

GLYCOSYLATED HEMOGLOBIN (HBA1C) AMONG TYPE 2 DIABETES MELLITUS PATIENTS ATTENDING THE DIABETIC AND ENDOCRINE CENTRE IN SULAIMANI CITY.

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Received date: 24 January 2023

Revised date: 13 February 2023

Accepted date: 05 March 2023

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ABSTRACT

Background: The high prevalence of type 2 diabetes mellitus results in substantial physical injury and financial burden for those who are affected. The most often used method for gauging glycemic control in people with diabetes mellitus is the HbA1c test. **Objectives:** To Assess control of HbA1C among type 2 diabetes mellitus patients, also to find out correlation between levels of plasma glucose and HbA1c. **Patients and Methods:** A retrospective study was done among patients with type 2 diabetes mellitus attending the Diabetic and Endocrine Centre in Sulaimani city, the study was carried out on 1000 patients from December 2012 to July 2013. **Results:** All of the patients had type 2 DM, most of them (59.6%) were females, majority of patients (75.9%) were living inside city and most of them (50.9%) were house wives, while family history was positive in (57.4%) and most of them were non-smokers and non-alcoholics, (65.9%) and (90.4%) respectively. **Conclusions:** The present study revealed that there was a significant relationship between HbA1c with age, sex, BMI, diastolic blood pressure, fasting blood sugar, occupation, smoking, alcohol intake no significant relationship between HbA1c and the duration of diabetes, residence, family history, systolic blood pressure, cholesterol and TG and no significant in the mean difference comparing FBS1 and FBS2.

KEYWORDS: Type 2 DM, HbA1c, FBS and diabetic treatment, Sulaimani.

INTRODUCTION

Definition

The metabolic condition diabetes mellitus (T2DM) is defined by persistent hyperglycemia and disruptions of the metabolism of carbohydrates, fats, and proteins as a result of errors in insulin secretion, action, or both.^[1]

It can be classified into

- 1-Type 1 (Insulin dependent diabetes mellitus)
- 2-Type 2 (Non-Insulin diabetes mellitus)
- 3-Gestational diabetes mellitus.
- 4- Other particular varieties, exocrine pancreatic disease, endocrinopathies, drug- or chemical-induced infections, rare forms of immune-mediated diabetes, and other genetic syndromes that are occasionally linked to diabetes include genetic defects in beta-cell activity and insulin action.^[2]

The World Health Organization estimates that 366 million individuals worldwide have diabetes; the mainstream has T2DM. Because diabetes mellitus prevalence is increasing globally and poses an increasing threat to global health^[3], the WHO predicts that by the year 2025, more than 5% of the total world's population will have the disease.^[3, 4] 3.96 million fatalities in the age range of 20 to 79 years were predicted to constitute excess deaths worldwide due to diabetes, or 6.8% of mortality worldwide (all ages).^[5]

Diagnostic criteria for DM

According to WHO guidelines, the diagnosis of diabetes is made simple when a patient exhibits the classic signs and symptoms of hyperglycemia (such as thirst, polyuria, weight loss, and blurred vision) and has a fasting plasma glucose concentration of 126 mg/dL (7.0 mmol/L) or higher, a random value of 200 mg/dL (11.1 mmol/L) or

higher, and this is confirmed on another occasion, or a two-hour value of an oral glucose.^[6,7]

In a recent expert consultation report published by WHO, hemoglobin A1c (HbA1c) was approved as an additional test for the diagnosis and detection of diabetes, with a cut point of 6.5% being suggested.^[8] The American Diabetes Association (ADA) revised its definition of diabetes mellitus (DM) in January 2010 to include the HbA1c criterion (48 mmol/mol, 6.5%) in addition to the traditional fasting plasma glucose (FPG) criterion.^[9,10]

The HbA1c enables the patients to make treatment decisions to achieve favourable diabetes control with the aim of reducing or avoiding complications associated with hyperglycemia; however, some studies have suggested that younger people have higher levels of HbA1c compared to older adults with diabetes.^[11,12]

