Diabetes in Pregnancy: Efficacy and Cost of Hospitalization as Compared with Ambulatory Management – A Prospective Controlled Study

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Abstract

Background: Pregnant diabetic women are often subjected to frequent and prolonged hospitalizations to assure tight glycemic control, but in recent years attempts have been made at ambulatory control. The financial and social advantages of ambulatory management are obvious, but no report to date has prospectively compared its efficacy with that of hospitalization.

Objectives: To evaluate the efficacy and cost of ambulatory care as compared to repeated hospitalizations for management of diabetes in pregnancy.

Methods: We conducted an 8 year prospective controlled study that included 681 diabetic women, experiencing 801 singleton pregnancies, with commencement of therapy prior to 34 gestational weeks. During 1986–1989, 394 pregnancies (60 pregestational diabetes mellitus and 334 gestational diabetes mellitus) were managed by hospitalization, and for the period 1990–1993, 407 pregnancies (61 PGDM and 346 GDM) were managed ambulatorily. Glycemic control, maternal complications, perinatal mortality, neonatal morbidity and hospital cost were analyzed.

Results: There was no difference in metabolic control and pregnancy outcome in women with PGDM between the hospitalized and the ambulatory groups. Patients with GDM who were managed ambulatorily had significantly lower mean capillary glucose levels, later delivery and higher gestational age at induction of labor as compared to their hospitalized counterparts. In this group there were also lower rates of neonatal hyperbilirubinemia, phototherapy and intensive care unit admissions and stay. The saved hospital cost (in Israeli prices) in the ambulatory group was $6,000 and $15,000 per GDM and PGDM pregnancy, respectively.

Conclusions: Ambulatory care is as effective as hospitalization among PGDM patients and more effective among GDM patients with regard to glycemic control and neonatal morbidity. This is not only more convenient for the pregnant diabetic patient, but significantly reduces treatment costs.

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PGDM = pregestational diabetes mellitus
GDM = gestational diabetes mellitus
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The improvement in maternal and perinatal outcome of diabetic pregnancies over the past two decades has been amply documented [1]. It is well established that the principal factor responsible for this is strict glycemic control, with particular emphasis on maintaining blood glucose levels within the normal range [1]. To obtain such control these women were subjected to frequent and prolonged hospitalizations [2–10]; beginning in the 1980s however, attempts were made at ambulatory control [11–22]. According to one report the ambulatory management of pregnant diabetic patients led to a significant rise in perinatal mortality among pregestational diabetic women [1], while other reports demonstrated a lower mortality rate but a high rate of maternal and neonatal morbidity [20].

The financial and social advantages of ambulatory management are intuitively well understood, but no report to date has prospectively compared it with hospitalization. This report summarizes the results of a prospective controlled study, comparing ambulatory and hospitalization management of diabetes in pregnancy, with regard to glycemic control, perinatal mortality, neonatal morbidity, maternal complications and hospital cost. Since a distinction has been drawn between gestational diabetes mellitus and pregestational diabetes mellitus with respect to the relative importance of treatment modalities in each of these pathologies, we analyzed a detailed breakdown of these respective subgroups.

Patients and Methods

Study design

Until 1986 all pregnant women with GDM and PGDM were managed in our department by repeated hospitalizations. We decided to conduct a prospective trial to compare hospitalization to ambulatory management. Since it was impractical to randomize patients due to our population's cultural background, the patients were routinely managed by repeated hospitalizations during the period 1986–1989, and between 1990 and 1993 ambulatory care was provided.

Study protocol

The inclusion criterion for the study was a singleton diabetic pregnancy in which therapy was started before 34 gestational weeks. The hospitalization and the ambulatory groups were managed prospectively by the same protocol. Patients were

assessed by a high risk obstetric team consisting of the staff obstetric specialist, a resident, an obstetric nurse, a social worker, a nutritionist and a neonatologist. Screening for and diagnosis of GDM were performed using the recommendations of the Second International Workshop Conference on GDM [23].

