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Assessing Patient Profiles and Outcomes with Vildagliptin 100 mg Sustained Release (SR) in Individuals Diagnosed with Type 2 Diabetes Mellitus

Rajeev Chawla[1], Ganapathi Bantwal[2], Joe George[3], Sona Warrier[4*] and Amit Gupta[4]

[1]North Delhi Diabetes Centre, New Delhi, India

[2]St Johns Medical College, Bengaluru, Karnataka, India

[3]Department of Endocrinology, Endodiab Clinic, Calicut, Kerala, India

[4]Scientific Services, USV Pvt Ltd, Mumbai, India

ABSTRACT

Background: This study centers around Vildagliptin 100 mg Sustained Release (SR) Once Daily (OD), a Dipeptidyl Peptidase IV (DPP-4) inhibitor used to treat Type 2 Diabetes mellitus (T2D). Its once-daily formulation reduces pill burden and improves compliance. With the sustained release formulation, there is an extended release of Vildagliptin in a programmed manner. Since real-world data on patient profile, outcomes, and safety are scarce, this study aims to assess the effectiveness of Vildagliptin 100mg SR OD in individuals with T2D with respect to glycemic parameters.

Methodology: A cohort of 3,316 participants from 146 Indian sites was enrolled based on the criterion of having visited twice within the preceding year, meeting inclusion criteria, and receiving a prescription for Vildagliptin 100mg SR once daily. All participating sites were provided with an electronic Case Report Form (eCRF) for the collection of anonymized data. Ethical approval for this study was obtained from the Institutional Ethics Committee (IEC) Udyaan Healthcare (Registration No. ECR/1300/Inst/UP/2019).

Results: The study involved 3,316 participants, with 65.5% males and 34.5% females. After a 3-month follow-up, HbA1c levels decreased on average by 0.7% (8.0% to 7.3%, p-value <0.001). Those with a baseline HbA1c of >=9% saw a notable drop of 1.1%. The obese group had a weight reduction of 2.7 kgs, surpassing the non-obese group's drop of 1.5 kgs. The HTN group showed a more considerable reduction in HbA1c levels (0.67% vs. 0.58%) compared to the non-HTN group.

Conclusion: The administration of 100 mg SR Vildagliptin once daily proves to be an effective and well-tolerated strategy for achieving glycemic control. However, it is essential to emphasize the necessity for additional future research to deepen our understanding and optimize the utilization of this treatment approach.

***Corresponding author**

Sona Warrier, Scientific Services, USV Pvt Ltd, Mumbai, India.

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Introduction

Diabetes has surged to epidemic proportions in India, witnessing a substantial increase in prevalence over recent decades. The country shoulders a significant burden of Type 2 Diabetes Mellitus (T2D), ranking as the second-highest globally, with a staggering 74.2 million diagnosed individuals. Projections indicate that this already formidable number is expected to rise to 124.9 million by the year 2045 [1]. According to the ICMR-INDIAB-17 study, the overall weighted prevalence of diabetes in India is 21.1%, comprising 11.4% diagnosed through OGTT and 13.3% through HbA1c testing [2]. The rise in diabetes cases can be attributed to a range of factors, encompassing lifestyle changes, genetic predisposition, and an aging population. In addressing this escalating health challenge, a multitude of medications has been developed to manage diabetes effectively. The primary goal of these medications is to attain glycemic control and, consequently, prevent the onset of complications associated with diabetes.

The Dipeptidyl peptidase IV (DPP-4) enzyme plays a crucial role in the degradation and inactivation of incretin hormones, specifically Glucagon-Like Peptide-1 (GLP-1) And Glucose-Dependent Insulinotropic Peptide (GIP). Following food intake, GLP-1 and GIP are released, triggering insulin release in a glucose-dependent manner [3]. Vildagliptin, as a DPP-4 inhibitor, inhibits the inactivation of GLP-1 and GIP, thereby maintaining their pancreatic levels above the threshold activity for 24 hours [4]. In the EDGE trial, Vildagliptin demonstrated effectiveness and good tolerance, particularly noteworthy for Indian subjects, where

reductions in HbA1c levels were found to be greater [5]. In the GUARD study, a total of 3,511 participants received Vildagliptin, and the findings showed a significant reduction in mean HbA1c levels from baseline by 1.17% [6].

