

Contraception in Women With IDDM

An epidemiological study

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OBJECTIVE— To study whether suitable contraceptive methods to women with diabetes mellitus in fact are applied.

RESEARCH DESIGN AND METHODS— A questionnaire survey on the use of contraceptives in all 18-to-49-yr-old women ($n = 261$) with IDDM in Funen County, Denmark, and an age-comparable control group, ($n = 287$) was performed. Data were collected from 1987 to 1990. Response was achieved from 94% diabetic women and 88% control subjects.

RESULTS— The overall use of contraception in diabetic women (77.1%) was almost identical to that of control subjects (73.6%). Compared with control subjects, significantly fewer diabetic women were using the OCP ($P < 0.005$) and partner sterilization ($P < 0.05$), whereas more diabetic women were sterilized ($P < 0.0005$). Among diabetic contraceptive users, the IUD, female sterilization, condoms, and the OCP each accounted for roughly 20%. Diabetic women using the OCP were predominantly young, and most had never been pregnant; ~20% of them used high-dose formulations. Sterilization was frequently used by older diabetic women, and most of these women had 2 or more children; 27% of the diabetic women using an IUD were nulligravidae. Further, 18% used a method with an unsuitable high failure rate.

CONCLUSIONS— Our study demonstrates that diabetic women are not sufficiently advised concerning use of contraception.

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IDDM, INSULIN-DEPENDENT DIABETES MELLITUS; OCP, ORAL COMBINED PILL; IUD, INTRAUTERINE DEVICE; EE, ETHINOLESTRADIOL; LNG, LEVONORGESTROL; NE, NORETHISTERON; POP, PROGESTERONE-ONLY PILL; NIDDM, NON-INSULIN-DEPENDENT DIABETES MELLITUS; HDL, HIGH-DENSITY LIPOPROTEIN; HIV, HUMAN IMMUNODEFICIENCY VIRUS.

Pregnancy in diabetic women is associated with increased rates of spontaneous abortions and fetal malformations (1,2). During the last few years, several studies have demonstrated that optimal metabolic control before and during early pregnancy reduces these risks to nearly normal levels (3–8). Diabetic women therefore must be educated to understand the importance of planning their pregnancies, and, as a consequence, contraceptive advice should be offered very meticulously.

A number of investigations on the relative advantage and risk of various contraceptives for women with IDDM have been performed. However, studies aimed to explore the actual use of contraceptives in women with diabetes are few, and have so far comprised selected and highly motivated women, as indicated by their regular attendance at specialized diabetic clinics (9,10). It is therefore doubtful whether the results of such studies reflect the condition of the general diabetic population.

The aim of this study was to investigate the current use of contraceptives in an unselected population of women with IDDM compared with a nondiabetic control group.

RESEARCH DESIGN AND METHODS

This study was performed in the county of Funen, with ~450,000 inhabitants, comprising ~9% of the Danish population. With regard to demographic and socioeconomic status, the population of the county is representative of the Danish population as a whole (11), and the area is therefore suitable for epidemiological investigation on unselected patient populations.

A detailed description of data sampling and methodologies is outlined in a previous study (12). In brief, all 18-to-49-yr-old women with IDDM in the county were identified by the prescription method (11); 245 women (94%) answered a questionnaire concerning gynecological/obstetric condi-

Table 1—Types of contraceptives used in diabetic and control groups

	DIABETIC WOMEN (N = 189)		CONTROL SUBJECTS (N = 184)	
	N	%	N	%
OCP	36*	19.0 (14–25)	61	33.2 (26–39)
POP	8	4.2 (2–8)	3	1.6 (0–5)
IUD	41	21.7 (16–28)	28	15.2 (10–21)
FEMALE STERILIZATION	44†	23.3 (17–30)	18	9.8 (6–15)
MALE STERILIZATION	11‡	5.8 (3–11)	22	12.0 (8–18)
CONDOM	38	20.1 (15–26)	45	24.5 (18–31)
DIAPHRAGM/SPERMICIDES	7	3.7 (1–7)	2	1.1 (0–4)
WITHDRAWAL/RHYTHM	4	2.1 (1–5)	5	2.7 (1–6)

Numbers in parentheses are 95% confidence limits.

