Combined use of non-thoracotomy cardioverter defibrillators and endocardial pacemakers

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Abstract

Objective—To study the potential interactions in patients with endocardial permanent pacemakers and non-thoracotomy implantable cardioverter defibrillator (ICD) systems.

Design—Case series and cohort study.

Setting—Tertiary referral centre.

Patients—Fifteen consecutive patients with both endocardial pacemakers (12 dual chamber and three single chamber) and non-thoracotomy ICD systems.

Main outcome measures—Detection inhibition of induced ventricular fibrillation; double counting; and pacemaker function after shocks. In the evaluation of detection inhibition, 124 VF inductions were analysed for detection duration compared with induced VF episodes in controls with an ICD but without a pacemaker.

Results—Two patients (13%) showed detection inhibition of VF and required pacemaker system change at the time of the ICD implant. With the final lead position, despite frequent pacemaker undersensing of VF, ICD detection of VF was not inhibited during any induction, and neither initial detection nor redetection times for VF were different from controls. Double/triple counting of pacemaker artefact and evoked electrogram was noted in three patients (20%). In two, this was remedied during the implantation procedure, and in the other it was abolished when amiodarone treatment was discontinued. Pacemaker function was affected by ICD discharges in two patients, one who showed postshock atrial undersensing and loss of capture, and another whose pacemaker reverted to VVI mode.

Conclusions—When careful testing is performed at implantation to detect and remedy device interactions, non-thoracotomy ICD treatment and endocardial pacemakers can be used safely in combination.

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Keywords: non-thoracotomy cardioverter defibrillators; pacemaker malfunction; cardiac pacing

Ventricular demand pacing is frequently available in newer implantable cardioverter defibrillators (ICD), permitting the treatment of both

bradycardia and tachycardia by a single device. Approximately 11% of patients receiving an ICD implant for the treatment of life threatening ventricular tachyarrhythmias also require a permanent pacemaker for the treatment of serious bradyarrhythmias.¹ Apart from the deleterious effects on battery depletion and device longevity caused by long term pacing from the ICD, the haemodynamic requirements for rate responsiveness and atrioventricular synchrony make combination therapy necessary in most patients with complete heart block and intact sinus node function, who usually require dual chamber (DDD) pacemakers, and frequently also benefit from rate modulated (DDDR) pacing.

Potential interactions between ICDs and permanent pacemakers have long been a concern and require detailed intraoperative testing.²⁻⁶ Interactions between the two implanted arrhythmia control devices may lead to inappropriate withholding of ICD shock during ventricular fibrillation (VF) as well as to inappropriate ICD shocks during normal rhythm. Despite these serious potential interactions, the safety of combined permanent pacemaker and epicardial ICD lead systems has been reported.⁷ Although reports of small series of patients with both permanent pacemakers and non-thoracotomy ICD systems suggest combined implantation is safe and effective, no systematic study has quantitatively addressed the issue of detection times in this population compared with a control group.⁸⁻¹⁰ We therefore studied the interactions between pacemakers and ICDs in 15 patients receiving both endocardial systems at Lahey-Hitchcock Medical Center; specifically, we compared ventricular fibrillation (VF) detection times to clarify whether the presence of undersensing by the pacemaker delays the time to arrhythmia detection by the ICD.

Methods

Between May 1991 and November 1994, 181 non-thoracotomy ICD systems were implanted at the Lahey-Hitchcock Medical Center. Fifteen patients (11 men) with a mean age of 67 years received an endocardial permanent pacemaker either before (nine patients) or after (six) the non-thoracotomy ICD implant, and these patients are the subject of the study. Indications for ICD implantation in these 15 patients were as follows: nine (60%) had monomorphic ventricular tachycardia (VT); four (27%) had both monomorphic VT and VF; one had sustained polymorphic VT; and one patient had VF alone. All patients were sur-

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Table 1 Patient demographics

	ICD control (n = 75)	ICD pacemakers (n = 15)
Age	62 (21–80)	67 (49–80)
Male	59 (78.7%)	11 (73.3%)
Female	16 (21.3%)	4 (26.7%)
Heart disease		
CAD	55	10
VHD	3	1
CMP	14	3
RVD	1	0
NSHD	2	1
Ejection fraction	0.34 (0.1–0.76)	0.3 (0.1–0.55)
Indication for ICD		
MVT	41	9
VF	24	1
VT	10	4
PVT	0	1

CAD, Coronary artery disease; VHD, valvar heart disease; IDC, idiopathic dilated cardiomyopathy; RVD, right ventricular dysplasia; NSHD, no structural heart disease; MVT, monomorphic ventricular tachycardia; VF, ventricular fibrillation; PVT, polymorphic ventricular tachycardia.

