

Telephone follow-up of patients with cardiovascular implantable electronic devices during the coronavirus disease 2019 pandemic: early results

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KEY WORDS

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ABSTRACT

BACKGROUND In the midst of the SARS-CoV-2 pandemic, basic healthcare challenges arise as lockdowns and social isolation are implemented to prevent the spread of the virus. In order to overcome these challenges, the Polish National Health Fund has facilitated telemedical consultations.

AIMS The aim of this study was to compare teleconsultations with regular visits at ambulatory clinic of implantable devices and to assess whether teleconsultations would be an adequate replacement during times of limited face-to-face contact.

METHODS Teleconsultations in the clinic were introduced for patients without the possibility of remote control of cardiac implantable electronic devices. Prior to planned visits, physicians phoned patients and interviewed them about their health. Further treatment decisions were made based on the interview and available medical records.

RESULTS Teleconsultations were carried out over 3.5 weeks (March 13 to April 1, 2020). Out of 400 patients who had visits planned at the clinic, 349 were consulted by phone. A total of 299 patients confirmed stable health status, 14 reported some symptoms, and 4 were hospitalized; 2 patients changed their primary clinic and were no longer under our care, 1 was undergoing quarantine, 15 required additional intervention, and 15 had died prior to contact. In general, patients gave positive feedback on their teleconsultations.

CONCLUSIONS Teleconsultations are a much-needed option during the SARS-CoV-2 pandemic. They are an effective way to decrease interpersonal contact and to overcome sudden changes to the ambulatory visit plan, which may otherwise put an overwhelming burden on the clinic.

INTRODUCTION Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which causes coronavirus disease 2019 (COVID-19) is an emerging zoonotic agent that first appeared in December 2019 in Wuhan.¹ The rapid spread of COVID-19 has led the World Health Organization to declare a pandemic. With 213 countries affected, a worldwide total of over 2 million cases, a mortality rate of 9.1% in Europe, and unprecedented economic implications, this has become the greatest health challenge of the 21st century.^{2,3} Nearly 2 months into

the epidemic in Poland, over 10 000 COVID-19 cases were reported.⁴ The number of hospitalizations due to COVID-19 ranges from about 25 000 cases in Italy to 3500 in Poland. This novel disease is also associated with severe outcomes in about 20% of cases. Patients with cardiovascular comorbidities are at highest risk.^{2,4}

The high rate of infections and the fact that healthcare facilities may be a source of infection have directed attention to new models that bypass face-to-face contact between physicians and patients.⁵ Therefore, it seems that

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WHAT'S NEW?

The severe acute respiratory syndrome coronavirus 2 pandemic has forced patients to limit contact with medical staff. In order to maintain care, teleconsultations have been implemented, as approved by the Polish National Health Fund (Narodowy Fundusz Zdrowia). The majority of patients with cardiac implantable electronic devices are not equipped with remote device monitoring. Teleconsultations without remote control but with known medical history allow to identify patients at higher risk. Perception of teleconsultation was positive mostly among patients living in areas more distant from hospitals. This type of medical advice may be helpful to reduce the burden of in-office visits but its safety needs further studies.

telehealth could fulfill a critical role in overcoming this crisis.⁶

In 2018, an expert opinion on telemedicine solutions in cardiology was published.⁷ It was emphasized that telecare is a complement to direct medical care. Moreover, there was an indication that teleeducation might be an answer to the need to educate cardiac patients about their health problems, which exceeds the possibilities of the current system. It is an important element of patient participation in prevention, rehabilitation, diagnosis, and therapy. This approach may improve compliance with physician's recommendations, which is ideal for, for example, hypertensive patients in whom home blood pressure measurements can be telemonitored and a reminder to take measurements can be sent through digital applications.⁸ The limitation at that time was lack of reimbursement for most telemedical procedures and a compatible system for providing such services.