Glycemic control

The dietary recommendations were 30–35 calories/kg ideal body weight, composed of 55% carbohydrates, 20–25% protein and 20% fat, with increased complex and decreased refined carbohydrates. Assessment of glycemic control was accomplished by glucose monitoring and serial measurements of glycosylated hemoglobin. Capillary whole-blood glucose was measured by the glucose kinase method in the hospitalization group and by self-monitoring glucose reflectance meters in the ambulatory group (the glucose values were verified by the glucometer's memory). Seven measurements were obtained daily at least once a week before 10 and after 32 gestational weeks, and bi-weekly between these periods. In the ambulatory group, telephone contact was made at least once a week. Hospitalization in this group was indicated if the patient required intensive educational efforts, or developed severe hypo- or hyperglycemia or any other medical or obstetric complication. Goals for glucose control were preprandial values of 60–95 mg/dl, 2 hour postprandial values of 120 mg/dl or less, and mean daily values of 80–95 mg/dl. Insulin was initiated when dietary treatment failed to obtain these levels. Goals for glycosylated hemoglobin (hemoglobin A1) were values below 9% (measured in whole blood by agar gel electrophoresis; Titan Gel Multi-Slot Glyco-17, Helena Laboratories, USA). Normal values were 5–9%. Short-acting and intermediate-acting human insulin were given in 2–4 injections per day, as indicated above.

Obstetric and medical follow-up

Baseline ultrasound was obtained for confirmation of gestational age and fetal anthropometric measurements, followed by serial ultrasound examinations to assess fetal growth. Maternal serum alpha-fetoprotein was measured at 16–18 gestational weeks in all patients. PGDM and insulin-treated GDM patients were screened for fetal anomalies by level II ultrasound and echocardiogram at 14–16 and 18–22 weeks. Patients were instructed to keep a fetal activity record of viability, and a non-stress test (backed up by contraction stress test or biophysical profile) was carried out weekly from 32 gestational weeks and twice weekly from 36 weeks. In patients with pregestational diabetes, ophthalmologic examination was performed on the first visit or admission and was repeated each trimester. Serum creatinine and blood urea nitrogen, creatinine clearance, urine culture and 24 hour urine protein levels were measured on the initial visit or at admission, and every trimester. If the results were abnormal, these tests were repeated monthly.

Labor and delivery

An important objective of the protocol was that infants be delivered at term. The timing of induction of labor was determined by an overall assessment of maternal and fetal risk factors, including poor compliance, sub-optimal glycemic control, vasculopathy, macrosomia, suspicious fetal biophysical test, and poor obstetric history. Uncomplicated gestational diabetes patients with unfavorable cervix were allowed to await spontaneous onset of labor. Delivery was induced if there was favorable cervix at 39–41 weeks gestation or if the patient had not delivered by 41 weeks. If a GDM pregnancy was complicated by one or more of the risk factors, treatment and delivery time were individualized to include increased frequency of glucose monitoring, hospitalization for diabetic control, evaluation of maternal problems, and increased frequency of fetal biophysical testing. Timing of delivery in PGDM women was also based on the overall obstetric, medical and metabolic assessment of the pregnancy, as well as cervical assessment. Amniocentesis for fetal pulmonary maturity was performed in diabetic women scheduled to be delivered before 39 weeks gestation. The goal for glucose levels during delivery was 60–100 mg/dl.

Neonatal care

At delivery, the neonate was attended by the neonatal staff. Serial blood samples were taken for neonatal plasma glucose, bilirubin, hematocrit and calcium levels.

Data collection

Historical, demographic, clinical course, laboratory, and maternal and neonatal outcome data were collected longitudinally for each patient from her first visit or admission until the postpartum examination, and were loaded onto an IBM-compatible personal computer.

Sample size and statistical analysis

Based on our previous results of hospitalized patients, 8% and 28% of infants born to GDM and PGDM mothers, respectively, were admitted to the neonatal intensive care unit. This was chosen as a parameter to reflect all cases of significant neonatal morbidity. We judged that a twofold increase of NICU admissions associated with ambulatory management would be clinically significant. A sample size of 680 GDM pregnancies and 120 PGDM pregnancies would provide a power of 0.9 to this estimation. The chi-square and two-tailed Student t-test were used to compare categorical data and continuous variables, respectively. The two-tailed t-test was chosen since we had no primary assumption as to the direction of the expected difference.

Results

During the 8 year study period 681 diabetic women experiencing 801 pregnancies were enrolled and completed the study. The hospitalization group comprised 60 pregestational diabetes and 334 gestational diabetes pregnancies, and the ambulatory group 61 and 346 pregnancies, respectively. The study groups were similar regarding baseline characteristics, obstetric and medical history (including diabetes in a first-degree relative,

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NICU = neonatal intensive care unit

past GDM pregnancy, past stillbirth, past pregnancy with hypertension, and past infant with congenital anomaly), and gestational age at diagnosis and at therapy initiation. There were no significant differences between the groups in the proportion of subgroups according to White's classification [23], which is based on the need for insulin therapy, the duration of the disease, and its complications [Table 1].

