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Global and national trends in the evolution of infective endocarditis

For the recent 20 years, substantial changes have occurred in all aspects of infectious endocarditis (IE), the evolution of risk factors, modernization of diagnostic methods, therapeutic and preventive approaches. The global trends are characterized by increased IE morbidity among people older than 65 who use intravenous psychoactive drugs. The epidemiological trend is represented by reduced roles of chronic rheumatic heart disease and congenital heart defects, increased proportion of IE associated with medical care, valve replacement, installation of intracardiac devices, and increased contribution of Staphylococcus spp. and Enterococcus spp. to the IE etiology. Additional visualization methods (fluorodeoxyglucose positron emission tomography with 18F-fludesoxyglucose (18F-FDG PET-CT), labeled white blood cell single-photon emission computed tomography (SPECT), and modernization of the etiological diagnostic algorithm for determining the true pathogen (immunochemistry, polymerase chain reaction, sequencing) also become increasingly important. The COVID-19 pandemic has also adversely contributed to the IE epidemiology. New prospects of treatment have emerged, such as bacteriophages, lysins, oral antibacterial therapy, minimally invasive surgical strategies (percutaneous mechanical aspiration), endovascular mechanical embolectomy. The physicians' compliance with clinical guidelines (CG) is low, which contributes to the high rate of adverse outcomes of IE, while simple adherence to the CG together with more frequent use of surgical treatment doubles survival. Systematic adherence to CG, timely prevention and implementation of the Endocarditis Team into practice play the decisive role in a favorable prognosis of dynamically changing IE. This article presents the authors' own data that confirm the evolutionary trends of current IE.

Keywords Epidemiology; infectious endocarditis; risk factors; intracardiac devices; acute kidney injury, AKI; PCR; PET-CT; oral antibacterial therapy; bacteriophages; antithrombotic therapy; reconstructive surgery; minimally invasive surgery; prevention; endocarditis team

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Incidence of infective endocarditis

The incidence of infective endocarditis (IE) has been increasing worldwide during the past ten years. According to the Global Burden of Infective Endocarditis study, In 2019, 1.09 million cases of IE were reported, with an age-standardized rate of 13.8 cases per 100,000 people. This was significantly higher than the same indicator in 1990, which was 9.9 cases per 100,000 people (a 39.4% increase in the incidence) [1, 2]. The number of IE cases treated in hospitals in Russia has not changed over the past ten years (6,439 in 2010 and 6,235 in 2019), according to the Russian Federal State Statistics Service (Rosstat); but in the last two years, there has been a trend towards a decrease in the number of hospitalizations with IE (4,422 in 2020 and 3,057 in 2021), with an increase in hospital mortality [3].

A local IE register was created at the Department of Internal Diseases (named after Academician V.S. Moiseev) of the Medical Institute of the Peoples' Friendship University that included 350 adult patients of Vinogradov City Clinical Hospital who were hospitalized with the diagnosis of IE between 2010 and 2022 (of whom 38 patients were subjects of large international register EURO-ENDO). The register was established in compliance with the Russian Federation law, the Good Clinical Practice, the Declaration of Helsinki, and the regulations of the local ethical committee of City Clinical Hospital No. 64 Protocol No. 3 dated May 16, 2017.

IE and COVID-19

The SARS-CoV-2 pandemic has had a negative impact on IE. The relationship between COVID-19 and IE has two main aspects: direct effect (damage to cardiac structures and the development of additional risk factors) and indirect effect (reorganization of the health care system). The immediate causes of the relationship between COVID-19 and IE are discussed in a series of publications: COVID-19-associated hypercoagulation [4], cytokine storm with damage to the heart valves [5], endothelial dysfunction [6], repeated intravenous injections/central venous catheter placement [5, 7], administration of glucocorticoid and immunosuppression [5, 8], late diagnosis [4, 5, 9]. IE during the COVID-19 pandemic, IE is characterized by late diagnosis and hospitalization, symptoms that are comparable to those of respiratory viral diseases, and challenges accompanying invasive diagnosis (transesophageal

