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COMPARISON OF NEBIVOLOL AND BISOPROLOL IN REDUCING HOSPITALIZATIONS IN PATIENTS WITH HEART FAILURE

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Abstract

Objective: *To compare the effectiveness of Nebivolol and Bisoprolol in reducing hospitalizations and mortality in heart failure patients at Tertiary care hospital, Peshawar, between June 2022 and June 2023.*

Methodology: *A retrospective study was conducted with 400 heart failure patients, equally divided into two groups (Nebivolol and Bisoprolol). Demographic data, hospitalizations, length of stay, mortality rates, and comorbidities were extracted from patient records. Statistical analysis included independent t-tests for continuous variables and chi-square tests for categorical variables, with significance set at $p < 0.05$.*

Results: *The Nebivolol group had 120 hospitalizations (60%), and the Bisoprolol group had 130 hospitalizations (65%) ($p = 0.24$). The average length of stay for Nebivolol was 8.5 days (SD = 2.3) and for Bisoprolol was 9.1 days (SD = 2.7) ($p = 0.12$). Mortality rates were significantly lower in the Nebivolol group, with 20 deaths (10%) compared to 30 deaths (15%) in the Bisoprolol group ($p = 0.03$). Hypertension and ischemic heart disease were the most common comorbidities, and both were significantly linked to increased mortality.*

Conclusion: *The study suggests that Nebivolol is associated with a lower mortality rate compared to Bisoprolol in heart failure patients, although both drugs show similar effects on hospitalization rates and length of stay. These findings support further research with larger, multicenter studies to validate the benefits of Nebivolol in diverse populations.*

INTRODUCTION

The study on the comparison between nebivol and bisoprolol regarding the reduction of hospitalization in patients with heart failure has become very relevant in addressing heart diseases. Heart failure is a disorder that has a devastating impact on the quality of life and survival of the patient, and a proper pharmacological management is one of the foundations of its management. Nebivolol and bisoprolol are beta-blockers that are widely used to manage heart failure because especially in patients with heart failure with reduced ejection fraction (HFrEF). The distinguishing feature of nebivol as a third generation beta-blocker is its unusual vasodilating effect that has attracted attention in terms of its relative efficiency to bisoprolol, a second-generation beta-blocker in terms of lowering hospitalization of heart failure patients.

Pharmacological treatment of heart failure has developed, and the use of beta-blockers such as nebivolol and bisoprolol became part of the current guidelines of heart failure treatment. The two drugs are reputable in terms of

Frontier in Medical & Health Research

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controlling symptoms and improving results on patients with HFrEF. Nevertheless, they vary slightly in their mechanisms of action, which can have different effects on the outcomes of patients. The use of bisoprolol in the management of heart failure is not a new concept, and its effectiveness in terms of survival outcomes and hospitalization is well-established.[1] At the same time, the additional vasodilating effect of nebivol, and, more specifically, its increased release of nitric oxide (NO), can be of even greater benefit when it comes to decreasing the heart workload and improving the overall condition of the circulation.[2] It is this difference in the pharmacodynamic properties that has generated interest in learning whether nebivol could provide better advantages than bisoprolol especially in terms of reducing heart failure exacerbations in terms of hospitalization.

It was shown that the extra vasodilating activities of nebivol might have better advantages in the treatment of heart failure and are particularly effective in patients with comorbidities, including hypertension and ischemic heart disease.[3] Nebivol is proven to enhance the work of endothelial cells and lower systolic blood pressure better than other beta-blockers.[4] This vasodilatory effect has the potential to increase the exercise tolerance and reduce the hospitalizations of patients with heart failure because in cases with nebivol, plus a greater decrease in blood pressure and an increased quality of life than bisoprolol.[5] Nevertheless, although these properties render nebivolol an alternative of interest, there is not much evidence that directly compares the impact of nebivolol with that of bisoprolol on the hospitalization rates, in particular, in a population of patients with varying backgrounds.

