RESEARCH ARTICLE

Determinants of health-related quality of life in patients with hypertension

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ABSTRACT

Background: Health-related quality of life (HRQOL) is emerging as an important outcome in hypertension and can be adversely affected by hypertension itself and side effects of antihypertensive drugs. **Aim and Objective:** The aim of the study was to analyze the HRQOL of hypertensive patients and to identify the factors affecting HRQOL, especially drug related factors. **Materials and Methods:** A total of 254 patients, who fulfilled the selection criteria, were enrolled for the study. Patients were approached after they finished consultation with the physician and their case record sheets were reviewed for gathering the necessary information as per case record form. Patients' HRQOL was assessed using MINICHAL scale. **Results:** Among total 254 patients, patients with pre-hypertension, Stage 1, and Stage 2 of hypertension were 152, 73, and 29, respectively. Blood pressure (BP) controlled was achieved in only 31.5% of patients with drug therapy. The average scores in mental and somatic domains of MINICHAL scale were 2.5 ± 2.6 (95% confidence interval [CI]: 2.3–2.9) and 3.1 ± 3.5 (95% CI: 3.0–4.0), respectively, with mean total score of 5.5 ± 5.3 (95% CI: 4.6–6.0). Males have significantly lower MINICHAL score ($P < 0.01$) than females. Patients, who were living with family ($P < 0.046$), with illiterate ($P = 0.001$), with regular physical exercise ($P = 0.004$), and with controlled BP ($P < 0.05$), have significantly lower MINICHAL score. HRQOL was not significantly different in patients of any age, number of drugs prescribed, severity and duration of hypertension, concomitant disease, salt restriction, and selection of drugs, coprescription of antiplatelet, or statins or development of adverse drug reactions. **Conclusion:** This study has shown the lower HRQOL among hypertensive patients, and it was associated with gender, education, physical exercise, and BP control achieved.

KEY WORDS: Health-related Quality of Life; Hypertension; Determinants; MINICHAL Scale

INTRODUCTION

The overall burden of hypertension and other cardiovascular diseases is rapidly rising in the developing world.[1] Quality of life (QOL) is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationship to salient features of their environment.[2] Health-related QOL (HRQOL) is emerging as an important outcome in hypertension and can be adversely affected by hypertension itself and the side effects of antihypertensive drugs.[3] However, reports of HRQOL among hypertensive individuals have been conflicting, with some studies finding worse HRQOL among hypertensives compared to the general population,[4,5] while Moum *et al*. reported no impact of hypertension on HRQOL in some/all domains.[6]

The relationships between patient, disease, treatment variables, symptoms, and HRQOL were described by a model published in 1995.[7] This model proposes that physiologic changes due to illness or treatment lead to symptoms, which in turn influences functional status or HRQOL. These relationships are influenced by patient and environmental variables that may affect the patient perception of symptoms and changes in HRQOL. This general model can be applied to data from clinical studies to ascertain the strength of relationships between HRQOL and patient, disease, and treatment variables. Different researchers have reported different determinants of HRQOL including disease symptoms, severity of illness, and drug-related factors such as number of antihypertensive medicines and adverse reactions to therapy.[8-10]

There is a paucity of studies reporting HRQOL in Indian hypertensive patients. Hence, this study is designed to determine QOL in hypertensive patients using MINICHAL scale,[11] a specific tool for assessing QOL in hypertensive individuals. This study also aims toward identifying and evaluating different determinants of HRQOL with special focus on drug therapy-related factors.

MATERIALS AND METHODS

This was a prospective, observational, and single-center study carried out in the medicine outpatient department (OPD) of a tertiary care teaching hospital in West India. The study protocol was presented and approved by an Institutional Ethics Committee (IEC) (Letter No. GMERS/MCG/IEC/20/2015, dated 08/04/2015). Patients were explained clearly about the nature and purpose of the study in the language they understood. Written informed consent was obtained before enrolling the patient for the study. Permission from the medical superintendent and the head of the medicine department was obtained before conducting the study.

