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Impact of Early Detection of Diabetes Mellitus in Antenatal Women on Maternal and Perinatal Outcome

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Diabetes in pregnancy is a major health problem in many parts of the world and the prevalence rates vary considerably depending upon population screened and the type of diagnostic method used. India is becoming the Diabetic capital of the world. The Type 2 Diabetes prevalence has increased, leading to increased number of pregnancies with these complications. In Indian context, screening is essential in all antenatal women as the Indian women have 11 fold increased risk of developing intolerance to Glucose during pregnancy compared to western women[1].

ABSTRACT- Background: The prevalence of Diabetes during pregnancy is high in India. So it is essential to detect diabetes early during pregnancy to prevent both maternal and fetal complications and to improve the outcome. **Aims:** To determine the incidence of diabetes in antenatal women who attended the out patient department in Government Victoria hospital, Visakhapatnam and to compare the diagnostic accuracy of HbA1C with 75 g Glucose challenge test (GCT) as a diagnostic tool for detection of diabetes during pregnancy.**Materials and methods:**This was a prospective study conducted in 500 antenatal women attending OPD in Government Victoria hospital from December 2018 to August 2019. Antenatal women before 16 weeks of gestation and who gave consent were included in the study. 75g GCT and HbA1C were performed for all the women recruited at first visit (12-16 weeks), at 24-28 weeks and at 34-36 weeks.**Results:**Out of 500antenatal women who were studied, 79 women (15.8%) were found to have diabetes when 75g GCT was used as diagnostic tool. DM was detected in 265 antenatal women(53%) when HbA1C was used for diagnosis. 20.25% (n=16) of women with diabetes were above 30 years of age. 17.7%(n=14) of women with DM had BMI >30 kg/sq.m and 55.69%(n=44) had BMI between 25-29.9 kg/sq.m.64.5% had past history of GDM in their previous pregnancy which is statistically significant. GDM was detected in 13.4%(66 subjects) at first AN visit by performing 75g GCT. Overt DM was detected in 1.2% cases(6 women). At 24-28 weeks, GDM was detected in 1.6% of women (n=18) and overt diabetes in 0.4% (n=2). Preeclampsia was seen in 18.98% (n=15), candidiasis in 45.56% (n=36), UTI in 25.4% (n=34), hydramnios in 16.4%(n=13), Macrosomia in 32.9% (n=26), intrauterine death in 2.53% (n=2) and neonatal death in 2.53%(n=2). Neonatal morbidity was seen in 53 newborns. Hypoglycaemia was seen in 20.25%(n=16), respiratory distress in 11.39% (n=9), hyperbilirubinemia in 17.7%(n=14) and low APGAR in 10.12%(n=8). **Conclusions:**75g glucose challenge test irrespective of last meal is a very simple and cost effective procedure for universal screening and diagnosis of GDM. Complications of DM during pregnancy can be well managed when it is detected early in pregnancy.

Keywords: Diabetes study group of India(DIPSI), gestational diabetes mellitus, glycosylated haemoglobin, glucose challenge test, hypoglycaemia, impaired glucose tolerance, intrauterine death, macrosomia, medical nutritional therapy(MNT), pre eclampsia, respiratory distress

Aims and Objectives

1. To determine the incidence of diabetes in antenatal women who were attending the out patient department in Government Victoria hospital, Visakhapatnam.
2. To compare the diagnostic accuracy of HbA1C with 75 g Glucose challenge test as a

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diagnostic tool for detection of diabetes during pregnancy.

3. To evaluate the maternal and fetal complications in diabetes complicating pregnancy.

I. INTRODUCTION

The incidence of Diabetes in pregnancy in India is high and is found to be 16.55%. In the recent study performed under the Diabetes in pregnancy –Awareness and prevention project, the prevalence is 17.8% in the urban,13.8%in the semi urban and 9.9% in rural areas. If the blood glucose level is not appropriately managed, apart from the complications of GDM, the mother and her offspring are at increased risk of developing diabetes in the future. Thus two generations are at risk of developing Diabetes.

