A COMPARATIVE STUDY OF EFFICACY OF DIPSI AND O'SULLIVAN'S METHOD OF SCREENING FOR GESTATIONAL DIABETES MELLITUS

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ABSTRACT

BACKGROUND

The incidence of GDM is higher in India - 10-17.8%. GDM has adverse outcomes of pregnancy and long term risk to mother and offspring which warrants an effective screening and diagnostic test for GDM. All complications of GDM are potentially preventable. This study compares the efficacy of DIPSI (Diabetes in Pregnancy Study Group India) with O'Sullivan's method in the screening of Gestational diabetes mellitus.

MATERIALS AND METHODS

This prospective study was conducted in antenatal clinic in outpatient department of Obstetrics and Gynaecology, Government Medical College during the period of August 2013 to July 2015. 500 pregnant women in each of study group between 24-28 weeks gestation were selected. DIPSI and O'Sullivan' tests were performed.

RESULTS

The incidence of GDM was 9% in O'Sullivan's group when compared to 12.5% in DIPSI group. The specificity of O'Sullivan's method in detecting GDM is only 95% when compared to DIPSI. Highest incidence of GDM was observed in age group of 21-25 yrs. (64.44% in O'Sullivan's group and 73.01% in DIPSI group), more in multigravida in both (88.88% in O'Sullivan's group and 74.66% in DIPSI group), in Class V socioeconomic status in both (88.88% in O'Sullivan's group and 83.33% in DIPSI group), with BMI > 25 kg/m² in both (73.33% in O'Sullivan's group and 83.3% in DIPSI group), incidence of polyhydramnios was 6% in O'Sullivan's group and 6.3% in DIPSI group. 83.33% delivered at term in both the groups. Caesarean section was 61.1 % in O'Sullivan's group and 74% in DIPSI group. The birth weight was in the range of 2.5-4 kg in both (77.77% in O'Sullivan's group and 68% in DIPSI group). 16.66% % were treated with meal plan and 83.33% with insulin in O'Sullivan's group and 25% with meal plan and 75% with insulin in DIPSI group. Hypoglycaemia and hyperbilirubinaemia in babies is 12.5% in both the groups.

CONCLUSION

Screening with 50 g O'Sullivan's method has only 95% specificity compared to screening with 75 g DIPSI. DIPSI being a one-step procedure offers both as a screening and diagnostic test for GDM.

KEYWORDS

Gestational Diabetes Mellitus, O'Sullivan's Method, DIPSI Method.

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BACKGROUND

The most common endocrine disorder to complicate pregnancy is diabetes. Gestational diabetes mellitus is defined as carbohydrate intolerance with onset/recognition during pregnancy¹. There is increase in incidence worldwide with a range of 0.4-10% (Dornhorst et al. 1998).² The incidence of GDM is higher in India and ranges from 10-17.8%. GDM has adverse outcomes of pregnancy including polyhydramnios, preeclampsia, macrosomia and shoulder dystocia. Longterm risk includes childhood obesity and type II DM in mother and offspring (Wilkins Huag L, et al³)

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Metzger et al) which warrants an effective screening and diagnostic test for GDM. Ethnically Indian women are prone to develop glucose intolerance by eleven fold when compared to whites necessitating universal screening during pregnancy. Hence, an appropriate screening test for GDM has been much emphasised. All complications of GDM are potentially preventable with early recognition and intense monitoring. Over years there have been many controversies regarding best screening and diagnostic test for GDM. The testing for GDM by appropriate method at the earliest detects women who need treatment with either diet alone or a combination of diet with insulin therapy. This helps in prevention of maternal morbidity and mortality. This study compares the efficacy of DIPSI (Diabetes in Pregnancy Study Group India) with O'Sullivan's method in the screening of Gestational diabetes mellitus in general population.

MATERIALS AND METHODS

This prospective study was conducted in antenatal clinic in outpatient department of Obstetrics and Gynaecology, Government Theni Medical College during the period of August 2013 to July 2015. 500 pregnant women randomly

allotted in each of study group between 24-28 weeks gestation who attend antenatal clinic of GTMCH, Theni. Inclusion criteria were women aged between 17-40 yrs., women with singleton gestation, women with no past history of GDM or DM, not on any treatment for other medical illness. Exclusion criteria were known case of type 1&2 diabetes mellitus, women with multiple gestations, autoimmune disorders like systemic lupus erythematosus, thyroid disorder, PCOS. 500 Pregnant women in each group between 24-28 weeks of gestation are selected for study.

