Cardiac Pulse Generators and Electromagnetic Interference

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Electromagnetic radiation (EMR) in the environment is a source of potential danger to a patient dependent on a cardiac pulse generator. We exposed a variety of demand pulse generators to a wide range of EMR. Reversion to "fixed rate" and occasionally complete cutoff was observed in several devices at power densities approximating those reported in one large metropolitan area. Practical techniques exist for producing pulse generators that are compatible with today's EMR environment, and steps must be taken by pulse generator manufacturers to reduce the sensitivity of their units.

Electromagnetic radiation (EMR) is increasing in the United States. Sources of EMR are electric motors fitted with commutators, radio and television transmitters, radar transceivers, microwave ovens, and electrosurgical and diathermy equipment. It is generally well recognized that electrosurgical and diathermy equipment can cause malfunctions of cardiac pulse generators.[1]

In 1971, Yatteau[2] reported a case of radar-induced pacemaker failure involving an external pulse generator. To our knowledge, there have been no reports of death due to pulse generator failure secondary to electromagnetic interference. This is understandable because a generator, after being removed from electromagnetic interference, resumes its normal functioning.

In order to test the vulnerability of implanted pulse generators to electromagnetic interference, laboratory animals underwent a series of exposures to wide ranges of EMR conducted by the USAF School of Aerospace Medicine.

Procedure

Eleven healthy dogs, each weighing 18 to 20 kg, underwent thoracotomy, and at this time, epicardial electrodes and demand pulse generators were implanted. At the time of the thoracotomy, complete atrioventricular block was produced by the instillation of formaldehyde solution in the region of the atrioventricular node. Complete atrioventricular block was assured by electrocardiographic monitoring. The pulse generators were placed under the skin of the right flank of each animal. After a postoperative recovery period of about two weeks, each of these animals demonstrated normal boisterous canine behavior (Fig 1).

In vitro (free field) and in vivo exposures to radio frequency fields were conducted in the frequency range of 10 to 30 megahertz, at the USAF School of Aerospace Medicine (USAFSAM) Brooks AFB, TX; 420 to 450 MHz, at the Georgia Institute of Technology Experiment Station (GIT): Atlanta; and 700 to 3,050 MHz, at US Army Walter Reed Army Institute of Research (WRAIR) Microwave Laboratory, Silver Springs, MD. The pulse generators evaluated in these tests are listed in Table 1.

The radio frequency band radiation fields were monitored with fixed electric-field monopole probes, portable electric-field dipole probes and magnetic-field loop probes, and an in-line differential power-measurement system. These instrumentation devices were designed, developed, and calibrated by the National Bureau of Standards, Boulder, CO. Field power measurements at GIT and WRAIR were made with calibrated dipoles feeding field power meters.

The test procedure was essentially the same for all animals. Immediately before testing, drugs (such as pentobarbital sodium, acepromazine maleate, or thiopental sodium) were administered to tranquilize or anesthetize the respective animal for the period of each exposure. The animal was placed on a pedestal and the pulse generator was oriented in the uniform portion of the radio frequency field. Test results were not influenced by the drugs used. Two standard silver-silver chloride electrocardiographic disk electrodes were attached—one at the cardiac apex, the other at the midline of the animal—and connected to a shielded frequency modulation (FM) telemetry trans-

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Table 1.—Cardiac Pacemakers Tested

Manufacturer	Model	Type
United States Medtronic, Inc.	5842 5942 5943	Ventricular inhibited
General Electric	A2072D	Ventricular inhibited
American Optical	281003 bipolar 281013 monopolar	Ventricular inhibited
Cordis	304070 Ectocor	Ventricular synchronous standby
	301060 Atricor	Atrial synchronous
	305070 Stanicor	Ventricular inhibited
Holland Vitatron	MP14004	Ventricular inhibited
Great Britain Devices	2980 3820 3821	Ventricular inhibited
	TF	Fixed rate
West Germany Biotronik	IDP44-50163	Schrittmacher

Table 2.—Typical in Vivo Results*

	Frequencies, MHz (Range of E Field)			
Pulse Generators	10-30 (0-800)	420-450 (0-100)	700 (0-350)	2,450 (0-600)
Medtronic 5842	50†	3†	5†	16†
Medtronic 5942	530†	40†	...	...
Medtronic 5943	240†	No effect (to 100 v/meter)	66†	No effect
Cordis Atricor	550	No effect (to 100 v/meter)	275	230
Cordis Stanicor	310	20	9†	25†
General Electric A2072D	540	30	No significant effect	No significant effect
American Optical 281013	115†	40†	50†	50†
Vitatron model MIP 400R	300	...	50†	50†
Devices 3821	No rate change	...	180	No rate change
Biotronik IDP44-50163	No rate change	...	No rate change	No rate change

*All values are in volts per meter and indicate the level at which a change in pulse generator function occurred (ie, intermittent rhythm and rate change, reversion to fixed rate, tachycardia, bradycardia, or cutoff). Cordis Ector was not implanted and was only tested in a free-field condition, the results of which are not included.