echocardiography (TEE)) [9, 10]. COVID-19 has a dual impact on the occurrence of IE: it both creates conditions for the disease to develop and places limitations upon patient examination and hospitalization. Cosyns et al. (2020, France, Belgium) noted that the rate of hospitalizations with IE decreased by 33% during the COVID-19 pandemic, while the severity of IE increased (cerebral embolism in 56%, nosocomial mortality of 61%) [9]. Pommier et al. (2022, France) found a 7% increase in hospitalizations of patients with IE during the COVID-19 pandemic [11]. Havers-Borgersen et al. (2020, Denmark) observed no differences in the IE incidence [12]. According to the Rosstat data for May 2022, hospitalizations for IE decreased by 30% and 50%, while hospital mortality increased to 32.6% and 40.9%, respectively, in Russia in 2020 and 2021 [13].

According to our findings, the number of patients with IE increased by 9.6% during the COVID-19 pandemic, especially in 2021–2022, while the number of hospitalizations decreased in Moscow during long lockdown periods with a subsequent surge after lockdown cancellation. During the COVID-19 pandemic, the period of diagnosis was long (33.0 (12.5–90.5) days) and echocardiography was rarely used (20.7%) in patients with IE. The incidence of complicated IE was independent of the presence of COVID-19, surgical interventions were performed three times more often during the COVID-19 pandemic.

Predisposing heart diseases

The fact that rheumatic heart disease (RHD) no longer served as the primary predisposing factor for IE in industrialized countries, and it did so mainly in developing countries, marks a significant historical shift [13–15]. Watkins et al. (2017) noted a 47.8% reduction in the global burden of RHD from 1990 to 2015 [16]. However, due to the growing significance of predisposing factors, such as degenerative valve disease, the presence of a prosthetic valve, an implanted cardiac device, and the prevalence of injection drug users (IDU), this shift did not result in a decrease in the prevalence of IE in industrialized countries.

An increase in the prevalence of IE was determined by the aging of the population, increasing comorbid burden, and more frequent heart surgeries involving the implantation of foreign devices, including transcatheter aortic valve implantation [17]. Jensen et al. (2021, Denmark) noted an increase in the percentage of cardiac device-related IE (CDIE) from 9.5% in 2004–2010 to 16.7% in 2011–2017 [18]. Prosthetic valve IE (PVIE) is distinguished by a complicated course, challenging etiological diagnosis (association with *Staphylococcus spp., Enterococcus spp.,* or unknown origin) and imaging, which determines an unfavorable prognosis. [19–21].

We observe multidirectional trends in Russia: while there is a decrease in the RHD burden and an increase in IE related to degenerative valve disease, PVIE and CDIE, and IDU IE in the cities with good living quality, RHD retains leadership in low-income cities [20, 22, 23].

According to our data, the median age of patients with IE was 58 (37; 73) years, 36.1% of them were older than 65 years, 29.5% were IDUs. 16.9% of patients had IE related to degenerative valve disease, 15.4% had PVIE, 8.9% had congenital heart defects, 6.2% had RHD, and 5.1% had CDIE.

Evolution of etiological structure and diagnosis of infective endocarditis

Modern treatments and enhanced diagnosis of IE did not improve the IE outcomes, which can be partially attributed to a shift in the etiological background. Concerns related to an increase in the incidence of IE associated with *Streptococcus Viridans* after the implementation of restrictive measures for the antibiotic prophylaxis of IE during dental procedures (2015) were not confirmed [19, 20, 24–27]. Several studies demonstrate growing incidence of IE associated with Staphylococcus spp. [26–28]. According to large international register of IE patients EURO-ENDO (2017–2019), the percentages of cases associated with *Staphylococcus spp., Enterococcus spp., Streptococcus spp.* was 27.1% (*Staphylococcus aureus* 18.6%), 10.0%, and 12.1% (*Streptococcus viridans* 8.0%), respectively [27]. A worrying trend is an increasing percentage of Enterococcus spp. in IE origin, especially among patients older than 65 years [19, 20, 23, 27–29]. Low incidence of IE caused by rare pathogens (*Coxiella burnetii, Bartonella spp., Brucella spp., Tropheryma whipplei*) is noteworthy [19, 20, 27, 28, 30], which is probably due to diagnostic challenges. Absence of a decrease in the incidence of IE of unknown etiology (2.5–31% in 2009 [31], 47.2% in 2016 [32], 20.4% in 2019 [27]) can be explained by early active use of antibiotic therapy before the diagnosis of IE, limitations of microbiological tests, and insufficient use of additional methods of etiological diagnosis (immunochemical and biomolecular testing) [14, 19, 20, 33]. It is necessary to frequently apply special etiological approaches in order to increase the rate of IE with known pathogen: Matrix-assisted laser desorption ionization coupled to time-of-flight mass spectrometry (MALDI-TOF MS), immunochemical analyses (antibodies to *Coxiella burnetii, Bartonella spp., Brucella spp., Mycoplasma spp., Legionella spp., Chlamydia/Chlamydophila spp.*) and PCR tests (species-specific or genus-specific)/sequencing [33].