*P < 0.005, significantly different from controls.

†P < 0.0005, significantly different from controls.

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tions. The questions related to this study included information on contraceptive practice, pregnancy outcome, social status, and time for diabetes debut. Data were collected from February 1987 to February 1990. When answering the questionnaire, the median age of respondents to the questionnaire was 32 yr (range 18–49 yr), and the median duration of diabetes was 17 yr (range 2–43 yr).

An age-comparable nondiabetic group (n = 289) was used as control subjects. The sample was drawn at random by using a random number generator from the computerized Electronic Data Processing Department of Odense University Hospital, where all citizens in Funen County are registered whether healthy or ill. The response rate was 88% (253/287). Median age of respondents was 33 yr (range 18–49 yr). There were no significant differences (P > 0.05) between diabetic women and control subjects with regard to age, marital status, education, or occupation.

The study was approved by the local ethical committee.

Definition of contraceptive use

If a woman used two methods for contraception concurrently, the method

with the lowest failure rate (13–15) was registered; if the methods were equally safe, the method used by the woman and not by the man was registered. Thus, if a woman used condoms and withdrawal or rhythm concurrently as contraception, she was registered as a condom user. If the IUD and condoms were used concurrently, the IUD was registered as the contraception. If the OCP and condoms were used concurrently, the OCP was registered. If the diaphragm and condoms were used concurrently, the diaphragm was registered. If foam and condoms, or foam and rhythm were used concurrently, spermicides were registered.

Statistics

If the variable was continuous, comparisons between groups were analyzed by the Kruskal–Wallis test and the Mann–Whitney U test. Other comparisons were performed using the χ^2 test.

RESULTS

Contraceptive practice

Information concerning the actual use of contraception was obtained from all diabetic women and from 250/253 (99%) of control subjects. At the time of the study,

77.1% of the diabetic women were using some type of contraception versus 73.6% among control subjects (P > 0.05). The distribution of contraceptive methods used is shown in Table 1.

In the diabetic group, a nearly similar proportion used female sterilization, IUD, OCP, and condom (Table 1). Among the 36 diabetic OCP users, 15 used low-dose triphasic formulation (30 μ g EE + 50 μ g LNG [\times 6 days]; 40 μ g EE + 75 μ g LNG [\times 5 days]; 30 μ g EE + 125 μ g LNG [\times 10 days]), 13 used low-dose fixed combinations (30 μ g EE + 150 μ g LNG or 1 mg NE), 6 used high-dose fixed combinations (50 μ g EE + 250 μ g LNG or 2 mg NE), 1 used a biphasic product (50 μ g EE [\times 7 days]; 50 μ g EE + 2.5 mg lynestrolum [\times 15 days]), and 1 used a formulation with genuine estrogens containing 4 mg estradiol + 2 mg estriol in a monophasic combination with 3 mg NE. Fifteen diabetic women used two contraceptive methods concurrently: 10 women used condom and withdrawal or rhythm; 2 women used IUD and condom; 1 woman used diaphragm and condom; 1 woman used foam and condom; and 1 woman used foam and rhythm concurrently.

Among the control subjects, 3 women used condom and withdrawal or rhythm concurrently, 2 women used OCP and condom, and 1 woman was using foam and condom. When comparing the same contraception method in the two populations studied, significantly fewer women in the diabetic group were using OCP (36/189 vs. 61/184, P < 0.005) and the method of partner sterilization (11/189 vs. 22/184, P < 0.05), whereas significantly more women in the diabetic group were sterilized (44/189 vs. 18/184, P < 0.0005). When comparing the methods of female or male sterilization in the two groups and the use of condom, there were no significant differences (P > 0.05).