The HbA1c test is regarded as the most accurate and trustworthy indicator of long-term metabolic control since it offers an index of a patient's average blood glucose level in the preceding two to three months.^[13] The risk of long-term consequences of DM, such as coronary heart disease, myocardial infarction, stroke, heart failure, renal failure, blindness, erectile dysfunction, neuropathy, gangrene, and gastroparesis, is increased by persistently elevated blood glucose levels (and, consequently, HbA1c). Additionally raising the chance of short-term surgical problems including slow wound healing is inadequate blood sugar management.^[14] In T2DM, intensive treatment significantly reduced microvascular and neuropathic consequences, according to the United Kingdom Prospective Diabetes Study (UKPDS).^[15]

HbA1c 6.5% being suggested as a diagnostic threshold for diabetes mellitus Glucose status monitoring has long been considered the cornerstone of diabetic care. The need of examining glycemic level has been shown by studies demonstrating a direct correlation between mean blood glucose (MBG) and the beginning and progression of chronic diabetes complications. Monitoring data is used to evaluate therapy effectiveness and to direct lifestyle changes for the best possible glucose control. Blood glucose and glycosylated hemoglobin tests are currently the most often utilized for this purpose.^[16]

Differences in HbA1c levels that cannot be explained by differences in glycemia have been described in several studies involving participants from different ethnic groups such as Hispanic whites, non-Hispanic blacks, Asians, and native Americans. The reason for these racial differences remains to be established. It is also important to determine whether these differences among individuals or groups have an impact on complications or merely reflect variation in hemoglobin glycation.^[17-19]

Aims of the study

To assess the rate of control of glycosylated hemoglobin (HbA1c) among T2DM patients attending the diabetic and endocrine centre in Sulaimani City-Kurdistan Region-Iraq and to find out correlation between levels of plasma glucose and HbA1c in diabetic patients.

Patients and method

A retrospective study was done among type 2 DM patients attending the diabetic and endocrine centre at Sulaimani city in Kurdistan –Iraq. The study was carried out on (1000) patients from December 2012 to July 2013, the information are obtained from registered files.

Inclusion criteria

- 1- All adult 16 years and above
- 2-All registered files for T2DM patients who were confirmed suffering from T2DM and receiving treatment at the Diabetic and Endocrine Centre were included in the study.
- 3-All registered files that had a full information about the patients like registered age, sex, blood sugar and at least one reading of HbA1c%, one reading of FBS and one reading for diabetic treatment and others which is included in questionnaire case sheet.

Exclusion criteria:

- 1-All adult below 16 years.
- 2-All patients with Type 1 DM.
- 3-Any file with no information which is included in the questionnaire case sheet.

Each Patient had own questionnaire case sheet which contain about 31 variables.

The components of the questionnaire include patient’s information about socio-demography, medical history, treatment, and others medical information; Anthropometric measurements such as weight (kg) and height (m), body mass index and measurements of blood pressure were taken from registered files, also fasting blood sample like fasting blood sugar (FBS1) at the first visit and fasting blood sugar of the second visit, also the questionnaire included the registered cholesterol, triglyceride, HbA1c at the first visit also HbA1c at the second visit, also treatment of first and second visit.

Statistical analysis

The data was entered into a Microsoft Excel Spreadsheet, after data cleaning; the data was transported into SPSS (Statistical Package for the Social Sciences-version 21.0). Nominal data was expressed in numbers and percentages while numerical data was expressed in means and standard deviations. The statistical analysis was done to find the relations between variables by using the appropriate statistical tests such as t-test and chi square test. The p-value ≤ 0.05 was considered as significant.

RESULT

A total number of 1000 patients aged 24 years old and above who were diagnosed with T2DM and receiving treatment were included in this study. The majority of patients 355 (35.5%) were aged between 50-59 year with mean age of 53.76±10.52 and most of the patients 569

(59.6%) were females. The majority of the patients 759 (75.9%) were living inside city and most of them 509 (50.9%) were house wives; while, family history was positive in 574 (57.4%) patients and most of them were neither smokers and nor alcoholics 659 (65.9%) and 904 (90.4%) respectively as shown in table (1).

Table (1): Socio-demographic characteristics of patients (N=1000).

