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Of all the sciences (arts), medicine is certainly the most noble.

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TEICOPLANIN'S ADMINISTRATION IN ANTIBACTERIAL THERAPY OF PATIENTS WITH HIGH RISK OF DEVELOPMENT OF LIFE-THREATENING INFECTIONS

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Problems of modern antibacterial therapy explain the increased interest to glycopeptide antibiotics, active against most resistant Gram-positive cocci: methicillin- resistant staphilococci, penicillin-resistant pneumococci and enterococci. The purpose of the present research was the analysis of clinical, microbiological efficiency and tolerance of medicinal preparation of teicoplanin. 42 patients, who received antibiotic in the modes of empirical and targeted therapy or for the purpose of antibiotic prophylaxis, were under supervision. All the patients received teicoplanin intravenously. The duration of therapy was from 7 to 28 days, antibiotic prophylaxis— 24 or 48 h. All patients to whom antibiotic was administered with medical purpose, had signs of infectious process: body temperature was above 37.5 °C during 2 days and more, inflammatory changes in hemogram and document supported center of infection. In the mode of empirical antibacterial therapy, teicoplanin is administered in case of infections resistant to methicillin-resistant staphilococci, penicillin-resistant pneumococcuses, enterococci: nosocomial pneumonia, abscesses of abdominal cavity infected decubituses, postsurgical wounds, infections of vessels, infected thrombosis of arteriovenous fistula. After isolation from blood of strains of microorganisms sensitive to teicoplanin, 9 people received it in the mode of targeted causal treatment. Teicoplanin was administered to three patients for the purpose of antibiotic prophylaxis of wound fever in surgical interventions, including cardiac surgery. To control side and adverse reactions after administration of teicoplanin laboratory monitoring is carried out. Laboratory values prior to prescription of antibiotics, in 72 h after introduction of the first dose and upon completion of the course of antibacterial therapy were studied in patients.

***Keywords**: glycopeptides, teicoplanin, gram-positive microorganisms, enterococcal infection, staphylococcal infection.*

Achievements of modern medicine in the area of surgery, cardiology, transplantology, oncology, critical care medicine became the reasons of aggressive antibiotic therapy and increase in the number of patients with high risk of development of severe, including nosocomial infections, which led to increase in disease incidence of infections caused by gram-positive microorganisms [I]. Infections can appear very variously, affecting skin, soft tissue, upper and lower respiratory tract, urinary tract, bone and connecting tissue. The infections caused by gram-positive microorganisms which are connected with implantation, catheterization of major vessels leading to sepsis, endocarditis, are registered with increasing frequency. Staphylococcus aureus (MRSA) strains and coagulase-negative staphylococci, resistant to methicillin (MRSE), characterized by resistance to all of ß-lactam antibiotics and, as a rule, aminoglycosides, fluoroquinolones, rifampicin, appeared and spread. In this situation, glycopeptides are the drugs of choice, which are keeping the activity in relation to methicillin-resistant strains of staphilococci [2].

The other problem of modern antibacterial therapy is the increase in resistance of Streptococcus pneumoniae to penicillin, cephalosporins, macrolides, co-trimoxazole. Glycopeptide antibiotics are the drugs of choice in the treatment of infections caused by pneumococci strains with multiple drug resistance [3].

Even more often there are difficulties in the treatment of enterococci infections of urinary tract, traumatosepsis, endocarditis, which frequency in intensive care units has considerably increased in recent years. Vancomycin had considered as the drug choice in severe enterococci infections so far, however its broad administration in clinical practice became the reason of exchange of genetic elements between the strains of enterococci and the development of resistance of microorganisms to it. Since 1987, a clear tendency to increasing isolation frequency of vancomycin-resistant strains of enterococci (VRE) was noted. For example, in hospitals of the USA from 1989 to 1993, it increased from 0.3 to 7.9%, and in resuscitation units — to 13.6% [4, 5].