†Indicates pulse generator cutoff.

mitter. A receiving antenna was located 3 to 5 meters away and out of the main radio frequency field. The electrocardiographic signal was then fed through an FM receiver and discriminator. The discriminator output was recorded on a strip chart (Fig 2).

After a base-line electrocardiographic record was established, transmitter power was applied and the intensity gradually increased from zero. This process was repeated for different pulse repetition frequencies and radio frequency field modulations. When changes in the electrocardiographic signal were noted, the field strength was reduced and then increased to repeat the effect. The strip charts were subsequently analyzed for changes in pulse rate upon field application.

Results

Table 2 presents typical test results from this series of studies. The test results from the 10 to 30-MHz exposures show, in most instances, that each of the pulse generators affected reverted to a different constant rate (generally its fixed rate) or cut off completely at the same E-field intensity, depending on the pulse repetition frequency.

Although not specifically illustrated here, it was not uncommon to see variabilities as high as a factor of 10 in the relative susceptibility level of two or more different pulse generators of the same make and model.

Also, the lowest high frequency band sensitivity level was about 50 v/meter. Most of the pulse generators

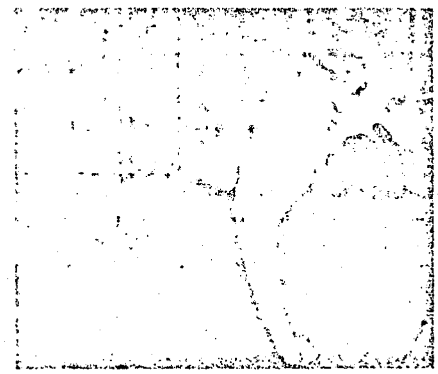

Fig 1.—Healthy canine approximately six weeks postoperatively. Pulse generator is in right flank.

tested had higher susceptibility levels, some exceeding even the 800 v/meter limit of these tests.

The test results obtained in two separate experiments conducted at GIT utilized radio frequencies between 420 and 450 MHz; pulse repetition frequencies between 14 and 40 Hz; and a maximum E-field strength of 100 v/meter. The pulse duration was held constant at 2.5 msec for most of these exposures. Pulse generator response at these frequencies is quite similar to that observed at the high frequency band, except that the effects appear at lower electric-field intensities. Pulse generators manufactured by Vitatron, Devices, and Biotronik were not evaluated at these frequencies.

Exposures to 700 MHz radiation gave results quite similar to those of 420 to 450 MHz, with the overall pulse generator responses appearing at essentially the same E-field intensity levels as the 450 MHz exposures.

Test results at 2,450 MHz utilized a double modulation—one having a pulse repetition frequency between 0.5 and 10 Hz at 65% of the maximum electric-field amplitude, and the other at 60 to 120 cycles. This double modulation simulates the effect of the mechanical mode-stirrer found in many modern microwave ovens operating at 2,450 MHz.[3] The electric-field threshold level for the double modulation is generally below that obtained without the modulation. However, the power density level at which most of these units were cut off or adversely affected with the double modulation is well below the threshold level for an unmodulated wave form. This result supports the position that a patient dependent on a pacemaker

Table 3.—Environmental Sources of Electromagnetic Radiation (EMR)		
Frequencies, MHz	Band	Sources of EMR
10-30	HF	Diathermy, auto ignitions, radio waves
54-108	VHF	AM-FM radio, VHF television, citizen-band radio
420-450	UHF	Radar
700-3050	UHF	Microwave ovens, UHF television, radar, microwave relay, diathermy

should not be any closer than a few meters from a standard microwave oven (with a permissible leakage of 5 mw/sq cm measured at 5 cm).