The Polish National Health Fund (Narodowy Fundusz Zdrowia [NFZ]) has authorized and agreed to refund specialist healthcare, such as outpatient care, delivered through information and communication technologies. Current legal conditions allow for consultations to be performed using information and communication technology systems (eg, a certified system or internet communicator) and basic communication tools (eg, telephone). Prescriptions and sick leave may also be issued electronically. Records of consults are kept in the standard form specified in the general regulations for outpatient specialist care (eg, using the electronic medical records) and only require to be coded appropriately (NFZ code 89.0099, medical consultation through teleinformation or communication system). Any teleconsultations performed after the date of the approval but before the signing of the agreement between the hospital and the NFZ is also eligible for reimbursement by the NFZ. Outpatient visits and teleconsultations are also available for physicians during their specialization training, provided they are certified by a specialist attesting to their qualifications and experience.⁹ With the NFZ's approval of remote

consultations, the 1st Department of Cardiology at Central Teaching Hospital in Warsaw was quick to adopt a telemedical system. Consultations were performed by telephone in patients without remote control of their cardiac implantable electronic device (CIED).

Our aim was to verify the effectiveness of teleconsultations in the ambulatory clinic of implantable devices (ACID) in conditions dictated by the need to reduce interpersonal contact in the hospital setting as well as during patients' travel to and from their visit. This was especially important for the ACID patients as they tend to have multiple cardiovascular comorbidities and are at the highest risk for severe SARS-CoV-2 infections.

METHODS Teleconsultations in the ACID were introduced on March 13, 2020, and shortly after, on March 17, 2020, all nonessential ambulatory visits were postponed. Teleconsultations were performed by 4 physicians: 3 specialists and 1 resident undergoing specialization training in cardiology. Regular follow-up protocol was maintained. Patients with pacemakers are followed-up every 12 months while those with implantable cardioverter defibrillators (ICDs), cardiac resynchronization therapy defibrillators (CRT-Ds), cardiac resynchronization therapy pacemakers (CRT-Ps) are followed every 6 months. Additional visits were made when abnormalities with the device were determined, device battery was low, or when the patient reported illness. Medical records were made available and special attention was paid to the battery life, incorrect control parameters, and symptoms observed during the patient's previous visit. Patients were divided into 3 groups according to age (≤ 50 , 50–79, ≥ 80 years old) and the number of coexisting diseases such as hypertension, dyslipidemia, atrial fibrillation, coronary artery disease, stroke, diabetes mellitus, heart failure, renal insufficiency, and malignant disease to define their mortality risk associated with COVID-19.

The distance between the place of accommodation and the hospital (ACID) was also analyzed in the context of patient satisfaction assessed on a scale from 1 to 5, where 1 point meant not satisfied; 2, slightly satisfied; 3, neutral; 4, satisfied; and 5, very satisfied. The shortest distance between 2 points on the map to drive was measured using the Google Maps application. After assessing the medical records, the patient was contacted by phone prior to the scheduled ambulatory visit, informed that the visit was postponed, and interviewed with regards to their health. Some patients reported feeling anxiety related to the epidemic and contacted the outpatient clinic on their own. In each case, a detailed history of patient condition was collected. First, patients were assessed if their condition was stable in relation to their

previous visit. Patients were asked if there were any worrying symptoms, that is, weakness, syncope, dyspnea, heart palpitations, decreased tolerance to exercise. Patients with an ICD were additionally asked if there were any device interventions, sound alerts, or signs of a break in the electrode insulation. Attending physicians confirmed that patients had access to all of their medication and issued electronic prescriptions

when necessary. The next follow-up was also scheduled and patients were given general instruction on COVID-19 prevention. The visit was documented with a short note in the hospital's electronic medical records. All teleconsultations were recorded as remote visits. If normal parameters were recorded during the previous control visit and patients reported no new symptoms, the skipped outpatient visit was postponed 6 months for those with pacemakers, and 3 months for those with ICDs, CRT-Ds, CRT-Ps. If patients were close to elective replacement indication, reported significant complaints, or made a request, an urgent visit was scheduled. Some traditional control visits were also performed during this period for both in- and outpatients. Patients with home-monitoring, equipped with transmitters were excluded from the analysis.

This was a retrospective analysis. Although we performed remote control instead of ACID, this was a standard of treatment considering the epidemic threat. Telemedicine solutions are allowed by law and widely promoted in Poland. This paper does not present results of a clinical trial or a clinical experiment. Additional consent of bioethics committee was not required. However, every patient signed informed consent on admission to the clinic for personal and medical data administration and analysis.

Statistical analysis Data were exported from electronic patient records to the database directly available for statistical analysis. Due to the large sample size, we assumed that the central limit theorem was met. Thus, continuous variables with normal distribution were presented as mean and standard deviation (SD). Categorical variables were presented as numbers and percentages. Statistical significance for individual groups was not considered.

