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Effects of implantable cardiac devices on the tricuspid regurgitation and right ventricle function

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Abstract

Background: Implantable cardiac pacemaker devices, like pacemakers and implantable cardioverter-defibrillators (ICDs), may adversely affect the function of the right side of the heart and the tricuspid valve. This study aimed to evaluate the presence of right ventricular (RV) dysfunction and tricuspid regurgitation (TR) using 2D echocardiography following cardiac pacemaker device implantation.

Methods: This prospective cohort study was carried out on 30 patients with indications of implanted permanent pacemaker's leads according to guidelines. All patients were subjected to 12-lead ECG and echocardiography assessment.

Results: After 6 months of pacemaker device implantation, TR and pulmonary artery systolic pressure (PASP) were significantly higher than baseline. Meanwhile tricuspid annular plane systolic excursion (TAPSE), RV E/E, RV S' velocity and Fractional Area Change (FAC) were significantly lower than baseline.

Conclusion: Implantable cardiac pacemaker devices showed a negative impact on both TR and RV function, as evidence of TR and RV dysfunction can be observed six months following device placement.

Keywords: Implantable cardiac pacemaker devices, right ventricle function, tricuspid regurgitation

Introduction

Patients with heart rhythm problems have seen a dramatic rise in the number of cardiac device implantations in the past decade, including biventricular pacemakers (BiV), implanted cardiac defibrillators (ICDs), and permanent pacemakers (PPMs). This trend is expected to persist due to several factors, including longer life expectancy, more frequent cardiac disease cases, better treatments for coronary heart disease resulting in higher patient survival rates, and an increase in conduction disturbances, left ventricular dysfunction, and heart failure (HF). As a result, there are more and more reasons to use these devices ^[1].

Devices such as permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs) are prevalent in modern medicine for the treatment of cardiac conduction abnormalities and potentially fatal arrhythmias. Tricuspid regurgitation (TR) is a common valve problem that has become more common since the introduction of new implant procedures and technologies. TR is mostly induced by secondary causes that result in right ventricle (RV) and tricuspid annular dilatation ^[2].

An estimated 7-45% of RV lead implantations experience right ventricular trans tricuspid pacing lead interference with the tricuspid valve, which could lead to or be a contributing factor in TR. There is a correlation between the RV leads of cardiac implantable electronic devices (CIEDs) and the progress of TR, which is linked to poor outcomes. The long-term effects of lead-induced TR on RV function are related to decreased survival ^[3].

There are two types of CIED-induced TR: the primary and secondary. New evidence suggests that secondary CIED-induced TR accounts for as much as 60% of worsening TR following CIED implantation. Secondary CIED-induced TR originates from RV dilatation caused by pacing or heart failure, in contrast to primary CIED-induced TR, which is generated by the lead's direct contact with the tricuspid valve. When primary CIED-induced TR goes untreated, it causes RV dilatation because of volume overload, which in turn causes secondary TR. Once lead extraction reaches this "point of no return," it will be unable to reverse TR ^[4].

A point of debate has been the use of echocardiography to assess RV systolic function and RV ejection fraction (RVEF). Our two-dimensional (2D) echocardiography system offers a variety of methods for assessing the heart, including tricuspid annular plane systolic excursion (TAPSE), right ventricular systolic excursion velocity (S' Velocity), the presence of a tricuspid annulus (TR), the length of the right ventricle (RV), the diameters of the basal and mid RV, the right ventricle (RV E/E'), fractional area change (FAC), and minor axis diameters, as well as visual estimation [5].

This study set out to use 2D echocardiography to determine how often RV dysfunction and TR occurred following the implantation of cardiac devices.

Patients and Methods

Participants in this prospective cohort study ranged in age from 33 to 78 years and were of both sexes. They were evaluated for symptoms associated with implanted PPM leads in accordance with established protocols.

The study took place from December 2022 to June 2023 at Tanta University Hospitals in Tanta, Egypt, with the permission of the Ethical Committee. Every patient gave their signed, informed consent.