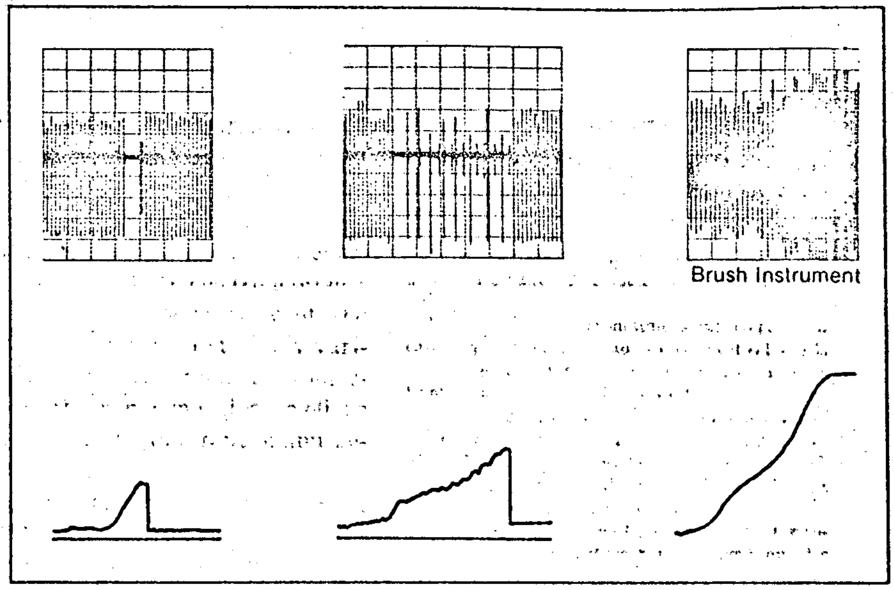

Fig 2.—Types of pulse generator responses to increasing electromagnetic radiation: left, cutoff; center, bradycardia; right, tachycardia. Top, ECG 5 mm/sec; bottom, electromagnetic radiation.

Comment

The EMR background is ever increasing in most major metropolitan areas today.[1] The sources of the EMR are, to mention a few, AM and FM radio stations, VHF and UHF television stations, military and civilian radar facilities, auto ignitions, and neon signs. In addition, EMR is being increasingly used by the general public in microwave ovens for the rapid preparation of food. There have been numerous studies[2-8] on the influence of electromagnetic interference on noncompetitive cardiac pacemakers. Furman et al,[7] using an alternating current similar to a spark coil or a "small brush" variety of electric motor, showed that both the maximum synchronous rate and fixed-rate operation could be induced with intracorporeal alternating currents. Erratic operation was initiated by a spark at distances of less than 30 cm, and intermittent extra pulses were emitted with an electric razor on the skin over the pulse generator. As shown by Sowton et al,[6] diathermy, an electric mixer, a hair dryer, a vacuum cleaner, and an electric razor, all induced tachycardia when placed in close proximity to the pulse generator. Sowton et al[6] and Furman et al[7] found the Medtronic 5841 to be unaffected by all the apparatus except physiotherapy diathermy. Sowton et al[6] found the Devices demand pulse generator (Model 2980) to be resistant to all domestic apparatus studied. In 1965, Lichter et al[9] studied the effects of radio-broadcasting stations on pulse generators manufactured by Elema and I.M.E., when tested in the free-field condition. They found that these pulse generators were sensitive to radio frequency wave interference. Hood et al[8] recently studied the effect of three weapon-detector systems that use an external electromagnetic field. They found that these systems could produce minor changes in the rates of certain pulse generators (Ectocor and Atricor models).

The effects of microwave ovens on pulse generators are well known. King et al[10] demonstrated effective blockage of an implanted Medtronic 5841 pulse generator when the patient was exposed to microwave radiation. They also reported that exposure of a Cordis Ectocor model to microwave radiation caused no change in pulse generator activity.

In our study we exposed various demand pulse generators (Table 1) to a wide range of EMR. These covered the spectrum of diathermy, UHF television, radar, and microwave (Table 3). The pulse generators were tested both in a free field and implanted in experimental animals.

The pulse generators were exposed to electric-field strengths up to 1,000 v/meter. A wide range of sensitivity to radio frequency EMR was evident among the different types and models of pulse generators tested. Some manufacturer's devices appear impervious to electromagnetic interference (reversion to a fixed-rate condition could not be ruled out), whereas others are very sensitive. This information suggests that practical techniques exist for producing pulse generators that are compatible with today's EMR environments.

