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Effects of Extracorporeal Shock Wave Lithotripsy on Cardiac Pacemakers and its Safety in Patients with Implanted Cardiac Pacemakers

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COOPER, D., ET AL.: Effects of extracorporeal shock wave lithotripsy on cardiac pacemakers and its safety in patients with implanted cardiac pacemakers. *Effects of extracorporeal shock wave lithotripsy (ESWL) were studied on 15 pacemakers (standard single chamber n = 5, dual chamber n = 6, rate responsive single chamber [Activitrix] n = 4). In-vitro testing involved suspending the pacemakers in a bath of degassed, deionized water firmly taped to a platform at the point of maximal pressure, i.e., second focal point (F2), where they received pressure shocks ($\bar{x} = 1300$) from the HM3 Dornier lithotripter. The pacemakers, programmed to their most sensitive setting, were continuously pacing at nominal outputs (atrial and ventricular pacing in the DDD mode). All units were assessed by a pacing system analyzer before and after the study, then underwent destructive analysis. During standard single chamber pacing (VVI) the pacing stimulus triggered ESWL. For dual chamber devices, ESWL was triggered by the atrial paced event which induced inhibition of the ventricular output in two pacemaker. This was eliminated by reprogramming to a less sensitive setting. The pacemaker can, hermetic seal and internal circuitry were undamaged in all units. Two rate responsive single chamber pacemakers had their activity sensing piezoelectric elements shattered when placed at F2. Two other units placed 5 cm from F2 were stimulated to their maximum upper programmed pacing rate with ESWL therapy, but were otherwise unaffected. Subsequent to this study, six patients with pacemakers programmed to the VVI (five), DDD (one) modes implanted in the thorax underwent successful ESWL without pacemaker or arrhythmic event. Conclusions: (A) It is generally safe for patients implanted with standard single chamber devices in a ventricular application to undergo ESWL without modifying the pacing/sensing parameters. (B) Patients implanted with dual chamber devices who pace in the atrium should be reprogrammed to the VVI mode during ESWL. (C) Patients with piezoelectric activity sensing rate responsive single chamber pacemakers should have this feature programmed off during ESWL and, if implanted in the abdomen, probably should not undergo ESWL. (PACE, Vol. 11, November 1988)*

extracorporeal shock wave lithotripsy (ESWL), cardiac pacemakers

Introduction

Extracorporeal shock wave lithotripsy (ESWL) has been used successfully to treat selected patients with urinary tract calculi. Since

FDA approval, the presence of an implanted pacemaker has been a contraindication^{1,2} based on possible detrimental effects of high intensity focused shock waves and/or electromagnetic interference on pacemakers.

ESWL is a noninvasive, contact-free method for disintegrating renal calculi. The shock waves are generated by an underwater high voltage spark discharge which lasts for 1 microsecond. The spark electrodes are placed under water at

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the geometric focus (F1) of an ellipsoidal reflector, and the high voltage discharge causes explosive evaporation of the water which induces high pressure shock waves due to sudden expansion. Because the shock wave source is in one focus of an ellipsoid, all the energy is reflected from the surrounding walls and is collected again at a second focal point (F2). Since F2 is the point of highest energy density, the target must be arranged so it lies at this point. Shock waves spread through the body unimpeded because the acoustic impedance of most body tissue is similar to that of water. The shock wave is partially reflected when it reaches the stone. A portion of the shock waves entering the stone is absorbed because of the abrupt change in acoustic impedance leading to a build-up of pressure gradients and forms tear and shear forces which eventually disintegrate the solid material at the focal point. The volume of the second focal point (F2) measures approximately 1.5 cm³. At F2, each shock wave generates pressures up to 1000 atmospheres. The strength of each shock wave is determined in part by the voltage of each spark which is programmable from 18 to 24 KV (clinically useful range). A few centimeters away from the focal point the pressure dissipates rapidly and pressures measured 2

cm away from F2 are only 20% of the maximal pressure. Further decreases in the shock wave pressures are observed as the reference area is moved further from F2.³⁻⁵

During a standard lithotripsy treatment, patients are given general or epidural anesthesia and are placed on a chair which is lowered into a bath of degassed, deionized water. The renal calculus is positioned at F2 using fluoroscopic guidance. The treatment of a single kidney stone usually requires 1300 to 1600 shocks.^{6,7} The lithotripter is interfaced with the patient's recorded electrocardiogram and the shock waves are synchronized with the patient's surface QRS to avoid provoking ventricular arrhythmias.⁷

The objective of this study was to determine any temporary and/or permanent effects of ESWL on cardiac pacemakers.

