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Advantages of biological analogues in blood glucose control of diabetes from a clinical perspective

Yifei Wang

Westfield Secondary School, Toronto, ON M3B 1S4, Canada

yifei20060607@gmail.com

Abstract. This study aims to explore the clinical advantages of biosimilar drugs in blood glucose control of diabetes, and analyze the challenges and coping strategies. This paper discusses the advantages of biosimilars through a review. The analysis reveals that biosimilar drugs have significant cost-effectiveness, improved patient affordability, and ease of clinical use in diabetic glycemic control. At the same time, through education, monitoring and scientific conversion strategies, the challenges of doctors and patients, immunogenicity and safety monitoring can be overcome. Biosimilar drugs have important clinical value in the field of diabetes treatment, which provide new perspectives and methods for improving the treatment effect, improving the quality of life of patients, and optimizing the allocation of medical resources. Medical professionals, patients, and policy makers should work together to promote the rational application of biosimilar medicines.

Keywords: Biological similar drugs, diabetic blood glucose control, clinical application advantages, challenges, coping strategies.

1. Introduction

As a global health challenge, diabetes prevalence continues to rise worldwide, and according to the latest report from the International Diabetes Federation (IDF), 30 to 40 percent of people with diabetes develop chronic kidney disease (CKD). In China, where the prevalence of diabetes has risen from 1% to 12% in the past 30 years, China is one of the countries with the largest number of diabetic patients, facing enormous medical challenges.[1]

As one of the important means of treating diabetes mellitus, insulin has some problems in its traditional treatment methods, such as delay in initiation and intensive treatment, hypoglycemia risk, blood glucose variability, and treatment compliance. These problems not only affect the treatment effect, but also bring inconvenience to the patients' lives. Compared with the traditional insulin preparations, the new insulin analog preparations show their advantages in many aspects.

The new insulin analogues have a longer duration of action and a more stable pharmacodynamics and pharmacokinetics, which significantly improve the safety of insulin therapy in clinical use. They are able to improve glucose variability, reduce the risk of hypoglycemia while increasing treatment willingness and compliance. These improvements provide a safer, more convenient and more stable blood glucose control method for patients with diabetes. The clinical application of short-acting insulin analogues also shows obvious advantages, including rapid onset, benefit to postprandial glycemic control, reducing the risk of hypoglycemia, and high flexibility, which can be injected during the meal.

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These characteristics make short-acting insulin analogues more effective and convenient in blood glucose control.

Therefore, the aim of this study was to investigate the clinical advantages of biosimilars in diabetic glycemic control compared to conventional insulin therapy, and to analyze the advantages, challenges, and coping strategies of biosimilars by means of a review. With the advancement of technology, new treatment modalities will gradually replace the traditional treatment modalities, and this paper can provide guidance and assistance for the change of treatment modalities, so as to minimize the rejection of biosimilars.

2. Clinical studies of biosimilars in diabetes glycemic control

2.1. Definition and characteristics of biosimilar drugs

Biosimilars are drugs that have similarities in quality, safety, and efficacy to approved biological drugs (i. e., reference drugs), which are usually produced by different manufacturers. The development and production of this type of drug is based on a deep understanding of the original biological drugs, and is made through a complex biotechnological process[2]. The molecular structure, biological activity, pharmacodynamics, pharmacokinetics and clinical effects are highly similar, but not exactly the same as the reference drugs.

Biosimilars are characterized by their ability to provide a therapeutic effect equivalent to the original biodrug while generally having a lower cost, which contributes to improving the availability of medicines and reducing the economic burden of healthcare. Due to the structural complexity of biological drugs, the development and approval process of biological similar drugs requires strict scientific evidence to ensure that their safety and effectiveness in clinical use can be comparable to the reference drugs, thus without the health risk of patients, provide more treatment options for doctors and patients, and promote the rational allocation and optimization of medical resources.

2.2. Comparison with traditional hypoglycemic drugs

Compared with traditional hypoglycemic agents, biosimilars have demonstrated their unique advantages in the treatment of diabetes, as they are able to more finely mimic the natural insulin secretion pattern in the human body, thus providing more precise and personalized blood glucose control. This precise regulation not only helps to maintain stable blood glucose levels, but also significantly reduces a patient's risk of diabetes-related complications. In contrast, traditional hypoglycemic agents such as sulfonylureas and biguanides, while effective in lowering blood glucose levels, have a single mechanism of action that often fails to meet the complex needs of all diabetic patients. In particular, insulin analogs have demonstrated superior performance in dealing with postprandial blood glucose fluctuations and reducing hypoglycemic events [3].

