

Comparative Study to Evaluate Efficacy, Safety and Quality of Life of Metoprolol and Telmisartan versus Metoprolol and Ramipril in Patients of Hypertension

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Abstract

Background: Hypertension (HTN) is a major cardiovascular disease and is a major worldwide clinical problem. The prevalence of hypertension increases in urban and rural areas. The treatment of hypertension began in the 1960s with oral diuretics. The other modalities of treatment of hypertension are beta-blockers, calcium-channel blockers, alpha-receptors blockers, ACE inhibitors and ARBs. The better compliance occurs with single-pill combination, and may be even double or even triple pill combination therapy should be used. Also quality of life was improved better with Metoprolol and Telmisartan as compared with Metoprolol and Ramipril. Quality of life was assessed by SF-36 Questionnaire. **Objective:** To compare the effect of Metoprolol and Telmisartan versus Metoprolol and Ramipril on BP and quality of life in patients of hypertension. **Material and Methods:** In this prospective, open, randomized, parallel group, comparative study, 80 patients of hypertension attending the Cardiology Outpatient Department, Govt. Medical College & Rajindra Hospital, Patiala were recruited. This randomized comparative study was done on 80 patients for 4 months. **Quality of Life:** In my project of Quality of life, I had taken total 80 patients and the patients were divided into two groups and 40 patients each of Metoprolol and Ramipril versus Metoprolol and Telmisartan. To assess quality of life questionnaire SF-36 was administered to the patients. **Results:** There was a marked decrease in SBP and DBP with the use of Metoprolol and Telmisartan than Metoprolol and Ramipril. There was also no change in demographic parameters. There was significant improvement in the quality of life with Metoprolol and Telmisartan. **Conclusion:** Metoprolol and Telmisartan was a better choice than Metoprolol and Ramipril in treating hypertension as this combination causes more reduction in BP and little effect on HR.

Keywords: DBP - Diastolic Blood Pressure, HR - Heart Rate, HRQOL - Health Related Quality of Life, HTN - Hypertension, SBP - Systolic Blood Pressure

1. Introduction

Hypertension is a risk factor for cardiovascular diseases.^[1] The treatment of hypertension significantly reduces the cardiovascular morbidity and mortality.^[2] According to JNC - VII guidelines hypertension is classified as: Normal <- 120 and <-80 (mm of Hg), Pre-hypertensive - 120-139 and 80-89 (mm of Hg), Stage I - 140-159 and 90-99 (mm of Hg) and Stage II - >-160 and >-100 (mm of Hg).^[3] Cardiovascular diseases are going to be double by 2020.^[4] Hypertension is

responsible for stroke deaths and cardiovascular diseases in India.^[4] Thus it is very important to control BP in hypertensive patients. The drugs most commonly used are Beta adrenergic blockers out of which Metoprolol is the most commonly used.^[5] Other drugs used are Calcium channel blockers, Angiotensin converting enzyme inhibitors, alpha receptor antagonists and Angiotensin receptor blockers. However according to JNC - VIII guidelines Beta-blockers are not used as initial treatment and treatment is given according to ethnicity.^[6-8] The JNC - VIII guidelines recommend that

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the general non-black population initial pharmacologic therapy should include a thiazide-type diuretics, calcium channel blockers, angiotensin converting enzyme inhibitors and angiotensin receptor blockers whereas in general black population initial therapy should include a thiazide type diuretics or calcium channel blockers. This difference is based on the fact that the black patients have a smaller reduction in blood pressure when given ACEI or ARBs.^[8] Another popularly used drug among the antihypertensives is Telmisartan which is used in my study along with Ramipril separately in combination with Metoprolol. Angiotensin receptor blockers were developed because of their good efficacy and lower side effect profile than angiotensin converting enzyme inhibitors.^[9] So, the aim of the study was to evaluate antihypertensive efficacy and effect on quality of life on patients of hypertension.