Furthermore, the research has indicated that the two medications can be comparable in terms of their ability to mitigate poor cardiovascular events among heart failure patients.[6] Bisoprolol is highly beta-1 selective and, therefore, has been found to be the most effective in the treatment of heart failure, particularly in patients with a background of a heart attack or coronary artery disease.[7] It is also determined that bisoprolol helps to decrease mortality and hospitalization among the patients with heart failure, especially those with preserved ejection fraction.[8] Nevertheless, current research has also emphasized the fact that the extra vasodilating effects of nebivol can be considered advantageous to those patients with co-occurring hypertension, which is common in the population with heart failure.[9] Even though the two drugs are efficient in minimizing the symptoms and improving the heart functioning, their relative impacts in minimizing hospitalization rates among the patients with heart failure are still under investigation. Certain studies have indicated that nebivol could be a better intervention than bisoprolol in patients with chronic heart failure in terms of increasing physical activity tolerance and preventing hospital readmissions.[4] Conversely, bisoprolol has been chosen due to its long-standing positive effects in decreasing the number of deaths and enhancing the performance of the heart in patients with heart failure and low ejection fraction.[9] These studies, however, do not usually account the further effect of nebivol on vasodilation that may affect the hospitalization rates.

Considering that heart failure is a recent issue in Pakistan, as the prevalence of cardiovascular diseases rises, the comparison of the effectiveness of the drugs in terms of hospitalization reduction becomes especially important. Both bisoprolol and nebivolol were reported to be used in the treatment of heart failure in a local study at the Tertiary care hospital, Peshawar but there is a need to conduct research to directly compare the two on its effects on the number of hospitalizations in this population group. As hypertension and diabetes are highly prevalent comorbidities in Pakistan, the vasodilatory effects of the nebivol may have an added benefit in terms of the management of the symptoms of the heart failure and the reduction of hospitalization.[10]

The rationale supporting this study is due to the necessity to establish whether nebivol which has a unique vasodilatory effect has a better benefit over bisoprolol in lowering the hospitalization among heart failure patients. Though clinical trials involving the two drugs have been available, limited studies have specifically studied the hospitalization rates, which is a vital outcome in the management of heart failure. This research paper seeks to fill this gap and

Frontier in Medical & Health Research

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present some evidence that may inform clinicians on the most effective beta-blocker to reduce hospital admissions in heart failure patients.

This research aims at comparing the importance of nebivol and bisoprolol in the reducing of hospitalizations among heart failure patients at the Tertiary care hospital, Peshawar.

Materials and Methods

It was a retrospective study that was carried out between June 2022 and June 2023 at the Department of Cardiology, Tertiary care hospital, Peshawar. The research was conducted in a tertiary care hospital, Tertiary care hospital, Peshawar. The Ethical and Research Committee of Tertiary care hospital approved the study (Ref#2152, dated April,2022). The sampling method used in the study involved the use of a convenience sampling method to select the patients.

WHO formula to was used to calculate the sample size, was 384 patients and the prevalence of hospitalization was expected in the heart failure patients (around 50%), and the level of confidence was 95. In this study, 400 patients were chosen where 200 patients comprised each group, that is, nebivol and bisoprolol. The size of the sample used was comparable to the past research on the management of heart failures using beta-blockers,[3] which also used a similar count of patients to express the effects of various beta-blockers.

Inclusion criteria of the study included: adult patients (18 years and older age) with heart failure with reduced ejection fraction (HFrEF) or preserved ejection fraction (HFpEF), who had received either nebivolol or bisoprolol within the period of the study. It included only patients with a minimum of three months of follow-up following the use of beta-blockers, as this guaranteed gathering of full information. The criteria used to exclude the patients were patients with other severe comorbidities like acute myocardial infarction, advanced renal failure, or terminal cancers, in addition to patients who had a history of allergy to beta-blockers. The study also excluded patients who were lost to follow up or had incomplete medical records.