In India,every year about 27 million pregnancies occur, and all these women need to be screened for GDM. Considering the wide gap between target and reality, a practical, cost effectiveand convenient screening test is required so that women can be tested during their initial visit even in non fasting state as many may not return subsequently in a fasting state. DIPSI recommends 75gm GCT at 1st antenatal visit as a universal screening,ADA &WHO have published the reliability of glycosylated haemoglobin (HbA1c) estimation in diagnosis of diabetes[2]. Various studies around the world have inconsistently documented usefulness of HbA1c as a screening tool in diabetes in pregnancy. Screening for glucose intolerance during the early period of pregnancy is beneficial as this would help in identifying diabetes which is undiagnosed prior to conception and to render appropriate care. It is also prudent to advise a pregnant women to undergo rescreening in the later weeks of pregnancy if she had normal glucose intolerance(NGT) in the first visit as they may develop gestational diabetes in later weeks of pregnancy. Gestational diabetes (GDM) is a common complication in pregnancy, associated with adverse maternal and perinatal outcomes including an increased risk for type 2 diabetes mellitus and cardiovascular disease later in life in mothers and an increased risk of macrosomia and obesity in offspring(2). Diabetes in pregnancy associated with neonatal morbidity and mortality, including macrosomia, shoulder dystocia, birth injuries and neonatal hypoglycemia,in addition to congenital anomalies and still births. Further, the off springs are potentially at a higher risk of developing childhood obesity later in life.

II. MATERIALS AND METHODS

Study design: Prospective study

Sample size: 500 antenatal women

Place of the study: Government Victoria hospital, Visakhapatnam

Study period: December 2018 to August 2019

Inclusion criteria:

1. Antenatal women who attended outpatient department before 16 weeks
2. Women who gave consent
3. Antenatal women who had family history of diabetes mellitus
4. Antenatal women who had past history of GDM

Exclusion criteria:

1. Antenatal women with gestational age >16 weeks at their first visit
2. Already a known case of diabetes mellitus
3. Women with chronic diseases like renal, cardiac and respiratory problems
4. Women taking drugs that alter the glucose metabolism
5. Women who have not given consent
6. Chronic anaemia

Prior permission is taken from institutional ethics committee, Andhra medical college, Visakhapatnam. After a written informed consent, women presenting to the antenatal outpatient department with gestational age <16 weeks were considered and a detailed history and thorough clinical examination was done. At first visit, questionnaire containing socio- demographic characteristics, detailed medical and obstetric history was filled. 500 women who fulfilled the inclusion criteria were recruited. Height and weight were noted. Pre-pregnancy weight was self reported. Body mass index was calculated and categorized in to normal weight (18.5 – 24.9 kg/m2), overweight (25- 29.9 kg/m2) or obese (>30 kg/m2). Family history of diabetes was noted. Bad obstetric history was noted which was defined as history of one still birth or neonatal death or two or more abortions. Medical comorbidities were noted. A venous blood sample was collected in EDTA tube for estimation of HbA1C. All women were given 75g glucose orally dissolved in 300ml of water within 10 minutes irrespective of their last meal as recommended by DIPSI. Blood glucose was measured after 2 hours. Diagnosis of GDM was made if 2 hour post glucose blood sugar was >= 140 mg/dl.If it is >200mg/dl, they were considered as overt diabetes andif the levels were between120-140 they were considered as impaired glucose tolerance. Women who were diagnosed as IGT and normal glucose values at first visit, were again subjected to 75gm GCT at 24- 28weeks and

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then at 34-36weeks. Women who had HbA1c >5.7%were considered as GDM and >6.4% were considered as overt diabetes. All the women who were diagnosed as GDM and overt diabetes were referred to a dietician and jointly managed by obstetrician and endocrinologist.

Women diagnosed as GDM and overt diabetes were monitored with FBS and PPBS. Initially patients were started on medical nutritional therapy (MNT). If blood glucose levels were not controlled on MNT after 2 weeks, antenatal women were either started on oral hypoglycemic agents or insulin in collaboration with endocrinologist. All antenatal complications like UTI, Candidiasis, pre eclampsia, polyhydramnios, preterm labour, etc were noted and followed.

