



COMPARATIVE STUDY ON EFFICACY AND SAFETY OF BISOPROLOL AND METOPROLOL IN HYPERTENSION

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ABSTRACT

Aim: to perform a comparative study on efficacy and safety of bisoprolol and metoprolol in hypertension. **objective:** to study the efficacy and safety of bisoprolol, and metoprolol and to ensure patient medication adherence. **methodology:** a follow-up prospective study is carried out in the hypertensive patients taking metoprolol or bisoprolol to evaluate the efficacy and safety of these drugs (metoprolol and bisoprolol) in the department of cardiology, durgabai deshmukh hospital, a 250 bedded multi-specialty hospital from october 2019 to march 2020.**results:** among the all outnumber of patients (200), metoprolol is given to 62% of patients and bisoprolol is given to 38% of patients. **Conclusion:** a comparative study on the efficacy and safety of bisoprolol and metoprolol in hypertension was examined. from the above data, it is apparent that metoprolol 50mg was considered more effective when compared to metoprolol 25mg and bisoprolol 5mg was considered more effective when compared to bisoprolol 2.5mg. Safety is ensured at a low dose because fewer side effects were observed at metoprolol 25mg and bisoprolol 2.5mg in hypertensive patients.

INTRODUCTION

Hypertension is a common disease defined as persistently elevated arterial blood pressure (BP) 140/90 mmHg or above. Arterial BP is that the pressure within the arterial wall measured in millimeters of mercury (mm Hg), it is hemodynamically generated by the interplay between blood flow and resistance to the bloodstream. It's mathematically defined as the product of flow (CO) and total peripheral resistance (TPR) consistent with the subsequent equation:

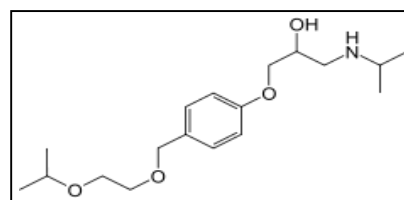
$$BP = CO \times TPR^{[1]}$$

Hypertension can be cause due to secondary conditions, essential hypertension conditions and also it may be drug induced. [2]. Generally, symptoms are silent but severe symptoms include: Headaches, shortness of breath, flushing or dizziness etc.

DRUGS IN THE STUDY:

CHEMICAL FORMULA: C₁₈H₃₁NO₄

THERAPEUTIC CLASS: Antihypertensive, Beta-Blocker
DOSE: 2.5-5mg PO a Day; may increase to 10 mg PO a day.



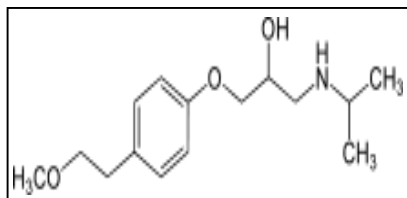
MECHANISM OF ACTION: Bisoprolol competitively binds to and blocks beta-1 adrenergic receptors in the heart, thereby decreasing cardiac contractility and rate. This results in a reduction in cardiac output and lowers blood pressure. Additionally, bisoprolol prevent the release of renin that causes constriction of blood vessels.

METOPROLOL

CHEMICAL FORMULA: C₁₅H₂₅NO₃

THERAPEUTIC CLASS: Antihypertensive

DOSE: 25-100 mg PO a day initially; usual range, 50-100 mg/day; not to exceed 400 mg/day



MECHANISM OF ACTION:

Metoprolol antagonizes beta 1 adrenergic receptors in the myocardium, thereby reducing the rate and force of myocardial contraction, and consequently a diminished cardiac output. This drug may also cause reduced secretion of renin with a subsequent reduction in levels of angiotensin II thus decreasing sympathetic activation, including vasoconstriction, aldosterone secretion.^[4]

MATERIALS AND METHODS: This Follow up Prospective study was conducted for 6 months in the Department of Cardiology, Durgabai Deshmukh Hospital and Research Centre, a 300 bedded multi-specialty hospital, Vidyanagar, Hyderabad. After obtaining the consent from the patients, they were accounted into the study; the study procedure was explained briefly before signing in the informed consent form. The study was conducted after informed

RESULTS AND DISCUSSION

written consent is taken from patients in all groups under the guidance of senior Cardiologist in the hospital. A total of 200 patients were enrolled in the study.