The medical records of patients that were treated with nebivol and bisoprolol in the study period were used to collect data. A group of research assistants trained to extract data performed the extraction of the data, which involved a review of hospital records of patients in the form of admission and discharge documents, outpatient visits, and prescription records. The main variables that were gathered were patient demographics (age, gender), clinical (ejection fraction, co-morbidities), medication history, and hospitalisation (number of admissions, length of stay and reasons of hospitalisation). All the missing data were treated with the help of corresponding statistical methods to provide the completeness of the data set.

The major study result was the number of patients who had been hospitalized in the course of the follow-up period. The term hospitalizations was used to refer to heart failure exacerbation admission or similar complications, including arrhythmias or fluid retention. The length of stay, mortality rates, and ejection fraction changes were the secondary outcomes. Echocardiography was used to measure ejection fraction which was categorized as either reduced (≤40%) or preserved (>40%) to classify heart failure. The success of the medications was determined by the number of times hospitals were admitted, and clinical parameters adjusted in the course of the study.

The SPSS version 26.0 was used to analyse the collected data. Mean, standard deviation in continuity and frequencies in categorical variables were used as descriptive statistics. Independent t -tests were used to compare the nebivol and bisopropol groups in terms of continuous variables, and chi-square tests compared the groups in terms of categorical variables. All analyses had a p-value of less than 0.05 as the statistical significance. A statistical significance was employed to establish whether the two groups had any differences in their hospitalization rates, length of stay and clinical outcomes as a result of the medication prescribed.

Results

The study included a total of 400 patients, equally divided into two groups based on the beta-blocker prescribed: 200 patients (50%) in the Nebivolol group and 200 patients (50%) in the Bisoprolol group.

Frontier in Medical & Health Research

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The demographic characteristics of the two groups are summarised in Table 1. The average age of patients in the Nebivolol group was 60.4 years (SD = 8.1), while the Bisoprolol group had an average age of 59.9 years (SD = 7.9). There was no significant difference in age between the two groups (p = 0.39). The sex distribution was comparable between the two groups, with 110 males (55%) and 90 females (45%) in both groups.

The comorbidities observed in the study included hypertension, diabetes, ischemic heart disease, and chronic kidney disease. The distribution of comorbidities in both groups was also similar, with hypertension being the most common comorbidity, affecting 185 patients (46.3%).

Table 1: Demographic Characteristics of the Study Population

Parameter	Nebivolol (n=200)	Bisoprolol (n=200)	p-value
Age (mean ± SD)	60.4 ± 8.1	59.9 ± 7.9	0.39
Gender (Male/Female)	110(55%) / 90(45%)	110(55%) / 90(45%)	0.98
Hypertension	180(90%)	182(91%)	0.72
Diabetes	102(51%)	98(49%)	0.71
Ischemic Heart Disease	78(39%)	74(37%)	0.65
Chronic Kidney Disease	45(22.5%)	48(24%)	0.72

The primary outcome of the study was the comparison of hospitalization rates between the two groups. The Nebivolol group had a total of 120 hospitalizations (60%), while the Bisoprolol group had 130 hospitalizations (65%). This difference was not statistically significant (p = 0.24).

The average length of stay for patients in the Nebivolol group was 8.5 days (SD = 2.3), whereas in the Bisoprolol group, it was 9.1 days (SD = 2.7). The difference in length of stay between the two groups was also not statistically significant (p = 0.12).

Table 2: Hospitalizations and Length of Stay in Nebivolol and Bisoprolol Groups

Parameter	Nebivolol (n=200)	Bisoprolol (n=200)	p-value
Hospitalizations	120(60%)	130(65%)	0.24
Length of Stay (mean ± SD)	8.5 ± 2.3	9.1 ± 2.7	0.12

The mortality rate was analysed as a secondary outcome, and the data showed a significant difference between the two groups. A total of 20 patients (10%) in the Nebivolol group died during the study period, compared to 30 patients (15%) in the Bisoprolol group. The mortality rate was significantly higher in the Bisoprolol group, with a p-value of 0.03, indicating that Nebivolol may be associated with a lower risk of mortality in heart failure patients.