All women with GDM on insulin/ metformin were induced at 38 weeks and those who were controlled on diet were induced at 40 weeks period of gestation. Intrapartum and postpartum complications were noted and follow up was done. Macrosomia was defined as birth weight >3.5kg. Neonatal complications were recorded. Neonatal hypoglycemia defined as plasma glucose levels <45 mg/dl and managed by paediatrician.

Ethics: We have taken permission from Institutional Ethical committee from Andhra medical college, Visakhapatnam.We have taken informed consent from all the women who were recruited in the study.

Statistical analysis: Data entry was done using the Microsoft excel 2010 sheet and the statistical analysis was performed with Chi-square test, Fisher's exact test and Student T- test. Statistical significance was considered at P< 0.05.

III. RESULTS:

During the study period,500 women attending the OPD for antenatal checkup and fulfilling the inclusion criteria were enrolled.

TABLE -01: ANALYSIS OF RESULTS WITH REFERENCE TO AGE

Age in years	Number of subjects	Number of cases of diabetes(%) by 75g GCT	Number of cases of diabetes (%) by HbA1C
< 20	70 (14%)	3 (4.2%)	39 (14.71%)
21- 25	303 (60.6%)	45 (14.8%)	167 (63%)
26- 30	85 (17%)	15 (17.6%)	35 (13.2%)
>30	42 (8.4%)	16 (38.09%)	24 (9.05%)

Most of the subjects in my study were below 26yr of age (n=373, 74.6%). The mean age of participants was 24.5(18-38).The mean of age of participants who had diabetes is 26.16 yrs. The standard deviation is 3.38. The prevalence rate was higher in women aged 26-30 and >30 yrs (17.6% and 38.09% respectively) compared to women aged 16-20 and 21-25 yrs (4.2% and 14.8% respectively)and this observation was found to be statistically significant(p<0.001).

TABLE 02: ANALYSIS OF RESULTS BASED ON PRE-PREGNANCY BMI (kg/m2)

BMI (kg/m2)	No. of subjects	No. of cases of diabetes based on 75g GCT	No. of cases of diabetes based on HbA1C
<18.5	7 (1.4%)	0	4 (57.14%)
18.5- 24.9	260 (52%)	21 (26.58%)	155 (59.61%)
25-29.9	201 (40.2%)	44 (21.8%)	84 (41.79%)
>30	32 (6.4%)	14 (43.7%)	13 (40.62%)

Most of the participants had BMI below 25kg/m2 and highest BMI was in between 18.5 -25 kg/m2(260,52%). 6.4% had BMI >30kg/m2. Mean of the participants who had diabetes was 26.16and standard deviation is 3.45. Mean BMI of participants is 24.19.and this observation was found to be statistically significant (p<0.05).

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TABLE 03: DISTRIBUTION BASED ON FAMILY HISTORY OF DM

	No. of participants	No. of cases detected
With family H/O DM	173	37 (21.38%)
Without family H/O DM	327	42 (78.62%)
Total	500	126 (100%)

In this study 173 women had family history of DM, but only 37 subjects(28.9%) had developed diabetes in pregnancy. Out of 79 cases 42 had no history of DM in their families. Diabetes in pregnancy associated more with cases who had family history of DM. It is proved significant ($p<0.05$).

TABLE 04: ANALYSIS BASED ON PAST HISTORY OF GDM

	No. of participants	No. of cases
With H/O GDM	20 (4%)	20 (23.51%)
Without H/O GDM	469 (96%)	98 (76.49%)
Total	500	126

Out of 500 participants, 31(64.51%) had past history of GDM in their previous pregnancy. p value is <0.05 which is statistically significant.

TABLE 05: DISTRIBUTION BASED ON DIAGNOSIS OF DIABETES BY 75g GCT AT FIRST VISIT (12- 16 weeks)

Blood glucose levels	No. of cases (n=500)	Percentage
100- 200 (normal)	229	45.8%
100-140 (IGT)	205	41%
140-200 (GDM)	60	12%
>200 (Overt diabetes)	6	1.2%

66 members were detected as GDM at 1st antenatal visit (13.4%) whereas 205 members had impaired glucose intolerance (41%).6 cases were detected as overt diabetes i.e GCT >200mg/dl(1.2%).

