Anaphylactic shock risk as a side effect of tolperisone: A clinical case overview

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Abstract

Background: **One of the side effects of tolperisone is anaphylactic shock. Even though this reaction is rare, it is the most dangerous effect of the drug, as it threatens the patient's life. The study of individual clinical cases of anaphylactic shock provoked by tolperisone determines the relevance of an analysis of the mechanism of its development, as well as occurrence risk identification. The research aimed to investigate the clinical case of a 51-year-old patient who developed anaphylactic shock after taking Mydocalm with the active ingredient tolperisone to determine the factors causing this reaction.**

Methods: **To achieve this goal, the methods of clinical trials, analysis and synthesis were used.**

Results: **The study resulted in a description and detailed analysis of a clinical case of anaphylactic shock. A 51-year-old female patient had been taking Mydocalm (tolperisone) orally twice a day for a long time with a frequency of several times a year at a total dosage of 300 mg per day to treat a pathological condition caused by degeneration of the spinal joints. Immediately after taking 150 mg of the drug on an empty stomach, she developed undesirable dermatological effects, which were accompanied by a sore throat and symptoms of digestive system disorders and were aggravated by a drop in blood pressure and loss of consciousness. The emergency doctors diagnosed anaphylactic shock due to the tolperisone and provided the necessary assistance. After the symptoms disappeared and her condition improved, the patient was discharged from the department, refusing to undergo diagnostic tests.**

Conclusion: **The analysis of this case made it possible to confirm the initial diagnosis, and the analysis of the pharmacodynamic and pharmacokinetic characteristics of the drug revealed the most likely cause of the severe anaphylactic reaction - the similarity of its mechanism of action to lidocaine. The practical significance of the study was to identify risk factors that can cause anaphylactic shock from tolperisone to avoid them when choosing a treatment for painful muscle spasms.**

Key words: Muscle relaxant, Mydocalm, lidocaine, hypersensitivity, post-stroke spasticity.

Introduction

The life cycle of any medicinal product, from development and introduction to its consolidation or withdrawal from the pharmaceutical market, mainly depends on efficacy and safety. Efficacy, the presence or absence of the desired therapeutic effect is initially determined at the stage of laboratory research and confirmed mainly in phase III clinical trials. Assessment of the safety level of a drug, which is determined by the presence, nature, and complexity of side effects, may continue during the IV post-registration phase of trials if the impact of side effects on the body is delayed or they occur extremely rarely, which does not always allow for the recording of such cases in phase III in a large population. An important criterion for the safety of medicines is the predictability of their side effects, especially those that pose a significant risk and can lead to death. Despite the high efficacy of the drug tolperisone, proven in clinical trials, (1,2) the list of its side effects includes those that pose a threat to life. The

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most dangerous effect of this drug for humans is anaphylactic shock. Although in terms of frequency of occurrence, it is an adverse reaction defined by the Medical Dictionary of Regulatory Activities (MedDRA) as rare (<1/10000), (3) it can lead to patient death without timely medical care. Identifying and predicting the risks of anaphylactic shock associated with the use of medicinal products containing tolperisone is an important task for the healthcare industry to save the lives of people who are medically treated with them.

The main problem identified during the study was the lack of statistical information on the frequency of this side effect. This is caused by the limited number of reported cases and the lack of cohort and randomized controlled trials. The current solution to this problem is to conduct a review of single clinical cases of anaphylactic shock to determine the risks of the study process. A. Chcialowski et al. (4) reviewed two clinical cases of a generalized hypersensitivity reaction to the drug Mydocalm, whose active ingredient is tolperisone. The link between the allergic reaction and tolperisone exposure was confirmed in both cases using an oral provocation test. The authors considered itching and urticaria, which occurred when taking the study drug, to be symptoms indicative of the risk of anaphylactic shock. Severe dermatological complications as possible side effects of tolperisone use were also mentioned by J. Woroń (5) in the study on the importance of an individual approach when choosing muscle relaxants in clinical practice. The researcher viewed the interaction of tolperisone with concomitant drugs selected without considering the specific mechanism of its action as one of the main risks that can lead to complex side effects.

