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Clinical Effect Analysis of the Combined Application of SGLT2i and ARNi in the Treatment of Patients with Atrial Fibrillation and Heart Failure in 2021-2022

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Abstract: The purpose of this study was to evaluate the combination of SGLT2i (sodium-glucose cotransporter 2 inhibitor) and ARNi (angiotensin receptor enkephalin inhibitor) in patients with atrial fibrillation and heart failure. The study used a randomized controlled trial design with 100 patients divided into control and experimental groups receiving conventional anti-heart failure therapy and combination therapy, respectively. The primary endpoint events included cardiovascular death, hospitalization for heart failure, and emergency department visits due to atrial fibrillation, while the secondary endpoint events included heart rate, blood pressure, improvement in cardiac function, and quality of life score. Strict quality control standards were followed during data collection, and data were collected using standardized questionnaires, physical examinations, laboratory tests, and electrocardiogram. Data were analyzed using SPSS software, including descriptive statistics, chi-square test, t-test, and the Cox regression model. The results showed that the combination group showed a trend to the control group at both primary and secondary endpoints, indicating that the combination of SGLT2i and ARNi may help to improve the treatment effect and quality of life in patients with AF and heart failure. This study provides new therapeutic strategies in the clinic and provides valuable reference information for research in related fields. However, due to the small sample size and short study duration, future larger, long-term tracked studies are still needed to further validate the effect of the combination.

Keywords: Atrial fibrillation; heart failure; SGLT2i; ARNi.

1. Introduction

In the 21st century, with the increasingly significant trend of the global population, and the influence of multiple factors such as the accelerating pace of life in modern society and the change of diet structure, cardiovascular disease has climbed to the forefront of global health problems and become the "number one killer" threatening human life[1]. Among them, atrial fibrillation (Atrial Fibrillation, AF) and heart failure (Heart Failure, HF), as two major "bombshell" in the cardiovascular field, not only can bring heavy health burden to patients, and the combination of the two is common. This combined state not only exacerbates the progression rate and severity of the disease, but also seriously affects the quality of life of patients, and the prognosis is worrying.

Atrial fibrillation, a common arrhythmia disorder characterized by disorganized electrical activity of atrial myocytes leading to rapid and irregular atrial rate. Heart failure, on the other hand, is a condition where the heart cannot effectively pump blood to meet the body's needs. When combined, patients often face higher hospital admission rates, more frequent cardiovascular events, and lower survival rates[2]. Although traditional treatments can relieve patients' symptoms to some extent, they are still limited in reducing the risk of cardiovascular events and improving patient survival rate and quality of life. Therefore, finding a more efficient and safe treatment method has become a major challenge for the medical community.

In recent years, with the rapid progress of medical science and technology, new drugs are constantly emerging, which has brought new hope for the treatment of cardiovascular diseases. Among them, sodium-glucose cotransporter 2 inhibitor (Sodium-Glucose Cotransporter 2 Inhibitors, SGLT2i) and angiotensin receptor enkephalinase inhibitor (Angiotensin Receptor Neprilysin Inhibitors, ARNi) have attracted much attention. Class SGLT2i drugs reduce blood sugar levels mainly by inhibiting the reabsorption of glucose by the kidneys, thus reducing the risk of cardiovascular disease[3]. ARNi drugs exert multiple effects by inhibiting the angiotensin receptor and enhancing the activity of enkephalin. These drugs have shown some efficacy when used alone, but the current research evidence remains limited regarding the effect of their combination in patients with AF with heart failure. Therefore, this study aimed to evaluate the therapeutic effect of combining SGLT2i with ARNi in patients with AF and heart failure. We hope to compare the difference in the efficacy of combination medication and conventional therapy to provide a more effective and safe treatment plan for these patients. At the same time, we also expect to provide valuable reference information for researchers in related fields through this study to promote the development of the treatment field of cardiovascular disease[4].

Specifically, we will select a certain number of patients with heart failure through the design of a randomized controlled trial. These patients were randomly divided into two groups, one group receiving conventional anti-heart failure treatment as a control group and the other group combining SGLT2i and ARNi on the basis of conventional therapy. The effect of the combination of SGLT2i and ARNi was comprehensively evaluated by comparing the treatment effect, the incidence of cardiovascular events, and the improvement of quality of life in the two groups.

We hope that through this study, we can provide new strategies and ideas for the treatment of AF patients with heart failure, and help them to better manage the disease and improve their quality of life. At the same time, we also expect

this study to provide a useful reference for the field of pharmaceutical research and development, promote the research and development of new drugs, and bring more possibilities for the treatment of cardiovascular diseases.

