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Digital Cellular Telephone Interaction With Implantable Cardioverter-Defibrillators

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Objectives. **This study sought to determine, in vivo, whether electromagnetic interference (EMI), generated by North American Digital Communications (NADC)/Time Division Multiple Access–50-Hz (TDMA-50) mobile cellular digital telephone model AT&T 6650, disturbs normal implantable cardioverter-defibrillator (ICD) operation and to verify these observations in vitro by testing a selection of telephones representing worldwide systems.**

Methods. **The effects of cellular phone interference on the operation of various models of market-released ICDs from a single manufacturer, Medtronic, Inc., were tested. The in vivo clinical test was undertaken in 41 patients using the AT&T 6650 digital telephone with the NADC/TDMA-50 technology. The in vitro component of the study was examined twofold: 1) antenna generated far field; and 2) analog/digital cellular telephone near field.**

Results. **None of the ICDs tested in 41 patients were affected by oversensing of the EMI field of the cellular telephones during the in vivo study. Therefore, the binomial upper 95% confidence limit for the failure rate of 0% is 7%. The in vitro antenna-generated field testing showed that telephone modulation frequencies used in the international Global System Mobile and TDMA-50 cellular telephone technologies did not result in ICD sensing interference at the predicted electric field intensity. The in vitro near field tests were performed using both analog and digital cellular telephones in service, or in the test mode, and indicated no interaction with normal operation. However, the static magnetic field generated by the cellular telephone placed over the ICD at a distance ≤0.5 cm will activate the internal reed switch, resulting in temporary suspension of ventricular tachycardia and fibrillation detection.**

Conclusions. **We conclude that TDMA-50 cellular telephones did not interfere with these types of ICDs. However, we recommend that the patient not carry or place the digital cellular telephone within 15 cm (6 in.) of the ICD.**

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The interaction of analog and digital mobile cellular telephones with pacemakers and defibrillators has been the subject of considerable recent interest (1). However, most existing studies have focused primarily on mobile cellular telephone interaction with pacemakers. For example, Hayes et al. (2) tested 980 patients with cardiac pacemakers with analog and digital cellular telephones and found a 20% incidence of interference. Similarly, Carrillo et al. (3) reported findings in 59 patients who did not depend on a pacemaker and who had digital telephones. Interference was seen in 21 patients (36.2%) and 19 pacemaker models (54%) when the telephone was held over the pacemaker. Subsequently, a pilot study of 30 patients who did not depend on a pacemaker and who had digital telephones showed tracking interference on the atrial lead, oversensing and undersensing in 16 patients (53%) (4). In contrast, another study examining the effects of interference from analog cellular telephones found no evidence of electrocardiographic (ECG) abnormalities with 24 implanted pacemakers (5). To date, there has not been any reported permanent damage, pacemaker dysfunction or changes in the program variables observed during these studies.

The risk to the patient caused by cellular telephone interference with an implantable cardioverter-defibrillator (ICD) could potentially be greater than that with a pacemaker. Any electromagnetic interference (EMI) with an ICD—that is, interference with its normal operation, thereby causing other inappropriate sensing and uncalled for shocks, or alternatively temporary suspension of arrhythmia detection—could be unpleasant or even life-threatening.

The objectives of this study were first to evaluate the susceptibility of tiered, single-chamber ICDs to EMI caused by commercially available digital mobile telephones during in vivo clinical testing, and second to confirm in vivo observations by in vitro tests using analog and digital cellular phones and antenna-generated fields. The ultimate goal was to provide guidelines regarding the safe use of mobile cellular telephones by patients with an ICD.