Method of Performing O'Sullivan's Test

Patient is asked to drink 50 g of glucose dissolved in 200 mL of water, without regard to time or day of last meal. Those with blood glucose level ≥ 140 mg/dL after 1 hour are considered to be positive.

Method of Performing 100 g OGTT (ADA Criteria): Those who are positive at screening test using a cut-off of ≥ 140 mg/dL will undergo confirmatory oral glucose tolerance test with 100 g of oral glucose. Patient will be instructed to come after 72 hours after overnight fasting (8-14 hours). She should take a carbohydrate unrestricted diet (not less than 150 grams per day) for 3 days before test is performed. Fasting venous sample is obtained. 100 grams of glucose is dissolved in 200-400 mL of water and is asked to drink in 5 minutes. Venous blood is drawn after 1, 2 and 3 hours. ADA CRITERIA -100 g OGTT by Carpenter and Coustan method

Time	-	Plasma glucose values
Fasting	-	≥ 95 mg/dL
1 hr	-	≥ 180 mg/dL
2 hr	-	≥ 155 mg/dL

When two or more values meet or exceed this value GDM is diagnosed.

Method of Performing DIPSI (Diabetes in Pregnancy Study Group India):

Glucose value (venous sample) is measured 2 hrs. after 75 g of oral glucose irrespective of last meal. GDM is diagnosed if plasma glucose level exceeds 140 mg/dL.

RESULTS

Total Number of Cases Screened Using O'Sullivan method	500
Total Number of Cases Screened Using DIPSI	500
Number of cases detected having GDM (Using O'Sullivan method)	45
Number of cases detected having GDM (Using DIPSI)	63
Incidence of GDM (Using O'Sullivan method)	9%
Incidence of GDM (Using DIPSI)	12.5%
Table 1. Incidence of Study	

The incidence of Gestational diabetes mellitus in this study is 11%.

Age in Years		No. with GDM (O'Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
17-20	No. of Pts.	0	97	97	0	86	86
	Percentage	0%	21.468%		0%	19.68%	
21-25	No. of Pts.	29	256	285	46	237	283
	Percentage	64.4%	57.07%		73.1%	54.25%	
26-30	No. of Pts.	14	90	104	15	101	116
	Percentage	33.3%	19.89%		23.8%	23.4%	
31-35	No. of Pts.	2	10	12	2	11	13
	Percentage	4%	0.5%		3.0%	2.65%	
36-40	No. of Pts.	0	2	2	0	2	2
	Percentage	0%	0.1%		0%	0.46%	
Total		45	455	500	63	437	500
Table 2. Age Distribution analysis of GDM							

The Value of Chi-square statistics was found to be 13.6609 with a P-value of 0.00846 which is much significant at $p < 0.05$ for O'Sullivan method.

The Value of Chi-square statistics was found to be 16.22 with a P-value of 0.002736 which is much significant at $p < 0.05$ for DIPSI method.

Gravida Status		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Primi	No. of Pts.	5	217	222	15	172	187
	Percentage	11.11%	47.69%		24%	39.36%	
G2	No. of Pts.	30	157	781	42	198	240
	Percentage	66.66%	34.55%		66.66%	45.3%	
G3	No. of Pts.	10	55	65	5	55	60
	Percentage	22.22%	12.08%		8%	12.7%	
G4 and above	No. of Pts.	0	26	26	0	13	13
	Percentage		6%			3%	
Total		45	455	500	63	437	500
Table 3. Gravida study for GDM							

The value of Chi-square statistics is found to be 29.473. With a P-Value of 0.00001 which is much significant at $p < 0.001$ -O'Sullivan.

The value of Chi-square statistics is found to be 11.801. With a P-Value of 0.008097 which is much significant at $p < 0.05$ -DIPSI.

Socio Economic Status		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Class III	No. of Pts.	0	95	95	0	74	74
	Percentage		20.94%		0	17	
Class IV	No. of Pts.	5	139	144	10	163	173
	Percentage	11.11%	31.93%		16.66	37.23	
Class V	No. of Pts.	40	221	261	53	200	253
	Percentage	88.88%	47.12%		83.33	45.74	
Total		45	455	500	63	437	500

Table 4. GDM Study in Socioeconomic Status

The value of Chi-square statistics is found to be 27.5199. With a P-Value of 0.00001 which is much significant at $p < 0.001$ - O' Sullivan.