Insufficient echocardiographic image quality, patients with congenital heart disease, prior endocardial leads, prior tricuspid valve surgery, severe aortic stenosis, mitral or tricuspid valve stenosis of any degree, MR > grade 2, and patients who refused to provide written informed consent were all excluded from the study.

All patients were subjected to: history taking (smoking, hypertension, hypercholesterolemia, coronary artery disease (CAD) and diabetes mellitus (DM)), complete clinical examination included measurement of [heart rate and rhythm, respiratory rate, temperature, systolic and diastolic blood pressure, and pulse] and 12-lead electrocardiogram (ECG).

Echocardiographic assessment: Every patient had it done twice: once at baseline and again after the device had been implanted for six months. The reported parameters included TR presence, RV length, basal and mid RV diameters, and right ventricular areas traced at end-diastolic and end-systolic periods. RV fractional area change (FAC) was estimated using these parameters right atrial (RA) major and minor axis diameters: RA size and function was assessed in the apical four-chamber view. Tricuspid annular plane systolic excursion (TAPSE) and tricuspid lateral annular systolic velocity (S-wave) were measured using M-mode and Doppler tissue imaging, respectively. Velocity, ratio of RV E to E', and FAC [6].

Follow-up

Echocardiographic examinations, evaluations of cardiac devices, and clinical assessments were all carried out throughout the follow-up period. Throughout the duration of the follow-up, an echocardiography was conducted. Every single patient who was a part of the study made it through the whole follow-up.

Statistical analysis

The statistical analysis was conducted using SPSS v26 (IBM Inc., Chicago, IL, USA). The quantitative data were displayed as mean and standard deviation (SD) and

compared between the two groups using an unpaired Student's t-test. Qualitative variables were displayed as frequency and percentage (%) and assessed using the Chi-square test or Fisher's exact test as needed. A two-tailed P value less than 0.05 was deemed statistically significant.

Results

The mean age was 69.1±8.99 years. There were 15 (50%) males and 15 (50%) females. The mean weight was 82.17±9.45 kg. The mean height was 165.57±6.55 cm. The mean body mass index (BMI) was 30.04±3.57 kg/m². Table 1.

Table 1: Demographic data of the studied patients

		N=30
Age (years)		69.1±8.99
Sex	Male	15 (50%)
	Female	15 (50%)
Weight (kg)		82.2±9.45
Height (cm)		165.6±6.55
BMI (kg/m ²)		30±3.57

Data are presented as mean ± SD or frequency (%). BMI: Body mass index

Regarding risk factors, 13 (43.33%) patients were smokers, 21 (70%) patients had hypertension (HTN), 18 (60%) patients had DM, 15 (50%) patients had hyperlipidemia, 13 (43.33%) patients had CAD. Rhythm was CHB in 24 (80%) patients, Mobitz II in 2 (6.67%) patients and HB 2:1 in 4 (13.33%) patients. The mean temperature was 37±0 °. The mean HR was 40.17 ±6.62 beat/min. The mean SBP was 118.33±19.13 mmHg. The mean DBP was 75.33±10.74 mmHg. The mean RR was 13.5 ±1.01 breath/min. Table 2.

Table 2: Risk factors and vital signs before implantation of the studied patients

		N=30
Smoking		13 (43.33%)
HTN		21 (70%)
DM		18 (60%)
Hyperlipidemia		15 (50%)
CAD		13 (43.33%)
Rhythm	CHB	24 (80%)
	Mobitz II	2 (6.67%)
	HB 2:1	4 (13.33%)
Vital Signs		
Temperature (°)		37±0
HR (beat/min)		40.2±6.62
SBP (mmHg)		118.3±19.13
DBP (mmHg)		75.3±10.74
RR (breath/min)		13.5±1.01

Data are presented as mean ± SD or frequency (%), HTN: hypertension, DM: diabetes mellitus, CAD: Coronary artery disease, CHB: Congenital heart block, HB: heart block, HR: heart rate, SBP: systolic blood pressure, DBP: diastolic blood pressure, RR: respiratory rate

TR, pulmonary artery systolic pressure (PASP) was significantly higher after 6 months of device implantation than baseline (P value <0.05). TAPSE, RV E/E', RV S' velocity and FAC were significantly lower after 6 months of device implantation than baseline (P value < 0.05). RV length, RV basal diameter, RV mid diameter, RA major axis and RA minor axis were insignificantly different between baseline and after 6 months. Table 3.

