Microwaves and pacemakers—just how well do they go together?

The question surfaced again this spring: How safe are cardiac pacemakers in the presence of microwave radiation?

An Air Force study cast doubt on the performance of some models.

In fairly rapid order, the study touched off lively debate in at least one medical meeting; prompted a federal agency to request additional safety information from pacemaker manufacturers; led to a meeting of some manufacturers' representatives and medical authorities to consider a suitable response to the federal query.

The safety question itself may be overemphasized, several sources—including even federal regulatory officials—suggested to MEDICAL NEWS. After all, there have been notably few clinical reports of pacemaker malfunction due to electromagnetic interference.

The incident illustrates, however, the sticky business of trying to regulate medical device safety. It raises a larger question: how far should government go in forcing changes in medical devices such as pacemakers; changes that may affect other aspects of the device's operation?

Furthermore, should the government change the pacemakers, or should the government change the sources of microwave radiation? There are disturbing suggestions that the federal government itself may be one of the largest contributors of microwave radiation in this country through still-secret Defense Department tests.

To obtain the following information, associate editor Larry Boston talked with cardiac surgeons, federal regulatory officials, manufacturers' representatives and the Association for the Advancement of Medical Instrumentation (AAMI).

Briefly, engineers at the USAF School of Aerospace Medicine, Brooks Air Force Base, Tex, tested 11 pacemakers produced by the seven largest manufacturers of the devices.

The pacemakers were implanted in large dogs which had surgically induced heart blocks. Tests were performed at 11 frequencies between 10 and 3,050 megahertz, with pulse repetition rates from 0.2 to 360 hertz, pulse durations from 0.5 to 5 microseconds, and energy-field strengths up to 1,000 volts/meter.

One test simulated power density levels that can be found near microwave ovens with legally permissible microwave leakage. Some pacemakers performed quite well, but the overall result "supports the position that a patient dependent on a pacemaker should not be any closer than a few meters from a standard microwave oven (with permissible leakage)," the report said.

In other tests, several demand-type pacemakers reverted to fixed-rate beat and occasional complete cutoff at power densities "approximating those reported in at least one metropolitan area (Washington, DC), and probably existing in many more."

Modulation—a periodic variation of the signal level—seemed to be a critical factor in the radiation-interference mechanism, the report noted.

"Field intensities as low as a few volts per meter caused complete cutoff of some pacemakers, whereas others in the same tests were essentially unaffected in fields 100 times higher."

"These results, plus data from other similar studies, indicate a need for further improving such medical prosthetic devices, so that they may be compatible with the even-increasing electromagnetic radiation background found in many major metropolitan areas," the study concluded.

Authors of the study include J. C. Mitchell, P. L. Rustan, J. W. Frazer, and W. D. Hurt, all of the School of Aerospace Medicine staff.

When Mitchell, an engineer, first presented the paper at the AAMI meeting this spring, physicians in the audience questioned some aspects of the study. Some of the points raised were that, in most cases only single units of a pacemaker model were tested, and that some of the test frequencies which produced pacemaker malfunctions are not frequently encountered. Other physicians wondered whether it would be desirable to improve pacemaker radiation resistance at the risk of compromising reliability.

The US Food and Drug Administration's Bureau of Radiological Health (BRH) collaborated on the study. When the report was presented, Robert L. Elder, MD, director of the BRH Division of Electronic Products, sent a letter to all pacemaker manufacturers.

"We believe the data sufficiently indicate degrees of susceptibility of some models (of pacemakers) to warrant further inquiry of pacemaker

continued on next page

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manufacturers in regard to the electromagnetic compatibility of their products," Dr. Elder wrote.

When the pacemaker interference problem was identified two years ago, the problem was thought to be common to all demand-type pacemakers, he pointed out.

"We know this is no longer the case," he added.

Dr. Elder asked manufacturers to report what they have done in the last two years to improve pacemaker resistance to electromagnetic interference; any actions to ensure future pacemaker electromagnetic compatibility, and a description of each company's quality control program to test for interference susceptibility.