The value of Chi-square statistics is found to be 33.98. With a P-Value of 0.00001 which is much significant at $p < 0.001$ - DIPSI.

BMI (in kg/m ²)		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Less than 18.5	No. of Pts.	0	35	35	0	58	58
	Percentage		7.85%			13.29	
18.5-24.9	No. of Pts.	3	272	275	5	285	290
	Percentage	6%	59.68%		8%	65.43%	
25-29.9	No. of Pts.	33	123	156	52	69	121
	Percentage	73.33%	27.22%		83.3%	15.95%	
30 and above	No. of Pts.	9	25	34	6	26	32
	Percentage	20%	5.23%		8%	5.3%	
Total		45	455	500	63	437	500

Table 5. GDM Study of BMI

The value of Chi-square statistics is found to be 65.272. With a P-Value of 0.00001 which is much significant at $p < 0.001$ (O'Sullivan).

The value of Chi-square statistics is found to be 143.17. With a P-Value of 0.00001 which is much significant at $p < 0.001$. (DIPSI).

Family History		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	with GDM (DIPSI)	without GDM (DIPSI)	Total
No Family history	No. of Pts.	21	376	397	33	349	382
	Percentage	44.44%	82.72%		50%	79.58%	
Father Diabetic	No. of Pts.	14	50	64	20	53	73
	Percentage	33.33%	9.4%		33.33%	10.47%	
Mother Diabetic	No. of Pts.	10	22	32	10	27	37
	Percentage	22.22%	5.75%		16.66%	6.28%	
No. of Pts. with family H/O DM	No. of Pts.	0	9	9	0	8	8
	Percentage		2.094%			2%	
Total		45	455	500	63	437	500

Table 6. Study of Family History of Diabetics

The value of Chi-square statistics is found to be 43.2984. With a P-Value of 0.00001 which is much significant at $p < 0.001$. (O' Sullivan).

The value of Chi-square statistics is found to be 28.10. With a P-Value of 0.00001 which is much significant at $p < 0.001$. (DIPSI).

Risk Factors		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	Number with GDM (DIPSI)	Number without GDM (DIPSI)	Total
History of Spontaneous Abortion	No. of Pts.	5	14	19	5	16	21
	Percentage	11.11%	3.14%		8.33%	3.72%	
History of Sudden IUD	No. of Pts.	0	0	0	0	0	0
	Percentage	0%	0%				
History of Preterm Delivery	No. of Pts.	0	9	9	5	14	19
	Percentage		2.08%		8.33%	3.191%	
History of previous GDM with IGT	No. of Pts.	0	0	0	0	0	0
	Percentage	0%	0%				
History of previous Pre-eclampsia	No. of Pts.	14	18	32	15	13	28
	Percentage	33.33%	4.18%		25%	3.12%	
History of previous babies with congenital anomalies	No. of Pts.	0	0	0	0	0	0
	Percentage	0%	0%				

Table 7. Studies for Risk Factors in Past Pregnancy

Risk Factors		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Obesity	No. of Pts.	10	12	22	15	13	28
	Percentage	22.2%	2.6%		25%	3.19%	
Pre-eclampsia	No. of Pts.	1	6	7	3	14	17
	Percentage	2%	1.45%		4.7%	3.19%	
Hydramnios	No. of Pts.	3	5	8	4	8	12
	Percentage	6%	1%		6.3%	1.59%	
Congenital Malformations	No. of Pts.	0	0	0	0	0	0
	Percentage	0%	0%		0%	0%	

Table 8. Risk Factors in the Present Pregnancy

O' Sullivan in 1-hour 50 g			in 2-hour 75 g DIPSI	
Blood Glucose Level	Number	Percentage	Number	Percentage
61-70	10	2%	2	.4%
71-80	32	6.5%	25	5%
81-90	107	21.5%	110	22%
91-100	150	30%	140	28%
101-110	95	19%	105	21%
111-120	50	10%	40	8%
121-130	5	1%	15	3%
131-140	10	2%	5	1%
141-150	15	3%	27	5.4%
151-160	11	2%	18	3.6%
161-170	14	2.8%	13	2.6%
171 & Above	5	1%	5	1%