Methods

In Vitro Study

We studied 15 standard unused pacemakers provided by six manufacturers for the in-vitro experiment, single chamber (n = 5), rate responsive single chamber (Activitrix (Medtronic Inc., Minneapolis, MN USA) [n = 4]) (Table I) and dual

Table I.
Standard Single Chamber Pacemakers

Manufact	Model #	POL	Mode	L/H Rate (BPM)	Sense (mV)	Output (V)	Pulse WT (ms)	REF (ms)
1. CPI	427	B	VVI	88	1.75	4.9	.49	325.
2. Medtronic	5985	U	VVI	120	1.25	4.8	.53	325.
3. Medtronic	8422	B	VVI	120	1.25	5.0	.5	325.
4. Siemens	675B	B	VVI	86	1.25	4.8	.5	250.
5. Telect.	5282A	B	VVI	120	0.7	5.0	.5	312.
Rate Responsive Single Chamber Pacemakers:								
1. Medtronic	8400	B	VVI + A	70/150	1.25	5.1	.51	225.
2. Medtronic	8402	B	VVI + A	70/150	1.0	5.1	.51	225.
3. Medtronic	8403	U	VVI + A	70/150	1.25	5.1	.51	225.
4. Medtronic	"dummy"—(piezoelectric crystal only).							

Activity setting low + 10 for all.

L/H rate (BPM): low/high rate in beats per minute.

Manufact: manufacturer.

Pulse WT: pulse width.

POL: polarity, U = unipolar, B = bipolar.

REF: refractory period.

Sense: sensitivity setting.

Programmed parameters analyzed before and after ESWL.

Table II.
Dual Chamber Pacemakers

Manufact	Model #	POL	Mode	L/H Rate BPM	Sense (mV)	REF (ms)	AVI (ms)	Output (Volts)	Pulse WT (ms)
					A/V	A/V		A/V	A/V
1. Cordis	415A	U	DDD	91/118	.5/.5 → 1.3	300/300	200	5 mA/5 mA	.63/.63
2. CPI	925	B	DDD	90/100	.3/.5	325/325	200.	5.1/5.2	.53/.56
3. Interm.	283-01	U	DDD	90/105	.5/1.0	200/320	200.	5.1/5.0	.5/.5
4. Medtron.	7005	U	DDD	110/125	.6/1.25	325/225	150.	4.8/4.7	.56/.57
5. Medtron.	7006	B	DDD	90/120	1.0/1.25	225/225	200.	4.8/4.7	.56/.57
6. Telect.	2291	U	DDD	87/115	.5/1.9 → 3.8	200/250	170.	4.8/4.9	.5/.5

A: atrium.

AVI: atrio-ventricular interval.

V: ventricle.

→: change in sensitivity settings.

Other abbreviations as in Table 1.

chamber (N = 6) (Table II). The experiment was designed to simulate the "worst case" in-vivo situation; thus, each pacemaker was tested at the point of maximal pressure, i.e., the focal point (F2) and submitted to 1300 shocks at 22 KV by a Dornier model HM3 lithotripter (Dornier Medical Systems, Inc., Marietta, Georgia, USA). Each pacemaker was connected to its respective lead(s) and all were positioned underwater in the tub at F2 with flat surface perpendicular to the shock waves, using X-ray guidance (Fig. 1). The distal electrodes of the pacing leads, positioned 10 cm from F2, were connected underwater, via alligator clips, to a heart pacemaker interactive simulator (Medtronic 9560) (Medtronic, Inc., Minneapolis, MN, USA) and output impulses from the heart simulator were connected to an oscilloscope for continuous on-line analysis (Medtronic 9552) a chart recorder (Instromedix 5112) (Instromedix, Beaverton, Oregon, USA) and Holter monitor (Del Mar 449B) (Del Mar Avionics, Irvine, California, USA) which allowed pacemaker function monitoring during the lithotripsy treatment (Fig. 2). All pacemakers were programmed to their most sensitive setting and had their rate programmed above the heart simulator rate (Table I).

The pacemakers were analyzed noninvasively before and after their exposure to the ESWL treatment by a pacing system analyzer (Medtronic model 5311). This allowed verification of the initial programmed parameters and determined whether the pacemaker electronics remained intact after the ESWL test protocol.

Following the noninvasive evaluation, each pacemaker was returned to its manufacturer for destructive analysis. During final evaluation, the titanium case was inspected for external damage, and the hermetic seal was tested. Subsequently, the titanium case was opened and the internal circuitry inspected and tested. Any pacemaker damaged by the lithotripsy at the focal point was retested with a similar model using the same testing protocol, 5 cm from the focal point.

Pacemakers which exhibited transient sensing of the ESWL therapy were retested after completion of the initial protocol. These units which were tested at the highest sensitivity were reprogrammed to nominal sensitivity settings (Table II). The pulse generators were then retested with an additional 200 shocks at the focal point.

In Vivo Study

Since commencing the ESWL program at our institution in February, 1986, approximately 2,500 patients have undergone this therapy for renal calculi. In that time, six patients (0.2%) with implanted pacemakers and symptomatic renal calculi were deemed otherwise suitable for this form of therapy and were referred to us for medical clearance. After obtaining institutional review board for human research approval, each patient gave informed written consent. All patients were given general anesthesia and had standard ESWL therapy (Table III).

