The effects of antihypertensive drug therapy on the health related quality of life of the patient

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Abstract
Hypertension is one of the leading causes of the global burden of disease. Approximately 7.6 million deaths (13-15% of the total) worldwide were attributable to high blood pressure in 200l.The 2003 global report showed that 7 million people die of hypertension each year and approximately 4.5% of serious diseases are caused by it. Written informed consent was obtained from every patient satisfying the inclusion criteria and they were thoroughly explained in writing as well as orally in English/Kannada about the study, methodology and possible risks during the study. In Amlodipine with Atenolol group 86% patients had good quality, and 14% had average physical quality compared to Amlodipine with Enalapril group which had 66.7% in good and 33.3% in average physical quality.In Amlodipine with Atenolol group nearly 88% patients had good quality and 12% had average physical quality compared to Amlodipine with Enalapril group which had 89% in good and 11% in average physical quality.

Keywords: Antihypertensive drug therapy, health related quality of life, hypertension

Introduction
Hypertension is a very common disorder, particularly past middle age. It is not a disease in itself, but is an important risk factor for cardiovascular mortality and morbidity[1].
From an epidemiologic perspective, there is no obvious level of blood pressure that defines hypertension. In adults, there is a continuous incremental risk of cardiovascular disease, stroke and renal disease across levels of both systolic and diastolic blood pressure. Among older individuals, Systolic Blood Pressure (SBP) and Pulse Pressure (PP) are more powerful predictors of cardiovascular disease than is Diastolic Blood Pressure (DBP)[2].
Clinically, hypertension may be defined as that level of blood pressure at which the institution of therapy reduces blood pressure-related morbidity and mortality. Current clinical criteria for defining hypertension generally are based on the average of two or more seated blood pressure readings during each of two or more outpatient visits.
Hypertension is one of the leading cause of the global burden of disease. Approximately 7.6 million deaths (13-15% of the total) worldwide were attributable to high blood pressure in 2001.
The 2003 global report showed that 7 million people die of hypertension each year and approximately 4.5% of serious diseases are caused by it.
The situation in India is more alarming. It was reported that out of a total 9.4 million deaths in India in 1990, cardiovascular diseases caused 25% deaths. It has been predicted that by 2020, there would be a 111% increase in cardiovascular deaths in India. This increase is much more than 77% for China, 106% for other Asian countries and 15% for economically developed countries[3].

According to 'WHO health statistics 2012', the prevalence of hypertension in India was 23.1% in men and 22.6% in women in more than 25 years age.

Epidemiological studies have shown that hypertension is present in 25% of urban and 10% of rural subjects in India. There is a difference in measurement methodology of BP in epidemiological studies as compared to clinic-based measurements. It has been reported that, epidemiological studies that rely on single-session measurements over diagnose hypertension by 20-25%. If we discount this proportion, 19% adults in the urban and 7.5% in the rural areas shall be eligible for hypertension therapies. Translating these proportions into numbers reveals a massive burden of this disease in India[4].

Hypertension has detrimental effects on a range of health outcomes including Health Related Quality of Life (HRQoL). There have been number of studies examining the impact of cardiovascular diseases either single or co-morbid conditions on the HRQoL, especially the co-morbidity of hypertension[5, 6].

Health outcome research and Patient-Reported Outcomes (PRO) in particular, aim at understanding patient value in terms of impact of disease and its treatment on physical functioning and psychosocial wellbeing, known also as "Health-Related Quality of Life" (HRQoL).

Methodology
Written informed consent was obtained from every patient satisfying the inclusion criteria and they were thoroughly explained in writing as well as orally in English/Kannada about the study, methodology and possible risks during the study.

First data (First visit)
A detailed history was taken regarding the disease, duration, co morbid condition, socio economic status, duration of antihypertensive therapy.

Blood pressure and pulse rate were recorded, drug therapy details were noted-like pattern (monotherapy or multitherapy), cost of the drugs, dosage of the drug and changes in the drug therapy if any.

Second data (After 6 months)
Second data collection was done after 6 months of treatment and same parameters were recorded again as in first time. In second recording, HRQoL was also evaluated. To evaluate the Health related quality of life, for every patient the SF 36 Questionnaire was filled, which contains 36 questions arranged in 8 components. Each question had multiple options and each option was given a score. Ultimately the scores were graded from 0 to 100 where 0 indicates the worst quality and 100 indicates the best quality. The scores were then summarised in the form of physical component score (PCS) and mental component score (MCS).

