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LONG-TERM EVALUATION OF FACTORS POTENTIALLY AFFECTING TRICUSPID VALVE AND RIGHT HEART CHAMBER FUNCTION IN PATIENTS WITH TWO ENDOCARDIAL RIGHT VENTRICULAR PACING LEADS A.B.Glumskov, S.S.Durmanov, V.V.Bazylev

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Aim. To assess factors influencing the degree of tricuspid regurgitation (TR) and the function of the right heart chambers in patients with two endocardial right ventricular leads of a permanent pacemaker.

Methods. A retrospective analysis of 5807 electronic medical records of patients who underwent primary implantation or planned replacement of a permanent pacemaker was performed. In 119 cases, a new right ventricular lead was additionally implanted, of which a group of 27 patients was selected according to the selection criteria. A control group of 129 patients was formed. Pseudo-randomization was performed, 27 comparable pairs were formed. To determine the predictors of TR progression, the logistic regression method for a multivariate model was used.

Results. In the late postoperative period, echocardiographic indices of both groups were virtually identical and were within the age norms. In the control group, minor TR was detected in 62.9% (n=17) of patients, moderate indices were diagnosed in 29.7% (n=8) of cases, and no TR was detected in 7,4% (n=2), respectively. In the observation group, minor TR was diagnosed in 74,1% of cases (n=20), moderate indices of insufficiency were diagnosed in 18.5% (n=5), severe TR was recorded in 3,7% (n=1) of patients, and TR was not detected in the same number of patients. Multivariate logistic regression identified the only independent predictor of TR progression in the postoperative period - the presence of non-paroxysmal atrial fibrillation (AF), which increases the probability of progression of the degree of tricuspid valve insufficiency in the remote observation period by 3/8 times. The relationship between the fact of the presence of two electrodes in the right ventricular cavity and the increase in the degree of tricuspid valve insufficiency was not determined.

Conclusion. In patients with two right ventricular leads, TR and right heart function don't change significantly in the long-term observation period. The leading factor influencing TR progression is the history of non-paroxysmal AF.

Key words: tricuspid valve; tricuspid regurgitation; right ventricular electrode; permanent pacemaker; atrial fibrillation.

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In 1958, A.Senning and R.Elmqvist in Sweden performed and described the first implantation of a permanent pacemaker (PM) in the anterior abdominal wall with an epicardial ventricular electrode. A few years later, in 1962, Parsonnet et al. (USA) and Ekstrom et al. (Sweden) developed and introduced the technique of transvenous implantation of permanent bipolar electrodes, which allowed for the implantation of pacemaker systems without thoracotomy and general anesthesia [1]. Since then, the use of such devices has increased exponentially. Over the past 60 years, cardiac implantable electronic devices (CIEDs) have become a standard method for treating cardiovascular diseases in patients with heart rhythm disorders: bradycardia, tachycardia, and chronic heart failure. In most cases, cardiac CIEDs are implanted with an electrode passing through the tricuspid valve (TV). The connection between the device electrode and the valve apparatus is a potential cause of tricuspid valve insufficiency, which, in turn, affects morbidity and mortality. Moreover, the severity of tricuspid regurgitation (TR) may progress over time. Early detection of electrode-associated TR is crucial for choosing optimal treatment.

The first reports of device-associated interference with the tricuspid valve apparatus appeared at the end of the 20th century, but only recently targeted efforts have been made to determine the scale of this problem. Since discontinuing the use of these devices is currently impossible and the benefit-to-harm ratio is considered optimal, better understanding of the mechanical complications associated with these interventions may potentially lead to improvements in device designs or, at least, the search for alternatives for certain patients. Implantation of any device requires positioning the endocardial ventricular electrode through the tricuspid valve.

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The relationship between surgical intervention and TR has not been widely studied, and published data on its frequency in the postoperative period contradict some authors, who report it as a rare phenomenon. However, interest in this topic has clearly increased due to the understanding that TR is not a benign condition, especially if associated with significant pulmonary hypertension and/or left ventricular dysfunction [2].