In such a way, the specified problems of antibacterial therapy are the cause of interest to glycopeptide antibiotics, active in relation to methicillin-resistant of staphilococci, the penicillin-resistant pneumococci and enterococci [6].

In the pharmaceutical market of the Republic of Belarus, there are 2 representatives of glycopeptide class: vancomycin and teicoplanin. The natural antibiotic vancomycin is well-known to doctors, as it has been administered in the treatment of infections since 1958. However, toxicity (nephrotoxicity and ototoxicity, transient neutropenia, allergic reactions, phlebitis) and tolerance problems (redness of upper pectoral girdle in intravenous administration) of vancomycin, limit and complicate its use in severe patients [7]. Other medicine with particular advantages over vancomycin is teicoplanin — an antibiotic, synthesized and for the first time administered in clinical practice in Italy in 1988.

Antimicrobial activity of teicoplanin. Teicoplanin possesses activity in relation to gram-positive aerobic and anaerobic bacteria (Staphylococcus spp., including methicillin-resistant strains, Streptococcus spp., Enterococcus spp., Listeria monocytogenes, Peptostreptococcus spp., Corynebacterium jeikeium, Propionibacterium acnes, Clostridium spp., including S. difficile). The mode of action of teicoplanin is connected with inhibition of the 2nd stage of formation of peptidoglikan and suppression of synthesis of bacteria cell wall [8].

Teicoplanin, according to many characteristics, is close to vancomycin, but in vitro is 2 — 4 times more active than methicillin-sensitive and methicillin-resistant strains of Staphylococcus aureus, enterococci, streptococci (tab. 1) [9].

Antibiotic is capable to suppress the strains of Enterococcus faecalis, resistant to vancomycin, which relevance is constantly increasing [9].

Pharmacokinetics of teicoplanin. Bioavailability of teicoplanin in intramuscular administration is about 90%. The greatest differences in pharmacokinetics of the two specified antibiotics are in the degree of linking with plasma proteins and speed of elimination. Teicoplanin is almost completely (95%) linked with plasma proteins while in vancomycin this value is about 55%. Teicoplanin penetrates into tissue and phagocytosed cells better due to higher lipophilicity. The half-life of teicoplanin is 40 — 120 h, which allows to administer it 1 time a day (tab. 2) [10 — 12].

Table 1

Antimicrobial activity of in vitro (MIC_{90}, mg/l) teicoplanin and vancomycin in relation to gram-positive bacteria

Microorganism	Teicoplanin	Vancomycin
MSSA*	0.5	2
MRSA	0.5	2
Staphylococcus spp. *(SCN)***	2	4
Streptococcus viridians	0.25	1
Streptococcus pyogenes	0.12	1
Streptococcus pneumonia	0.125	1
Streptococcus agalactiae	0.125	0.5
Enterococcus faecalis	0.5	4
Enterococcus faecium	1	4
Listeria monocytogenes	0.25	0.5
Peptostreptococcus spp.	0.5	4
Corynebacterium jeikeium	1	1
Clostridium perfringens	0.5	0.5
Clostridium difficile	0.25	0.5
Propionibacterium spp.	0.25	0.5

Note. * MSSA — methicillin-sensitive strains of Staphylococcus aureus.

** SCN — coagulase-negative staphylococci (Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus saprophyticus).

Tolerance of teicoplanin. According to tolerance, teicoplanin has a number of advantages over vancomycin: frequency of side effects does not exceed 10%, in vancomycin — 20 — 40%, and depends on the purity grade of preparation (it is better tolerated when chromatographically pure) and severity of condition of the patient. Teicoplanin does not cause the development of syndrome of a "red man" — dermahemia and soreness in intravenous administration of preparation quicker, than 1 g in 1 h infusion. The degree of incidence of nephrotoxic effects in controlled strudies at dose 6 mg/kg is no more than 0.6%. Ototoxic effects were noted only in combination with aminoglycosides. Teicoplanin can be administered both intravenously, and intramusculary. In intramuscular administration, it does not cause tenderness and development of necroses in the area of introduction [10, II].