These six patients (five males) mean age of 72 ± 10 years, has standard single chamber devices

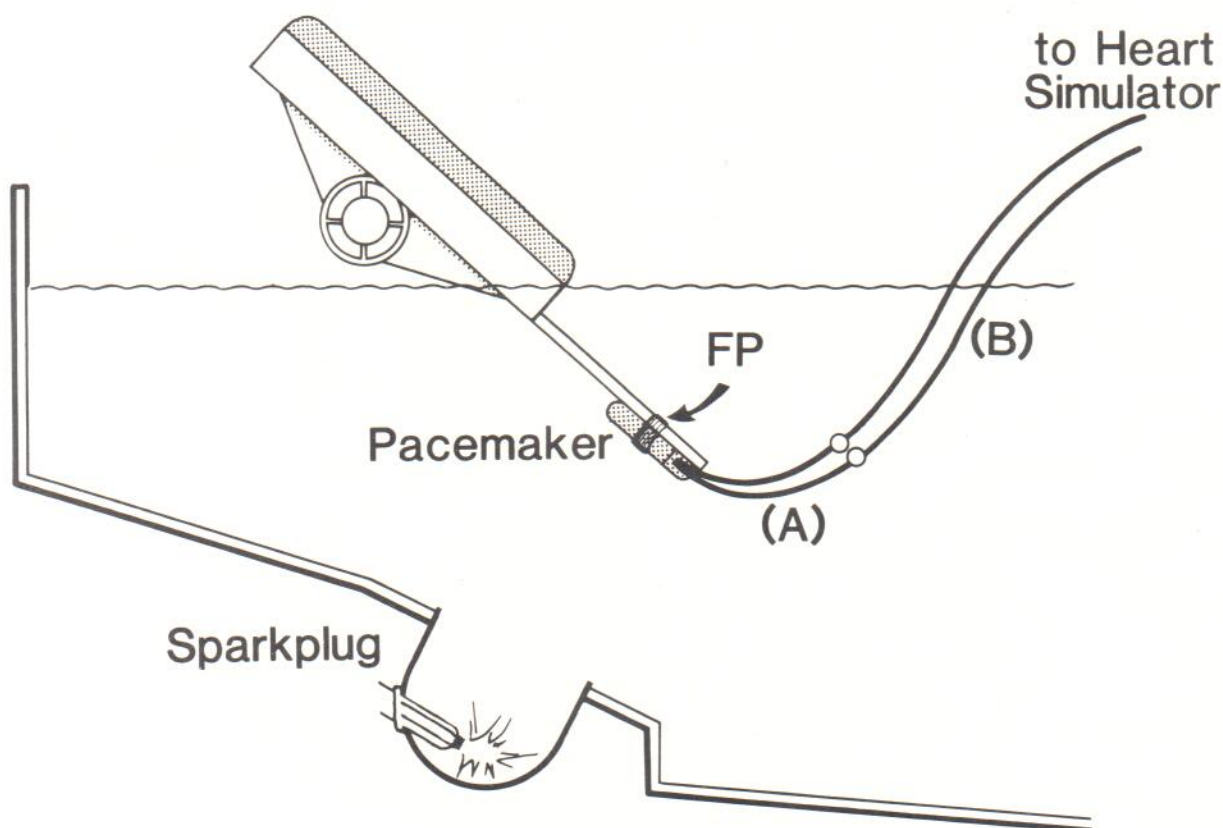


Figure 1. Schema of pacemaker in ESWL bath at the focal point (FP) connected via standard pacing leads (A) and alligator clip electrodes (B) to a heart simulator.

(N = 3), and dual chamber devices (N = 3) because of complete heart block N = 3 and sick sinus syndrome N = 3. All devices were implanted subcutaneously in the thorax and had telemetry of their programmed parameters with determination of pacing and sensing thresholds 24 hours prior to and after ESWL. During the ESWL therapy, all patients were continuously electrographically monitored and observed by one of the authors.

Results

In Vitro Study

Standard Single Chamber Pacemakers

All standard single chamber pacemakers demonstrated normal sensing and pacing function during ESWL testing. Analysis of all units using the pacing system analyzer (PSA) revealed no change in the initial programmed parameters as a

result of exposure to ESWL (Table I). Destructive analysis performed on all units showed that the external case, hermetic seal, and internal circuitry were not damaged.

Dual Chamber Pacemakers

During ESWL, the shock waves were triggered off the paced atrial event for all units (unipolar and bipolar), which intermittently inhibited the ventricular output in two unipolar pacemakers (Cordis Gemini 415A and Teletronics Autima II 2291) (Cordis Corp., Miami, FL, USA and Teletronics, Englewood, CO, USA) when tested at their most sensitive settings. When retested at nominal sensitivity settings this phenomenon was no longer observed (Fig. 3). Other dual chamber pacemakers functioned normally during the ESWL testing protocol.

