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PREGNANCY OUTCOME IN PATIENTS WITH OVERT DIABETES- A PROSPECTIVE STUDY

Gynaecology

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ABSTRACT

INTRODUCTION: Two major forms of maternal diabetes may occur during pregnancy are 1. Preexisting or Pregestational diabetes and 2. Gestational. Prevalence rate of pre-gestational diabetes appear to be in the range of 0.1% to 0.3%. These pregnancies are at risk for both maternal and fetal complications.

Aim of the Study

Primary Objective:

1. To estimate the maternal outcome in pregnant patients with overt diabetes.
2. To estimate the peri- natal out come.

Secondary Objective: To estimate the Hospital Prevalence and Complications in diabetic complicated pregnancies.

MATERIALS AND METHODS: Study Design: Prospective Study; Setting : SAT Hospital, Thiruvanathapuram.

Study Population: All diabetic patients attending the antenatal clinics as overt diabetes in SAT Hospital.

Sample Size: All Cases registered in the period June 2004 to 2005 and were followed up till 7th day of delivery.

Data Collection: Researcher administered structured questionnaire.

Data Analysis: By using statistical package EPI 6,SPSS.

Exclusion Criteria: Pregnant women with Gestational Diabetes were excluded.

Outcome Variables: MMR and Morbidity; Fetal and Peri -natal Mortality and Morbidity.

DISCUSSION: During the study period in SAT, Thiruvananthapuram, there were16022 obstetrics admissions and out of this 72 were overt diabetes, prevalence of 0.44%. It is reported that the prevalence of overt diabetes gradually increase in its quantum.

MULTIVARIATE ANALYSIS: Outcome Variable- Maternal Complications

		B	S.E	Wald	df	Sig.	Exp(B)
Step 1	ANTE NATAL	-3.135	1.554	4.070	1	.044	.043
	META BOLI	.023	1.077	.000	1	.983	1.023
	YRS.M ARR	-.102	.120	.716	1	.397	.903
	PRE_O BS	2.189	1.146	3.650	1	.056	8.925
	AGE	-.030	.083	.129	1	.719	.971
	GRAVIDA	-.236	.400	.347	1	.556	.790
	MODE _DEL	-2.158	.569	14.383	1	.000	.116
	CONSTANT	5.698	2.234	6.507	1	.011	298.234

Outcome Variable- Fetal Outcome

		B	S.E	Wald	df	Sig.	Exp(B)
Step1	PRE_O BS	-.300	.734	.167	1	.682	.741
	GRAVIDA	-.012	.255	.002	1	.962	.988
	YRS_O F_M	-.003	.640	.000	1	.996	.997
	TYPE_ OF	-1.238	1.109	1.246	1	.264	.290
	AGE_ DIA	-.073	.048	2.264	1	.132	.930
	META BOLI	1.777	.628	8.001	1	.005	5.912
	Constant	1.538	1.824	.711	1	.399	4.653

CONCLUSION: When maternal complications were taken as outcome variable, the ante natal care p=0.044, mode of delivery p=0.000 found significant. When fetal outcome was taken as outcome variable, metabolic control found significant, p=0.005.

The prevalence of overt diabetes in the present study from June 2004-June 2005 is 0.44%.

Thus it is clear that good glycemic control and Ante natal care can bring down the adverse maternal and fetal outcomes. Introduction of pre conceptual clinics and provision for estimation of glycosylated hemoglobin in the primary health centre levels will enable the patients to have a better outcome.

KEYWORDS

Overt Diabetes, Gestational Diabetes, Glycaemic Control, HbA1C, Multivariate Analysis.

INTRODUCTION

The first recorded case of diabetic pregnancy was reported in 1823. The mother survived but the child died during delivery due to dystocia. The birth weight of the child was 5.4 Kgs. The Prevalence of maternal diabetes is 1-14%. Two major forms of maternal diabetes may occur during pregnancy. 1. Preexisting or Pregestational diabetes and 2. Gestational. Prevalence rate of pre-gestational diabetes appear to be in the range of 0.1% to 0.3%. These pregnancies are at risk for both maternal and fetal complications.[1]

Depending on the specific population, abnormal maternal glucose regulation occurs in 3-10% of pregnancies. The prevalence of diabetes among women of child bearing age is due to,

