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CARDIAC IMPLANTABLE ELECTRONIC DEVICE INFECTIONS - PREVENTION, DIAGNOSIS, TREATMENT AND IMPACT ON QUALITY OF LIFE

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In recent decades, with the development of medicine, the implantation of cardiac electronic devices with various functions, such as pacemakers, cardioverter defibrillators (ICD), and cardiac resynchronization therapy devices (CRT) has been widely introduced. These cardiac implantable electronic devices (CIED) saved the lives of many patients and improved their quality of life. Despite confirming the benefits of these devices in many recent studies, complications, such as cardiac implantable electronic device-related infections occurred. When it comes to infection, the most effective strategy against it is to make prevention and properly assess the risk factors that may contribute to the development of the infection. Risk factors for CIED infection may be divided into three groups: patient-related, procedure-related, and device-related. Numerous studies have shown that the importance of various risk factors is different, which is often related to the patient's age and other comorbidities.

The patient-related risk factors include such conditions as end-stage renal disease, diabetes mellitus, heart failure, COPD, past CIED infection, malignant tumors, fever before implantation, use of corticosteroids or anticoagulants. One of the most important procedure-related risk factor is a hematoma, which is identified as a significant precondition for the development of CIED infection [13,19]. It should be noted, that early reoperation due to pocket hematoma or lead dislodgement significantly increases the risk of CIED infection [34]. Many scientists also pay attention to the duration of the procedure. Prolongation of the procedure increases the risk of infection [30]. As well the route of entry is a very important factor. The cephalic cutdown technique is the access of choice in terms of avoiding infectious complications. Due to various emergencies, temporary pacing is indicated prior to the procedure, although there is some evidence that temporary cardiac pacing has been shown to contribute to CIED infection [33]. Therefore, temporary pacing should be avoided as much as possible. Also, device pulse generator replacement/upgrade roughly increases the risk of CIED infection.

Regarding device-related factors, type of devices (CRT or ICD) and/or the numbers of leads (≥2) may be associated with increased risk of CIED infection [30]. Considering the above-

mentioned risk factors, it's obvious that preparing the patient before the procedure and the risk stratification is extremely important to avoid further complications.

The most effective treatment of cardiac implantable electronic device-related infections is prevention. An individual approach to each patient and an individual risk assessment are essential. Therefore, nowadays, a novel infection risk score, the PADIT score, is proposed for CIED recipients. The PADIT

score consists of 5 independent factors related to the patient's medical history and procedural details. However, the research has shown that the PACE DRAP score, which firstly was created, to assess the risk of significant bleeding complication after CIED implantations [40], was better able to identify patients at high risk of CIED infection than the PADIT score [39]. The criteria of PADIT and PACE DRAP score are shown in tables 1 and 2.

Table 1. PADIT score

PADIT SCORE				
Risk factor	Definition			
	No. of previous procedures			
Prior procedures	1 ≥2	+1 +4		
Age	<60 years 60–69 years	+2 +1		
Depressed eGFR <30 mL/min/1.73 m2	Renal insufficiency	+1		
Receiving therapy that suppresses resistance to infection (e.g., immunosuppression, high-dose steroids) or having a disease that suppress resistance to infection (e.g., leukemia, HIV infection)		+3		
Procedure type	ICD CRT Revision/upgrade	+2 +4 +5		

Scoring fewer than four (4) points: A patient is deemed at the lowest risk for infection.

Scoring between five (5) and six (6) points: A patient is deemed at moderate to intermediate risk.

Scoring seven (7) or above: A patient is deemed at a high risk of developing a serious infection

Table 2. PACE DRAP score

PACE DRAP SCORE				
Risk factor	Definition			
Prosthesis	Biological/mechanical valvular prosthesis			
Arterial hypertension uncontrolled (+ using VKA)	Blood pressure ≥160/100 mmHg (+ using VKA independently of the INR level)			
Cancer	Any malignancy diagnosed or treated within the past 5 years	+2		
Elderly	Age ≥75 years	+2		
Device type	CRT/ICD	+2		
Renal failure	eGFR <60 mL/min/1.73 m ²	+1		
Antiplatelets	Clopidogrel Ticagrelor	+2 +3		
Procedure type	System upgrade	+2		

Score of 6 is identified as the cutoff point for high risk of significant bleeding complication with a sensitivity of 88.24% and a specificity of 87.23%

It is important that if there is a significant risk of infection, such as fever or other reliable signs of active infection, delay of implantation should be considered until a patient has been afebrile for at least 24h [20] or until the other signs of active infection have resolved.