Individuals with T2D frequently necessitate the use of multiple Oral Hypoglycemic Agents (OHAs) as part of polytherapy. However, a substantial body of evidence suggests that engaging in polytherapy and adhering to multiple daily dosage schedules can significantly decrease patient adherence [7,8]. In an effort to address concerns related to dosing frequency, side effects, and enhance patient compliance, a Once-Daily (OD) Sustained-Release (SR) Vildagliptin 100 mg tablet was developed [9,10]. This formulation aims to achieve uniform drug release over time, potentially providing comparable DPP-4 inhibition coverage as the conventional twice-daily regimen. The focus of this study was to evaluate the impact of Vildagliptin 100 mg SR once-daily therapy on the reduction of weight, blood pressure, and HbA1C levels.

Materials and Methods

This study employed a retrospective design, collecting data from individuals diagnosed with T2D who were prescribed Vildagliptin 100 mg SR once daily. The data was obtained from individuals who attended a follow-up visit between May 1, 2022, and January 31, 2023. Ethical approval for the study was granted by an independent ethics committee, Udyaan Healthcare, on February 12, 2023 (Registration No. ECR/1300/Inst/UP/2019). Initially, a total of 3,494 clinical records from 146 centers across the country were included based on predefined inclusion criteria. After excluding records with missing essential information, the analysis focused on 3,316 records (Figure 1). Eligible participants for this study were adults diagnosed with diabetes who had been prescribed Vildagliptin 100 mg SR once daily.

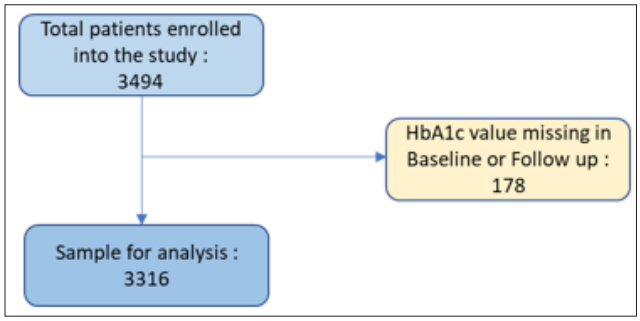

Figure 1: Sample Achieved

The study employed an electronic Case Report Form (eCRF) to systematically collect data on participants' medical history, comorbidities, diabetes complications, medications, and laboratory values. Primary outcomes of interest included alterations in glycemic parameters, specifically HbA1C, FBS, and PPBS levels. Routine measurements of blood glucose levels, HbA1C levels, weight, and blood pressure were conducted during both baseline and follow-up visits, adhering to established hospital protocols as part of routine care. To ensure consistency and adherence to the study protocol, only individuals with both baseline and 3-month outcome measurements were included in the data analysis for outcome assessment. Categorical data is presented as counts and percentages (n%), and comparisons are made accordingly. Continuous data is compared and presented as mean with Standard Deviation (SD). The study thoroughly examined changes in continuous data within each group and compared mean changes between groups to provide comprehensive insights into the impact of Vildagliptin 100 mg SR once-daily therapy on the measured parameters. The t-test and ANOVA are used to test for significant differences between groups, and the paired t-test is used to test for significance in the difference between baseline and follow-up measurements.

Results

The study comprised a total of 3,316 participants, with 65.5% being male and 34.5% female. The average age of the participants was 54.4 years, with a standard deviation of 10.2. The mean Body Mass Index (BMI) was 29.0 kg/m², with a standard deviation of 16.3. For a more comprehensive understanding of participant demographics, the duration of diabetes was categorized into two groups: less than or equal to 5 years and over 5 years. Additionally, baseline HbA1c levels were stratified into three groups: HbA1c < 7%, HbA1c ≥ 7% and < 9%, and HbA1c ≥ 9%. Hypertension was the predominant condition, showing a notably high prevalence of 72.4%. Following hypertension, the second and third most common conditions observed were obesity (33.5%) and dyslipidemia (24.4%).

