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Research Article

A COMPARATIVE STUDY ON RIGHT VENTRICULAR OUTFLOW-TRACT AND RIGHT VENTRICULAR APICAL PACING IN ELDERLY PATIENTS WITH COMPLETE HEART BLOCK HAVING NORMAL LEFT VENTRICULAR EJECTION FRACTION

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ABSTRACT

Background: *Right ventricular apical pacing is the traditional location for implantation of ventricular leads, However RVA-Pacing stimulates the ventricles in a non-physiological manner, causes myofibrillar disarray, and asymmetric left ventricle hypertrophy and, hemodynamic dysfunctions. The current research focuses, to evaluate RVOT pacing as an alternative site, in relation to RVA pacing in patients having persistent high-grade AV block with standard signs for irreversible ventricular pacing.*
Methods: *Our study consists of 70 patients with permanent pacing indications. All of them underwent for dual chambers pacemaker implantation, at the Department of Cardiology, 1st Affiliated Hospital of Xi'an Jiaotong University, from 1st June 2017 to May 2020 and, prospectively randomized to two groups (RVA=35) and, (RVOT=35) groups, with median of 25-months' follow-up.*
Results: *In 25 months of follow-up, the mean QRS-complex narrowed from the widened baseline-QRS in the RVOT pacing group compared to RVA pacing group (143.36±12.90 to 106.52±14.12), P=0.001 ;(142.18±10.83 to 143.62±12.90), P=0.901. Total 9 (9/35, 32.52%) cases of new chronic atrial fibrillation were observed in RVA pacing P=0.001 (P < 0.05), while only 3 (3/35, 10.83%) were observed in RVOT group. A statistical significant relationship found between the baseline and final LVEF% in RVA pacing group (P=0.02), while no statistical difference between the RVOT pacing group. The patients with Plasma B-type Natri-uretic peptide (BNP) level (100-400 pg/mL) were 15, 3 patients in RVOTS (P=0.963) while 11 in RVA (P=0.05). In RVA-pacing there were six (6/35) patients whose, BNP level was > 400 pg/mL, (P=0.04), but only one patient in the RVOTS pacing group (P=0.153).*
Conclusion: *RVOT pacing is associated with significant increase in hemodynamic functions, and limited cases of new Chronic atrial fibrillation.*

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Keywords: *Right Ventricular Apical Pacing, Right Ventricular Out flow tract pacing, Permanent pacemaker, Complete Heart Block, Chronic Atrial Fibrillation, NYHA, and Atrioventricular valves Regurgitation, AV Blocks.*

1. INTRODUCTION:

The right ventricular apical (RVA) pacing has been extensively used as the best suitable pacing site for years and, has been conventionally desired for the interpolation of long-lasting cardiac pace-maker leads due to immense familiarity with their procedure, their simplicity of implantation, the coherence of active leads insertion [1] and, relatively low probability of penetration in the Right Ventricular apical trabeculae [2]. However Right ventricular apical Pacing stimulates the ventricles in such a non-physiological manner, almost opposite to the standard stimulation of the ventricles from its base to the apex. Previous research studies have shown that, right ventricular apical (RVA) pacing causes myofibrillar disarray, asymmetric left ventricle hypertrophy [3], dystrophic calcification, mitral regurgitation [4] [5], fat deposits, progressive fibrosis [6] and, impaired quality of life [7].

The specific pathophysiology for the significant negative consequences of right ventricular apical (RVA) has still not been adequately documented and appears to be complex and multifaceted [8]. Though several investigations indicated that the extent of ventricular dyssynchrony throughout RV pace-setting was depending on several physiological conditions of myocardium [9]. The RVAP conduction associated with perpendicular activation of muscle fibers and, it is twice as fast in muscle fibers, while slowed conduction is observed when the stimulation appears elliptical, especially in the epicardial and myocardial layers [10]. Though not surprised that, electrical asynchrony is concerned for both intra and inter-dyssynchrony in left ventricle myocardial contraction. Many other research studies demonstrated that asynchrony affects both diastolic and systolic functions at certain stages, particularly in isovolumetric contraction and relaxation [11].