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Abbreviations and Acronyms

ECG = electrocardiogram, electrocardiographic
EMI = electromagnetic interference
ICD = implantable cardioverter-defibrillator
GSM = Global System Mobile
NADC = North American Digital Communications
RMS = root-mean-square
TDMA-50 = Time Division Multiple Access–50 Hz

Methods

In vivo testing. *Patients and device configuration.* The study group consisted of 41 patients (7 women and 34 men). Twenty-one patients had a model 7217 PCD cardioverter-defibrillator (Medtronic, Inc.) implanted in an abdominal location, and 20 had a model 7219 Jewel ICD—18 in the pectoral region (6 subcutaneous and 12 deep to the pectoralis major muscle) and 2 in the abdominal region. Forty of the ICDs were connected to bipolar lead systems. One lead system consisted of an integrated bipolar design. Thirty-five of the patients had an implanted transvenous ventricular lead with 34 leads (Medtronic model 6936) consisting of polyurethane insulation and coaxial wound conductors, a high voltage coil, a ring and active fixation helix at 12-mm spacing for bipolar sensing and one lead (Cardiac Pacemaker, Inc., model 0115) consisting of silicone insulation with multilumen conductors, a high voltage coil and a passive fixation electrode with 12-mm spacing for integrated sensing implanted in the right ventricular apex. Six of the patients had an epicardial lead system consisting of two unipolar active fixation leads (Medtronic model 6917) with a nominal separation of 2 cm between electrodes, connected in a bipolar configuration. The separation between the lead conductors varied during the length of the lead, and any excess length was coiled at the implantation site, which would have very little effect on the antenna properties of the lead.

Digital phones. The hand-held mobile telephone used for all tests was an AT&T model 6650 capable of analog and digital operation with 0.6 W peak power. The digital transmission mode in this North American Digital Communications/Time Division Multiple Access–50-Hz (NADC/TDMA-50) technology consists of an 828-MHz carrier signal modulated at a 20-ms pulse period (50 Hz pulse rate). This telephone had the advantage of displaying the actual power that was used during a call.

Study protocol. All tests were thoroughly explained to each patient, and consent was obtained and coordinated with the primary care physician before commencing the test. All patients tested used the same mobile telephone at the same location in the clinic. The transmitting power of the mobile telephone was recorded for each patient test. All patients were connected to an ECG monitor and continuously observed during the tests. The tests were conducted with the telephone ringing (receiving) and transmitting (calling) 1) at both the right and left ears, simulating regular use; 2) moving over the entire route of the lead from electrode in the heart to its connector end; and 3) on top of the implantation site to simulate carrying the telephone in the upper shirt pocket or at the belt. All tests were with telephone configurations consisting of the antenna withdrawn (in) into the base (strongest magnetic field) and the antenna fully extended (out) using the tip (strongest electrical field). The ICDs tested in this study were able to provide noninvasive, telemetered, internal event counter information on detected episodes of ventricular tachycardia or ventricular fibrillation. Specific variables were reprogrammed to "worst case" values for this test (Table 1) to enhance the probability that detection of EMI from the cellular telephone would produce inappropriate device operation. The sensitivity was reprogrammed to the most sensitive value, and the number of intervals to detect tachycardia or fibrillation was set to the minimal value to satisfy the detection algorithm. All tachycardia pacing and shock therapies were temporarily disabled as a precaution in the event that the EMI was sensed, thereby initiating therapy. The pacing rate was increased ~10 ppm above the patient's intrinsic rate to produce continuous overdrive pacing. The programmer head was not left in place over the ICD during testing.

Table 1. Implantable-Cardioverter Defibrillator Variables Temporarily Reprogrammed During Clinical Testing

Variable	Nominal	Test
Sensitivity	0.3 mV	0.15 mV (model 7219)
	0.3 mV	0.3 mV (model 7217)
No. of intervals to detect VT	16	4
No. of intervals to detect VF	18 of 24	12 of 16
VF detection	On/320 ms	On/400 ms
VT detection	On/400 ms	On/600 ms
VT/VF therapies	On	Off
Stability	On or off	Off
Onset	On or off	Off
Pacing rate	—	10 ppm above intrinsic

ppm = pulses per minute; VF = ventricular fibrillation; VT = ventricular tachycardia.