Variables		Frequencies	Percentages
Age	less than40	76	7.6
	40-49	291	29.1
	50-59	355	35.5
	60 or more	278	27.8
Gender	Male	431	43.1
	Female	569	56.9
Residence	Inside city	759	75.9
	Outside city	241	24.1
Occupation	Gov. employ	206	20.6
	Self-employ	213	21.3
	House wife	509	50.9
	Retired	72	7.2
Family history	Negative	426	42.6
	Positive	574	57.4
Smoking	No	659	65.9
	Yes	341	34.1
Alcohol	No	904	90.4
	Yes	96	9.6

The age of the patients was demonstrated in table (2), it was ranged between 24 year and 86 year with mean age of 53.76±10.52 year. The duration of T2DM disease was ranged from 1 month to 360 months with mean of 45.72±58.99 months. The average mean of SBP and DBP was 119.78±18.00 mm Hg and 77.13±11.6 mmHg respectively. Regarding the BMI value was ranged between 16.85 and 48.54 kg/m² with mean of 30.2±5.1 kg/m² the value of serum cholesterol of the patients was from 70 to 1676 mg/dl with mean 185.71±64.98 mg/dl; while, serum triglyceride mean was 198.38±132.32

mg/dl. The Min and Max value for the fasting blood sugar in the first visit of 1000 patients was 73, 450 mg/dl respectively with mean 184.95±55.51 mg/dl in comparison with the Min and Max value for FBS in the second visit of 578 patients was 58 and 559 mg/dl respectively with mean 188.78±71.00 mg/dl. Finally the HbA1c in the first visit of patients was ranged between 5.0 and 15.0 with mean 10.20±2.61 and the HbA1c value in the second visit was ranged between 5.0 and 15.0 with mean 8.79±2.20.

Table (2): Blood pressure, body mass index, bio-chemical profile, blood sugar and HbA1c of patients.

Variables	Minimum	Maximum	Mean ± SD
Age	24	86	53.76±10.52
Duration	1	360	45.72±58.99
SBP	85	200	119.78±18.00
DBP	40	130	77.13±11.6
BMI	16.85	48.54	30.2±5.1
cholesterol	70	1676	185.71±64.98
TG	47	1222	198.38±132.32
FBS1	73	450	184.95±55.51
FBS2	58	559	188.78±71.00
HbA1c1	5.0	15.0	10.20±2.61
HbA1c2	5.0	15.0	8.79±2.20

The socio-demographic characteristics of patients were showed in table (3) and revealed that in the first visit (N=1000, 569 females and 431 males) and the second visit (N=578, 334 females, 244 males) in relation to HbA1c in the first visit and the second visit. The mean of

the HbA1c reading of the males in first and second visit was 10.4 ±2.5 and 8.5± 2.0 respectively; while, the mean of HbA1c reading of females in first and second visit was 10.0± 2.6 and 8.9± 2.2 respectively with p value in both males and females was <0.001. Regarding the

patients less than 40 year of age the mean of HbA1c in the first and the second visit was 9.8±2.5 and 8.5±2.1 respectively which is the lowest HbA1c value among age groups, on other hand the mean of HbA1c in the patients more than 60 year of age in the first and the second visit was 10.1±2.6, 8.7±2.11 respectively which was the

highest HbA1c value among age groups at p= <0.001. Concerning BMI of the patients the mean of HbA1c of obese patients in first and second visit was 9.7±2.6 and 8.7±2.1 respectively which is the lowest value in comparison with other BMI groups with p=<0.001.

Table (3): Distribution characteristics of patient in relation to HbA1c in the first visit and the second visit.

Variables		HbA1c		P values*
		The First visit Mean± S.D	The second visit Mean± S.D	
Sex	Male	10.4± 2.5	8.5± 2.0	<0.001
	Female	10.0± 2.6	8.9± 2.2	
Age	<40	9.8±2.5	8.5±2.1	<0.001
	40-49	10.2±2.6	8.8±2.1	
	50-59	10.3±2.5	8.8±2.2	
	≥60	10.1±2.6	8.7±2.1	
BMI (Groups)	under weight	11.0±2.3	7.5±1.6	<0.001
	Normal	10.5±2.7	8.9±2.3	
	Overweight	10.5±2.4	8.8±2.2	
	Obese	9.7±2.6	8.7±2.1	