Long-term right ventricular apical (RVA) pacing studies demonstrated a great interest for alternate pacing sites with some more positive effects on LV-contraction and better hemodynamic effects, to mitigate the above-mentioned damaging effects. The right ventricular outflow tract (RVOT) has become the most extensively researched of these RVNA (right ventricular non-apical) pacing sites. Many experimental studies have demonstrated that the pacing of the RVOTS (right ventricular outflow tract septum) tends to become effective in improving hemodynamic, Left Ventricle diastolic and systolic functions, providing a better cardiac-output and stroke volume as compared to right ventricular apical (RVA) pacing, all because the ventricles are triggered by almost natural physiological stimulation of purkinje system, in right ventricular outflow tract (RVOT) pacing [12-15].

The current research focuses, to evaluate RVOT pacing, in relation to RVA pacing in patients, having persistent high-grade AV block with standard signs for irreversible ventricular pacing. As well as, new occurrence of atrial fibrillation, NYHA (New York heart association) functional class, degree of atrio-ventricular valves regurgitation, ECG axis & duration of QRS, LVEF (Left Ventricular Ejection Fraction), and BNP (B-type natriuretic peptide) level to determine long-term evaluation of Right Ventricular Outflow Tract (RVOT) pacing to cardiac structure and functioning may be advantageous to RVAP.

2. MATERIALS AND METHODS

It was a single Centre prospective study of chronic high degree Atrioventricular or complete heart blocks patients, needs of permanent pacemaker implantation for their treatment. Our study consists of 70 patients with predictable pacing symptoms for permanent pacing were enrolled. All of them underwent for dual chamber permanent pacemaker implantation, at the Department of Cardiology, 1st Affiliated Hospital of Xi'an Jiaotong University, from 1st June 2017 to May 2020 and prospectively randomized to receive right ventricular apical (RVA) or right ventricular outflow tract septum (RVOTS) pacing. A dual chamber pacemaker (models 5286 and 5356, St. Jude Medical, MN, USA) along with two bipolar activated-fixation pacing leads (models TENDRILTMST 1888TC, St. Jude Medical) were suggested for implantation in patients. The inclusion criteria were as follows: (1) participants should be within the age of 60-85 years old (2) participants must free of CHF (Congestive Heart Failure) and, CRF (Chronic Renal Failure) symptoms and (3) patients should not have prior pacemaker implantation and, (4) all participants should not have a history of prior atrial fibrillation before implantation of the pacemaker. The participants were equally divided into two groups; RVA-paced group (n = 35) and RVOTS group (n = 35). All participants were subject to give a written consent to participate in the study. And formal approval from the research and ethics board of hospital was taken. Throughout total 25 months' duration of follow-up, all the accessible data was compiled including, QRS axis and duration, Plasma BNP (B-type Natri-uretic peptide) level, Echocardiographic characteristics, and functional class of NYHA (New York Heart Association). These parameters were then correlated between both the RVOT group and the RVA group, as well as in between the pre-implantation and post-implantation of pacemakers in the RVOTS group and in the RVA pacing group.

3. FOLLOW-UP CRITERIA

The pacemakers were configured with a minimum frequency of 60 beats per minute and a maximum frequency of 160 beats per minute. Initially, the atrio-ventricular interval of

pacemakers, model 5286 / 5356 was configured to the average value of 160 ± 30 milliseconds. Follow-up visits were performed at 12 and 24 months after implantation by a qualified electrophysiologist. Additional investigations were carried whenever patients had discomfort, possibly triggered due to pacemaker implantation. The data was analyzed and documented in the database during follow-up. The devices data which was controlled and programmed, such as the percentage of ventricular pacing, pacing limit, susceptibility and electrodes affinity. In particular, the assessment of the NYHA status of the patient was associated with clinical indications, chest X-rays to validate the position of the electrode implanted (projections of PA, RAO 30 ° and LAO 45 °), 12-lead ECG recordings, the existence of persistent atrial fibrillation, 24-hour Holter observation, echocardiography for the cardiac function and structure, and also measurements of the BNP- level. Completed results been used for statistical data analysis, comprising mean ventricular pacing percentage, median pacing period, and functional class of the NYHA, while statistical analysis was conducted using Plasma B-type Natri-uretic peptide (BNP), first or last QRS complex, QRS axis, and echocardiographic data. Effective medical care has been provided to patients during the follow-up period.

