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MANUAL INTRACARDIAC ELECTROGRAM METHOD IS ACCURATE ALTERNATIVE TO ECHOCARDIOGRAPHY FOR ATRIOVENTRICULAR AND INTERVENTRICULAR OPTIMIZATION IN CARDIAC RESYNCHRONIZATION THERAPY

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SUMMARY – Some manufacturers do not provide automated intracardiac electrogram method (IEGM) systems for atrioventricular (AV) and interventricular (VV) delay optimization in cardiac resynchronization therapy (CRT). We aimed to evaluate the accuracy of manual IEGM method in 48 patients previously implanted with Medtronic Syncra CRT. All patients underwent standard device interrogation followed by CRT optimization by IEGM method and by echocardiography one month after implantation. The patient mean age was 60.7±11.8 years and there were 33 (68.8%) males. After CRT implantation, the left ventricular ejection fraction increased from 28.0±7.9% to 39.1±11.0% ($p<0.001$). Optimal aortic flow Velocity Time Integral (aVTI) was obtained when VV was set to 20-50 ms left ventricular pre-activation. There was a strong correlation between VV values determined by echocardiography and IEGM ($R=0.823$, $p<0.001$). We found no significant difference in AV, VV and aVTI values between echocardiography and IEGM method. However, IEGM was significantly less time-consuming than echocardiography [20 (10-28) *vs.* 40 (35-60) minutes, $p<0.001$]. Manual IEGM method may be good alternative to echocardiography and automated IEGM method. It also emphasizes the need for implementation of automated IEGM systems in as many CRT devices as possible.

Key words: *Intracardiac electrogram; Optimization; Cardiac resynchronization therapy; Atrioventricular delay; Interventricular VV delay*

Introduction

In refractory congestive heart failure (CHF) accompanied by left bundle branch block (LBBB), cardiac resynchronization therapy (CRT) with biventricular pacing has been shown to be associated with better outcomes and has been established as an adjunctive heart failure treatment[1-3]. It has been shown in multicenter studies that CRT reduces mortality, and improves exercise tolerance and quality of life[4-6].

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Sequential ventricular pacing can increase mechanical efficiency, decrease delay in contraction between adjacent left ventricular (LV) walls, reduce mitral regurgitation[7,8], and increase ejection fraction (EF). However, up to 30% of patients who underwent CRT implantation show no improvement. The reasons for failure to respond include suboptimal lead placement, device programming and/or patient selection. Atrioventricular (AV) delay also has a significant effect on the hemodynamic performance of cardiac pacing since insufficient LV filling in diastole leads to a decline in cardiac output[9]. Optimizing the third parameter of dyssynchrony, the interventricular (VV) delay, with sequential biventricular pacing compared to simultaneous biventricular pacing has also been shown to incrementally improve cardiac function[7-12]. AV/PV and VV delay optimization is not commonly performed in routine clinical practice despite being one of the programmable parameters available. Only those that do not show improvement from CRT undergo echocardiographic optimization of their AV and VV intervals due to the costs, time constraints, and skill and expertise required to perform accurately.

The intracardiac electrogram method (IEGM) has been designed to calculate optimal AV/PV and VV delays during routine device follow-up[1]. Several studies have reported diagnostic accuracy of IEGM performed by using the software provided along with St. Jude's devices[1,13,14]. Such automated IEGM yielded similar results as echocardiography for AV and VV optimization. However, some CRT device manufacturers do not provide automated IEGM systems for AV and VV optimization.

The aim of this study was to evaluate diagnostic accuracy of manual application of IEGM formula used by St. Jude's devices in patients undergoing CRT with Medtronic devices and to evaluate whether the IEGM of AV/PV and VV delay optimization would produce similar hemodynamic results as assessed by aortic VTI as a surrogate for stroke volume compared with the standard Doppler echocardiogram technique.