1. More sedentary Lifestyles
2. Continued immigration from high-risk populations and
4. Childhood and Adolescent obesity

Infants of mothers with pre existing diabetes experiences double the risk of serious injuries at birth, triple the likelihood of cesarean section and quadriple the incidence of newborn intensive care unit admissions. Recent studies indicate that the risk of these morbidities in individual cases is proportional to the degree of maternal hyperglycemia.[6]

Patients with symptoms of diabetes and a casual plasma concentration of 200 mgs/dl or more is considered overt diabetes. The condition may be pre existing or detected during the present pregnancy for the first time. Overt diabetes is a syndrome of disordered metabolism with inappropriate hyper glycemia due to an absolute deficiency of insulin secretion or a reduction in biologic effectiveness of insulin or both.

Williams reported a maternal mortality of 30% and perinatal loss of 70% in 1909. Prior to the advent of insulin the co existence of diabetes mellitus and pregnancy was a rare event and it was likely to be fatal for

both the mother and child. Various anomalies and risks of birth defects have been associated with pregnancies with overt diabetes. However over the years, with strict metabolic control and intensive fetal surveillance, the perinatal mortality has been reduced to less than 3%, nearly same as in normal non-diabetic pregnancies. The MMR was reduced to nil. The congenital mal formations has been reduced from 12% to 5% by pre pregnancy counseling, ante- natal care and control of diabetes prior to conception.[7]

Over the years overt diabetes in pregnancy is increasing and so the complications also. This study will help to know the frequency of occurrence of overt diabetes and its complications, the importance of ante- natal care in preventing end- organ damage like blindness, renal damage, diabetes keto acidosis, fetal or perinatal complications like miscarriage, birth defects and growth abnormalities.

OBJECTIVES

Primary

1. To Estimate the maternal outcome in pregnant patients with overt diabetes.
2. To Estimate the peri- natal out come.

Secondary

To Estimate the hospital Prevalence and Complications in diabetic complicated pregnancies.

MATERIALS AND METHODS

Study Design: Prospective Study
Setting : SAT Hospital, Thiruvanathapuram.
Study Population: All diabetic patients attending the antenatal clinics as overt diabetes in SAT Hospital.

Reference Population: People from south Kerala and adjacent areas of Tamil Nadu.
Sample Size: All Cases registered in the period June 2004 to 2005 and were followed up till 7th day of delivery.
Data Collection: Researcher administered structured questionnaire.
Data Analysis: By using statistical package EPI 6,SPSS.
Selection of Cases: All Case of pregnant women with overt diabetes.
A women with random plasma glucose level more than 200 mgs/dl and classical symptoms and signs such as polidypsia, polyuria, unexplained weight loss, fasting glucose level of 126 mgs/dl or more is considered to have overt diabetes. American diabetes association 1999b.
Exclusion Criteria: Pregnant women with Gestational Diabetes were excluded.
Outcome Variables: MMR and Morbidity; Fetal and Peri -natal Mortality and Morbidity.

RESULTS

During the present study of 16022 obstetrics admissions 72 were overt diabetes cases and thus the prevalence 0.44%. There were 67 booked and 5 un-booked cases. Booked means those patients who had already registered and done the antenatal check up in SAT, Trivandrum. Un booked means those had not done antenatal visit but came for delivery only.

Age Distributions: (Standard Deviation:5.506) p=0.000 Mean: 29.28yrs Median:29yrs and Mode:29yrs.

Table 1: Years of marriage before pregnancy

Mean/ sd	6.47/4.36;p=0.03
Minimum	1 yr
Maximum	16yrs

Table 2: Domicile, p=0.230

Urban	15/ 21%
Rural	57/79

Table 3: Religion, p=0.530

	frequency	Percent
Hindu	50	69.4
Christian	8	11.1
Muslim	14	19.4
Total	72	100

Table 4: Occupation

	Frequency	Percentage
Manual labourer	4	5.6
Skilled	9	12.5
Office work	8	11.1
Professional	3	4.2
House wife	48	66.7
Total	72	100

Table 5: Socio Economic Status

BPL	18/ 25%
APL	54/75%

P=0.040

Table 6: Education

Father	Mean yrs of Schooling= 9.57(3.54)	Minimum 0(1)	Maximum 22
Mother	10.18(3.514)	0(1)	19