R. Kuthan and G. Zaremba-Wróblewski (6) in their study on muscle relaxants for the treatment of back pain, in addition to the high efficacy of tolperisone, drew attention to the reassessment of its safety by the European Medicines Agency, which was associated with adverse hypersensitivity reactions, including anaphylactic shock. Given the benefit-risk ratio of this drug in the European Union, the only indication for its use is currently post-stroke spasticity. A study on the efficacy of tolperisone in the treatment of increased muscle tension also drew attention to the safety of this drug. J. Kochanowski and K. Tomalka (7) emphasized the possibility of developing hypersensitivity to it in patients prone to allergic reactions. An aspect of tolperisone safety was considered in the reviewed studies without providing clinical examples of its side effects, so the problem of this study was not resolved. The analysis of registered cases of anaphylaxis in the West Pomeranian Voivodeship of Poland was conducted by I. Poziomkowska-Gęsicka and M. Kurek. (8) According to the results of the study, tolperisone as a factor of anaphylactic reaction was classified as the smallest group, along with local anesthetics, the effect of which was considered at the level of single reactions. The information obtained is useful for the formation of local statistics on anaphylaxis, but no risk data were provided in the publication due to the lack of description of specific clinical cases of anaphylaxis caused by tolperisone.

The research aimed to investigate a clinical case of anaphylactic shock as a side effect of tolperisone (Mydocalm) to study the risk factors associated with this process.

Materials and methods

To study the clinical case of anaphylactic shock due to the use of Mydocalm, the active ingredient of which is tolperisone, the methods of clinical trials and analysis and synthesis of the data obtained were used. The clinical trial method was used to record the pathological manifestations that accompanied the anaphylactic attack and changes in biological parameters that indicated the body's response to anaphylactic shock. Methods of analysis and synthesis were used to study the anaphylactic reaction as a process and to identify the risks of its occurrence due to the administration of tolperisone.

The clinical examinations performed on a 51-year-old patient included objective methods, which included physical, and instrumental examinations and observations, and subjective methods, such as taking anamnesis. Physical examinations were carried out to identify the existing external signs that could be defined as symptoms of the relevant pathological process. Instrumental examinations were carried out to measure blood pressure as an indicator of the body's reaction caused by the development of a pathological process. A tonometer was used as a tool for measuring this indicator. The observation method was used to record changes in the patient's condition from the moment the necessary medical measures were taken to provide emergency care until the symptoms of the anaphylactic reaction disappeared. Anamnesis was taken to obtain information from the patient about complaints, the nature of the course, the alternation of symptoms, and to identify possible causes of anaphylactic reaction.

Analysis as a research method was applied to the results of clinical examinations of the patient, the results of the study of pharmacodynamics and pharmacokinetics of tolperisone (Mydocalm), and the mechanism of development of anaphylactic reaction in the human body. By analyzing objective clinical

examinations, the compliance of the patient's condition with the signs and symptoms of a generalized immediate anaphylactic reaction (anaphylactic shock) to a synthetic drug was determined. The analysis of the collected anamnesis was used to determine the factor that provoked this reaction. The synthesis of the findings was used to make a diagnosis based on the established clinical picture. Using the analysis of laboratory and clinical studies of the drug tolperisone for pharmacodynamics, the mechanism of its action was investigated to identify factors that could potentially provoke an anaphylactic reaction in the body. The same concept was used to study the pharmacokinetics of the drug and to investigate the possibility of an anaphylactic reaction caused by the concentration or mechanisms of biotransformation or excretion of the drug substance. Drugs with a similar mechanism of action to tolperisone and with anaphylactic shock in the list of side effects were also considered. The mechanism of development of anaphylactic reaction was analyzed to identify factors that can provoke it. The synthesis of the data obtained made it possible to identify overlaps between the pharmacodynamics of tolperisone and other medicinal products whose side effects included anaphylactic shock and to establish a link between their mechanism of action and the mechanism of anaphylactic reaction in the human body, which was used to identify the risks of its development. The materials used for the analysis were scientific literature sources containing pharmaceutical and medical information on the stated topic.