Age among contraceptive users

Figure 1 shows the age, median, and range for diabetic women and control

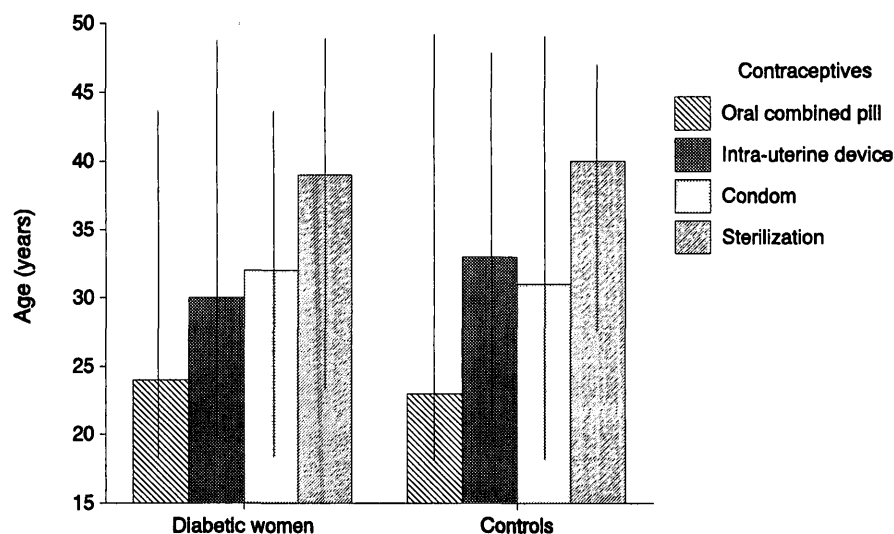


Figure 1—Age, median, and range for diabetic women and control subjects using various contraceptives.

subjects using OCP, IUD, condom, and sterilization (female and male), respectively. No age differences were observed between diabetic women and control subjects who used the same contraceptive method. In the diabetic group, the women who used OCP were significantly younger than those using IUD ($P < 0.0005$), condom ($P < 0.0003$), and a method of sterilization ($P < 0.0001$), respectively. The women who were sterilized or had a sterilized partner were

significantly older than those using condom ($P < 0.0001$) and IUD ($P < 0.0001$), respectively. In the control group, similar findings were observed. Among the diabetic OCP users, 3 women were >35 yr; 2 used a low-dose fixed combination, and 1 used a high-dose fixed combination.

Proportion of nulligravidae among contraceptive users

There was no significant difference ($P < 0.05$) between the proportion of

nulligravidae among diabetic women and controls using the same method of contraception. In the diabetic group, there were significantly more nulligravidae among the women who used OCP ($22/36 = 61\%$) than among those using IUD ($11/41 = 27\%$, $P < 0.005$), condom ($13/38 = 34\%$, $P < 0.05$), or a method of sterilization ($2/55 = 4\%$, $P < 0.0001$), respectively. There were significant fewer nulligravidae among the women who used a method of sterilization compared with those using IUD ($P = 0.01$) or condom ($P < 0.0001$), respectively. In the control group, we observed no significant difference between the proportion of nulligravidae among women using IUD and sterilization, respectively. Otherwise, control subjects did not differ from diabetic women (Table 2).

Proportion of women with two or more children among contraceptive users

We noted no significant difference ($P > 0.05$) between the proportion of women who had two or more children among diabetic women and control subjects using the same contraceptive method (Table 1). In the diabetic group, there were significantly more women who had two or more children among those who were sterilized or had a ster-

Table 2—Proportion of nulligravidae and women with two or more children among diabetic patients and control subjects using various contraceptives

	DIABETIC WOMEN				CONTROL SUBJECTS			
	NULLIGRAVIDAE USERS		USERS WITH TWO OR MORE CHILDREN		NULLIGRAVIDAE USERS		USERS WITH TWO OR MORE CHILDREN	
	N	%	N	%	N	%	N	%
OCP	22	61.1* (43–77)	4	11.1* (3–26)	34	55.7 (42–68)	16	26.2 (16–39)
IUD	11	26.8 (14–43)	12	29.3 (16–46)	4	14.3 (4–33)	14	50.0 (31–69)
STERILIZATION†	2	3.6 (0–13)	40	72.7 (60–84)	1	2.5 (0–13)	35	87.5 (73–96)
CONDOM	13	34.2 (20–51)	15	39.5 (24–57)	14	31.1 (18–47)	24	53.3 (38–68)

Numbers in parentheses are 95% confidence limits.

*All percentages are to be read as follows: of the women on OCP, 61% were nulligravida and 11% had two or more children.