Glycemic control

Parameters of metabolic control and the cost needed to achieve it (number of hospitalizations, hospital days and outpatient clinic visits) are listed in Table 2. Mean glucose levels were lower in the ambulatory GDM group than in the GDM hospitalization group (93.2 ± 8.3 vs. 95.8 ± 7.7 mg/dl, 95% confidence interval -0.21 to -7.29, $P<0.0001$). Weight gain during pregnancy and insulin requirement at delivery did not differ significantly between the groups. Of the GDM and PGDM ambulatory groups, 55% and 67% respectively needed at least one hospitalization. The GDM hospitalization group needed an average of 5.3 hospitalizations and a stay of 15.4 hospital days to achieve glycemic control, as compared to 0.9 hospitalizations, 1.1 hospital days and 8.6 outpatient clinic visits in the GDM ambulatory group ($P<0.0001$). In the PGDM patients the values were 8.9 hospitalizations and 38.6 days for the hospitalization group, and 1.9 hospitalizations, 3.1 days and 15.7 visits for the ambulatory group ($P<0.0001$). Taking into account the cost per day of hospitalization ($443.3) and outpatient visit ($47.7) in Israel, the reduction in medical costs for each pregnancy was $6,000 and $15,000 for GDM and PGDM, respectively.

Birth data

Gestational age at birth and at labor induction were more advanced among the GDM patients in the ambulatory group as compared to the hospitalization group (39.1 ± 1.7 and 39.5 ± 1.2 weeks vs. 38.5 ± 2.0 and $39.01.3$ weeks, 95% CI 0.32–0.88, $P<0.0001$ and 95% CI 0.31–0.69, $P<0.005$, respectively). Other parameters including birth weight, rate of preterm birth (not shown), type of birth (vaginal, cesarean), and rate of labor induction (not shown) did not differ significantly [Tables 2 and 3].

Perinatal outcome

There was one neonatal death in the GDM hospitalization group and none in the GDM ambulatory group. There were two perinatal deaths in each PGDM group. Major congenital

CI = confidence interval

Table 1. Characteristics of diabetic pregnancies according to study groups*

	Gestational diabetes		Pregestational diabetes	
	Hospitalization	Ambulatory	Hospitalization	Ambulatory
N	334	346	60	61
Age (yr)	33.0 ± 5.3	33.2 ± 5.4	30.4 ± 5.9	31.7 ± 5.5
Body mass index	27.9 ± 2.5	27.8 ± 2.4	26.8 ± 3.0	27.1 ± 2.9
Parity	2.6 ± 1.2	2.7 ± 1.3	2.3 ± 1.8	2.4 ± 1.9
Gestational age at therapy start (wk)	28.0 ± 6.9	27.4 ± 6.8	12.9 ± 7.0	12.4 ± 6.2
Diet/Insulin	154/180	182/164	–	–
Vasculopathy**	–	–	12 (20%)	14 (23%)

Data are means ± SD or *n*.
* No significant differences were found between the respective groups
** Class D, R and F according to White's classification [24]

Table 2. Parameters for glycemic control and obstetric data of diabetic pregnancies according to study group

	Gestational diabetes		Pregestational diabetes	
	Hospitalization	Ambulatory	Hospitalization	Ambulatory
N	334	346	60	61
Weight gain (kg)	11.4 ± 3.5	10.7 ± 5.8	12.5 ± 4.0	12.0 ± 4.5
Capillary whole-blood glucose (mg/dl)	95.8 ± 7.7	$93.2 \pm 8.3*$	106.9 ± 18	103.0 ± 14
Hemoglobin A1 (%)	6.3 ± 1.5	6.1 ± 1.8	7.9 ± 2.4	7.7 ± 2.1
Insulin at delivery (U/day) **	40 ± 29	42 ± 28	98 ± 63	88 ± 50
Hospitalizations (not for delivery)	5.3 ± 3.3	$0.9 \pm 1.0*$	8.9 ± 4.0	$1.9 \pm 1.8*$
Hospital stay (days)	15.4 ± 10.9	$1.1 \pm 2.5*$	38.6 ± 19.4	$3.1 \pm 7.6*$
Outpatient visits	0	$8.6 \pm 4.5*$	0	$15.7 \pm 8.3*$
Gestational age at delivery (wk)	38.5 ± 2.0	$39.1 \pm 1.7*$	37.9 ± 2.1	38.2 ± 2.8
Cesarean sections	87 (26.0)	72 (20.8)	21 (35.0)	13 (21.3)
Pregnancy-induced hypertension	38 (11.4)	25 (7.2)	6 (10.0)	3 (4.9)