Results

Tolperisone, as a centrally acting muscle relaxant, demonstrates high efficacy in the treatment of painful muscle spasms and spasticity caused by stroke. The advantage of this drug is its pharmacological property, which provides muscle relaxation without sedation and withdrawal symptoms. (9) However, side effects include the possibility of developing anaphylactic shock, which to some extent affects the safety of medicines containing tolperisone as an active ingredient. No official statistics on cases of anaphylactic shock as a side effect of tolperisone are currently available. However, to understand the general situation regarding this life-threatening reaction to the drug, it is worth paying attention to the available information on the number of cases. Most often, databases indicate a common cause as a side effect of tolperisone - hypersensitivity, which is not always differentiated by severity - symptoms such as itching or urticaria are included in the list along with its more severe manifestations, such as anaphylactic reaction. (10)

Data from the World Health Organisation's VigiAccess database, which contains a list of adverse reactions divided into categories, is worth paying attention to. As of 2023, there were 6394 cases of adverse reactions from taking tolperisone: 8% from the immune system, 49% from the skin and subcutaneous tissue, and 57% of hypersensitivity reactions in general. As a result of these spontaneous reports of adverse reactions to tolperisone, anaphylactic shock was recorded in 3.6% of reports. In clinical trials of the efficacy and safety of the drug, the manifestations of tolperisone side effects include mild effects that do not significantly affect the general condition. (1,2) The anaphylactic shock was not recorded in these studies. The difference in the statistics of anaphylactic shock in spontaneous reports and clinical trials may be explained by the limited sample in the latter and the difference in conditions between a controlled trial and real cases of clinical practice. Given this, it makes sense to study the reaction of anaphylactic shock to tolperisone and find out the factors of its development by investigating individual clinical cases.

Clinical case report

A 51-year-old female patient had been undergoing treatment for spinal joint degeneration for many years. As a pharmacological therapy, the patient took Mydocalm, a pill-based drug containing the active ingredient tolperisone. This therapy was used for a long time with a frequency of several times a year and a duration of several days. The dosage was 300 mg/day. In the morning, the patient took one 150-mg pill of Mydocalm on an empty stomach. Immediately after taking it, she felt itching of the skin of her hands, legs, and thighs, which spread throughout her body. Later, hives appeared on her face, torso, abdomen, upper and lower extremities. The dermatological symptoms were accompanied by a scratchy throat, nausea, which turned into vomiting, severe abdominal pain, and diarrhea, and the situation was complicated by the loss of consciousness. The doctor of the emergency team that arrived at the scene measured her blood pressure at 90/40 mmHg. The patient was taken to the emergency department due to the severity of her condition. Using physical and instrumental examinations, as well as anamnesis, an anaphylactic reaction was diagnosed, and appropriate treatment was provided. The patient was monitored throughout her stay in the department and discharged 7 hours after her arrival, having previously recorded the disappearance of her urticaria symptoms. No diagnostic tests were performed on the patient, given ethical considerations and the lack of her consent.

The initial diagnosis was confirmed by the clinical picture of this case being consistent with the clinical picture of anaphylactic shock provoked by a synthetic drug and the positive effect of the treatment measures specific to this condition. It was not possible to confirm the cause of this reaction with clinical studies, as the patient refused to undergo diagnostic examinations. Therefore, skin prick tests for standard inhalation and food allergens, blind oral tests, and a blind tolperisone test were not performed. However, given the short time between taking Mydocalm and the onset of the first symptoms of an anaphylactic reaction, a causal link between the two events can be traced. The presence of an anaphylactic reaction to the active substance tolperisone in the list of side effects of Mydocalm confirms the possibility of such a connection. Considering all the initial data and the conclusions drawn on their basis, this clinical case can be considered as an anaphylactic shock resulting from the side effects of Mydocalm, the active ingredient of which is tolperisone and can be statistically compared with other cases of the studied reaction.

