 12-month special care program (phase 1), the patients returned to usual care at the ambulatory clinic of the General Hospital or at another public institution. After three years, the patients were again evaluated in all aspects used in phase 1 to compare the maintenance of behavior identified in this phase.

Usual care consisted of clinical visits every four months, oftentimes with a different physician. The medications were provided by the hospital drugstore, which had an approximately two-hour waiting time and potentially could have been out of medication. No group meetings with a multidisciplinary team were held, nor were any informative pamphlets distributed.

Patients enrolled in phase 1 were called by phone to schedule their appointment with the outpatient service.

Age, sex, race, educational level, marital status, job status, smoking status, alcohol use, physical exercise, medical history, number of medications taken, and whether treatment was received at the General Hospital were determined by questionnaire (identification questionnaire) in both phases. Weight and height were measured to determine the body mass index (calculated as weight in kilograms divided by height in meters squared).

#### *Blood pressure measurement*

A nurse measured the patient's blood pressure five consecutive times with a one to two minute interval between

each measurement using a validated automatic device (DIXTAL DX 2710)<sup>27</sup> and an appropriate cuff size for the right arm. The five measurements were taken with the patient in a sitting position after a five minute rest. The average of the last three measurements was used for analysis.

The “without complications” group received eight weeks of treatment with placebo followed by one of the following treatment regimens: a) hydrochlorothiazide (6.25 mg, two times a day) and atenolol (25 mg, two times a day) or b) losartan (25 mg two times a day) and amlodipine (2.5 mg two times a day). If the blood pressure was unable to be controlled using these regimens, the doses were doubled or another antihypertensive was added. The “with complications” group did not undergo treatment with placebo. Patients in this group were randomized to receive drug regimens similar to the ones administered to the “without complications” group, considering the specificity of each condition. The addition of other antihypertensive agents in the “without complications” group, as well as the specific details of the treatment regimens for the “with complications” group, were decided according to established standards from the V Brazilian Guidelines on Arterial Hypertension.

#### **Health-related quality-of-life (HRQL) assessment**

##### *Bulpitt and Fletcher's Specific Questionnaire for HRQL assessment of hypertensive patients*

Bulpitt and Fletcher's Questionnaire was designed for hypertensive patients undergoing treatment in the outpatient setting. It addresses the physical and psychological aspects of treatment, as well as the patient perception of the effect of antihypertensive treatment upon their lifestyle. It includes questions related to clinical conditions, adverse effects of the medications, as well as social, professional, emotional, and sexual subjects related to hypertension or its treatment. The questionnaire was translated into Portuguese and validated. The questions allowed for answers including yes, no, or open answers, which when analyzed provided a score ranging from 1 to 100. A higher score is correlated with a higher HRQL.

##### *General Questionnaire for HRQL assessment by the Medical Outcomes Study 36-item short-form Health Survey (SF-36)*

The SF-36 is a general questionnaire for health assessment that has been applied in several studies and shown to be reproducible, valid, and responsive to changes in HRQL. It has been used for assessing several diseases by other investigators. For this study, it was translated into Portuguese and validated. The SF-36 is a multidimensional

questionnaire, composed of 36 items, and it covers eight domains of health: functional capacity, physical aspects, bodily pain, overall health status, vitality, social aspects, emotional aspects, mental health, and one question that assesses the difference between the current health status and the status one year prior.

Each question in the SF-36 is given a score that is later translated to a scale from 0 to 100, in which zero corresponds to the worst health status and 100 to the best. Each domain is assessed separately in order to avoid not identifying real health-related problems as well as specific problems in each domain. Both HRQL assessment questionnaires were conducted via interview.

### Statistical analysis

Microsoft Excel was using for the processing, inference, and descriptive analyses of the data. Descriptive statistics was used to characterize the demographic and clinical data of patients, whereas the differences between groups were analyzed using the chi-square test and the Student's *t*-test.