The details of patients are assembled by directly collecting the outpatient card and asking the patients. Then details were recorded in the data collection form.

All 200 patients both males and females with Hypertension with or without co morbidities are included and are divided into two groups based on their treatment.

GROUP A: Patients with Hypertension of age greater than 30yrs; undergoing treatment with METOPROLOL 25 mg/ 50 mg once daily.

GROUP B: Patients with Hypertension of age greater than 30yrs; undergoing treatment with BISOPROLOL 2.5mg/5mg once or twice daily.

Blood pressure and heart rate were assessed each month for two groups and values are then statistically evaluated.

Statistical analysis:

All the data was analyzed using GraphPad Prism software version 8. Comparison among two groups was performed using unpaired ‘t’ test and p-value < 0.05 was considered statistically significant.^[1]

| TREATMENT | NO. OF PATIENTS |
|----------------------|-----------------|
| Group A (Metoprolol) | 124 |
| Group B (Bisoprolol) | 76 |
| | 200 |

TABLE 5.1: SAMPLE SIZE

AGE DISTRIBUTION

TABLE-5.2 COMPARISON OF AGE DISTRIBUTION IN TWO GROUPS:

| AGE | METOPROLOL | BISOPROLOL |
|-------|------------|------------|
| 30-60 | 72 | 42 |
| >60 | 52 | 34 |

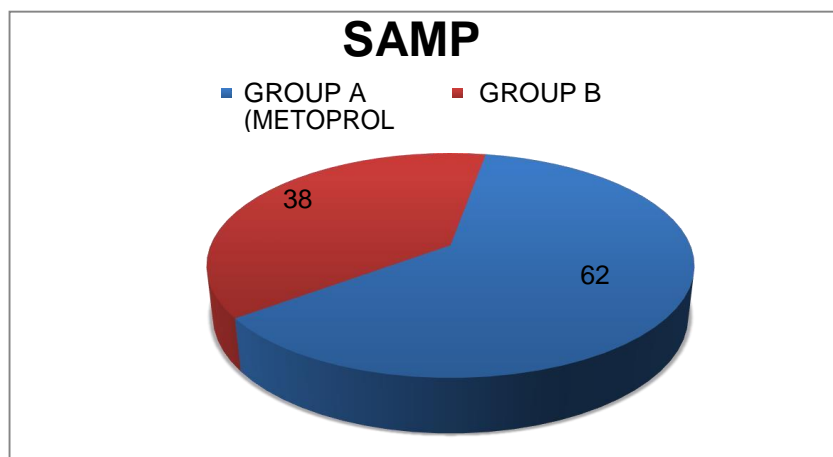
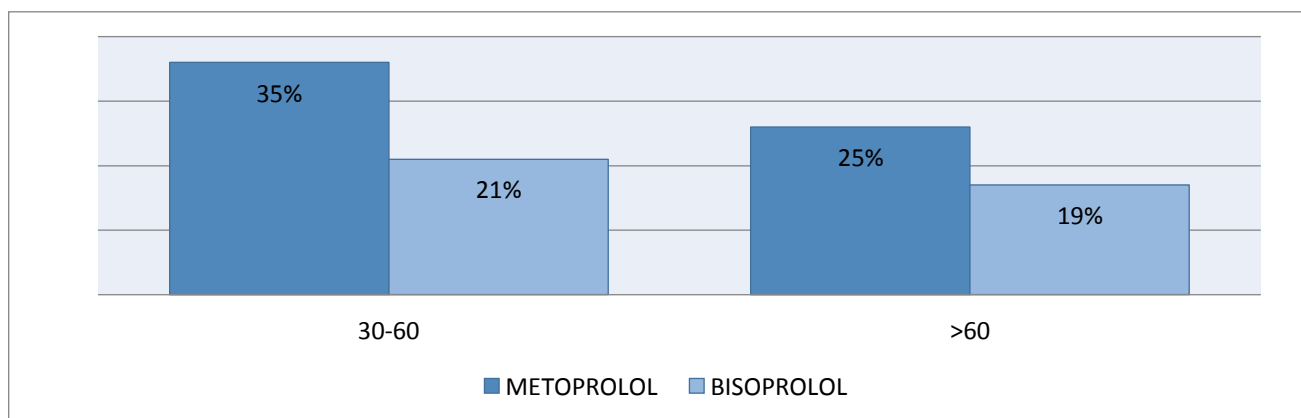