Analysis using the PSA after testing disclosed that there were no changes in the initial pro-

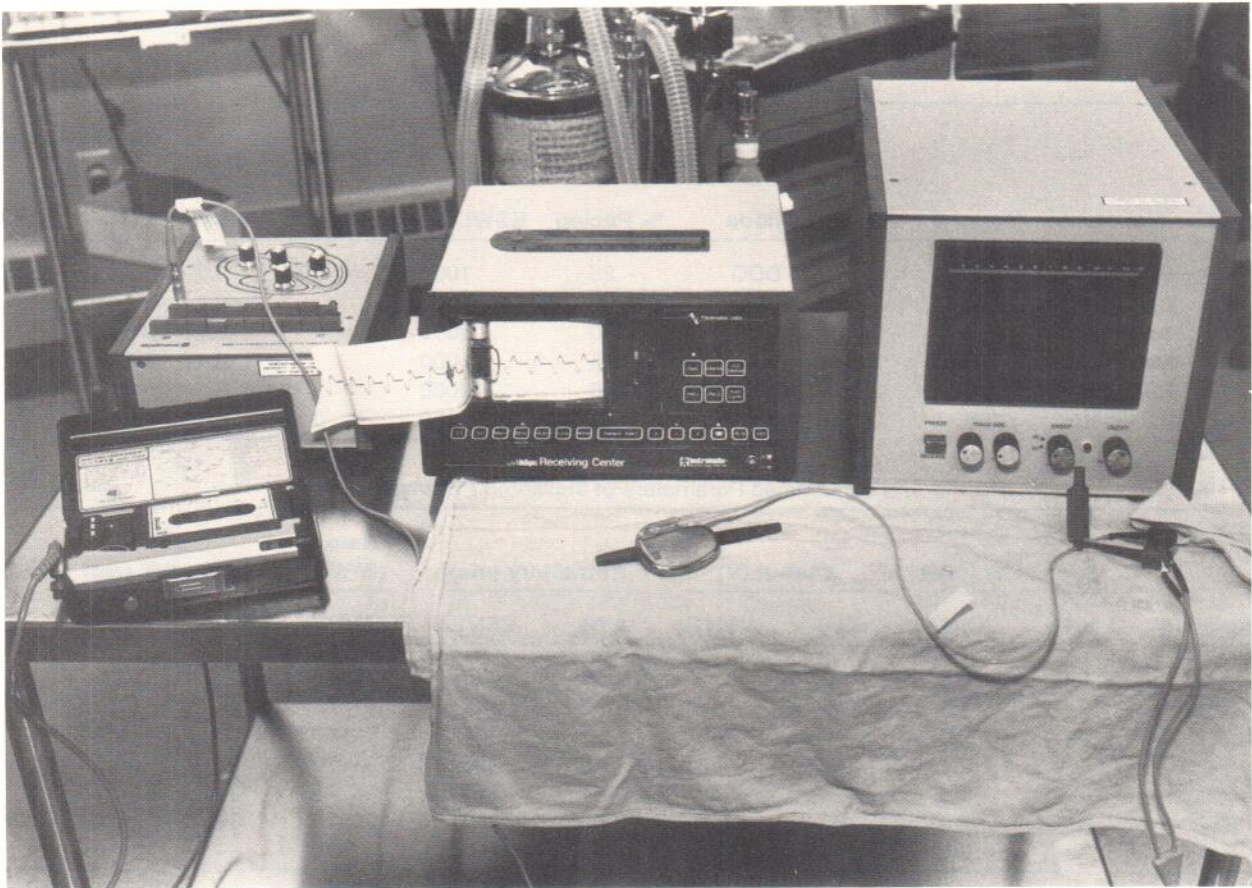


Figure 2. The pacemaker (A) connected via standard pacing leads (B) and alligator clip electrodes (C) to a pacemaker interactive heart simulator (D) and then to the Holter recorder (E), strip chart recorder (F) and oscilloscope.

grammed parameters (Table II). Destructive analysis was performed on all units, confirming the external case, hermetic seal, and internal circuitry remained intact.

Rate Responsive Single Chamber Pacemakers

The first activity sensing rate responsive pacemaker (Activitrax 8400), tested at F2, exhibited normal pacing and sensing and achieved a maximum rate of 80 beats per minute (BPM) during ESWL. Upon shaking the can after the test, there was audible evidence of loose components within the can. PSA analysis disclosed the programmed parameters remained unchanged. Destructive analysis disclosed the can, hermetic seal and internal circuitry remained intact; however, the rate sensing piezoelectric crystal was shattered (Fig. 4).

A second pacemaker can, with a piezoelectric element without internal circuitry, was then

placed at the focal point and submitted to a similar protocol of ESWL. Once again, the piezoelectric crystal was shattered.

Two additional Activitrax pacemakers, models 8402 and 8403 were tested 5 cm away from the focal point. Both units paced normally throughout the protocol; however, they attained their maximum programmed pacing rate (150 BPM) rapidly with ESWL therapy (Fig. 5). Analysis using the PSA disclosed the pacing parameters were unchanged by therapy. Destructive analysis confirmed the pacemaker can, hermetic seal, internal circuitry and the piezoelectric elements were intact.

