The Impact of Preconception Counseling on Pregnancy Outcomes

The experience of the Maine Diabetes in Pregnancy Program

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OBJECTIVE — To determine if a noncentralized, statewide program could be established to educate health-care providers and women with pregestational diabetes on available strategies to prevent adverse outcomes in pregnancies complicated by diabetes. Characteristics of women who participated in the program and the outcomes of their pregnancies are evaluated.

RESEARCH DESIGN AND METHODS — A network of regional providers caring for pregnant women with diabetes was developed. Continuing education sessions were delivered to both providers and women with existing diabetes on the importance of preconception counseling.

RESULTS — Maine health-care providers collaborated on the development and adoption of three patient-care guidelines that address preconception counseling, prenatal care, and contraception for women with established diabetes. A total of 185 pregnancies among 160 women with pregestational diabetes reporting estimated delivery dates between 1 January 1987 and 31 December 1990 were identified. Of the total pregnancies, 62 (34%) occurred in women who received preconception counseling: among these 62 pregnancies were one major congenital defect (1.6%) and four fetal or neonatal deaths (6.4%). Among the 123 (66%) pregnancies occurring in women that had not received preconception counseling, 8 (6.5%) infants were born with congenital abnormalities, and 26 (21.1%) fetal or neonatal deaths were documented.

CONCLUSIONS — A program promoting preconception counseling can be implemented on a statewide basis by using various health-care providers to deliver the program. Participation in such a program appears to be related to improved pregnancy outcomes among women with pregestational diabetes.

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DIEP STUDY, DIABETES IN EARLY PREGNANCY STUDY; MDPP, MAINE DIABETES IN PREGNANCY PROGRAM; FBR, FOUNDATION FOR BLOOD RESEARCH; TYPE I DIABETES, INSULIN-DEPENDENT DIABETES MELLITUS; TYPE II DIABETES, NON-INSULIN-DEPENDENT DIABETES MELLITUS; OR, ODDS RATIO; CI, CONFIDENCE INTERVAL; NS, NO SIGNIFICANCE.

Each year an estimated 10,000–12,000 babies (1,2) are born to women with pregestational (overt) diabetes. For women with diabetes receiving appropriate management of their pregnancy, the perinatal mortality rate for their offspring approaches the corresponding rate for the nondiabetic population. Risks of morbidity to the fetus, however, still remain higher among pregnancies complicated by diabetes than those in the general prenatal population. Women with pregestational diabetes, compared with the general population, are three to four times more likely to have offspring with major congenital malformations (3–5). Of women with pregestational diabetes, ~9% will have babies with cardiac, CNS, renal, skeletal, and other malformations. This rate increases to 20–25% if the woman has very poor glycemic control during the first weeks of pregnancy (6–8). Research over the last decade has demonstrated that these diabetes-related congenital malformations occur in the first 6 wk after conception during the period of organogenesis (9-11). Several centers have demonstrated success in reducing the rate of major congenital malformations by instituting programs of strict glycemic control before conception and during organogenesis (12–17). In 1988, Mills et al. (18) published results from the DIEP Study and concluded that women who received early prenatal care had a significantly lower rate (4.9%) of congenital malformations than those women who received prenatal care >21 days after conception (9.0%). DIEP study results reported no association between the level of blood glucose in early pregnancy and the incidence of congenital birth defects (18). This conclusion, however, is controversial because the majority of women in the study were in a narrow range of fair to good glycemic control.

Beginning in 1985, the Maine Diabetes Control Project received funding through a cooperative agreement with the Centers for Disease Control, Division

of Diabetes Translation, to create the MDPP. Designed as a statewide initiative, the MDPP focuses its activities on reducing the adverse outcomes associated with pregestational diabetes in pregnancy. Development of MDPP activities was challenged by Maine's geographically large and rural nature, a population base barely exceeding one million people, a lack of local health departments and clinics, and a maldistribution of specialized health-care providers. Despite the infrequent nature of practitioners caring for pregnant women with pregestational diabetes, the MDPP promoted the local management of these pregnancies and focused the program's continuing education sessions on the importance of good diabetes control before conception, the benefits of preconception counseling, and appropriate antepartum and postpartum care. The objective of this study was to determine if such a program could be established to educate obstetricians, family practitioners, and women with pregestational diabetes statewide on the available strategies to prevent adverse outcomes in pregnancies complicated by diabetes. A secondary objective of this study was to identify and describe the characteristics of the women who participated in the program, and to determine if such participation in the MDPP was associated with a reduction in the rate of congenital abnormalities. The results of this study serve as a model for state public-health departments, health centers, and private physician offices where personnel and resources for centralized prenatal care for women with pregestational diabetes may be limited.