2. Material and Methods

In the prospective, open, randomized, parallel group, comparative study, 80 patients of HTN were included. The study was conducted for 4 months and follow up was done at 2nd and 4th months. A written informed consent was taken from patients after explaining them about study drugs. A thorough history such as HTN, bronchial asthma, tuberculosis, smoker and alcoholic was taken. Patients were randomly divided into two groups.

Group 1 patients were started on Metoprolol and Ramipril at a dose of 50 mg and 2.5 mg respectively. The subsequent titrations were carried up to maximum recommended dose of 200 mg with Metoprolol and 20 mg with Ramipril depending on therapeutic response.

Group 2 patients were put on Metoprolol and Telmisartan at a dose of 50 mg and 20 mg respectively. The subsequent titrations were carried up to maximum recommended dose of 200 mg with Metoprolol and 80 mg with Telmisartan.

3. Quality of Life

In my project of Quality of life, I had taken total 80 patients who were prescribed Metoprolol and Ramipril and Metoprolol and Telmisartan. The patients were randomly given medications of which two groups were made and 40 patients each of Metoprolol and Ramipril versus Metoprolol and Telmisartan.

To assess quality of life questionnaire SF-36 was administered to the patients. The questionnaire was

administered face to face to every patient and it took about 15 min to administer this questionnaire to the patient.

SF 36v2 is a multidimensional questionnaire. It is composed of 36 items, and it covers eight domains of health: physical functioning (10 items), role limitations caused by physical health problems (4 items), pain (2 items), general health perceptions (5 items), energy and/or fatigue (4 items), social functioning (2 items), role limitations caused by emotional health problems (3 items), and emotional well-being (5 items). Each question in the SF-36 is given a score and it is later translated to a scale number.

Composition of domains of SF-36 Questionnaire

Domains	Questions
1. Physical functioning	Q 3 a, b, c, d, e, f, g, h, i, j
2. Role limitations due to physical health	Q 4 a, b, c, d
3. Role limitations due to emotional health	Q 5 a, b, c
4. Fatigue/Vitality	Q 9a, 9e, 9g, 9i
5. Emotional well –being	Q 9b, 9c, 9d, 9f, 9h
6. Social functioning	Q 6, Q10
7. Pain	Q 7, Q8
8. General health	Q 1, Q2, Q11a, b, c, d

The responses were recorded on SF-36 Questionnaire as told by the patients. Each question in the SF-36 was given a score and it is later translated to a scale number. The responses with scale number were translated from 0 to 100. The responses with 0 were given the worst score and responses with score 100 were given the highest score.

Question	Original response	Scoring
1, 2, 6, 8	1	100
	2	75
	3	50
	4	25
	5	0
3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	1	0
	2	50
	3	100
4a, 4b, 4c, 4d, 5a, 5b, 5c	1	100
	2	0

7	1	0
	2	20
	3	40
	4	60
	5	80
	6	100
9a,9b,9c,9d,9e,9f,9g,9h,9i	1	100
	2	80
	3	60
	4	40
	5	20
	6	0
10,11a,11b,11c,11d	1	100
	2	75
	3	50
	4	25
	5	0

4. Study Design

In this prospective, open, randomized, parallel group, comparative study, 80 patients of hypertension attending the Cardiology Outpatient Department, Govt. Medical College and Rajindra Hospital, Patiala were recruited. Patients were selected based on the following criteria:-

Inclusion Criteria:

- Patients with newly diagnosed HTN.

Table 1. Baseline characteristics of Group 1 and Group 2

Characteristics	Group 1	Group 2
Number of patients	40	40
Age Range(years)	45-79	40-83
Mean Age (years)	61.90±8.58	61.18±9.26
Sex (Male / Female)	25/15	14/26
Systolic BP (mm Hg)	141.25±9.43	144.30±9.35
Diastolic BP (mm Hg)	91.80±8.91	95.20±8.54
Heart Rate (Pulse/minute)	77.42±11.97	74.75±9.66
Hb	11.04±0.85	10.78±1.00
FBS	87.85±16.61	86.75±13.59
Blood urea	30.95±2.60	31.35±2.91
Serum Creatinine	0.99±0.15	1.04±0.21
Lipid profile	162.50±13.21	161.15±12.13
SGOT	22.25±4.73	22.60±6.20
SGPT	23.70±4.88	24.12±5.24

