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PROGNOSTIC VALUE OF DELAYED GADOLINIUM ENHANCEMENT ON CARDIAC MAGNETIC RESONANCE IMAGING IN PATIENTS WITH ISCHEMIC CARDIOMYOPATHY AND AN IMPLANTED CARDIOVERTER-DEFIBRILLATOR

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Aim. To examine the impact of late gadolinium enhancement (LGE) in the left ventricular myocardium on magnetic resonance imaging (MRI) on overall mortality and the phases of arrhythmic events in patients with ischemic cardiomyopathy and implantable cardioverter defibrillator (ICD).

Methods. This was a single-center retrospective study. A total of 382 medical records of patients from the period between 2019 and 2022, who underwent ICD implantation as part of primary prevention of sudden cardiac death at National Centre of Cardiovascular Surgery, were analyzed. Seventy-four patients were selected for the study. Observation was conducted through in-person examinations and remote monitoring. Endpoints evaluated included overall mortality and arrhythmic events. The cause of death was determined based on the “Promed” medical database. Patients who reached a specific endpoint constituted the case group, while those who did not reach any endpoint formed the control group.

Results. During the observation period, arrhythmic events were registered in 26 patients (35.1%), with a total of 27.1 ± 13.2 events. Twenty-one patients (28.4%) deceased. In univariate regression analysis, the presence of LGE, the extent of LGE (%), and the number of segments with LGE served as predictors of ICD activation and overall mortality. Two multivariate logistic regression models were constructed. ROC curves were used to determine the quality of the regression model, with an area under the curve of 0.807 for ICD activation and 0.789 for mortality. The highest sensitivity and specificity of the method were observed with a LGE value equal to or greater than 14% for ICD activation (sensitivity 81%, specificity 75%) and 26% for overall mortality (sensitivity 89%, specificity 64%).

Conclusion. Substantiated ICD activations (shock/antitachycardia pacing) were observed in 35.1% of cases, and the overall mortality rate was 28.4%. The association between ICD activation and the extent of LGE occurred when LGE was $>14\%$. The association between overall mortality and the extent of LGE occurred when LGE was $>26\%$.

Key words: ischemic cardiomyopathy; implantable cardioverter-defibrillator; cardiac magnetic resonance therapy; late gadolinium enhancement; antitachycardia pacing; mortality

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Despite the strategy of early revascularization and a large choice of modern drugs for the treatment of chronic heart failure (CHF), about 5% of patients after myocardial infarction (MI) have a left ventricular (LV) ejection fraction (EF) of less than 35%. It is this category of patients who have the highest risk of sudden cardiac death (SCD). Implantable cardioverter-defibrillator (ICD) has been shown to be effective in the primary prevention of CHD in a number of large randomized trials. The reduction of absolute risk of death in this group of patients according to different data ranged from 23-31% [1-3].

The problem of selecting patients who will benefit most from ICD implantation has not been addressed, as only one-third of patients with ICDs experience activations within 3 years of implantation [4]. It remains unclear how

to identify patients who meet the current clinical indications for ICD therapy but are not actually at high risk for life-threatening arrhythmias.

In the context of this problem, cardiac magnetic resonance imaging (MRI) with gadolinium-containing contrast agent enhancement and assessment of delayed myocardial contrast (late gadolinium enhancement - LGE) is currently under active investigation. The ability of the gadolinium-based contrast agent to accumulate in fibrotic tissue, allows visualization of a potential substrate for life-threatening arrhythmias [5, 6]. Current clinical guidelines recommend the use of this method as an additional factor for decision-making in favor of ICD implantation in patients with hypertrophic (class of recommendations 1; level of evidence B) and dilated

cardiomyopathies (class of recommendations 2A; level of evidence B) [7]. It has also been reported that the presence of LGE areas of patients with ischemic cardiomyopathy (ICMP), has been associated with mortality and more arrhythmic events [8]. However, a number of fibrotic tissue characteristics in ICMP patients with reduced EF have been insufficiently studied, in particular, scar tissue volume (LGE%), localization, transmural, and extent of scar tissue (number of involved LV segments).