Scores obtained using the Bulpitt and Fletcher's and SF-36 questionnaires, as well as parametric data, were analyzed using the Kruskal-Wallis test.

A *p* value less than 0.05 was considered significant.

## RESULTS

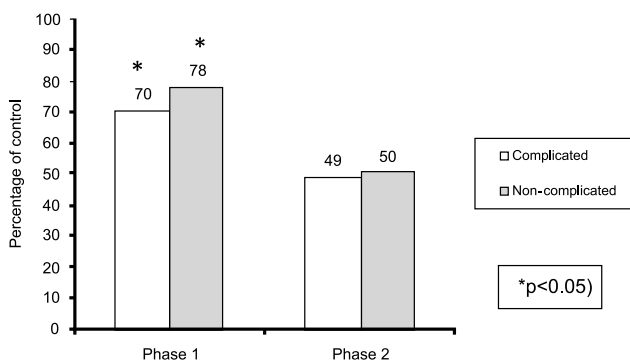
### Subjects

Seventy-seven hypertensive patients receiving outpatient treatment were enrolled in phase 1 (special care) and phase 2 (usual care).

The assessment of hypertensive outpatients in the two phases of the study revealed the following results: a) both the systolic and diastolic blood pressure of showed a significant increase ( $p<0.05$ ) between phase 1 ( $128\pm17/75\pm13$  and  $128\pm15/83\pm11$  mm Hg for the patients with complications and patients without complications, respectively) and phase 2 ( $143\pm18/84\pm11$  and  $144\pm21/93\pm11$  mm Hg patients with complications and patients without complications, respectively); b) the patients with complications were significantly different from patients without complications with regards to the number of different drugs taken for antihypertensive treatment over the two phases ( $\geq 4$  medications compared to 1–3 drugs,  $p<0.05$ ); c) for phase 1, all hypertensive patients received treatment at the institution where the study was carried out, whereas over phase 2, 78% of the patients with complications, while only 65% of the patients without complications remained under treatment at the same institution ( $p<0.05$ ); d) there were no

significant difference in the age, BMI, gender, race, marital status, education level, job, alcohol intake, physical exercise routine, smoking habits, or associated co-morbidities observed in the patients studied in both phases (Table 1).

Satisfactory blood pressure control ( $<140/90$  mm Hg) was attained in 70% of the patients with complications and 78% of the patients without complications in phase 1. In phase 2, there was a statistically significant decrease ( $p<0.05$ ) in the proportion of patients who maintained satisfactory blood pressure control, as only 49% of the patients with complications and 50% of the patients without complications maintained blood pressure control (Figure 1).



**Figure 1** - Blood pressure control in hypertensive patients with and without complications, according to phase of treatment.

### HRQL assessment using Bulpitt and Fletcher's Questionnaire

The HRQL scores from the Bulpitt and Fletcher Specific Questionnaire for hypertensive patients were close to the maximum score of 100, showing that the HRQL of the patients studied was quite good. There was no statistically significant difference between the HRQL scores of patients with controlled blood pressure and those with uncontrolled blood pressure (Table 2). However, when comparing hypertensive patients with and without complications in phase 2, hypertensive patients without complications had HRQL scores (96.21) significantly higher than hypertensive patients with complications (94.98;  $p<0.05$ ; Figure 1).

### HRQL assessment using SF-36

The scores obtained from the eight domains of the SF-36 demonstrated that the functional capacity and overall health status domains had the highest HRQL scores, whereas the vitality and mental health domains had the worst scores in both patients with and without complications, regardless of blood pressure control.

