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

Sonia Arora¹*, Vijay K. Sehgal², Jasbir Singh³ and Harcharan Singh⁴

¹Post Graduate Student, ²Professor, ³Associate Professor, Department of Pharmacology, Government Medical College, Patiala, Punjab - 147001, India; soniadr58@gmail.com ⁴Associate Professor, Department of Medicine, Government Medical College, Patiala, Punjab - 147001, India

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.⁵ 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.⁶ 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.⁷ The JNC - VIII guidelines recommend that
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. 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. 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, 2, 3, 4, 5 | 100, 75, 50, 25, 0 |
| 3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j | 1, 2, 3 | 0, 50, 100 |
| 4a, 4b, 4c, 4d, 5a, 5b, 5c | 1, 2 | 100, 0 |
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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.

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

| Time Interval | Group 1 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  | 127.4±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 systolic blood pressure (SBP) comparison in two groups at baseline, 2 months, and 4 months.]

Bar Diagram Showing DBP in 2 Groups at Different Visits

[Bar diagram showing diastolic blood pressure (DBP) comparison in two groups at baseline, 2 months, and 4 months.]

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

| Time Interval | Group I | Group II | Mean Diff. | T     | p value | Sig. |
|---------------|---------|----------|------------|-------|---------|------|
| Baseline      | 77.42±11.97 | 74.75±9.66 | 2.67±2.31  | 1.100 | 0.276   | 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

| Physical Functioning | N | Mean | SD | Std. Error | t-test | p value |
|----------------------|---|------|----|------------|--------|---------|
| At Baseline          | 40| 76.37| 25.12| 3.37       | 3.957  | 0.001   |
| At 4th Months        | 40| 89.13| 21.36| 3.38       | 1.00   | 0.323   |
| Role Limitations due to Physical Health | N | Mean | SD | Std. Error | t-test | p value |
| At Baseline          | 40| 1.87 | 6.67 | 1.05       | 4.38   | 2.67    | 2.67   |
| At 4th Months        | 40| 4.38 | 16.88| 2.67       | 3.33   | 16.54   | 2.61   |
| Role Limitations due to Emotional Health | N | Mean | SD | Std. Error | t-test | p value |
| At Baseline          | 40| 0.00 | 0.00 | 0.00       | 1.275  | 0.210   |
| At 4th Months        | 40| 3.33 | 16.54| 2.61       | 1.00   | 0.323   |
| Fatigue/Vitality     | N | Mean | SD | Std. Error | t-test | p value |
| At Baseline          | 40| 41.00| 7.66 | 1.24       | 3.323  | 0.003   |
| At 4th Months        | 40| 44.25| 7.12 | 1.13       | 0.001  | 0.001   |
| Emotional Well Being | N | Mean | SD | Std. Error | t-test | p value |
| At Baseline          | 40| 28.70| 5.65 | 0.89       | 0.313  | 0.756   |
| At 4th Months        | 40| 28.90| 5.47 | 0.87       | 0.313  | 0.756   |
| Social Functioning   | N | Mean | SD | Std. Error | t-test | p value |
| At Baseline          | 40| 49.63| 10.40| 1.64       | 0.443  | 0.660   |
| At 4th Months        | 40| 49.37| 8.47 | 1.34       | 0.061  | 0.061   |
Bar Diagram Showing Domains of Quality of Life in Group 1

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

| Domain                          | At Baseline | Mean | SD  | Std. Error Mean | t-test | p value |
|---------------------------------|-------------|------|-----|-----------------|--------|---------|
| Physical Functioning            | At Baseline | 74.87| 23.19| 3.67            | 3.452  | 0.001 (HS) |
|                                 | At 4th Months| 84.63| 22.08| 3.49            |         |          |
| Role Limitations due to Physical Health | At Baseline | 10.00| 21.78| 3.44            | 1.533  | 0.133 (NS) |
|                                 | At 4th Months| 6.87| 19.60| 3.09            |         |          |
| Role Limitations due to Emotional Health | At Baseline | 5.67| 15.47| 2.45            | 1.00   | 0.324 (NS) |
|                                 | At 4th Months| 5.00| 14.22| 2.24            |         |          |
| Fatigue/Vitality                | At Baseline | 37.75| 6.09 | 0.96            | 8.657  | 0.001 (HS) |
|                                 | At 4th Months| 26.75| 10.35| 1.64            |         |          |
| Emotional Well Being            | At Baseline | 28.29| 6.96 | 1.10            | 1.684  | 0.100 (NS) |
|                                 | At 4th Months| 29.50| 6.82 | 1.08            |         |          |
| Social Functioning              | At Baseline | 47.50| 5.80 | 0.92            | 3.074  | 0.001 (HS) |
|                                 | At 4th Months| 51.25| 5.52 | 0.87            |         |          |
| Pain                            | At Baseline | 10.50| 21.06| 3.33            | 1.740  | 0.090 (NS) |
|                                 | At 4th Months| 3.81| 17.75| 2.81            |         |          |
| General Health                  | At Baseline | 50.52| 9.86 | 1.56            | 5.433  | 0.001 (S)  |
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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 | 0.273 | 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 | 2.057 | 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 |        |         |
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 |        |         |
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 both 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.