Aim of the study: to investigate the effect of MRI indicators of LGE on overall mortality and the incidence of arrhythmic events in patients with ischemic cardiomyopathy with a LVEF of 35% or less and an implanted cardioverter-defibrillator.

METHODS

The design of the present study was of a case-control nature and appropriate local ethical committee approval was obtained for its conduct. We analyzed the medical histories of patients who had an ICD implanted between 2019 and 2022. A total of 382 case histories were analyzed, from which 74 individuals were selected.

Inclusion criteria:

- device implantation for primary prevention of SCD;
- patient with primary implantation of a 1,2,3-chamber ICD;
- ICMP (reduced LVEF of 35% or less in patients who have suffered a MI or have a coronary lesion without MI, undergone aortocoronary bypass / percutaneous coronary intervention);
- cardiac MRI with gadolinium less than 3 months before implantation;
- the possibility of obtaining data from the implanted device (regular face-to-face examinations or functioning remote monitoring).

Exclusion criteria:

- patients with non-ischemic cardiomyopathy (NICMP);
- secondary prevention of SCD;
- lack of surveillance results and remote monitoring not functioning;
- cardiac MRI more than 3 months prior to implantation;
- cardiac MRI without contrast enhancement.

The clinical and demographic characteristics of the patients are presented in Table 1, MRI characteristics in Table 2. Patients underwent cardiac MRI with contrast on a Siemens Magnetom Avanto MR tomograph, 1.5 Tesla. LV systolic function was assessed using short-axis motion pictures on breath-hold (in the exhalation phase) retrospectively synchronized with ECG. The cut thickness was 8 mm. Cine-MRI was performed in standard projections (2- and 4-chamber long-axis and short-axis LV) with assessment of LVEF, LV end-diastolic volume, LV end-systolic volume, LV myocardial mass, and local contractility impairment by 17-segment LV model. TR 57 ms. TE 1.21 ms. Field of view 376 mm. A unimolar gadolinium-containing contrast agent was injected at a rate of 0.2 mL/kg and the study was performed 2 minutes after contrast injection (early contrast injection) and between 10 and 20 minutes (delayed contrast injection). Contrast agent accumulation (CA) was assessed on an inversion-recovery sequence performed on a short axis spanning the entire LV, slice thick-

ness 8 mm. The inversion time range is 380 to 410 ms. The presence of areas of contrast agent accumulation was also confirmed in 2- and 4-chamber projections along the long axis of the ventricles. Localization and quantification of areas of delayed contrast agent accumulation were assessed. Quantification was performed using Medis QMASS MR 7.6 software. A series of LV images along the short axis (inversion-recovery psir single-shot sequence) was used, the mass of contrasted areas was determined by FWHM (Full Width Half Maximum) method, in % of myocardial mass of the whole LV (Fig. 1).

Scar tissue volume was estimated as a percentage of total LV mass. The extent of scar tissue was estimated by the number of affected segments c LGE used the 17-segment model defined by the American Heart Association. In this model, the LV myocardium was divided into five larger segments: anterior (1, 7), lateral (5, 6, 11, 12), inferior (4, 10), septal (2, 3, 8, 9), and apical (13-17) for data analysis (Fig. 2) [9]. Depending on the localization of scar tissue, the following were distinguished: anterior, lateral, septal, apical, and inferior. The pattern of LGE was defined as subendocardial in the case of lesions less than 75% of LV wall thickness and transmural in the case of 75% more.

Table 1.

Clinical and demographic characteristics of patients (n=74)

Indicator	Result
Age, (years)	59.3±7.0
Men, n (%)	71 (95.9)
Body mass index, (kg/m ²)	29.4±4.4
CHF of III-IV functional class, n (%)	40 (54.1)
Atrial fibrillation, n (%)	28 (37.8)
Hypertension, n (%)	72 (97.3)
Diabetes mellitus, n (%)	11 (14.9)

Note hereafter: CHF, chronic heart failure.

Table 2.