4. STATISTICAL ANALYSIS

Statistical analysis was performed using IBM, SPSS version 25. Continuous variables are presented as mean, SD, whereas categorical variables are expressed as percentages. Comparisons among different parameters were performed by the chi-square and independent t-test. Results among the Initial and Final variables were considered statistically significant with the (P <0.05).

5. RESULTS

The baseline characteristics was statistical non-significant between the two group patients Table1.

5.1 ECG and Pacing Parameter changes during the Follow-up:

There was no difference for mean pacing period among the RVOT and RVA groups, 25 months (Table 1). The mean QRS-complex narrowed from the widened baseline QRS in the RVOT pacing group in comparison with the QRS complex of RVA pacing group (143.36±12.90 to 106.52±14.12), P=0.001 ;(142.18±10.83 to 143.62±12.90), P=0.901 (Figure1). As compared with the initial axis, the final investigational axis had a trend to left axis deviation in the right ventricular apical (RVA) pacing group 41.2(-44-99) to -11(-45-53), P=0.004, in comparison to RVOT pacing group 42.4(-50-102) to 50(55-105), P=0.003, the frontal plane axis returned roughly to the normal axis (Table 2). For statistical analysis, comprehensive pacing variables, which include ventricular and atrial pacing threshold, electrode impedance and sensitivity, were documented without either apparent intragroup or intergroup variations.

5.2 Patients clinical assessment:

In the right ventricular apical (RVA) group, total 9 (9/35, 32.52%) cases of new CAF (chronic atrial fibrillation) were observed during follow-up, P=0.001 (P < 0.05), while only 3 (3/35, 10.83%) were observed in RVOTS (right ventricular outflow tract septum) group. (Table 2 & Figure6).

A statistically significant association (P=0.041) was found, when the NHYA class II and III patients increased in RVA group, at the end of follow-up, (Table 2). At the completion of follow-up, significant association (P=0.001) was found between pre and post implantation as the mean BNP level increased to (153 pg/mL) in the RVA group which was 40.2 pg/mL initially (Figure 2). Additionally, there was a statistically significant variation observed between the RVA and RVOTS group, in the overall average BNP level. The patients with Plasma B-type Natri-uretic peptide (BNP) level (100-400 pg/mL) were 15 which includes 3 patients in RVOTS (P=0.963) while 11 in RVA (P=0.05). In RVA (right ventricular apical) pacing there were six (6/35) patients whose, BNP level was > 400 pg/mL, (P=0.04), but only one patient in the RVOTS pacing group (1/35), P=0.153 (Table 2) (Figure 3).

5.3 Echocardiography evaluation:

A statistical significant relationship found between the bassline and final left ventricular ejection fraction (LVEF %) in RVA pacing group (P=0.02), (P < 0.05), while no statistical difference between the RVOT pacing group. Figure 4. The (IVS, interventricular septum and PW, posterior wall) thickness was found to be significantly increased in RVOT pacing group, IVS (P<0.01) and PW (P=0.02), though the ratio of PW/IVS remained the same as compared to initial thickness, (1.06 ± 0.17 vs 1.01 ± 0.18), (P=0.171). A difference in IVS was not reported during final echocardiographic tests in the RVA group in comparison to the original values; however, significant association was found in PW thickness as well, PW (P = 0.004) and IVS (P = 0.001) (Figure5). The Echocardiography found no initial and final Statistical significance among the (LA, LVESD, and LVEDD or A and E peak velocity) in RVA, while Significant association was observed (P=0.039), as moderate increase in tricuspid valve regurgitation with in RVA pacing group (Figure 6).