According to our data, the etiological structure of IE included: Staphylococcus aureus in 25.0% (methicillin-sensitive (MSSA) 20.2%, methicillin-resistant (MRSA)

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4.8%), Enterococcus spp. in 20.2%, Staphylococcus spp. coagulase-negative CoNS in 7.7%, Streptococcus spp. in 6.5%, gram-negative flora in 6.5%, and Bartonella spp. in 1.8%. IE of unknown etiology was found in 35.7%. The department is currently engaged in research to discover the actual causative agent of IE by updating the etiological diagnostic algorithm and the introduction of simultaneous use of microbiological and biomolecular tests of blood and resected valve samples. This approach allowed increasing the frequency of detecting etiopathogenetic agent of IE from 27.6% to 72.4%.

Advances in imaging techniques for the diagnosis of IE

Imaging techniques are crucial for the diagnosis of IE, and transthoracic echocardiography (TTE) and transesophageal echocardiography being unconditional leaders for PVIE and CDIE [19, 20, 34]. Modern imaging techniques include multislice computed tomography (MSCT), positron emission tomography (PET) using fluorodeoxyglucose [18F] (18F-FDG PET-CT), or single-photon emission computed tomography (SPECT-CT) with labeled leukocytes. MSCT of the heart/vessels is useful in the diagnosis of valvular and paravalvular abnormalities, mycotic aneurysms. SPECT-CT with labeled leukocytes and 18F-FDG PET-CT are highly effective for PVIE and CDIE. It allows identifying extracardiac pathology (infectious complications, embolisms, cancer), as well as valvular and paravalvular abnormalities [19, 20, 35–37]. However, supplementary imaging techniques are not common: 1.2–16.6% according to EURO-ENDO [27], other authors reported that such studies were rare or never performed [14] due to high cost and limited availability.

During the hospitalization in our center, TTE was performed in 99.4% of patients with IE, TEE in 51.0%, and specialized imaging studies (MSCT of the heart, 18F-FDG PET-CT and SPECT-CT with labeled leukocytes) in 1.8%.

Clinical manifestations of IE

Clinical manifestations of IE are diverse and non-specific, which is the disease is often diagnosed late. Lukin's spots, Roth's spots and Osler's nodes are unique for IE and occur only in 5–10% of patients mainly with long-term untreated disease [19, 20, 22]. Modern IE is characterized by a blurred clinical picture (possibly due to early administration of antibiotics before the diagnosis and the aging of IE), and long-term involvement of one leading organ (the so-called cardiological, neurological, nephrological, anemic, vascular masks of IE). High incidence of nephrological complications is noteworthy: acute kidney injury (AKI) in every third patient [38, 39], acute kidney disease (AKD) in every two of three patients [40], mainly associated with hemodynamic disorders, nephrotoxic drugs and limiting antibiotic regimens and surgical treatment [41].

The understanding of the pathophysiological mechanisms of the development of IE underwent major changes in connection to embolism. The disease is considered as a unique model of immunothrombosis, a thrombo-inflammatory lesion of the endocardium with a close relation between the hemostasis system and innate immunity [42]. Immunothrombosis combines the activation of the endothelial, platelet, and plasma links of hemostasis, which contribute to the release of neutrophil extracellular traps (NETs) involved in the protection against bacteria entering the blood circulation. However, IE is an example of a thrombo-inflammatory system imbalance, when inflammation progresses, containment of pathogens, and leads to embolic and septic complications [42].