Data are means ± SD or *n* (%)
* $P<0.0001$: other parameters did not differ significantly
** GDM hospitalization group = 180 pregnancies, ambulatory group = 164 pregnancies

anomalies were found in four infants in the GDM hospitalization group (1.2%) and two in the GDM ambulatory group (0.6%), comparable to our low risk population. In the PGDM hospitalization group three infants suffered from major congenital anomalies (5.0%) as compared to four in the PGDM ambulatory group (6.6%). All these mothers were enrolled after the first trimester in a poor metabolic state.

Analysis of other measures of neonatal morbidity [Table 3] revealed that in the GDM hospitalization group as compared with the ambulatory group, there were higher rates of hyperbilirubinemia (33.2% vs. 14.2%, odds ratio 3.02, CI 2.07–4.40, $P<0.0001$), phototherapy (29.3% vs. 8.1%, OR 4.72, CI 3.00–7.42, $P<0.0001$), NICU admissions (10.8% vs. 2.9%, OR 4.06, CI 1.98–8.39, $P<0.0001$) and NICU stay (29.921.9 days vs. 8.37.5 days, 95% CI 19.15–24.05, $P<0.001$). All the above mentioned differences between ambulatory and hospitalization GDM groups remained significant after breakdown to diet-treated and only insulin-treated subgroups. There were no significant

OR = odds ratio

Table 3. Perinatal and neonatal outcome by study group in diabetic pregnant women

	Gestational diabetes		Pregestational diabetes	
	Hospitalization	Ambulatory	Hospitalization	Ambulatory
N	334	346	60	61
Birth weight (g)	3369 ± 670	3436 ± 589	3316 ± 627	3209 ± 728
Mortality	1 (0.3)	0	2 (3.3)	2 (3.3)
Major congenital anomalies*	4 (1.2)	2 (0.6)	3 (5.0)	4 (6.6)
SGA = 10th percentile	23 (6.9)	15 (4.3)	2 (3.3)	3 (4.9)
Macrosomia = 4,000 g	51 (15.3)	58 (16.8)	5 (8.3)	5 (8.2)
Apgar score <7 at 5 min	4 (1.2)	3 (0.9)	1 (1.7)	2 (3.3)
Admission to NICU	36 (10.8)	10 (2.9)#	9 (15.0)	16 (26.2)
Hyaline membrane disease	5 (1.5)	1 (0.3)	1 (1.7)	0
Hypoglycemia**	25 (7.5)	15 (4.3)	8 (13.3)	12 (19.7)
Hypocalcemia***	12 (3.6)	5 (1.4)	2 (3.3)	7 (11.5)
Polycythemia****	5 (1.5)	9 (2.6)	2 (3.3)	8 (13.1)
Hyperbilirubinemia*****	111 (33.2)	49 (14.2)#	27 (45.0)	38 (62.3)
Phototherapy	98 (29.3)	28 (8.1)#	25 (41.7)	23 (37.7)
Birth trauma******	7 (2.1)	6 (1.7)	1 (1.7)	1 (1.6)
NICU stay (days)	29.9 ± 21.9	8.3 ± 5.7#	27.8 ± 20.8	26.8 ± 21.3

Data are n (%) or means ± SD
*   Major congenital anomalies were defined as either fatal, requiring surgery or having significant psychological effects
**   Hypoglycemia was defined as plasma glucose value < 40 mg/dl
***   Hypocalcemia was defined as serum calcium < 2.0 mmol/L
****   Polycythemia was defined as venous hematocrit > 65%
*****   Hyperbilirubinemia was defined as $\geq$ 205 mmol/L $\geq$ 34 weeks gestation, or $\geq$ 137 mmol/L at < 34 weeks gestation
******   Birth trauma included peripheral nerve injury and/or bone fracture
# $P<0.0001$
SGA = small for gestational age, by Brenner et al. [25]

differences in those values between the PGDM ambulatory and hospitalization groups.