Magnetic resonance imaging characterization of patients (n=74)

Indicator	Result
LGE positive, n (%)	63 (85.1%)
LGE degree, %	22.8 ±11.7
LVEF, %	27.0±6.3
LV volume index, ml/m ²	142.1±33.6
Number of segments with LGE, n	7.8±4.0
Transmural pattern, n (%)	47 (63.5%)
Subendocardial pattern, n (%)	27 (36.5%)
LGE apical segment, n (%)	52 (70.3%)
LGE lower segment, n (%)	33 (44.6%)
LGE anterior segment, n (%)	47 (63.5%)
LGE lateral segment, n (%)	38 (51.4%)
LGE apical segment, n (%)	52 (70.3%)

Note hereinafter: LGE, late gadolinium accumulation; LVEF, left ventricular ejection fraction.

Patients were implanted with Protecta VR, Protecta DR, Protecta CRT-D, and Evera VR DF-1 cardioverter-defibrillators from Medtronic (USA); Lumax 540 VR-T and Iforia HF-T DF-1 from Biotronik (Germany). At discharge, all patients were programmed with single-zone therapy: ventricular fibrillation (VF) 200 beats/min, detection count 30/40 or 24/30, 1 antitachycardia stimulation (ATS) during charge set, shock therapy with 6 charges of 40 J or 35 J depending on the device manufacturer's company; further parameters were adjusted at the discretion of the treating physician. Patients were followed up by face-to-face examinations in the outpatient clinic of the Center or one of the satellite clinics 3 months after implantation, then once every 6-12 months throughout the entire period of follow-up [10]. As well as using one of the remote monitoring networks Home Monitoring (Biotronik, Germany) or CareLink (Medtronic, USA) [11].

All patients received optimal drug therapy for the main and concomitant diseases, according to modern clinical recommendations. The primary endpoint was taken to be the occurrence of sustained ventricular tachycardia/VF, controlled by ATS or shock application (justified ICD triggers). The secondary endpoint is death from any cause. Information about the patient's death was clarified through telephone contact with relatives or from the PROMED electronic medical record. Upon reaching the primary and secondary endpoints, patients were divided into two groups and compared with each other.

Statistical analysis

All patients' clinical data were extracted from electronic medical records (Medialog 7.10 B0119). Statistical processing of the material was performed using SPSS software package version 22 (SPSS, Chicago, IL, USA). Quantitative measures were described and compared on a distributional basis. The test for normality of distribution was assessed using the Kolmogorov-Smirnov criterion. When normality of distribution was confirmed, data were described using arithmetic mean (M) and standard deviation (SD) comparison was performed using Student's t-test. If the distribution was not normal, the median (Me), lower and upper quartiles (Q1-Q3) were indicated, and the values were compared using the Mann-Whitney test. Comparisons of indicators measured in nominal scale were made using Pearson's χ^2 criterion. Multivariate analysis in a binary logistic regression module was used to assess the effect of LGE percentage on overall mortality and the chance of triggering an ICD. The regression analysis considered parameters whose predictive role in the occurrence of endpoints was proven by single factor analysis at a significance level of $p < 0.05$. The one-step method of including variables in the equation was used to build the model. The dependent variable in one of the models was ICD activation, in the other total mortality. Data are presented by the achieved level of significance (p) and 95% confidence interval (95%CI). The critical level of significance was taken as < 0.05 .

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RESULTS

Justified ICD treatment

The follow-up period for the patients was 27.1 ± 13.2 months. During the follow-up period, justified ICD activations (shock/ATS) were recorded in 26 patients (35.1%). Of these, 15 patients had triggers due to paroxysms of ventricular tachycardia, and 11 patients had VF. Unreasonable triggers, as well as cases where episode endograms were unavailable, were not included. In the ICD triggered group, there was a higher percentage of LV scar tissue (30% [27;34] and 21% [10;27], respectively, $p = 0.001$) and a greater extent of scar tissue expressed by the number of affected LV segments ($p = 0.003$). Atrial fibrillation was more common in the group of justified ICD activations (53.8% and 29.2% respectively $\chi^2 = 4.367$, $p = 0.037$). The diagnostic significance of LGE percentage in predicting reasonable ICD activation was evaluated using the ROC-curve method. The area under the curve was 0.809 ± 0.051 (95% confidence interval (CI) 0.7-0.9), and an optimal separating value of 14% was chosen (sensitivity 81% and specificity 75%). The chance of a reasonable trigger was increased by 11% for LGE greater than 14% (odds ratio (OR) 1.111 CI 95% 1.023-1.205).