The defibrillator was interrogated after the patient completed each specific telephone test to determine whether the ventricular tachycardia or fibrillation detection algorithms were satisfied by detection of EMI. The telemetered data would identify any detected episode of ventricular tachycardia or fibrillation by indicating an increment in the internal counter used to monitor for arrhythmia detection in the Tachycardia Counter Data Report. All variables were reprogrammed to original values after completion of the test.

The cellular telephone has a built-in speaker with a small, permanent magnet in the earpiece that generates a static magnetic field. A magnetic field could activate a reed switch in the cardioverter-defibrillator and temporarily inhibit detection of ventricular tachycardia or fibrillation. However, this magnetic field interference would not be detected in this in vivo study, because, unlike standard pacemakers, the pacing circuit of the ICDs being tested will not revert to an asynchronous

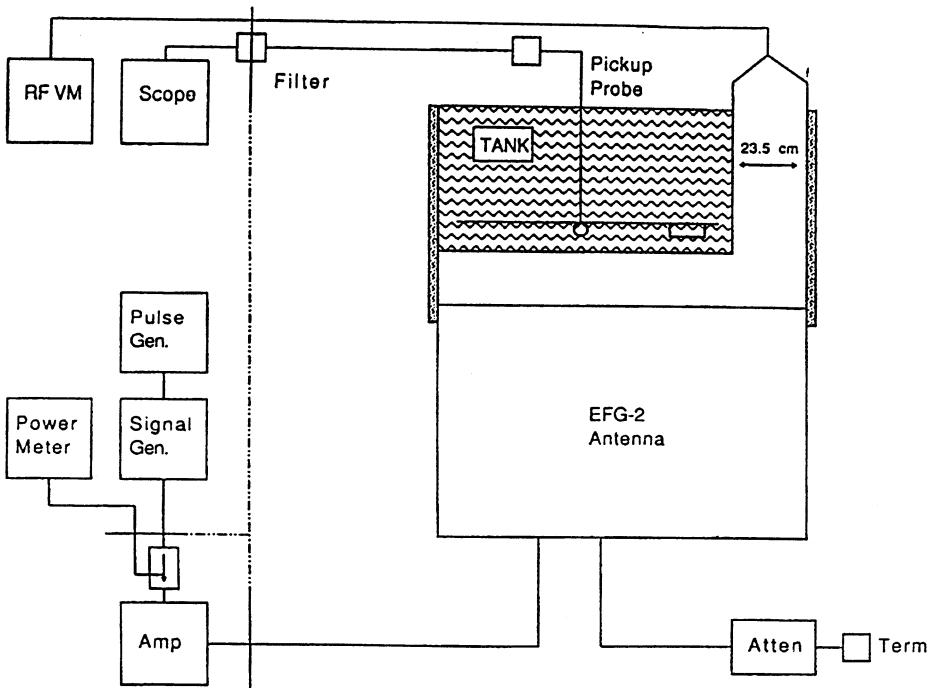

Figure 1. Top view of tank simulation model used for the antenna-generated field in vitro test of the ICDs. Amp = amplifier; Atten = attenuator; EFG-2 = electric field generator-2; Gen. = generator; RF VM = radiofrequency volt meter.

pacing mode. Therefore, this test could not be done in vivo, but was accomplished with a custom device during in vitro testing (see In Vitro Testing, Magnet test).

Statistical analysis. An exact binomial upper 95% confidence limit was used on the failure rate.

In vitro testing. *Antenna-generated field.* The ICD was connected to either a transvenous or epicardial lead system. The complete system was then immersed in a 375 ± 15 ohm cm saline solution bath and placed within 1 cm (typical implant depth) of the liquid surface in a frontal orientation, as shown in Figure 1. A transmitting antenna was connected to a frequency pulse generator to simulate cellular telephone modulation. The testing was structured to assess susceptibility of the ICD's normal operation to modulations that are known to be used in two digital cellular telephone systems: NADC/TDMA-50 and international Global System Mobile (GSM). Four models of ICDs—PCD 7217, Jewel 7219, Jewel Plus 7220 and Micro Jewel 7221—were subjected to radiated continuous carrier wave and modulated interference fields at two frequencies—836 MHz and 900 MHz. Modulations that simulate the digital systems patterns as shown in Table 2. The field intensity was increased until the ICD began to sense the interference, and the level at that point was recorded.