Although anticoagulants increase the risk of developing a hematoma after the procedure, in patients who are at high risk for thromboembolic events and are on warfarin therapy, continuing anticoagulation is recommended. In patients with CHA₂DS₂-VASc Score<4, it is better to hold anticoagulation before the procedure and restart when the bleeding risk is reduced. As for heparin, a "bridging" is no longer recommended [2,12,36]. The use of P2Y12 inhibitors is associated with a significantly increased risk for bleeding and if it is possible, they should be

discontinued for 5-10 days before the intervention, especially if they are combined with oral anticoagulation [24]. Besides these factors, it is very important that the electrophysiology laboratory, where the procedure is performed, meets the international sterilization standards. All staff must be adequately trained for developing appropriate skills, by which they will be able to follow all the rules for sterilization, to manage the patient, before and during the procedure, as well in the postoperative period. It significantly reduces the incidence of infection. Besides, one of the most important aspects of an operating room setting is a strict limitation to room traffic. As for pre-procedure antibiotic therapy, their use for prophylactic purposes is associated with lower infection rates [8,10] and is the standard of care. Preventive use of systemic antibiotics reduces the risk of procedure-re-

lated infections by 70% [33]. Staphylococcus aureus is the most common cause of CIED infections, because of this, antibiotics should cover it. According to randomized trials i.v flucloxacillin (1-2g) and cefazolin (1-2g) are used as antibiotic therapy [8,10,22]. They should be injected 1 hour before the procedure. In case of allergy to these antibiotics, Vancomycin (15mg/kg i.v over 1hour) may be used 90-120 min prior to the procedure. Due to several considerations, alcoholic 2% chlorhexidine has demonstrated superiority to povidone-iodine for skin preparation before surgery [9], but no randomized data exist about it. Alongside the skin disinfection, changing gloves before handling the generator and the routine use of double gloving may be favorable. The risk of infection is also reduced by smaller incisions, strict control of hemostasis during implantation, and adequate wound closure. Recently, an antibacterial mesh envelope is accessible, in which the device is placed during the procedure. The WRAP-IT trial has demonstrated that in high-risk patients (undergoing pocket or lead revision, pulse generator replacement, system upgrade, or initial CRT implantation) without a higher incidence of complications, the envelope significantly reduces CIED infection [45]. Although the fibrous capsule, that forms after cardiac device implantation inhibits the body's natural immune defense mechanism and the local effect of antibiotics, however during reimplantation, excision of this fibrous tissue is not recommended as it significantly increases the risk of bleeding and hematoma [25]. For wound closure, various types of material can be used, such as an absorbable or non-absorbable suture. No data are indicating which type of material is preferable to use. Many operators prefer non-braided monofilament sutures for skin closure as they are less susceptible to bacterial adhesion. Noteworthy, that closure in layers reduces wound tension and minimizes the risk of dehiscence and infection.

Post-surgical wound care is also an important issue. It's recommended to use pressure dressing for the first 24h. Also, patients should be advised to avoid soaking the wound, until it's entirely healed. Some physicians use i.v and/or oral administration of postoperative antibiotic therapy [46]. The recent PADIT trial about the use of antibiotic has shown, that the local use of antibiotic or antiseptic has no benefits [22]. It is also well-known that early re-intervention dramatically increases the risk of infection [20,33,38]. Some operator considers, that delay re-intervention by weeks (e.g. for lead repositioning) can significantly reduce the risk of infection. Because it is only some operator's point of view, further research is still needed to assess if that decision is effective. Post-procedure pocket hematoma is the important precondition for the development of infection. In case of its existence, it is not recommended to take a sample of pocket material for diagnosis or treatment purposes, because of the high risk of pocket infection [13,20]. Evacuation of hematoma may be performed only in the presence of acute pain, which is not manageable, or if there is a risk of wound dehiscence. The exact and proper diagnosis is crucial for the early detection of CEID infection.