Table 1; Baseline Characteristics and Co-Morbid Diseases among the Study-Population			
Contents	RVA Pacing (n=35)	RVOT Pacing (n=35)	p-values
Age (years), Median	72 (60—80)	73 (60—80)	0.683
Pacing duration, months	25.5	25	0.732
Percentage of pacing	83.82±12.64	81.39±13.31	0.771
Men	21 (57%)	23(59%)	0.735
CAD	7 (18%)	8 (19%)	0.958
DM-2	3 (10%)	4 (12%)	0.573
Hypertension	16 (59%)	15 (58%)	0.633
LA (mm)	34.25 ± 3.94	35.28 ± 5.82	0.653
IVS (mm)	11.01 ± 1.32	10.01 ± 1.87	0.869
PW (mm)	10.00 ± 1.45	9.95 ± 1.93	0.563
LVEDD (mm)	46.28 ± 3.36	47.16 ± 3.05	0.517
LVESD (mm)	33.18 ± 4.13	34.45 ± 4.88	0.647
IVS/PW	1.02 ± 0.13	1.01 ± 0.15	0.667
LVEF%	62.5 ± 5.41	61. 3 ± 5.02	0.281
QRS Duration (ms)	105.28± 17.32	105.3 ± 17.34	0.688
QRS Axis(^{0}), median	40(-44-100)	38 (-45-105)	0.232
BNP (pg/ml)	39.78 ± 12.27	40.65 ± 13.46	0.861
Indications for pacing			
(II^0)	9(11%)	10 (13%)	0.655
(III^0)	26 (89%)	25 (87%)	0.427
Pacemaker mode			
DDD	29 (92%)	27 (89%)	0.762
DDDR	6 (9%)	8(11%)	0.617
Diuretics	11(39%)	10 (32%)	0.423
Beta blockers (BB)	12(45%)	12 (45%)	0.674
Calcium channel blockers(CCB)	14 (54%)	14 (54%)	0.827
ACEI/ARBs	9 (13%)	10 (15%)	0.738

Table 2: Comparison of Electrocardiogram, BNP, and Echocardiography found during follow-up in both groups.

Contents	RVAP		RVOTP		P values	
	initial	final	initial	final	RVAP initial vs. final	RVOTP initial Vs. final
QRS duration(MS)	142.18	143.62	143.36	106.52	0.901	0.001
QRS axis^0, Median	41.2(-44-99)	-11(-45-53)	42(-50-102)	50(55-105)	0.004	0.003
New cases of CAF	1(4.49%)	10(32.52%)	1(4.49%)	3(10.83%)	0.001	0.109
LVEF %	62.53±6.21	48.24±8.73	61.82±6.06	58.37±5.54	0.002	0.152
NYHA class;						
II	1	9	1	3	0.041	0.173
III	0	4	0	1		
Moderate "MR/TR"	2(11.75%)	10(53.38%)	1(5.34%)	4(20.89%)	0.039	0.131
BNP, Median(pg/ml)	40.2	153	39.4	56.2	0.001	0.102
100—400 (pg/ml	0	11	0	3	0.050	0.963
>400	0	6	0	1	0.048	0.153

Comparison of parameters between RVAP and RVOTP from preoperative to postoperative treatment. CAF=chronic Atrial Fibrillation, LVEF=Left Ventricular Ejection Fraction, MR=Mitral Regurgitation, TR =tricuspid Regurgitation, BNP= B-Type Natriuretic Peptide.

Figure 1, QRS duration Comparison among the RVAP vs RVOTP

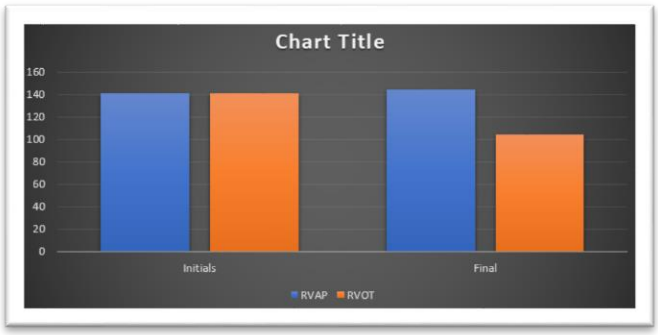


Figure1: QRS-Duration comparison between RVAP and RVOTP groups, from pre-implantation to End of follow-up. The RVOT pacing group shows narrowing in width of QRS duration from preoperative to end of follow-up, while in RVAP group the QRS width remain unchanged.