The SF-36 HRQL assessment also revealed that

**Table 1** - Age, gender, race, school level, marital status, job, body mass index (BMI), life habits, blood pressure, and number of medications taken of hypertensive patients with and without complications

Characteristics	Hypertensives			
	Complicated (n=37)		Non-complicated (n=40)	
	Phase 1	Phase 2	Phase 1	Phase 2
<b>Age</b> (years) mean $\pm$ standard deviation	53 $\pm$ 8	56 $\pm$ 8	51 $\pm$ 9	55 $\pm$ 9
<b>BMI</b> (kg/m <sup>2</sup> )	32 $\pm$ 4	32 $\pm$ 4	29 $\pm$ 4	29 $\pm$ 4
<b>Systolic BP</b> (mmHg)	128 $\pm$ 17	143 $\pm$ 18*	128 $\pm$ 15	144 $\pm$ 21*
<b>Diastolic BP</b> (mmHg)	75 $\pm$ 13	84 $\pm$ 11*	83 $\pm$ 11	93 $\pm$ 11*
<b>Gender</b> n (%)				
Female	20 (54)	20 (54)	35 (87)	35 (87)
Male	17 (46)	17 (46)	5 (12)	5 (12)
<b>Race</b> n (%)				
White	22 (59)	22 (59)	23 (57)	23 (57)
Non-white	15 (41)	15 (41)	17 (43)	17 (43)
<b>Marital status</b> n (%)				
Married	23 (62)	23 (62)	28 (70)	28 (70)
Non-married	14 (38)	14 (38)	12 (30)	12 (30)
<b>School level</b> n (%)				
Illiterate/ Read-write	6 (16)	6 (16)	6 (15)	6 (15)
Elementary	22 (60)	22 (60)	24 (60)	24 (60)
Middle	9 (24)	9 (24)	8 (20)	8 (20)
University	0 (0)	0 (0)	2 (5)	2 (5)
<b>Job</b> n (%)				
Non-specialized manual	18 (49)	18 (49)	27 (67.5)	27 (67.5)
Specialized manual	11 (30)	11 (30)	7 (17.5)	7 (17.5)
Not manual	2 (5)	2 (5)	4 (10)	4 (10)
Unemployed/ retired	6 (16)	6 (16)	2 (5)	2 (5)
<b>Alcohol intake</b> n (%)				
Never	27 (73)	27 (73)	30 (75)	30 (75)
Quit	7 (19)	7 (19)	5 (12.5)	5 (12.5)
Often	3 (8)	3 (8)	5 (12.5)	5 (12.5)
<b>Physical exercise routine</b> n (%)				
Never	18 (49)	17 (46)	18 (45)	15 (38)
Quit	7 (19)	8 (22)	13 (33)	14 (35)
Often	12 (32)	12 (32)	9 (22)	11 (27)
<b>Smoking</b> n (%)				
Never	18 (49)	18 (49)	23 (58)	23 (58)
Quit	16 (43)	16 (43)	11 (27)	11 (27)
Often	3 (8)	3 (8)	6 (15)	6 (15)
<b>Mellitus Diabetes</b> n (%)	12 (32)	12 (32)	-	-
<b>Acute Myocardial Infarction</b> n (%)	2 (5)	4 (11)	-	-
<b>Stroke</b> n (%)	7 (19)	7 (19)	-	-
<b>Renal disease</b> n (%)	4 (11)	4 (11)	-	-
<b>N° of medications</b> n (%)				
1 to 3	16 (43)	15 (41)	34 (85)**	35 (88)**
$\geq$ 4	21 (57)	22 (59)	6 (15)**	5 (12)**
<b>Treated at the General Hospital</b> n (%)	37 (100)	29 (78)*	40 (100)	26 (65)*

\*p&lt;0.05, phase 1 vs. phase 2; \*p&lt;0.05, complicated vs. non-complicated; BP=blood pressure

**Table 2.** Health-related quality of life scores obtained using Bulpitt and Fletcher's Specific Questionnaire for Hypertensive patients of the two treatment groups across both phases of this study.