Table 3: Echocardiography assessment between Baseline and after 6months of device implantation and pacemaker's device implantation of the studied patients

	Baseline	After 6 months	P value
Device Implantation			
TR	2 (6.67%)	12 (40%)	0.002*
Pacemakers' Device Implantation			
RV length (mm)	57.1±6.72	54.9±6.45	0.086
RV basal diameter (mm)	33.4±4.85	31.6±5.18	0.162
RV mid diameter (mm)	25.4±4.91	25.5±4.15	0.931
RA major axis (mm)	39.1±6.64	40.9±7.14	0.230
RA minor axis (mm)	31.6±7.05	31.2±7.39	0.825
PASP (mmHg)	21.7±5.21	26.1±2.67	<0.001*
TAPSE (mm)	21.3±4.6	19±2.59	0.020*
RV S' velocity	13.9±2.34	11±2.64	<0.001*
RV E/E	9.9±2.34	7.6±2.31	0.002*
FAC (%)	42±4	37.8±6.69	0.006*

Data are presented as mean ± SD or frequency (%), *significant p value <0.05, TR: Tricuspid regurgitation, RV: right ventricle, RA: right atrium, PASP, pulmonary artery systolic pressure, TAPSE: tricuspid annular plane systolic excursion, FAC, fractional area change

There were two patients with TR at baseline, one had HTN, one had DM, one had hyperlipidemia and one had CAD. No one of TR patients were smokers. There were twelve patients with TR after 6 months, 4(33.3%) patients were smokers, 8(66.6%) patients had hypertension, 7(58.3%)

Table 5: Multiple regression between TR measurements and risk factors

	TR at baseline			TR after 6 months		
	Coefficient	OR	P value	Coefficient	OR	P value
Age	-4.046	0.0175	0.997	0.076	1.07	0.266
Sex	-115.13	9.9738	0.998	0.178	1.19	0.919
Smoking	159.38	1.6635	0.997	0.362	1.43	0.845
HTN	-40.04	4.065	0.523	0.835	2.30	0.460
DM	-20.73	9.8817	0.772	0.063	1.06	0.940
Hyperlipidemia	-11.44	0.0000	0.806	-0.121	0.88	0.907
CAD	-61.21	2.6109	0.495	0.076	0.99	0.996

TR: tricuspid regurgitation, HTN: hypertension, DM: diabetes mellitus, CAD: coronary artery disease. OR: odds ratio

Discussion

The right side of the heart and the tricuspid valve are two areas that implantable cardioverter-defibrillators (ICDs), pacemakers, and other similar devices can affect in both good and bad ways [7].

In the present study, there were two (6.67%) patients with TR were found at baseline then the patients' number increased after 6 months follow up to 12 (40%) patients, TR was significantly higher after 6 months of pacemakers' device implantation than baseline (P value= 0.002).

In accordance with the present study, Abd Elaziz *et al.* [8] reported that 25 patient had trace TR (grade 0), and 6 patients after device implantation, 75 patients had mild TR (Grade 1), and 82 after device implantation, with no patient had moderate TR (Grade 2), and 12 patients after device implantation. TR worsened by one grade in 25 patients, (16 patients from grade 0 to grade 1 and 9 patients from grade 1 to grade 2) and by 2 grades in 3 patients (from grade 0 to grade 2). They concluded that TR was significantly higher after pacemaker's device implantation than baseline (P value= 0.002).