Analog/digital cellular phones. The ICDs listed in Table 3, immersed in saline, were subjected to the near fields radiated from the antennas of the cellular telephone models used in North America and worldwide, as shown in Table 4. The telephones were tested in both analog and digital modes, where applicable. Some telephones, designated as group 1 in Table 4, could be fully operated, and the susceptibility was evaluated while the telephone was transmitting and receiving calls with the antenna withdrawn (in) and extended (out). Other technologies, designated as group 2 in Table 4, were used in an open-loop transmit mode (i.e., producing the typical pulsing format of that technology without being in communication with an active cell site or base station simulator). Keypad programming was used to configure the telephone in the full power transmit mode. The distance from the telephone antenna to the ICD was kept within 1 cm.

Magnet test. A custom ICD was modified with special software so that when the reed switch was activated with a magnet, the pacing rate would change to a train of 7 pulses of low amplitude and a fast rate (100 ppm), and then return to normal pacing. The cellular telephone, with its magnet in the earpiece, was brought into direct contact with the ICD in free air and then moved around on and at incremental distances from the surface while the pacing output was monitored.

Table 2. Antenna-Generated Fields Used to Simulate Digital Cellular Telephone Technology Modulation During In Vitro Testing of Implantable Cardioverter-Defibrillators*

Carrier Frequency	Modulation	Cellular Telephone Technology
900 MHz	0.6 ms PW/480 ms PP (125 Hz)	Global System Mobile
900 MHz	0.6 ms PW/120 ms PP (500 Hz)	Global System Mobile
900 MHz	0.6 ms PW/4.61 ms PP (13 kHz)	Global System Mobile
836 MHz	6.7 ms PW/20 ms PP (3 kHz)	Time Division Multiple Access–50 Hz

*See Table 3 for a list of the implantable cardioverter-defibrillators. PP = pulse period; PW = pulse width.

Table 3. In Vitro Test Results of Implantable Cardioverter-Defibrillators Subjected to Near Field Effects of Analog and Digital Telephone Technologies

ICD Model/Lead System	Cellular Telephone Technology				
	AMPS	GSM	TDMA-50	TDMA-11	PCS
7217B/epicardial	NE	NE	NE	NE	NE
7217B/endocardial	NE	NE	NE	NE	NE
7219D/epicardial	NE	NE	NE	NE	NE
7219D/endocardial	NE	NE	NE	NE	NE
7219C/endocardial	NE	NE	NE	NE	NE
7220D/epicardial	NE	NE	NE	NE	NE
7220D/endocardial	NE	NE	NE	NE	NE
7220C/endocardial	NE	NE	NE	NE	NE
7221D/epicardial	NE	NE	NE	NE	NE
7221C/endocardial	NE	NE	NE	NE	NE

AMPS = Advanced Mobile Phone System; GSM = Global System Mobile; NE = no effect; PCS = Personal Communications System; TDMA-11 = Time Division Multiple Access–11 Hz; TDMA-50 = Time Division Multiple Access–50 Hz.

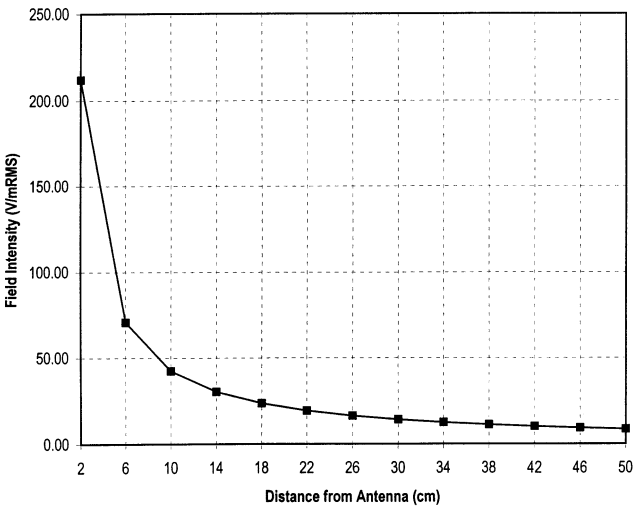

Figure 2. Theoretically predicted electric field intensity for a 0.6-W isotropic point source antenna, as measured in axis in all directions in air at incremental distances from the antenna.