An important feature of this clinical case was the fact that the patient had been treated with tolperisone (Mydocalm) for a long time and did not cause any complications. There are at least two possible reasons for the delayed anaphylactic reaction. The first is the interaction of tolperisone with other drugs that can adversely affect its mechanism of action, provoking the activation of side effects. (5) The second is the cumulative effect of the allergenic substance, which, after no manifestations at all or possible moderate allergic reactions for a long time, can lead to an acute reaction with rapid development, which is anaphylactic shock. Since there was no information about the use of concomitant medications in the anamnesis, the most likely reason for the delayed anaphylactic reaction in this patient was the cumulative effect of the allergen. To identify the risks of developing anaphylactic shock as a side effect of tolperisone, its pharmacodynamic and pharmacokinetic characteristics were reviewed, and the mechanism of anaphylactic shock in the body and the mechanism of development of the drug's allergic reaction itself were studied.

The pharmacodynamics of tolperisone as a centrally acting muscle relaxant is based on its inhibition of the spinal reflex pathway and its inhibitory effect on descending conduction pathways. This mechanism of action is due to the high ability of the drug to bind to nerve tissue receptors, which allows it to reach the highest concentration in the brain stem and reduce the electrical excitability of neurons and afferent fibers. A high level of concentration is also maintained in the spinal cord and peripheral nervous system. The drug has membrane-stabilising properties and the ability to reduce the electrical excitability of motor neurons, and, depending on the dosage, inhibits the activity of sodium channels and voltage-dependent calcium channels. (11-13) Due to the similarity of its chemical structure to lidocaine, tolperisone has an analgesic effect based on the aforementioned sodium channel-blocking property and membrane stabilizing effect. The similarity of both drugs in terms of structure, mechanism of action and side effects indicates that the risk of tolperisone anaphylactic reaction is associated with its anesthetic effect. Despite a well-developed dosage formula for anesthetic drugs, which makes it possible to avoid an acute immune response, anesthetic substances remain an irritant to the body, in rare cases provoking sensitization, which leads to allergic reactions of varying severity (**Table 1**).

According to its pharmacokinetic characteristics, tolperisone has good absorption in the small intestine. The maximum plasma concentration is reached 30-90 minutes after ingestion. First-pass metabolism affects the bioavailability of the drug. Usually, this figure is 20%, but its change can be influenced by the choice of food that is absorbed simultaneously with the drug. For example, fatty foods increase bioavailability by about 100%, i.e., it will be about 40%, and insufficient or no food intake (when the drug is taken on an empty stomach) can significantly reduce it. Tolperisone is metabolized in the liver, and the resulting metabolites are excreted via the kidneys (via urine). The half-life of the drug after oral administration is about 2.5 hours. (14-16) It is worth noting here that according to the case report, the patient took the medication on an empty stomach, which could reduce the bioavailability of the drug but slightly accelerate the time to reach its maximum plasma concentration. The possibility of this event to influence the acceleration of the onset of the reaction can only be determined through clinical trials under the supervision of a physician with all resuscitation measures in place, and only with the patient's informed consent.

The analysis of the information obtained was used to find out that the anesthetic effect was most likely to be the factor provoking the onset of anesthetic shock from tolperisone. This conclusion was confirmed by the structural similarity of this drug to lidocaine, which has a similar mechanism of action and side effects, including anaphylactic reaction. Regarding the role of tolperisone pharmacokinetic characteristics in the development of hypersensitivity reactions provoked by the drug, it is assumed that its metabolites, whose pharmacological activity has

not yet been established, can activate the immune system through covalent modification of proteins, acting as haptens.