TABLE 1 Patient characteristics

Parameter	Value
Patients, n	400
Male sex	241 (60.3)
Age, y, mean (SD)	75.96 (12.66)
Hypertension	258 (64.5)
Hypercholesterolemia	258 (64.5)
Heart failure	269 (67.3)
LVEF, %, mean (SD)	45.8 (13.7)
Coronary artery disease	184 (46)
Previous myocardial infarction	120 (30)
Atrial fibrillation	217 (54.3)
History of stroke	38 (9.5)
Diabetes mellitus	103(25.8)
Renal insufficiency	153 (38.3)
Malignant disease	28 (7)
AV block or SSS	269 (67.3)
Incomplete patient data	27 (6.8)
Pacemaker	251 (62.8)
ICD	107 (26.8)
CRT-D	36 (9)
CRT-P	6 (1.4)

Data are presented as number (percentage) of patients unless otherwise indicated.

Abbreviations: AV, atrioventricular; CRT-D, cardiac resynchronization therapy defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; ICD, implantable cardiac defibrillator; LVEF, left ventricular ejection fraction; SSS, sick sinus syndrome

RESULTS During a 3.5-week period from March 13 to April 1, 2020, 400 patients (159 women) with CIEDs were scheduled for

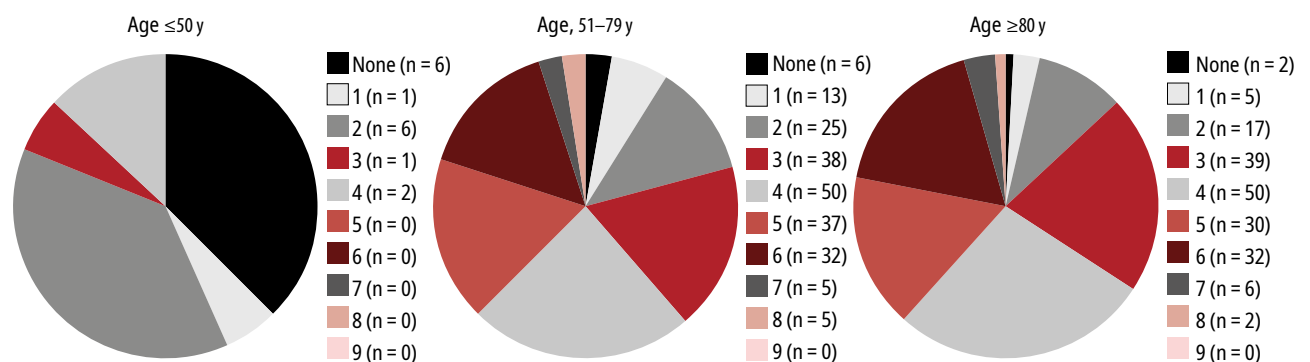


FIGURE 1 Number of comorbidities in specific age groups

TABLE 2 Frequency of comorbidities for specific age groups

Variable	Age ≤50 y (n = 16)	Age, 51–79 y (n = 211)	Age ≥80 y (n = 183)
Heart failure	7 (44)	140 (66.4)	122 (66.7)
Renal insufficiency	1 (6)	59 (28)	93 (50.8)
Hypertension	4 (25)	135 (64)	142 (77.6)
Diabetes mellitus	1 (6)	61 (28.9)	41 (22.4)
Coronary artery disease	0	103 (48.8)	81 (44.3)
Malignant	1 (6)	10 (4.7)	17 (9.3)
Hypercholesterolemia	4 (25)	149 (70.6)	123 (67.2)
Atrial fibrillation	5 (31)	94 (44.5)	118 (64.5)
Stroke	1 (6)	18 (8.5)	19 (10.4)

Data are presented as number (percentage) of patients.

TABLE 3 Technical parameters from the previous visit

Atrial sensitivity, mV	
Atrial lead	3.97 (2.93)
Right ventricular lead	14.64 (6.79)
Left ventricular lead	14.28 (6.89)
Pacing threshold, V	
Atrial lead	0.72 (0.37)
Right ventricular lead	0.75 (0.57)
Left ventricular lead	1.52 (0.85)
Lead impedance, Om	
Atrial lead	461.72 (147.17)
Right ventricular lead	506.21 (146.23)
Left ventricular lead	791.85 (315.65)
AHRE	90 (22.5)
VHR	55 (13.8)

Data are presented as mean (SD).