The control group consisted of all patients receiving P + P2 devices without a pacemaker. There were no significant differences between the groups.

vivors of sudden cardiac death or haemodynamically unstable ventricular arrhythmias.

Thirteen patients (87%) received a permanent pacemaker for high degree atrioventricular block, including two that were iatrogenic following atrioventricular junction ablation, and two because of sinus node disease. Table 1 describes the clinical characteristics of the population.

PREOPERATIVE EVALUATION

Preoperative evaluation included coronary angiography, left ventriculography, electrophysiological study, and cross sectional echocardiography. Holter monitoring and exercise testing were performed as indicated. Acute myocardial infarction was ruled out in all patients, as were other reversible causes of ventricular arrhythmias.

DEVICES

Five patients received a Ventak P ICD pulse generator, five received a Ventak P2, and three a Ventak PRX connected to the Endotak C

model 0064 or 0074 transvenous lead system with or without a subcutaneous patch (all manufactured by CPI, St Paul, Minnesota, USA). One patient received a Res-Q connected to a ventricular lead model 497–09 and a subcutaneous patch model 497–15 (Intermedics, Angleton, Texas, USA). One received a Jewel 7219C connected to a ventricular lead model 6936–65 (Medtronic, Minneapolis, Minnesota, USA).

In order to minimise pacemaker artefact and thereby reduce the risk of pacemaker-ICD interaction, all permanent pacemaker systems were required to be bipolar. Three patients needed a revision from a unipolar to a bipolar pacing system before ICD implantation. Thirteen patients (87%) received a dual chamber pacemaker, and two received a single chamber. Table 2 gives the device features.

OPERATIVE PROCEDURES

ICDs and permanent pacemakers were all implanted at separate sessions. The order of implantation was entirely determined by clinical factors. Ten ICDs were implanted in the operating room and five in the electrophysiology laboratory. The cephalic vein was exposed, and the ICD lead system was inserted using the modified Ong-Barold technique.¹¹ If the cephalic vein was not adequate, direct puncture of the subclavian vein was used. The ICD lead system was advanced into the right ventricular apex under fluoroscopic guidance. Care was taken to document the smallest pacing stimulus relative to the native and paced R waves sensed by the rate detection circuit. The average defibrillation threshold was 14 joules (range 8–20).

Pacemakers were always implanted in the electrophysiology laboratory; however, two pacemaker system revisions were performed in the operating theatre at the time of ICD implantation. The pacemaker leads were also inserted preferentially through the cephalic

Table 2 Device features

Patient	ICD model	PPM model	Mode of pacing	PPM and ICD lead location	Implant order	Rate threshold of ICD
1	Ventak P	Pacesetter Synchrony II	DDD	VS _A –VA _P	PPM–ICD	200
2	Ventak P	Intermedics Relay	DDD	VS _A –VA _P	PPM–ICD	180
3	Ventak P2	Intermedics Relay	DDDR	VOT _A –VA _P	PPM–ICD	165
4	Ventak P	Pacesetter Synchrony II	DDIR	VOT _A –VA _P	ICD–PPM	200
5	Ventak P	Pacesetter Paragon II	DDD	VOT _A –VA _P	PPM–ICD	180
6	Ventak P2	Intermedics Relay	DDDR	VOT _A –VA _P	PPM–ICD	200
7	Ventak P	Teletronics META	DDDR	VS _A –VA _P	PPM–ICD	200
8	Ventak P2	CPI Triumph	VVIR	VOT _A –VA _P	ICD–PPM	175
9	Ventak P2	CPI Vista	DDD	VS _A –VA _P	ICD–PPM	200
10	Ventak P2	Pacesetter Synchrony II	DDDR	VS _A –VA _P	ICD–PPM	165
11	Ventak PRX	Pacesetter Solus 2002	VVIR	VS _A –VA _P	ICD–PPM	165
12	Ventak PRX	Pacesetter Synchrony II	DDDR	VS _A –VA _P	ICD–PPM	135
13	Jewel	Teletronics META	DDDR	VA _P –VOT _A	PPM–ICD	180
14	Res-Q	Intermedics Relay	DDDR	VA _P –VOT _A	PPM–ICD	170
15	Ventak PRX	Pacesetter Solus 2002	VVIR	VOT _A –VA _P	PPM–ICD	150