Phase	Controlled (n=38)	Uncontrolled (n=39)
Phase 1	95.41 $\pm$ 2.86	95.68 $\pm$ 2.53
Phase 2	95.56 $\pm$ 2.56	95.68 $\pm$ 2.44

hypertensive patients without complications had a HRQL score significantly higher ( $p<0.05$ ) than patients with complications in the functional capacity ( $80.88 \pm 16.83$  vs.  $75.00 \pm 20.68$ ), bodily pain ( $72.00 \pm 22.0$  vs.  $59.73 \pm 20.68$ ), and vitality ( $56.25 \pm 16.67$  vs.  $47.57 \pm 17.50$ ) domains. The hypertensive patients with complications had a lower HRQL score in phase 1 than in phase 2 for the bodily pain ( $61.08 \pm 24.24$  vs.  $59.73 \pm 20.68$ ), vitality ( $62.57 \pm 23.94$  vs.  $47.57 \pm$

**Table 3** - Health-related quality of life scores by SF-36 dimensions.

Dimensions	Hypertensive Patients			
	Complicated (n=37)	Non- Complicated (n=40)	Controlled (n=38)	Uncontrolled (n=39)
<b>Physical functioning</b>				
Phase 1	76.35 ± 21.23	75.00 ± 20.25	78.29±20.67	73.08±20.48
Phase 2	75.00 ± 20.68	80.88 ± 16.83*	80.53±17.27	75.64±20.27
<b>Role-physical</b>				
Phase 1	70.27 ± 38.11	73.75 ± 35.33	76.32±36.74	67.95±36.25
Phase 2	62.84 ± 38.02	76.25 ± 36.23	67.76±37.18	71.79±38.12
<b>Pain</b>				
Phase 1	61.08 ± 24.24	62.50 ± 22.50	59.74±19.10	63.85±26.72
Phase 2	59.73 ± 20.68**	72.00 ± 22.10*	64.74±24.36	67.44±27.50
<b>General health perception</b>				
Phase 1				
Phase 2	72.84 ± 15.75	72.00 ± 19.96	68.82±18.94	75.90±16.42
	70.95 ± 17.27	73.50 ± 20.58	70.39±18.25	74.10±19.73
<b>Vitality</b>				
Phase 1	62.57 ± 23.94	57.13 ± 23.86	58.03±23.41	61.41±24.55
Phase 2	47.57 ± 17.50**	56.25 ± 16.67*	51.45±15.51**	52.69±19.46**
<b>Social functioning</b>				
Phase 1	73.24 ± 24.67	64.25 ± 29.31	65.33±29.43	71.73±25.20
Phase 2	66.28 ± 22.80	68.50 ± 20.58	66.18±22.15	68.65±21.18
<b>Role-emotional</b>				
Phase 1	62.16 ± 44.56	56.67 ± 43.49	56.14±43.91	62.39±44.05
Phase 2	76.58 ± 32.27	65.83 ± 41.68	72.81**	69.23±38.53
<b>Mental Health</b>				
Phase 1	64.65 ± 24.32	54.00 ± 26.49	58.63±26.83	59.59±25.23
Phase 2	59.78 ± 17.51**	58.80 ± 19.75	59.26±18.60	59.28±18.83

\*p<0.05, complicated vs. non-complicated

\*\*p<0.05, phase 1 vs. phase 2

17.50), and mental health (64.65 ± 24.32 vs. 59.78 ± 17.51) domains. A statistically significant decrease in the vitality component summary score was observed between phase 1 and phase 2 (58.03 ± 23.41 vs. 51.45 ± 15.51). However, a significant increase was observed from phase 1 to phase 2 in the emotional aspect component summary score (56.14 ± 43.91 vs. 72.81 ± 39.87) (Table 3).

## DISCUSSION

The HRQL scores obtained using Bulpitt and Fletcher's Specific Questionnaire for hypertensive patients showed no change in the HRQL between the two phases of the study. Overall, the HRQL scores were very high in both phases, suggesting that the antihypertensive treatments had few or no adverse effects on the patient quality of life. These results are similar to those found in other studies<sup>28-30</sup> and they are likely due to the minimal side effects of modern antihypertensives. We also observed that patients without complications exhibited a significant improvement in quality of life compared to complicated hypertensive patients, even after phase 1.