Abbreviations: AHRE, atrial high-rate episodes; VHR, ventricular high-rate episodes

a follow-up visit at the ACID (TABLE 1). The mean (SD) age of patients was 75.96 (12.66) years. An analysis of potential risk factors of the mortality due to COVID-19 such as age and comorbidities was performed and the results are presented in FIGURE 1 and TABLE 2. Patients younger than 50 years presented less comorbidities in comparison with those older than 50 years. Only 14 patients (3.5%) did not have any coexisting disease.

There were 251 patients (62.8%) with pacemakers, 107 (26.8%) with ICD, 36 (9%) with CRT-D, and 6 (1.4%) with CRT-P. The mean dwell time related to leads was 88.5 months (range, 3–480 months). During the previous follow-up visit, pacemaker dependency was determined in

77 cases (19.3%). Device control parameters are presented in TABLES 3 and 4. A total of 41 patients (10.3%) reported symptoms such as weakness, syncope, dyspnea, heart palpitations, and device intervention. An abnormality related to the device's functioning was found in 21 cases (5.3%). All of the above-mentioned abnormalities pertained to the previous on-site visit. Based on the available medical records, 16 patients (4%) were not compliant and made irregular follow-ups.

Teleconsultation was carried out in 349 patients (87.2%) due to restrictions on ambulatory visits. It was not possible to contact 41 patients (10.3%) due to unavailability of correct phone number. Ten patients (2.5%) came to ACID for their scheduled ambulatory visit. Contact was initiated by 59 patients (16.9%), and 290 patients (83.1%) were contacted by the physicians. 15 patients (4.3%) had died before telephone contact was initiated. Upon contact, 4 patients (1.2%) were undergoing hospitalization, including 1 patient who was in intensive care (as reported by the family). One patient (0.3%) was in quarantine due to suspicion of COVID-19. Two (0.6%) patients changed their primary ACID and were no longer under our care. Fourteen patients (4%) reported signs and symptoms, mainly heart palpitations and weakness (FIGURE 2). One patient reported receiving an ICD shock and another reported symptoms suggesting phrenic nerve stimulation. Fifteen (4.3%) patients required additional interventions and 2 of them were summoned by a physician. The first of these cases was due to a device alarm. The elective replacement indicator in the ICD was detected. The patient was admitted to the hospital and underwent device replacement. The second case was due to syncope. The pacemaker was assessed and its proper function was confirmed. Medical records provided by the patient revealed significant aortic valve stenosis (echocardiography). The patient was referred to the hospital.

Elective replacement was scheduled for 12 patients (3.4%) due to low battery life observed during the previous control visit. In 1 patient (0.3%), pharmacotherapy for heart failure was modified.

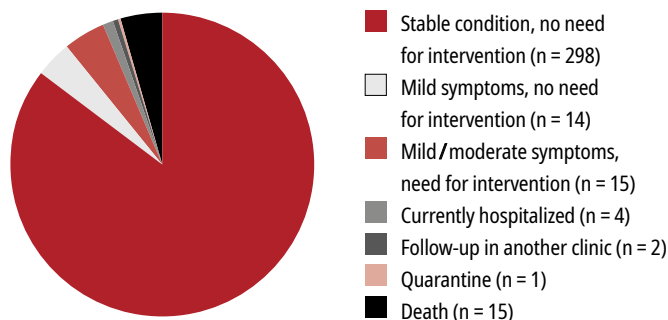
Out of 41 patients who reported symptoms during their previous visit, 3 patients (7.3%) reported problems during their teleconsultation, contact was lost with 4 patients (9.8%), and one (2.4%) died (FIGURE 3).

Of 21 patients who had abnormalities related to the device during the previous visit, 20 (95.2%) did not report any symptoms upon teleconsultation and 1 (4.8%) died prior to contact (FIGURE 3). The patient who died suffered from chronic heart failure and analysis of the previous follow-up visit revealed 2 episodes of ventricular tachycardia treated with high-energy therapy.