PPM, Permanent pacemaker; VS, right ventricular septum; VOT, right ventricular outflow tract; VA, right ventricular apex. Subscripts A and P refer to active and passive fixation lead, respectively.

Figure 1 Episode of induced VF undersensed by a pacemaker programmed to the DDD mode. The lower rate limit of the pacemaker has been set at 80 beats/min. Four atrial spikes are clearly seen every 750 ms. The last two atrial spikes are followed by two ventricular spikes with an AV delay of 150 ms. The first two ventricular spikes are difficult to see and are buried in the VF electrogram. Despite undersensing of VF by the pacemaker, adequate detection by the ICD was noted in this case. Note that the event marker of the ICD is counting VF beats.

Figure 2 Example of double counting from the ICD. Arrows indicate sensed events in the ICD. Intermittent counting of the atrial spike causes the ventricular spike to fall within the VF window; therefore the event marker counts these events as VF beats.

vein. All except one patient had both the pacemaker and ICD lead systems implanted in the contralateral cephalic or subclavian vein. Care was taken to position the two ventricular leads in order to minimise the size of the pacing stimulus in the electrogram of the sensing lead of the ICD, and to provide an adequate as well as stable pacing threshold.

INTERACTIONS STUDIED

The implant and follow up testing of all devices in this study sought to exclude the following interactions between the pacing and defibrillator systems.

Detection inhibition

Demand pacemakers frequently fail to sense the small intracardiac electrograms during VF and therefore may pace inappropriately during the arrhythmia. If the pacemaker artefact presents a large enough signal to the automatic gain control of the ICD, the arrhythmia electrogram is not sensed, and therefore will not trigger a discharge from the ICD. This phenomenon may occur with both unipolar or bipolar configurations of pacemakers, but is particularly common with unipolar units because of the much larger pacing artefact.² In order to evaluate detection inhibition during induced VF episodes, 47 and 77 initial detection times of the patients with the Ventak P and the Ventak P2, respectively, were compared with 123 and 317 initial detection times of a control group of patients with ICDs but without pacemakers. We also compared redetection time in this group in case of a failed first shock.

Table 3 Comparative ventricular fibrillation detection times

	P	P-PPM	P2	P2-PPM
IDT (s)	3.9	4.2	2.3	2.3
n	123	47	317	77
25th-75th centiles	2.6-5.4	3.6-5.6	2.1-3	2.1-2.7
RDT (s)	3.7	4.7	2.5	2.7
n	124	16	48	15
25th-75th centiles	2.7-5.7	4-5.9	2.3-3.1	2.5-3.1

PPM, permanent pacemaker; IDT, initial detection time; RDT, redetection time; P2-PPM, patients with Ventak P2 and PPM; P2, patients with Ventak P2 without PPM; P-PPM, patients with Ventak P and PPM; P, patients with Ventak P without PPM. There were no significant differences ($P > 0.05$) between detection times in either paced or non-paced VF inductions.

Double counting

Double or triple counting may occur if the interval between the pacemaker stimulus (or stimuli in the case of dual chamber pacemakers) and the R wave in the bipolar ICD sensing electrogram is greater than 150 ms (refractory period of the ICD); under these circumstances both the pacemaker and the cardiac signals may be interpreted as ventricular depolarisation. If these signals occur together at a combined rate greater than the ICD tachycardia detection rate, the ICD rate detection criterion will be satisfied, a charge will be initiated, and a shock will be delivered although the underlying rhythm is neither VT nor VF.¹² With the ICD programmed to the electrophysiological testing mode, double or triple counting was assessed by double or triple beeping, by means of the electrogram or event markers, depending on the ICD features. To increase the chances of double or triple counting and simulate a "worst case scenario", the permanent pacemaker was set at the maximum output and pulse width in order to magnify the size of the pacing stimulus. If no double counting was observed, the device was implanted. If double or triple counting was seen during this test the pacing lead was repositioned and the test was repeated.