Single-factor regression analysis revealed 4 parameters with the highest predictor potential: percent-

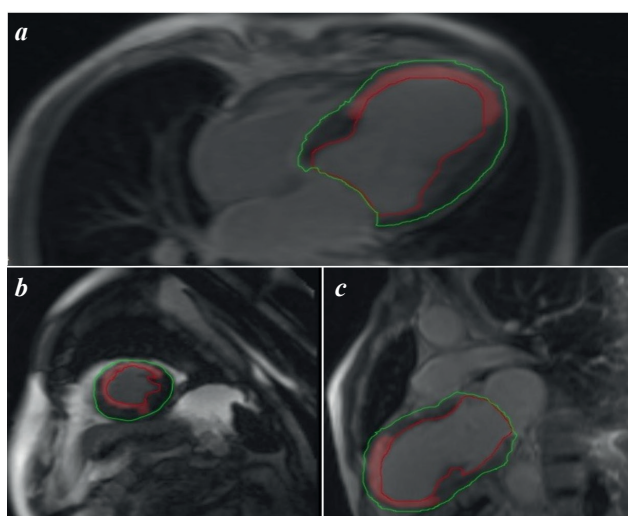


Fig. 1. Example of slices in short-axis (a), two-chamber (b) and four-chamber (c) projections of the left ventricle, psir single-shot program, delayed accumulation of contrast agent by scar tissue, with subsequent image processing using Medis QMASS MR 7.6 software. Scar tissue is highlighted.

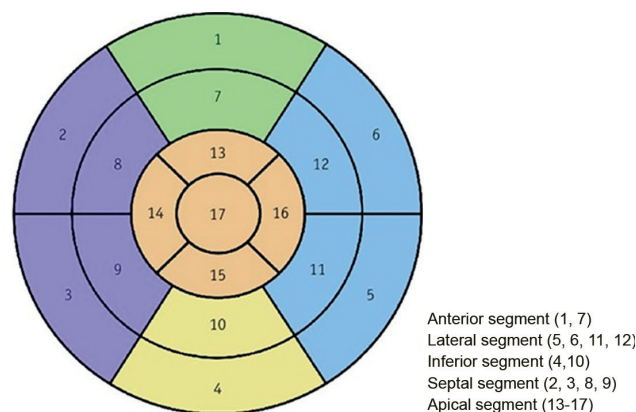


Fig. 2. Left ventricular segmentation: the 17-segment model of the left ventricle as defined by the American Heart Association is divided into five large segments.

age of LGE, atrial fibrillation, number of segments with LGE and LGE>14% (Table 3). To avoid possible multicollinearity, only LGE>14% was used in the multivariate analysis. The data obtained were used to construct a multivariate logistic regression model to predict ICD triggering. The model constructed is statistically significant ($\chi^2=23.331$; $p=0.001$). Nijelkerk's coefficient of determination was 0.378 and Hosmer-Lemeshow's coefficient of determination was 0.331. A ROC curve is plotted to determine the quality of the resulting model. Area under the ROC curve 0.802 ± 0.44 (CI 95% 0.715-0.890) sensitivity 97.6%, specificity 78.3%. The Kaplan-Meier method was used to assess the pattern of ICD triggering in LGE>14% and LGE<14% groups (Fig. 3).

Total mortality

During the follow-up period, 21 patients (28.4%) died; the mortality pattern is presented in Fig. 4. In the group of deceased patients, more severe functional class of CHF was more frequent. Also deceased patients had a higher percentage of LV myocardial fibrosis compared to survivors (31% [22;36] and 19% [10;28] $p=0.001$), a higher number of LV myocardial segments with fibrotic tissue (9 [5;11] and 7 [3;9] $p=0.029$). The diagnostic significance of LGE percentage in predicting reasonable ICD activation was evaluated using the ROC-curve method. The area under the curve was 0.769 ± 0.051 (95% CI 0.67-0.89), and an optimal separating value of 26% was chosen (sensitivity 81% and specificity 75%). The odds of a valid ICD was increased 4-fold for LGE greater than 26% (OR 4.474 CI 95% 1.401-13.205). Single-factor regression analysis re-