It is also important to note that during planned PM replacement, in some cases, the implantation of new electrode(s) is required, and the «old» electrodes are not always safely removable. For these reasons, it is clear that the extraction of a non-functional electrode is generally not required during reimplantation, except for certain infectious and non-infectious causes. The electrode of the device is considered a source of complications, including interference with the function of the tricuspid valve, caused by mechanical impact on the leaflet mobility or coaptation. Theoretically, direct intervention by the electrode in valve closure should increase in proportion to the number of implanted electrodes. The goal of this study was to perform a long-term evaluation of factors influencing the function of the right heart chambers and the degree of TR in patients with two endocardial right ventricular electrodes of a PM.

METHODS

The study was retrospective observational in nature, and the corresponding approval was obtained from the local ethics committee. A total of 5807 electronic medical records were analyzed for patients who underwent primary implantation or planned replacement of a permanent PM between 2008 and 2021. Among these, 119 patients had an additional right ventricular electrode implanted during planned PM replacement. Inclusion criteria:

• Presence of ≥ 2 endocardial electrodes in the right ventricular cavity (RV).

• Availability of echocardiography (Echo) results before planned PM replacement with implantation of the «new» right ventricular electrode and during long-term follow-up. Exclusion criteria:

- Severe valvular stenosis.
- Severe valvular insufficiency (excluding TR).
- Persistent severe TR postoperatively.
- History of open heart valve surgery.
- History of endocardial electrode extraction.
- Significant pulmonary hypertension in the preoperative
- period (pulmonary artery systolic pressure \leq 50 mmHg).
- Indications for implantation of ICD and cardiac resynchronization therapy (CRT).
- Postoperative follow-up ≤ 12 months.
- Left ventricular ejection fraction $\leq 40\%$.
- Age ≤ 18 years.

Based on the above conditions, a group of 27 patients was selected. Considering the exclusion criteria, 129 medical records of patients who underwent primary PM implantation during the same period were chosen. The main clinical and demographic characteristics of the groups are presented in Table 1. To ensure maximum comparability of the main and reference groups regarding existing confounders, pseudo-randomization was performed using a pair-matching method 1:1 by the nearest neighbor search. After balancing the groups, 27 pairs were formed, comparable based on the factors used in pseudo-randomization.

All interventions were performed in accordance with the recommendations of the VNOA [3] and the standard procedure [4]. Implantable PMs, both during planned replacements and primary implantations, were from manufacturers including Medtronic (Sensia SR and Vitatron G20

Table 1.

Baseline clinical and demographic characteristics of the patient groups

Indicator	Study group (n=27)	Control group (n=129)	p ₁	Control group PP (n=27)	p ₂
Male gender, n (%)	15 (55.6)	78 (60.5)	0.073	12 (44.4)	0.414
Age, years	67.6±12.9	74.3±9.8	0.106	73.9±9.8	0.065
Body mass index, kg/m ²	29.7±5.9	30.1±5.9	0.797	30.3±5.9	0.701
Hypertension, n (%)	24 (88.9)	124 (96.1)	0.14	26 (96.3)	0.299
Diabetes mellitus, n (%)	7 (25.9)	31 (24.0)	0.527	8 (29.6)	0.761
Ischemic heart disease, n (%)	9 (33.3)	59 (45.7)	0.263	11 (40.7)	0.573
TIA/ACVA, n (%)	3 (11.1)	25 (19.4)	0.19	4 (14.8)	0.685
Non-paroxysmal AF, n (%)	17 (63.0)	120 (93.0)	0	24 (88.9)	0.064
COPD, n (%)	1 (3.7)	13 (10.1)	0.266	1 (3.7)	1
Follow-up duration, months	64.4±39.9	75.7±39.0	0.085	74.6±37.5	0.339
Ventricular pacing, %	90 [82; 100]	48 [16; 92]	0	56 [28; 92]	0.011
Septal location of RV electrode (n)	22 (81.5)	104 (80.6)	0.485	24 (88.9)	0.444
Single-chamber pacemaker (VVIR) (n)	13 (48.1)	101 (78.3)	0.001	20 (74.1)	0.093
Ventricular pacing ≥40%, n (%)	22 (81.5)	-	-	18 (66.7)	0.089

Notes: PP - post pseudo-randomization; p_1 and p_2 - significance of differences between the study group and control groups; TIA - transient ischemic attack; ACVA - acute cerebrovascular accident; AF - atrial fibrillation; COPD - chronic obstructive pulmonary disease; PVE - right ventricular electrode; PM - permanent pacemaker.

