CONTRACEPTION I

IUD's: Approval of a renaissance

The idea of placing an object in the uterus to block conception is mentioned in the writings of Hippocrates and was investigated extensively by scientists during the nineteenth century. In 1929 the German scientist Ernst Grafenberg inserted silver rings into the uteri of 2,000 women, and reported a pregnancy rate of only 1.6 percent.

Despite this history, the use of intrauterine devices, or IUD's, was not generally accepted. Reports of IUD-related infection and other suspected adverse reactions kept gynecologists chary of the devices, and wholly suitable materials for making IUD's had not been developed. The idea lay dormant for nearly thirty years.

In 1959 there was a revival of interest in Grafenberg's work. Devices made of stainless steel and plastic were employed, and methods of insertion in the uterus were devised that did not involve dilation of the cervix and a concomitant risk of infection. Successes in this renaissance of the IUD stimulated further investigation. Though eclipsed somewhat by the advent of oral contraceptives, the IUD now has an estimated six to eight million users worldwide, about a million of them in the United States.

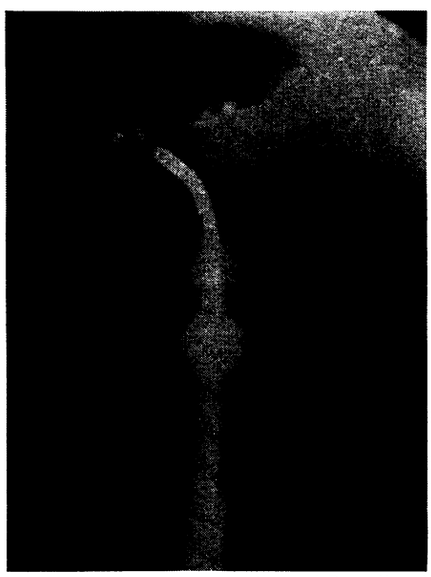
Because of the expanding use of IUD's, the U.S. Food and Drug Administration a year ago began a study of the devices. A report made public last week by the FDA's Advisory Committee on Obstetrics and Gynecology concludes that, while it doesn't know how they work, it finds IUD's to be safe and effective in blocking conception.

Under controlled conditions IUD's have proved to be slightly less effective than birth control pills. However, in the field the effectiveness of the two contraceptive methods is comparable, because many women fail to take the pills as directed. Population control authorities note that only temporary motivation is required to get people to use the IUD; once it's in it can be forgotten. Pills on the other hand require a daily decision in favor of family planning, on top of fairly extensive education in the method.

As yet scientists have no concrete evidence to explain the way IUD's work. There are two popular theories. One is that the device speeds the transport of the egg through the reproductive tract, preventing implantation. The other theory holds that an IUD prevents proper maturation of the lining of the uterus, again preventing implantation of a fertilized ovum.

So far there is very little theory governing the design of IUD's. The devices now are being used in some 30 different shapes, ranging from springs to bows to loops to coils to Maltese crosses. Basically, however, they are either closed designs (originating from a circle) or open designs (originating from a straight line.) The most popular device is the Lippes loop, an open device in the form of a double S. Far more open devices are used than closed, though there is a greater variety of closed devices on the market.

The FDA committee concludes that presently available closed devices are "not to be used except in specially indicated circumstances." The committee reports several instances of intestinal obstruction following perforation of the uterus by a closed IUD. Such accidents have not been reported with open devices.



Planned Parenthood

Inserter and spiral device in place.

Speaking generally of the safety of the IUD's, the committee verifies some of the adverse reactions reported previously by individual physicians. "The insertion of IUD's carries a definite, albeit small, risk of infection and uterine perforation," the report says. The incidence of perforation, the committee believes, can be reduced by more careful sounding of the depth of the uterine cavity before insertion, since most perforations apparently are the result of injury caused by the introducing device.

Infection is largely attributed to lack of proper sterile procedures during insertion. Many IUD's are sold nonsterile in bulk. They have to be sterilized before insertion. The introducer also is often sold nonsterile and must be autoclaved. The problem is that the plastic device must be folded into the tubelike introducer for insertion. This cannot be done before autoclaving since the plastic would lose its ability to spring back into shape. Therefore the physician must scrub up, don sterile gown, and follow careful sterile procedures to place device into introducer and introducer into uterus. Dr. Louis M. Hellman, chairman of the committee, says all this is a complex operation that often is not properly performed.

The committee in its report endorses proposed legislation which would require that manufacturers prove the safety of medical devices such as the IUD before placing them on the market. At present it is up to the FDA to prove any suspect medical device unsafe or ineffective before sale can be blocked. The FDA is interested, for instance, in requiring that IUD's be sold sterile with disposable introducers. It seeks similar control over all medical devices.

CONTRACEPTION II

Dangers of the pill

Nearly 13 million women throughout the world use the eight types of oral contraceptives popularly lumped as the pill; several thousand of them may be expected to suffer for it.

The extent of the hazard is unknown; many physicians still will not prescribe the regimen for most patients; many more will. Meanwhile millions of dollars continue to be spent on research concerning hazards of present use, as well as on the search for substitutes.

Dr. Louis M. Hellman, chairman of the Food and Drug Administration's Advisory Committee on Obstetrics and Gynecology, says there is no ideal contraceptive available, even though the element of risk with the presently used birth control pills is small.

The most serious hazard seems to be with blood clots. A thrombo-embolism, for example, can travel to the lungs, heart or brain, obstructing a major blood vessel. The numbers of affected women, however, are small. The death rate in a recent British study was three per 100,000 per year. This would indicate that in 20 years 60 pill users per 100,000 would risk death from this cause in comparison with about 20 nonusers.