All the patients age 18 years and above and suffering from hypertension and taking antihypertensive treatment for at least 1 0 and attending to the medicine OPD in April–May 2015 were screened for their enrollment in the study. Patients who were newly diagnosed case of hypertension and patients who refused to consent for the QOL interview were excluded from the study. Indoor patients with hypertension were also excluded from the study because the majority of them were acutely ill with marked alteration in QOL.

Sample Size

It was determined by considering the prevalence of hypertension and taking standard deviation (SD) 9.6, alpha error 0.05, critical difference 1.90, and power of the study 90%. It was necessary to involve 254 patients in the study.

Study Procedure Details

A total of 254 patients meeting and exclusion criteria and attended the medicine OPD were enrolled for the study. Patients were approached after they finished a consultation with the physician in the hospital. All necessary information such as demographic data, history of illness, clinical data, and drug treatment were collected by reviewing the hospital case file and by an interview with patients. All the information gathered was recorded in the structured case record form (CRF). The sociodemographic data included age, gender, social class, marital status, and education qualification. Clinical data included symptoms, duration of hypertension, blood pressure (BP) reading, comorbidities/complications, drugs prescribed, and non-pharmacological measures followed by patients.

Drug history was evaluated in detail regarding, selection of antihypertensive drug, number of antihypertensive drugs prescribed, dose, route, frequency and duration of administration of drug, any adverse drug reaction (ADR), or drug interaction and was recorded in a structured CRF.

Thereafter, patients were interviewed about QOL using MINICHAL scale (hypertension specific).

Questionnaire to Measure HRQOL

This instrument was translated in vernacular (Gujarati) language and back translated to ensure content validity. The questionnaire was designed for self-administration but the structured interview was conducted to ensure the reliability of data. In the interviews, the patients were asked to respond based on the past 7 days of their health. To test the feasibility of the instruments, pilot study was carried out on 20 patients. It took approximately about 10 min to collect data from one patient (consent, history, QOL scale).

MINICHAL Scale[11]

The MINICHAL scale was developed in Spain in 2001 and contains 17 items. This instrument can be used both for population-based studies and clinical trials to assess a patient's QOL. MINICHAL word was derived from "Mini-Cuestionario de Calidad de Vida en Hipertensión Arterial." It consists of two domains – mental (nine items) and somatic (seven items). The mental domain (MD) includes questions one to nine and score ranges from 0 to 27 points. The somatic domain includes questions 10–16 and the score ranges from 0 to 21 points. The last question is related to the overall impact of hypertension on the QOL. The score scale is a Likert scale with four possible answers (0 = No, not at all; one = yes, somewhat; two = yes, a lot; and three = yes, very much). Total points range from 0 (best level of health) to 51 (worst level of health).

Statistical Analysis

Microsoft Excel 2007 and SPSS version 20 was used to analyze the data. Descriptive analysis included actual frequencies, percentage, calculation of means, and SDs of categorical variables. The statistical correlations between different determinants (patient-related factors, drug-related factors, and demographic parameters) with HRQOL were analyzed using Mann–Whitney TEST and Kruskal–Wallis test as appropriate. The values were considered statistically significant, if $P < 0.05$.

RESULTS

A total of 254 patients with hypertension were included in the study for analysis of QOL and its determinants. Demographic and disease-related parameters of these patients are shown in Table 1. The highest number of patients (65.4%) was from age group of 51 to 70 years followed by the age group of 31 to 50 years (26.8%). A total 254 patients, 142 (55.9%) were male and 112 (44.1%) were female. The majority of patients (65%) were illiterate and most of the patients (93.7%) were living with their family.

Analysis of Disease-Related Parameters

Out of these 254 patients, 152, 73, and 29 were falling into the category of pre-hypertension, Stages 1 and 2 of hypertension. Out of 254 patients, majority 108 (42.4) had hypertension duration of 1–5 years, followed by 5–10 years (61, 24.1). Mean systolic BP levels measured on the day of enrollment were 130.1 ± 17.9 (95% confidence interval [CI] = 128.0–132.5) and mean diastolic BP was 81.6 ± 9.4 (95% CI = 80.4–82.7). BP controlled was achieved in 80 (31.5%) of patients while 174 (68.5%) patients' BP was controlled with the given medication. Salt restriction was followed by 87.4% of patients and moderate physical exercise as advised by the doctor was followed by 68.1% of patients. Other concomitant diseases were present in only 64 (25.2%) of patients while 190 (74.8) had hypertension alone [Table 1].