The various manufacturers approach the problem of external electrical interference in the same way, that is, reversion to a fixed-rate pacing mode. Medtronic reverts to an asynchronous rate which is slower than the demand rate. The remaining units tested (Cordis, American Optical, General Electric, Vitatron Devices, and Biotronik) revert to a rate similar to or slightly higher than their demand rate. In our opinion, reversion to the same or slightly higher rate is preferable in order to assure a sufficient cardiac output if EMR is encountered by the patient.

Reversion to fixed rate and occasionally to complete cutoff was observed for several devices at power densities approximating those reported in at least one metropolitan area and probably existing in many more. For instance, Smith and Brown[1] reported that the peak ambient radiation originating from man-made radio frequency sources at sites monitored in the Washington, DC, area approached a maximum of 10^{-2} mw/sq cm (6 v/meter).

Although we did not specifically

udy the frequency range of AM-FM radio and VHF television, Pickers and Goldberg[11] showed that radio frequency transmission could interfere with external pulse generators.

In our study, field intensities as low as 3 v/meter caused complete inhibition of some pulse generators, whereas others in the same test were essentially unaffected in fields 100 times stronger.

Our test results indicate that some of the demand pulse generators tested were susceptible to levels of EMR known to occur in metropolitan areas.[4] Two of the generators (manufactured by Devices and Biotronik) appeared resistant to electromagnetic interference, but reversion to fixed rate could not be ruled out. The Vitatron pulse generator was resistant at the lower-frequency electromagnetic interference, but sensitive in the microwave frequencies.

We believe that the manufacture of a cardiac pulse generator resistant to moderately high electromagnetic interference is not beyond the scope of today's technology. Indeed, some manufacturers have apparently solved this problem (Table 2).

Conclusion

Many demand cardiac pulse generators are sensitive to electromagnetic interference. The sensitivity of the various generators is extremely variable. Their variability includes generators of the same model as well as generators from different manufacturers.

In view of the ever-increasing amount of electromagnetic interference in the environment, steps must be taken by pulse generator manufacturers to reduce the sensitivity of their units.

This investigation was conducted by personnel of the Clinical Sciences and Radiobiology Divisions, USAF School of Aerospace Medicine, Aeromedical Division, AFSC, United States Air Force, Brooks AFB, TX.

The animals involved in this study were maintained in accordance with the *Guide for Laboratory Animal Facilities and Care* as published by the National Academy of Sciences–National Research Council.

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Mutiny of the Bounty

Now if we could account for any irritation to the endothelium of the blood vessel walls, we might perhaps be able to account for the production of sclerosis. As the blood is the only tissue which is constantly in contact with the endothelium lining the blood vessel walls, and as the blood is constantly changing its composition, according to the amount and variety of food which is directly poured into it, it would seem rational to find the source of irritation which gives rise to the production of fibrous tissue, to reside in our food itself. In other words, it is indirectly our food which eventually kills us. In the vegetable world we see the same thing among bacteria during the process of putrefaction. At first we have only aerobic bacteria, which give rise to the production of carbonic acid, which finally encompasses their destruction; these are followed by the so-called facultative bacteria, which are both aerobic and anaerobic; these are again followed by anaerobic ones, and each finally disppears by the products of its own chemic changes. We are at once faced with the terrible proposition that that which is absolutely necessary to our existence eventually brings about our destruction.

. . . All living bodies are resolvable into their chemic elements; that is, our tissues are made up of a not very large number of chemic elements, whose molecules are held together in such peculiar arrangement that they are capable of exhibiting those phenomena which we are in the habit of calling vital. Could we increase our knowledge of the chemic changes which go on in the cells during absorption and elimination, and of the consequent physical changes which take place, we would be in a better condition to contend with disease, and I believe that it is along these lines that our greatest discoveries will probably come. And perhaps it may be eventually proven that the same physical laws which govern the movements of the planets, govern what we are pleased to call vital phenomena.

If we look over the list of diseases which we are able to cope with successfully by the use of medicine, diseases in which we would all agree upon the treatment, malaria and syphilis stand out prominently. Upon what is their treatment based? Empiricism pure and simple. Quinin was used long before the discovery of the plasmodium malariae. What the future may hold for us, when time has been able to sit in judgment on the results of serum therapy and treatment by animal extracts, it is yet too early to say. . . .

It seems to me that it is sometimes healthful to stop and consider what we are really doing; not to rest too comfortably on our laurels already obtained, but by a just and honest view of our possible shortcomings, to remember that there are new fields to be cultivated, new glory to be won in our everlasting battle with disease, and that each one of us, however humble we may be, may by diligent work, thought and observation, be able to add our mite to that grand sum which makes up the total of human knowledge.