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OVULATION REGULATION

HAROLD M. GRODEN, M.D.

PART I: THEOLOGICAL CONSIDERATIONS

The Catholic Church cannot, and will not, change its stand with regard to the moral aspects of the procreative process of man. Nor should it. The basic principle with regard to this is unalterable, since it is an essence of the natural law which, of necessity, forbids the unnatural. Contraception, whether mechanical or chemical, has for its sole purpose the prevention of pregnancy. It is by obstruction—preventing the sperm from coming in contact with the ovum, by destruction—using agents of a chemical nature which destroy the sperm, or by hormonal suppression of ovulation, that this end is sought and/or achieved. When such techniques are labeled "ovulation control," this term is truly a euphemism, since elimination is hardly a synonym for control. Even temporary ovulation suppression, having for its sole purpose the prevention of pregnancy, is still chemical sterilization.

As Catholics we must, in faith, believe in the fall of man, else the redemption of man is meaningless. This fall was spiritual *and* physical. The Crucifixion provided us with the means of salvation for our souls. Through it we can elect to regain the spiritual perfection in which man was originally created.

Physically, however, we have not been granted original perfection. All of us are heir to defects—mechanical, structural and functional. Through our God-given faculties we have been able to develop corrective procedures in medicine and surgery, to find means to prevent fatal and crippling disease

and to treat diseases with agents having incredible therapeutic effect.

As physicians, therefore, we are dedicated to the achievement of the normality of the Divine design whether the problem is morbidly mechanical or malfunctional. So long as we direct our efforts toward these goals, employing means which justify these ends, we are in compatibility with the law of God. No thing is intrinsically evil; it is the employment of anything in an evil way—even when a so-called good is achieved—that constitutes an immorality or a wrong.

In the normal physiology of the female we find the design of perfection which was meant to follow a unique pattern to ensure the propagation of mankind. If we pursue this pattern through microscopic and gross changes in the procreative organs, we come to recognize what is normal and perfect. Since menstruation is, in fact, the end of a cycle, I will begin by describing the initial building up process or regeneration of the lining of the uterus, known as the endometrium. Each cycle is intended to provide an ideal environment for a fertilized ovum (pregnancy). Under the stimulus of sex hormones a proliferative phase begins, and the lining or endometrium increases in thickness and blood supply to reach a peak of ideal environment on or about the fifteenth day of the cycle. Precisely at this point the ovum erupts from the surface of the ovary and is drawn into the Fallopian tube through which it is propelled by the action of whip-like hairs, called cilia, and the muscular

action of the tube, towards the uterus. Here, after a definite time, it implants in the lining. The pregnancy then commences by literally rooting, by sending out filaments which invade the lining, thrusting into lakes of blood through which the transfer of oxygen and nutritive elements pass from the maternal organism, and conversely, waste products pass into the mother's blood stream. The development of the foetus then progresses in a pattern that even in the light of our present knowledge is astonishing. This, then, is the perfect pattern of human procreation, ending in the production, ideally, of a perfect human being.

It is an interesting fact that only man has been penalized. The lower animals still maintain the physiological perfection in which they were created. To state this simply: the obstetrical problems that we constantly see in the human, almost never occur in the animal. Such catastrophes as miscarriages, stillborns, hemorrhages and toxemias are unknown. It is significant that the animal, not possessing a rational nature, could not offend its Maker, not having the capacity to alter the conduct of its life. It continues to glorify God in its original perfection.

Since the basic goal of the medical and allied professions is to restore pristine physical perfection to man both structurally and functionally, we must establish a set of norms or ideals, by which we are guided, and towards which we must strive. One hears so often when a tragedy occurs, as an illness, defect or accident: "It is God's will." God does not and could not in His infinite goodness will an evil or imperfection. Man has been granted free will to seize or reject, and has been granted the means to both prevent or correct. Thus the diabetic is restored to relative normalcy by in-

ulin; the pernicious anemia patient by liver extract or Folic acid and B-12. This is restoration of natural function. Prevention of pregnancy by whatever technique is suppression of a natural function.

I am proposing a program which is a regularization of the procreative process—by bringing about ovulation at the correct physiological time in the cycle. That such requires the use of external agents does not constitute an unnatural process, since these same agents are normally produced and, of utmost importance, in a definite productive pattern which can bring about the perfect cycle. These agents specifically control the orderly process of 1) building up the lining of the uterus to its optimal point; 2) inhibiting, at the same time, premature ovulation which must be considered a departure from the perfect pattern and 3) permitting the process of ovulation at the ideal physiological time by withdrawal of these agents at a given point in the cycle.