Comparison of Systolic BP and Diastolic BP at Baseline, 2nd month and at 4th month in both the groups is mentioned in Table 2. Table 3 describes the comparison of HR of two groups at different visits. Quality of life parameters within Metoprolol and Ramipril within group 1 are described in Table 4 and Quality of life parameters within Metoprolol and Telmisartan within group 2 are described in Table 5. Comparison of Quality of life parameter between 2 groups at baseline is illustrated in Table 6. Table 7 describes the comparison of Quality of life between 2 groups at 4th month.

- Those patients who have discontinued antihypertensive medication.

Exclusion Criteria:

- Patients with history of hypersensitivity to Metoprolol, Telmisartan and Ramipril.
- Pregnant/lactating/women planning to conceive.
- Patients on other anti-hypertensive therapy.
- Patients of secondary hypertension.
- Patients with impaired liver function.
- Patients with impaired kidney function.
- Patients with bronchial asthma, chronic pulmonary disease and peripheral arterial disease.

5. Statistical Analysis

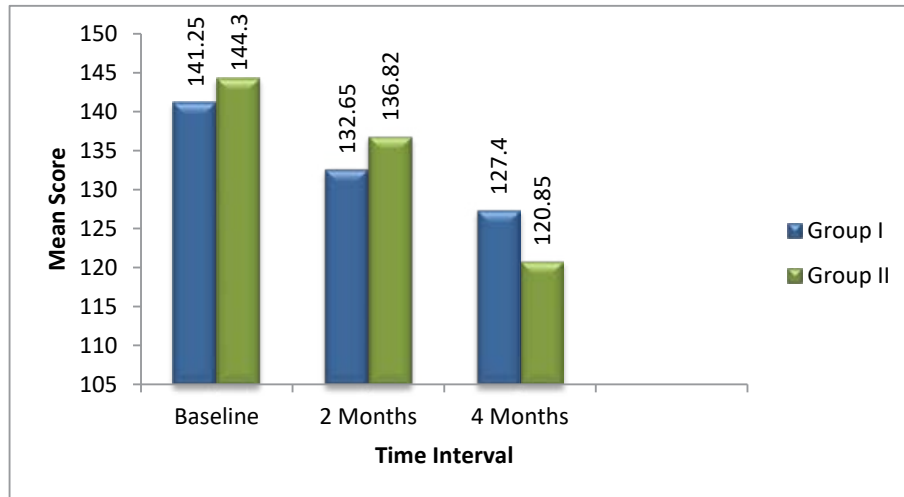
Statistical analysis was done using IBM SPSS version 22 software. p-value<0.05 was considered significant.

Baseline characteristics of patients with Metoprolol and Telmisartan versus Metoprolol and Ramipril on BP were summarized in Table 1. There was no significant difference in BP and other demographic parameters at baseline but at 2nd month there was a significant difference in BP and at 4th month there was a highly significant difference in BP at supine position.

Table 2. Comparison of Systolic BP and Diastolic BP at baseline, 2nd month and at 4th month in both the groups

Time Interval	Group1 Mean±S.D.	Group 2 Mean±S.D.	Mean Diff.	T	P value	Sig.
Baseline SBP	141.25±9.43	144.30±9.35	3.05±0.08	1.452	0.150	NS
DBP	91.80±8.91	95.20±8.54	3.40±0.37	1.742	0.085	NS
2 Months SBP	132.65±9.46	136.82±8.85	4.18±0.61	2.038	0.045	S
DBP	84.07±7.61	87.92±6.58	3.85±1.03	2.420	0.018	S
4 Months SBP	127.40±9.14	120.85±8.23	6.55±0.91	3.369	0.001	HS
DBP	81.05±6.21	85.75±4.60	4.70±1.61	3.846	0.001	HS