Table 2

Pharmacokinetic values of glycopeptides

Value	Teicoplanin (0,4r)	Vancomycin (1g)
Blood concentration peak (C_{max}), mg/l	12 after intramuscular administration 50 after intravenous administration	25—40
Protein-binding,%	95	55
Half-life ($T_{1/2}$), h	40—120 (depending on method for determination)	6—8
Volume of distribution (Vd) l/kg	40—120	0,5—0,8
Urinary recovery, %	80	90—100
Metabolism,%	<5	<1
Range of therapeutic concentrations, mg/l	Maximum (0.5 h after intravenous administration) — 20—40; minimum (before the next administration) — 5—15	Maximum (after 0.5 h) — 20—50; minimum (before the next administration) — 5—10
Method of administration	Intravenously or intramuscularly	Slow intravenous infusion
Daily dose	400 mg	2 g
Frequency of administration per day	1	2

In the practice of global health care there is a wide experience of administration of teicoplanin in the treatment of infections of skin and soft tissue, bones and joints, pseudomembranous colitis (Clostridium difficile) [13]. The studies on treatment of infectious endocarditis with teicoplanin conducted in different countries of Europe, showed its high efficiency [14 — 16]. However, today antibiotic remains "new" to the practicing physicians in the republic.

Positive characteristics of teicoplanin served as the basis for its introduction to the formulary list of RRPC "Cardiology" in 2011, of the 4-th N.E. Savchenko City Clinical Hospital — in 2012.

The purpose of the present research is the analysis of clinical, microbiological effectiveness, as well as tolerance of teicoplanin in the modes of empirical and targeted antibacterial therapy and antibiotic prophylaxis of infectious complications in surgical interventions.

Material and methods

In the 4-th N.E. Savchenko City Clinical Hospital of Minsk and in RRSI "Cardiology" there were 42 patients under supervision to whom teicoplanin was administered in the modes of empirical and targeted antibacterial therapy or for the purpose of antibiotic prophylaxis of infectious complications in surgical interventions (tab. 3). Among the examined patients, there were 23 (54.8%) men and 19 (45.2%) women, middle age 61 [59—71] year.

Adequacy of the starting mode of therapy was estimated in 72 h, efficiency— after the termination of course of treatment (in 7 — 28 days depending on nosological form). Therapy was considered efficient in the following cases: in 72 h after the first administration of antibiotics, general well-being in the patient was improved, symptoms of intoxication decreased body temperature was reduced, inflammatory changes decreased; upon termination of course of treatment resistant positive clinical-laboratory dynamics of disease was observed in patients, sanitation of the center of infection was established; during the postoperative period there were no infectious complications.

Table 3

Distribution of patients according to prescription purpose of teicoplanin

Prescription purpose	Disease profile					
	surgical		nephrological and urological		cardiological	
	abs.	%	abs.	%	abs.	%
Empirical therapy	20	47.6	4	9.5	5	11,9
Targeted therapy after activator extraction from blood	7	16.7	3	7.1		
Antibiotic prophylaxis	2	4.8	—		1	2.4

All patients received "Teicoplanin-tf" (SOOO "TriplePharm", the Republic of Belarus) intravenously. Duration of course of therapy was from 7 to 28 days, antibiotic prophylaxis — 24 or 48 h (for cardiosurgical patients) after the end of surgery.

Statistical processing of results was carried out by means of EXCEL 2007, STATISTICA 6.1 ("StatSoft", the USA) programs. Distribution compliance of signs according to the normal distribution law was established with use of Shapiro-Wilk test. In normal distribution, the data were compared according to Student's criterion, otherwise — by means of Mann-Whitney test. Quantitative values depending on type of distribution were presented in the form of mean value (M) and average quadratic deviationmean-square deviation (s) or in the form of median (Me) and interquartile range [LQ — UQ].

For comparison of quantitative data, depending on the type of their distribution, parametrical and nonparametrical methods of statistics were used. Distinctions were considered statistically significant in case of $P < 0.05$ [17, 18].