Figure 2: NYHA class comparisons among the patients of RVAP vs RVOTP

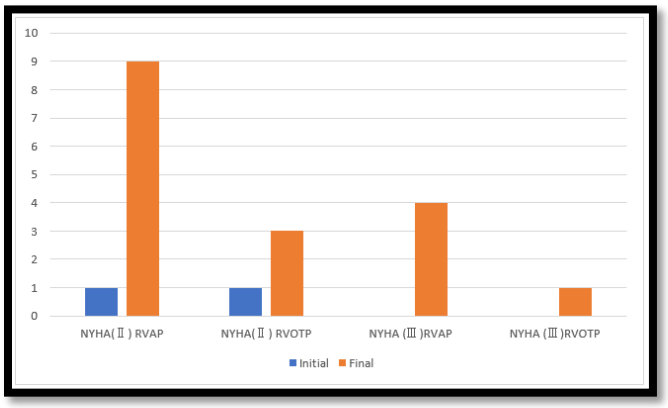


Figure 2: Graph shows that there is increasing tendency of heart failure patients in RVAP group after permanent pacing as compared to RVOT, NYHA (New-York heart Association).

Figure 3: BNP measurements and comparisons among the patients in follow-up

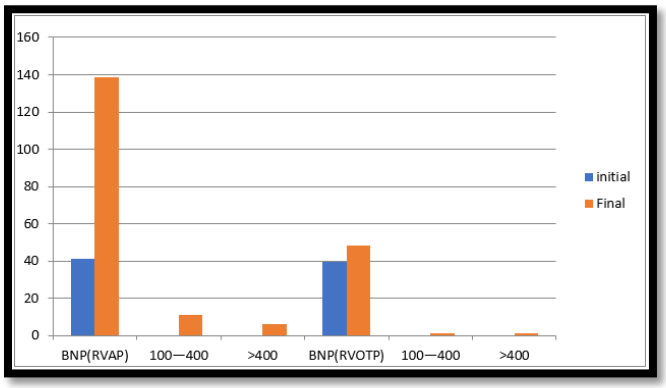


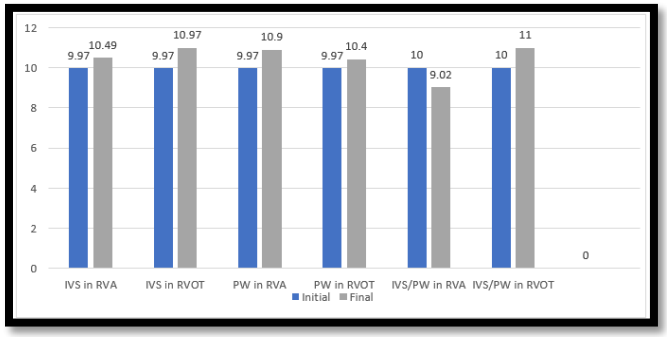
Figure 3; RVAP shows increment in BNP value after permanent pacing, while RVOT pacing preserving the BNP value after pacing,

it shows, RVOT have better outcome than that of RVAP on the basis of BNP value. (BNP, B-Type Natriuretic Peptide).

Figure 4; Pre and Post Comparison of LVEF% among the patients of RVAP vs RVOTP

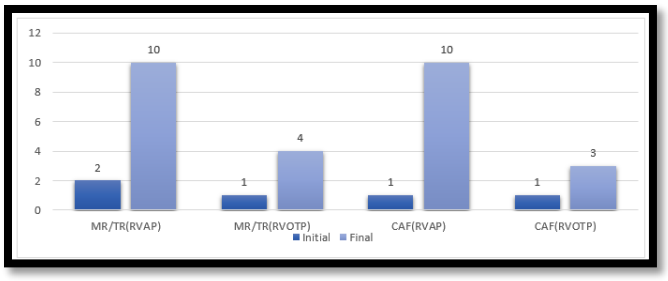
Figure 4; LVEF% significantly Decreases in RVA pacing group as compared to RVOT pacing group, RVOT group preserving the ejection fraction near to normal. (LVEF, Left Ventricular Ejection Fraction).