RESEARCH DESIGN AND METHODS— Throughout 1985 and 1986, the MDPP delivered ~30 continuing medical education programs statewide to local hospital staff, county medical societies, and professional association meetings and two statewide symposiums on issues related to diabetes and pregnancy. At these meetings, preconception counseling and appropriate antepartum and postpartum strategies for the management of pregnancies complicated by pregestational diabetes were emphasized. In addition, the goals and structure of the MDPP were reviewed and promoted, and local physicians were recruited to work with the MDPP to form a regional network of providers caring for pregnant women with diabetes. The MDPP formed an executive committee with 12 representatives from the state's major health-care organizations and named 18 local physician volunteers as area coordinators to serve as the liaison between the MDPP and health-care providers in a region. In addition, an ex-officio committee was named, consisting of state and nationally recognized experts in the field of diabetes and pregnancy, that would assist in developing the MDPP.

To promote local management of diabetic pregnancies and ensure quality and consistent antepartum and postpartum care, national experts worked with members of the MDPP executive committee and area coordinators to develop written patient-care guidelines for use by Maine physicians. In addition, the MDPP biannually sponsored continuing education sessions for the MDPP executive committee and area coordinators. At each meeting, a guest facilitator would present material on a specified management topic involving diabetes and pregnancy and other areas of perinatal medicine. Finally, the MDPP biannually prepared a newsletter describing the current activities of the program to keep all members of the MDPP executive committee, area coordinators, and other interested health-care professionals current with the activities of the program.

To promote preconception counseling by health-care professionals caring for women with diabetes, the MDPP registry was created. When a diabetic woman of childbearing age is identified during an office visit, the physician completes an MDPP registration postcard collecting information on the woman's date of birth, age at diabetes onset, current address, physician name and address, and reason for visiting the physician. At the same visit, the woman completes an MDPP medical information release form that allows the MDPP to collect data on the woman, the pregnancy and the outcome, with the form filed in the woman's medical record. Referral to the MDPP registry also could be made by diabetes educators located at over 30 hospitals, rural health centers, and home health agencies located statewide and by self-referrals. The MDPP computerized all registration postcards, and letters were sent back to both the referring provider and woman with diabetes, reemphasizing the importance of preconception counseling and providing patient and professional educational materials on diabetes and pregnancy. Included in these mailings were two of the MDPP patient-care guidelines: *Maine Guide for Preconception Care of Women with Established Diabetes Mellitus* and the *Maine Guide for Prenatal Care for Women with Established Diabetes.*

To promote the importance of preconception counseling to women with existing diabetes, the MDPP worked in coordination with diabetes educators statewide and the American Diabetes Association-Maine Affiliate to develop television public service announcements, education seminars, and educational brochures. A toll-free telephone number was established to increase the accessibility of the MDPP to both health-care professionals and women with diabetes.

All pregnancy-related data were collected on a standardized form. Maternal demographic data, and diabetes and obstetrical history information were obtained by reviewing the woman's medical record maintained by the obstetrician's office. Unless the record specifically noted a particular characteristic (e.g., maternal smoking habit), the data were considered missing. Information about the infant's delivery and any reported morbidity or mortality was abstracted from the hospital record when possible.