Bar Diagram Showing SBP in 2 Groups at Different Visits



Bar Diagram Showing DBP in 2 Groups at Different Visits

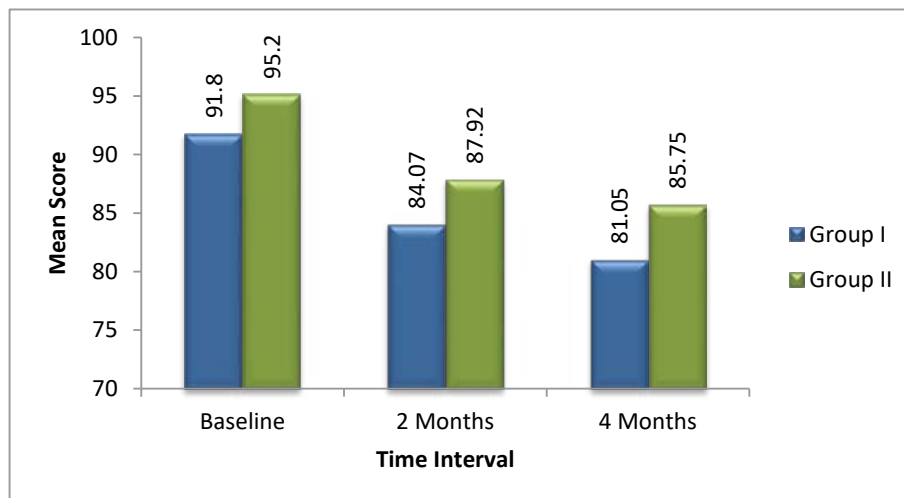


Table 3. Comparison of HR of 2 groups at different visits

Time Interval	Group I Mean±SD	Group II Mean±SD	Mean Diff.	T	p value	Sig.
Baseline	77.42±11.97	74.75±9.66	2.67±2.31	1.100	0.275	NS
2 Months	74.55±10.85	72.40±7.35	2.15±3.50	1.038	0.303	NS
4 Months	76.30±9.15	72.80±7.17	3.50±1.98	1.903	0.061	S

Bar Diagram Showing HR at 2 Different Visits

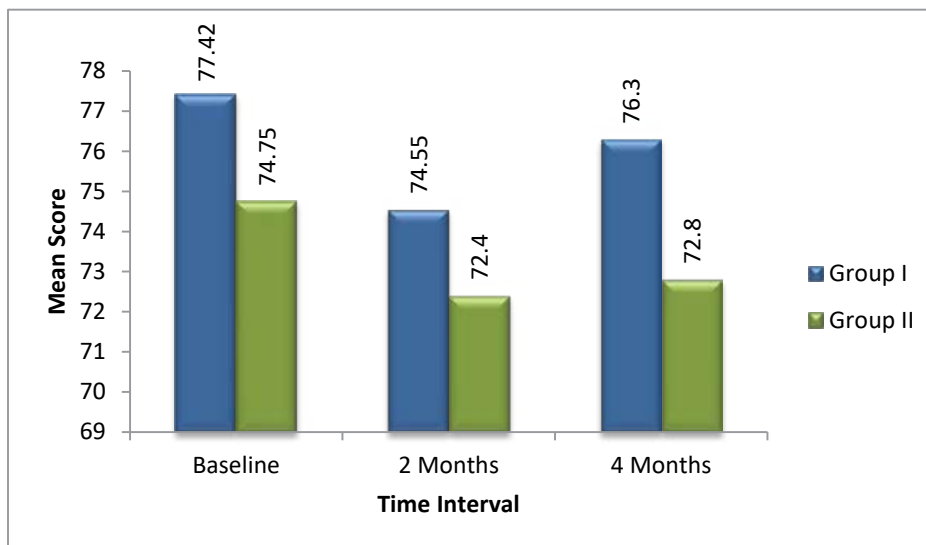
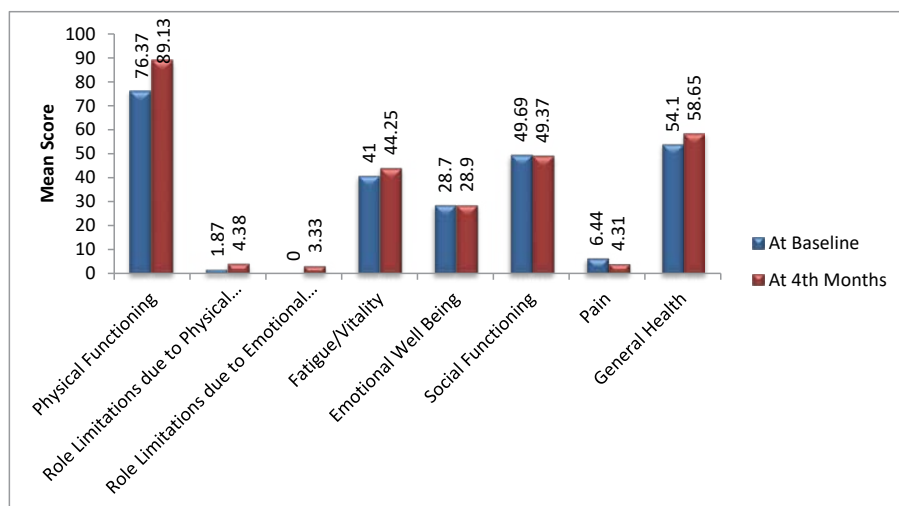