To obtain a comprehensive overview of patient demographics, baseline glycemic parameters, complications, and comorbidity patterns, please consult Table 1 provided below.

Table1 : Patient Demographic Details

		Overall
	n=	3316
Age, n (%)	< 50 years	1098 (33.1%)
	>= 50 & < 60 years	1158 (34.9%)
	>= 60 years	1060 (32.0%)
	Mean (SD)	**54.4 (10.2)**
Gender, n (%)	Male	2173 (65.5%)
	Female	1143 (34.5%)
BMI, n (%)	Underweight (<18.5 kg/m²)	20 (0.6%)
	Normal weight (18.5-22.99 kg/m²)	323 (9.7%)
	Overweight (23.0-24.9 kg/m²)	549 (16.6%)
	Pre-Obesity (25.0-29.9 kg/m²)	1465 (44.2%)
	Obesity (>=30 kg/m²)	959 (28.9%)
	Mean (SD)	**29.0 (16.3)**
Blood Pressure, n (%)	Optimal BP (SBP<130 & DBP<85)	818 (24.7%)
	High Normal BP (SBP:130to139 / DBP: 85to89)	831 (25.1%)
	Grade 1 Hypertension (SBP:140to159 / DBP:90to99)	1285 (38.8%)
	Grade 2 Hypertension (SBP>=160 & DBP>=100)	382 (11.5%)
Duration of Diabetes	<5 years	1462 (60.0%)
	>5 years	975 (40.0%)
	Mean (SD)	**5.0 (3.7)**
T2DM complications	Neuropathy	528 (37.8%)
	Retinopathy	322 (23.0%)
	Diabetic Foot	308 (22.0%)
	Nephropathy	269 (19.2%)
	Coronary Heart Disease	138 (9.9%)
	Others	1129 (34.0%)
	None	**1918 (57.8%)**
Known comorbidities	Base:	2180
	Hypertension	1579 (72.4%)
	Obesity	730 (33.5%)
	Dyslipidemia	532 (24.4%)
	CKD	79 (3.6%)
Key Glycemic Parameters		
Baseline HbA1c, n(%)	<7%	354 (10.7%)
	7%-7.99%	1373 (41.4)
	8%-8.99%	1030 (31.1)
	>=9%	559 (16.9%)
	Mean (SD)	**8.0 (1.1)**
Baseline FBS, n(%)	Normal (<100 mg/dL)	24 (0.7%)
	Prediabetes (100 mg/dL - 125 mg/dL)	548 (16.5%)
	High Diabetic (126 mg/dL - 150 mg/dL)	1065 (32.1%)
	Very high Diabetic (>150 mg/dL - 200 mg/dL)	1421 (42.9%)
	Extremely high Diabetic (>200 mg/dL)	258 (7.8%)
	Mean (SD)	**156.6 (36.0)**
Baseline PPBS, n(%)	Normal (<100 mg/dL)	4 (0.1%)
	Prediabetes (100 mg/dL - 140 mg/dL)	82 (2.5%)
	High Diabetic (>140 mg/dL - 200 mg/dL)	1077 (32.5%)
	Very high Diabetic (>200 mg/dL - 300 mg/dL)	1890 (57.0%)
	Extremely high Diabetic (>300 mg/dL)	263 (7.9%)
	Mean (SD)	**228.0 (54.2)**

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Impact of Vildagliptin 100 mg OD SR on Glycemic Parameters