Patients and Methods

Patients

We included 48 patients previously implanted with Medtronic Syncra CRT-P cardiac resynchronization therapy devices. All patients at our institution who fulfilled the standard indications for CRT according to ESC guidelines at the time of inclusion[15] were invited to participate in this prospective study, which was approved by the local research Ethics Committee. Patients were excluded from IEGM studies if they had no intrinsic atrial activity (atrial rate ≤40 bpm); had atrial fibrillation at the time of the study testing and evaluation; or were unable to provide analyzable echocardiogram images. One month after CRT implantation, all patients underwent standard device interrogation followed by optimization of the CRT pacemaker settings by IEGM and by echocardiography (ECHO). The study was performed during a single scheduled follow up visit. All patients were first programmed, utilizing the IEGM, and after that, all patients underwent ECHO optimization. The investigator performing the ECHO study was blinded to the results of the IEGM evaluation.

The study was approved by the institutional Review Board. Considering human and animal rights, all procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Methods

Cardiac resynchronization therapy optimization using intracardiac electrogram method

Calculation of the optimal sensed AV interval is based on atrial intrinsic depolarization (atrial IEGM). The atrial IEGM (P-wave duration) represents atrial conduction time and enables estimation of mitral valve closure. The algorithm measures the width of the atrial IEGM, which is off-set by a factor of 30 ms if the intrinsic depolarization is >100 ms, or 60 ms if the intrinsic depolarization is <100 ms. The off-set enables delivery of ventricular pacing after completion of atrial mechanical contraction ensuring complete mitral valve closure and maximizing preload. The optimal paced AV delay is calculated as the sum of sensed AV delay and the pacing latency of 40 ms[16].

The IEGM VV delay calculation algorithm is based on the hypothesis that during optimal depolarization, two paced wavefronts from the RV and LV leads will meet near the interventricular septum. The VV delay algorithm has two components: the conduction delay (Δ) and the correction term (ε) (1). Δ represents difference between the time of peak intrinsic activation on the LV lead (R_{LV}) and the RV lead (R_{RV}) [Δ R_{LV} - R_{RV}]. ε is difference in the inter-ventricular conduction delay (IVCD) between two ventricular paced propagation waveform time delays. The IVCD RL is the interventricular conduction delay when the RV lead is paced and the delay is sensed at the LV lead, while the IVCD LR is estimated when the LV lead is paced and the delay represents the time when the signal is sensed at the RV lead. Furthermore, each chamber is paced after a short AV delay to ensure no fusion occurs. The correction term equation is ε = IVCD LR - IVCD RL. The IEGM optimal VV delay equals 0.5 ($\Delta + \varepsilon$). If measured VV is more than 0, the LV is activated first, and if VV is less than 0, the RV is activated first. Previous studies showed promise for the IEGM since the predicted optimal VV delays were linearly correlated with echocardiographic aortic VTI[1,17-19].

Cardiac resynchronization therapy optimization by echocardiography

Atrioventricular optimization

Optimization of the AV and VV intervals was undertaken using Pulse Wave Doppler of the General Electric Vivid 7 ultrasound machine. The AV interval was optimized first since it has been shown to provide more hemodynamic benefit than adjusting the VV interval[20]. The mitral inflow velocity profile was obtained in apical four-chamber view at the level of mitral valve leaflet tips at the sweep speed of 100 mm/s. First measurements were taken with either a very long (200 ms) or very short (60 ms) AV interval and the duration of the mitral inflow velocity profile (EA duration) was measured in expiration. The AV interval was then adjusted in 10 ms decrements/increments, respectively, and the EA duration was measured for each AV interval. The optimal AV interval was defined as the shortest AV interval that resulted in maximal EA duration, thus representing the longest LV filling time without truncating the A wave of mitral inflow by the onset of ventricular systole[21,22].