Table 4. Quality of life parameters within Metoprolol and Ramipril within group 1

		N	Mean	SD	Std. Error Mean	t-test	p value
Physical Functioning	At Baseline	40	76.37	25.12	3.97	3.957	0.001 (HS)
	At 4th Months	40	89.13	21.36	3.38		
Role Limitations due to Physical Health	At Baseline	40	1.87	6.67	1.05	1.00	0.323 (NS)
	At 4th Months	40	4.38	16.88	2.67		
Role Limitations due to Emotional Health	At Baseline	40	0.00	0.00	0.00	1.275	0.210 (NS)
	At 4th Months	40	3.33	16.54	2.61		
Fatigue/Vitality	At Baseline	40	41.00	7.86	1.24	3.232	0.003 (S)
	At 4th Months	40	44.25	7.12	1.13		
Emotional Well Being	At Baseline	40	28.70	5.65	0.89	0.313	0.756 (NS)
	At 4th Months	40	28.90	5.47	0.87		
Social Functioning	At Baseline	40	49.69	10.40	1.64	0.443	0.660 (NS)
	At 4th Months	40	49.37	8.47	1.34		

Pain	At Baseline	40	6.44	15.05	2.45	2.429	0.020 (S)
	At 4th Months	40	4.31	12.05	1.91		
General Health	At Baseline	40	54.10	8.22	1.30	5.283	0.001 (HS)
	At 4th Months	40	58.65	7.27	1.15		

Bar Diagram Showing Domains of Quality of Life in Group 1

**Table 5.** Quality of life parameters within Metoprolol and Telmisartan within group 2

		N	Mean	SD	Std. Error Mean	t-test	p value
Physical Functioning	At Baseline	40	74.87	23.19	3.67	3.452	0.001 (HS)
	At 4th Months	40	84.63	22.08	3.49		
Role Limitations due to Physical Health	At Baseline	40	10.00	21.78	3.44	1.533	0.133 (NS)
	At 4th Months	40	6.87	19.60	3.09		
Role Limitations due to Emotional Health	At Baseline	40	6.67	15.47	2.45	1.00	0.324 (NS)
	At 4th Months	40	5.00	14.22	2.24		
Fatigue/Vitality	At Baseline	40	37.75	6.09	0.96	6.657	0.001 (HS)
	At 4th Months	40	26.75	10.35	1.64		
Emotional Well Being	At Baseline	40	28.29	6.96	1.10	1.684	0.100 (NS)
	At 4th Months	40	29.50	6.82	1.08		
Social Functioning	At Baseline	40	47.50	5.80	0.92	3.674	0.001 (HS)
	At 4th Months	40	51.25	5.52	0.87		
Pain	At Baseline	40	10.50	21.06	3.33	1.740	0.090 (NS)
	At 4th Months	40	8.81	17.75	2.81		
General Health	At Baseline	40	50.52	9.86	1.56	5.433	0.001 (S)
	At 4th Months	40	56.04	11.20	1.77		