In Vivo Study

Patients with Implanted Pacemakers

The patients with standard single chamber pacemakers programmed VVI underwent successful ESWL uneventfully and without effect on

Table III.
Pacemakers Implanted in Patients Having ESWL

Pt #	Manufact	Model #	POL	Mode	% Pacing	ESWL Shocks	Pace Thresh. (ms)		Sense Thresh. (mV)	
							ATR.	VENT.	ATR.	VENT.
1	Cordis	233F	U	DDD	25	1000	0.1	0.2	>2.5	>2.5 mV
2	Cordis	233G	U	VVI	50	500		0.1	>2.5	
3	Intermedics	253	U	VVI	50	3000		0.1	>3.0	
4	Medtronic	8420	B	VVI	75	4000		0.1	>2.5	
5	Pacesetter	251-6	U	VVI	100	2000		<0.1	>3.5	
6	Pacesetter	283	U	DDD → VVI	100	3900	0.1	0.1	2.6	—

Programmed Parameters of Implanted Pacemakers

Model #	Sensitivity (mV)		Output (V)		Refractory (ms)		Rate (BPM)	Pulse WT (ms)		AVI
	ATR.	VENT.	ATR.	VENT.	ATR.	VENT.	H/L	ATR.	VENT.	
233F	0.5	2.5	5	5	350	300	108 60	0.6	0.5	200
233G	—	1.3	—	5	—	300	— 70	—	0.5	
253	—	2.0	—	5.4	—	325	— 73	—	0.6	
8420	—	2.5	—	5	—	325	— 70	—	0.5	
251-6	—	2.0	—	5	—	325	— 70	—	0.4	
283	1.0	2.0	4	4	250	250	110 70	0.6	0.6	165
*	—	2.0	—	4	—	325	— 70	—	0.6	

ESWL = extra corporeal shock wave lithotripsy (all shocks at 18 kV)

* = programmed settings during ESWL.

Model # = pacemaker model number.

Other abbreviations as in Table 1.

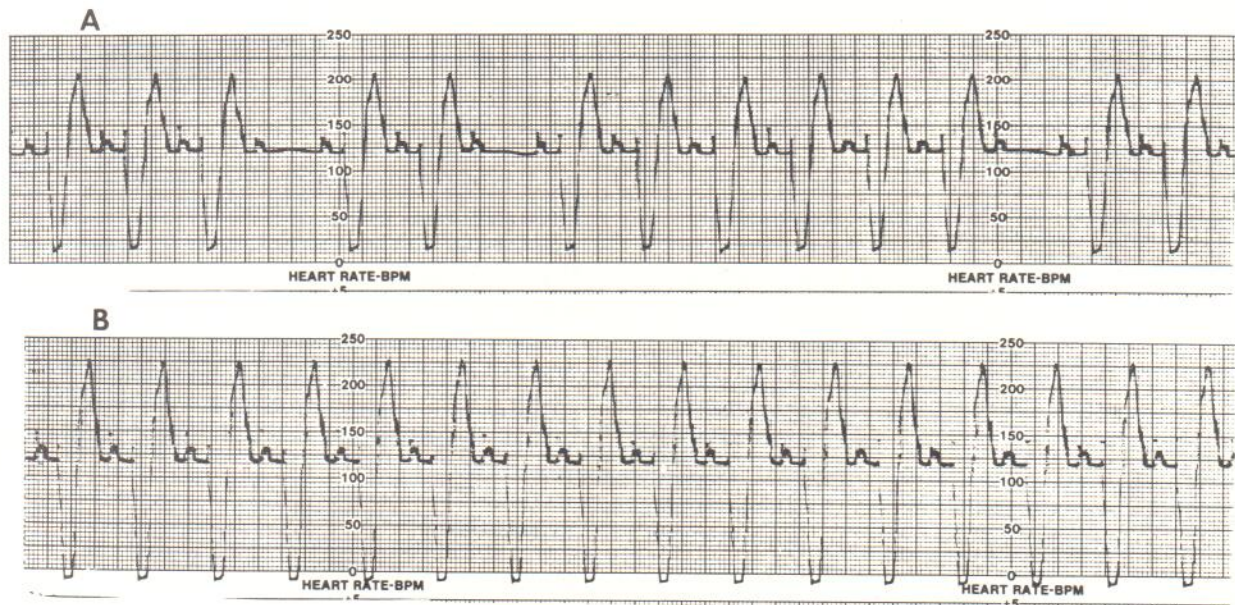


Figure 3. Electrograms of pacemakers 1 and 6 from Table II disclosing atrial pacing with ESWL induced episodic inhibition of the ventricular output (A) which was eliminated by reprogramming to a less sensitive ventricular chamber setting (B).