Discussion

Stallone and Ziel in 1974 [21] were the first to describe ambulatory management of GDM patients as an alternative for frequent and prolonged hospitalization. They reported 100 GDM pregnancies that did not require insulin and 7 that did. Perinatal mortality rate was only 1% in the diet-treated group, but extremely high in the insulin-treated women (three of seven). Twenty-eight percent of the infants were macrosomic and 4.7% of them suffered from birth trauma. Two years later, an attempt to manage PGDM women in the outpatient setting was successful, but the number (16 patients) was two small to draw conclusions [18]. Schneider et al. [20] reported a larger series of 108 PGDM pregnancies. The uncorrected perinatal mortality rate of 2.7% and the corrected rate (excluding major congenital malformations) of 0.9% were encouraging, but the maternal and neonatal morbidity rates (60% and almost 100%, respectively) were extremely high, as were the rates for cesarean section (70%), major congenital anomalies (7.3%) and neonates large for gestational age (40%). The authors suggested in explanation of these findings that preterm attempts had been made to deliver a significant number of patients before the cervix was favorable for induction, and whose mean glucose level was high

(165 mg/dl 2 hour postprandial). Conversely, in another series the change from prolonged hospitalization beginning at 32 weeks gestation until delivery of PGDM patients, to ambulatory care, was associated with an unexplained doubling of perinatal mortality from 4.5% to 9%. Therefore, the authors returned to prolonged hospitalizations from 34 weeks until delivery [1].

The introduction of self-monitoring of capillary whole-blood glucose by reflectance meters in the 1980s enabled physicians to manage pregnant diabetic patients ambulatorily. This approach gained popularity and numerous studies were published [11–21]. However, these reports present different populations, screening and diagnostic criteria for GDM, management protocols, and the definition of maternal and neonatal morbidity. To the best of our knowledge, no report to date has prospectively compared ambulatory management to hospitalization.

We conducted a controlled prospective trial in order to answer this question. Although we compared treatment in different time frames, the study was conducted in the same population using the same protocol. The groups were similar in maternal characteristics and initiation of therapy. Comparison between the ambulatory and the hospitalization PGDM groups revealed no differences. In contrast, among the GDM patients, ambulatory management was superior in terms of metabolic control and neonatal outcome. Gestational age at delivery and at induction of labor was higher, and this may be a result of better glycemic control. While these differences were slight, both higher gestational age at birth and lower blood glucose values may have contributed to lower rates of neonatal morbidity as expressed by lower rates of hyperbilirubinemia, phototherapy, and NICU admissions and stay. Our results for metabolic control and pregnancy outcome in both groups are comparable to those in the literature. The most difficult problem we faced, as did others [11], was the inclusion of PGDM women in the prepregnancy program in order to reduce abortion and congenital anomalies rates. Only one woman in the hospitalization group and three in the ambulatory group were enrolled before pregnancy. However, as our intensive educational effort among medical personnel and the population at large continues, we expect this to change.

The advantages of ambulatory management are:
- It avoids the psychological, mental and social trauma that may result from in-hospital care.
- It prevents disruption of the family unit, with the patient

hospitalized at a time when children and husband must be cared for and provided with food and the other daily necessities of life, but perhaps most important of all, with love, affection and attention.

- It enables the patient to continue working.
- Home glucose monitoring reflects the true ambient glycemic control in contrast to the hospital setting with its different diet, level of physical activity, and emotional stress.
- The patient plays an active role in caring for herself in contrast to her passive attitude in the hospital. The availability of home glucose monitoring and phone contact with the medical staff throughout the pregnancy allows frequent insulin and diet therapy adjustments that contribute to glycemic control. Interestingly, nearly all our patients continued home glucose monitoring postpartum.
- It relieves the load on the high risk pregnancy hospitalization unit, especially as the number of diagnosed patients increases due to improved screening and detection of GDM.
- It reduces hospital costs. Extrapolating this value and assuming the same rate of PGDM (1:300 births) and GDM deliveries (1:50) and the same medical cost in the USA, the sum would be approximately $750 million per year. It is noteworthy that this calculation involves only costs directly related to prenatal care; however, inclusion of projected costs of NICU admissions would have increased the costs even further.
- Since the patients in this study were not randomized, the results should be interpreted with caution. However, we may conclude that ambulatory care is as effective as hospitalization among PGDM patients and more effective among GDM patients with regard to glycemic control and neonatal morbidity. In addition, pregnant diabetic women under ambulatory management benefit from convenience and lower hospital costs.

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