Another important finding was that the Bulpitt and Fletcher's Questionnaire HRQL scores remained high regardless of blood pressure control. Even three years after

the special care phase, when hypertension control had decreased significantly, the HRQL scores remained above 90 out of a possible 100. This finding may be explained by the minimal impact of hypertension on quality of life, as it is an asymptomatic disease that only presents with long-term complications. To illustrate this aspect of the disease, a study conducted in eight different countries measured quality of life in several chronic diseases. Hypertensive patients showed the best HRQL indices, which were close to those obtained by the control group, when compared with other diseases such as arthritis, pulmonary diseases, diabetes, congestive heart failure, and heart ischemic disease.<sup>30</sup>

The twelve-month special care program used in phase 1, which involved multidisciplinary activities, individualized and personalized assistance, easy access to pharmacological treatment, frequent meetings, and active telephone calls, undoubtedly contributed to the rate of successful hypertension control achieved. However, this situation was not sustainable after the special care program was terminated. Three years after phase 1, blood pressure control decreased significantly in both "with complications" (70% to 49%) and "without complications" patients (78% to 50%). However, during this period, none of the patients without complications studied had their condition worsen to the complicated status, and the blood pressure control

level remained similar or better than those observed in other countries.<sup>10-16</sup> A major reason for inadequate control of hypertension is poor adherence to treatment. Many reasons exist for non-adherence to medical regimens, including adverse drug effects, poorly provided instructions, a poor provider-patient relationship, poor patient memory, patient disagreement with the need for treatment, or patient inability to pay for treatments.<sup>31</sup>

The relationship between quality of life and compliance is complex and merits careful study. Monitoring quality of life may be one of the best ways to improve treatment adherence. Therefore, when developing an approach for hypertension treatment, physicians should consider the impact of different antihypertensives on the overall well being of the patient. Consideration of quality of life issues, along with side effects and contraindications, should determine the choice of medication administered.<sup>32</sup>

The SF-36-based HRQL assessment revealed that there were differences between the two phases of the study as well as between patients with and without complications. Three of the eight domains analyzed in the “with complications” group exhibited a decrease in the HRQL between phase 1 and phase 2: bodily pain, vitality, and mental health. As hypertension is often asymptomatic, it is not surprising that the functional capacity and physical aspects domains would remain unchanged. However, according to Bulpitt et al.,<sup>24</sup> the awareness of having the disease and the association of hypertension with death can be responsible for changing quality of life. Furthermore, a change in one HRQL dimension can impact other dimensions. Indeed, the mental health domain could be responsible for changing the bodily pain and vitality domains due to somatization caused by the awareness of having the disease. This phenomenon has been demonstrated in a study carried out in Japan, which observed that changes in the mental health domain were responsible for worsening other HRQL domains assessed by the SF-36.

In the hypertensive group without complications, there was no change in scores in any HRQL domain in the SF-36 during either phase. This finding suggests that quality of life is not related to blood pressure level, but rather to how severe the co-morbidities caused by hypertension are. A study to assess the impact of co-morbidities in hypertensive patients has demonstrated that patients with associated co-morbidities show significant reduction in the quality of life when compared with those who do not suffer from co-morbidities.<sup>29</sup>

Although the HRQL was not measured at baseline, the scores found for the different SF-36 domains were similar and even superior<sup>29</sup> to those observed in other studies of hypertensive patients with and without complications.<sup>33,34</sup> These scores tended to be lower than those found for

normotensives,<sup>35</sup> suggesting that hypertension really causes several changes in the life of a patient. The SF-36 assesses hypertensive patients more broadly and, as such, was more sensitive than Bulpitt and Fletcher’s Questionnaire to detect changes in quality of life.