* Paired t-test

Socio demographic characteristics of the patients in relation with FBS was demonstrated in table (4) and is showed that the (mean difference between the first N=1000 and the second visit N=578) and the HbA1c (mean difference between the first and the second visit). Concerning the sex, the FBS (mean difference between the first and the second visits) was higher in the males -0.93 mg/dl than the females -7.7 with no p value significant=0.243 and the HbA1c (mean difference between the first and the second visits) also was the higher in the males 1.79 than the females 1.24 with p value statistically significant=0.007. The patients live inside the city of Sulaimani shown the highest values of FBS - 3.52 mg/dl with p value =0.434 which is statistically not significant and the HbA1c of the patients live inside the city had also the highest value 1.55 with p value=0.185 which is statistically not significant. Regarding the FBS (-2.53 mg/dl) of patients with positive family history of DM disease was higher than those with negative family history -7.81 with P value 0.362 which is statistically not significant. Also the HbA1c of Patients with positive family history of DM disease had the highest value 1.52 with p value=0.605 which is statistically not significant. Concerning the smoker patients shown the highest value in FBS 3.96 mg/dl with P value =0.434 which is statistically not significant and the HbA1c of the same patients had the highest value 1.71 with p value=0.011 which is statistically significant. Alcohol drinking patients shown the highest value in FBS 6.83 mg/dl with P value=0.215 which is statistically not significant, also the HbA1c of the same patients had the highest value 1.62 with p value=0.031 which is statistically significant.

Table (4): Socio-demographic characteristics in relation with mean difference of FBS and HbA1c between the first and the second visits.

Socio demographic		FBS	P values*	HbA1c	P values*
Sex	Female	-7.71	0.243	1.24	0.007
	Male	-0.93		1.79	
Residence	Outside city	-8.66	0.434	1.24	0.185
	Inside city	-3.52		1.55	
Family history	Negative	-7.81	0.362	1.41	0.605
	Positive	-2.53		1.52	
Smoking	No	-8.71	0.042	1.37	0.011
	Yes	3.96		1.71	
Alcohol	No	-5.93	0.215	1.46	0.031
	Yes	6.83		1.62	

* Paired t-test

Relation of Variables with controlled and uncontrolled HbA1c in the first visit and the second visit was demonstrated in table (5) and showed that according to the number the males with controlled HbA1c (< 6.5%) were more in second visit 28(45.9%) than in first visit

33(54.1%) with significant p=0.002; while, more females with controlled HbA1c were found in the first visit 41(56.2%) compared to second visit 32(43.8%) with significant p= 0.026. Concerning the mean duration of diabetes disease in relation with controlled HbA1c in

first and second visit was 38.4±49.1 and 25.8±35.7 months respectively with insignificant p=0.327. Regarding the occupation, the housewife patients shown the highest percentage of controlled HbA1c in the first and the second visit was 35(58.3%) and 25(41.7%) respectively with significant p= 0.041; while, the retired patients showed the lowest percentage of controlled HbA1c in the first and the second visit was 4(44.4%) and 5(55.6%) respectively with significant p=0.003. The number of smokers patients with controlled HbA1c were more in second visit 25(56.8%) than in first visit 19(43.2%) with significant p=0.001. The percentage of alcoholic patients with controlled HbA1c were higher in second visit 11(55.0%) than first visit 9(45.0%) with

significant p=0.031. The mean of SBP in the patients with controlled HbA1c in first and second visit was 77.83±13.2, 117.0±14.9 mmHg respectively with insignificant p=0.081 and the mean of DBP in patients with controlled HbA1c in first and second visit was 77.83±13.2 and 77.2±8.3 mmHg respectively with significant p=0.026. The mean of the cholesterol in controlled HbA1c in first visit (193.4±186.1) mg/dl was higher than in second visit (166.6±38.5) mg/dl with insignificant p=0.605. The mean of TG in controlled HbA1c in first visit (169.90±80.0) mg/dl was higher than in second visit (167.9±81.4) mg/dl with insignificant p=0.986.

Table (5): Relation of Variables with controlled and uncontrolled HbA1c in the first visit N=1000 and the second visit N=578.