Table 7: Gravid wise distribution: parity/p=0.039

Gravida	Number	%	Parity	Number	%
1	20	27.8	0	35	48.6
2	23	31.9	1	27	37.5
3	16	22.2	2	9	12.5
>3	13	18	3	1	1.4

Table 8: Classification

Class of disease	number	%
B	65	90
C	3	4.16
D	1	1.3
R	3	4.16

Table 9: EYE Examination

Retinopathy	3
Cataract	1
Normal	68

S. Cr: Elevated=6, Normal=66
Previous Obstetric History/Hazard

Table 10: Total Pregnancies=100

Bad Obstetrics Indications	Number	%
Abortion	34	34
Neonatal death	5	5
Vulvitis	14	14
UTI	21	21
PIH	12	12
Hydramnios	8	8
Macrosomia	10	10
IUD	13	13
Traumatic delivery	1	1
Congenital anomalies	3	3
DK	1	1
Infertility	18	18
PROM	5	5
Pre term labor	5	5

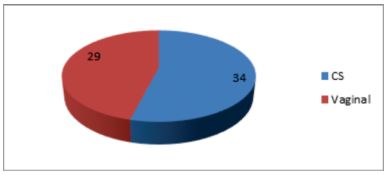
HBA1C: Normal=53, Elevated=13, Not Done=6

Table 11: Present Obstetric History

Complications	Number	%
Abortion=9 2nd trimester abortion=2	9	13
Hyperemesis	2	2.7
UTI	31	43
Vulvitis	29	40
PIH(Pre eclampsia)	22	30
Hydramnios	12	16
IUD(before 28 weeks of gestation)	4	5
Traumatic delivery	1	1.3
Hypoglycemia	3	4
Congenital anomalies	1	1.3
DK	1	1.3

PROM	14	19
Preterm	5	7

Fig 1: Mode of Delivery:



CS=34/47.22% Fetal distress=7
Vaginal =29/40.28%; Normal=24, Instrumental=4, VBAC=1

Table 12: Complications during Labour (Number/%)

Hypoglycaemia	2	2.7
PPH	6	8.3
Shoulder Dystocia	1	1.3
Single umbilical artery	1	1.3

Table 13: Birth Weight: in kgs, p=0.001

Mean	2.933	<2.516/25% 2.6-3.942/67% >45/8%
Median	3	
Mode	3.5	
sd	0.8474	

Table 14: Neonatal complications

Hypoglycemia	1	1.6
Hyperbilirubinemia	8	12.3
RDS	14	22
NND	3	4.7
Macrosomia	5	8

Table 15: POST-PARTUM COMPLICATIONS

No complications	50	79%
Complications	number	%
Wound infection	2	3.1
Other infection	3	4.7
DK	5	7.9
hypoglycemia	3	4.7

ANTENATAL CARE
Good=54(75%)/ Poor=18(25%)

METABOLIC CONTROL IN THE PERI-CONCEPTIONAL/m IST TRIMESTER

Good(well controlled)45(62.5%)
Poor(high hba1c or /PPBS>120 mgs/dl)27(37.5%)

CROSS TABULATION:

Table 17: Metabolic control(peri-conceptional/1st trimester)* fetal outcome
OR=4(95%ci 1.22-13.67)p=0.013

Metabolic control	Fetal outcome adverse	Feal outcome good	total
Poor	21	6	27
Good	21	24	45
Total	42	30	72

Table 18: Antenatal care*fetal outcome
OR=3.25(95% CI 0.84-13.54)p=0.060

Metabolic control	Fetal outcome adverse	Feal outcome good	total
Poor	21	6	27
Good	21	24	45
Total	42	30	72

Table 19: Age group*fetal outcome
P=0.475

AGE	FETAL OUT COME ADVERSE/GOOD	
>=30	21/12	33
<30	21/18	39
TOTAL	42/30	72

Table 20: Age group* maternal complications
OR=3.65(95% CI 1.19-11.49)

AGE	MAT.COMPLI ADVERSE	NIL	
>=30	25	8	33
<30	18	21	39
TOTAL	43	29	72

Table 21: RURAL/URBAN*FETAL OUTCOME
P=0.230

Domicile	Fetal outcome Adverse/good	total
R/U	Rural=35/22	57
	Urban=7/8	15
Total	42/30	