Results

In vivo testing. *Digital cellular phone.* The ICD was interrogated after each phase of telephone status and location testing. At no time was any ventricular tachycardia or fibrillation counter activated by the EMI from the antenna of the cellular telephone for any test conducted on any patient. There was no damage or reprogramming of any ICD during the tests. The ECG that was recorded continuously during the patient test to monitor the ventricular demand overdrive pacing mode (VVI) was thoroughly reviewed for abnormalities. At no time were there any indications of pacing inhibition or changes to the programmed pacing intervals during any test on any patient. Therefore, the binomial upper 95% confidence limit for the failure rate of 0% is 7%.

Table 4. Analog and Digital Cellular Telephone Models Used During In Vitro Testing for Near Field Effects on Implantable Cardioverter-Defibrillators*

Cellular Telephone Technology	Cellular Telephone Model	Maximal Power of Pulse (W)
Group 1		
AMPS	Motorola, model FOSHLD84168G	NA
AMPS/TDMA-50	Motorola LE Bag Phone, model 19902XTLSA	5.0 (TDMA)
AMPS/TDMA-50	AT&T, model 6650	0.6†
Group 2		
TDMA-11 (MIRS)	Test transmitter	3.7
GSM	Test transmitter	1.7
PCS	Test transmitter	0.5
AMPS/TDMA-50	Test transmitter	1.0 (TDMA)

*See Table 3 for a list of the implantable cardioverter-defibrillators. †Power value provided in the manufacturer's technical manual. Group 1 = cellular telephone in service. Group 2 = transmitter operated in test mode. NA = not applicable; MIRS = Motorola Integrated Radio Services; other abbreviations as in Table 3.

In vitro testing. *Antenna-generated field testing.* Field strength levels at which the ICDs began to sense the interference started at 230 V/m root-mean-square (RMS). Interference oversensing resulted in partial inhibition (changed pacing rates); satisfied the ventricular tachycardia or ventricular fibrillation detection algorithm and could have caused either therapy to be delivered; or caused the device to go power-on-reset. The most susceptible ICD to EMI was the early generation model 7217 connected to a bipolar epicardial lead system that occurred at field intensities of 230 V/m RMS. A bipolar, coaxial, polyurethane, insulated, endocardial lead connected to the model 7217 ICD increased the susceptibility interference level to 300 V/m RMS.

Predicted field intensity. To estimate the field values in the vicinity of the ICD, the predicted electric field intensity for a 0.6-W isotropic antenna point source, as recorded at measured distances in free space from the antenna, is plotted in Figure 2. The predicted electric field intensity (E) for a 0.6-W isotropic antenna point source, as measured along axes in all directions for free space conditions (air at 377 Ω), was calculated at incremental distances from the transmitting antenna using the following equation (6):

$$E = \frac{(30\,P)^{1/2}}{R}\ (\text{volts/meter}),$$

where P = transmitted power in watts (0.6 W), and R = distance in meters.

The field intensity decreases exponentially and rapidly drops <50 V/m RMS at 10 cm from the antenna. At 15 cm (6 in.), the distance recommended for cellular telephone use for patients with ICDs, the field intensity would be 20 V/m RMS, which is well below the susceptibility level measured during the in vitro antenna-generated field testing. Field intensity predictions at distances <2 cm from the point source were not attempted, as this near field also contains magnetic fields that

affect the accuracy of the equation. The near field characteristics for the cellular technologies were assessed by in vitro testing with the analog and digital cellular telephones.