FIGURE 5.1: SAMPLE SIZE



GENDER DISTRIBUTION

TABLE 5.3 COMPARISON OF GENDER DISTRIBUTION IN TWO GROUPS:

| GENDER | METOPROLOL | BISOPROLOL |
|--------|------------|------------|
| MALE | 78 | 38 |
| FEMALE | 46 | 38 |

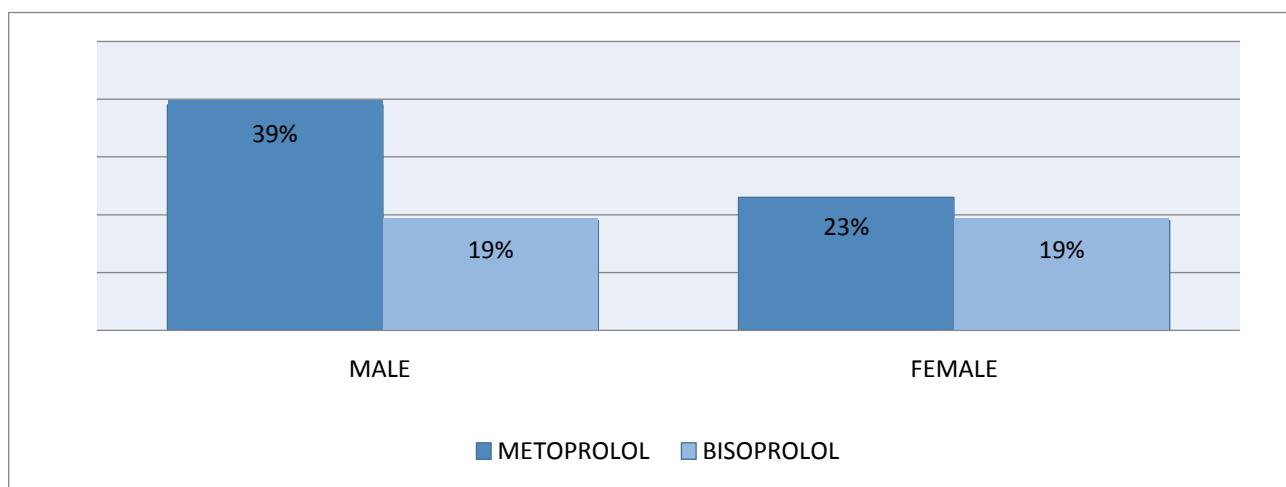


FIGURE 5.3. COMPARISON OF GENDER DISTRIBUTION IN TWO GROUP

BODY MASS INDEX

TABLE 5.4 COMPARISON OF BMI IN TWO GROUPS:

| BMI | METOPROLOL | BISOPROLOL |
|-------------|------------|------------|
| UNDERWEIGHT | 15 | 10 |
| NORMAL | 48 | 28 |
| OVERWEIGHT | 36 | 23 |
| OBESE | 25 | 15 |