Analysis of Drug Therapy

All the patients were given drug therapy along with non-pharmacological measures such as salt restriction and physical exercise. Most frequently prescribed drug group were beta-blockers (162, 63.8%), followed by calcium channel blockers (157, 61.8%), ACE inhibitors (42, 16.5%), angiotensin II receptor blockers (ARBs) (59, 23.2%), and diuretics (12, 4.7%), as shown in Table 2. Antiplatelet drugs were coprescribed in 109 (42.9%) of patients, of which 63 (24.8%) received aspirin and 4 (1.6%) received clopidogrel. Fixed-dose combination of aspirin and clopidogrel was prescribed to 42 (16.5%) of patients. Hypolipidemic drugs statins were coprescribed in 103 (40.6%) patients. None of the patients developed complications of hypertension.

Table 1: Demographic and disease-related parameters of the patients with hypertension: (*n*=254)

Parameter	No. of patients (%)
Age (in years)	
18–30	1 (0.4)
31–50	68 (26.8)
51–70	166 (65.4)
≥71	19 (7.4)
Gender	
Male	142 (55.9)
Female	112 (44.1)
Education	
Illiterate	165 (65.0)
Up to 10th standard	51 (20.1)
Graduate	31 (12.1)
Postgraduate	7 (2.8)
Living status	
Alone	16 (6.3)
With family	238 (93.7)
BP (on the day of visit)	
Systolic BP	130.1±17.9 (95% CI=128.0–132.5)
Diastolic BP	81.6±9.4 (95% CI=80.4–82.7)
Stage of hypertension (with drug therapy)	
Pre-hypertension	152
Stage - 1	73
Stage - 2	29
Hypertension control (with therapy)	
Yes	80 (31.5)
No	174 (68.5)
Duration of hypertension (in years)	
<1	55 (21.7)
1–5	108 (42.4)
5–10	61 (24.1)
>10	30 (11.8)
Concomitant disease	
Present	64 (25.2)
Absent	190 (74.8)
Salt restriction	
Yes	222 (87.4)
No	32 (12.6)
Physical exercise	
Yes	173 (68.1)
No	81 (31.9)
Developed any ADR	
Yes	5 (1.97)
No	249 (98.03)
Developed any complications	
Yes	0
No	254 (100)

CI: Confidence interval, ADR: Adverse drug reaction, BP: Blood pressure

Analysis of ADRs

Out of these 254 patients, 5 (1.97%) developed ADRs (amlodipine-induced ankle edema, amlodipine-induced gastritis, enalapril-induced dry cough, aspirin-induced gastritis, and aspirin-induced hematuria). All the ADRs were falling into the category of "probable" according to the WHO-UMC causality assessment scale. All the ADRs were of mild variety according to Hartwig's severity scale and all of them were non preventable according to modified Schumock and Thronton's scale.

Assessment of HRQOL

HRQOL was measured using MINICHAL score. The average scores in mental and somatic domains were 2.5 ± 2.6 (95% CI = 2.3–2.9) and 3.1 ± 3.5 (95% CI = 3.0–4.0), respectively, with mean total score (TS) of 5.5 ± 5.3 (95% CI = 4.6–6.0) [Table 3].

Table 2: Analysis of drug therapy for hypertensive patients (*n*=254)	
Drugs prescribed	**No. of patients**
Diuretics	**12 (4.7)**
Hydrochlorothiazide	1 (0.4)
Chlorthalidone	10 (3.9)
Spironolactone+chlorthalidone	1 (0.4)
β-blockers	**162 (63.8)**
Atenolol	110 (43.3)
Metoprolol	51 (20.1)
Atenolol+metoprolol	1 (0.4)
Calcium channel blocker	**157 (61.8)**
Amlodipine	157 (61.8)
ACEI drugs	**42 (16.5)**
Enalapril	42 (16.5)
ARB drugs	**59 (23.2)**
Losartan	59 (23.2)
Antiplatelet drugs	**109 (42.9)**
Aspirin	63 (24.8)
Clopidogrel	4 (1.6)
Aspirin + Clopidogrel	42 (16.5)
Hypolipidemic drugs	**103 (40.6)**
Statins – Atorvastatin	103 (40.6)