Variables		HbA1c (The first visit)		HbA1c (The second visit)		P values
		<6.5	≥6.5	<6.5	≥6.5	
Sex	male	28(45.9)	403(65.6)	33(54.1)	211(34.4)	0.002*
	female	41(56.2)	528(63.6)	32(43.8)	302(36.4)	0.026*
Duration (months)		38.4±49.1	46.2±59.6	25.8±35.7	45.2±56.8	0.327**
occupatio n	gov. employ	17(47.2)	189(65.9)	19(52.8)	98(34.1)	0.021*
	self employ	13(44.8)	200(66.9)	16(55.2)	99(33.1)	0.017*
	house wife	35(58.3)	474(62.8)	25(41.7)	281(37.2)	0.041*
	Retired	4(44.4)	68(66.0)	5(55.6)	35(34.0)	0.003*
Smokers		19(43.2)	322(68.1)	25(56.8)	151(31.9)	0.001*
alcoholics		9(45.0)	87(69.6)	11(55.0)	38(30.4)	0.031*
SBP		120.2±19.9	119.7±17.8	117.0±14.9	121.9±17.4	0.081**
DBP		77.83±13.2	77.0±11.7	77.2±8.3	78.5±11.3	0.026**
Cholesterol		193.4±186.1	185.1±44.6	166.6±38.5	189.9±46.3	0.605**
TG		169.90±80.0	200.49±135.1	167.9±81.4	201.2±143.4	0.986**

*Chi square test; ** t-test

FBS and HbA1c relation to the first and the second visit was demonstrated in table (6) and showed that regarding the mean of FBS (mg/dl) in the first and the second visit was ranged between 184.95 ±55.51 (mg/dl) and 188.78±71.00 (mg/dl) with p value 0.091 which is statistically not significant. The mean of HbA1c in the first and the second visit was 10.20±2.61, 8.79±2.20 respectively with p value < 0.001 which is statistically significant.

Table (6): FBS and HbA1c relation to the first and the second visit.

Readings	Mean ± SD	P value *
BS1	184.95 ±55.51	0.091
BS2	188.78±71.00	
HbA1c1	10.20±2.61	< 0.001
HbA1c2	8.79±2.20	

*Paired t-test

DISCUSSION

In the present study a total number of 1000 patients were included, with age 24 years and above who were diagnosed as having type 2 DM and receiving treatment from diabetic and endocrine centre in Sulaimani City. Similar results were found in a study done in Oman by

AL-*et al.*^[20] with sample of 1266 patients and in a study done by Ismail *et al.*, 2011^[21] 350 patients were included. Majority of the patients in this study were females 569 (56.9%), which is similar to the study done in Oman, 696(55%), and in Malaysia study, (61.9%). In the present study the mean ±SD of the patient's age was 53.76±10.52 years, which is in concordance with Oman study, 53.3±11.5 years^[20], but differ from the Malaysia study, 56.9±9.5 years.^[21] According to this study the mean ±SD of duration of diabetes was 45.72±58.99 months, while in Oman study the mean duration of diabetes was 4.7±3.8years, in this study the mean BMI was 30.2±5.1kg/m², which is in agreement with Oman study, 30.1±5.7 kg/m².

In the present study there was statistically a significant relationship between the level of HbA1c with patient's age p= <0.001 and this is in concordance to the study of Ismail *et al.*,^[21] in Malaysia, that showed a significant relationship between the level of HbA1c and patient's age p=0.047. There are several studies done by Eid *et al.*,^[22] 2003; Suhaiza *et al.*, 2004,^[23] showed a significant relationship between the level of HbA1c and patient's age; however, the present study revealed that patients aged more than 60 years old with mean HbA1c1 and HbA1c2, 10.1±2.6 and 8.7±2.1 respectively were more

controlled than younger patients <40 years with mean HbA1c1 and HbA1c2, 9.8 ± 2.5 and 8.5 ± 2.1 respectively and this difference was statistically significant $p < 0.001$. This result was in agreement to Malaysia study^[21], USA conducted by Coro *et al.*,^[24] and among Malay population in Singapore by Charumathi *et al.*,^[25] that revealed patients aged more than 60 years old had better control of HbA1c as compared to younger age less than 40 years.