TABLE 06: 75GM GCT

Statistics	Value
Sensitivity	83.54%
Specificity	100%
Positive likelihood ratio	68.04%
Negative likelihood ratio	0.16%
Disease prevalence	15.8%
Positive predictive value	100%
Negative predictive value	97%
Accuracy	97.4%

TABLE 07: DISTRIBUTION ACCORDING TO GDM DETECTED AT 24-28 WEEKS (who are normal at first visit)

Blood glucose levels (mg/dl)	No. of cases (n=434)	Percentage
100-120	288	57.6%
120-140	136	27.2%
140-200	8	1.6%
>200	2	0.4%

At 24-28 weeks, total 434 participants underwent 75gms GCT. Of these, 1.6% (n=8) had values >140 mg/dl and were diagnosed as GDM. 2 had values >200mg/dl and they were labelled as overt diabetes.

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TABLE 08: DISTRIBUTION ACCORDING TO GDM DETECTION AMONG IGT WOMEN AT 34-36 WEEKS.

Blood glucose values (mg/dl)	No.of cases (n=424)	Percentage
100-120	389	91.76%
120-140	32	7.54%
140-200	3	0.7%
>200	-	-

Total 424 women were again subjected to 75g GCT at 34-36 weeks, of which 0.7% (n=3) of women had values >140mg/dl.

TABLE 09: DISTRIBUTION OF CASES BASED ON HBA1C LEVELS

HbA1C values	No. of cases (n=500)	Percentage
<5.7%(normal)	235	47%
5.7-6.4% (GDM)	197	39.4%
>6.5% (overt diabetes)	68	13.6%

TABLE 10: STATISTICAL ANALYSIS OF HBA1C

True positives	False positives	True negatives	False negatives
60	205	226	9

The HbA1c levels among the study subjects varied from 4.3% to 8.2%.The mean Hba1c levels among those diagnosed as GDM by 75gm GCT was 5.82+-1.1% and among those without GDM was 5.13+-0.7%. False positives (n=205) were more in HbA1C group.

TABLE 11: STATISTICAL ANALYSIS OF HBA1C

Statistical analysis	Value
Sensitivity	89.77%
Specificity	61.57%
Positive likelihood ratio	2.34%
Negative likelihood ratio	0.17%
Disease prevalence	15.38%
Positive predictive value	29.81%
Negative predictive value	97.07%
accuracy	65.91%

TABLE 12: DISTRIBUTION BASED ON ANTENATAL COMPLICATIONS

Obstetric complication	No. of cases	Percentage
Pre eclampsia	15	18.98%
PROM	10	1.26%
Candidiasis	36	45.56%
IUGR	4	5.06%
UTI	34	25.4%
Polyhydramnios	13	16.4%
Macrosomia	26	32.9%
IUD	2	2.53%
NND	2	2.53%

TABLE 13: DISTRIBUTION BASED ON MODES OF TREATMENT

Mode of treatment	No. of cases (n=79)	Percentage
Diet	31	39.24%
Oral hypoglycaemic agents	24	30.37%
Insulin	11	13.9%
Combined method	13	16.45%

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TABLE 14: DISTRIBUTION BASED ON MODE OF DELIVERY

Mode of delivery	No. of cases (n=79)	Percentage
Vaginal delivery	26	32.91
Preterm delivery	18	22.7
Vacuum extraction	2	2.53
Forceps	5	6.3
Emergency LSCS	18	22.7
Elective LSCS	8	10.12
IUD expulsion	2	2.53

LSCS was done in 32.82% of cases. Common indications were previous caesarean section, cephalopelvic disproportion, pre eclampsia, fetal growth retardation and failed induction.

TABLE 15: ANALYSIS OF RESULTS BASED ON APGAR SCORE

APGAR score	No. of cases (n=79)	Percentage
<4	2	2.53
5-7	6	7.5
>8	71	89.87

TABLE 16: DISTRIBUTION BASED ON PERINATAL MORBIDITY

Type of perinatal morbidity	No. of cases	Percentage
Hypoglycaemia	16	20.25
Respiratory distress	9	11.39
Hyperbilirubinaemia	14	17.72
Poor sucking	6	7.59
Low APGAR	8	10.12
Meconium aspiration syndrome	3	3.79

TABLE 17: DISTRUBUTION ACCORDING TO PERINATAL MORTALITY

Type of mortality	No. of cases	Percentage
IUD	2	2.53
Neonatal death (NND)	2	2.53
Still births	-	-

Perinatal mortality occurred more in uncontrolled and poorly controlled diabetes.