Investigations
The study does not require any investigation to be conducted on patients.

Statistical analysis
The details so obtained were analysed for the pattern analysis and cost effectiveness with appropriate statistical tests.
Statistical tests used were:
1) Chi Square test
2) 'T' Test

Results
In Atenolol group 100% patients had good quality of life compared to Amlodipine group which had 71.4% patients had good, 23.8% had average and 4.8% had poor quality of life.

In Atenolol group 80% had good, 20% had average mental quality compared to Amlodipine group which had 76.2% patients with good quality, 19% had average and 4.8% had poor mental quality of life.

In Amlodipine with Atenolol group 86% patients had good qualityand 14% had average physical quality compared to Amlodipine with Enalapril group which had 66.7% in good and 33.3% in average physical quality.

In Amlodipine with Atenolol group nearly 88% patients had good quality and 12% had average physical quality compared to Amlodipine with Enalapril group which had 89% in good and 11% in average physical quality.

Table 1: Comparison of physical quality of life among the two monotherapy treatment groups

Physical quality	AT	AM	P value
Good	5 (100.0)	15 (71.4)	0.839
Average	0 (0.0)	5 (23.8)	
Poor	0 (0.0)	1 (4.8)	
Total	5 (100.0)	21 (100.0)	

Table 2: Comparison of mental quality of life among the two monotherapy treatment groups

Mental quality	AT	AM	P value
Good	4 (80.0)	16 (76.2)	0.885
Average	1 (20.0)	4 (19.0)	
Poor	0 (0.0)	1 (4.8)	
Total	5 (100.0)	21 (100.0)	

Table 3: Comparison of physical quality of life among the two multitherapy treatment groups

Physical quality	AT,AM	AM,EN	P value
Good	49 (86.0)	6 (66.7)	0.135
Average	8 (14.0)	3 (33.3)	
Poor	0 (0.0)	0 (0.0)	
Total	57 (100.0)	9 (100.0)	

Table 4: Comparison of mental quality of life among the two multitherapy treatment groups

Mental quality	AT,AM	AM,EN	P value
Good	50 (87.7)	8 (88.9)	0.357
Average	7 (12.3)	1 (11.1)	
Poor	0 (0.0)	0 (0.0)	
Total	57 (100.0)	9 (100.0)	

Discussion

A multinational, randomized, double blind study was conducted by Degl'Innocenti A *et al*., to assess the effects of Candesartan 8-16mg daily on cardiovascular events and cognitive functions in elderly patients aged 70-89 years with mild to moderate hypertension. The aim of this health related quality of life (HRQoL) sub study analysis was to investigate changes in HRQoL during antihypertensive treatment and possible difference in patients receiving other antihypertensive treatment like Diuretics, Beta blockers, Calcium antagonists. The study concluded that there should be no reason to withhold the modern antihypertensive therapy in elderly patients due to concerns for negative effects on health related quality of life (HRQoL), as several of the observed changes in the score from baseline to last visit favoured Candesartan compared to control treatment with other therapies[7].

In a study conducted by De Gusmao JL *et al*., with the aim to assess the influence of

hypertension control upon HRQoL in hypertensive patients with and without complications. In the study 77 hypertensive patients were observed for 12 months with special care program. Phase-1 consisted clinical visits every 2 months, donation of all antihypertensive medications, meetings with multidisciplinary teams and active phone calls. Phase-2 consisted clinical visits every 4 months, medication provided by drug store of hospital with 2 hours wait and possible lack of medication, no meetings with multidisciplinary team and no active phone calls. The patients Health Related Quality of Life (HRQoL) assessed using Bulpitt and Fletchers specific questionnaire as well as Short Form (SF)-36 scores. Study concluded that special care program significantly controlled the hypertension but did not interfere with the health related quality of life (HRQoL)[8].

In Our studyfollow up period was 6 months, with phone calls and personal meetings in OPD. Drugs were supplied in the hospital itself. SF-36 questionnaire is used to evaluate the health related quality of life, in which quality was concluded in physical and mental dimensions. Not much difference was observed in QoL of patients in both the therapy groups.

Conclusion
Not much difference was observed in quality of life in both the treatment groups.

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