†Female or male.

Table 3—Characteristics of diabetic women and control subjects not using contraception

	DIABETIC WOMEN (N = 56)		CONTROL SUBJECTS (N = 66)	
	N	%	N	%
PREGNANT	7	12.5 (5–24)	9	13.6 (6–24)
PREGNANCY DESIRE	10	17.9 (9–30)	16	24.2 (15–36)
HYSTERECTOMIZED*	5	8.9 (3–20)	11	16.6 (9–28)
LIVING ALONE	14	25.0 (14–38)	14	21.2 (12–33)
VARIOUS†	5	8.9 (3–20)	5	7.6 (3–17)
NO OBVIOUS REASON	15	26.8 (16–40)	11	16.6 (9–28)

Numbers in parentheses are 95% confidence limits.

*Only for women not sterilized.

†Various includes amenorrhea, infertility, breastfeeding, and impotence.

itized partner (40/55 = 73%) than among those using OCP (4/36 = 11%, $P < 0.0001$), IUD (12/41 = 29%, $P < 0.0002$), or condom (15/38 = 39%, $P < 0.002$) respectively. In the control group, similar findings were observed.

Use of contraceptives and duration of diabetes

The use of contraceptive method was not related to diabetes duration when adjusted by age.

Characteristics of women not using contraception

As shown in Table 3, there was an obvious explanation for not using contraception for all but 27% (15/56) of diabetic women vs. 17% (11/66) of control subjects ($P > 0.05$).

CONCLUSIONS— The choice of contraception may be influenced by a number of factors, such as economic considerations, religion, or simple tradition. Consequently, there is a large variation from country to country and especially from continent to continent on the methods used. Oral contraception is the preferred method of contraception in Western Europe, whereas the IUD is the most popular method in China. Sterilization is the predominant method in the United States, and traditional barrier and natural methods have the highest prevalence in the USSR (16–18). It is unavoidable that

the use of contraception in the general population will influence conditions in the diabetic population.

The ideal contraception, characterized by high efficacy and no serious side-effects, is still not available. Therefore, an individual assessment of risks and benefits must be performed before the type of contraception is recommended. Among diabetic women, a method should be used with a low failure rate, because pregnancy planning in these patients is important to ensure the best possible outcome of the pregnancy.

In this study, both the diabetic and control groups were unselected. Advice on contraceptive matters was received from gynecologists, pediatricians, diabetologists, and general practitioners. The contraceptive habits observed among our control subjects, are fully comparable with those obtained from the Danish National Board of Health in 1988 (19).

In a 1973 Danish study (9) on 79 diabetic women, it was reported that 4% used OCP, 1% POP, 43% IUD, 22% sterilization, 17% condom, 8% diaphragm, and 5% other methods, respectively. In a 1983 French study (10) on 209 16-to-50-yr-old diabetic women, 1% used OCP, 26% POP, 32% IUD, 14% sterilization, 17% condom or diaphragm, and 10% natural method as contraception, respectively. These data differ markedly from our results, in which nearly 20%

used OCP, 20% IUD, 20% sterilization, and 20% condom. However, in both surveys, the subjects studied also comprised women with NIDDM, and all patients were selected as indicated by their attendance at specialized diabetic departments. Furthermore, in the Danish study (9), only women who had delivered were included. Thus, meaningful comparisons to our results are hardly possible.

Our investigation has shown that the proportions of women using contraception were almost identical among diabetic women and control subjects. However, the distribution of various contraceptive methods differed substantially. This may be attributed to earlier recommendation advising IUD, low-dose progesterone, or sterilization to diabetic women in Denmark (9,20). These recommendations were based on the observations that none of these methods had any negative influence on glucose regulation or increased the risk of vascular disease. In 1982, OCP was not ruled out, but caution was advised because of the theoretical risk of increasing the occurrence of vascular complications (21). This policy seems to explain that a minor number of our diabetic women used OCP and that a major portion (29.1%) of these women was sterilized. It is surprising, however, that comparatively few diabetic women used POP.

Sterilization has a very low failure rate (13), and this method seems ideal to women who do not want more children. As expected, both among diabetic women and control subjects, those women who were sterilized or had a sterilized partner were in the higher end of the age range, and only few of them had never been pregnant, whereas most had two or more children.