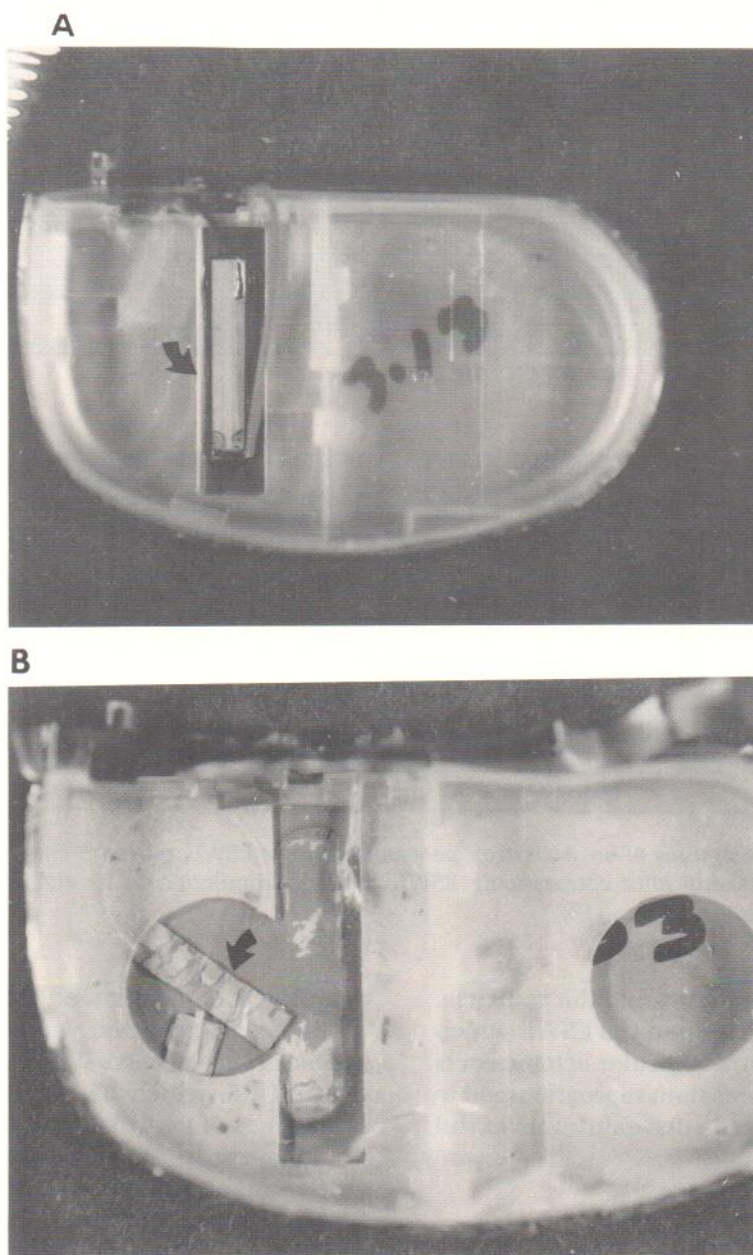


Figure 4. Intact piezoelectric crystal of an Activitrax pacemaker placed 5 cm from the focal point during ESWL (A) and a piezoelectric crystal of a similar pacemaker shattered by ESWL when placed at the focal point (B) during testing.

the pacemaker or sensing and pacing thresholds (Table III).

The other three patients undergoing ESWL had dual chamber devices, one device was previously programmed to VVI (atrial fibrillation) and this patient had uneventful ESWL. The sec-

ond patient, tracking his intrinsic P-wave activity, had ESWL triggered by the ventricular paced event and had successful, uneventful ESWL. There was no increase in the pacing rate throughout ESWL therapy. The third patient, with his pacemaker programmed to the DDD