The production of biosimilars relies on advanced bioengineering technology, which ensures high purity and stability of the drug, thus reducing the risk of allergic reactions and viral infections that may occur during use. In contrast, conventional hypoglycemic drugs may have a certain amount of impurities left over from the chemical synthesis process, which can sometimes be the source of adverse reactions. Biosimilars are undoubtedly superior in terms of therapeutic flexibility, reduction of side effects and improvement of patients' quality of life, and they provide a safer and more effective treatment option for diabetic patients [3].

Biosimilars often provide cost savings to patients and healthcare systems while ensuring efficacy, which is especially important for patients who require medication for long periods of time. Although there are still some challenges in the clinical application of biosimilars, such as physician awareness, patient acceptance, and regulatory policies, these issues are gradually being addressed with more in-depth research and clinical experience.

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3. Clinical application advantages of biosimilar drugs

3.1. Cost-effectiveness

According to several studies and market analysis, the price of biosimilars is usually 20 to 30 percent lower than the original drug, and in some cases, the price difference can be as high as 80 percent. According to the US Drug Pricing Laboratories (IQVIA), the average price discount for biosimilar the US market is 28%. This significant price difference brings great potential for savings in the healthcare system. In Europe, the European Commission report states that the use of biosimilar drugs saved EU member states more than 6 billion euros in medical spending between 2018 and 2020 [4].

The cost-effectiveness of biosimilar drugs is also reflected in improving treatment adherence. A study of European patients with diabetes found that patients using biosimilar drugs tended to follow treatment plans more than those using the original drug because the lower treatment cost reduced the financial pressure on patients and thus reduced treatment interruption due to cost issues. This improvement in treatment compliance can not only help to improve the glycemic control of patients, but also can reduce the complications caused by poor glycemic control, and then reduce the long-term medical costs.

3.2. The patient affordability

In the management of chronic diseases, such as diabetes, which require long-term treatment, the low cost of biosimilar drugs allows more patients to bear the economic burden of continuous treatment. According to a study by the International Drug Pricing Association (ISPOR), the average price of biosimilar drugs is about 25 to 30 percent lower than the original one. This price difference is significant for people with diabetes, as they often require long-term or even lifelong use of insulin to achieve blood sugar control.

Using the biosimilar insulin can reduce the annual cost of hundreds to thousands of dollars compared to the original insulin. For people with diabetes, this means significant savings in long-term treatment, and in low-income families, such savings may mean ability to afford other basic living needs. The World Health Organization (WHO) report also states that the use of biosimilar drugs can enable diabetes in developing countries, which is important for improving the treatment and control rates of patients with diabetes in these areas [5].

In developing countries, the emergence of biosimilar drugs has greatly reduced the price of biological drugs such as insulin, allowing more low-income patients to obtain effective treatments. According to the World Health Organization, the use of biosimilar drugs has reduced the price of insulin by more than 50 percent in some developing countries, greatly improving access to treatment. In India, the falling price of biosimilar drug insulin has increased the number of people with diabetes mellitus from 7 million in 2015 to 23 million in 2022, indicating the importance of lower prices for increasing treatment penetration [6].

3.3. Convenience of clinical use

Biosimilars bring great convenience to physicians and patients by simplifying treatment processes, increasing flexibility in drug use, and reducing management complexity. Biosimilar drugs usually have similar therapeutic effects to the original biodrugs, but may have improvements in terms of administration, storage conditions, and ease of use. Some new insulin analogues biologics offer more convenient pre-filled pens or needle-free injection devices that reduce pre-injection preparations and also improve patient comfort and satisfaction.

In terms of storage conditions, bioanalogues generally have a wider temperature range, which makes patients more flexible when storing drugs. Some biologics can be stored at room temperature without refrigeration, which is very convenient for patients who go out frequently. Some long-acting insulin analogues allow patients to be injected once a day, which greatly improves the treatment experience compared to traditional insulin regimens that require multiple injections.

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4. Challenges and coping strategies for biosimilar drugs in the clinical application

4.1. Perceptions and acceptance of doctors and patients

As bioanalogues are a relatively new treatment option, many physicians and patients have doubts about their safety and efficacy, which affects their widespread adoption in clinical practice. More than three-quarters of the doctors surveyed said they had some knowledge or very good knowledge of biosimilars, and 63% said their views on biosimilars became more positive [7].