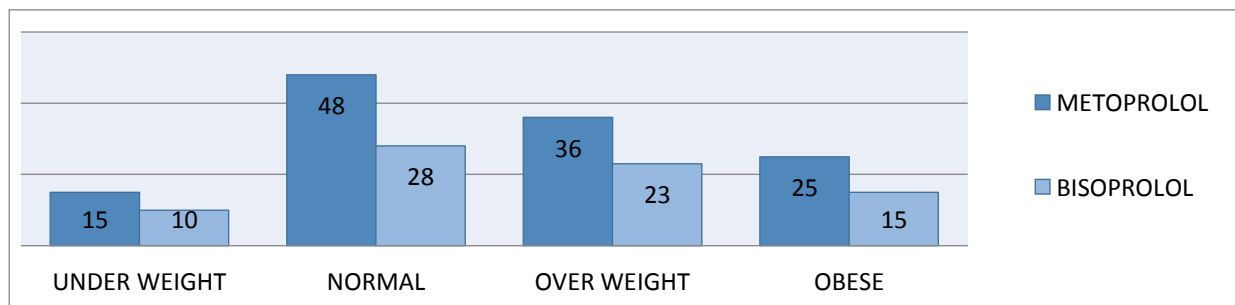


FIGURE 5.4 COMPARISON OF BMI IN TWO GROUPS:

CHIEF COMPLAINTS

TABLE 5.5 COMPARISON OF CHIEF COMPLAINTS IN TWO GROUPS:

| CHIEF COMPLAINTS | METOPROLOL | BISOPROLOL |
|------------------|------------|------------|
| SOB | 33 | 34 |
| CHEST PAIN | 37 | 24 |
| PALPITATIONS | 9 | 4 |
| GIDDINESS | 14 | 5 |
| ANXIETY | 8 | 8 |
| COUGH | 20 | 13 |

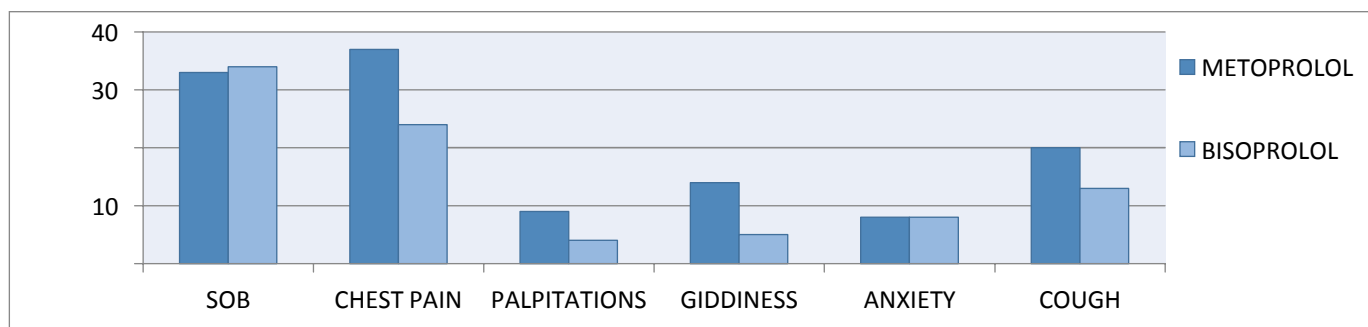


FIGURE 5.5 COMPARISON OF CHIEF COMPLAINTS IN TWO GROUPS

SIDE EFFECTS

TABLE 5.6.1 COMPARISON OF SIDE EFFECTS IN GROUP A

| SIDE EFFECTS | 25MG | 50MG |
|--------------|------|------|
| HEADACHE | 1 | 3 |
| DIZZINESS | 2 | 4 |
| CONSTIPATION | 4 | 4 |
| COUGH | 2 | 5 |
| DYSPNEA | 2 | 2 |
| DIARRHEA | 1 | 2 |
| FATIGUE | 2 | 3 |