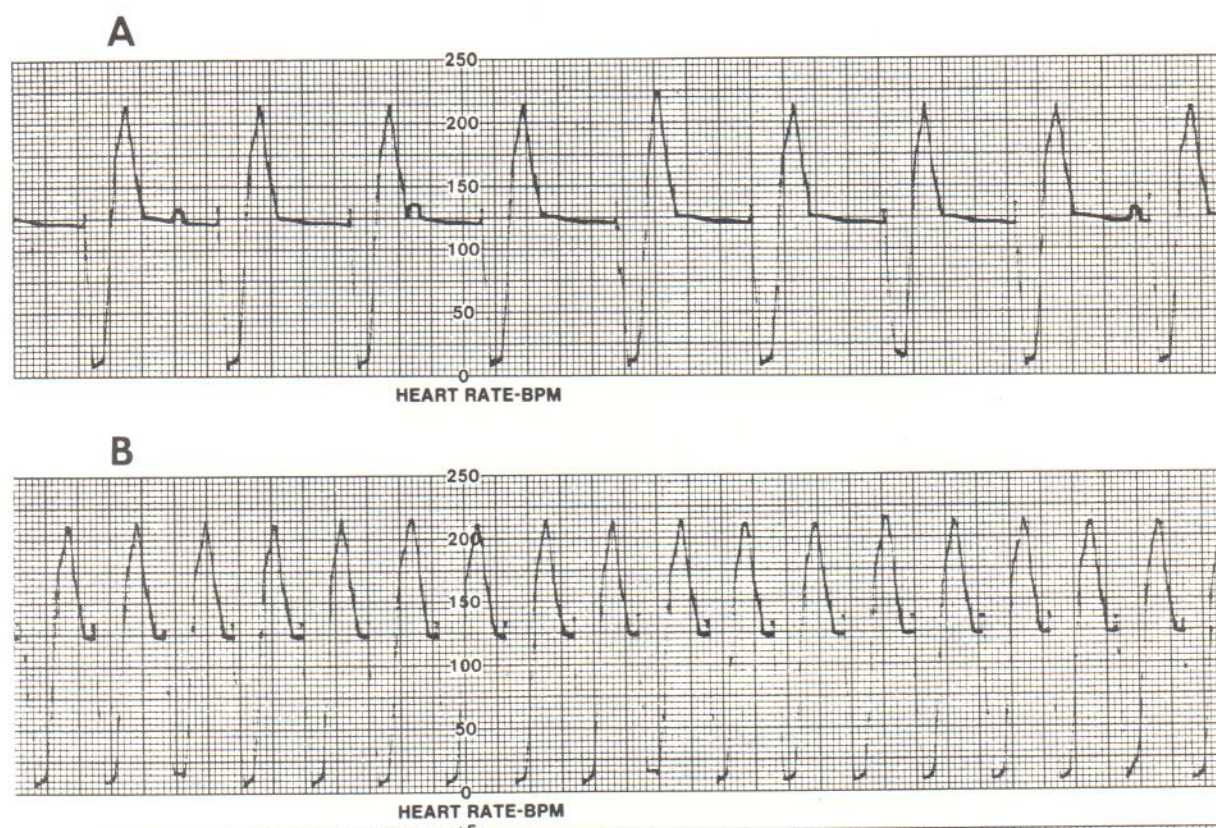


Figure 5. Electrograms of an Activitrax pacemaker before ESWL, placed 5 cm from the focal point (A) and shortly after commencing ESWL showing stimulation to its maximum activity related pacing rate (150 bpm) (B).

mode, was pacing in the atrium and the ventricle. The atrial paced event triggered the ESWL which in turn induced uniform ventricular ectopic beats (Fig. 6); his pacemaker was then reprogrammed to the VVI mode and he had successful uneventful ESWL.

Discussion

Extracorporeal shock wave lithotripsy has emerged as the treatment of choice in selected patients with upper urinary tract calculi.⁶ Currently the presence of an implanted cardiac pacemaker is a contraindication to this therapy because of the unknown effects of pressure shock waves and electromagnetic interference that may impact upon pacemakers.

In view of the expanding role of ESWL, patients with implanted pacemakers will also be candidates for this form of therapy. Since the ini-

tial clinical application of ESWL therapy, it's arrhythmogenic potential was noted. Subsequently, all shocks have been synchronized with the intrinsic QRS, which has virtually eliminated the occurrence of ventricular arrhythmias.⁸

The results of this study suggest that ESWL will probably have little effect on pacemaker function. Standard single chamber pacemakers subjected to ESWL synchronized with the pacemaker output, had their pacing and sensing function unaffected. Subsequent destructive analysis disclosed the pacemaker can, hermetic seal and internal circuitry remained intact. Studies by other centers^{9,10} have shown that standard single pacemakers have been unaffected by ESWL synchronized with the pacing output or QRS; however, reversion to magnet mode was noted in 10% of one series.¹⁰ In another series,⁹ when the pulse generators were subjected to shock waves delivered asynchronously at a rate greater than the