Working directly with hypertensive patients through the special care program demonstrated that blood pressure can be reduced to a satisfactory level without changing the HRQL. However, these reductions were not sustainable, regardless of the inherent characteristics of the population studied. It is important to point out that improving access to pharmacological treatments is a key factor our country needs to improve upon in order to ensure better treatment compliance and effective blood pressure control. A study conducted in Hungary also assessed the effectiveness of a special care program called “Manage it well” for hypertensive patients. The outcomes of this study showed that strategies similar to those used in the present study significantly increased treatment success, decreased the in-office blood pressure measurements, and significantly increased blood pressure control (from 2.9% at baseline to 40.9% after a six-month intervention).<sup>36</sup> There is no doubt that the best levels of hypertension control are observed in randomized, prospective clinical trials that assess the efficiency of antihypertensive drugs. However, it is evident that each of these studies does not represent the treatment reality for hypertensive patients.<sup>37-40</sup>

Hypertension control is clearly related to treatment compliance, which is one of the greatest challenges faced by physicians today. Several factors can influence compliance with antihypertensive treatment. These factors can be related to the patient (e.g., gender, age, race, marital status, school level, and social economical level), to the disease (e.g., how chronic it is, absence of symptoms, and late consequences), to health beliefs, life circumstances and cultural habits (e.g., perception and severity of the problem, unawareness of the disease, experience with the disease in a family context, and self-esteem), to the treatment (e.g., cost, side effects from drugs, complex treatment programs), to the institution (e.g., health policy, health service utilization, waiting time vs. care delivered time), and to the patient-health team relationship.<sup>22</sup>

The high HRQL scores attained in phase 1 in the present study are likely due to the special care program and more aggressive treatment over twelve months, but this practice is not usual in public health services in Brazil. Less aggressive treatments and physician apathy towards high blood pressure<sup>1,9</sup> have been identified as being responsible for the lack of blood pressure control.<sup>21-22</sup> In the present study, roughly 60% of the patients with complications were required to take more than four antihypertensive medications, whereas only

15% of the patients without complications needed to take the same number. Antihypertensive treatments aim to reduce cardiovascular morbidity and mortality. Thus, pharmacological treatments should not only seek to lower blood pressure, but also decrease the number of fatal and non-fatal cardiovascular events. Blood pressure should be reduced to lower than 140/90 mm Hg, taking into account individual characteristics, presence of co-morbidities, and patient quality of life.<sup>1</sup> Often multiple medications are required to achieve therapeutic goals. It has been observed that, in general, at least three therapeutic classes are needed to attain an acceptable blood pressure, which is often beyond

recommendations.<sup>41</sup> Excellent well-designed clinical trials have restated the importance of medication for hypertension treatment.<sup>38,42</sup>

In conclusion, the present study showed that a special care program for hypertensive patients reduced blood pressure and significantly increased blood pressure control without greatly affecting the HRQL. It is important to note that hypertensive patients with higher distress levels, more co-morbidities, and complications from their disease have a different quality of life and degree of blood pressure control compared to hypertensive patients without complications.

---

## REFERENCES

1. Mion Jr. D, Praxedes JN, Amodeo C, Gomes MAM, Machado CA, Gusmão JL, et al. V Brazilian Guidelines in Arterial Hypertension. *Arq Bras Cardiol.* 2007; 89:e24-e79.
2. Hamet P. The burden of blood pressure: where are we and where should we go? *Can Cardiol.* 2000;16:1483-7.
3. Vega CE, Kahhale S, Zugaib M. Maternal mortality due to arterial hypertension in São Paulo City (1995-1999). *Clinics.* 2007;62:679-84.
4. Martinelli LM, Mizutani BM, Mutti A, D'elia MP, Coltro RS, Matsubara BB. Quality of life and its association with cardiovascular risk factors in a community health care program population. *Clinics.* 2008;63:783-8.
5. Bocalini DS, dos Santos L, Serra AJ. Physical exercise improves the functional capacity and quality of life in patients with heart failure. *Clinics.* 2008;63:437-42.