SR); BIOTRONIK SE & Co. KG (Effecta SR, Philos SR, and Talos SR); St. Jude Medical (Verity ADx XL SR and Sustain XL SR); Boston Scientific Corporation (Altrua 20 SR). The new implanted right ventricular endocardial electrodes used were coated with silicone and silicone polyure-thane and had active fixation, including Capsurefix® Novus 5076-58cm (Medtronic) and Safio S 60 (BIOTRONIK SE & Co. KG), with diameters of 2.0 mm (6 Fr), Flextend 2 (Guidant Corporation) with a diameter of 2.4 mm (7.2 Fr), and Tendril ST (St. Jude Medical) with a diameter of 2 mm (6 Fr).

Conservative management, both during hospitalization and outpatient follow-up, was aimed at providing patients with optimal multi-component pharmacological therapy for both primary and comorbid diseases. In the postoperative period, routine evaluations of PM function were carried out, including interval echocardiography. The Echo studies were performed following current recommendations [5] using General Electric diagnostic ultrasound systems (Vivid 9, Vivid 7 Pro) with frequency-adjustable transducers ranging from 1.5/3 MHz to 2.3/4.6 MHz for thoracic studies. TR progression was defined as an increase in the degree of insufficiency by 1 or more levels.

Statistical analysis

The statistical analysis of the study results was performed using the IBM® SPSS® Statistics version 26 software (SPSS, Chicago, IL, USA). For the analysis, pseudo-randomization (propensity score matching, PSM) was used to balance the indicators in the groups to minimize the limitations of observational studies. Logistic regression with pair matching of corresponding observations was used based on a 1:1 ratio with the closest propensity score (PS) values. Matching of the observation pairs was carried out based on several factors, including gender, age, body mass index, duration of follow-up, history of hypertension, diabetes, ischemic heart disease, transient ischemic attack and/or acute cerebrovascular accidents, non-paroxysmal (persistent/permanent) atrial fibrillation (AF), chronic obstructive pulmonary disease, as well as the location of the right ventricular electrode and the type of implanted PM.

According to a number of studies, the threshold value for right ventricular stimulation is considered to be 40%, with exceeding this threshold potentially triggering the appearance or progression of signs of congestive heart failure and the progression of TR as a consequence [6]. Both groups differed in the absolute median value of cumulative right ventricular stimulation percentage both before and after matching the observation pairs. However, this parameter in both groups exceeded known threshold values for any type of implanted pacemaker. Thus, both groups were comparable in this regard.

Normality of the distribution of parameters was assessed using the Shapiro-Wilk test. For normally distributed data, the arithmetic mean with standard deviation (M±SD) was used, while for data with non-normal distribution, the median with interquartile range (25th and 75th percentiles) was reported. Frequencies and proportions (%) were used for qualitative data. Data from populations with normal distribution were compared using the Student's t-test for independent samples. Data from populations with non-normal distribution were compared using the Mann-Whitney U test and the chi-square (χ 2) test (Fisher's exact test was applied in some cases). For dependent samples, the Wilcoxon test was used. The critical level of statistical significance for hypothesis testing was set at 0.05.

To analyze the predictors of the appearance/progression of TR, multiple logistic regression was used. The dependent variable was defined as the increase in the degree of TR by 1 or more grades according to Echo during the follow-up period. The independent variables included age, body mass index, history of ischemic heart disease, non-paroxysmal AF, number of right ventricular electrodes, and electrode position (apical/septal).

RESULTS

When evaluating the dynamics of Echo indicators in both groups, a slight increase in left heart overload markers (degree of mitral regurgitation and/or left atrial volume)

Table 2.