vealed 4 parameters with the highest predictor potential: percentage of LGE, CHF 3-4 f.cl., number of segments with LGE, LGE>26% (Table 3). Only LGE>14% was used in the multivariate analysis. The data obtained were used to construct a multivariate logistic regression model to predict total mortality. The analysis of predictors is presented in Table 4. The model constructed is statistically significant ($\chi^2=23.438$; $p=0.001$). Nijelkerk's coefficient of determination is 0.39 and Hosmer-Lemeshow's is - 0.15. A ROC curve is plotted to determine the quality of the resulting model. Area under the ROC curve 0.822 ± 0.53 (CI95% 0.717-0.929) sensitivity 95%, specificity 77.4%. The Kaplan-Meier method was used to estimate survival in LGE>26% and LGE <26% groups (Figure 5).

DISCUSSION OF FINDINGS

This retrospective study aims to investigate the MRI characteristics of the scar in patients with ICMP and implanted ICD to see if this technique can improve risk stratification of life-threatening arrhythmias. Among the technically available MRI indicators of the scar, we selected the main ones based on the literature data: the percentage of LGE, scar localization, the pattern of contrast agent accumulation, and the extent expressed in the number of affected LV segments. It is known that fibrosis percentages can vary depending on the method used. In addition to visual assessment for analysis, there are several automatic threshold-based quantification methods [12]. These methods are based on differences in signal intensity between fibrotic and normal myocardium. In one method, the degree of

Table 3.

Predictors of adverse outcomes, single-factor regression analysis

Indicator	ICD electrotherapy			Total mortality		
	P	OR	CI 95%.	P	OR	CI 95%.
Age	0.911	1.004	0.937-1.075	0.519	1.026	0.951-1.101
Sex	0.196	0.999	0.887-1.112	0.247	0.322	0.611-1.112
Body mass index	0.152	1.086	0.970-1.216	0.982	0.999	0.890-1.122
Diabetes mellitus	0.560	0.657	0.157-2.705	0.423	0.515	0.101-2.61
Hypertension	0.661	0.532	0.030-8.870	0.498	0.385	0.25-6.445
CHF of III-IV functional class	0.649	1.255	0.479-3.284	0.016	3.867	1.236-12.097
LVEF	0.242	1.047	0.970-1.130	0.451	1.032	0.962-1.17
End diastolic volume index	0.397	1.006	0.992-1.021	0.944	1.001	0.986-1.016
LGE >14% (>26%)*	0.009	1.963	1.575-14.17	0.024	1.421	1.252-11.4
Number of segments with LGE	0.002	1.272	1.074-1.507	0.029	1.183	1.010-1.385
LGE quantitatively (%)	0.001	1.130	1.049-1.217	0.001	1.162	1.062-1.217
LGE on the front wall	0.459	1.174	0.535-4.064	0.727	1.212	0.418-3.512
LGE on the septum	0.159	2.303	0.736-7.206	0.490	1.223	0.341-1.534
LGE on the side wall	0.865	0.920	0.354-2.390	0.364	1.475	0.665-2.314
LGE on top	0.150	2.322	0.144-12.22	0.490	0.621	0.244-1.721
LGE on the bottom wall	0.245	1.781	0.679-4.669	0.403	1.550	0.561-4.288
Transmural pattern	0.214	1.939	0.686-5.482	0.051	3.275	0.965-11.005
Subendocardial pattern	0.467	1.495	0.512-4.312	0.418	0.596	0.172-2.065
Atrial fibrillation	0.037	2.833	1.052-7.632	0.621	0.762	0.264-2.202

Notes: CI, confidence interval; OR, odds ratio; *, for ICD electrotherapy and overall mortality, respectively.

hyperenhancement is determined using various SI thresholds such as 2, 4, or 6 standard deviations (SD) above remote normal myocardium. Another quantification method, known as FWHM, involves a threshold value equal to half of the maximum signal within the scar. Currently, there is no gold standard for quantification of LGE in the myocardium. The preference of the quantification method differs depending on the myocardial disease: the FWHM is often used for ICMP, and the SD threshold method is often used for NICMP [13-16]. In this paper, we used the FWHM method to quantify the LGE. According to the literature, this technique is the most reproducible for any etiology of myocardial lesions and allows using a smaller volume of the necessary sample compared to others [17].