Analog/digital cellular telephones. Testing was completed and the results summarized (Table 3) on models of market-released ICDs, and testing was completed on various lead systems, with the analog/digital cellular telephones in groups 1 and 2 listed in Table 4. No interference was noticed on any ICD with any cellular telephone technology.

Magnet test. The static magnetic field generated by the magnet of the speaker in the telephone was measured to be 288 gauss RMS at the telephone surface and decreases exponentially to 19 gauss at 1 cm (0.4 in.) from the surface. The cellular telephone placed over and moved around on the ICD surface activated the reed switch when the telephone was on the upper left corner of the engraved side, where the reed switch is located. When the cellular telephone was placed at 0.5 cm (0.2 in.) or further from the ICD surface, reed switch activation did not occur.

Discussion

The findings of this study indicate that EMI transmitted by digital cellular technologies, commonly used in North America, did not interfere with in vivo normal functional operation of the specific ICDs tested. Inappropriate sensing did not occur and ventricular tachycardia or fibrillation detection plus pacing function remained normal. The average overdriven VVI pacing rate of 80 ppm (750 ms) resulted in a postpace blanking period of 320 ms, leaving 430 ms available for sensing during each paced interval. The nonpaced blanking period was 120 ms, increasing the sensing period to 630 ms. However, the test was designed so that the EMI was present for many pacing cycles, allowing more than adequate time to detect interference during the pace intervals, and similar results would be expected for nonpaced rhythms. These results were substantiated by comprehensive test data from independent in vitro studies using digital telephone technologies used worldwide: 1) antenna-generated field testing to evaluate far field interference; and 2) in vitro analog and digital cellular telephone testing that evaluated near field effects. In these in vitro studies it was observed that the magnetic field from the earpiece speaker magnet in the cellular telephone can activate the reed switch in the ICD at distances <0.5 cm (0.2 in.) and temporarily suspend ventricular tachycardia or fibrillation detection.

At this time there are few published data pertaining to cellular telephone interference with ICDs. In one preliminary report of 25 patients with ICDs, Stanton et al. (7) found that North American–type analog and digital cellular telephones did not cause any interference oversensing, arrhythmia overdetection or interference with sensing or pacing. Similarly, Madrid et al. (8), who assessed 40 patients with an ICD using international, high power (3-W) analog cellular telephones, found EMI in only one patient. In contrast, an in vitro study by Bassen et al. (9), who tested the interference effect of digital cellular phone modulation schemes used in North America on four ICDs, noted that discharges occurred when the bases of the antennae of certain model telephones were placed within ~5 cm from the header of the defibrillator or at branches of bifurcated leads. An explanation for the discrepancy between the results reported by Bassen et al. and those of our in vitro tests may be related to their use of early models of unidentified ICDs.

Bipolar versus unipolar sensing. Forty of the 41 ICDs tested in this report used bipolar sensing; 34 of the 35 transvenous lead systems used standard true bipolar sensing and 1 used integrated bipolar sensing. The remaining six lead systems consisted of two epicardial unipolar leads configured into a bipolar pair. Neither bipolar nor paired unipolar lead systems exhibited susceptibility to EMI. In contrast, Irnich et al. (10) conducted in vitro testing of mobile telephone interference with 44 pacemakers from the same manufacturer and found that 5 (18.5%) of 27 unipolar systems and 4 (23.5%) of 17 bipolar units were susceptible. However, other studies comparing bipolar to unipolar pacemaker susceptibility to mobile cellular telephone interference indicated the superiority of bipolar lead systems in rejecting EMI (11–13). Naegeli et al. (14) tested 39 patients with pacemakers using digital mobile telephones and found that when the incidence of VVIR pacemaker inhibition was compared in the bipolar and unipolar modes in the same patients, ventricular inhibition occurred in none of the 112 tests in the bipolar mode compared with 14 (12.5%) of the 112 tests in the unipolar mode.