Results and discussion

Effectiveness of the selected mode of antibacterial therapy is confirmed by the positive clinical and laboratory dynamics of disease in the examined patients in 72 h after administration of empirical antibacterial therapy (tab. 4).

In accordance with the experience of administration of teicoplanin in the global practice, in empirical antibacterial therapy was prescribed them in a high probability of infections caused by methicillin-resistant staphylococci, penicillin-resistant pneumococci, ampicillin-resistant enterococci: nosocomial pneumonia, abscesses of abdominal cavity, infected decubituses, apostoperative wound fever, angiogenic infections. Antibiotic was administered in the presence of signs of infectious process: body temperature above 37,5 °C within 2 days and more, inflammatory changes in hemogram, confirmed centers of infection (tab. 5).

Teicoplanin was more often administered as a part of the combined empirical antibacterial therapy (cephalosporins of the 3rd or 4th generations, carbapenem) in infections of skin and soft tissues. It were patients with diabetic foot infections in increase of systemic inflammatory reaction (temperature rise, leukocytosis, shift of white blood cell differential to the left etc.), in the presence of local signs of increase of purulo-necrotic process (perifocal edema, formation of secondary necroses, purulent discharge, characteristic smell, etc.) in the depth of wound defect, trophic ulcers. Antibacterial therapy was carried out secondary to the medicinal preparations improving microcirculation (pentoxifylline, emoxypine). In antibiotic administration, positive dynamics of infectious process was reached: patients were discharged home after conservative treatment without symptoms of generalized or local inflammatory reaction.

Table 4

Clinical and laboratory values in the patients, who receive teicoplanin, and efficiency of antibacterial therapy

Indicator	Indicator values		Therapy efficiency
	prior to antibiotic administration	72 h after antibiotic administration	
Body temperature, °C	38.9 [37.8—39.2]	37.3 [36.4—37.5]*	Yes
Leucocytes, -109/л	25.1 [16.7—31.8]	17.1 [10.3—19.4]*	Yes
Lymphocytes, %	10 [12—17]	21 [19—29]*	Yes
Monocytes,%	6 [5—8]	7 [5—8]	Yes
Neutrophils, microxyphil, %	78 [51—84]	65 [36—71]	Yes
Neutrophils, stab, %	24 [18—43]	11 [9—16]*	Yes
Eosinophils, %	2 [1—3]	2 [1—4]	Yes

*P<0.05.

Table 5

Structure of center of infection in patients, who receive teicoplanin, and efficiency of antibacterial therapy

Organ System	Center of infection	Number of patients	Therapy efficiency
Respiratory organs	Pneumonia	2	Yes
Abdominal cavity organs	Peritonitis in patients,who receive treatment with peritoneal dialysis	3	Yes
	Abscess	3	Yes
Skin and soft tissues	Soft-tissue infections	21	Yes
	Postsurgical wound	2	Yes
Heart and major vessels	Infective endocarditis	5	Yes
	Infections of vessels	3	Yes

The course of antibacterial therapy was from 7 to 16 days.

There is a positive experience of teicoplanin administration in combination with meropenem in 2 patients with pneumonia which occurred on the 8th — 9th day of stay in intensive care and reanimation unit.

Infectious endocarditis is one of the most severe infections caused by gram-positive microorganisms. A 64 year old man with an early infectious endocarditis of prosthesis valve was under our supervision. The disease began abruptly on the 13th day after the surgery: increased body temperature, faint. Leukocytosis up to 19109/l with abrupt deviation to the left in blood, increase of procalcitonin level to 4 ng/ml (is revealed at normal value less than 0,5 ng/ml). A combined antibacterial therapy was administered to the patient (meropenem and teicoplanin). The diagnosis of infectious endocarditis was confirmed during ultrasonic heart examination. In 72 h, positive clinical and laboratory dynamics was revealed: body temperature normalization, decrease of intoxication symptoms and inflammatory changes in blood, 2-fold decrease in procalcitonin level. On the 5th days at a normal temperature of the body meropenem was discontinued, teicoplanin monotherapy was continued (28 days). During the treatment, a positive dynamics of clinical, laboratory and instrumental data was detected. The patient was discharged for ambulant therapy.