The present study showed that the uncontrolled HbA1c1 and HbA1c2 ≥ 6.5 according to male were 403 (65.6%), 211 (34.4%) respectively; while, females 528 (63.6%), 302 (36.4%) respectively. This study showed that uncontrolled HbA1c in the second visit either in male or female patients better than uncontrolled HbA1c in first visit but in general most of the patients did not have good control of HbA1c levels; however, this is similar to Malaysia study results of Ismail *et al.*, 2011^[21] a total of 214 patients (73%) showed poor control of HbA1c. The present study revealed a significant difference between the level of HbA1c with patient's gender male $p = 0.002$, female $p = 0.026$; while, Malaysia study found insignificant difference between the level of HbA1c with gender ($p = 0.655$).^[21]

In this study, the mean duration of DM in relation to HbA1c was 45.72 ± 58.99 months with $p = 0.327$ which is statistically not significant, this similar to other studies that showed insignificant difference between the HbA1c and the duration of illness.^[21, 26], in comparison with other studies had shown significant difference between the controlled level of HbA1c and duration of illness.^[27, 28]

Elevated cholesterol level is known to be one of the factors associated with uncontrolled T2DM. In this study there was no significant relationship between the levels of HbA1c and cholesterol $p = 0.605$; while, the other study in Malaysia found that there was a significant relationship between the levels of HbA1c among T2DM patients and total cholesterol with a p value of 0.039. Malaysia study by Ismail *et al.*, 2011^[21] revealed that it is important to control the level of cholesterol among T2DM patients. Eid *et al.*, 2003^[22]; Coro *et al.*, 2004^[24]; Charumathi *et al.*, 2009^[25] had indicated that there was a significant relationship between the control of T2DM and cholesterol level.

In the present study, the obese patients according to BMI groups, the mean of HbA1c reading in the first and second visit was 9.7 ± 2.6 and 8.7 ± 2.1 respectively, which revealed that there was a highly significant P value < 0.001 . This result is similar to other studies results by Turner *et al.*, 1999^[29], which revealed that the obesity is a risk factor and is very closely associated with type 2 diabetes mellitus. However, the present study revealed that there was a highly significant relationship between HbA1c and BMI $p = 0.001$, which is in discordance to other studies by AL-Lawati *et al.*,^[20]; Ismail *et al.*,^[21];

Hartz *et al.*,^[26] that showed there were no significant relationship between the level of HbA1c and BMI. This study is similar to the Turner *et al.*,^[29] study which showed that the occurrence of diabetes has a significant relationship with BMI.

In the present study, the mean of HbA1c in the first and second visit were 10.20 ± 2.61 and 8.79 ± 2.20 respectively with p value < 0.001 which is highly significant. This result is similar to Oman study conducted by AL-Lawati *et al.*,^[20] which revealed that the mean of HbA1c was 8.2 ± 2.0 with p value = 0.001 and it is statistically significant. In this present study, the mean of FBS in the first and the second visit was 184.95 ± 55.51 mg/dl and 188.78 ± 71.00 mg/dl respectively with p value = 0.091 which was statistically not significant. So the relation between FBS and HbA1c as shows in figure 3, there was a scatter plot linear relation between FBS mg/dl and HbA1c% with R^2 Linear = 0.310 which is statistically significant. In the other study in France by Droumaguet *et al.*,^[30] study which revealed that by establishing a correlation HbA1c with FBS levels, as the levels of HbA1c rise the FBS levels rises also. In comparison to other studies conducted in USA by Davidson *et al.*,^[31] which have given a cut-off for FPG in relation to the HbA1c and have emphasized the importance of HbA1c. Even other studies conducted by Mulkerrin *et al.*,^[32] and Yoshinaga *et al.*,^[33] found that HbA1c along with FPG is more reliable for diagnosis and control of diabetes; while, other study results showed that HbA1c when used alone in the absence of FPG has a poor sensitivity and specificity.

CONCLUSIONS

The present study revealed that there was a significant relationship between HbA1c with age, sex, BMI, diastolic blood pressure, fasting blood sugar, occupation, smoking, alcohol intake no significant relationship between HbA1c and the duration of diabetes, residence, family history, systolic blood pressure, cholesterol and TG and no significant in the mean difference between FBS1 and FBS2.

Recommendation

- 1-HbA1c test is one of the important follow-up tool in the management of T2DM, so it must be done for every patient with T2DM every 2-3 months especially when previous HbA1c ≥ 6.5 .
- 2- Education of patients about HbA1c test and its direct link to FBS and complications of T2DM and informing them that HbA1c < 6 should be the target of diabetic management.
- 3-The test should be available in all hospitals and health centres.

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