Similarly, Kunal *et al.* [9] showed that TR was significantly higher after 6 months of pacemaker's device implantation than baseline. Arabi *et al.* [10] observed that TR was higher

patients had DM, 6(50%) patients had hyperlipidaemia and 5(41.6%) patients had CAD. There was no relation between TR (at baseline and after 6 months) and risk factors. Table 4.

Table 4: Relation between tricuspid regurgitation (At baseline and after 6 months) and risk factors

TR at baseline (n=2)		
		P value
Smoking	0 (0%)	0.492
HTN	1(50%)	0.517
DM	1(50%)	0.765
Hyperlipidemia	1(50%)	1.00
CAD	1(50%)	0.843
TR after 6 months		
Smoking	4(33.3%)	0.366
HTN	8(66.6%)	0.745
DM	7(58.3%)	0.879
Hyperlipidemia	6(50%)	1.00
CAD	5(41.6%)	0.880

Data are presented as frequency (%), TR: tricuspid regurgitation, HTN: hypertension, DM: diabetes mellitus, CAD: coronary artery disease

The risk factors (Smoking, HTN, DM, hyperlipidemia and CAD) were not predictors for TR at baseline and after 6 months and right ventricular function (RVF). Table 5.

after 6 months of pacemakers' device implantation than baseline, but the difference was insignificant.

This study revealed that there was no incidence of heart failure either initially or during the follow-up period after pacemaker device implantation.

The absence of adverse clinical outcomes, such as heart failure, might be attributed to the short duration of the follow-up period [10].

This study showed that PASP were significantly higher after 6 months of pacemakers' device implantation than baseline (p value <0.001).

Concurring with the current study, Höke *et al.* [11] confirmed that PASP were significantly higher after 12-18 months of pacemaker's device implantation than baseline. Similarly, Kunal *et al.* [9] found that PASP were significantly higher after 6 months of pacemaker's device implantation than baseline. On the contrary, Arabi *et al.* [10] found that PASP was insignificant between baseline and after 6 months of pacemakers' device implantation, however this can be due to larger sample size. In this study, TAPSE, RV E/E, RV S' velocity and FAC were significantly lower after 6 months of pacemakers' device implantation than baseline (P value<0.05). In accordance with the current study, Kunal *et al.* [9] noted that TAPSE, RV E/E, RV S' velocity and FAC

were significantly lower after 6 months of pacemakers device implantation than baseline. On the contrary to the current study and Kunal study, Höke *et al.* ^[11] observed that TAPSE and FAC showed insignificant differences after 12-18 months of pacemaker's device implantation than baseline. This difference may be attributed to the large sample size.

Arabi *et al.* ^[10] found that TAPSE was insignificant between baseline and after 6 months of pacemakers' device implantation.

This controversy to results of present study may be due to the presence of implantable cardiac devices that can have an impact on RV function. The placement of leads and the presence of the device itself can lead to changes in RV mechanics and function. Lead-related issues, such as suboptimal lead placement or lead-induced tricuspid valve dysfunction, can affect parameters like TAPSE ^[12].

Moreover, Abd Elaziz *et al.* ^[8] stated that TAPSE was insignificantly different after pacemakers device implantation compared to follow up. This difference may be attributed to variations in the type of implanted devices, lead placement can influence the effects on RV function and the measured parameters. Differences in lead positioning or lead-related complications can impact outcomes.

These results revealed that RV length, RV basal diameter, RV mid diameter, RA major axis and RA minor axis were insignificantly different between baseline and after 6 months. Similarly, Kunal *et al.* ^[9] noted that RV length, RV basal diameter, RV mid diameter, RA major axis and RA minor axis were insignificantly different between baseline and after 6 months.

Limitations: The sample size was limited. The study was conducted at a single center. Patient follow-up was confined to a relatively short duration. Additional prospective multicenter trials are required. Patients undergoing cardiac device implantation are recommended to be subjected to Echocardiography after 6 months of device implant.

Conclusion

Implantable cardiac devices have a negative impact on both TR and RV function, as evidence of TR and RV dysfunction can be observed as soon as six months following device placement.

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Conflict of Interest: Nil.

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