EF, %	Study group (n=27)			Contro	*		
	EDV, ml		p	PreOp	PostOp	p	p.
Degree of MR	57 [53; 66]	60 [53; 65]	0,703	59 [55; 64]	60 [53; 62]	0,622	0,917
LA volume, ml	112 [101; 141]	113 [87; 137]	0,153	120 [106; 150]	116 [92; 150]	0,171	0,698
Degree of TR	1 [0; 1]	1 [1; 1]	0,035	1 [0; 1]	1 [1; 1]	1,000	0,978
TV FR, mm	71 [49; 83]	75 [68; 114]	0,005	80 [67; 108]	108 [86; 147]	0,001	0,013
RV size, mm	1 [1; 1]	1 [1; 1]	0,071	1 [0; 1]	1 [1; 2]	0,346	0,144
RA volume, ml	35 [29; 35,5]	34 [32; 37]	0,127	35,5 [33; 39]	36 [34; 38]	0,615	0,690
TR gradient, mm Hg	25 [23; 29]	27 [25; 34]	0,001	28 [25; 29]	28 [26; 30]	0,464	0,060
TAPSE	69 [48; 79]	62 [54; 102]	0,055	75 [52; 83]	81 [55; 115]	0,002	0,421
Градиент ТР, мм рт.ст.	22,1 [20; 29]	28,7 [24; 33]	0,018	22,1 [15; 33]	28 [22; 37]	0,064	0,959
TAPSE, CM	20,3 [19; 23]	21 [19; 23]	0,440	20,3 [20,3; 21]	21 [19; 21]	0,474	0,591

Comparison of EchoCG parameters in preoperative and remote follow-up periods

Note: PreOP and PostOP - preoperative and postoperative periods; p* - level of statistical significance for comparison of echocardiographic parameters in the distant postoperative period; EF - ejection fraction (by Simpson's method); EDV - end-diastolic volume (by Simpson's method); MR - mitral regurgitation; LA - left atrium; TR - tricuspid regurgitation; FR - fibrous ring (diameter); TV - tricuspid valve; RV - right ventricle; RA - right atrium.

was observed. There was also a minor increase in the RV, right atrial volume, and TR gradient, which indirectly indicated volume overload of the right heart chambers and subthreshold progression of TR. However, no change in the TR indicator was detected. Other ultrasound parameters showed no significant differences and were within the age-related norm (Table 2).

In the long-term postoperative period, Echo parameters for both groups showed no differences and were generally within the age-specific norms. The only exception was the left atrial volume in the control group, which was higher compared to the study group.

In the control group, 62.9% (n=17) of patients showed mild TR, 29.7% (n=8) had moderate TR, and 7.4% (n=2) had no TR. In the observation group, mild TR was diagnosed in 74.1% of cases (n=20), moderate TR in 18.5% (n=5), and severe TR was recorded in 3.7% (n=1) of patients, with the same percentage of patients having no TR (3.7% (n=1)) (Fig. 1).

Using multivariate logistic regression, the only independent predictor of TR progression in the postoperative period was the presence of non-paroxysmal AF, which increased the likelihood of progression by 3.8 times. No correlation was found between the presence of two electrodes in the right ventricular cavity and the degree of tricuspid insufficiency (Table 3). Additionally, no relationship was found between the dependent variable and the position of the stimulating electrode in the right ventricle (septal/apical).

DISCUSSION

TR is classified as primary (organic, degenerative) and secondary (functional). Primary TR is caused by structural damage to the TV apparatus and is observed in 8-10% of patients [7]. Secondary TR is more commonly seen, caused by either RV dilation due to volume or pressure overload (e.g., from pulmonary hypertension associated with left heart failure), «senile» degeneration of the tricuspid valve ring, or isolated dilation of the tricuspid valve ring due to long-standing persistent AF [8]. A special form of TR is associated with implantable electronic devices (CIEDs), occurring in 20-30% of patients with an implanted right ventricular electrode [9]. This type of insufficiency is also divided into primary and secondary. Primary TR is caused by the direct impact of the electrode on the structures of the tricuspid valve, while secondary TR occurs due to right ventricular dilation (as a result of chronic cardiac pacing and heart failure).