In conclusion, the objective of this study was to evaluate the therapeutic effectivenesss of combining SGLT2i and ARNi in patients with atrial fibrillation (AF) and heart failure. By doing so, we aim to contribute to the evolving field of cardiovascular medicine by providing clinicians with more effective and safer treatment options for their patients. We believe that with the advancement of research and medical technology, the treatment of cardiovascular diseases will continue to improve, ushering in a better future for patients worldwide.

2. Materials and Methods

2.1. Study design

In this study, we chose a randomized controlled trial (Randomized Controlled Trial, RCT) as the study design to more accurately assess the combination of SGLT2i (sodium-glucose cotransporter 2 inhibitor) and ARNi (angiotensin receptor enkephalin inhibitor) in patients with atrial fibrillation and heart failure. RCT is a classic experimental design method that can effectively control of potential bias and interference factors by randomly assigning patients to different treatment groups, thus ensuring the reliability and validity of study findings. Moreover, RCT is able to provide direct evidence on the effect of treatment, providing strong support for clinical practice. In this study, we randomly assigned 100 patients with AF and heart failure to the experimental and control groups, 50 patients in each group. Patients in the experimental group combined SGLT2i and ARNi on the basis of conventional treatment, while patients in the control group only used conventional anti-heart failure treatment. By comparing the condition changes and prognosis between the two groups during the treatment period, we were able to more accurately evaluate the treatment effect of SGLT2i in combination with ARNi. In addition, we also used multiple evaluation indicators to comprehensively evaluate the effect of treatment, including the incidence of cardiovascular events, heart rate, blood pressure, and the improvement of cardiac function. All data were subjected to rigorous data collection and processing procedures to ensure the accuracy and reliability of the results. In conclusion, this study uses a design of randomized controlled trial, combining multiple evaluation indicators and rigorous data processing process, aiming to more accurately evaluate the treatment effect of SGLT2i and ARNi in patients with AF and heart failure to provide strong support for clinical practice.

2.2. Patient selection and screening

To ensure the accuracy and reliability of the study results, we rigorously screened the patients participating in this study. First, we set clear inclusion criteria requiring patients to be at or over 18 years old and to have already been diagnosed with atrial fibrillation with heart failure. In addition, we require the patient's New York Heart Association (New York Heart Association, NYHA) cardiac function to grade between grades II and IV, a standard that ensures that the patient's cardiac function status meets the study requirements. In addition to the inclusion criteria, we also set a series of exclusion criteria to ensure the accuracy of the study results. We excluded those who were <3 months after AMI because their condition may not be stable and not suitable to participate in the study. Meanwhile, we also excluded patients with severe hepatic and renal insufficiency and malignancy that might affect the findings. These exclusion criteria were chosen based on our awareness of the disease and our consideration of patient safety. After a rigorous screening process, we finally successfully included 100 patients who met the study requirements. To ensure the reliability and validity of the study results, we randomized these 100 patients into two groups, with 50 patients in each group. Such a grouping method can minimize potential bias and interference factors, ensuring similar baseline characteristics of both groups before treatment, so as to more accurately evaluate the treatment effect of the combination of SGLT2i and ARNi. In conclusion, we ensured the accuracy and reliability of the study results by rigorous screening and randomization of patients. Such a way of patient selection was able to provide us with reliable evidence on the therapeutic effect of combining SGLT2i with ARNi in patients with atrial fibrillation combined with heart failure.

2.3. Treatment methods

For the patients in the control group, we used a conventional anti-heart failure treatment regimen. This protocol involves the use of diuretics to reduce the excessive fluid load in the body and to help patients reduce the symptoms of edema and dyspnea. In addition, we used an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor antagonist (ARB) to expand blood vessels, reduce blood pressure, and inhibit the remodeling process of the heart.β Beta-blockers are used to slow heart rate and myocardial oxygen consumption, thus reducing the burden on the heart. The use of these drugs is based on extensive clinical practice and scientific research and has been shown to have certain therapeutic effects in patients with heart failure.

For patients in the experimental group, we combined SGLT2i (sodium-glucose cotransporter 2 inhibitor) and ARNi (angiotensin receptor enkephalin inhibitor) on the basis of conventional therapy. SGLT2i Drugs such as dagliflozin or empagliflozin reduce blood glucose levels and exert cardioprotective effects. ARNi drugs, such as sacubuvalsartan, expand blood vessels, reduce blood pressure and reduce blood pressure, and inhibit adverse cardiac remodeling processes such as cardiac hypertrophy and fibrosis. The combination of the two drugs aims to exert synergistic effects to further improve patient cardiac function and prognosis. To ensure that we could fully evaluate the effect of this combination regimen, we followed all patients for a period of 12 months. During the follow-up period, we regularly collected clinical data, laboratory results and electrocardiogram information, so as to timely understand the patient's condition changes and treatment response. Such a long-term follow-up can provide us with more reliable evidence to evaluate the effect of SGLT2i and ARNi in the treatment of AF patients with heart failure.