In a systematic review of 19 studies, including 5 studies with ICM, 8 with NICMP, and 6 with a mixed ICMP/ NICMP group, the authors concluded that there was a direct «degree-effect» relationship between the number of LGE and arrhythmic events, regardless of the etiology of ICMP. The odds ratio for ICMP is 5.05 (2.73-9.36), for the general population 5.62 (4.20-7.51) [18]. In the present work, we obtained comparable results, namely the presence of LGE as well as the percentage of LGE correlated with ICD triggering. We obtained a cutoff value of the percentage of LGE of 14%, which is confirmed by both multivariate logistic regression data and the Kaplan-Meier method. In general, the results of the present work complement the data of the world literature; however, in a number of similar works, the authors obtained excellent values of the percentage of LGE. For example, for patients with non-ischemic cardiomyopathy, threshold values of LGE

with prognostic value, according to literature data, range from 1.5% [19], 8% [20] to 13% [21].

Two studies with a similar design from the above meta-analysis that present values for the percentage of LGE in patients with ischemic etiology of CMP should be discussed in more detail. In one study, the authors stated a critical value of 5% for LV LGE in the ICMP group with respect to triggered ICDs with an OR: 6.3 (95% CI: 1.4 to 28.0) [22]. In the work of F.Demirel et al. patients with LGE>11% were more often subjected to ICD activations [23]. These differences, as mentioned above, are probably due to the difference in the methods of LGE quantification in the first paper a visual assessment of the scar was performed, in the second the method of signal intensity thresholding.

Currently, there is limited literature on the effect of LGE pattern on arrhythmia risk in patients with ICMP. In patients with NICMP, subepicardial patterns have been reported to be associated with SCD and intramural pattern with overall mortality [24]. In the study of B.P.Halliday et al., intramural localization of LGE was associated with a 9-fold increase in the risk of SCD in patients with dilated cardiomyopathy and LVEF >40% [19]. In contrast to the above-mentioned studies, the present group was represented only by ICMP patients; therefore, 2 classic patterns of contrast agent accumulation were observed, transmural and subendocardial, in a ratio of 63.5% to 36.5%. No pat-

Table 4.

Predictors of adverse outcomes, multivariate regression analysis

Indicator	P	OR	CI 95%.
Defibrillator triggers			
LGE >14%	0.012	1.111	1.023-1349
Number of segments*	0.363	1.118	0.879-1.422
Atrial fibrillation	0.031	3.563	1.125-11.289
Total mortality			
CHF III-IV FC	0.049	3.485	1.067-12.559
LGE >26%	0.008	1.198	1.045-1.566
Number of segments*	0,970	0,995	0,762-1,299

Note: *, with LGE; FC, functional class

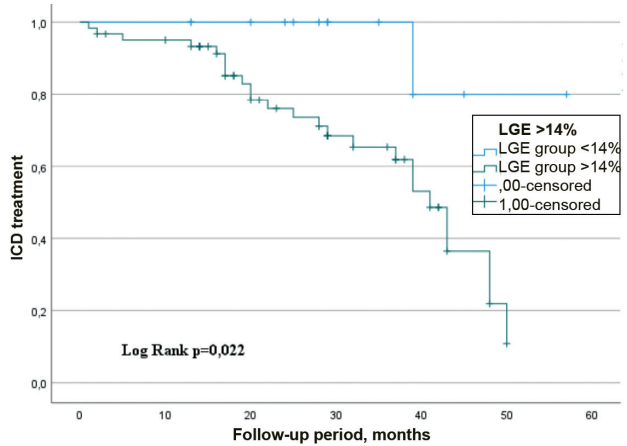


Fig. 3. Kaplan-Meier curve showing the relationship between ICD triggering and LGE levels.