The mechanism of anaphylactic shock in the human body is associated with the presence of immunoglobulins - specific antibodies that provide an immune response upon contact with an antigen. When immunoglobulin interacts with an allergen, an antigen that enters the body from the environment, it can attach to mast cells and basophils. Repeated contact with the allergen triggers the release of a significant amount of biologically active substances from these cells, such as histamine and tryptase, which are mediators of the allergic reaction. The action of histamine and tryptase creates a clinical picture of an anaphylactic reaction, manifested through mucosal edema, suffocation, and all the visual symptoms of anaphylactic shock. Even though the mechanism of an anaphylactic reaction is clear and understandable, its occurrence in a particular case is difficult to predict. This is because immunoglobulin determines whether or not to recognize a substance as an antigen based on individual characteristics of the body (e.g., hypersensitivity) and/or the presence of a particular factor or several factors at the same time. An example of an allergic reaction is the development of antibodies to metabolites of medicinal substances that a patient has been taking for some time. In this case, if liver or kidney function deteriorates and the excretion of these metabolites from the body is impaired, an acute allergic reaction may develop to a drug that was previously completely safe for the patient. Another example of two factors that, when intersecting, can trigger an anaphylactic reaction is, on the one hand, the ability of proteins released from cells destroyed by inflammation to trigger immune mechanisms that provoke allergic reactions, and, on the other hand, the ability of certain drugs to increase the binding to tissue transport proteins (most often serum), which manifests itself after the onset of inflammatory processes.

The mechanism of drug allergic reactions to synthetic drugs differs from similar reactions to food, insect bites, and drugs of biological origin, such as insulin or corticotropin, which are derived from animal substances, or albumin or gamma globulin, which are human blood proteins. This difference lies in the allergy triggers. Thus, drugs of biological origin can act as an antigen on their own, while drugs of synthetic origin, in most cases, do not have this property, but can acquire it through their mechanism of action. This is manifested when the drug binds to protein molecules in the blood serum by a covalent bond, which leads to sensitization.

Based on the analysis of the clinical case, pharmacological characteristics of tolperisone and the mechanism of the anaphylactic process in the body, the risks of anaphylactic shock provoked by tolperisone can be summarized. The main factor that should be avoided is the presence of a history of acute allergic reactions to lidocaine or other synthetic drugs with a similar mechanism of action to tolperisone (mainly anesthetics). Attention should also be devoted to less pronounced allergy symptoms that may occur when taking other medicinal products. In general, any mention of an allergic reaction, regardless of the severity, should be considered as a reason to test the body's reaction to tolperisone before prescribing it.

Discussion

Research into the side effects of drugs is relevant for the development of both the pharmaceutical industry and the healthcare sector in general. There have been cases in the history of pharmaceuticals when a drug was completely banned from use due to side effects. The most famous and resonant of these cases is related to the history of radium's widespread medical use. Discovered in 1898, the element with radioactive properties attracted the attention of the scientific medical community because of its ability to destroy cancer cells. (17-19) This property expanded the prospects for its use, and subsequently, drugs containing this element were used to treat tuberculosis, diabetes, rheumatism, gout, and hypertension. Due to the absence of clear and strict requirements for clinical trials of all medicines on sale and the accumulative delayed radioactive effect of the element, the deadly danger of radium was discovered after numerous cases of irreversible pathological changes caused by radiation. This led to more thorough research on the safety of the element, which led to the complete closure of the pharmaceutical market for radium-based products. (20-23)

There are also examples when the side effects of a drug have revealed an unexpected positive effect on another body system, leading to a complete or partial reformatting of the drug concept. The most famous case is the story of sildenafil, which was developed to treat hypertension and angina pectoris, but trials, in addition to confirming the effectiveness of hypertension treatment (angina treatment did not prove effective), revealed an unexpected property of the drug - an increase in erectile function in men. (24,25) Currently, the drug is widely known on the pharmaceutical market under the commercial name Viagra. Such examples demonstrate the importance of studying both dangerous and beneficial side effects of medicines and continuous monitoring of their detection during all phases of the trial. Trials