In conclusion, we developed targeted treatment plans for patients in the control and experimental groups. The control group was treated with conventional anti-heart failure treatment, while the experimental group combined SGLT2i and ARNi on the basis of conventional treatment. With a 12-month follow-up, we will comprehensively evaluate the effect of this combination treatment regimen, providing strong support for clinical practice.

2.4. Evaluation indicators

To comprehensively and accurately evaluate the therapeutic effect of combining SGLT2i and ARNi in patients with AF and heart failure, we set a series of evaluation metrics. These include both primary endpoint events reflecting long-term patient outcomes and secondary endpoint events that reflect short-term improvement in short-term efficacy and physiological status. The primary endpoint events were the focus of our study, which included cardiovascular death, hospitalization for heart failure, and emergency department visits due to atrial fibrillation. These events directly reflect the patient's cardiovascular health status and disease control and are essential for assessing treatment efficacy. By tracking and recording the occurrence of these events, we were able to more intuitively understand the impact of the combination on long-term patient outcomes. In addition to the primary endpoint events, we set secondary endpoint events as supplements. These indicators include the improvement of physiological parameters such as heart rate and blood pressure, the improvement of cardiac function (such as left ventricular ejection fraction, heart structure changes), and the quality of life score. These indicators can reflect the changes of the patient's physiological status and quality of life in the course of treatment, and provide us with a more comprehensive evaluation of the treatment effect. To collect data on these assessment indicators, we employed multiple means. It includes standardized questionnaires (used to collect information on patients' quality of life and symptom improvement), physical examination (used to measure physiological parameters such as heart rate and blood pressure), laboratory tests (such as blood routine, urine routine, liver and kidney function, etc.), and electrocardiogram. These means can provide us with accurate and objective data support and ensure the reliability of the evaluation results.

2.5. Data collection and processing

During the data collection process, we always follow strict quality control standards to ensure the accuracy and integrity of the data. We developed the detailed data collection procedures and operational specifications, and professionally trained the personnel involved in the data collection to improve the data quality. To ensure the authenticity and reliability of the data, we used multiple methods to verify and check the data. For example, for the questionnaire survey data, we set a reasonable option range and logical check to avoid filling in errors or unreasonable data. For the physical examination and laboratory examination data, we employed standardized operating procedures and equipment to ensure the accuracy and consistency of the data. In the data processing phase, we will analyze it by using the SPSS software. Descriptive statistics were first performed to understand the distribution and basic characteristics of the data. Then, the chi-square test and t-test were used. In addition, we will use advanced statistical methods such as Cox regression model to further explore the potential factors affecting treatment effects. Through a rigorous data collection and processing process, we will ensure the accuracy and reliability of the study results to provide strong support for evaluating the treatment effect of SGLT2i and ARNi in patients with AF and heart failure.

3. Results

3.1. Basic Information Description of the Patients

In this study, we enrolled patients with atrial fibrillation (AF) and heart failure to assess the efficacy of the combination therapy of Sodium-Glucose Co-Transporter 2 Inhibitors (SGLT2i) and Angiotensin Receptor Neprilysin Inhibitors (ARNi). The baseline characteristics of the patients were carefully evaluated to ensure comparability between the two groups. Upon analysis, we found no significant differences in age, gender, and comorbidities between the experimental group and the control group. This similarity in baseline characteristics is crucial for accurate interpretation of the study results.

The mean age of the patients in the experimental group was 65.3 years, with 56% being male. Similarly, the mean age of the patients in the control group was 64.9 years, and 54% were male. This indicates that both groups were comparable in terms of demographic features, reducing the potential for confounding factors to influence the study outcomes.

3.2. Changes in Various Indicators Before and After Treatment

After initiating the combination therapy of SGLT2i and ARNi, the experimental group exhibited significant improvements in heart rate and blood pressure. Furthermore, there was a marked improvement in cardiac function, as evidenced by a decrease in the NYHA (New York Heart Association) grade. Additionally, the quality of life score improved significantly in the experimental group. In contrast, the control group exhibited smaller improvements in these parameters.

These findings suggest that the combined use of SGLT2i and ARNi may be effective in improving cardiovascular outcomes in patients with AF and heart failure. The improvement in heart rate and blood pressure may contribute to reduced cardiac stress and improved overall functioning.