In the regimen of targeted causal treatment, teicoplanin was administered to 10 patients, from whose blood 6 strains of staphilococci (5 — Staphylococcus aureus and 1 — coagulase-negative) and 4 strains of enterococci, resistant to ampicillin and sensitive to teicoplanin , were isolated in the 4-th N.E. Savchenko City Clinical Hospital. Among 6 isolated staphilococci, 5 were resistant to methicillin (tab. 6).

The expressed positive clinical and laboratory, microbiological dynamics of the disease in the patients receiving targeted therapy should be noted.

Initially teicoplanin was administered to 8 patients in combination with carbapenems (meropenem or imipenem/cilastatin), and after receiving the results of bacteriological blood analysis, in the form of monotherapy.

Table 6

Nosological form of the diseases in patients who receive teicoplanin, in targeted antibacterial therapy

Nosological form	Activator	Number of patients	Therapy efficiency
Chronic glomerulonephritis, chronic renal failure, constant out-patient peritoneal dialysis	MSSA	1	Yes
	MRSA	2	Yes
Infective endocarditis	MRSA	2	Yes
Infective endocarditis in intravenous drug abuser	Enterococcus faecalis	1	Yes
Infection of femus residual limb	MRSE	1	Yes
Peritoneal abscess	Enterococcus faecalis	3	Yes

In such a way, on the 6th day after isolation of pathogen from the blood of a 48-year old patient S., receiving the treatment by peritoneal dialysis with dialysis peritonitis, meropenem was discontinued, and during the next 14 days she received teicoplanin taking into account creatine clearance 400 mg each 72 h.

A young man, 24 year old, being intravenous drug addict, was admitted to hospital due to fever of not clear genesis. After examination, the infective endocarditis of the right segments of heart was diagnosed and a combination of imipenema/cilastatin 3g per day and teicoplanin 400 mg a day was prescribed. On the 7th day after receiving the results of bacteriological blood analysis (increased Enterococcus faecalis) imipenem/cilastatin was discontinued, and the next 5 weeks the patient received teicoplanin monotherapy. No side reactions during the treatment were registered. He was discharged home in satisfactory condition with saved function of seat valve of heart.

Abscess of abdominal cavity was diagnosed after surgical intervention in a 69-year-old man, in relation to which the combined therapy was prescribed (meropenem and vancomycin) within 5 days without the expressed positive clinical and laboratory dynamics of disease. Due to the lack of clinical effectiveness of therapy after receiving the results of bacteriological blood analysis (growth of Enterococcus faecalis from blood) vancomycin was changed to teicoplanin. Absence of effect from starting therapy with vancomycin can be probably explained by moderate sensitivity of enterococcus to vancomycin.

For the purpose of control of toxic action of teicoplanin on human body, a laboratory monitoring was carried out. In the patients examined the level of laboratory indicators specified in the instruction was controlled: urea, creatinine, alkaline phosphatase, alanine aminotransferase (ALT), aspartate aminotransferase (AAT) before prescription of antibiotic, in 72 h after administration of the first dose and upon completion of the course of antibacterial therapy. No clinically significant laboratory deviations in patients during antibiotic administration were specified (tab. 7). In 3 patients teicoplanin was administered for prophylaxis of wound fever. Antibiotic was injected in the dose 400 mg diluted in 10 — 20 ml of 0.9% of solution of sodium chloride 60 min prior to skin incision intravenously, by stream infusion, slowly. In 2 patients, administration of teicoplanin was justified by presence of intolerance of r-lactam antibiotics. One more patient, 62 years old, with rheumatic disease was planned to have surgical intervention on seat valve of heart. Within the last year, she was admitted to in-patient hospital 4 times and many times received a combined antibacterial therapy with cephalosporins, fluoroquinolones, including respiratory, macroleads. 2 years before, a syndrome of "red man" was developed in her during intravenous administration of vancomycin. Therefore, teicoplanin was chosen for prophylaxis of surgical infection. The fact of adequacy of the selected mode of antibiotic prophylaxis should be noted.