It would be well at this point to speculate on the consequences of premature ovulation. It is not presumptuous to state that implantation of a fertilized ovum in a lining not providing a proper environment may well be responsible for many miscarriages. Poorly prepared soil, at an inclement time of the year, can hardly be expected to nourish seeds that could develop to healthy mature blossoms or fruit. Indeed, we might impute many human defects not compatible with life (e.g., the congenitally defective heart, the retarded intelligence, malformed limbs) to the inadequacy of the soil: lining of the uterus.

After the production of the ovum, the lining of the uterus changes to what is known as the secretory phase, in which the glands become filled with a fluid which is meant to nourish an early pregnancy. This alteration

is the result of the stimulus of hormones produced at the site of ovulation by a strikingly yellow body resembling a serrated crater, and called the corpus luteum. If the ovum is not fertilized, this phenomenon undergoes a process of absorption just prior to the onset of menstruation, leaving but a tiny white scar on the surface of the ovary. This secretory phase has in itself an inhibiting effect on ovulation. I am not aware of any history of a second pregnancy on one cycle due to late ovulation except in the most rare case of a woman having a double uterus. This must, of course, be considered an extremely unusual and abnormal condition and organ; women with such defects are highly prone to have miscarriages. It is a fallacy to assume that, because any one woman has a fairly constant interval between menstrual cycles, she is 1) producing healthy ova and or 2) ovulating at the ideal time to ensure a healthy pregnancy.

It is a well recognized gynecological fact that these same hormones I have selected, used clinically, produce what we refer to as a rebound effect, i.e., subsequent healthy ovulation. The fact that ovulation has occurred can be determined by removing a small piece of the lining of the uterus at the time when we would normally expect ovulation to occur. What we *cannot* establish is that a healthy fertilized ovum has been produced. All of us who work in the field of fertility have handled any number of unsuccessful cases that leave us puzzled since we have determined that ovulation has occurred and that the ovum is able to traverse the pathway from the ovary to the uterus through an open tube. Needless to say, the husband's sperm have been, in such situations, found to be of normal number, structure and motility. We do know that a singular effect is achieved in

these women when we place them on a regime of hormonal overlay, i.e., adding to their own hormonal production. This is called the "rebound phenomenon" in the subsequent healthy ovulation as attested by normal pregnancy results in later months. This approach, however, has been used throughout a cycle, day by day, thoroughly sterilizing the patient for a given cycle for a subsequent effect in later cycles.

If we apply this overlay program which conforms to the normal or perfect cycle, we would use these hormones in a pattern to prevent what we may call ovulation variability, i.e., ovulation taking place at the incorrect or unphysiological time. This would not in any sense constitute ovulation suppression, since we would be striving to bring about ovulation at the optimum time; when the lining of the uterus has provided the ideal environment for implantation of the fertilized ovum. We can now offer such a program. Its most specific application would be to those women who have a wide ovulation variability, either pre- or post mature production of the ovum. It is possible now to regulate ovulation, i.e., to bring about production of the ovum at a definite *predictable* time. In the attainment of this we can, without too much presumption, foresee more normal pregnancies, decrease in catastrophes such as miscarriages, abnormal implantation of a fertilized ovum and defects in the infant.

That this program may be used to space pregnancies by abstaining from marital relations during the fertile days does, in no way, constitute any infraction of the natural law. Abstaining from marital relations during a presumed period of fertility is the essence of the so-called rhythm theory. Abstention from marital relations dur-

ing a known predictable period of fertility is no different.

Our Lord created in all his creatures an enormous drive in the sexual impulse. In the animal, it is almost frightening in its intensity. In man it is no less intense but differs in that he has a rational nature, a will and an intelligence to control it—to a degree. Like a heady wine once tasted, it places a demand on the human body which must command an almost insuperable degree of control to abstain from its compulsion. Here we find our problem conversely. The period of tolerable abstinence varies from couple to couple. It is hardly an area of criticism that one couple has a greater drive—they were created in this capacity. I might also suggest that a compatible connubial relationship is a cornerstone of marital harmony—granting that the balance of their other relationships and sense of values are healthy.