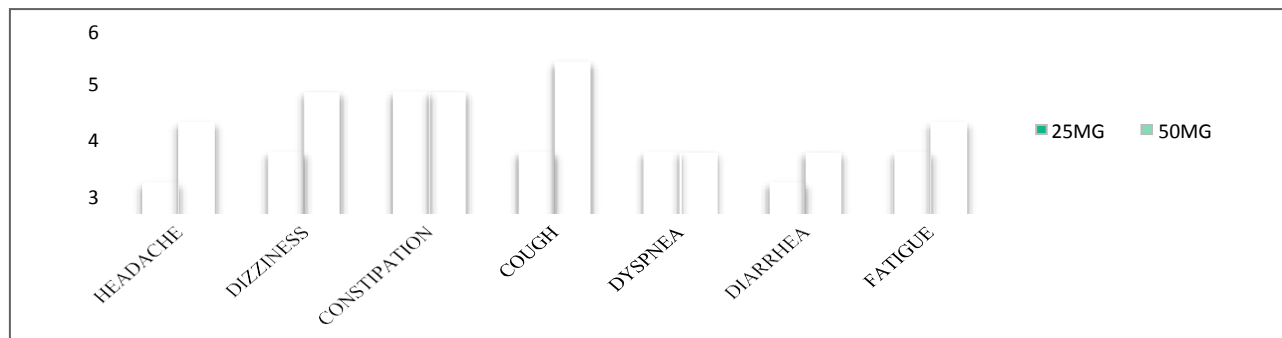


FIGURE 5.6.1 COMPARISON OF SIDE EFFECTS IN GROUP A

TABLE 5.6.2 COMPARISON OF SIDE EFFECTS IN GROUP B:

| SIDE EFFECTS | 2.5MG | 5MG |
|--------------|-------|-----|
| HEADACHE | 2 | 3 |
| FATIGUE | 2 | 6 |
| CONSTIPATION | 1 | 1 |
| COUGH | 1 | 1 |
| DYSPNEA | 2 | 2 |
| DIARRHEA | 1 | 3 |

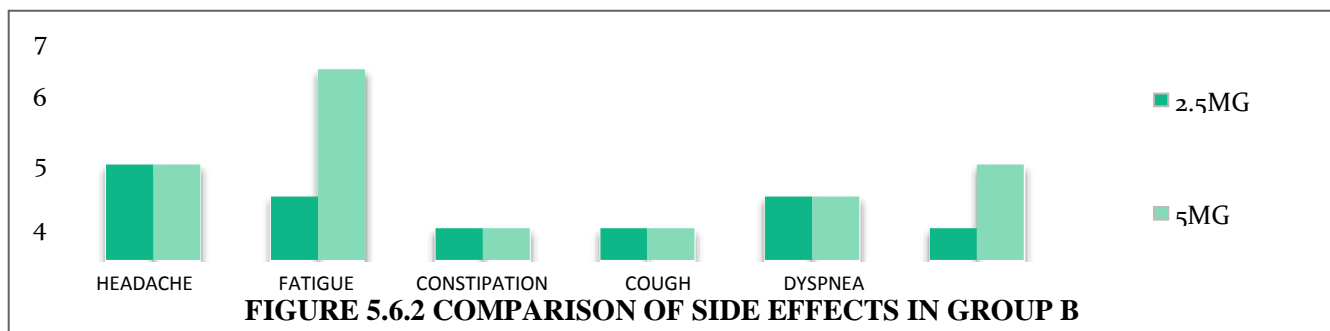


FIGURE 5.6.2 COMPARISON OF SIDE EFFECTS IN GROUP B

PATIENT MEDICATION ADHERENCE SCORE

TABLE 5.7.1 PATIENT MEDICATION ADHERENCE SCORE IN GROUP A:

| SCORE | <6 LOW | 6-<8 (MEDIUM) | (HIGH) |
|-------|--------|---------------|--------|
| 25mg | 3 | 14 | 30 |
| 50mg | 7 | 29 | 41 |