Dr. Roy Hertz, one of the members of the Advisory Committee, formerly with the National Institutes of Health and now a professor of obstetrics and gynecology at George Washington University, takes the most sober view of

the present status of oral contraceptives. Present knowledge, he declares, is inadequate. The relationship of estrogens (basis of the treatment) to cancer in women, particularly breast cancer, requires 10 more years of prospective study, he feels.

The additional possibility that the regimen can lead to strokes has gained some support from cases reported by a North Carolina physician last fall. In the November ARCHIVES OF INTERNAL MEDICINE, Dr. Monroe Cole of the Bowman Gray School of Medicine in Winston-Salem says that five young women treated for strokes showed none of the medical disorders that usually cause strokes but that all five were taking birth control pills when they were admitted to the hospital.

He does not claim his evidence is conclusive, but it should be a warning to doctors.

Another fear that has developed around the dosage concerns sugar retention.

Sugar retention indicates diabetes or some similar disease. Last year at a meeting of the New Jersey Academy of General Practice, Dr. Herbert Gershberg of the New York University Medical Center reported that some oral contraceptives produce a condition resembling diabetes.

In 1964 a high percentage of women taking oral contraceptives were found to react as diabetics do to glucose tolerance tests. Because of this fear, the National Institute of Arthritis and Metabolic Diseases has recently awarded a grant to Dr. Victor Wynn of the University of London to continue his studies on impaired carbohydrate metabolism among women using oral contraceptives.

Three separate British studies, reported last May in the BRITISH MEDICAL JOURNAL by a unit of the Medical Research Council, conclude that there is no doubt that some types of thromboembolic disorder are associated with the use of oral contraceptives. More British studies to be published soon are expected to corroborate this finding.

The last major U.S. report on oral contraceptives, by the FDA's Advisory Committee in August of 1966, gave an equivocal answer only. It found "no adequate scientific data, at this time, proving these compounds unsafe for human use."

Dr. Hellman, who is chairman of obstetrics and gynecology at the State University of New York in Brooklyn, says the next report of his committee on oral contraceptives will be in 1969. He concedes that there is a cause-and-effect relationship between birth control pills and sometimes fatal lung clots, although the still-to-be-published British studies show a "very, very small risk."

MENTAL DYNAMICS

Smokers vs. non-smokers

Heavy smoking is a drug dependence that society has until recently viewed with favor.

It is at the same time a drug abuse and a social activity; add to that a possible physical addiction, or at least habituation, to nicotine, and the problem of why people smoke becomes almost hopelessly complicated.

Some light has been shed on the subject by a 34-year follow-up study of 200 children, now in their mid-40's. The study group, one of three begun at the University of California, Berkeley, in the 1920's and 30's, was originally aimed, not at smoking, but toward a long-range investigation of mental, physical and emotional development in adolescents.

Then Dr. John A. Clausen, at Berkeley's Institute of Human Development, saw the value of the old material as a means of discovering adolescent roots for adult smoking habits.

In his latest follow-up, released last month, Dr. Clausen found striking differences between heavily smoking men and women.

"The dynamics are just not the same," says Dr. Clausen. As a group, women who became heavy smokers were the adventurous type with a quest for power and social recognition. They married younger, sampled more experiences and were far less conventional than women who never smoked. At the same time, female smokers were somewhat aggressive as adolescents and were given to frequent emotional upsets—the blues, psychosomatic ills and the like.

Non-smoking women, however, showed up as conventional, unaffected and timid adolescents. They are still that way.

Mental dynamics underlying heavy male smoking are quite different and less attractive, Dr. Clausen declares. With individual exceptions, heavy smoking (consistently more than a pack a day) in men is linked with adolescent aggression and adult tendencies toward escapism and self-defeatism. Today, the group is what sociologists call "downwardly mobile," that is, they are losing status and position compared to their fathers.

The characteristics of non-smoking men, however, are those making for success—control, motivation and good personal adjustment.

The differences were very sharp between adolescent girls who smoked and those who didn't, says Dr. Clausen. This was the time (the 1930's) when female smoking became acceptable. Now those differences have tended to smooth, mainly because the smoking women in the sample became less aggressive in their mid-40's.

By contrast, the differences between men who smoke heavily and not at all are greater now than during adolescence.

But, he says, his study reveals that people change, and still the habit may hang on. "Whatever needs tobacco fills," says Dr. Clausen, "people do change and continue to smoke. I think this really is a kind of addiction, presumably a nicotine addiction."

A STENCH OF SULFUR

Volcano may follow Sicilian quakes

The violent, but not major (see page 127) earthquakes that rocked western Sicily last month came in a part of the island not normally known for either seismic or volcanic activity.

Geologists are looking hard at the rock formations around and under the island off the toe of the Italian boot in an effort to determine if the quakes were a precursor of more deadly activity to come.

One strong possibility, though it is not yet generally accepted, is that the disturbance was volcanic in origin—that the volcanism feeding volcanoes like Etna on the island's eastern end underlies the entire island and is building toward a major eruption in the west.

All earthquakes have a link to volcanic activity, though the link—as is the case in the western United States—often bridges major periods of geologic time. While, for instance, mountains in the region of California's San Andreas Fault are of volcanic origin, volcanism there is ancient and current disturbances along the Fault are not construed as resurgences of volcanic action.

This may not be the case, however, with western Sicily.

Dr. William T. Pecora, director of the U.S. Geological Survey, emphasizes that eruptions there cannot be predicted. Nevertheless, he speculates, the Sicilian earthquakes could be "caused by subsurface movements of gas-charged lava that could eventually break through to the surface and cause volcanic explosions, followed by lava flows."

Other volcanologists are skeptical. Dr. Fred M. Bullard of the University of Texas, for instance, believes that