Figure5; Echocardiographic findings of IVS, PW, and IVS/PW measurements among the patients of RVAP vs RVOTP



Graph 5: At the end of the follow up, the mean values of IVS and PW were significant among the two groups, though the ratio (IVS/PW) Remains the same (IVS –Inter ventricular septum) (PW; Posterior wall)

Figure6; Echocardiographic measurements and CAF among the patents of RVAP vs RVOTP



Graph 6; Shows, Incidence of new Mitral regurgitation and, CAF (Chronic Atrial Fibrillation) cases increased in RVAP. (MVR-Mitral Regurgitation) (CAF- Chronic Atrial Fibrillation).

6. DISCUSSION

First of all, our study has the following core findings, (1) The mean QRS-complex narrowed from the widened baseline QRS in the RVOT pacing group in comparison with the QRS complex of RVA pacing group (143.36±12.90 to 106.52±14.12), P=0.001 ;(142.18±10.83 to 143.62±12.90), P=0.901. The final investigational axis had a trend to left axis deviation in the right ventricular apical (RVA) pacing group 41.2(-44-99) to -11(-45-53), P=0.004, in comparison to RVOT pacing group 42.4(-50-102) to 50(55-105), P=0.003. (2) According to the patient clinical assessments, there were (9, 32.52%) new cases of CAF observed in RVA pacing, P=0.001, while only (3, 10.83%) cases were observed in RVOT pacing group, P= 0.109. (3) We found that, the NHYA class II and III patients increased in RVA group, at the end of follow-up associated with surge of BNP level, from (100-400 pg/mL) there were total patients 15 patients in which 3 patients in RVOTS (P=0.963) while 11 in RVA (P=0.05), additionally (6,17.1%) patients in RVA-pacing group whose, BNP level was > 400 pg/mL, (P=0.04), but only one patient in the RVOTS pacing group, (P=0.153). (4) Statistically significant relationship found between the bassline and final left ventricular ejection fraction (LVEF %) in RVA pacing group (P=0.02), while no statistical difference between the RVOT pacing group (P=0.152).

Our study results mostly agree with, Ewa Lewicka-Nowak et al. [28] documented the outcomes of the first prospective randomized research in which, the results of patients with normal Left Ventricle functioning were treated for more than 7 years and evaluated the consequences of pacing in different areas of the Right Ventricle. The results demonstrated that Right Ventricular Outflow Tract pacing has been correlated with reduced frequency of new CAF and has a beneficial effect on LV comprehensive diastolic and systolic functioning compared to RVA Pacing. The current study also showed that RVOT is significantly associated with a substantial increase of PW, IVS, and LA, width although, the IVS/PW ratios doesn't vary. The interpretation of this observation is complicated, particularly as the 2 groups did not vary with reference to the occurrence of hypertension, although in patients with RVOT, the CAF was found significantly less common. The explanation is often obstructed by the limited number of participants in the categories studied. Probably "high" electrodes tip optimization on IVS contributes to improvements in local contractility and perfusion, leading to unique reconfiguration after many years. The research indicated that following 18 months of RVOT, perfusion and contractility throughout the IVS area was considerably reduced, however improved across the posterior Left Ventricular wall (P <0.05). Cate et al. [28] have demonstrated that the inappropriate electrical stimulation triggered by RVA pacing can cause wall motion abnormalities (WMA), leading to regions of impaired perfusion relative to normal electrical stimulation, in a large population of participants utilizing computed tomography with protected single-photon emissions. Giudici et al. [20] with their research on 89 patients, they drew considerable attention who found a substantial improvement in cardiac performance acutely with RVOT pacing, though we didn't studied the acute affect in our study. Meta-analysis by De Cock et al. included 217 participants, and demonstrated that as comparison to apical pacing, Right Ventricular Outflow Tract pacing obtained a higher hemodynamic contribution, particularly in patient subgroups with Brady-arrhythmias and left ventricular impairment, the RVOT strategy was suggested [26]. Tse et al. [3] documented the same results in their study that was utterly planned and executed, explaining that a protecting influence is developed on Left Ventricle function and perfusion by RVOT pacing as compared with RVA pacing. Buckingham et al. [27] discovered that activation of apical and RVOT areas contributed to an elevated dP/dT ratios, however it was not significant statistically. Barin et al. [23] initially proved the safety and effectiveness of RVOT lead positioning, and the effective stimulation of His-Purkinje System was demonstrated by Karpawich [24]. De Cock et al. in 1992, documented the hemodynamic advantage of RVOT pacing over apical pacing [25].