TABLE 18: ANALYSIS OF RESULTS BASED ON MATERNAL MORBIDITY

Puerperal complication	No. of cases (n=79)	Percentage
Normal	60	75.94
Puerperal pyrexia	5	6.3
Wound infection	12	15.1
Lactation failure	2	2.53

IV. DISCUSSION

GDM is the most common metabolic disorder complicating pregnancy. Approximately 3-5% of all pregnancies are complicated by diabetes and 90% of these are GDM and rest are pre gestational. Recent data in our country on the prevalence of GDM was 16.55% according to WHO criteria. The prevalence of GDM is reported to vary widely from 3.8 to 21% in different parts of India depending upon geographical location and on the diagnostic criteria used. Incidence of GDM in present study was found to be 15.8%. According to Nair[3]et al study, incidence was 13%, which is lower than present study. Rajput et al[4]conducted a study in Rohtak,Haryana in which incidence was found to be 7.17%. Zargaret al[5]from Kashmir found the incidence to be 3.8%. Seshaih et al in study found incidence high 17.8% in urban,13.8% in semi urban and 9.9% in rural areas of Tamilnadu. Seshaih V et al [6] found the incidence of 13.4% by DIPSI criteria.

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TABLE 19: COMPARISION BASED ON INCIDENCE

Study	Incidence
Nair et al	13%
Rajput et al (2012)	7.17%
Zargar et al	3.8%
Seshaih et al	17.8%(Urban)
Mamata Soren et al (2017)[11]	8.3%
Present study	15.8%

Maternal age-
Age is established risk factor for gestational diabetes mellitus,but there is no consensus on the age abovewhich there is significantly increased risk of GDM.
According to Jovanovic L[8]et al,advanced maternal age, family history of diabetes and obesity are established risk factors for GDM.Seshiah et al and Kalra et al[9]proved age>25years as a risk factor for GDM. So as the age advances the incidence of GDM increases.Yellayi ASS et al[10]in their study, found that 66.7% women were above 25 years.

TABLE 20: COMPARISION BASED ON MATERNAL AGE

STUDY	AGE (years)	PERCENTAGE
Mamata Soren et al (2017)	>30	80
Seshaih et al	>25	44.5
Yellayi ASS (2017)	>25	66.7
Present study	>25	55.69

BMI- Several authors suggested that pre pregnancy overweight or obesity predisposes to GDM. Das et al[11] found that 25% of women with GDM had BMI >27kg kg/m2, while Seshiah et al and Kalra et al [9] found that 21.4% and 67% of women with GDM, respectively had BMI >25kg/m2. In present study,GDM is commonly associated with BMI>25kg/m2 i.e 65.5%,which is almost similar to Yellayi ASS[10] study and Kalra et al[9] study. Of all the independent risk factors for diabetes in pregnancy BMI has emerged as a modifiable risk factor. GDM also increases risk of women developing diabetes in the future. So they are the ideal group to be targeted for life style modification or pharmacologic intervention in order to delay the onset of overt type 2 DM in later life.

TABLE 21: COMPARISION OF BMI

Study	BMI (kg/m2)	Percentage
Das et al	>27	25
Seshaih et al	>25	21.7
Kalra et al	>25	67
Yellayi ASS	>25	66.7
Present study	>25	65.5

Family history of diabetes- Family history of diabetes was significantly higher in GDM cases.In studies by Das et al[11] and Kalra et al, 33.33% of women with GDM had family history of diabetes. Sharma[12] et al found 24.9% of their GDM patients had positive family history of perinatal losses.