According to our data, fever, dyspnea, and heart murmur were the most common symptoms of IE (90.8%, 67.9%, and 61.8%, respectively), and a small percentage of patients had specific manifestations: purpura (18.9%), Lukin's spots (10.04%), Janeway lesions (0.77%), and Osler's nodes (0.39%). Heart failure (51.8%), embolism (49.4%), and uncontrolled infection (33.3%) were the most common the complications of IE. IE-associated nephropathy was noted in 90%, including AKI in 66% and AKD in 64%. Embolism [odds ratio (OR) 1.9 (1.1–3.1), p=0.013], chronic kidney disease [OR 2.1 (1.2–3.3), p=0.005], and MRSA [OR 2.6 (1.2–5.6), p=0.018] were independent predictors of hospital mortality. We also showed that the postoperative levels of NETs above 14% was associated in patients with IE with the presence of intracardiac (abscess, fistula) and postoperative complications (sepsis, recurrence of IE).

Special forms of IE

The incidence of IE is constantly increasing in IDUs [19, 20, 22, 23, 43]. IE of IDUs is characterized by the involvement of the right heart, association with S. aureus, complicated course of IE (embolism, heart failure), but low hospital mortality after the first episode of IE [22, 23, 43]. Recent years have seen in IDUs an increasing incidence of IE with the involvement of the left heart, which is a more complex problem [44, 45]. IE of IDUs is characterized by early discharge at the patient's without the appropriate antibiotic regimen, which leads to recurrence of IE, repeated hospitalization, and escalation of antibiotic therapy, including the administration of reserve-group antibiotics, and surgical interventions, which determines an unfavorable prognosis in this case [22, 23, 43, 45]. The continued use of intravenous psychoactive drugs is one of the main causes of such course of IDU IE, and because of this, it is suggested to manage such patients together with experts in addiction

medicine during hospitalization and after discharge. These specialists should also be included in the endocarditis team (ET) [43, 46–48].

In addition to higher prevalence, IE is getting older in IDUs over the past ten years, with the highest morbidity at the age of 70–80 years [49, 50]. IE in patients older than 65 years is associated with medical interventions [OR 14.9 (8.6–25.9), p<0.05], Enterococcus spp. [OR 3.3 (1.4–7.9), p<0.05], and late diagnosis against the blurred atypical clinical picture (fever, splenomegaly, isolated anemia and kidney injury are also common). Given the high comorbidity in this category of patients (Charlson index 5.5±2.3), surgical treatment for IE is less likely (8%), which contributes to the high hospital mortality (30.7%) [23]. Thus, the distinctive features of the presented groups of IE patients should be taken into consideration during at the diagnostic stage with greater caution for IE, especially in atypical clinical situations, and when selecting the best-possible antibiotic therapy.

More frequent invasive procedures, including widespread intravenous manipulations, increased the incidence of healthcare-associated IE to 16.0–43.2% (including nosocomial IE in 50–79.5%), which is associated with Staphylococcus spp., often complicated (heart failure, embolism, kidney injury, sepsis), and high hospital mortality (25.0–44.9%) [22, 51, 52].

According to our data, the percentage of patients with IDU IE was 29.5%, the percentage of patients older than 65 years was 36.1%, and PVIE and CDIE – 20.4%. Patients with IDU IE are mainly young (33.4±6.4 years) males (68.4%) with prevalent tricuspid valve involvement (52.6%), and frequent incidence of left-sided (26.3%) and bilateral IE (13.1%) associated with S. aureus (MSSA) in 64.2% and low hospital mortality (18.4%). Patients older than 65 years were more likely to have subacute IE, higher Charlson index of 5.58 ± 4.05, more common and severe heart failure (NYHA II–IV; 53.9%), generally high incidence of complicated IE (76.9%), and high hospital mortality (41.1%).

Perspectives in the treatment of IE

Updated clinical guideline for the diagnosis and treatment of IE of the Russian Federation Ministry of Health (2021), as well as the international guidelines, contain detailed information on both empirical and etiotropic antibiotic regimens with the division into IE phenotypes by pathogens, lesion sites, and the presence of prosthetic valves and/or cardiac devices [19, 20, 34]. The standard duration of antibiotic therapy is 4–6 weeks, it is possible to consider reducing the duration of treatment to 2–4 weeks in certain situations in IDU IE [19, 20, 34].