A superficial incisional infection should be differentiated from a pocket infection [5,21]. Pocket infection is only limited to the pulse generator pocket, which is associated with local signs of inflammation, such as mild to severe erythema, warmth, and fluctuation. Deformation of the pocket and skin erosion is one of the common signs of local infection. In some cases, CIED systemic infection and infective endocarditis (IE) may be presented without any signs of local infection. As well non-specific symptoms can appear, like fever, chills, and night sweats. Pulmonary and pleural embolisms are serious complications of CIED infection. The laboratory data, like CRP and PCT tests, are an im-

portant tool for diagnosis, especially in case of pocket infection [7,28]. According to current data, major and minor diagnostic criteria are provided by the European Heart Rhythm Association (Table 3) for the diagnosis of CIED infection or associated infective endocarditis (Table 4) [3].

In case of CIED infection, identification of the causative microorganisms is crucial for effective antibiotic therapy. For these three sets of blood, cultures should be taken (at least 30 min in between). In order to identify lead vegetations and assess valvular involvement in case of diagnosed CIED infection or even suspected one, transthoracic and transesophageal echocardiography is recommended [16]. A chest X-ray is mandatory for all patients with suspected CIED infection. In complex cases, some complementary tools, such as Fluorine-18 fludeoxyglucose ([18F]FDG) positron emission tomography/computerized tomography (PET/CT) scanning and radiolabelled leucocyte (WBC) scintigraphy may be performed for the diagnosis of CIED infections and related complications. Additionally, in selected patients, contrastenhanced CT combined with PET may be useful as well.

The most important step after the diagnosis of CEID infection is the proper management. In case of a confirmed diagnosis of CIED infection complete removal of all parts of the system and intravenous hardware, including the device and all leads (active, abandoned, epicardial, and lead fragments) as well as vascular ports or permanent hemodialysis catheter is recommended [27,32]. This approach applies to both local and systemic infectious complications [23]. In patients with infective endocarditis without a confirmed diagnosis of the CIED system complete CIED removal is definitely indicated [18]. After device removal complete excision of the fibrotic capsule and all non-absorbable suture material and subsequent wound irrigation with sterile normal saline solution is crucial. During 48-72h after the removal of infected CIED blood culture should be taken. As well, during an extraction procedure, distal and proximal lead fragments, lead vegetation if present and pocket tissue should be sent for culture [17].

According to recent studies, antibiotic therapy without device removal is associated with an increased risk in 30-day mortality [26]. Appropriate timing plays an important role after the diagnosis of CIED infection, because delayed removal increases the risk of life-threatening complications. Also noteworthy, that systemic infection is a major predictor for increased all-cause mortality.

In case of confirmed diagnosis of a newly implanted (≤1 year) cardiac device, percutaneous transvenous extraction techniques are the methods of the first choice, since open surgical approaches are followed by the high risk of complications [31,37]. If some vegetations appear during the transvenous extraction procedure, in that case, its size should be taken into account. In the presence of lead vegetations with a diameter of more than 10mm, transvenous extraction procedures are as well preferred. But if the size of lead vegetations is more than 20mm, an open surgical extraction may be considered [16,23]. Complete CIED removal is indicated as a first-line treatment in bacterial and fungal infection when no other identifiable source for recurrence or continued infection is found. [27,29,47,48,49] Patients with superficial wound infections should not undergo device and lead removal, only oral antibiotic therapy during 7-10 days is preferable because in such patient's superficial infections are confined to the skin and the subcutaneous tissue, without involvement of any parts of the CIED system [1]. After complete CIED removal and lead extraction, long-term appropriate antibiotic therapy is pivotal.