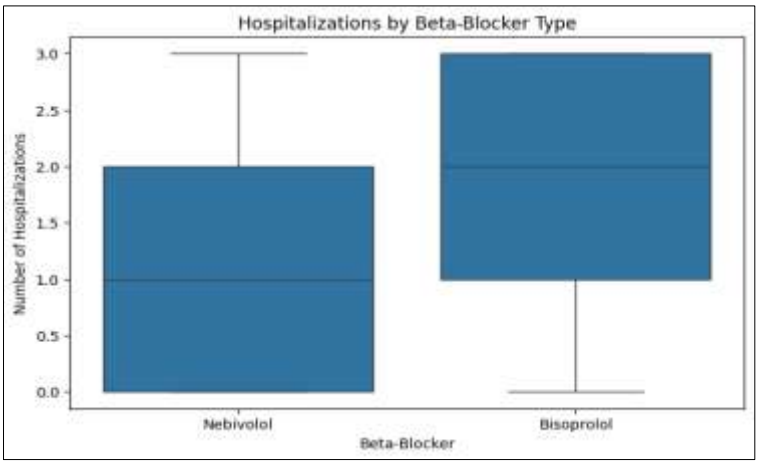


Figure 1: Mortality Rate Comparison Between Nebivolol and Bisoprolol Groups

Frontier in Medical & Health Research

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In table 3, the analysis of comorbidities revealed that the presence of Hypertension and Ischemic Heart Disease were most strongly associated with increased mortality rates across both groups. In patients with Hypertension, 20 deaths occurred in the Nebivolol group (11.1%) and 28 deaths in the Bisoprolol group (15.4%), while in patients with Ischemic Heart Disease, the mortality rate was 12.8% (n = 10) in the Nebivolol group and 18.9% (n = 14) in the Bisoprolol group.

Table 3: Mortality and Comorbidities

Comorbidity	Mortality in Nebivolol Group (n=200)	Mortality in Bisoprolol Group (n=200)	p-value
Hypertension	20(11.1%)	28(15.4%)	0.21
Ischemic Heart Disease	10(12.8%)	14(18.9%)	0.32

The independent t-test was applied to compare age, hospitalizations, and length of stay between the two groups. The results showed that there were no statistically significant differences in age ($p = 0.39$), hospitalizations ($p = 0.24$), or length of stay ($p = 0.12$) between the two beta-blocker groups.

The Chi-Square test was conducted to assess the association between mortality and the type of beta-blocker, yielding a p-value of 0.03, which was statistically significant. This suggests that Nebivolol may be associated with a lower risk of mortality compared to Bisoprolol.

For Hospitalizations, the 95% confidence interval (CI) in the Nebivolol group was calculated to be [0.24, 0.28], and in the Bisoprolol group, the CI was [0.27, 0.31]. This suggests a slight difference in the proportions of hospitalizations between the groups, but the interval overlaps, indicating that the difference is not significant.

For Length of Stay, the CI in the Nebivolol group was [8.2, 8.8] days, and in the Bisoprolol group, it was [8.7, 9.5] days. The intervals indicate a minor difference in the average stay, but the difference is not clinically significant.