Table 22: Rural/urban*maternal complications p=0.379

Domicile	Maternal complications		total
	adverse	good	
Rural	33	24	57
Urban	10	5	15
Total	43	29	72

Table 23: Metabolic control*maternal complication
OR=0.59(95% CI 0.20-1.75)

MC	MC ADVERSE	GOOD	TOTAL
POOR	14	13	27
GOOD	29	16	45
TOTAL	43	29	72

Table 24: ANTE NATAL CARE* MATERNAL COMPLI CAT ION
OR=0.43(95% CI 0.13-1.46)

AC	MC ADVERSE	GOOD	TOTAL
POOR	8	10	18
GOOD	35	19	54
TOTAL	43	29	72

Table 25: MULTIVARIATE ANALYSIS
OUTCOME VARIABLE- MATERNAL COMPLICATIONS
Variables in the equation

		B	S.E	Wald	df	Sig.	Exp(B)
Step 1	ANTE NATAL	-3.135	1.554	4.070	1	.044	.043
	META BOLI	.023	1.077	.000	1	.983	1.023
	YRS.M ARR	-.102	.120	.716	1	.397	.903
	PRE_O BS	2.189	1.146	3.650	1	.056	8.925
	AGE	-.030	.083	.129	1	.719	.971
	GRAVIDA	-.236	.400	.347	1	.556	.790
	MODE _DEL	-2.158	.569	14.383	1	.000	.116
	CONSTANT	5.698	2.234	6.507	1	.011	298.234

Table 26: OUTCOME VARIABLE- FETAL OUTCOME
Variables in the equation

		B	S.E	Wald	df	Sig.	Exp(B)
Step1	PRE_O BS	-.300	.734	.167	1	.682	.741
	GRAVIDA	-.012	.255	.002	1	.962	.988
	YRS_O F_M	-.003	.640	.000	1	.996	.997
	TYPE_ OF	-1.238	1.109	1.246	1	.264	.290
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	META BOLI	1.777	.628	8.001	1	.005	5.912
	Constant	1.538	1.824	.711	1	.399	4.653

DISCUSSION

During the study period in SAT, Thiruvananthapuram, there were16022 obstetrics admissions and out of this 72 were overt diabetes, prevalence of 0.44%. it is reported that the prevalence of overt diabetes gradually increase in its quantum.

The increase in prevalence may be due to
1. Early detection of diabetes by screening of high risk cases.

2. Reference of high risk cases from periphery to this tertiary centre.
3. Increased in survival of juvenile diabetes.
4. The early onset of type 2 diabetes due to life style changes.

Age Distribution:
In the present study the mean age was 29 yrs (*sd* 5.5). in this study 67 are booked cases and 5 are unbooked. These cases accounts for the favorable peri natal outcome. In a previous study done at sat hospital during 1996 also shows the maximum number of patients between the age group 25 and 34. The mean age of SAT admissions during the study was 25.1 yrs. The increase in the mean age of study group may be due to the obstetrics mishaps in the study group.

The present study 45.8% of overt diabetes pregnancies belong to more than 30 yrs and 54.16% below 30 yrs of age group where as it is only 23.8% and 76.2% viz. in the total hospital admissions. This may be due to the obstetrics mishaps in the study group. When maternal complications are concerned the women having age more than 30 yrs had an odds ratio of 3.65.

The mean yrs of marriage before pregnancies were 6.47 yrs. 80% of normal couple conceives within year. Here only 6(8.3%) become pregnant within one year. The maximum years of 16 were noted in 4 persons (5.6%).

DOMICILE:
In the present study 79% patients belong to the rural population and 21% from urban where as it is 53.8% and 46% respectively in the current SAT admissions. This may be due to increase reference of overt diabetes from periphery hospitals. In India 65% of people live in rural areas.

Religion:
In this study the proportion of overt diabetes with pregnancy among Hindus: Christians: Muslims=69.4%:1.1%:19.4% where as the proportion among the current SAT admissions are 71.2%:5.8%:23.1%.

Socio economic status:
The present study reveals a 75%: 25% proportion of APL: BPL viz the admissions in sat 91.6%:8.4%. this may due to the fact that people belonging to the affordable group take acceptable treatment from private institutions having modern facilities and increased reference of bpl group from periphery to here.