Interventricular interval optimization

The LV outflow tract (LVOT) Pulse Wave Doppler velocity profiles were measured in the apical five-chamber view at the sweep speed of 100 mm/s. The LVOT VTI was measured in expiration at each VV interval ranging from -40 to +40 ms in 10 ms increments. Only if the optimal LVOT VTI was measured at a VV interval of -40 or +40 ms, further measurements of LVOT VTI were performed with 10 ms increments (i.e. at -50 or +50 ms). The optimal VV interval was defined as the VV interval with highest LVOT VTI (a surrogate measure of stroke volume and cardiac output). Inter-observer variability was eliminated by ensuring all measurements were performed by a single senior echocardiographer. Intra-patient variability was

Table 1. Characteristics of the study population (continuous variables expressed as mean ± standard deviation and categorical variables expressed as number and percentage)

Patient characteristic	
Age (years)	60.7±11.8
Male gender, n (%)	33 (68.8%)
BMI	27.7±3.4
DM type 2, n (%)	17 (35.4%)
PAD, n (%)	7 (14.6%)
CRI, n (%)	7 (14.6%)
Therapy, n (%)	
Furosemide	43 (89.6%)
Spironolactone	35 (72.9%)
ACE inhibitor	46 (95.8%)
Ca channel antagonists	48 (100%)
Beta-blockers	45 (93.8%)
Amiodarone	20 (41.7%)
Digitalis	1 (2.1%)
NYHA status, n (%)	
1	4 (8.3%)
2	11 (22.9%)
3	33 (68.8%)
Type of cardiomyopathy, n (%)	
dilated	35 (72.9%)
ischemic	10 (20.8)
non-specified	3 (6.3%)
LV ejection fraction (%)	28.0±7.9
LVEDV (mL)	241±84
LVESV (mL)	177±68
QRS duration (ms)	183.5±19.9
Placement of RV electrode, n (%)	
RVA	46 (95.8%)
RVS	2 (4.2%)
Placement of LV electrode, n (%)	
PLV	35 (72.9%)
MCV	3 (6.2%)
AIV	9 (18.8%)
PV	1 (2.1%)

BMI = body mass index; DM = diabetes mellitus; PAD = peripheral artery disease; CRI = chronic renal insufficiency; LV = left ventricle; LVEDV = left ventricular end-diastolic volume; LVEDS = left ventricular end-systolic volume; RVA = right ventricular apex; RVS = right ventricular septum; PLV = posterolateral vein; MCV = middle cardiac vein; AIV = anterior intracardiac vein; PV = posterior vein

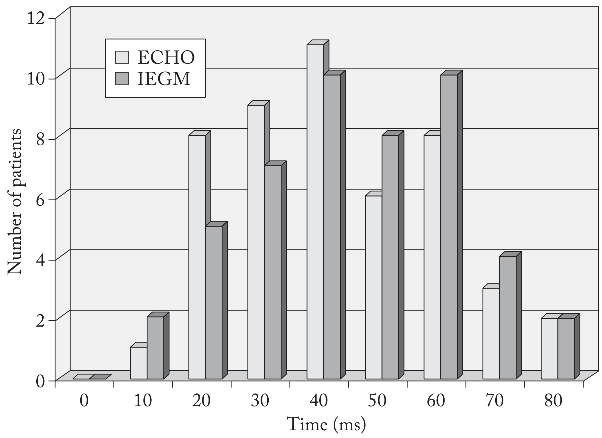

Fig. 1. Number of patients in each interventricular delay (VV) interval determined by echocardiography (ECHO) and intracardiac electrogram method (IEGM).

minimized by ensuring measurements were performed at end-expiration and the mean of three consecutive measurements taken.

Statistical analyses

Patient characteristics were assessed with descriptive statistics presented as mean and standard deviation or median with interquartile range values. Independent variables were compared using the Mann-Whitney test and Fisher exact test, as appropriate. Dependent variables were compared using the Wilcoxon test. All correlations were performed using the Spearman's correlation coefficient. Sample size was calculated to be 45, when considering type 1 error (a) to be 5% and type 2 error (b) to be 20%. Statistical analyses were performed using STATISTICA, ver. 6.0. The value of p<0.05 was considered significant.