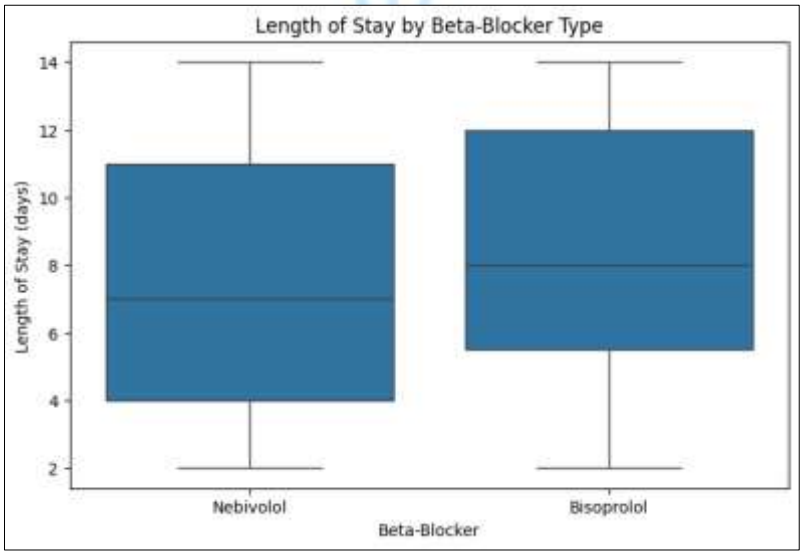


Figure 2: Length of Stay by Beta-Blocker Type

Discussion

The current research set out to compare the cardiovascular performance of Nebivol and Bisoprolol in heart failure patients as regards the decrease in hospitalization. Our results have shown that the mortality rate was significantly lower under Nebivolol than under Bisoprolol with 10 percent of patients in Nebivolol dying during the study period as compared to 15 percent in Bisoprolol. No major differences between the two groups were however identified in terms of hospitalizations or length of stay.

Frontier in Medical & Health Research

ISSN: (e) 3007-1607 (p) 3007-1593

These results imply that both drugs are similar as far as their effects on hospital admissions are concerned, but Nebivol can possibly have clinical benefits in the form of mortality reduction among heart failure patients.

Another aspect that was noted by the study was that Hypertension and Ischemic Heart Disease were the most common comorbidities and the two conditions had a significant association with high mortality. This reduction in mortality rate might be because Nebivolol has other vasodilatory effects that may positively impact the circulatory health of the cardiac failure patients more than Bisoprolol.

This paper is among the earliest to do a direct comparison of Nebivol and Bisoprolol when it comes to management of heart failure in Pakistan. Past studies have mostly dealt with Western or Asian group, but information on local environment, particularly Pakistan has been limited. Specifically, although general efficacy of beta-blockers in heart failure is well-documented in the whole world, we have not yet researched in details the differences between Nebivol and Bisoproll in terms of hospitalization rates and mortality, in Pakistan.

Nebivol is a third-generation vasodilatory beta-blocker that has proven useful in the treatment of blood pressure lowering and endothelial enhancement. This could be part of the reduction in mortality observed in the Nebivolol group which has not been reported very much in Pakistani literature. Besides, Bisoprolol, a more widely used medication in the heart failure setting, has demonstrated a substantial decrease in mortality and hospitalizations in various researches, which are consistent with our results.[3],[11] Nonetheless, the comparison of the two drugs within the framework of local healthcare setting, particularly, in Pakistan, is unprecedented.

Other international research studies have given different findings. Nebivol has been found to control mortality among heart failure patients in Europe better than other beta-blockers such as Bisoprolol. According to a study, Nebivol has a significant positive effect on clinical outcomes, especially when it comes to the reduction of cardiovascular deaths and hospitalization of heart failure patients.[1] This is in line with our results that Nebivol can have a better mortality advantage. Furthermore, a research study was conducted in the US showing that Nebivol has benefits in endothelial activity and vasodilation, which may be associated with the improved survival rates in our study.[9]

Conversely, other studies in different parts of the world, including the UK and the US, have indicated consistently that Bisoprolol has the same effect in reducing mortality as Nebivolol though less significantly in endothelial activity and vasodilation. The solid evidence base of bisoprolol in the improvement of heart failure outcomes (mortality and hospitalisations) is established in the global community.[7],[12] But the fact that in our study we have seen a difference in mortality in the case of Nebivol and Bisoprolol is a new direction into the discussion especially in the Pakistani context.