Table 9. Study for Blood Glucose Level of Patients

Gestational Age		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Term	No. of Pts.	37	410	447	53	376	429
	Percentage	83.33%	90.20%		83.33%	86.17%	
Preterm	No. of Pts.	8	25	33	10	27	37
	Percentage	16.66%	5.6%		16.66%	6.3%	
Post Dated	No. of Pts.	0	19	19	0	23	23
	Percentage	0%	4.12%		0%	5.3%	
Total		45	455	500	63	437	500

Table 10. Gestational Age at Delivery

Mode of Delivery		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. With GDM (DIPSI)	No. Without GDM (DIPSI)	Total
Labour naturale	No. of Pts.		61	61	0	35	35
	Percentage		13.54%			8%	
Labour naturale with episiotomy	No. of Pts.	17	251	268	15	276	291
	Percentage	38.88%	55.2%		24%	63.3%	
Outlet forceps	No. of Pts.		19	19		13	13
	Percentage		4.1%			3%	
Assisted breech	No. of Pts.		5	5		2	2
	Percentage		1.04%			0.5%	
Emergency section	No. of Pts.	13	76	89	20	63	83
	Percentage	27.77%	16.66%		31%	14.36%	
Elective section	No. of Pts.	15	43	58	28	46	74
	Percentage	33.33%	9.37%		43%	10.6%	
Total		45	455	500	63	437	500

Table 11. Mode of Delivery of Patients for GDM Study

Range of Weight		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	N with GDM (DIPSI)	N without GDM (DIPSI)	Total
<2.5 Kg	No. of Pts.	8	36	44	16	26	42
	Percentage	16.66%	8%		25%	6%	
2.5 To 4 Kg	No. of Pts.	35	412	447	43	405	449
	Percentage	77.77%	90.20%		68%	93%	
>4 Kg	No. of Pts.	2	5	9	4	5	9
	Percentage	4%	1%		6%	1.1%	
Total		45	455	500	63	437	500

Table 12. Birth weight Study for GDM

Management		No. with GDM (O' Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
No Treatment	No. of Pts.	0	455	455	0	437	188
	Percentage		100%			100%	
Meal Plan	No. of Pts.	8	0	8	16	0	16
	Percentage	16.66%	0%		25%	0%	
Insulin	No. of Pts.	37	0	37	47	0	47
	Percentage	83.33%	0%		75%	0	
Total		45	455	500	63	437	500

Table 13. Management plan of GDM

Admission Status		No. with GDM (O'Sullivan)	No. without GDM (O' Sullivan)	Total	No. with GDM (DIPSI)	No. without GDM (DIPSI)	Total
Not Admitted	No. of Pts.	30	396	426	52	350	402
	Percentage	66.66%	87.11%		83.33%	80%	
Admitted	No. of Pts.	15	59	74	11	87	98
	Percentage	33.33%	12.88%		16.66%	20%	
Total		45	455	500	45	455	500

Table 14. Neonatal Admission

DISCUSSION

In this study group, that involves 1000 pregnant women, 500 were randomly allocated to undergo either O'Sullivan or DIPSI. The incidence of Gestational diabetes mellitus in this study was 11%, out of which DIPSI detected 12.5% and O'Sullivan detected 9% of cases. (Table 1,9). The incidence of GDM is higher in India and ranges from 10-17.8%. A national survey conducted recently reported the prevalence of Impaired Glucose Tolerance (IGT) in age group between 20-29 yrs. as 12.2% and between 30-39 yrs. as 15.3% respectively (Seshiah et al).⁽⁴⁾ The prevalence of GDM in urban, semi-urban and rural areas are 17.8%, 13.8% and 9.9% respectively in a community based survey by Seshiah et al, 2008.⁽⁵⁾ Study conducted by Prathiba et al,⁽⁶⁾ 17% had abnormal glucose challenge test in O'Sullivan's group and 24% had abnormal glucose tolerance in DIPSI group which is higher than this study. The prevalence of GDM in India varies from 3.8% to 21% depending on geographical location.