The transition to oral antibiotic regimens is promising, primarily in IDU IE of the right heart [53], which was included in the previous clinical guideline (2015) [19, 20, 34, 45]. Large randomized trial Partial Oral Endocarditis Antibiotic Treatment (POET; Denmark, 2019) and the long-term outcomes of the 5-year follow-up (2022) demonstrated that an early transition from parenteral to oral therapy in patients with uncomplicated left-sided IE with known origin is non-inferior and safe [54, 55].

Multiple drug resistance (MDR) is still a pressing issue because novel antibacterial drug are not being developed fast enough. Reports on the effective use of bacteriophages (bacterial viruses) and antistaphylococcal lysine (produced by bacteriophage) in patients with sepsis and hopeless IE, for example, when surgical treatment is impossible and/or Multiple drug resistance develops, are of interest [56–58].

No new classes of drugs have been approved in addition to the conservative antibiotic treatment of IE over the past nearly 100 years, although potential benefits of the antithrombotic therapy in IE appear to be reasonable from the pathogenetic point of view [42]. Except for patients with other indications for antithrombotic therapy (coronary artery disease, atrial fibrillation, or prosthetic heart valves), who can continue it in the absence of contraindications (for example, bleeding), it is currently believed that administering antithrombotic drugs is not justified for the prevention of embolism in IE [19, 20, 34, 42, 59].

Given the technical challenges of operating on tissues during active infection, surgically treating patients with IE is never an easy task. However, survival is significantly higher in operated patients with IE than in non-operated IE patients regardless of the presence/absence of indications [19, 20, 34]. It is traditionally recommended to perform valve replacement with biological or mechanical prosthesis in left-sided IE, and reconstructive operations (due to frequent IE recurrences) or implantation of predominantly biological prostheses (due to low compliance with anticoagulant therapy when mechanical prostheses are used) are preferred in right-sided IE [43, 60].

Percutaneous mechanical aspiration, a new direction of minimally invasive surgery promising for the treatment of right-sided IE, including CDIE, are of interest. It allows reducing the bacterial burden, decreasing the size of vegetations, the risk of embolism and postoperative complications of open surgeries, and facilitating antibiotic therapy [61–63]. Transseptal access is a relatively new method for treating left-sided IE [43]. The development of new minimally invasive cardiac device implantation procedures, including those without electrode pacemakers, is promising [64–67].

The Ozaki procedure is a promising new approach to aortic valve reconstruction in patients with IE. It is an improved method of aortic valve replacement using autogenous tissue (pericardium), which allows interrupting

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antithrombotic therapy, for example, in case of neurological complications in the early postoperative period [68–70].

The success of IE treatment depends primarily on compliance with the existing clinical guidelines [19, 20, 34]. Giannitsioti et al. (2021, Greece) showed that timely surgical treatment [hazard ratio (HR) 0.4 (0.2–0.9), p=0.028] and antibiotic therapy complying with current clinical guidelines [HR 0.5 (0.3–0.9), p=0.026] are the only independent predictors of survival. Moreover, survival was 89% when both criteria were met and 45% when neither was [30]. The findings by Tissot-Dupont et al. (2017) were disappointing; they showed that the overall compliance with clinical guidelines was only 58%, with the lowest rate of 54–62% for S. aureus/CoNS and 0.0–15% for IE with unknown causative agent [71].

According to our register, antibiotic therapy was used before the diagnosis of IE in 59.7% of the examined patients, empirical antibiotic therapy was ordered following the clinical guideline in 41.7%: aminoglycosides (71.4%), cephalosporins (60.2%), and glycopeptides (46.7%) were preferred. Heart failure (44.6%), prevention of embolism (37.9%), and uncontrolled infection (33.3%) were the main indications for surgery. And only 45.6% of the examined patients underwent surgery, despite the fact the 66% had indications for surgical treatment.