"Gravida" wise distribution
The gravida wise distribution shows that 52 cases were muti- gravida. This is due to the obstetrics mishaps in diabeteic women. In this study 20 are primi and 15 are multi gravida without children.

Class of disease:
In this series 65 of the total 72 were under class B, only one in Class D, and three in each C and R.

Eye Examination:
Of the total 72 pregnancies 3(4.2%) having retinopathy. All the 3 had type 1 retinopathy changes. Retinopathy was classified into four types. In Grade 0- the patients showed no retinopathy changes. Grade 1- there was background retinopathies with micro aneurisms, and in Grade 2- pre proliferative retinopathy the criteria included hard exudates, hemorrhages and infarcts. Grade3- was classified as proliferative retinopathy wit neo – vascularisations and fibrous tissues. Aggregations of retinopathy was defined as any progression of pre-existent retinal changes during pregnancies.

Renal functions:
The results shows that 6(8.3%) has elevated Serum Creatinine Level.

Several studies of diabetic retinopathies in pregnant women have been shown that moderate to severe renal insufficiency at conception (S. Cr >1.4 mgs/dl) is associated with a high risk for progression of the renal disease during pregnancies. But reports of whether the same pre disposition to regression is seen in diabetic women with mild renal insufficiency are controversial. The well known phenomenon of tubular secretion of creatinine, which increases variability with decreased renal function and proteinuria, reduces the rise in s.cr and falsely elevates Creatinine Clearance in patients with renal insufficiency. GFR is therefore over estimated when one calculates Cr Clearence , especially when the filtration rates are below 20ml/minute.

Post obstetrics hazards:
The present study results shows that previous pregnancies were complicated by 34% abortions, 13% IUDs and 5% neonatal deaths. These bad obstetrics performances may be due to poor metabolic controls. In a similar study conducted in SAT in 1996 abortions rate was 27.45, IUDs 8.82%, & 7.84% Neonatal deaths. The increase in rates of abortions and IUDs may be due to the increase in the reference of cases with BOH from periphery. The decrease in NND may be due to the better neonatal facilities now available.

HBA1C Level:
The HB A1C was found to be increased in 13(18%) subjects.

The correlation between control of the diabetes and the risk of congenital malformations was first noted in the 1970s. In 1978, the BH A1C was correlated with major anomalies. The higher the A1C above normal , the greater the percentage of abnormalities. Also, early pregnancy losses were found to correlate with high hba1c values at the time of conception. Hypoglycemia does not increase the rate of anomalies in humans. HBA1C values should to be in the normal range prior to the pregnancy and every 1-2 months during the pregnancy.[12]

Present obstetrics hazards:
The results show that vulvitis and UTIs are the most common ailments. There were 30% pre eclampsia, 16% hydramnios and 7% pre term labour. A similar study from SAT Hospital in 2000 shows 31.96% of pre eclampsia in diabetic population and 8% in non diabetic, 18% hydramnios and 10% pre term labour. Fetal loss rate (abortions) =13%. Woman with overt diabetes exhibit a threshold of pre-gestational glycemic control above which spontaneous pregnancy loss is increased.[13]

Mode of delivery:
In this study, of the total 72 cases 29(40.28%) had vaginal delivery of which 14% was instrumental delivery.47.22% had CS of which 21% of CS was due to fetal distress. The CS rate in diabetes pregnancy is high; in addition to the increased rates of failed inductions, macrosomia and fetal distress contribute to this. CS rates in diabetic woman have been reported to be 45-50%, the corresponding percentages being 9-12 in the background population.

Complications during labour:
Birth Weight:
There was 8% macrosomia, low birth weight 25%,pre maturity 7% in this study . the previous study the proportions were 27.6% for macrosomia, 21.1% for prematurity. The decreased rate of macrosomia and pre maturity may be due to the good glycemic control and ante natal care.

During last five decades perinatal mortality in the largest tertiary level centres fell from 28.5% to 2.4%. In this study the perinatal mortality rate was 5%.