Permanent pacemaker function after ICD discharge

External and internal defibrillation has the potential to both damage pacemaker systems and reprogramme pacemaker pulse generators, usually to the "backup" mode. In addition, abnormal pacemaker sensing, as well as failure to capture, has been reported after external and endocardial shocks.^{6,12} All pacemakers were interrogated and a full evaluation of sensing and capture thresholds was performed after each ICD testing session in which an internal shock was delivered. All patients underwent ICD follow up electrophysiological study before discharge. In addition, 11 patients had follow up tests at two and six months. VF was induced during asynchronous pacing at least once in all patients to assess detection inhibition. Attention was paid to oversensing, double or triple counting, detec-

Figure 3 Episode of defibrillation with subsequent loss of atrial sensing and capture. From top to bottom are surface ECG leads II, aVF, and V1. PAP, pulmonary artery pressure; CVP, central venous pressure; AP, arterial pressure; P_1 and P_2 , sensed P waves; P_3 and P_4 , undersensed P waves; A_1 and A_2 , failure of atrial capture.

tion and redetection times, and function of the pacemaker after ICD discharge. Before discharge the permanent pacemakers were programmed to the lowest safe output and pulse width, to minimise the possibility of later development of oversensing by the ICD.

STATISTICAL ANALYSIS

Detection times are expressed as median, 25th, and 75th centiles since they are not normally distributed. The Mann-Whitney rank sum test was used to compare detection times. A P value less than 0.05 was considered statistically significant.

Results

DETECTION INHIBITION

Two patients (13%) required a change of the permanent pacemaker system (generator and leads) at the time of the ICD implant because of inappropriate ICD inhibition during asynchronous pacing. Although undersensing of VT and VF by the pacemaker was commonly observed, ICD detection of VF was not inhibited during any induction with the final lead revisions (fig 1). Table 3 gives the data of detection times for the Ventak P and P2 compared with control groups without pacemakers. There were no differences between either initial detection or redetection times in VF episodes where pacemaker was present compared with VF episodes without pacemaker.

DOUBLE COUNTING

Double counting during paced rhythm was noted in three patients (20%, fig 2). This appeared to be sensing of the atrial pacing artefact in two, and was eliminated when the lower rate limit of the pacemaker was lowered in order to minimise atrial pacing. In one patient double and triple counting during paced rhythm was eliminated when amiodarone treatment was discontinued, thereby allowing both the pacing stimulus and evoked electrogram to occur within the refractory period of the ICD.

PERMANENT PACEMAKER FUNCTION AFTER ICD DISCHARGE

Pacemaker function was affected by defibrillation in two patients (13%). One patient had the pacemaker changed because of repetitive shock induced reversion to backup mode. In another patient undersensing of atrial activity occurred as well as loss of atrial capture which lasted less than six seconds after shock (fig 3).

FOLLOW UP

Clinical and device data from the 15 patients in this series are presented in tables 1 and 2, respectively. Follow up durations ranged from three to 48 months; there have been no sudden or unexplained deaths. Two patients died in hospital because of progressive heart failure. There were no early or late infections of any implanted system in any patient during this period of follow up. Five patients received 46 spontaneous ICD discharges; 24 of them were classified clinically as appropriate. No failure to convert VT/VF was seen during spontaneous shocks. One patient required pacemaker pocket revision for generator migration which was corrected creating a deeper pocket, and another required a new ICD lead system for an insulation failure. All patients have undergone regular outpatient pacemaker and ICD system evaluation and there has been no evidence of lead or pulse generator malfunction. There have been no symptomatic veno-occlusive complications.

Discussion

Permanent pacemakers and ICDs are designed to save the lives of patients with malignant cardiac rhythm disorders. Paradoxically, combined implantation of both devices in patients is a source of potentially lethal interactions.^{2,3,5,12} Techniques for the safe implantation of epicardial ICD systems and transvenous permanent pacemakers have been reported,⁷ but the close proximity of leads in non-thoracotomy ICD systems raises new safety concerns.