Bar Diagram Showing Domains of Quality of Life in Group 2

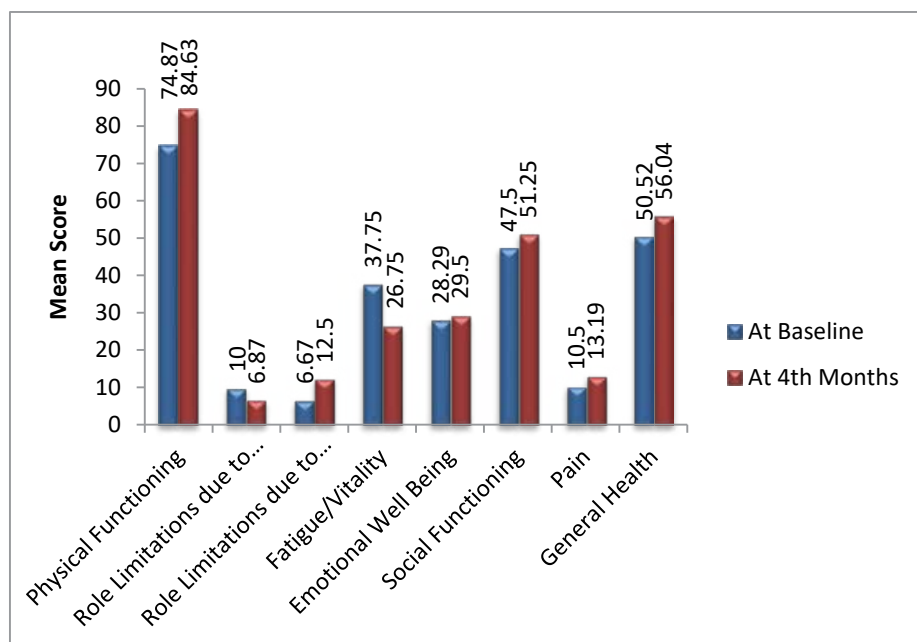
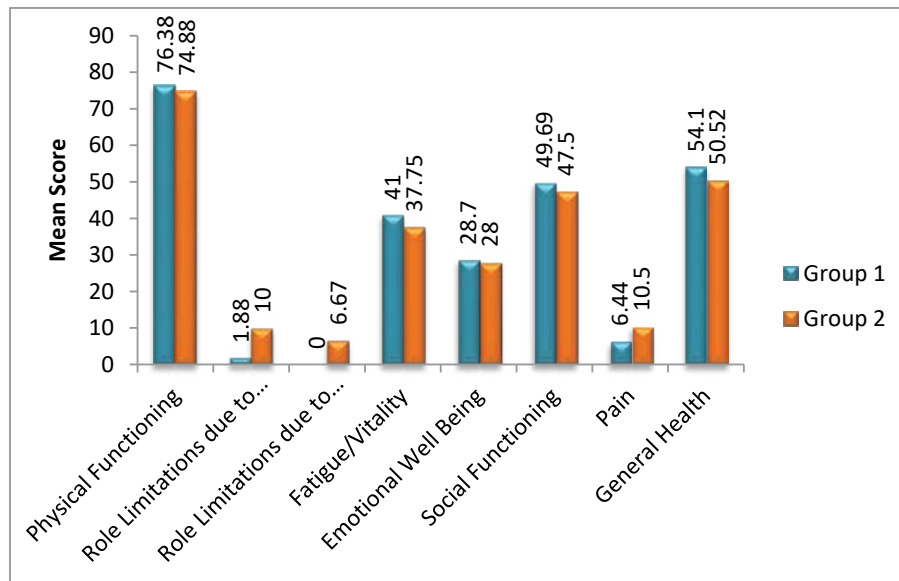