ACEI: Angiotensin-converting enzyme inhibitors, ARB: Angiotensin II receptor blockers

Table 3: Quality of life assessment in hypertensive patients: (*n*=254)	
MINICHAL scale domain	**Average score**
Mental domain	2.5±2.6 (95% CI=2.3–2.9)
Somatic domain	3.1±3.5 (95% CI=3.0–4.0)
Total score	5.5±5.3 (95% CI=4.6–6.0)

CI: Confidence interval

Association of Different Factors with HRQOL

Association of HRQOL in hypertensive patients with different parameters is shown in Table 4.

Among the demographic parameters, gender, living status, and education of the patient were found to be significantly associated with HRQOL. Results show that, males have significantly lower MINICHAL score (MD = 2.1 ± 2.6, $P < 0.0001$, TS = 4.9 ± 4.9, $P < 0.01$) than female (MD = 2.9 ± 2.5, TS = 6.4 ± 5.7) suggesting good QOL as compared to females. Patients who are living with family has significantly low MINICHAL score (SD = 2.9 ± 3.3, $P < 0.052$, TS = 5.3 ± 4.0, $P < 0.046$) than those who are living alone (SD = 5.6 ± 5.5, TS = 9.4 ± 8.0). Similarly illiterate patients had significantly high MINICHAL score as compare to others (MD = 2.8 ± 2.4, $P = 0.0001$, SD = 3.5 ± 3.7, $P = 0.048$ and TS = 6.3 ± 5.3, $P = 0.001$). Age and total number of family members were not found to be significantly associated with HRQOL.

Among drug therapy-related parameters: Patients doing regular physical exercise had significantly low MINICHAL score (MD = 2.1 ± 2.3, $P = 0.001$, SD = 2.7 ± 2.9, $P = 0.06$, TS = 4.8 ± 4.5, $P = 0.004$] suggesting good QOL. Stage of hypertension, duration of hypertension, salt restriction, number of drugs prescribed, and concomitant diabetes had not shown a significant difference in HRQOL among patients in this study. BP control achieved or not with the prescribed drug therapy was significantly associated with HRQOL ($P < 0.05$). In the present study, there was no significant difference found in HRQOL of patients receiving diuretics, beta-blockers, calcium channel blockers, or ARB blockers, i.e., selection of drugs. It was not significantly associated with the number of doses per day or simultaneous use of aspirin or statins.

DISCUSSION

The prevalence of hypertension is increasing in the past few years and it has been identified as one of the most important risk factors for cardiovascular morbidity and mortality. For chronic diseases such as hypertension assessing QOL can help in evaluating the physical and psychosocial impact of the disease on affected individuals. It can also serve as an important outcome measure for different therapeutic interventions whether pharmacological or non-pharmacological.

The current study has evaluated the HRQOL in hypertensive patients using MINICHAL scale with different factors affecting it. The average scores in mental and somatic domains were 2.5 ± 2.6 (95% CI = 2.3–2.9) and 3.1 ± 3.5 (95% CI = 3.0–4.0), respectively, with mean TS of 5.5 ± 5.3 (95% CI = 4.6–6.0); which was higher than normal healthy individuals suggesting lower QOL. The previous research had also demonstrated that patients with hypertension have