6. Pierin AM, Ignez EC, Jacob Filho W, Barbato AJ, Mion Jr D. Blood pressure measurements taken by patients are similar to home and ambulatory blood pressure measurements. *Clinics*. 2008;63:43-50.
7. Prospectives Studies Collaboration. Cholesterol, diastolic blood pressure and stroke: 13.000 strokes in 450.000 people in 45 prospectives cohorts. *Lancet* 1995;346:1647-53.
8. Coca A. Actual blood pressure control: are we doing things right? *J Hypertens* 1998;16:S45-51.
9. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The JNC 7 Report. *JAMA*. 2003;289:2560-72.
10. Fagard RH, Van den Enden M. Treatment and blood pressure control in isolated systolic hypertension vs diastolic hypertension in primary care. *J Hum Hypertens* 2003;17:681-7.
11. Cifkova R, Skodova Z, Lanska V, Adamkova V, Novozamska E, Jozifova M, et al. Prevalence, awareness, treatment, and control of hypertension in the Czech Republic. Results of two nationwide cross-sectional surveys in 1997/1998 and 2000/2001, Czech Post-MONICA Study. *J Hum Hypertens*. 2004;18:571-9.
12. Bharucha NE, Kuruvilla T. Hypertension in the Parsi community of Bombay: a study on prevalence, awareness and compliance to treatment. *BioMed Central Public Health*. 2003;3:1. Epub 2003.
13. Fodor JG, Lietava J, Rieder A, Sonkodi S, Stokes H, Emmons T, et al. Work-site hypertension prevalence and control in three Central European Countries. *J Hum Hypertens*. 2004;18:581-5.
14. Wolf-Maier K, Cooper RS, Kramer H, Banegas JR., Giampaoli S, Joffres MR, et al. Hypertension Treatment and Control in Five European Countries, Canada, and the United States. *Hypertension*. 2004;43:10-17.
15. Whelton P K, He J, Muntner P. Prevalence, awareness, treatment and control of hypertension in North America, North Africa and Asia. *J Hum Hypertens*. 2004; 18:545-51.
16. Sarafidis PA, Lasaridis A, Gousopoulos S, Zebekakis P, Nikolaidis P, Tziolas I, et al. Prevalence, awareness, treatment and control of hypertension in employees of factories of Northern Greece: the Naoussa study. *J Hum Hypertension*. 2004;18:623-29.
17. Piccini RX, Victoria CG. How well is hypertension managed in the community? A population-based srvey in a Brazilian city. *Cad Saude Publica*. 1997;17:151-83.
18. Gus I, Harzheim E, Zaslavsky C, Medina C, Gus M. Prevalence, awareness, and control of systemic arterial hypertension in the state of Rio Grande do Sul. *Arq Bras Cardiol*. 2004;83:424-28.
19. Strelec MAAM, Pierin AMG, Mion Jr. D. The Influence of Patient's Consciousness Regarding High Blood Pressure and Patient's Attitude in Face of Disease Controlling Medicine Intake. *Arq Bras Cardiol*. 2003;81:349-54.
20. Fletcher A. Quality of life in the management of hypertension. *Clin and Exper Hypertension*. 1999;21:961-72.
21. Bulpitt CJ, Dollery CT, Carne S. Change in symptoms of hypertension patients after referral to hospital clinic. *Br Heart J*. 1976;38:121-8.
22. Plaisted CS, Lin P-H, Ard JD, McClure ML, Svetkey LP. The effects of dietary patterns on quality of life: a substudy of the Dietary Approaches to Stop Hypertension trial. *J Am Diet Assoc.* 1999;99:S84-S89.
23. Batey DM, Kaufmann PG, Raczkinski JM, Hollis JF, Murphy JK, Rosner B. Stress management intervention for primary prevention of hypertension: detailed results from Phase I of Trials of Hypertension Prevention (TOHP-I). *Ann Epidemiol*. 2000;10:45-58.