3.3. Occurrence of the Primary and Secondary Endpoint Events

The incidence of primary endpoint events, such as cardiovascular death, hospitalization for heart failure, and emergency department visits for atrial fibrillation, was significantly lower in the experimental group compared to the control group. This reduction in primary endpoint events is a crucial outcome, indicating that the combination therapy may be effective in reducing the risk of adverse cardiovascular events.

In terms of secondary endpoint events, the patients in the experimental group exhibited better outcomes compared to the control group. Specifically, there were improvements in heart rate, blood pressure, cardiac function, and quality of life score. These findings further support the beneficial effects of the combined use of SGLT2i and ARNi in patients with AF and heart failure.

3.4. Statistical Analysis Results

To further evaluate the effectiveness of the combination therapy, we conducted a Cox regression model analysis. The results revealed that the combination of SGLT2i and ARNi significantly reduced the risk of primary endpoint events in patients with AF and heart failure. The hazard ratio (HR) was

0.63, with a 95% confidence interval (CI) of 0.45 to 0.88, indicating a statistically significant reduction in risk. The P-value was less than 0.01, further confirming the significance of the observed effect.

In conclusion, the findings of this study suggest that the combined use of SGLT2i and ARNi may be an effective treatment option for patients with atrial fibrillation and heart failure. The significant improvements in heart rate, blood pressure, cardiac function, and quality of life scores observed in the experimental group compared to the control group provide strong evidence for the beneficial effects of this combination therapy. The reduced risk of primary endpoint events further reinforces the clinical relevance of this treatment approach.

4. Discussion

The randomized controlled study of 100 patients with atrial fibrillation and heart failure showed a significant clinical effect of SGLT2i and ARNi in the treatment of such patients[5]. This combination treatment regimen is not only effective in reducing the risk of cardiovascular events, including cardiovascular death, hospital admission for heart failure, and emergency department visits due to atrial fibrillation, but also significantly improved the cardiac function and quality of life of patients. This finding has important clinical implications for the treatment of patients with AF and heart failure[6].

These positive therapeutic effects may be related to the synergistic effects of SGLT2i and ARNi in regulating blood glucose and blood pressure, as well as in improving cardiac remodeling. SGLT2i By reducing blood glucose levels by reducing the reabsorption of glucose by the kidney, it also has the effect of reducing heart burden and improving heart function. This means that it can not only control the symptoms of diabetes, but also can be protective of the heart[7]. ARNi, however, dilates blood vessels, reduces blood pressure, by inhibiting the angiotensin receptors and enhancing the activity of enkephalinase, and inhibiting adverse cardiac remodeling processes such as cardiac hypertrophy and fibrosis. This drug can comprehensively improve the function of the cardiovascular system and reduce the risk of cardiovascular disease. When the two drugs are combined, they can together exert a stronger cardiovascular protective effect, resulting in better therapeutic effects[8].

Compared with the existing literature, the results of this study further confirm the effectiveness of combining SGLT2i with ARNi in the treatment of cardiovascular diseases. However, we must also admit that there are some limitations in this study. First, the sample size was relatively small, which may affect the stability and reliability of the results. Therefore, larger studies are needed to further validate these findings[9]. Second, the follow-up period was relatively short enough to inadequately assess the long-term treatment effect. Future studies should extend the follow-up period to more comprehensively evaluate the long-term effects of this combination treatment regimen. Furthermore, we should also focus on the safety issue of this combination treatment regimen. Although no serious adverse reaction events occurred in this study, close monitoring and evaluation of possible side effects are still required. In future studies, we can further explore the safety issue of this combination treatment regimen and develop corresponding risk management strategies[10].

5. Conclusion

After carefully examining the evidence and analyzing the data presented, we have arrived at a noteworthy conclusion. Specifically, the use of SGLT2i and ARNi in treating patients who suffer from atrial fibrillation along with heart failure has demonstrated remarkable clinical outcomes. This therapeutic approach has not only been effective in mitigating the chances of cardiovascular complications but has also led to significant improvements in patients' cardiac function and overall quality of life. As such, we strongly advocate for the adoption of this combined treatment strategy for individuals dealing with both AF and heart failure.

However, it is important to acknowledge the inherent limitations of our current understanding. Despite the promising results, the scope of this study may have been insufficient to fully capture all potential risks and benefits. Therefore, there is a pressing need for more extensive research endeavors that involve larger patient populations and longer-term monitoring. Such endeavors will undoubtedly provide greater clarity and a more robust foundation for clinical decision-making.

Moreover, while the benefits of this treatment regimen are substantial, we must remain vigilant in our assessment of its safety profile. It is imperative that healthcare professionals closely monitor patients receiving this combination therapy and implement appropriate risk management strategies to ensure their well-being. By taking these precautionary measures, we can confidently move forward in our quest to provide the best possible care for those affected by these debilitating conditions.

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