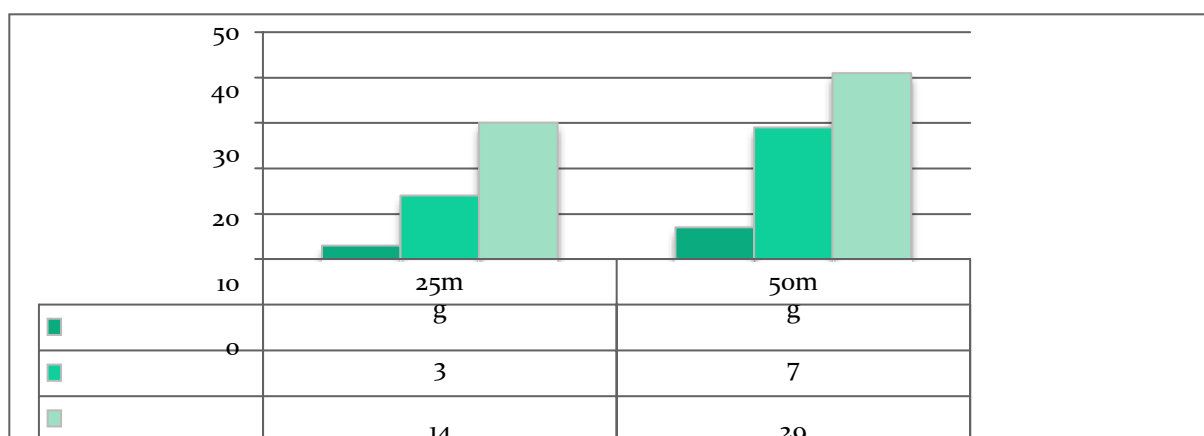


FIGURE 5.7.1 PATIENT MEDICATION ADHERENCE SCORE IN GROUP A:

TABLE 5.7.2 PATIENT MEDICATION ADHERENCE SCORE IN GROUP B:

| SCORE: | <6 (LOW) | 6- <8 (MEDIUM) | 8 (HIGH) |
|--------|----------|----------------|----------|
| 2.5 mg | 5 | 15 | 14 |
| 5mg | 4 | 17 | 23 |

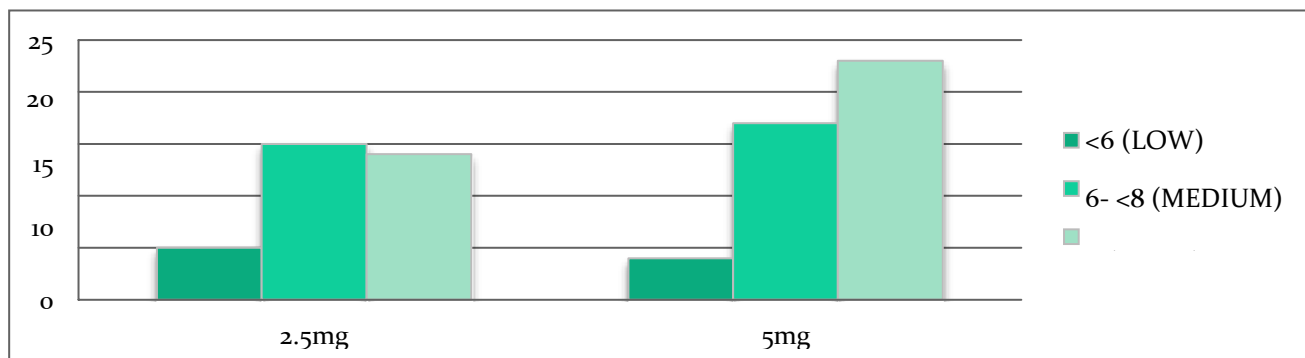


FIGURE 5.7.2 PATIENT MEDICATION ADHERENCE SCORE IN GROUP B

STATISTICAL ANALYSIS:

Unpaired t - test:

BLOOD PRESSURE:

Systolic blood pressure analysis of Group A (Metoprolol): Review (50mg) vs. Review (25mg)

| TEST | DF | P value | T statistic | One tailed ortwo tailed | Statistical Significance |
|-----------------|-----|---------|-------------|-------------------------|--------------------------|
| Unpaired t-test | 122 | 0.0192 | 2.372 | Two-tailed | Yes |

Result: The above table shows that there is a significant difference between systolic bloodpressure after treatment with Metoprolol in Review of 50mg and Review of 25mg. Diastolic blood pressure analysis of Group A (Metoprolol): Review (50mg) vs. Review (25mg)

| TEST | DF | P-value | T statistic | One-tailed ortwo-tailed | Statistical Significance |
|-----------------|-----|---------|-------------|-------------------------|--------------------------|
| Unpaired t test | 116 | 0.7747 | 0.2868 | Two tailed | No |

Result: The above table shows that there is no significant difference between diastolic bloodpressure after treatment with Metoprolol in Review of 50mg and Review of 25mg.

Systolic blood pressure analysis of Group B (Bisoprolol): Review (5mg) vs. Review (2.5mg)

| TEST | DF | P-value | T statistic | One-tailed ortwo-tailed | Statistical Significance |
|-----------------|----|---------|-------------|-------------------------|--------------------------|
| Unpaired t test | 74 | 0.0013 | 3.336 | Two-tailed | Yes |

Result: The above table shows that there is a significant difference between systolic blood pressure After treatment with Bisoprolol in Review of 5mg and Review of 2.5mg.

Diastolic blood pressure analysis of Group B (Bisoprolol): Review (5mg) vs. Review(2.5mg)

| TEST | DF | P value | T statistic | One tailed ortwo tailed | Statistical Significance |
|-----------------|----|---------|-------------|-------------------------|--------------------------|
| Unpaired t test | 74 | 0.0002 | 3.871 | Two-tailed | Yes |

Result: The above table shows that there is a significant difference between diastolic blood pressure After treatment with Bisoprolol in Review of 5mg and Review of 2.5mg.

HEART RATE:

Heart rate analysis of Group A (Metoprolol): Review (50mg) vs. Review (25mg)

| TEST | DF | P value | T statistic | One tailednor two tailed | Statistical Significance |
|-----------------|-----|---------|-------------|--------------------------|--------------------------|
| Unpaired t test | 114 | 0.0084 | 2.681 | Two tailed | Yes |

Result: The above table shows that there is a significant difference between heart rateafter treatment with Metoprolol in Review of 50mg and Review of 25mg.

5.10.2. Heart rate analysis of Group B (Bisoprolol): Review (5mg) vs. Review (2.5mg)

| TEST | DF | P-value | T statistic | One-tailed or two- tailed | Statistical Significance |
|-----------------|----|---------|-------------|---------------------------|--------------------------|
| Unpaired t test | 74 | 0.9621 | 0.0476 | Two tailed | No |

Result: The above table shows that there is no significant difference between heart rate after treatment with Bisoprolol in Review of 5mg and Review of 2.5mg.

CONCLUSION:

A comparative study on the efficacy and safety of Bisoprolol and Metoprolol in Hypertension was studied. From the above data, it is evident that Metoprolol 50mg was considered more effective when compared to Metoprolol 25mg and Bisoprolol 5mg was considered more effective when compared to Bisoprolol 2.5mg. Safety is ensured at a low dose because fewer side effects were observed at Metoprolol 25mg and Bisoprolol 2.5mg in hypertensive patients.

ETHICS AND CONSENT

The entire study was conducted according to the ethical committee guidelines of Durgabai Deshmukh hospital. All the relevant and necessary data was collected from out-patient record, laboratory investigation reports, prescriptions and

patient medication adherence questionnaire by interviewing the patients.

CONFLICTS OF INTEREST: None.

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