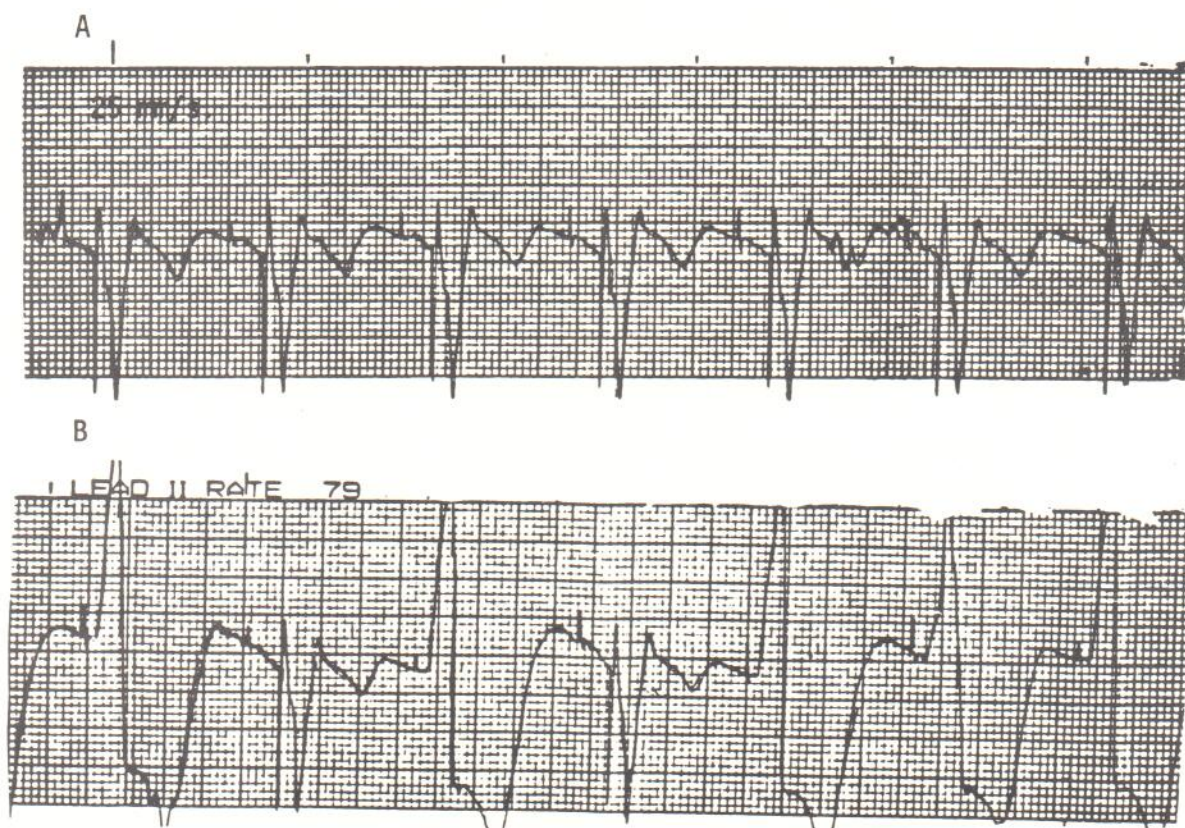


Figure 6. Electrocardiogram of patient 6, Table III showing atrial and ventricular paced rhythm before ESWL (A) and during ESWL (B) disclosing that the ESWL triggered off the atrial paced event inducing ventricular ectopy. This was eliminated by reprogramming the pacemaker to the VVI mode.

programmed pacing rate, 50% of the pulse generators were inhibited by the electromechanical interference; however, this situation is unlikely to be clinically relevant as the lithotripter is triggered by the QRS or pacing stimulus. In this series, patients with pacemakers programmed to the VVI mode⁵ functioned normally without difficulty throughout ESWL and 24 hours later.

Thus, we believe that patients with standard single chamber pacemakers can be treated with ESWL therapy as long as it is synchronized with the ventricular pacemaker output or QRS. A small percentage of pacemakers may revert temporarily to their noise reversion mode.

Patients with dual chamber pacemakers may exhibit electromagnetic interference.

If the patient is pacing in both chambers, the ESWL will trigger off the atrial paced event (unipolar or bipolar) and may cause inhibition of the

ventricular output or induce ventricular arrhythmias (Fig. 6). It has also been reported during in vitro dual chamber pacing studies, that pacemaker acceleration to the upper rate limit may occur.¹⁰

The sensing of the electromagnetic activity demonstrated in the in vitro study was only present when the pulse generators were programmed to the highest sensitivity setting. This problem was eliminated by reprogramming to a less sensitive setting. Patients with pacemakers tracking intrinsic P-wave activity can probably have ESWL therapy without further programming; however, in the event of pacing in the atrium, these patients should have their pacemakers programmed to the VVI mode.

Rate responsive single chamber pacemakers with a piezoelectric activity sensing crystal exhibited serious deleterious consequences of

ESWL. In two units placed at F2, both devices had their piezoelectric crystals shattered by ESWL therapy. Two similar devices positioned 5 cm from F2 were undamaged but attained maximum programmed pacing rate (150 bpm) very rapidly with ESWL.

Limitations

In the in vitro study, all pulse generators were subjected to destructive analysis; thus, due to study design, only the acute effects of ESWL could be determined.

The effects of ESWL on implanted pacemakers were evaluated during therapy and again 24 hours later; however, careful long-term follow-up will be required to insure absence of any detrimental effects.

All patients studied had chronically implanted endocardial leads thus no assessment could be made regarding the hazard of dislodgment of recently implanted leads.

Conclusions

Based on our limited in vitro and early clinical experience, we conclude:

1. It is generally safe for patients with stan-

dard single chamber pacemakers, in a ventricular application, to undergo ESWL whether their devices are implanted in the abdomen or thorax.

2. Patients with dual chamber devices should have their pulse generators reprogrammed to the VVI mode to avoid induction of ventricular arrhythmias or inhibition of ventricular output.

3. Patients with piezoelectric activity sensing rate responsive pacemaker implanted in the thorax can probably undergo ESWL safely provided the activity mode is deactivated. In view of the damage to the piezoelectric crystal, we feel patients with an activity sensing rate responsive pacemakers implanted in the abdomen probably should not undergo ESWL.

4. Comprehensive pacemaker and patient review before, during, and after ESWL therapy is mandatory until sufficient data can be accumulated regarding this form of therapy in patients with pacemakers.

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