Prevention of IE

Prevention of IE is a key mechanism used to for the prophylaxis of IE and its recurrence. According to the most recent clinical guidelines, only patients at very high risk during procedures with a high risk of bacteremia, which include only some dental manipulations and only few operations on the respiratory, gastrointestinal, and genitourinary tracts, are eligible for specific prevention. [19, 20, 72, 73]. The most recent clinical guidelines, which were released in 2021, are generally consistent with the previously approved indications and preventive regimens, with the exception of clindamycin, which was excluded as being unsafe for patients with penicillin allergy [20, 73]. The clinical guidelines also clearly distinguish patients who are at a high risk of IE, while moderate and insignificant risk groups are still subject to debate. However, this is not relevant in terms of prevention strategies because all patients are advised to comply with non-specific measures generally aimed at maintaining a healthy lifestyle. [20, 73].

Endocarditis team

It has always been challenging to manage patients with IE, from diagnosis to selecting treatment strategy. For this reason, the establishment of a multidisciplinary Endocarditis team of different specialists, primarily a cardiologist, a cardiovascular surgeon, a functional diagnostics physician, a microbiologist, and a clinical pharmacologist, is widely advocated in all current clinical guidelines and can play a significant role in enhancing the standard of care for patients with IE [19, 20, 60]. The Endocarditis team is created to enhance the management of IE patients at any stage of diagnosis, provide complex case counseling, detect surgical indications early, and select conservative treatment strategy with the appointment and switching of antibiotics, and follow-up after the discharge from the hospital. According to several studies, the establishment of the Endocarditis team resulted in the diagnosis being corrected in 24% of cases, the antibiotic regimen being changed in 42% of cases, and a 2–2.5 – fold reduction in mortality [74–76]. The establishment of the Endocarditis team as an independent predictor of annual survival, according to Kaura et al. (2017, UK) HR 0.24 [95% CI: 0.07 ± 0.87; p = 0.03], Ruch et al. (2019, France) HR 0.45 [95% CI: 0.20–0.96, p = 0.048] [46, 47]. With the significant rise in IDU IE incidence, it seems promising to include experts in addiction medicine in the Endocarditis team [43, 48].

During the COVID-19 pandemic, we observed the greatest influence of the coordinated efforts of the Endocarditis team to improve the quality of medical care provided to IE patients, which was seen in the absence of COVID-19's effect on hospital mortality of patients who were hospitalized in during the COVID-19 pandemic and patients who had both IE and COVID-19. Surgical treatment was provided to more patients hospitalized during the COVID-19 pandemic (3 times more often) and patients with both IE and COVID-19 (2.5 times more often). In the group of patients with IE and active COVID-19, the maximum number of surgical interventions by the indicated/performed ratio was 87.5%, which is explained by the excellent organization of medical care in severe epidemiological conditions and the coordinated efforts of the Endocarditis team.

Conclusion

The currently global trends point to an increasing incidence of infective endocarditis, particularly in the injection drug users and patients over 65 years. Epidemiology seems dangerous due to the increased percentage of healthcare-associated infective endocarditis, prosthetic valve infective endocarditis, and cardiac device-related infective endocarditis, as well as higher incidence of infective endocarditis caused by *Staphylococcus spp.* and *Enterococcus spp.* (especially in elderly patients), which determines worsening the disease course. Given the advances in etiological methods and imaging techniques, traditionally complex diagnosis of infective endocarditis can reach a new level, but the rare application of new examinations (immunochemical and PCR tests, 18F-FDG

PET-CT, SPECT-CT with labeled leukocytes) determines the late diagnosis and high frequency of infective endocarditis of unknown origin. COVID-19 had a negative impact on the epidemiology of infective endocarditis by creating prerequisite for infective endocarditis and directly affecting the heart by compromising the endothelium. Treatment of infective endocarditis evolves in multiple directions, with the search for new, both conservative and surgical treatment options, and efforts to lighten the burden of hospital treatment with the successful transfer of patients to oral antibiotic regimen. However, strict adherence to the current clinical guidelines remains the key to success. The establishment of the infective Endocarditis team primarily to address challenging cases of infective endocarditis, with the widespread established in the long run, and timely prevention, mostly nonspecific, are vital for a good prognosis in patients with infective endocarditis.

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