Fig. 1. Prevalence of tricuspid regurgitation in the longterm postoperative period

According to recent meta-analyses addressing the issue of electrode-associated TR, factors influencing the progression of TR were identified, including the interference of the TV leaflets with the electrode and the time of CIED implantation on one hand [10], and the enlargement of the right atrium and female gender on the other [11]. No significant difference was found between the type of implanted device (ICD or permanent pacemaker) and the degree of TR progression in the postoperative period. Additionally, in a meta-analysis by S. Alnaimat et al. (2023), seemingly logical predictors such as RV dysfunction, pulmonary artery pressure, preoperative significant mitral regurgitation, left ventricular ejection fraction, preoperative non-paroxysmal AF, and patient age were not associated with postoperative TR progression [11].

This issue in patients with multiple electrodes in the right ventricular cavity is not well addressed in meta-analyses and is generally underexplored. Part of this may be due to the extraction of «excess» electrodes and the characteristics of this patient group. The need for electrode removal arises in several situations, including when an electrode stops functioning properly, hindering optimal patient treatment, or when infection-related complications arise due to the implanted device [12]. In Russia, just over 40,000 devices are implanted annually, and the total number of patients with such devices is approaching 1 million (reliable statistics are unavailable). Of these, up to 5% of the total number of electrodes require removal [13]. The decision regarding transvenous extraction of electrodes is based on the opinion of several authors, such as M.S. Silvetti et al. (2008) and L.M. Epstein et al. (2017), who, despite the lack of randomized controlled studies comparing extraction with non-extracted electrodes, confirm the argument that «the potential future benefit of electrode removal outweighs the risks of not removing the electrode, and this refusal should be considered as a 'palliative procedure,' simply postponing the inevitable electrode removal in the future» [14, 15]. Transvenous extraction of electrodes may not be justified in patients with a poor prognosis or those whose intervention risks clearly outweigh the risks of not removing the electrodes [16]. In such cases, the electrode is left in the heart cavity, and it is essential to understand how this «additional» electrode will «coexist» with valve structures. Theoretically, the direct intervention of the electrode in the valve closure process should increase proportionally to the number of implanted electrodes in the RV cavity. The relationship between the number of electrodes in the RV and the degree of potential TR progression is reflected in a few studies. N. Postaci et al. (1995) [17] showed that the frequency of TR progression was predominant in patients with two right ventricular electrodes. In the study by C. Celiker et al. (2004), the overall frequency of mild and moderate TR did not show a significant difference between the groups (83% in the group with two right ventricular electrodes vs. 77% in the group with one) [18]. Compared to the results of N. Postaci et al. (1995), TR was less frequent and less pronounced in the two-electrode group. No significant TR or substantial differences in RV function were found in any group.

The frequently discussed idea of a connection between the progression of TR and RV failure with the location of RV

stimulation is reflected in several studies. Apical stimulation leads to «delayed» contraction of the RV papillary muscles, resulting in TR [9, 19]. The assumption that RV remodeling, dilation of the tricuspid ring, and, consequently, the development of functional TR, are outcomes of either systolic dyssynchrony in the case of apical stimulation or progressive reduction of LV systolic and diastolic function is supported by the retrospective study of M. Sadreddini et al. (2014). It was found that the degree of TR increased significantly after the implantation of a dual-chamber pacemaker but did not progress under biventricular stimulation, suggesting the «suppression» of the pathophysiological mechanisms of valve insufficiency development due to ventricular dyssynchrony in the CRT group [20]. In contrast, the analysis of the PROTECT-PACE study (145 patients, of whom 76 had apical and 69 had non-apical stimulation) showed that after 2 years of follow-up, the degree of TR increased, but the location of stimulation in the RV was not associated with changes in the echocardiographic parameters of the right heart chambers [21].