Table 6. Comparison of quality of life parameter between 2 groups at baseline

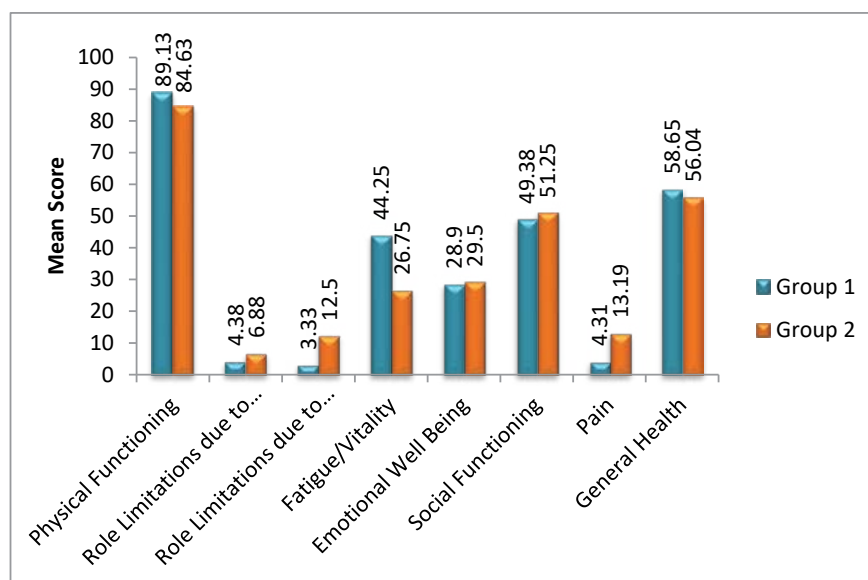
At Baseline	Groups	N	Mean	SD	Error Mean	t-test	p value
Physical Functioning	Group 1	40	76.38	25.11	3.97	0.278	0.782 (NS)
	Group 2	40	74.88	23.19	3.67		
Role Limitations due to Physical Health	Group 1	40	1.88	6.67	1.05	2.256	0.027 (S)
	Group 2	40	10.00	21.78	3.44		
Role Limitations due to Emotional Health	Group 1	40	0.00	0.00	0.00	2.725	0.008 (S)
	Group 2	40	6.67	15.47	2.45		
Fatigue/Vitality	Group 1	40	41.00	7.86	1.24	2.067	0.042 (S)
	Group 2	40	37.75	6.09	0.96		
Emotional Well Being	Group 1	40	28.70	5.65	0.89	0.494	0.623 (NS)
	Group 2	40	28.00	6.96	1.10		
Social Functioning	Group 1	40	49.69	10.40	1.64	1.162	0.249 (NS)
	Group 2	40	47.50	5.80	0.92		
Pain	Group 1	40	6.44	15.50	2.45	0.983	0.329 (NS)
	Group 2	40	10.50	21.06	3.33		
General Health	Group 1	40	54.10	8.22	1.30	1.766	0.081 (NS)
	Group 2	40	50.52	9.86	1.56		