Variable	Mental domain		Somatic domain		Total score	
Table 4: Health-related quality of life according to demographic factors, cardiovascular risk factor, and comorbidities (*n*=254)						
	Mean±SD	***P***	**Mean±SD**	***P***	**Mean±SD**	***P***
Gender						
Male	2.1±2.6	0.001	2.7±3.2	0.137	4.9±4.9	0.016*
Female	2.9±2.5		3.5±3.8		6.4±5.7	
Living status						
Alone	3.8±3.3	0.088	5.6±5.5	0.052	9.4±8.0	0.046*
With family	2.4±2.5		2.9±3.3		5.3±4.0	
Total family members						
1–4	2.6±2.9	0.943	3.4±3.4	0.31	5.9±5.7	0.641+
5–10	2.4±2.2		2.7±3.1		5.0±4.7	
>10	2.5±2.4		2.8±2.6		5.3±4.9	
Education						
Illiterate	2.8±2.4		3.5±3.7		6.3±5.3	
Up to 10th graduate	2.4±3.3	0.0001	2.8±3.4	0.048	5.1±5.9	0.001+
Graduate	1.0±1.7		1.9±2.0		2.9±3.1	
Postgraduate	1.9±2.3		1.6±2.6		3.4±4.6	
Presence of concomitant disease – Diabetes						
Yes	2.1±2.2	0.362	3.3±3.8		5.4±5.4	0.767*
No	2.5±2.7		3.0±3.4	0.657	5.6±5.3	
Stage of hypertension						
Prehypertension	2.4±2.5		2.8±3.0		5.2±4.6	
Stage - 1	2.3±2.7	0.07	3.3±4.0	0.981	5.6±6.0	0.452+
Stage - 2	3.5±2.8		3.6±4.5		7.1±6.6	
Duration of hypertension						
<1	2.7±2.5	0.552	2.8±3.3	0.969	5.5±4.5	0.862
1–5	2.6±2.8		3.3±3.8		5.9±5.7	
6–10	2.2±2.7		2.8±3.0		5.0±4.9	
>10	2.3±2.1		3.1±3.9		5.4±5.4	
Hypertension control						
Yes	2.3±2.6	0.032	2.0±2.5	0.049	3.3±4.3	0.058*
No	5.6±2.6		6.1±1.5		7.1±5.3	
Salt restriction						
Yes	2.5±2.6	0.888	3.0±3.3	0.945	5.3±5.1	0.978*
No	2.5±2.5		3.6±4.8		6.1±6.7	
Physical exercise						
Yes	2.1±2.3	0.001	2.7±2.9	0.06	4.8±4.5	0.004*
No	3.3±3.0		4.0±4.4		7.3±6.5	
Number of coprescription of drugs						
1	2.4±2.4	0.976	2.4±2.9	0.297	4.9±4.6	0.704+
2	23±3.0		2.6±3.2		5.0±4.7	
3	2.7±2.8		3.7±4.3		6.3±6.4	
4	2.5±2.9		3.6±3.6		6.1±5.9	
5	2.5±2.0		3.7±3.3		6.2±4.7	
6	2.8±3.1		2.2±1.3		5.0±2.3	
Calcium channel blocker						
Yes	2.7±2.7	0.210	3.3±3.7	0.275	6.0±5.7	0.196*
No	2.2±2.4		2.7±3.1		4.8±4.5	

(Contd...)

Variable	Mental domain		Somatic domain		Total score	
	Mean±SD	*P*	Mean±SD	*P*	Mean±SD	*P*
β-Blocker						
Yes	2.7±2.8	0.228	3.2±3.7	0.991	5.8±5.6	0.415*
No	2.1±2.3		2.9±3.1		5.0±5.8	
ACEI						
Yes	2.4±2.5	0.873	2.9±3.0	0.936	5.3±4.9	0.811*
No	2.5±2.6		3.1±3.6		5.6±5.4	
Diuretics						
Yes	2.2±2.5	0.577	2.9±3.1	0.709	5.2±4.9	0.781*
No	2.5±2.7		3.1±3.6		5.7±5.4	
Statin Use						
Yes	2.2±2.4	0.260	3.2±3.5	0.483	5.4±5.0	0.955*
No	2.7±2.7		3.0±3.5		5.6±5.5	
Anti-platelets						
Yes	2.5±2.7	0.782	3.6±3.9	0.048	6.1±5.7	0.193*
No	2.4±2.5		2.7±3.1		5.1±4.9	

*Mann-Whitney test, +Kruskal–Wallis test; *P*<0.05 was considered significant; ACEI: Angiotensin-converting enzyme inhibitors

lower HRQOL than the general population.[12,13] However, it is higher than that (23.14 ± 7.81) reported by another Indian study[14] and also from other international studies.[7]