Commenting on the Elder letter, Mike Miller of the AAMI staff suggested that (1) BRH has authority to regulate radiation sources, but no authority to regulate pacemakers, and (2) that the Air Force study "leads to certain wrong conclusions."

"The environment is slowly but surely being polluted with electromagnetic radiation," Miller said. "We can either do something with the pacemaker, or we can do something with the environment."

Meanwhile, in yet another federal health agency reorganization, responsibility for pacemakers was transferred from the Bureau of Radiological Health to the Medical Devices section of FDA.

Said an official of the newly responsible agency: "Better shielding and better circuitry are the obvious answers" (to improving pacemaker interference resistance). "But we realize the answers are not that simple," said Larry Pilot, assistant to David Link, director of the section. "Changing these things might create other problems in pacemaker operation."

Seymour Furman, MD, agrees. Dr. Furman, of Montefiore Hospital, the Bronx, has probably the largest series of pacemaker patients in the country—950 permanent implants.

"It's my personal opinion that the interference problem has been overplayed," the New York surgeon said. "We have not seen in our group of patients . . . any patient who has had a deleterious effect from interference."

Among Dr. Furman's patients, there have been at least two cases over the past few years in which radiation clearly was to blame for pacemaker malfunction. But even allowing for overlooked cases, the total incidence is very small. In both cases, these were pacemaker models that have been discontinued.

"There are other problems involved here," he said. "Admittedly, pacemakers can be made better. They certainly should be resistant to 60-cycle interference (the type emitted by conventional household appliances)."

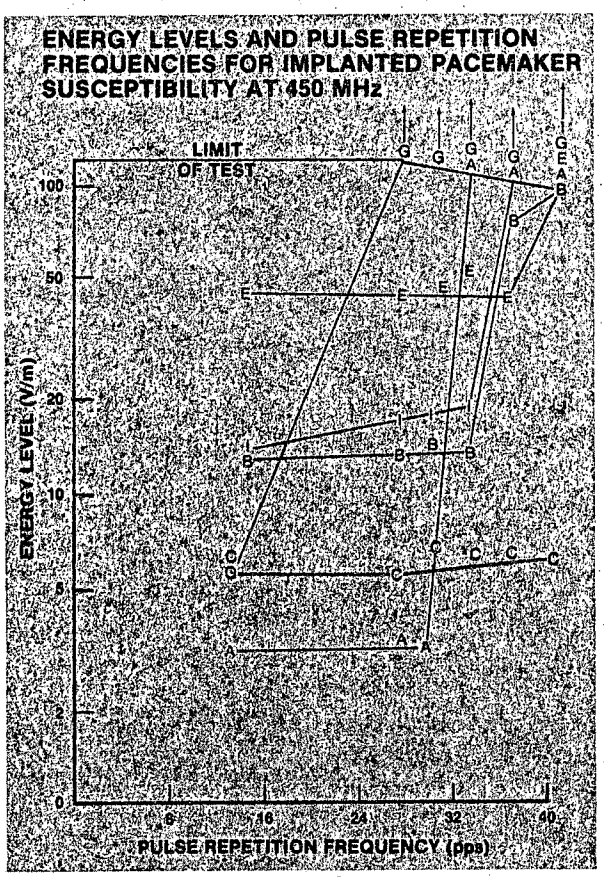
"However, there are a great many frequencies being thrown out all over the country, now, in radar stations and whatever other activities are being carried out by the Defense Department. All of these are frequencies which are unkown to us.

"In a sense, the medical profession and pacemaker manufacturers may be unduly burdened to make pacemakers resistant to electromagnetic interference when they do not know which frequencies are involved.

"It may or may not be possible to make pacemakers totally resistant to interference—remembering that the essence of pacemaker operation now is sensitivity to the electrical activity of the heart," Dr. Furman said.

"My concern is that there may be tradeoffs—that if manufacturers are pushed by the govern-

The summary of test results at Brooks AFB indicates that, in general, once an energy-field level of susceptibility for a pacemaker was established, the effect (reversion to fixed rate, reduction to a lower rate, or complete cutoff) appears to depend on the radiation pulse frequency. The pacemakers tested: Medtronic 5842 (A,B,C,D), Medtronic 5942 (E), Medtronic 5943 (F), Cordis Stanicor (G), General Electric A2072D (H), American Optical (I) and Cordis Atricor (J).



ment into making highly resistant pacemakers, there may be tradeoffs that are not good for the patient."