To determine the estimated number of pregnancies that would be com-

plicated by diabetes in the state, a rate of 2.1 per 1000 births (2) was applied to Maine's estimated female population and corresponding pregnancy rate for the specified study year. To ascertain if all known births to diabetic women were included in the study, a review of Maine birth certificates was conducted. This review was undertaken under a cooperative agreement with the Maine Office of Data, Research, and Vital Statistics/Vital Records Unit. For the time period 1987–90, Maine vital records reported a total of 94 births complicated by pregestational diabetes, and 55 were already registered with the MDPP. Follow-up was done with the mother's physician listed on the record for the remaining 39 births. Of these, 10 births either occurred in women who did not have diabetes, or were lost to follow-up. The remaining 29 births were births complicated by diabetes, where the mother had not been registered previously with the MDPP. In 10 of 29 cases identified through vital records, preconception counseling was noted in the woman's medical record.

GHb levels were obtained for some but not all women. To ensure comparable test results, participating physicians were requested to have four blood samples (first prenatal visit, and end of first, second, and third trimester) drawn locally but sent to a central laboratory (the FBR in Scarborough, Maine) for analysis. GHb levels reported by the FBR were measured with Isolab's Glyc-Affin Assay (normal range for nondiabetic, nonpregnant population is 4–8%). Many physicians and women, however, were reluctant to have blood drawn in addition to the blood drawn for the physician to clinically manage the patient. In many cases, the woman's GHb was measured by another laboratory.

For the purpose of this study, women with pregestational diabetes were defined as those women who were diagnosed with diabetes mellitus before they were pregnant. Data were not routinely collected on maternal diabetes or type of therapy used during the pregnancy. To obtain a surrogate classification of the type of diabetes in the study participants, women reporting an age of onset 0–14 yr were classified as having type I diabetes; women reporting an age of onset >20 yr were classified as having type II diabetes; and women reporting an age of onset 15–20 yr had their medical records individually reviewed to determine type of diabetes. If a woman was pregnant more than once during the study period, each pregnancy was counted separately. Women were classified as receiving preconception counseling if the woman's medical record documented a minimum of one physician visit before conception at which time pregnancy issues were discussed. Participating physicians were encouraged to use the *Maine Guide for Preconception Care of Women with Established Diabetes Mellitus* when conducting a preconception visit, but no data are available as to the extent it was used. Women registered postconception, or those identified through vital records were encouraged to obtain preconception counseling from their physician for any subsequent pregnancies.

Statistical analysis was performed with the statistical package BMDP. Statistics used include χ^2 test, Fisher's exact test, and Student's t test. Results are expressed as means ± SD. Level of significance was ≤ 0.05.

RESULTS — From 1985 to 1990, the MDPP sponsored two statewide symposiums on topics related to diabetes and pregnancy, with over 200 health-care professionals attending each program. Second, the MDPP sponsored 10 continuing education sessions, which were attended by ~200 health-care professionals, including members of both the MDPP executive committee, area coordinators, and other professionals involved in caring for pregnant women with pregestational diabetes. Throughout 1986 and 1987, a core group of providers, including physicians, nurses, and dietitians from the MDPP executive committee, collaborated to prepare the following three guidelines: *Maine Guide for Preconception Care of Women with Established Diabetes Mellitus, Maine Guide for Prenatal Care for Women with Established Diabetes*, and *Maine Guidelines for Contraception for Women with Diabetes Mellitus*. Copies of these guides were distributed to all of Maine's 70 obstetricians and 400 family practioners in 1988 and 1990.

Educational activites directed at women with diabetes were largely conducted on an individual basis by over 60 diabetes nurse educators and nutritionists at 30 outpatient diabetes education sites statewide. Issues related to the management of diabetes in pregnancy were incorporated into the curriculum used by the diabetes educators delivering the Maine Diabetes Control Project's education program. In addition, diabetes educators used the MDPP's patient-care guidelines as appropriate. A statewide educational program for women with diabetes and their families was held in coordination with the American Diabetes Association-Maine Affiliate in 1989 and had 150 participants. Finally, the MDPP developed two public service announcements that were aired on Maine's two major television networks in 1987 and 1988.