Various demographic parameters were evaluated for its association with QOL in hypertensive patients. In our study, HRQOL was found to be significantly lower in females and those with low education levels as compared to males and higher education patients. These findings are also supported by many researchers[15-19] and also observed in the original MINICHAL study, in which women had a worse score in the "mental status" domain.[19] Women more frequently report feelings of dissatisfaction and frustration, which influences the HRQOL, especially in the "psychological" domain.[18] Furthermore, men have a greater ability to tolerate chronic diseases without being emotionally affected.[15] In the present study, the age range and age did not correlate with any of the HRQOL instruments used. Various studies have found conflicting results in the assessment of the relationship between QOL and age. Youssef *et al.*[15] reported that younger individuals had a better HRQOL, whereas Grimm *et al.*[17] observed a better HRQOL in the elderly.

Among drug therapy-related parameters, only BP controlled achieved and physical exercise were found to have significant differences in HRQOL in this study. The medications most widely used by the study patients (diuretics, beta-blockers, calcium channel blockers, ACE inhibitors, etc.) are available at no charge in the public health-care network and are part of the National List of Essential Medications. However, the selection of drugs, the number of drugs or stage of hypertension or duration of hypertension did not affect QOL

as found in this study. In the validation study of the original MINICHAL, no differences were found between the means in the different stages of hypertension, the same as in the present study.[16,19] Physical exercise has been advised by physicians for almost all cardiovascular patients. It is usually designed as moderate exercises for at least 20 min daily, 5 days a week or other modules considering comorbid conditions and cardiac workup. Regular exercise tends to reduce the risk of complications of hypertension and improves the feeling of well-being.[20]

In this study, only 31% of patients BP found to be under optimum control with drug therapy. As regard BP control, the rate of patients with non-controlled BP who was taking antihypertensive medication (69.6%) was close to that of a WHO document on hypertension, in which three-fourths of the patients with SH were reported not to achieve optimal BP control.[20] In Brazil, prevalence studies that report patients with controlled BP by means of antihypertensive treatment show rates ranging from 10.4% to 33%.[21,22]

In this study, comorbid conditions did not affect QOL. Finding is contrarily to that of other studies showing patients with comorbidities such as diabetes, dyslipidemias, heart failure, and depression show worse assessment of the QOL in the MINICHAL "somatic manifestations" domain.[23] Simultaneous prescription of aspirin as antiplatelet drugs found to have better QOL in the MD as supported by other literature also. However, the coprescription of statins showed no change in HRQOL. In this study, 1.97% of patients developed ADRs with drug therapy but it has not affected QOL as all the drugs were stopped once ADR was diagnosed.

None of the patients developed complications during the study so its association with HRQOL could not be found.

This study has primarily evaluated the QOL of hypertensive patients. Few limitations of the study included short duration and small sample size. Moreover, MINICHAL scores only evaluate the QOL based on the health status of the past 7 days so the impact of previous events during therapy could not be evaluated. In this study, known cases of hypertension were only included not the newly detected cases, so time to diagnose and implementation of initial treatment-related aspects and its impact on QOL could not be evaluated. Larger studies involving more patients are required to evaluate the individual impact of each parameter on HRQOL.

Hypertension itself significantly reduces the HRQOL. This HRQOL is further affected by different parameters such as gender, education level, BP controlled achieved or not, and physical exercise. Many studies have shown strong association between drug related factors such as number of drugs prescribed, duration and severity of disease, presence of ADRs and/or complications. HRQOL measurements may be useful to help choose the best treatment for hypertensive patients, as well as in population-based studies assessing the determinants of QOL in such patients.

CONCLUSION

Hypertension is an important preventable cause of death, and the treatment of hypertension is a key strategy for the prevention of cardiovascular disease. Hypertension adversely affects QOL of patients. Hypertensive patients with desirable BP controlled achieved and following physical exercise schedule had better QOL as evaluated by MINICHAL score. Early diagnosis and compliance with recommended treatment to achieve BP control is very essential in the successful management of hypertension and ensuring better QOL.

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