The program I am offering is designed to shorten the period of abstinence from marital relations for those couples who are desirous of spacing their children for reasons of health, psychology, or economics. We

will begin with a period of abstinence of six days which would be the time of ovulation: the 14th day plus or minus 4 days. We are confident that we can realize ovulation on 14 plus or minus one which would mean a period of abstinence of four days. The ovum has a life of 12 hours; the sperm has a life of approximately 48 hours in the birth canal. The latter viability has been grossly extended in some statistics. The simple fact, well known to urologists, is that sperm cannot tolerate the temperature in the birth canal. The two time factors total 60 hours.

The specific program is directed towards correcting ovulation variability by bringing about ovulation at a predictable time. The administration of the tablet, containing both oestrin and progestin elements, will begin on the 15th day of the cycle and continue to the 25th day inclusive. Within approximately 48 hours a menstrual period will ensue. For sterility, or fertility, the period from the tenth day of the cycle up to and including the 15th day will represent the time when ovulation will occur, most probably on the 14th day.

CALENDAR EXAMPLE:

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| M | M | M | M | M | M | M | M | M | M | M | F | F | F | O | T | T | T | T | T | T | T | T | T | T | T | T | M |

Code: M—Menses
 F—Fertile Period
 O—Ovulation
 T—Tablet

PART II: CLINICAL OBSERVATIONS

In proposing a program of perfection of the female reproductive cycle, indisputable proof of such attainment must be presented. It is superfluous to say that the proof of healthy ovulation is conception itself; the difficulties involved in gathering such data should be quite evident, as far as the individual investigator is concerned. Needless to say the passage of time will provide ample evidence of such.

However, it is of paramount importance not only to establish the fact of ovulation, which pregnancy would proclaim, but the exact time of ovulation for every woman in every cycle. Hence the need for the research which is herein recorded.

I selected thirty-five Catholic women who, I was certain, were not employing, and would not employ any unnatural means to prevent conception, and who are of established fertility. All are in an age group from 20 to 40 years, all free from systemic disease. Each woman reported to the Norwood Hospital Out-Patient Department on Day 15 on one cycle, Day 16 on the second, Day 12 on the third, and Day 17 on the fourth. *None* had been on medication since Day 25 of the previous cycle at each testing time. Each had taken her basal body temperature from Day 5 to Day Test. (Day 1 is the first day of menstrual flow.)

The following tests then were conducted on each woman on each cycle over a six-months period:

1. Basal body temperature
2. Glycogenesis in cervical mucus
3. Arborization of cervical mucus
4. Vaginal pool Pap smear
5. Endometrial biopsy

To establish the fact of normal receptive secretory endometrium, I also performed endometrial biopsies on

Day 23, at which time the patients had been on medication since Day 15 of that cycle.

The only known procedures in determining ovulation not carried out were electro-potential studies and pregnanidiol urine levels; these are of little value with regard to the overall purposes of my investigation.

The most astonishing results immediately achieved were in regulation of cycles of women who had previously had the most bizarre patterns—if these could be termed "patterns." One very skeptical patient, the mother of five children, had had but two or three menstrual periods since the age of thirteen. For the past six months she has had a 28 day cycle. Women who had had the history of menstrual flow for seven to ten days now reported a "period" of four day flow. But far more important, the testing showed that they all were ovulating on Day 14.

To achieve bleeding every 28 days is hardly an attainment, since withdrawal from medication used for contraceptive purposes will produce this. Such merely brings into concept a feeling of "being normal," since monthly bleeding is the female heritage in the child-bearing years. Actually, it is nothing more than a sort of periodic self-deception. If at any time a woman discontinued the medication, she would bleed. Conversely, if she took the medication daily without omission, she would never flow, except rarely in what is termed "break-through bleeding."

The basal body temperature charts showed a constancy not seen in women not on the program. The research patients showed the dip in the temperature curve followed by the elevation occurring with regularity on Day 14. Practically all deviations from this

thermal pattern were due to minor ailments, forgetfulness, or inability to take temperature because of children in distress, and so forth.

Since the medicine is thermogenic, no temperatures were taken after the testing day.

Extensive prior research has clearly demonstrated the glycogenic effect of progestational hormones on cervical mucus. In this work cinistix were inserted in the endo-cervix. All patients showed slight glycogenesis on Day 12, moderate on Day 15, and intense on Day 16 and Day 17. Controls tested on Day 5 to Day 10 showed no reaction.