The choice of an alternative stimulation site, such as the outflow tract of the RV according to several authors [22], is a priority. Experts believe that apically implanted electrodes carry a higher risk of damaging the TV apparatus, especially the posterior leaflet, compared to electrodes fixed in the outflow tract of the RV [23, 24]. However, in the study by S. Hemayat et al. (2014), comparing both strategies [25], no clear influence of the implantation site on the progression of TR was found. It is important to note that stimulation of the RV septum is also far from physiological, but it leads to a narrower QRS complex on the ECG and may be associated with less negative long-term effects on both left and right ventricular echocardiographic and hemodynamic parameters. Despite the theoretical justification for positioning the RV electrode in the interventricular septum, clinical study data have contradictory results due to the lack of uniform criteria on this aspect. The middle part of the interventricular septum near the septomarginal trabecula is considered to be the most optimal site for electrode positioning [23].

In the review article by F. Akerström et al. (2013), a cumulative right ventricular pacing percentage of 40% was recognized as the threshold value, above which progression of heart failure and, consequently, an increase in TR could occur [6]. However, some studies show that a high percentage of right ventricular pacing does not correlate with TR progression [26, 27]. In our 2019 study, we evaluated the consequences of short-term active right ventricular pacing

length of the electrode. This results in encapsulation, possible adhesion to the leaflets and chordal apparatus, and subsequent malcoaptation [29]. It should be noted that such valve dysfunction manifests as significant increases in TR during the postoperative period and typically requires surgical correction of the developed defect.

It is worth mentioning that TR is present in 70-90% of the general population, not necessarily in those with implanted devices. Demographic aging, i.e., the increase in the elderly population within the general population, both globally and in the Russian Federation specifically, remains one of the most pressing issues in modern society [30]. The prevalence of moderate or severe TR increases with age and reaches 4% in patients aged 75 and older [31]. In other words, the onset and progression of TR is a natural process of age-related degeneration of cardiac structures and is not always directly or indirectly related to implanted electronic devices.

Our study results are similar to those of the research groups of N. Postaci et al. (1995) and C. Celiker et al. (2004), where no significant increase in TR was observed in the group with two electrodes. No effect of the RV stimulation site on the measured parameter was found either. However, the increase in TR and a number of linear and volumetric parameters in the postoperative period in both observation groups is most likely due to the «burden» of AF. This finding supports the study of M.F. Dietz et al. (2020) [8] and aligns with the results we obtained. Despite this, the normal range of ultrasonographic parameters suggests that these changes do not cause significant hemodynamic overload at this stage of patient follow-up.

Limitations of the study

The limitations of our study include the typical drawbacks of retrospective research. The selected patient group is limited to a single center, which prevents the avoidance of sample bias. The intervals between Echo studies were variable, making it impossible to fully assess the chronological structural and functional changes in the heart chambers and structures. This certainly requires prospective observation. Additionally, this study lacks 3D Echo data, which hinders the ability to determine the exact mechanism of TR progression, and the true severity of valve insufficiency after pacemaker implantation may have been underestimated. There are also questions regarding the differences in defining the progression of tricuspid valve insufficiency in various studies, which could lead to discrepancies in the final results.

Table 3.

(60-90 minutes), and no acute effects on the function of the right heart chambers or degree of TR were observed [28]. Another mechanism of electrode-associated TR is the fibrotic and inflammatory reaction to the foreign body. Chronic repeated contact between the device electrodes and the valve leaflets or chordal structures leads to the formation of neoendocardium and the development of a fibrinous shell

that can extend along the entire

Predictors of TR progression: results of multiple logistic regression.

	В	Significance	Exp (B)	95% CI
Age	0,005	0,797	1,005	0,970-1,041
Body mass index, kg/m ²	-0,024	0,446	0,977	0,919-1,038
Ischemic Heart Disease	0,123	0,730	1,131	0,562-2,279
Group*	0,489	0,349	1,631	0,586-4,544
Electrode Position	-0,066	0,882	0,936	0,390-2,246
Non-paroxysmal AF	1,341	0,025	3,824	1,179-12,401
Constant	-0,902	0,627	0,406	-

Note: * - observations or controls.

CONCLUSION

In patients with two right ventricular electrodes, tricuspid regurgitation and the function of the right heart

chambers do not change significantly in the long-term follow-up period. The main factor influencing the progression of tricuspid regurgitation in the long-term follow-up period is a history of non-paroxysmal atrial fibrillation.

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