A total of 185 pregnancies in 160 different women with estimated delivery dates between 1 January 1987 and 31 December 1990 were reported to the MDPP by 51 providers, of which 15 were MDPP area coordinators, and an additional 7 were attendees of MDPP educational sessions. These 185 pregnancies agree closely with the estimated 180 pregnancies among women with established diabetes expected in Maine during the study time period. Of these 185 pregnancies, 34% (62) occurred in women with pregestational diabetes who received preconception counseling, and 66% (123) occurred in women who did not receive preconception counseling. Prenatal care was provided by a private physician in 83% (154) of the pregnancies and in a hospital outpatient setting

Table 1—*Selected demographic and health-related factors in pregestational diabetic women who did and did not receive preconception counseling*

Factor	Preconception counseling		No preconception counseling		
	n (%)	Mean ± SD	n (%)	Mean ± SD	P
Maternal age (yr)	61	28.3 ± 5.7	123	26.3 ± 5.6	0.02
Duration of diabetes (yr)	61	11.2 ± 7.3	123	9.0 ± 7.4	0.02
Prenatal visits (n)	51	16.3 ± 6.5	86	15.2 ± 7.7	NS
Maternal weight at first prenatal visit (lbs)	61	149 ± 34	122	160 ± 40	0.06
Age at onset (yr)	61		123		
0–14	33 (54)		57 (47)		NS
15–20	9 (15)		20 (16)		
>20	19 (31)		46 (37)		
Smokes cigarettes	61		123		
Yes	8 (13)		38 (31)		0.01
No	53 (87)		85 (69)		
Diabetes complications*	47		98		
Yes	13 (28)		23 (23)		NS
No	34 (72)		75 (77)		
Prima gravida	60		110		
Yes	12 (20)		37 (34)		0.06
No	48 (80)		73 (66)		
Poor obstetrical history†	35		76		
Yes	16 (46)		32 (42)		NS
No	19 (54)		44 (58)		
Cesarean section	37		71		
Yes	30 (81)		47 (66)		NS
No	7 (19)		24 (34)		

*Diabetes complications defined as cardiovascular, renal, or retinal complications associated with diabetes.
†Poor obstetrical history defined as previous spontaneous abortion, neonatal death, or stillbirth.

in 17% (31) of the pregnancies. None of the women cared for in the hospital outpatient setting had preconception counseling documented in their medical charts, and the majority did not initiate prenatal care before the second trimester. Of the pregnancies, ~65% (119) were complicated by maternal type I diabetes, and 35% (65) were complicated by maternal type II diabetes. An analysis of selected maternal characteristics (Table 1) showed that the mean age for those women who received preconception counseling were significantly older and had diabetes significantly longer than the women without preconception counseling. Women who did not receive preconception counseling were significantly ($P < 0.01$) more likely to be smokers, with >30% of these women reporting that they were smokers at the time of the first prenatal visit. Even though women with preconception counseling had diabetes longer, no significant difference was observed among the two groups in the number of women with diabetes-related complications. Approximately 25% (36) of the women in both groups had cardiovascular, renal, or retinal complications associated with diabetes. Primigravidas were nearly significantly ($P < 0.06$) more likely not to have received preconception counseling. For those women in both groups who had been pregnant previously, >40% (48) of these women reported having a poor obstetrical history, defined as a previous spontaneous abortion, neonatal death, or stillbirth. Although no significant difference was noted among the two groups in the number of women having cesarean deliveries, >70% (77) of the women studied had cesarean deliveries.

An analysis of characteristics of the 157 live-born infants shows no significant differences between the infants in gestational age or birth weight when stratified by whether or not the mothers received preconception counseling. The mean gestational age ± SD for both groups was >37 wk (37.5 ± 2.2 and 37.9 ± 2.1 wk for the 60 receiving and the 97 not receiving preconception

Table 2—*Pregnancy outcomes for pregestational diabetic women who did and did not receive preconception counseling*

	Preconception counseling	No preconception counseling	
	n (%)	n (%)	Total
Live born	58 (93)	93 (74)	151
Fetal death (including stillborn)	3 (5)	21 (17)	24
Neonatal death*	1 (2)	5 (4)	6
Voluntary abortion	0 (0)	3 (2.5)	3
Lost to follow-up	0 (0)	3 (2.5)	3
Total	62 (100)	125 (100)	187†

*Neonatal deaths are not included in the live-born category.
†Includes one set of triplets.