Figure 4 Lateral chest radiographs displaying a permanent pacemaker and transvenous ICD lead system implanted through the contralateral cephalic vein. The pacemaker atrial lead has been placed in the right atrial appendage. (A) The pacemaker ventricular lead has been placed in the right ventricular outflow tract and a transvenous ICD lead in the apex of the right ventricle. In addition, a subcutaneous patch is located in the left lateral chest wall. Both the transvenous lead and the subcutaneous patch have been tunnelled to the ICD generator (not shown) located in the abdominal wall. (B) Inversely, the pacemaker ventricular lead has been placed in the apex of the right ventricle and the transvenous ICD lead in the right ventricular outflow tract. The ICD generator is located in the right pectoral area.

We have shown in this study of 15 patients undergoing combined pacemaker/ICD implantation that with careful intraoperative testing, dangerous interactions between the two devices can be revealed and remedied. Of most importance in the safety of these combined implants, we have shown that pacing during induced VF does not prevent or delay arrhythmia detection by the ICD. Our data indicate that although interactions between permanent pacemaker and ICD are common in the implantation testing of these devices, they can almost all be corrected by altering lead position and the programmed parameters of the devices. Follow up of these patients has revealed no late mortality or other complications attributable to the combined implantation, and suggests that intraoperative testing is a good index of pacemaker-ICD interaction after the patient is discharged from the hospital.

Our experience with this group of 15 patients (being a subset of 181 patients implanted with non-thoracotomy ICD alone) prompts recommendations about the management of such combined implantation procedures. Although in our series, six patients required ICD before pacemaker implants, the permanent pacemaker should if possible be implanted first and the ventricular lead placed in the right ventricular outflow tract or septum, at a distance from the rate sensing lead of the ICD, which is usually in the apex of the right ventricle (fig 4).¹³ The ICD lead position in the right ventricular apex generally is optimal for defibrillation energy requirements and for lead stability, and this justifies our approach of preserving, where possible, the right apical site for the ICD lead.¹⁴ Nevertheless, clinical exigencies may preclude this strategy (fig 4 B) and the use of an active fixation ICD lead permits the necessary implant flexibility.

Damage to the permanent pacemaker, as well as reversion to the backup mode, has been recorded following ICD shocks⁵; we observed one patient with this phenomenon due to an

external shock before ICD implant, but none during laboratory testing and up to 48 months of follow up. This suggests that a formal evaluation of the potential for pacemaker system disruption at ICD implant is a valid index of future risk.

The ICD sensing/defibrillating lead should be placed in the right ventricular apex in order to optimise the defibrillation threshold; it should also be sited away from the permanent pacemaker lead in order to both minimise the relative amplitude of the pacing artefact seen by the ICD sensing electrode and to prevent "chatter" by electrodes making contact with each other during movement of the heart.

To prevent inappropriate ICD discharges precipitated by rapid pacing or double counting, the maximum pacing rate of the permanent pacemaker should be set at half the ICD rate detection criterion, provided that the rate of the clinical tachyarrhythmia permits this. If there is substantial crossover between physiological heart rates and the rate of the VT, then exercise testing and the use of detection enhancements such as rate stability or sudden onset criteria in the ICD is indicated; these programmed settings all require rigorous testing in the electrophysiology laboratory as well as by exercise testing before the discharge of the patient from the hospital.

The presence of bulky leads in the right and left brachiocephalic venous systems and right sided cardiac chambers might predispose patients to veno-occlusive disease and tricuspid valve regurgitation; however, this group of patients, over a relatively brief period of follow up, have experienced no such complications. Despite the previously expressed reservations of other investigators,⁷ we have shown that insertion of a transvenous ICD system is not precluded by the presence of a permanent endocardial pacemaker. However, the combined transvenous approach limits flexibility regarding lead placement in the right ventricle because of the need to ensure adequate sensing of both devices. Our experience reported

in this study suggests that safe and stable lead position can be obtained in all patients, although the long term reliability of these systems needs further evaluation.

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