Table 3. The Novel 2019 International CIED Infection Criteria

	Major criteria			
Microbiology	A. Blood cultures positive for typical microorganisms found in CIED infect negative staphylococci, S. aureus)			
	B. Microorganisms consistent with IE from 2 separate blood cultures:			
	a. Viridans streptococci, Streptococcus gallolyticus (S. bovis), or	HACEK group, S. aureus;		
	b. Community-acquired enterococci, in the absence of a primary	focus		
	C. Microorganisms consistent with IE from persistently positive			
	a. ≥2 positive blood cultures of blood samples drawn >12 h apart;	01		
	b. All of 3 or a majority of ≥4 separate cultures of blood (first and	last samples drawn ≥1 h		
	apart); or c. Single positive blood culture for Coxiella burnetii or phase I IgG	antibody titre >1:800		
	c. Single positive blood culture for Coxiena burneth of phase rigo	antibody title >1.800		
Imaging positive for	D. Echocardiogram (including intracardiac echocardiography)	positive for:		
CIED	a. CIED infection:	•		
Infections and/or IE	i. Clinical pocket/generator infection			
	ii. Lead-vegetation			
	b. Valve IE			
	i. Vegetations			
	ii. Abscess, pseudoaneurysm, intracard			
	iii. Valvular perforation or aneury			
	iv. New partial dehiscence of prosthetic va			
	E. Fluorine-18 fludeoxyglucose [18F]FDG PET/CT (caution should be taken in case of recent implants) or			
	radiolabelled WBC SPECT/CT detection of abnormal activity at pocket/gene	rator site, along leads, or at		
	valve site			
	F. Definite paravalvular leakage by cardiac CT			
	Minor criteria			

- a. Predisposition such as predisposing heart condition (e.g. new onset tricuspid valve regurgitation) or injection drug use b. Fever (temperature >38_C)
- c. Vascular phenomena (including those detected only by imaging): major arterial emboli, septic pulmonary embolisms, infectious (mycotic) aneurysm, intracranial hemorrhage, conjunctival hemorrhages, and Janeway's lesions
- d. Microbiological evidence: positive blood culture which does not meet a major criterion as noted above or serological evidence of active infection with organism consistent with IE or pocket culture or leads culture (extracted by non-infected pocket)

Table 4. Recommendations for diagnosis of CIED infections and/or infective endocarditis according to the Novel 2019 International CIED Infection Criteria

Definite CIED/IE	presence of either 2 major criteria or 1 major + 3 minor criteria	
Possible CIED/IE presence of either 1 major + 1 minor criteria or 3 minor criteri		
Rejected CIED/IE	patients who did not meet the aforementioned criteria for IE	

According to several studies, therapeutic strategies, including the specific combination of antibiotic therapy is recommended, which is summarized in Table 5 and 6 [1,3,16,23,38].

Table 5. Therapeutic strategies for patients with CIED infections

CIED infection therapy				
	2. Definite CID infection			infection
Type of infec-		2.1 Isolated masket	2.2 Systemic infection	
tion	incisional infection	2.1. Isolated pocket infection (negative blood culture)	2.2.1 Without vegetation on leads or valves ± pocket infection	2.2.2 CIED endocarditis with vegetation on leads and/or valves ± embolism
Therapeutic strategy	Antibiotic therapy 7-10 days	Removal/Extraction + Antibiotic therapy 10- 14 days	Removal/Extraction + Antibiotic therapy 4 weeks (2 weeks if negative blood culture)	Removal/Extraction + Antibiotic therapy 4-6 weeks + oral antibiotic therapy FU if indicated by second- ary infectious focus

Table 6. International consensus recommendations for antibiotic therapy including long-term suppressive therapy