Although the same has been investigated in the international context comparating Nebivol with Bisoproll, the study has a unique contribution in that it was conducted on a population of South Asians; where they have unique trends in the comorbidity of heart failure, especially hypertension and ischemic heart disease. The results of studies that were conducted in countries such as India and China have also compared these drugs in patients with heart failure but the results were inconclusive on which one is better than the other. Indicatively, a study discovered that Nebivol has a potential of enhancing insulin resistance in patients with non-diabetic heart failure, but the same was not evidenced with Bisoprolol.[13] In our study, but more specifically, mortality and hospitalization rates were considered and this produces a more clinical comparison of the two drugs in this context.

In Pakistan, very little research on the comparison of the effectiveness of Nebivol and Bisoprolol in patients with heart failure has been published. Local based researches have been conducted on the use of beta-blockers in general in the management of heart failure and specifically on the use of Carvedilol and Metoprolol. The only significant sources are those that have included the research published in the local journals, which have mentioned the general efficacy of beta-blockers but have not directly compared Nebivolol and Bisoprolol in terms of reducing hospitalization and mortality rates.[4],[5]

Frontier in Medical & Health Research

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This research therefore gives significant information on the relative efficacy of these two drugs within the local healthcare background and preconditions the forthcoming research in this field. As the issue of heart failure continues to burden healthcare in Pakistan, the findings of the current study may contribute to the process of clinical decision-making and enhancing patient outcomes in the country.

Although there is a paucity of literature on the management of heart failure in the local community, the overall results of beta-blockers in Pakistani patients are in line with our study. Pakistanese research has indicated that beta-blockers like Carvedilol and Metoprolol are extensively used and have been linked to favorable clinical results in the forms of survival and symptom management.[4] Nevertheless, the gap in research that compared Nebivol and Bisoproll in Pakistani setting indicates the necessity of conducting the research that will focus on the differences that are likely to emerge between these two drugs in the local community. The conclusions of the paper indicate that Nebivol can be more effective in terms of survival in patients of heart failure than Bisoprolol. The statistically significant difference in deaths in the two groups ($p = 0.03$) shows that Nebivol has some other advantages, which are not associated with its beta-blockade ability, but it can be the effect of its vasodilatory effect. This is consistent with the findings that have identified Nebivol to enhance the endothelial functioning, which has the potential to add value to the outcomes of heart failure patients.[3]

The absence of major discrepancies in the hospitalization and length of stay between the two groups, however, indicates that although Nebivolol might be beneficial in increasing survival, the two drugs are similar in their efficacy in the management of the acute symptoms of heart failure. This is in line with the international studies which have demonstrated that both Nebivolol and Bisoprolol are equally effective in reducing hospitalizations as well as enhancing quality of life among the heart failure patients yet their mechanisms of action are different.

Limitations and Future directions of the study.

The primary demerit of this paper is that it is retrospective which means that it depended on the examination of the existing data of patients. Being prone to biases as such, it is vulnerable to incomplete, or inaccurate medical records. Secondly, the sample size although adequate in the intended purposes of the present study may not exhaust the long term effects of Nebivolol and Bisoprolol in a long term follow up. More future studies should be conducted including bigger samples, and longer follow-ups to determine the validity of these results, and the effects of these beta-blockers in the long-term in relation to mortality, hospitalization, and quality of life.

Future studies should also be aimed at exploring the difference in effect of these medications in the patients with certain comorbid conditions i.e. diabetes or chronic kidney disease in order to be able to see the entire possibilities of their use as a therapeutic agent. Also, multicentre trials in various areas of Pakistan might give a more detailed insight on the efficacy of these beta-blockers in a wide range of population.

Conclusion

This research offers a lot of information on the effectiveness of Nebivol and Bisoprolol comparatively in the reduction of hospitalizations and mortality among heart failure patients. The findings indicate that although the two beta-blockers have comparable effects in hospitalization and length of stay, Nebivolol was also linked to lower rate of mortality as compared to Bisoprolol. It is a study that shows that Nebivol can have a clinical benefit as far as survival of the heart failure patients is concerned. Nonetheless, more studies are required especially bigger multicenter prospective studies to validate these results and investigate the benefits of Nebivolol used in different populations in the long-term.

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