related to the efficacy and risks of tolperisone have been conducted since its development in the early 1970s and continue to the present day (2023). (1,2)
SA Vaughan et al. (26) conducted a phase III trial to investigate the efficacy and safety of tolperisone in the treatment of painful back spasms. The researchers conducted a double-blind, randomized, placebo-controlled study that lasted 14 days. It involved 1000 patients of both genders from about 70 clinical centers in the United States. The selected participants had complaints of back pain due to acute muscle spasms. The study design involved randomly assigning patients to four groups in a 1:1:1:1 ratio, three of which received tolperisone three times daily orally in different dosages (50, 100, and 200 mg), and the fourth group took placebo tablets with the same frequency. On the twenty-first day after the completion of the trial, all participants were contacted by phone at the healthcare facilities to monitor safety. According to the study results, side effects that were satisfactorily tolerated by patients were recorded in 18.1% of participants in the tolperisone group, while in the placebo group, the percentage was 14.1. No deaths or more serious side effects than headache and diarrhea were reported in any of the groups during the study.
Similar tasks to determine the efficacy and safety of tolperisone, but for use in spasticity after cerebral stroke, were solved by P. Stamenova et al. (27) The randomized, double-blind, placebo-controlled trial, conducted by the researchers, involved 120 patients who were treated for 12 weeks. According to the trial results, mild to moderate side effects were recorded in 15.8% of the tolperisone-treated group and 21.6% of the placebo group. Variations in the individual dosage of the drug (an increase in the maximum daily dose of 450 mg) also did not provoke severe side effects but instead optimized the therapeutic effect. (28) A study of tolperisone in terms of its prophylactic use was conducted by P. Bajaj et al. (29) The authors conducted a double-blind, randomized, crossover control study to determine the effectiveness of the drug in preventing muscle pain after exercise. The study involved 20 male volunteers with an average age of 25 years. They were divided into two groups, one of which received oral tolperisone at a dosage of 150 mg three times a day for 8 days, and the other received a placebo with the same frequency. The study included 10 sessions. During the entire study period, there were no reports of severe side effects from the participants.
The results of a phase IV observational, multicenter, open-label study to establish the efficacy and safety of tolperisone for the treatment of painful muscle spasms associated with inflammatory or degenerative diseases of the musculoskeletal system were published by R. Prabhoo et al. (30) The trial involved 920 adult participants from 174 orthopedic centers in India who had complaints of painful muscle spasms caused by inflammatory or degenerative processes in the body. Patients were divided into two groups, one of which took non-steroidal anti-inflammatory drugs at regular intervals and in the appropriate dosage, and the other took tolperisone orally three times a day at 150 mg. During the seven-day trial, less than 2% of participants in the tolperisone group experienced side effects, mainly stomach irritation and nausea. A comparative study of therapeutic efficacy in spasticity of baclofen and tolperisone was conducted by S. Agarwal et al. (31) The study was conducted with the participation of 150 patients with spinal cord injury, cerebral palsy, and post-stroke spasticity. The patients were divided into two groups, each of which included 75 participants. The trial lasted 6 weeks. According to its results, treatment with tolperisone showed fewer side effects compared to baclofen. All minor side effects of tolperisone were perceived as satisfactory by patients, which led to the conclusion that the drug was safe. (32-34)
Analysing the published works, (26,27,29,35) the following conclusions were drawn. Given that all the results were obtained through double-blind, randomized, placebo-controlled trials, which had the highest level of scientific rigor and were the gold standard of clinical trials, they could be considered reliable but insufficient to determine the safety of the investigational drug. This was because, while achieving the goal of determining the efficacy of a medicinal product, no account was taken of the fact that some side effects, especially severe ones such as anaphylactic reactions, were quite rare, so a quantitatively formed sample might not be sufficient to detect their occurrence. The same conclusions applied to the results of comparative studies, (30,31,36,37) which revealed the benefits of the therapeutic effect of tolperisone, but all the risks associated with its side effects were not clarified. One of the ways to study the risks of anaphylactic shock provoked by tolperisone may be a retrospective study of the reaction to it in patients with a confirmed allergic reaction to lidocaine. The advantage of such a study is its safety compared to a real experiment, and the disadvantage is the risk of low informativeness, which may lead to false results.
Currently, alongside scientific research, statistical information to ensure the safety and control of medicines, including the registration of spontaneous reports of adverse reactions to the drug is also conducted. The recording of single, but life-threatening

cases of anaphylactic shock from tolperisone has reduced the level of its safety compared to the previous results of three clinical phases of trials, and several European countries have led to a narrowing of the list of recommended indications for symptomatic treatment of post-stroke spasticity in adults and restriction of the dosage form to oral administration.