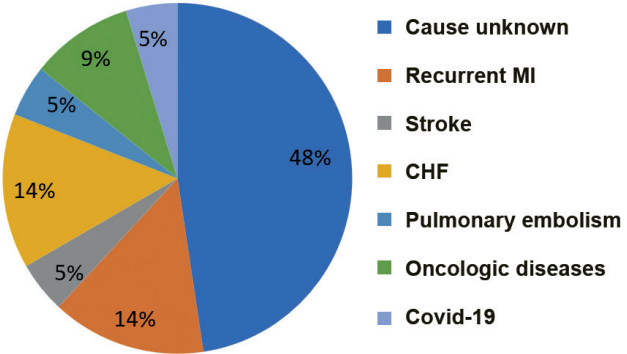


Fig. 4. Patient mortality patterns.

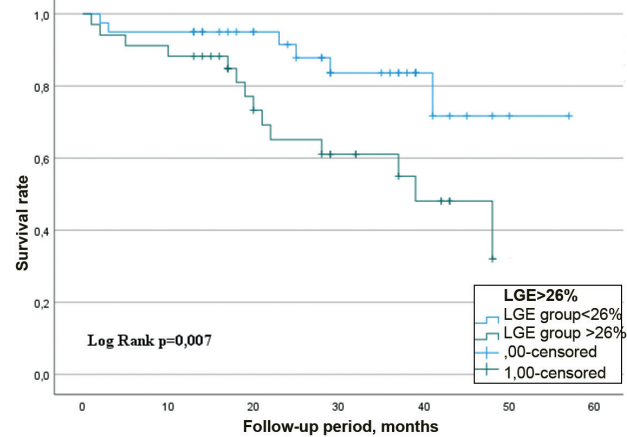


Fig. 5. Kaplan-Meier curve showing the relationship between total mortality and LGE rates.

tern demonstrated an effect on mortality and ICD therapy. Probably, the transmural nature of LV wall damage itself does not increase the risk of life-threatening arrhythmias in comparison with subendocardial damage, but the fact of scar tissue presence as a substrate for re-entry is of importance. The obtained data confirm the result of the study by A. Barison et al. who also found no significant association between LGE pattern and the risk of ICD shock or the combination of ICD shock and cardiac death [21].

LGE localization in the present observation group was not associated with either appropriate ICD therapy or mortality. However, a number of authors have stated that localization of LV fibrotic tissue may be of great importance in predicting rhythmic events in both the ICMP and NICMP groups. In a study by A. Barison et al., the septal LGE was a single-factor predictor of VA, the lateral wall LGE was a single-factor predictor of mortality, and the inferior wall LGE was a single-factor predictor of both adverse outcomes of patients with NICMP [21]. In another study in ICMP patients, the presence of LGE in the interventricular septum was the strongest predictor of VA and major cardiac events (MACE), the authors attributed this to involvement of the conduction system. The localization of LGE on the anterior wall was the most significant predictor of ventricular arrhythmias [16]. The differences may be explained by the fact that the first study examined NICMP patients with fundamentally different mechanisms of scar tissue formation, and the second study had differences with respect to end points, such that the present study evaluated reasonable actuations and

overall mortality, whereas the colleagues' study recorded both sustained and unstable ventricular tachycardia and a list of major cardiac events.

From the results of this study, we can conclude that patients with EF less than 35% and LGE greater than 14% may potentially have a higher chance of life-threatening arrhythmias. Further study may allow for individualization of approaches to primary prevention of SCD, which is particularly important in the context of the limited availability of these devices. We also see that patients with LV fibrosis volume exceeding 26% have worse prognosis in the remote period despite ICD implantation.

Limitations of the study

The limitations of the study include its retrospective nature and small sample size. The technique of LGE determination allows to verify only local fibrosis, while diffusely fibrosed myocardium is problematic to verify, which may explain the absence of fibrosis in 15% of our patients. This can be avoided by using more advanced scanning and post-processing programs such as T1-T2 mapping, extracellular space volume (ECV) determination. Also, peri-infarct (or «gray») areas were not evaluated in the present study, nor were the entropy values of scar tissue assessed.

CONCLUSION

In the present study, reasonable ICD triggers (shock/ATS) were recorded in 35.1%, with an overall mortality of 28.4%. The association between ICD triggering and degree of LGE occurred at LGE >14%. The association between total mortality and the degree of LGE occurred at LGE >26%.

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