TABLE 4 Data from last, current, and follow-up results

Previous follow-up result	
Symptoms reported by the patient	41 (10.3)
Abnormalities related to the device	21 (5.3)
Pacemaker dependency	77 (19.3)
Irregular visits	16 (4)
Current follow-up methods	
Telephone contact	349 (87.2)
Patient-initiated contact	59 (16.9)
Physician-initiated contact	290 (83.1)
Ambulatory visit	10 (2.5)
Out of contact	41 (10.3)
Follow-up result	
Next follow-up – normally scheduled date	220 (63)
Next follow-up – earlier scheduled date	93 (26.6)
Current hospitalization	4 (1.2)
Urgent hospitalization	2 (0.6)
Scheduled hospitalization	12 (3.4)
Drug therapy modification	1 (0.3)
Death	15 (4.3)
Follow-up clinic change	2 (0.6)

Data are presented as number (percentage) of patients.

**FIGURE 2** Information obtained from patients based on telephone contact on current follow-up

Thirteen patients (86.7%) who died were in stable condition during the previous follow-up visit. As mentioned before, one patient had interventions and another reported weakness. The mean (SD) age of patients who died was 79.53 (12.67) years, 5 (33.3%) were women. All patients were compliant with regular follow-up visits. Nine had pacemakers, 5 had ICDs, and 1 had a CRT-P.

One patient insisted on a visit at the ACID despite reporting no symptoms and being informed that due to the current epidemiological situation such a visit is not recommended and is associated with high risk. The patient, however, was scheduled for an earlier visit. An earlier

visit was scheduled in 93 cases (26.6%) due to expected elective replacement indicator, significant complaints, or patient request.

Teleconsultations received a positive response. Patients reported satisfaction with the method of consultation and some were glad to talk to a physician. Cooperation was effective and patients answered all questions and reported that the consultation made them feel safer.

The average satisfaction with the teleconsultations was 4.5, while for patients from outside Warsaw it was higher compared with the residents of the capital (4.9 vs 4.2). A total of 305 out of 400 patients (77%) lived in a city, including 224 patients (56%) from Warsaw. The median (interquartile range) distance from the place of accommodation to ACID was 9.6 (47.9) kilometers; the mean (SD) distance for patients from Warsaw was 5.5 (3.8) kilometers and for patients living outside the capital, 81.9 (33.4) kilometers.

DISCUSSION SARS-CoV-2 is a highly contagious virus associated with a significant morbidity and mortality.^{10,11} It is recommended to minimize face-to-face contacts, including all non-essential healthcare visits. Guidance for Cardiac Electrophysiology During the Coronavirus (COVID-19) Pandemic from the Heart Rhythm Society¹² underline that medical visits should be limited. Visits to clinics should be avoided where possible. Instead, the use of telehealth methods are recommended to minimize unnecessary exposure.¹²

Prior to the pandemic, the use of telemedical services was not common. Patients were used to contacting medical staff in person. The COVID-19 era raises awareness among patients and physicians about the important role of telemedicine in healthcare. Both sides have begun to appreciate the benefits of such solutions. Furthermore, these sorts of services are supported legally in Poland by the Act on the Professions of Doctor and Dentist.¹³

Based on the performed teleconsultations, we found that this service was satisfactory for most of the patients. Patients felt comfortable and safe. They realized that despite restrictions caused by the ongoing pandemic, they could safely contact their doctor and consult their health condition. Patients with problems such as the end stage of battery life were scheduled for hospitalization without additional visits. Patients with abnormalities in devices or due to reported symptoms were scheduled for an earlier appointment. An earlier date was also given to patients upon their request. Patients who had a poor record for previous follow-up visits were easily identified.

The postponed follow-up visits for over 300 patients will surely burden the clinic in