TABLE 22: FAMILY HISTORY OF DIABETES

Study	Percentage
Das et al(2004)	33.33
Kalra et al	33.33
Sharma et al	24.9
Yellayi ASS et al (2017)	66.7
Present study	21.38

HbA1C- An HbA1C level represents the summation of glucose variability in the past 3 months and is a reliable determinant of diabetes compared to the one day blood glucose status determined by fasting/post prandial glucose estimation or OGTT as clarified by American Diabetic Association. But in diabetes during pregnancy, 75gm GCT has remained most reliable test.

A similar study done by Rajput et al[13], documented that an HbA1C cut-off value of >-5.95% had sensitivity of 28.6% , specificity of 97.2% in diagnosing Diabetes in pregnancy while an HbA1C cut off value of >-5.45% had sensitivity of 85.7% and specificity of 61.1% in diagnosing GDM.

TABLE 23: HBA1C VALUES

Study	HbA1C values	Sensitivity	Specificity
Rajesh Rajput et al	>5.7	85.7%	61.1%
Khalafalah et al	>5.45	27%	95%
Agarwal M	>5.4	82.1%	-
Present study	>5.7	89.77%	61.57%

75g Glucose Challenge Test- The sensitivity of 75g GCT was 98.04% and specificity was 98.26% when compared to WHO OGTT. The diagnostic accuracy was 98.25%.Sharma et al [41] found 75gm GCT to be 100% sensitive and 100%specific for diagnosing GDM. According to study conducted by Badikillayya et al [14],the sensitivity was 100% and specificity was 89%.

TABLE 24: 75g Glucose Challenge Test

Study	Sample size	Sensitivity	Specificity
Present study	500	83.54%	100%
Sharma et al [12]	500	100%	100%
Badikilayya[14]	200	100%	89%
Mohan et al [15]	1031	27.7%	89%

Pre eclampsia-

Diabetes in pregnancy known to associated with increased risk of pre eclampsia. In the trail done by Crowther et al[16],pre eclampsia occurred in 12% of women. Bhat et al have reported a much higher rate (29%) of pre eclampsia in GDM from Thiruvananthapuram.

TABLE 25: INCIDENCE OF PRE ECLAMPSIA IN DM

Study	Percentage
Kalra et al	36.4
Saxena et al [42]	40
Yellayi ASS et al	8.3
Present study	18.98

Caesarean section rate-

In the study by Kalra et al[9], caesareansection rate was found to be 78.8% amongst the GDM patients, with arrest of labour being the most common indication. While rate of caesarean section in a study by Gorgal et al was 19.5%.

TABLE 26: CAESAREAN SECTION RATE

Study	Percentage
Yellayi ASS et al	58.3
Gorgel et al	19.5
Kalra	78.8
Present study	32.82

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Macrosomia-

Balaji et al[6] and Kalra et al[9] reported 9.9% and 18% incidence of macrosomia in GDM mothers respectively. In present study, only 7 babies were macrosomic (>4kg) i.e 8.8% which is almost similar to remaining studies. This is attributed to good glycaemic control.

TABLE 27: INCIDENCE OF MACROSOMIA

Study	Percentage
Balaji et al	9.9%
Kalra et al	18%
Yellayi ASS et al	8.3%
Present study	8.8%

Neonatal complications-

Complications in neonates were seen in cases where mothers had poor glycemic control at the time of delivery.

TABLE 28: NEONATAL COMPLICATIONS

Study	Hypoglycemia	Hyperbilirubinaemia	Respiratory distress
Yellayi ASS et al	37.5%	37.5%	12.5%
Nagy et al	39%	32%	22%
Present study	20.25%	27.75%	11.39%

V. CONCLUSION

In resource limited countries like India, DIPSI recommended 75gm oral glucose challenge test irrespective of the last meal which is a very simple, cost effective and feasible procedure for universal screening and diagnosis of GDM, as selective screening misses 50% of cases. To conclude, although at present time the HbA1c level cannot replace 75gm GCT for diagnosis of GDM, which has high diagnostic sensitivity and specificity, but it can be used in combination with 75gm GCT. The results of various studies from different parts of the world suggest that there is a need to define population specific values for HbA1c levels rather than using single value to rule out GDM in all pregnant women.

With early diagnosis of GDM and good antenatal &intra natal care, maternal and perinatal outcome can be improved.

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