Interference rejection mechanisms. The ICD and lead system were scanned with the cellular telephone antenna during telephone operation and in vitro near field testing. It was observed that scanning over any portion of the lead produced no interference effects to the ICD. Electromagnetic interference on pacemakers was observed to be the greatest when the antenna was extended and located over the header assembly. The effect could not be duplicated during this study in the ICDs. The susceptibility at the header and lack of substantial lead contribution to EMI were substantiated during in vitro studies with pacemakers by Carrillo et al. (15). Much of the energy injected at the tip electrode and along the length of the lead is attenuated to the surrounding medium (cardiac tissue in vivo and saline in vitro) along the entire length of the lead. Generally, on all manufacturers' ICDs, the feedthroughs and connecting wires to the sense amplifier on the hybrid circuit, although short in length, act as an antenna to the high frequency (short wavelength) interference signal. Protection to the sense amplifier for the ICDs tested in this study was accomplished with capacitors on the input to the sense amplifier located on the hybrid circuit. The differential input configuration and very high input impedance of the sense amplifier will also contribute to cancellation of interference signals appearing on each conductor of the bipolar lead.

It has been observed during patient testing that the implantation techniques did not have any relation to interference detection by the ICD. It has been implied in other published reports that the thick layer of pectoralis muscle or abdominal muscle would reduce interference penetration compared with

a subcutaneous pocket where the device is closer to the surface skin (16). However, the magnetic field of the radiated energy penetrates through the skin and muscle, subjecting the implanted device to a significant amount of interference energy. Six of the 41 patients tested had their cardioverter-defibrillator implanted subcutaneously, but showed no difference in their susceptibility to EMI. A subpectoral or abdominal implant would increase the distance between the cellular telephone and implantable device and reduce the potential for reed switch activation by the speaker magnet.

Study limitations. The patients were tested with a single-model cellular telephone capable of analog and digital operation (AT&T model 6650), using the NADC/TDMA-50 technology with 0.6 W peak power. The in vitro antenna-generated test and the analog/digital cellular telephone test were comprehensive enough to include the main cellular telephone technologies, with the exception of Code Division Multiplex Access, as the equipment was not available at the time of this study. All tests were conducted using one manufacturer's ICDs, because identical models of devices required for the in vivo and analogous in vitro tests, including modified custom devices, were unavailable from other manufacturers. The lead system tested was primarily a bipolar configuration, because the manufacturer of the ICDs tested did not produce any integrated bipolar leads at that time. In vivo testing was not performed during ventricular fibrillation, as the clinical protocol did not include this type of patient test. However, the tests described herein, performed without ventricular fibrillation, have shown that the ICDs were not susceptible to EMI, and therefore would not hinder normal ventricular fibrillation detection. Further studies are required with an expanded representation of ICDs and leads and different new generations of cellular telephones to access any changes in the devices that would affect interference potentials.

Clinical implications and conclusions. We conclude that typical NADC/TDMA-50 cellular telephones with 0.6 W power do not appear to interfere with the in vivo operation of specific ICD systems. Damage or reprogramming to any of the tested ICDs during use of the cellular telephone would seem to be highly unlikely. Nevertheless, provision of a transvenous bipolar lead system could provide an additional measure of resistance to sensing interference energy fields.

In contrast, there is a potential for temporary suspension of ventricular tachycardia and fibrillation detection from the static magnetic field generated by the speaker in the cellular telephone earpiece only if the telephone is placed directly on top of and at a distance <0.5 cm from the cardioverter-defibrillator—primarily those implanted in a subcutaneous pocket. It would be prudent to provide an extra margin of safety when patients implanted with a cardioverter-defibrillator use a cellular telephone by 1) maintaining a minimal separation of 15 cm (6 in.) between a 0.6-W cellular phone and antenna to the implanted device and 30 cm (12 in.) for telephones with power >3 W; 2) holding the telephone to the ear opposite the side of the implanted device; 3) not holding the telephone near their chest while dialing or conversing, nor carrying the telephone in a breast pocket or on a belt within 15 cm (6 in.) of the implanted device, regardless of whether it is not in use; and 4) storing the telephone in a location opposite the side of the implanted device.

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