Prevalence of GDM

Author	Location	Prevalence
Magee	Seattle	3.2-5.0
O'Sullivan	Boston	2.5
Beischer	India	15
Ranchod	India	3.8

The age group for which GDM test was conducted ranged from 18 – 40 yrs. Majority of patients were in the age group of 21-25 yrs. in both the groups (Table 2). Advancing maternal age is associated with increased trend of gestational diabetes. The incidence of GDM was 66.66 % in multigravida in both the groups (Table 3). Socioeconomic status was inversely associated with risk of GDM. The risk of GDM was two-thirds higher in women with lowest socioeconomic status. According to Timothy D. Dye et al,⁽⁷⁾ women of higher socioeconomic status who were obese and did not exercise had high risk of GDM compared to their counterparts of lower socioeconomic status. In this study, the incidence of GDM was high in women belonging to class V socioeconomic status (88.88 % in O'Sullivan group and 83.33 % in DIPSI group-

Table 4). Majority of diabetic patients had BMI of >25 kg/m² (73.33% in O'Sullivan group and 83.3% in DIPSI group-Table 5). There is strong association between high BMI and GDM which is similar to earlier study by Seshiah et al and Shin Y.Kim et al.⁽⁸⁾ The proportion of GDM cases that belong to overweight, obesity and extreme obesity was 15.4%, 9.7% and 21.1% summing up to 46.2%. Lifestyle intervention to reduce BMI can lower GDM risk. GDM was present in 55.55% of patients with positive family history in O'Sullivan group and 49.99% in DIPSI group. Mother was diabetic in 22.22% and 16.66% of diabetic patients in O'Sullivan and DIPSI group respectively. Father was diabetic in 33.33% of diabetic patients in both the groups. (Table - 6). There was past history of Spontaneous Abortion and Pre-eclampsia in both groups (Table -7). In present pregnancy, the risk factors like pre-eclampsia was 2% in O'Sullivan group and 4.7% in DIPSI group and hydramnios was 6% in both the groups-(Table- 8). In this study, nearly all patients with GDM delivered at term. (Table -10). Rate of preterm delivery is same in both the groups. A study by Yariv Yogev et al ⁽⁹⁾ concluded that there was no difference in rate of spontaneous preterm delivery in GDM patients when compared to non-GDM patients. Out of 45 patients in O'Sullivan group, 38.88% delivered by labour naturale with episiotomy, 27.77% by emergency caesarean and 33.33% by elective caesarean. In DIPSI group, 24% delivered by labour naturale, 31% by emergency caesarean and 43% by elective caesarean (Table -11). The most common indication for caesarean was foetal distress and previous LSCS. According to study by Hawthorne G Robson et al⁽¹⁰⁾ the caesarean rate in diabetic patients is 75%. In Gabbe et al⁽¹¹⁾ study, Caesarean section ranged from 50-80% among GDM patients. Majority of babies of diabetic mother weighed between 2.5-4 kg (77.77% in O'Sullivan group and 68% in DIPSI group- Table -12). The incidence of macrosomia was 4% and 6% in O'Sullivan and DIPSI group respectively. Foetal macrosomia complicates 50% of women with GDM – Gabbe.⁽¹²⁾ According to study by R G Moses et al,⁽¹³⁾ the mean birth weight of Infant of Diabetic Mother was 3293+/- 493 g when compared to matched groups, which had a birth weight of 3315+/- 460 g. Out of 45 patients diagnosed to be GDM in O'Sullivan group, 8 was on meal plan and 37 were started on

insulin. Out of 63 GDM patients in DIPSI group, 16 were on meal plan and 47 were on insulin (Table -13). In women with well-controlled diabetes, the risk of respiratory distress was no higher when compared to general population. According to study by Kjos and Walther,^[14] the incidence of respiratory distress syndrome was 0.95%. In this study, there was no respiratory symptom. The reason for neonatal admission was low birth weight, preterm, sepsis, transient tachypnoea of newborn, hypoglycaemia and hyperbilirubinaemia. (Table -14). Hyperbilirubinaemia was reported in about 38% of pregnancies complicated by GDM. The incidence of hyperbilirubinaemia is 12.5% and the incidence of hypoglycaemia is 12.5% in both the groups. Only 35 patients in O' Sullivan group and 57 patients in DIPSI group came for followup. In both the groups, GDM patients had normal plasma glucose levels on followup at 6 weeks using 75-gram OGTT. Only two women in DIPSI group continued to have increased glucose levels even after 6 weeks and were managed appropriately.

CONCLUSION

Screening with 50-gram O'Sullivan's method has only 95% specificity compared to screening with 75-gram DIPSI. DIPSI being a one-step procedure works both as a screening and diagnostic test for GDM. It avoids the need of multiple hospital visits, and multiple blood samples. This one step procedure of challenging pregnant woman with 75-gram oral glucose appears to be simple, feasible and easily reproducible screening method of GDM.

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