Results

The mean patient age was 60.7±11.8 years and there were 33 (68.8%) males. The remaining characteristics of the study population are presented in Table 1. After CRT implantation, EF increased from 28.0±7.9% to 39.1±11.0%, LVEDV decreased from 241±84 mL to 189±80 mL, and LVESV decreased from 177±68 mL to 121±64 mL (p<0.001 all). Optimal aortic VTI was obtained when VV was set to 20-50 ms left ventricular pre-activation. The distribution of VV determined by echocardiography or IEGM was similar (Fig. 1). Moreover, we found no significant difference in sensed atrioventricular interval (SAV), paced atrioventricular interval (PAV), VTI and VV values between echocardiography and IEGM. However, IEGM was significantly less time-consuming (Table 2). There was a strong correlation between VV values determined by echocardiography and IEGM (ρ=0.823, p<0.001) (Fig. 2). We also found similar positive correlations between PAV and SAV values determined by echocardiography and IEGM, but this correlation was substantially weaker (ρ=0.477, p<0.001).

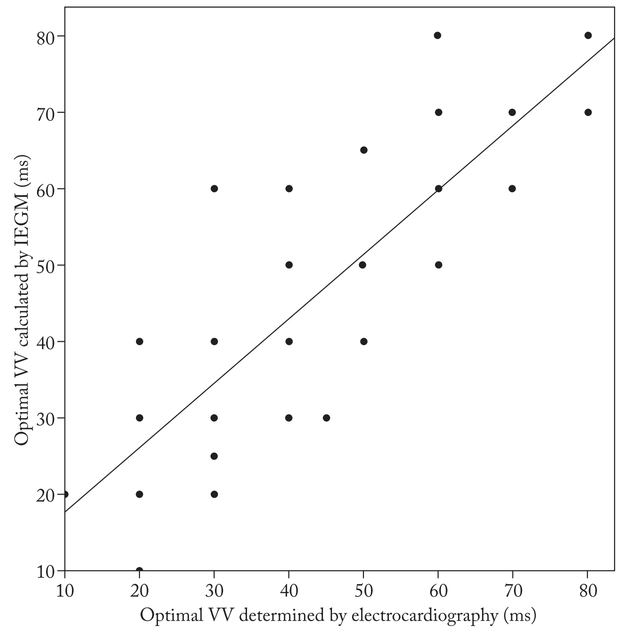

Fig. 2. Correlation between optimal interventricular delay (VV) determined by echocardiography and intracardiac electrogram method (IEGM).

Table 2. Difference in LVOT, SAV, PAV, optimal VV and time between ECHO and IEGM

	ECHO	IEGM	p*
LVOT (cm)	17.2 (6.8-25.6)	17.2 (6.4-25.1)	0.2432
SAV (ms)	100 (70-120)	100 (90-120)	0.0953
PAV (ms)	140 (110-160)	140 (130-160)	0.0953
VV (ms)	40 (10-80)	45 (10-80)	0.3613
Time (min)	40 (35-60)	20 (10-28)	<0.001

* Mann-Whitney test; LVOT = left ventricular outflow tract; SAV = sensed atrioventricular delay; PAV = paced atrioventricular delay; VV = interventricular delay; ECHO = echocardiography; IEGM = intracardiac electrogram method; data presented as median and interquartile range

Discussion

This prospective clinical trial of AV/PV and VV delay programming is the first one that compared manual IEGM based on St Jude's CRT (Quick Opt™ algorithm) pacemakers with standard echocardiography optimization method[1,18,23,24]. Our study is the first to show that manual IEGM can be used for VV optimization after CRT implantation, even for devices that do not have automated IEGM system. Previous studies have shown that IEGM is an accurate alternative to time-consuming echocardiography techniques for VV optimization[14,18,23-25]. St Jude's CRT devices have automated IEGM systems, which can accurately calculate AV and VV delay in one minute. However, Medtronic CRT devices do not provide automated IEGM system and therefore, echocardiography techniques are the only possibility for AV and VV optimization. Our study showed that IEGM could be manually applied using caliper in patients implanted with Medtronic CRT devices. Correlation coefficient between echocardiographic and IEGM determined VV interval was somewhat lower than in previous studies (R=0.823)[1], but VTIs were exactly the same when VV interval was estimated with echocardiography or IEGM [17.2 (6.8-25.6) *vs*. 17.2 (6.4-25.1), p=0.243]. Although manual IEGM takes a median of 20 (10-28) minutes, which is substantially longer when compared with automated IEGM, it is still less time-consuming than echocardiography [40 (35-60) minutes]. Therefore, we can conclude that manual IEGM is a valuable option for AV and VV optimization. However, we suggest that automated IEGM system be implemented by all manufactures of CRT devices.