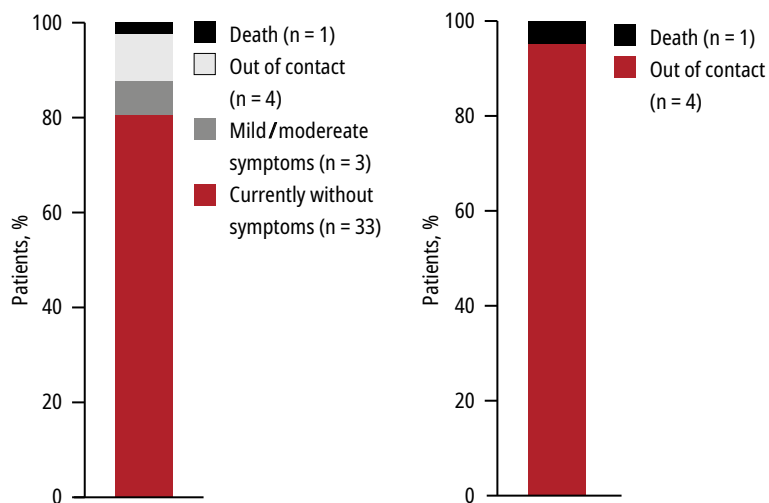


FIGURE 3 Current follow-up results in patients who reported symptoms (A) or with device abnormalities on a previous visit (B)

the following months. The standard application of teleconsultations for patients in permanent cardiac care can help to reduce this burden. Therefore, careful consideration should be given to determine the appropriate patient control scheme in order to minimize the epidemiological risk. Furthermore, epidemiological recommendations including personal protective equipment will impede outpatient care even more. Based on the performed teleconsultations, implemented due to the demand to limit the spread of COVID-19, we were able to create a scheme for ambulatory control of patients. It seems appropriate to connect remote visits and teleconsultation, which would provide relief to the overburdened system. Standard procedures and admission restrictions have been introduced to reduce the risk of infection as much as possible. Patients who have to be consulted at the clinic are included in safety procedures, also recommended by the Heart Rhythm Section of the Polish Cardiac Society.¹⁴ At each visit, an epidemiological interview is collected with regard to the risk of SARS-CoV-2 infection and symptoms suggesting infection. Currently, patients are provided a surgical mask and asked to wear it and to disinfect their hands. The medical records are completed after the patient has left the room in order to shorten mutual exposure. After each visit, the room is ventilated. All persons who are not essential to the control visit are excluded from the room. The rule of one lab, one desk, one telephone has been implemented. It seems that these efforts should help to reduce the risk of infection for both staff and patients.

Calton et al¹⁵ underline that with the appearance of the coronavirus epidemic, the importance of telehealth has grown to a role that is essential. For example, the University of California recommended telemedicine whenever possible in the outpatient setting. Strict restrictions on

hospital visitors have made it possible to hold virtual consultations and family meetings, especially for people with palliative conditions. The United States of America has mitigated many regulations to help support telemedicine. For example, since April 2020, it has been possible to provide teleconsultation across state borders as well as to prescribe drugs without prior personal evaluation.

The United States Department of Health and Human Services has recently allowed telemedical services to be delivered on nonpublic video communicators such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, and Skype.¹⁶ Unfortunately, telehealth also has its limitations. To be able to use it, patients must have access to internet connection as well as a smartphone, tablet, or computer. Video contact is preferred, but if this is not possible, telephone contact is sufficient. Further, older patients in particular may have problems with operating these devices. Efforts should be made to facilitate volunteer help as well as easy-to-use applications.^{15,17}

Our patients with CIED are typically aged over 50 years with comorbidities as presented in FIGURE 1. It was shown that coexisting diseases and older age significantly increase the risk of death in patients with COVID-19.¹⁸ The average mortality rate for people under 50 years old is about 0.2% to 0.4%; in the group aged 50 to 79 years, 1.3% to 8%; and for people over 80 years old it is around 14.8%—the older group, the higher the mortality.¹⁹ Recent data showed that patients with COVID-19 admitted to the intensive care unit were older and had more coexisting conditions than those who did not require admission to the intensive care unit.²⁰ Liu et al²¹ reported that patients over 60 years of age had a higher rate of respiratory failure and required longer treatment times than those under 60 years old. It was revealed that older patients presented more severe clinical symptoms, greater severity, longer disease courses, and worse response to treatment. It was also suggested that the elderly should be monitored more closely. The main risk factors for the development of serious infections beyond age include the presence of comorbidities or underlying diseases, such as hypertension, diabetes, and cardiovascular diseases.^{22,23} In a study concerning patients with cancer, it was shown that they had a 2-fold higher risk of COVID-19 than the general population.²⁴ When analyzing the structure of the patient population in ACID, it is the group with the highest risk and severe course of COVID-19. Therefore, all possible actions should be taken to prevent the infection.

Teleconsultations seem to be a good medical practice. They could reduce in-office visits; however, they will never replace remote control of the device and personal consultations. Safety of this approach requires further study.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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