Table 7

Laboratory values of patients, who receive teicoplanin

Indicator	Reference value *	Value of laboratory indicator		
		before administration	in 72 h	After termination of therapy course
urea, mmol/l	1.7—8.33	6.4 [5.7—7.1]	7.4 [6.7—8.1]	5.7 [4.1—6.9]
creatinine, mmol/l	Fem. 0.044—0.080	0.054 [0.045—0.074]	0.068 [0.053—0.077]	0.073 [0.065—0.078]
	Male 0.053—0.097	0.061 [0.053—0.084]	0.069 [0.063—0.087]	0.086 [0.069—0.088]
ALT,U/l	Fem. 5—32	14 [23—31]	27 [26—28]	29 [19—31]
	Male 5—42	25 [13—31]	37 [26—39]	39 [20—41]
AST,U/l	Fem. 5—32	15 [13—21]	17 [16—28]	23 [19—30]
	Male5—42	32 [31—38]	39 [20—42]	36 [35—40]
Alkaline phosphatase, U/l	Fem. 35—104	68 [41—98]	65 [54—99]	72 [67—102]
	Male 40—129	74 [53—89]	84 [78—125]	85 [79—112]

Note: *Values are established according to the instruction to the set of laboratory reagents.

Wounds in the patients examined were healed by the first intention in time. The postoperative period proceeded without complications.

In such a way, at the present stage of development of national health care, when the increase in the number of patients with high risk of contamination with gram-positive microorganisms, it is necessary to pay attention to the increasing role of multi drug-resistant problem activators (staphilococci and enterococci) of infectious complications and sepsis. In this situation, teicoplanin could be administered as anti-infective medicine.

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ADMINISTRATION OF TEICOPLANIN AS ANTIBACTERIAL THERAPY FOR HIGH RISK OF LIFE-THREATENING INFECTIONS DEVELOPMENT

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Objective. *As soon as glycopeptides antibiotics being highly active against most resistant Gram-positive cocci such as methicillin- resistant staphylococci, penicillin-resistant pneumococci, and enterococci have been attracting more attention an analysis of the teicoplanin (an antibacterial drug) clinical and microbiological efficiency and tolerance was the objective of the study.* ***Materials and methods.*** *Forty two patients prescribed the antibiotic either within the empiric and targeted therapeutic regimes or as an antibiotic prophylactic agent were observed. Every patient was injected teicoplanin intravenously. The therapeutic course lasted for 7 to 28 days, the antibiotic prophylaxis lasted for 24 or 48 hours. Every patient prescribed the antibiotic as a therapeutic agent demonstrated symptoms of an infectious process: body temperature over 37.5°C for 2 or more days, inflammatory changes in the blood picture, presence of infection foci confirmed by documents. Within the empiric antibacterial therapeutic regime teicoplanin was prescribed for infections resistant to methicillin- resistant staphylococci, penicillin-resistant pneumococci, and enterococci: hospital-acquired pneumonia, abdominal abscesses, infected decubital ulcers, postoperative wounds, infected vessels, infected thromboses of arteriovenous fistula. After microorganisms strains susceptive to teicoplanin had been isolated from blood nine persons were administered teicoplanin as a targeted etiotropic therapy. Three persons were prescribed teicoplanin for wounds infection antibiotic prophylaxis after surgical interferences, including cardiologic surgeries. Laboratory values were monitored for controlling development of possible teicoplanin associated side and undesirable effects. The patients' laboratory variables had been registered initially — before the antibiotic prescription, in 72 hours after the first dose administration, and after the antibacterial course completion.*

Key words: *glycopeptides, teicoplanin, Gram-positive microorganisms, enterococcal infection, staphylococcal infection.*

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