High-dose OCP formulations exert a negative effect on glucose and lipid metabolism and carry an increased risk for cardiovascular complications (22–25). Low-dose fixed combinations and triphasic formulations seem not to influence glucose tolerance in nondiabetic women or in women with previous ges-

tational diabetes. Neither do triphasic formulations increase the insulin response during a glucose tolerance test. The incidence of abnormal glucose tolerance test seems to be related mostly to the dose and potency of the progestin and not the estrogen component (26). Neither low-dose fixed combinations or triphasic formulations caused alterations of HDL-cholesterol levels. However, triphasic formulations elevate plasma triglyceride concentration that has not been observed during administration of low-dose fixed combinations (27,28). Based on these observations and surveys on morbidity during use of OCP with different hormone content, it is generally recommended to use low-dose OCP with content of the estrogen component of $\leq 35 \mu\text{g}$ and the lowest dose/potency progestin. Furthermore, smokers >35 yr are advised not to use OCP, because this combination carries an increased risk for vascular complications (29).

In diabetic women, neither low-dose fixed OCP containing EE and NE, triphasic preparations of EE and LNg, low-dose NE alone, or genuine estrogens in combination with NE seem to change glucose control or lipid metabolism (30). The low-dose OCP results in a higher triglyceride level in the blood compared with the other groups. Accordingly, if OCP is considered by diabetic women, low-dose preparations with the lowest dose of progestin should be preferred, whereas high-dose OCP should be avoided. These recommendations obviously are not implemented among our OCP users, where 7 used an unsuitable method. Furthermore, 2 women using OCP were >35 yr. We do not know whether these women were smokers.

Low-dose progesterone does not influence glucose and/or lipid metabolism either in diabetic or nondiabetic women (25,30,31), and the failure rate is acceptably low (13). Low-dose progesterone therefore seems an ideal contraceptive for diabetic women. The reason why so few of our diabetic women used this method is unknown, but may be

related to a rather high rate of side effects, especially intermenstrual bleeding, variable cycle length, and amenorrhea (32).

In this study, 27% of the diabetic IUD users were nulliparous, which is medically unacceptable, because this contraception method carries a substantial risk for inflammatory pelvic disease and later infertility, mainly related to the woman's exposure risk for sexually transmitted disease (number of partners, no condom use) more than to parity (33). Otherwise, the use of IUD does not lead to adverse systemic effects, and this method has an acceptable safety, with a failure rate of $\sim 2/100$ women per yr (13,34). Because the removal rate necessitated by pelvic inflammation is similar among diabetic and nondiabetic women using IUD (35), this contraceptive can be recommended to diabetic women who have given birth, and one might argue best for women completed their child-bearing.

The condom was used by 20% of our diabetic patients and 25% of control subjects. There is no doubt that these data are influenced by the increase of sexually transmitted diseases, especially HIV. With regard to side effects and protection against venereal disease, this method seems ideal, but it has an unacceptable high failure rate of up to 15/100 women per yr (15), probably attributable to inappropriate application. Among diabetic women, the condom can only be recommended as a supplement to more effective methods. In our view, methods such as diaphragm/spermicides or withdrawal/rhythm are unsuitable as sole contraceptives in diabetic women because of their high failure rates (13,15).

With reference to current research, our study indicates that 52 (28%) of our diabetic contraceptive users used an unsuitable method: 7 used high-dose OCP, 11 nulligravidae women used IUD, 26 used condoms as the only method, 4 used diaphragm/spermicides, and 4 used withdrawal/rhythm as the only method. Thus, there seems to be a need for better

information and guidance for diabetic women concerning contraception.

In summary, sterilization, IUD, or low-dose progesterone should be recommended as the method of choice in diabetic women who do not want to have more children. Because OCP is the most effective reversible method for preventing unwanted pregnancies (13,15), low-dose combinations should, along with IUD and low-dose progesterone, be considered in young diabetic women without vascular complications. The IUD should be reserved for women who have completed their families. In women without a permanent partner, the condom should be advised as a supplement to one of the previously discussed methods.

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