The largest manufacturer of pacemakers is Medtronics, Inc., Minneapolis, Minn. Said Alan R. Kahn, MD, vice-president, research and engineering: "We can make our pacemakers more resistant by spacing components closer together, putting on a circuit board, and making a lot tighter package.

"This is dangerous, for a much more serious reason. When you make a few pacemakers, this is easy to do. When there is mass production, closer tolerances mean greater failure rates. In patients, this is a much more serious problem than radiation interference."

Medtronics has added shielding to its pacemakers, and this has reduced susceptibility, Dr. Kahn said. Future models will have redesigned circuitry, but these are still being tested, he said.

FDA has given no indication it intends to force changes in pacemaker design or manufacture. It has asked only for information, and information, all agree, is scarce at this point. The pacemaker interference problem has been known for several years, but there were few studies, primarily because the problem was considered insignificant. More studies are being done, and within six months, some of the answers may be clearer.

WHO group finds opiates are not indispensable

Opium, morphine, and codeine are "no longer indispensable in the practice of medicine," says an advisory group of the World Health Organization.

Synthetic compounds are as effective as opiates for relief of moderate to severe pain—and in some respects may be superior to them, concludes a technical report of a 13-member WHO advisory panel. The report, WHO Technical Series No. 495, added that for relief of mild to moderate pain, available compounds are equivalent to codeine, although none is clearly superior to it.

"There is also substantial evidence that some synthetic drugs are as effective against cough as codeine, and to some extent have been used in place of codeine," the report added, noting the lack of well-controlled trials.

As far as diarrhea is concerned, the study finds that synthetic drugs are equivalent or superior to opiates.

"In general, therefore, the report concludes that opiates cannot be considered indispensable in the practice of modern medicine," the WHO group said.

Urokinase may prevent formation of adhesions

Physicians have believed for several years that the formation of intraperitoneal adhesions following surgery is somehow related to the presence of persistent blood clots around the surgical site.

It now looks as if urokinase might be an answer to this troublesome problem.

A Duke University Medical Center team has shown that experimental injury to the canine bowel results in a precipitous drop in fibrinolytic activity in the serosa of the bowel, followed by appearance of adhesions at that site within 72 hours. Adhesion formation appeared to be correlated both with the site and the amount of decreased fibrinolytic activity. (Massive adhesions occurred when activity fell by more than half.) Presumably, focal fibrin deposits persist and become a nidus for adhesion formation.

Yet the adhesions were completely *prevented* in 12 of 15 dogs (and greatly reduced in the other 3) by administration of urokinase, an activator of the fibrinolysin system, Alfred S. Gervin, MD, a resident in surgery, reported to the Society for Surgery of the Alimentary Tract meeting in San Francisco.

Dr. Gervin and co-workers Charles L. Puckett, MD, and Donald Silver, MD, see no reason why urokinase would not also be useful in preventing adhesions in man, since they have also known that the human bowel exhibits a similar drop in fibrinolytic activity after experimental injury. As yet unproven in man, however, is whether adhesions occur in the same anatomic sites that exhibit the drop in fibrinolytic activity.

In any case, the team believes that its "evidence warrants a clinical trial of urokinase in man", and they plan to apply soon for an IND for human work.

Drs. Gervin, Puckett, and Silver first demonstrated fibrinolytic activity in intestinal serosa by the fibrin slide and fibrin plate techniques. They found that the mid portion of the dog's ileum contained the highest amount. Next, they ascertained fibrinolytic activity in an 18-inch bowel segment in a number of dogs before and after cotton sponge abrasion. In both serosa and subserosa fibrinolytic activity was decreased from 30% to 100% (average 60%) following the abrasion. Necropsies four weeks after abrasion showed that adhesion formation was proportional in amount to the decrease in fibrinolytic activity (or the decrease in plasmin activator).

Similar findings on the existence of the fibrino-

continued on page 962