24. Grimm Jr. RH, Grandits GA, Cutler JA, Stewart AL, McDonald RH, Svendsen K, et al. for the TOMHS Research Group. Relationships of quality of life measures to long-term lifestyle and drug treatment in the Treatment of Mild Hypertension Study (TOMHS). *Arch Inter Med*. 1997;157:638-48.
25. Bulpitt CJ, Fletcher AE. Quality of life instruments in hypertension. *Pharmaco Economics*. 1994;6:523-35.
26. Aydemir O, Ozdemir C, Koroglu E. The impact of co-morbid conditions on the SF-36: a primary-care-based study among patients. *Arch Med Res*. 2005; 36:136-41.
27. Mano GM, Souza VF, Pierin AM, Lima JC, Ignez EC, Ortega KC, et al. Assessment of the DIXTAL DX-2710 automated oscillometric device for blood pressure measurement with the validation protocols of the British Hypertension Society (BHS) and the Association for Advancement of Medical Instrumentation (AAMI). *Arq Bras Cardiol*. 2002;79:606-10.
28. Palmer AJ, Fletcher AE, Rudge PJ, Andrews CD, Callaghan S, Bulpitt CJ. Quality of life in patients treated with atenolol or captopril: a double-blind crossover trial. *J Hypertens*. 1992;10:1409-16.
29. Fletcher AE, Chester PC, Hawkins CMA, Latham AN, Pike LA, Bulpitt CJ. The effects of verapamil and propranolol on quality of life in hypertension. *J Hum Hypertens*. 1989;3:125-30.
30. Alonso J, Ferrer M, Gandek B, Ware Jr. J, Aaronson NK, Mosconi P, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Qual Life Res*. 2004;13:283-98.
31. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence (Cochrane Review). In: *The Cochrane Library*, Issue 3, 2008.
32. Nunes MI. The relationship between quality of life and adherence to treatment. *Curr Hypertens Rep*. 2001;3:462-5.
33. Erickson SR, Williams, Gruppen LD. Perceived symptoms and health-related quality of life reported by uncomplicated hypertensive patients compared to normal controls. *J Hum Hyperetens*. 2001;15:539-48.
34. Bardage C, Isacson D, Ring L, Bingefors. A swedish population-based study on the relationship between the SF-36 and health utilities to measure health in hypertension. *Blood Press*. 2003;12:203-10.
35. Hemingway H, Stafford M, Stansfeld S, Shipley M, Marmot M. Is the SF-36 a valid measure of change in population health? Results from the Whitehall II study. *BMJ*. 1997;315:1273-9.
36. Szirmai LA, Arnold C, Farsang C. Improving control of hypertension by an integrated approach - results of the "Manage it well" programme. *J Hypertens*. 2005;23:203-11.
37. Hanson L, Zanchetti A, Carruthers SG, Dahlof B, Elmfeidt D, Julius S, et al., for the HOT Study Group. Effects of intensive blood pressure lowering an low-dose aspirin in patients with hypertensive: principal results of the Hypertension Optimal Treatment (HOT) randomized trial. *Lancet*. 1998;351:1756-62.
38. Haynes BR, McRibbon KA, Kanani R. Systematic review of randomized trials of interventions to assist patients to follow prescriptions for medications. *Lancet*. 1996; 348:383-6.

39. McIness GT. Integrated approaches to management of hypertension: promoting treatment acceptance. *Am Heart J.* 1999;138:252-6.
40. Bakris GL, Weir MR, Black HR. Improving blood pressure control rates: is there more we can do? *J Clin Hypertens.* 2007;9:134-42.
41. Mancia G, Grassi G. Systolic and diastolic blood pressure control in atipatients drugs trials. *J Hypertens.* 2002;20:1461-4.
42. Hypertension Detection and Follow-up Program Cooperative Group. Five years finding of the Hypertension Detection and Follow-up Program: I. Reduction on mortality of persons with high blood pressure, incluinding mild hypertension. *JAMA.* 1979;242:2562-71.