On the side of patients, according to a survey of the European Diabetes Research Association, only about 40% of patients with diabetes are aware of biosimilar drugs, and more than half of the population are cautious about using biosimilar drugs[8]. Patient doubts about biosimilar drugs may arise from concerns about their efficacy and side effects, as well as a preference for the original drug. This preference may be driven by the long-established brand trust of the original drug, with patients concerned that biosimilar drugs may bring different therapeutic effects or increase the potential risk[8].

To address these challenges, medical institutions and drug manufacturers should adopt a range of strategies to improve the awareness and acceptance of biosimilar drugs among physicians and patients, such as conducting physician education and training programs to provide information on research data on biosimilar drugs, approval processes, and clinical applications to enhance physician expertise.

Patient education and communication activities can improve patients' understanding of biosimilars, including their development process, approval criteria and cost-effectiveness compared with originator drugs. Governments and health departments should also support the use of biosimilar drugs by developing policies and guidelines that can issue guidelines on their nomenclature rules to reduce confounding and increase transparency.

4.2. Immunogenicity and safety monitoring

Immunogenicity refers to the ability of drugs to induce immune responses in the body, which is an important safety consideration for biosimilar drugs, as immunogenic reactions may lead to reduced efficacy or adverse effects of the drug. In clinical application, immunogenicity and safety monitoring is the key link to ensure the safe and effective use of biosimilar drugs. Although biosimilar drugs and original biodrugs are highly similar in structure, small differences may still affect the recognition of the immune system, thus triggering an immunogenic response.

Studies have shown that the incidence of immunogenic responses may vary between different biological drugs, and may be related to individual differences in the drug composition, manufacturing process, and patients. The incidence of immunogenic reactions of insulin analogues is about 1% to 3%, which is comparable to the original grind insulin. Certain biologics may have a high risk of immunogenicity, which requires rigorous monitoring in clinical applications [9].

To monitor immunogenicity, antibody detection methods, such as enzyme-linked immunosorbent test (ELISA) or radioimmunoprecipitation assay (RIPA), are commonly used in clinical practice to detect specific antibodies against the drug in patients. According to the European Medicines Agency (EMA) guidelines, the monitoring of immunogenicity risk should include basal level testing before treatment, and regular testing during treatment [10]. In terms of safety monitoring, continuous safety assessments are required after marketing, which includes passive monitoring systems such as adverse drug reaction reporting, and active monitoring studies such as observational cohort studies. Biosimilars are similar to the originator drug, indicating an overall favorable safety profile in clinical use. There was no significant difference in the incidence of adverse reactions between patients using biosimilars and those using the originator, which provides strong evidence for the safety of biosimilars [11]. According to the EMA, the use of biosimilars on the EU market has not added new safety concerns since 2018 [10].

4.3. Drug conversion and dressing change strategies

Drug switching, an important strategy in the clinical application of biologics, is switching between different biologics with the aim of improving access to treatment and reducing costs. This process needs to be performed cautiously to ensure the efficacy and safety of the treatment. According to multiple

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studies and guidelines, the implementation of drug conversion and dressing change strategies should be based on adequate scientific evidence and individualized treatment planning [12].

In terms of drug conversion, several international guidelines, including recommendations from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), support the conversion of insulin analogues in appropriate clinical settings, provided that this conversion does not adversely affect the patient's glycemic control [13]. A systematic review analysis showed that more than 90% of patients who converted from original insulin to biosimilar insulin maintained good glycemic control after conversion without significant adverse events [14].

The implementation of a dressing-change strategy needs to consider multiple factors, including the patient's disease status, treatment history, drug tolerance, and individual preferences. To ensure safety during the conversion process, it is recommended to enhance blood glucose monitoring in the first few months after the conversion to timely detect any possible changes in blood glucose levels.

5. Conclusion

The clinical application of biosimilar drugs in diabetic glycemic control shows significant advantages, but also faces certain challenges. Bioanalogues, especially novel insulin analogue preparations, provide important options for the treatment of diabetes with their cost-effectiveness, convenience of clinical use, and remarkable effects on glycemic control. These drugs not only reduce the patient's economic burden and improve the accessibility and compliance of the treatment, but also play an important role in maintaining the stability of glycemic control.

Physician and patient recognition and acceptance of biosimilar drugs, immunogenicity and safety monitoring, as well as the implementation of drug conversion and dressing change strategies, are issues of concern in clinical application. These challenges are being overcome progressively through ongoing education, rigorous surveillance, and scientific switching strategies.

It can be seen that biosimilar drugs have important clinical value in the field of diabetes treatment, and they provide new perspectives and methods for improving the treatment effect, improving the patient's quality of life, and optimizing the allocation of medical resources. In the future, with more research and clinical experience accumulating, biologics will play a more important role in diabetes management worldwide.

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