Table 3—*Poor pregnancy outcome in pregestational diabetic women who did and did not receive preconception counseling*

Outcome	Preconception counseling (*N* = 62)	No preconception counseling (*N* = 123)	OR (95% CI)
Fetal or neonatal death	4	26	3.9 (1.2–13.9)
Congenital malformation	1	8	4.2 (0.5–29.7)

counseling, respectively). The mean birth weights ± SD were ~3600 g for both groups (3648 ± 835 and 3549 ± 857 g for those receiving and not receiving preconception counseling, respectively).

Outcome information on the 187 fetuses indicates 151 (81%) resulted in live births (Table 2). There were 24 (13%) fetal deaths including spontaneous abortions, 6 (3%) neonatal deaths, and 3 (1.5%) voluntary abortions; 3 (1.5%) cases were lost to follow-up. Table 3 indicates that women who did not receive preconception counseling were significantly more likely to have pregnancies that resulted in a fetal or neonatal death (OR 3.9, CI 1.2–13.9). Women receiving preconception counseling reported 1 offspring with a major congenital defect, and women not receiving preconception counseling reported 8 offspring with congenital defects (OR 4.2, CI 0.5–29.7). This difference between the two groups was not significant. Table 4 lists pregnancy-related demographics and other data for the nine pregnancies associated with congenital abnormalities.

CONCLUSIONS— This study demonstrates the feasibility of developing a statewide network of health-care professionals that collaborated on improving the quality of care provided to pregnant women with pregestational diabetes. Through the MDPP network, Maine physicians were able to develop three guidelines of care for pregnant women with pregestational diabetes mellitus, and were able to have these guidelines widely accepted by Maine's community of obstetricians and family practitioners. More than 50 of Maine's physicians voluntarily reported on pregnancies among their patients with diabetes, identifying the expected number of pregnancies complicated by diabetes during the study period. Furthermore, these physicians reported a 34% preconception counseling rate among these pregnant women with pregestational diabetes. Characteristics of participants in this study suggest that a woman with pregestational diabetes who visits her physician before conception to discuss pregnancy is older and more likely to have had diabetes longer. She also is significantly less likely to smoke than the women not seeking preconception counseling, but does not have more diabetes-related complications. This profile describes a woman who received prenatal care in a private physician's office and is committed to a planned and healthy pregnancy. Women who received prenatal care in an outpatient clinic did not have preconception counseling and generally did not seek care during the first trimester. In this study, women who did not receive preconception counseling from a physician before conception were 4.2 (0.5–29.7) times as likely to have an infant with a congenital defect and 3.9 (1.2–13.9) times as likely to have an infant who did not survive because of either a fetal or neonatal death.

Clearly, more public and professional education is needed to encourage women with pregestational diabetes to seek care before conception. Special efforts should be targeted at women who

Table 4—*Pregnancy-related demographic, biochemical, and outcome information on the nine pregnancies associated with congenital malformations*

Case no.	Preconception counseling	Maternal age (yr)	Age of diabetes onset (yr)	Diabetes complications	Smokes cigarettes	Gravida	Prenatal visits (*N*)	Congenital malformation
1	No	33	23	Yes	No	2	5	Menigomyelocele
2	No	22	2	Yes	Yes	2	5	MCA; situs inversus
3	No	42	17	No	No	3	11	MCA
4	No	25	20	Yes	No	1	20	MCA; congenital heart disease
5	No	26	—	No	—	2	—	MCA; no kidney
6	No	30	6	Yes	Yes	1	25	Omphalocele
7	No	30	20	No	Yes	6	6	MCA
8	No	23	12	No	No	1	24	VSD heart; pelvic abnormalities
9	Yes	21	11	No	—	3	8	MCA

MCA, multiple congenital anomalies; VSD, ventricular septal defect.

receive their care in an outpatient clinic setting. The challenge is to assure that all women with diabetes, whether or not they have a private physician for obstetrical care, must have the information needed to make decisons that may impact their health and the health of their offspring. Further analysis is warranted to determine additional factors either related to the physician or the woman with diabetes, which may be associated with a woman's decision to seek preconception counseling. This study provides encouraging findings that preconception counseling results in improved pregnancy outcome.

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