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EVALUATION OF VACCINE IMMUNOGENIC ACTIVITY AGAINST CLOSTRIDIOSIS

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Abstract:

The article provides information on the methods and advantages of evaluating the immunogenic activity of vaccines against clostridiosis, as well as the use of standard drugs and antitoxic sera.

Key words: Clostridium, Cl. haemolyticum, Cl. Septicum, Cl. Oedematiens, immunity, antitoxin

Introduction

Relevance of the research. The rapid effect of clostridial toxins on the animal's body, despite timely treatment, often ends in death. Special prevention should be considered as the best way to fight diseases of clostridial etiology. Taking into account the importance of toxoids in the fight against anaerobic infections, special attention should be paid to the quality of manufactured immunobiological preparations, especially their immunogenic activity. [5, 9]

Level of study of the research. The need to standardize quality control systems for bacterial preparations has long existed. This topic was debated in the International Veterinary Congress in

1909, when the notion of standardization of techniques of monitoring immunobiological preparations was agreed upon and adopted.[1, 2]

At the next international microbiological conference in 1961, it was decided to create worldwide standards and reference medications. Examples of such standards were developed initially by the League of Nations Health Organization and then by the World Health Organization. However, due to the large number of manufactured drugs that require the use of international standards, demand frequently exceeds supply, and as a result, countries develop their own national standards and reference drugs, which, after comparative testing and certification, can be used to control the activity [6, 10].

Drug immunogenicity is assessed using qualitative and quantitative approaches. Only the minimal activity limit may be used to establish the acceptability of a medication for usage using qualitative approaches. Quantitative approaches may be used to determine the presence of antibodies following vaccination, as well as the amount of specific activity of induced immunity. To use quantitative techniques of evaluating vaccinations against clostridial diseases, international standard samples of toxins and antitoxic sera are employed. [3, 10]

This method of studying the drug's activity consists of a two-stage procedure in which rabbits are immunized with test samples, and then the resulting hyperimmune blood cells are injected into mice; if there are antitoxic antibodies in the serum, the toxin is neutralized, and the experimental animals survive. In this situation, the drug's quality is determined by the presence of a certain number of international activity units (IU), which is then compared to the international or national activity standard.

The suggested immunogenicity evaluation approach has several advantages, including the use of more animals and the ability to analyze medication quality more accurately. [4, 5]

A significant amount of work has been done on Cl. chauvoei, Cl. haemolyticum, and Cl. septicum. Drugs used to treat carbuncle ephysematosis are tested in guinea pigs. At least eight animals are immunized with twice the required dosages of the medicine, which is normally half the recommended dose for vulnerable animals. They are then infected with a pre-titrated spore freeze-dried culture of the control strain 14-16 days later. A medicine that satisfies regulatory criteria must ensure the safety of at least seven animals in the control group.

If at least 80% of vaccinated guinea pigs survive 5 days after infection, vaccination is deemed immunogenic, but all control animals should die of infection within 48-72 hours. The test is repeated if more than 20% of the vaccinated pigs die. If the series produces inadequate results, it is rejected and destroyed.[1, 3, 10]

Experiments with other animal species, especially white mice and lambs, have yielded promising results. However, mice were shown to be less vulnerable to infection (more than 60% of animals died in parallel studies), but sheep were found to be more sensitive. This also creates some difficulties for the researcher, as it is difficult to generate results that can be replicated numerous times in a sequence [1, 8]. In most situations, a toxin neutralization reaction with species-specific hyperimmune sera is used to verify it.Many nations with a biological industry utilize this strategy to control the quality of practically all components as well as the quality of produced or imported medications. As an example, consider the following scheme: Cl. oedematiens to assess the component's efficacy. A minimum of 10 healthy rabbits of type B, aged 3-6 months, are vaccinated beneath the skin. The manufacturer regulates the dose, although it should not exceed half the amount

for sensitive animals. After 21-28 days, the animals are inoculated again with the same amount, and blood is drawn from the rabbits after 14 days. Equal amounts of serum are obtained from all experimental rabbits, combined with a well-defined dosage of toxin, held at room temperature or in a thermostat for 60 minutes, and then administered intravenously into two or more mice apiece. The mice will live if the poison is neutralized by rabbit serum; otherwise, they will die within 24-72 hours. Referencing the Results Cl. In comparison to the antitoxin effectiveness of oedematiens.[2, 4, 7]

When the manufacture of medications needs their compliance with defined requirements, the country established a more current control technique with the evaluation of blood serum activity in international units, the quantity of which is compared with the standards of drugs against a specific illness.

This approach became popular with the development of the "Multivalent toxin against sheep clostridiosis" (authors Kirillov L.V., Kagan F.I., and others). The use of conventional medications and antitoxic sera allowed researchers to evaluate the titer of antitoxic antibodies in the blood of vaccinated animals.[1, 2, 5, 7]

The use of standards allowed the impact of factors such as laboratory animal quality and storage circumstances on the release of the medicine batch to be excluded. Animals were kept in similar settings and were given the same test dosage of culture and toxin. In this situation, the tested batch of the medicine should offer immunity equal to or greater than that generated by the reference drug.

Conclusion. Based on a review of the literature and our own research into methods for assessing vaccine immunogenicity, we concluded that at the current stage of development of the biological industry, there is no distinction between medical and veterinary drugs, and their production and control are governed by the same documents. These regulations also address the necessity to develop standards for managing the action of certain preventive measures for Clostridium infections.

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