Due in part to the complications of RVA pacing, alternate pacing site in the Right Ventricle like RVOT septal-pacing has been extensively studied [4,16-18],. The positive effect of RVOT Pacing is assumed related to its much more physiological pattern of stimulation resulting in very little Left Ventricle dyssynchrony [19-22].

7. STUDY LIMITATIONS

The study has multiple limitations, first it was single center study and, small number of patients are the two main limitations of current work. Different modes of pacemaker as well as different kind of optimal medical therapy (OMT) didn't considered in follow-up. According to type of rhythm (A-V block II°/III°, CAF) and HF, both of these groups were comparatively identical, which could have direct impact on the outcomes. The patients with motion wall abnormalities in the follow-up period underwent for coronary interventions and, some patients received the stent implantation as well, though data related to coronary interventions were not included in

final analysis which may have bias in the LVEF% outcomes regarding improvement or decrement after Percutaneous interventions.

8. CONCLUSION

In conclusion, the current results of the study have shown that, RVOT pacing is significantly associated with increase in hemodynamic functions, limited cases of new Chronic atrial fibrillation (CAF) with increment in LVEF throughout 26 months of follow-up, this pacing area should be considered as an appropriate alternative site for RVA pacing in near future.

9. ABBREVIATIONS

1. RVA; Right ventricular apical

2. RVOT; Right ventricular out flow tract

3. LVEF; Left ventricular ejection fraction

4. OMT; Optimal medical therapy

5. CAF; Chronic atrial fibrillation

6. HF; Heart failure

7. AVB; Atrial ventricular block

8. IVS; Interventricular septum

9. PW; Posterior wall

10. NYHA; New York heart association

11. BNP; B-type natriuretic peptide

12. LVEDD; Left ventricular end diastolic diameter

13. CCB; Calcium channel blockers

14. BB; Beta Blockers

15. LA; Left atrium

16. LVESD; Left ventricular end systolic diameter

17. CAD; Coronary artery diseases

18. DM; Diabetic Miletus

19. LAO; Left anterior oblique

20. RAO; Right anterior oblique

10. AUTHORS CONTRIBUTION

(1). Professor Yuan Zu Yi, Professor Guo Ning and Dr. Hameed Ullah, contributed to the conception and design of the study, Dr. Hameed Ullah collected the data and, wrote the manuscript.

(2). Professor Yan Rong, Professor Han Ke, Dr. Hameed Ullah and Dr. Karim Elakabawi contributed as Leading,1st and, 2nd Assistant surgeons for permanent pacemaker implantation at Cath lab.

(3). Najeeb Ullah and Chen Yi Ke contributed to the SPSS analysis for research data.

(4). Dr. Sardar Ali Shah, Dr. Habib Ullah, Dr. Hamad Haider khan, Dr. Muhammad Asad Khan and Dr. Feng Jia Hao contributed to the literature review and help in patient's data collection.

(5). Professor Yuan Zu Yi, Professor Guo Ning, Dr. Fazlullah and Professor Han Ke critically revised the manuscript, all authors have read and approved the final manuscript.

11. ACKNOWLEDGMENTS

None

12. DISCLOSURES

The authors declare no conflicts of interest.

13. ETHICS APPROVAL (IRB)

The study approved by the Xian Jiaotong university Ethical committee of medical and biological center Shaanxi China, and informed written consents was obtained from all patients to participate in the study. Reference Number (2017-4553).

14. DATA AVAILABILITY

The data used to support the findings of this study are available from the First Affiliated Hospital of Xi'an Jiaotong University, the data are available from the authors upon reasonable request and with permission from the Hospital.

15. FUNDING

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16. CONSENT FOR PUBLICATION

Not applicable

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