Only one congenital anomaly (Anencephaly) detected 1.39%. But that does not rule out the possibility of more congenital malformations since autopsies were not conducted on IUD babies. A proportion of 2.1% for malformations was noted in previous study. In the post partum period 31% developed post partum complications.[14]

Co morbid conditions:
One person was HBS Ag ,HBE positive.

No maternal mortality in the present series. In a similar study in 1996 in SAT Hospital also did not show any maternal mortality. Studies by Agarwal et al 1983 and Goyal U 1980 also showed similar results.

The present study clearly supports the hypothesis that good metabolic control p=0.009 and good ante natal care p=0.047 reduces bad fetal outcome bad outcome(bad outcome means neonatal death, congenital anomalies., babies required resuscitations).

But the study could not find a statistical significance, between maternal complications and metabolic control p=0.292 and ante natal care p=0.127.

There is a 3.65 times risk for mothers having overt diabetes more than or equal to 30 yrs to develop complications p=0.010. maternal complications was assessed by considering that PIH, Hydramnios

,DK, Hypoglycemia and pre term labour as bad outcome. Pedersen and Moelsted 1965 presented 4 groups with a poor prognosis for the infants in diabetic pregnancy. These prognostic ally bad signs of pregnancy were clinical pyelonephritis, pre-comatose or severe acidosis, pre eclampsia and negligence of care. In a study accepted by Oulu University on September 21st 2001 shows poor glycemic control during the first weeks of pregnancy was found to be the most important factor predicting adverse neonatal outcome such as increased CA rate, neonatal morbidity and mortality in diabetic pregnancy. There is 4 times risk for a bad fetal outcome when the mother has bad metabolic control and 3 times risk if had bad antenatal care.[15]

The multivariate analysis shows: When fetal outcome was taken as outcome variable metabolic control during peri- conceptual period and first trimester found significant, p=0.005. When maternal complications was taken as outcome variable, antenatal care ,p=0.044, and mode of delivery, p=0.000 found to be significant.

CONCLUSIONS:

1. There were 72 overt diabetic cases in 16022 obstetrics admissions. The prevalence of overt diabetes in the present study from June 2004-June 2005 is 0.44%.
2. Mean age was 29yrs ***sd*** 5.5 >=30-45.8%, <30 yrs-54.16%. Rural: Urban=79%:21%. Hindu: Christian: Muslims= 69.4%: 11.1%: 19.4%. BPL:APL=25%:75%
3. Multi Gravida-52, Primi-20; The mean yrs before present conception-6.47yrs; Class B-65,D=1,C=3,R=3.
4. Complications: Retinopathy Type 1-3, Elevated S. Creatinine=6(8.33%), Increased HB1c-13(18%), Past obstetrics hazards: Abortions=34%, IUDs-13%, NND-5%.
5. Mode of delivery: Vaginal Delivery-29(40.28%), Instrumental Delivery-14%,CS-47.22%(21% of CS was due to fetal distress.)
6. The peri natal mortality rate -5%; Anencepahaly-1, single umbilical artery-1. Post partum complications-31%; One person was HBS Ag and HBE Ag positive. 8% macrosomia, low birth weight 25%,pre maturity-7%. Maternal mortality-0; Fetal loss rate (abortions)-13%.
7. Overt diabetes in obstetrics patient is a high risk situation for both mother and the baby. Proper management from the pre conceptional period till delivery can bring about a very favourable outcome. 45.8% of overt diabetes pregnancy belong to above 30yrs. (OR=3.65(1.19-11.49), & 54.16% below 30 yrs f age group.
8. The mean yrs of marriage before pregnancies were 6.47yrs. Of the total 6(8.3%) were become pregnant at or below 1 yr. The maximum yrs duration of 16yrs were noted in 4 persons(5.6%).
9. The present study clearly supports the hypothesis that good metabolic control p=0.009 and good antenatal care p=0.47 reduces bad fetal outcome.
10. The Multi Variate Analysis Shows:When maternal complications were taken as outcome variable, the ante natal care p=0.044, mode of delivery p=0.000 found significant. When fetal outcome was taken as outcome variable, metabolic control found significant, p=0.005.

Thus it is clear that good glycemic control and Ante natal care can bring down the adverse maternal and fetal outcomes. Introduction of pre conceptual clinics and provision for estimation of Glycosylated hemoglobin in the primary health centre levels will enable the patients to have a better outcome.

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