This study confirmed the efficacy of CRT in increasing EF of the left ventricle and decreasing both LVEDV and LVESV. These changes were even greater than reported in previous studies, since we enrolled only patients with substantial QRS prolongation, who obviously gain substantial benefit from CRT. Moreover, our study demonstrated that AV and VV optimization was necessary in patients undergoing CRT, and that further effort should be made in providing automated IEGM system by all CRT device manufacturers.

The main limitation of our study was the absence of long-term follow-up in patients undergoing CRT. Moreover, this was a non-randomized prospective study and thus, conclusions regarding diagnostic accuracy of manual IEGM should be interpreted with caution. However, our study provided a rationale for performing a randomized clinical trial that would compare long-term outcomes between patients in whom VV optimization performed with manual IEGM technique and by echocardiography.

In conclusion, our study indicated that manual IEGM could be good alternative to echocardiography and automated IEGM. It also emphasized the need for implementation of automated IEGM systems by all CRT device manufacturers in order to provide better understanding of conduction properties and optimal device programmed setting to get best cardiac function. The IEGM could also be an additional method providing faster ECHO optimization.

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Sažetak

PRIMJENA RUČNE METODE INTRAKRDIJALNIH ELEKTROGRAMA ODGOVARAJUĆA JE ZAMJENA EHOKARDIOGRAFSKOJ ATRIOVENTRIKULSKOJ I INTERVENTRIKULSKOJ OPTIMIZACIJI RESINKRONIZACIJSKOGA ELEKTROSTIMULATORA SRCA

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Neki proizvođači nemaju automatski sustav intrakardijalnog elektrokardiograma (IEGM) za atrioventrikulsku (AV) i interventrikulsku (VV) optimizaciju u srčanoj resinkronizacijskoj terapiji (CRT). Cilj ovoga istraživanja bio je procijeniti točnost ručnog namještanja IEGM kod bolesnika s ugrađenom CRT. U istraživanje je bilo uključeno 48 bolesnika kojima je prethodno ugrađen Medtronic Syncra CRT. Jedan mjesec nakon ugradnje svim bolesnicima je učinjena standardna kontrola elektrostimulatora, nakon čega je učinjena optimizacija CRT, prvo metodom IEGM, a potom ultrazvučno. Srednja dob bolesnika bila je 60,7±11,8 godina; bila su 33 (68,8%) muškarca. Nakon ugradnje CRT, ejekcijska frakcija lijeve klijetke narasla je s 28,0±7,9% na 39,1±11,0% (p<0,001). Najveći integral brzine protoka nad aortnom valvulom (aVTI) dobiven je pri VV intervalu od 20-50 ms lijeve preekscitacije. Utvrđena je snažna korelacija između trajanja VV intervala dobivenog ultrazvučno i IEGM (R=0,823, p<0,001). Nismo našli statistički značajnu razliku između vrijednosti AV, VV i aVTI dobivenih ultrazvučno i metodom IEGM. Ipak, metoda IEGM zahtijeva bitno manje vremena od ultrazvučne metode [20 (10-28) prema 40 (35- 60) minuta, p<0,001]. Naše istraživanje pokazuje da ručna metoda IEGM može biti dobra alternativa ehokardiografskoj optimizaciji i automatskoj metodi IEGM. Također ukazuje na potrebu omogućavanja automatske IEGM optimizacije kod što više CRT uređaja.

Ključne riječi: *Intrakardijalni elektrogram; Optimizacija; Srčana resinkronizacijska terapija; Atrioventrikulski interval; Interventrikulski interval*