To demonstrate arborization in dried endocervical mucus, the material was obtained by gently inserting a cotton swab in the canal, and rotating carefully to avoid any bleeding, since this can alter crystallization. The character of the mucus on Day 15 and Day 16 was consistently clear and elastically tenacious. The classification of Zondek and Rosten indicating the degree of arborization was employed: Palm Leaf 1, 2 or 3. (The phenomenon is also known as "ferning.") The mucus was allowed to dry at room temperature for one-half hour before evaluation. This crystallization indicates oestrogenic activity. Hence on Day 12 it was found that it reached its height in the number and definition of ferns. With the beginning production of progestational hormones there is an increased response and gradual diminution in the number and definition of ferns. Day 12 showed predominately PL3 and no less than PL2; Day 15 and Day 16 predominately PL1. Day 23 testing showed no arborization.

Vaginal pool Pap smears were taken on all patients on each test day. The material was obtained from a point on the vaginal wall lateral to the exocervix, this area being highly sensitive to hormonal impact. The smear was

then scanned for a cell ratio known as the maturation index and a count of the following cells was tabulated:

1. Parabasal
2. Intermediate
3. Superficial

An average index reading establishing the fact of ovulation would be 0; 40; 60. A reading with a reverse ratio to the left indicates estrogenic activity. A shift to the right indicates progestational impact. In the studies conducted we have observed this shift: Day 12 showed parabasal cells and intermediate (preconified) cells; days 15 and 16 showed a disappearance of parabasal with commensurate increase in intermediate and superficial (conified) cells, generally conforming to the ratio 0; 40; 60.

Endometrial biopsies consistently showed healthy proliferative endometrium on Day 12. No stromal hypertrophy was observed. Day 15 produced late proliferative or prosecretory (subnuclear glycogen vacuolization), Day 16 and 17 early to well established secretory endometrium. Testing on Day 23 (on medication) showed healthy secretory phases, this in contrast to the "secretorily exhausted" endometrium seen in the patient on straight contraception (medication taken from Day 5 to Day 25).

It is now obvious that each cycle is regulated by the previous cycle, and on the proposed program, since there has been no premature ovulation, it is safe to assume that the natural progestational output reinforced by the medication has succeeded in preventing premature or excessive production of follicle stimulating hormone thereby precluding premature maturation. The result has been established, since all patients ovulated on Day 14.

I had requested the patients to report any and all unusual reactions to the medication, pleasant or other-

wise. It might be thought that some of these are psychological, but I feel that this is unlikely, since the women I selected for the research I have known for years and were individually screened for stability. The commonest complaint was transient nausea on first taking the medication in the initial cycle; this did not recur on subsequent cycles. Many who had habitually experienced premenstrual tension with a variety of symptoms, related that these no longer occurred. Since every patient had expressed the intention of having more children, it cannot be relief from fear of pregnancy that is responsible. It is superfluous to add that single women also find this to be a distressing time.

Several of the group have varicosities in varying severity; none has had any aggravation of symptoms on the program. In fact, eight patients had had superficial thrombo-phlebitis post-partum.

I am not disturbed about the possibility of teratogenic effects as far as patients who conceive while on the program. Over the years I have had patients on oral progestational agents in the latter half of the cycle on which they conceived, and I have never observed masculinization in the female infant—nor do I personally know any obstetrician who has. I question whether the small amount of medication over a period of ten days on this program—during which time the patient conceives, the fertilized ovum traverses its customary path, and nidates—could possibly affect the developmental process of the foetus.

SUMMARY

Thirty-five women of established fertility, who have never employed any artificial method of contraception, were medicated from Day 15 to day 25 of each cycle.

1. 100% had a cycle of 28-29 days with 4-5 days of moderate flow, regardless of previous menstrual pattern.

2. Ovulation occurred at Day 14 by the following tests:

- (a) Basal Body Temperature
- (b) Glycogenesis of cervical mucus
- (c) Cervical abortion
- (d) Maturation Index from vaginal pool Pap
- (e) Endometrial biopsy

Except for Test Day 23 which demonstrates the endometrium under the effect of the medication, all tests were conducted prior to medication on each cycle.

Such a program can regularize the female procreative cycle with predictable ovulation and normal endometrium pattern.

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