Table 6. International consensus recommendations for antibiotic therapy	including long-term suppressive therapy			
Superficial incisional infection				
Empirical treatment: Oral antibiotic treatment covering S. aureus Flucloxacillin oral (amoxicillin-clavulanate is an alternative) If high MRSA prevalence: Trimethoprim-sulfamethoxazole, Clindamycin, Doxycyclin, Linezolid To be adjusted after culture result. Duration: 7–10 days	Flucloxacillin p.o. 1 g every 6–8h (amoxicillin-clavulanate standard dose)			
Isolated pocket infection (negative blood	cultures)			
Empirical treatment: Directed at methicillin-resistant coagulase-negative staphy- lococci (CoNS) and S. aureus: Vancomycin (Daptomycin is an alternative)	Vancomycin: 30–60 mg/kg/d i.v. in 2–3 doses (Daptomycin 8–10 mg/kg i.v. od)			
If systemic symptoms: For additional Gram-negative coverage, combine with 3rd generation Cephalosporin (or a broader betalactam antibiotic) or Gentamicin	Vancomycin: 30–60 mg/kg/d i.v. in 2–3 doses (Daptomycin 8–10 mg/kg i.v. od) +/- Cephalosporin: standard dose Gentamicin 5–7 mg/kg i.v od			
To be adjusted after culture result If sensitive staphylococcus: Flucloxacillin (1st generation cephalosporin as an alternative). Partial oral treatment is often used. Duration post-extraction: 10–14 days	Flucloxacillin: 8 g/d i.v. in 4 doses or (1st generation cephalosporin standard dose)			
Systemic infections without vegetation on leads or valves 6 pocket infection				
Empirical treatment: (directed at methicillin-resistant staphylococci and Gram- negative bacteria): Vancomycin (Daptomycin is an alternative) + 3rd generation Cephalosporin (or a broader betalactam antibiotic) or Gentamicin	Vancomycin: 30–60 mg/kg/d i.v. in 2–3 doses (Daptomycin 8–10 mg/kg od) + Cephalosporin: standard dose i.v or Gentamicin 5–7 mg/kg i.v. odb			
To be adjusted after culture result If sensitive staphylococcus: Flucloxacillin i.v. (1st generation cephalosporin i.v. as an alternative). Duration post-extraction: 4 weeks (2 weeks if negative blood culture, see text)	Flucloxacillin i.v. dosages as above. (1st generation cephalosporin standard dose i.v.)			
Systemic infections: CIED endocarditis with vegetation on le	ads and/or valves±embolism			
Empirical treatment: Vancomycin (Daptomycin is an alternative) + 3rd generation Cephalosporin (or a broader betalactam antibiotic) or Gentamicin	Vancomycin; 30–60 mg/kg/d i.v. in 2–3 doses (Daptomycin 8–10 mg/kg od) + Cephalospo- rin; standard dose or Gentamicin 5–7 mg/kg i.v. odb			
Adjust to culture result according to ESC endocarditis guidelines 2015				
If prosthetic valve and staphylococcal infection: Rifampicin to be added after 5–7 days	Rifampicin: 900–1200 mg/day orally (or i.v.) in 2 doses			
Duration for native valve infective endocarditis: 4 weeks post extraction, for prosthetic valve endocarditis: (4-) 6 weeks, for isolated lead vegetation: 2 weeks therapy after extraction may be sufficient (in total 4 weeks) except for S. aureus infection				
Bacteraemia in a CIED patient without signs of pocket infection or echocardiographic evidence of lead or valve involvement				
According to pathogen specific treatment guidelines				
Attempted salvage therapy and long-term supp	ressive therapy			
I.v. antibiotics as in prosthetic valve endocarditis for 4–6 weeks Stop antibiotic therapy under close follow-up or continue individualized long-term suppressive oral therapy.				

In case of CIED infection, after the device extraction appropriate timing and the indication for reimplantation should be assessed individually [14,42]. Reimplantation should be delayed or even postponed until signs and symptoms have resolved and/or also blood cultures are negative for at least 72 h after extraction [11,42,44]. The contralateral side, the femoral vein or epicardially, is preferable for the access of replacement device [6,42,50]. Implantations of leadless pacemakers and subcutaneous ICD should be considered as an alternative during CIED infection. For prognosis and outcomes, cardiac implantable elec-

tronic device infection has an in-hospital or 30-day mortality of 5–8% [4,35,41] including mortality from lead extraction and sepsis. For patients who do not have complete removal of hardware, particularly because of considering too frail, in-hospital mortality is significantly high, as well over the months following discharge [15,43].

It's obvious that CIED implantation mostly has a positive impact on patients' quality of life, however, according to the above-mentioned information, CIED infections can negatively alter the quality of life and in some cases even worse it. Conse-

quently, patients should be selected very carefully for implantation, and also all the safety rules and requirements must be strictly followed to prevent CIED infection.

As a conclusion, it's worth to be mentioned that despite the development of medical technologies and improved methods of treatment, CIED infections still remain as a major problematic issue. Preventive strategies, early diagnosis, and proper treatment are key goals in modern cardiology. It is important both in terms of maintaining the health condition of each patient and quality of life, as well as in terms of financial expenses. Despite the problems described in the article, due to the rapid development of medicine and the introduction of advanced methods of prevention or treatment, there exists a strong optimism that the risk of infection will be minimized and CIED implantation can significantly improve the quality of life in every case.