Conclusions

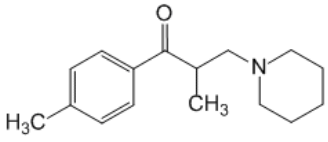
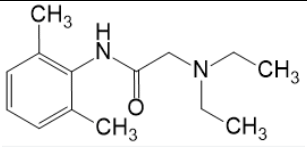
The study described and analyzed the clinical case of a 51-year-old female patient who had a disease associated with degeneration of the spinal joints. For a long time, several times a year, to improve her health, the patient had been taking Mydocalm orally with the active ingredient tolperisone at a dosage of 150 mg twice a day. The next dose of the drug caused unwanted dermatological symptoms that spread throughout the body, followed by digestive system disorders, low blood pressure, and loss of consciousness. Physical and instrumental examinations, as well as anamnesis, gave grounds to diagnose anaphylactic shock provoked by tolperisone. The treatment measures taken following the diagnosis stabilized the patient's condition. Despite her refusal to undergo diagnostic examinations, the diagnosis was confirmed based on the obvious, given the speed of the first symptoms, the causal relationship between the drug and the body's anaphylactic reaction, and the positive impact of resuscitation measures taken according to the relevant protocol.

To identify the risks of anaphylactic reaction to tolperisone, its pharmacodynamic and pharmacokinetic characteristics were analyzed. Based on the results of the analysis, the most likely reason for the development of this immune response to the drug was the similarity of its structure and mechanism of action to lidocaine, which periodically causes the same life-threatening reactions. Comprehension of the research topic led to the conclusion that the design of randomized controlled and cohort studies cannot fully determine the degree of safety of tolperisone since a sample size of less than ten thousand does not guarantee the detection of a low-incidence side effect. Therefore, to study the topic in depth, it is necessary to record and analyze in detail each case of anaphylactic shock provoked by tolperisone, which is the practical significance of this study. Primary recommendations, based on the results of a conducted research, are to increase the attention of general practice doctors on the side effects of the drug and to avoid prescribing it to patients with increased lidocaine sensitivity. Considering the overall danger of anaphylactic shock - its unexpectedness, one of the main further research vectors in the sphere should be surveyed to determine the overall knowledge of what to do in case of emergencies. Survey results could be used to develop socially beneficial programs for medical education to improve civil health in Poland.

Conflict of interest

There is no conflict of interest.

Table 1. Structure, mechanism of action, and side effects of tolperisone and lidocaine

Characteristics	Tolperisone	Lidocaine
Structure		
Formula	C16H23NO	C14H22N2O
Pharmacological group	Centrally acting muscle relaxant	Anaesthetic
Mechanism of action	Membrane stabilizing and local anesthetic effects. Inhibits afferent fiber excitation. Blocks sodium channels. Inhibits potassium channel activity. Blocks synaptic reflexes of the spinal cord.	Membrane stabilizing and local anesthetic effects. Causes reversible inhibition of neuronal, axonal, and synaptic conduction. Blocks sodium channels. Inhibits ionic fluxes through neuronal membranes, forming an irritant. Reduces the level of depolarisation and the amplitude of the action potential. Inhibits nerve conduction.
Side effects related to disorders of the immune system	Hypersensitivity reaction. Anaphylactic reaction. Anaphylactic shock.	Hypersensitivity reaction. Anaphylactic reaction. Anaphylactic shock.

Source: compiled by the author.

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