Bar Diagram Showing Domains of Quality of Life Between 2 Groups at Baseline

**Table 7.** Comparison of quality of life between 2 groups at 4th month

At 4th Months	Groups	N	Mean	SD	Std. Error Mean	t-test	p value
Physical Functioning	Group 1	40	89.13	21.36	3.38	0.926	0.357 (NS)
	Group 2	40	84.63	22.08	3.49		
Role Limitations due to Physical Health	Group 1	40	4.38	16.88	2.67	0.611	0.543 (NS)
	Group 2	40	6.88	19.60	3.10		
Role Limitations due to Emotional Health	Group 1	40	3.33	16.54	2.61	2.018	0.047 (S)
	Group 2	40	12.50	23.49	3.71		
Fatigue/Vitality	Group 1	40	44.25	7.12	1.13	8.810	0.001 (HS)
	Group 2	40	26.75	10.35	1.64		
Emotional Well Being	Group 1	40	28.90	5.47	0.87	0.434	0.665 (NS)
	Group 2	40	29.50	6.82	1.08		
Social Functioning	Group 1	40	49.38	8.47	1.34	1.173	0.244 (NS)
	Group 2	40	51.25	5.52	0.87		
Pain	Group 1	40	4.31	12.05	1.91	2.379	0.020 (S)
	Group 2	40	13.19	20.29	3.21		
General Health	Group 1	40	58.65	7.27	1.15	1.327	0.188 (NS)
	Group 2	40	56.04	11.20	1.77		

Bar Diagram Showing Domains of Quality of Life Between 2 Groups at 4th Month



6. Discussion

Hypertension is a major health problem. Hypertension ranks number one amongst the non-communicable diseases.^[10]

Here my study included combination therapy with two drugs to patients. The patients were prescribed Metoprolol and Ramipril in group 1 and Metoprolol and Telmisartan in group 2 in Rajindra Hospital, Patiala. Metoprolol being the common drug in two groups. Out of Telmisartan and Ramipril, Telmisartan was found to be more effective drug than Ramipril. Metoprolol, a beta-adrenergic receptor antagonist was given in combination with these two separately to have an additive action on both these drugs to treat raised BP.

The fall in BP was more with Metoprolol and Telmisartan than Metoprolol and Ramipril. Similarly, there was a fall in heart rate in Metoprolol and Telmisartan than Metoprolol and Ramipril. Also, in my study I had reported no adverse effect with both the groups although adverse effects may occur with Ramipril as angioedema and cough.

In my study of Quality of life with both the groups there was a significant difference in role limitations due to emotional health and pain and there was a highly significant difference in fatigue or vitality.

MAPHY study showed the significantly lower risk for coronary events for Metoprolol as compared to diuretics.^[11]

The clinicians regard ACE inhibitors and ARBs as equally effective drugs although it is not clear whether it is appropriate.^[12]

A study conducted by Shahin et al., reported that ACE inhibitors improve endothelial function and are superior to beta – blockers.^[11]

According to some study there was a significant change in BP and HR at the end of twelve weeks ($p < 0.001$). When an intergroup comparison was made in Metoprolol and Telmisartan groups, there was no significant difference ($p > 0.05$) at baseline but at twelve weeks the values of BP and HR showed a significant difference ($p < 0.05$).^[13]

The idea that the ACEI/ARB to be used as cardioprotective agents came from placebo – controlled trials in patients at high risk for cardiovascular events.^[10]

From several studies Telmisartan is better in lowering blood pressure efficacy as compared with other ARBs.^[14]

There were six trials were done which compared Telmisartan with Ramipril and with Telmisartan there was a greater SBP reduction.^[15]

Studies regarding HRQOL are mostly conflicting with some studies show worse HRQOL but here the mechanism for the low HRQOL is not known and some studies show no impact of hypertension in some or all domains.^[16]

Recent study shows that by using ACEI or ARBs had high scores on HRQOL assessment scale.^[17]

7. Conclusion

Following conclusion was drawn from my study.

Although hypertension is a world-wide problem, it can be treated with single pill combination however if the desired BP lowering does not occur then double or triple pill combination can be used. The blood pressure and heart rate decreased more with Metoprolol and Telmisartan combination as compared with Metoprolol and Ramipril also quality of life improved better with Metoprolol and Telmisartan in role limitations due to emotional health and pain and majority in parameter of fatigue or vitality. Quality of life was assessed with SF-36 questionnaire.

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How to cite this article: Arora S., Sehgal V. K., Singh J. and Singh H. Comparative Study to Evaluate Efficacy, Safety and Quality of Life of Metoprolol and Telmisartan Versus Metoprolol and Ramipril In Patients of Hypertension. *Int. J. Med. Dent. Sci.* 2019; 8(2):1728-1738.