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SUMMARY

CARDIAC IMPLANTABLE ELECTRONIC DEVICE IN-FECTIONS - PREVENTION, DIAGNOSIS, TREATMENT AND IMPACT ON QUALITY OF LIFE

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For several decades, highly refined cardiac implantable electronic devices (CIED) are used to prevent and manage various types of cardiac pathology, which have saved the lives of many patients. Cardiac implantable electronic devices help maintain and improve the quality of life by regulating the heart rate, terminating life-threatening arrhythmias, and improving systolic function, including pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices. Regardless of the benefits received after its implantation, in some cases, serious complication has appeared, such as CIED infections, associated with severe morbidity, mortality, financial expenses and changes in the quality of life. Exactly, in this article will be addressed the issues of prevention, diagnosis, and treatment of this condition, which will help specialists to properly assess the problem and to find a way to effectively solve it.

Keywords: Cardiac implantable electronic device, cardiac pacemaker, implantable cardioverter defibrillator, resynchronization therapy device, CIED infection.

РЕЗЮМЕ

ИНФЕКЦИЯ ИМПЛАТИРУЕМЫХ ЭЛЕКТРИЧЕ-СКИХ КАРДИОУСТРОЙСТВ - ЕЕ ПРЕВЕНЦИЯ, ДИА-ГНОСТИКА, ЛЕЧЕНИЕ И ВЛИЯНИЕ НА КАЧЕСТВО ЖИЗНИ

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Уже несколько десятилетий для лечения и превенции различных типов кардиологических проблем используются кардиоустройства, которые регулируют частоту сердечных сокращений, купируют угрожающие жизни виды аритмий

и улучшают систолическую функцию. Однако во время имплантации данных устройств весьма часто выявляется инфицирование электрических кардиоустройств, которые связаны с заболеваемостью, смертностью, финансовыми затратами и изменением качества жизни.

В данной статье затронуты вопросы превенции, диагностики и лечения инфицирования электрических кардио-устройств, которые помогут специалистам правильно оценить и найти наиболее эффективные пути решения вышеуказанной проблемы.

რეზიუმე

იმპლანტირებადი ელექტრული კარდიომოწყობილობების ინფექცია - მისი პრევენცია, დიაგნოსტიკა, მკურნალობა და გავლენა ცხოვრების ხარისხზე

 12 ნ. ქურიძე, 2 ბ. რუხაძე, 2 ნ. ბაკაშვილი, 12 თ. ვერულავა, 12 ა. ალადაშვილი

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რამდენიმე ათწლეულია სხვადასხვა ტიპის კარდიოლოგიური პათოლოგიის პრევენციისა მკურნალობისთვის გამოიყენება მეტად დახვეწილი ელექტრული კარდიომოწყობილობები, რომლებმაც მრავალი პაციენტის სიცოცხლე გადაარჩინა ან მნიშვნელოვნად გააუმჯობესა მათი ცხოვრების ხარისხი. იმპლანტირებად ელექტრულ კარდიომოწყობილობებს, რომლებიც გულისცემის სიხშირის რეგულირებით,სიცოცხლისთვის საშიში სხვადასხვა არითმიის კუპირებით და გულის სისტოლური ფუნქციის გაუმჯობესებით ხელს უწყობენ სიცოცხლის შენარჩუნებას და ცხოვრების ხარისხის გაუმჯობესებას, მიეკუთვნება კარდიოსტიმულატორი, კარდიოვერტერ-დეფიბრილატორი და რესინქრონიზატორი. აღნიშნული მოწყობილობების იმპლანტაციისას მიღებული სარგებლის მიუხედავად, ზოგიერთ შემთხვევაში თავი იჩინა ისეთმა გართულებამ, როგორიცაა იმპლანტირებადი ელექტრული კარდიომოწყობილობების ინფექცია, რაც დაკავშირებულია ავადობასთან, სიკვდილობასთან, ფინანსურ დანახარჯებთან და ცხოვრების ხარისხის ცვლილებასთან. სტატიაში განხილულია ამ მდგომარეობის პრევენციის, დიაგნოსტიკისა და მკურნალობის საკითხები, რაც დაეხმარება დარგის სპეციალისტებს აღნიშნული პრობლემის სწორად შეფასებასა და მისი ეფექტურად გადაჭრის გზების ძიებაში.