The study documented the HbA1c levels of individuals both before and after the administration of Vildagliptin 100 mg SR once-daily therapy. Following a 3-month treatment with the medication, there was a noticeable average decrease of 0.7% (8.0% - 7.3%, p-value <0.001) in HbA1c levels, with a standard deviation of 0.2. Additionally, the findings revealed a correlation between the baseline HbA1c values and the magnitude of the subsequent reduction. Specifically, individuals with higher baseline HbA1c values experienced a more significant drop. The group with a baseline HbA1c of >=9% exhibited the most substantial reduction, with a notable drop of 1.1%, compared to the 7.0-8.9% group, which had a 0.6% reduction, and the <7.0% group, where the reduction was 0.3%. Moreover, the duration of diabetes was identified as a contributing factor, with a greater reduction in HbA1c levels among participants with longer diabetes duration. Specifically, those with a diabetes duration exceeding 5 years experienced a reduction of 0.7%, compared to a 0.5% reduction in those with a duration of less than 5 years. Furthermore, there was an average reduction of 24.2 mg/dL in Fasting Blood Glucose (FBS) and 40.5 mg/dL in postprandial blood glucose (PPBS) levels. Similar trends to HbA1c were noted in FBS and PPBS levels among baseline HbA1c groups and diabetes duration groups. For a comprehensive view of the reduction in glycemic parameters based on age groups, gender, baseline HbA1c groups, and duration of T2D groups, please refer to Table 2 below.

Table 2: Impact on Glycemic Parameters

Table 2 : Impact on Glycemic parameters			Gender		
	Overall	Male	Female	P-Value	Test
n=	3316	2173	1143		
HbA1c (Glycosylated Hemoglobin): (%), mean (SD)					
Baseline	8.0 (1.1)	8.0 (1.0)	8.0 (1.1)	0.542	Two Sample T-test
Follow up	7.3 (0.9)	7.3 (0.9)	7.3 (0.9)	0.492	Two Sample T-test
Difference	0.7(0.2)	0.7 (0.6)	0.7 (0.6)	0.950	Two Sample T-test
P-Value (for Difference)	<0.001	<0.001	<0.001		
FBS (Fasting Blood Sugar): (mg/dL), mean (SD)					
Baseline	156.6 (36.0)	156.6 (35.9)	156.6 (36.1)	0.965	Two Sample T-test
Follow up	132.4 (27.9)	133.0 (28.6)	131.3 (26.6)	0.082	Two Sample T-test
Difference	24.2(8.1)	23.6(7.3)	25.3(9.5)	0.883	Two Sample T-test
P-Value (for Difference)	<0.001	<0.001	<0.001		
PPBS (Postprandial Blood Sugar): (mg/dL), mean (SD)					
Baseline	228.0 (54.2)	229.0 (54.1)	226.2 (54.2)	0.158	Two Sample T-test
Follow up	187.5 (41.3)	188.7 (42.3)	185.3 (39.1)	0.024	Two Sample T-test
Difference	40.5(12.9)	40.3(11.8)	40.9(15.1)	0.134	Two Sample T-test
P-Value (for Difference)	<0.001	<0.001	<0.001		
		Age			
	Age < 50	Age >= 50 & Age < 60	Age >= 60	P-Value	Test
n=	1098	1158	1060		
HbA1c (Glycosylated Hemoglobin): (%), mean (SD)					
Baseline	8.0 (1.1)	7.9 (1.1)	8.0 (1.0)	0.172	One-way ANOVA
Follow up	7.2 (0.8)	7.3 (0.9)	7.4 (0.9)	<0.001	One-way ANOVA
Difference	0.8 (0.3)	0.7 (0.2)	0.6 (0.1)	<0.001	One-way ANOVA
P-Value (for Difference)	<0.001	<0.001	<0.001		
FBS (Fasting Blood Sugar): (mg/dL), mean (SD)					
Baseline	158.1 (37.4)	154.1 (35.4)	157.8 (35.1)	0.011	One-way ANOVA
Follow up	129.1 (26.5)	130.9 (27.8)	137.5 (28.7)	<0.001	One-way ANOVA
Difference	29.1(10.9)	23.2(7.6)	20.3(6.4)	.	
P-Value (for Difference)	<0.001	<0.001	<0.001		
PPBS (Postprandial Blood Sugar): (mg/dL), mean (SD)					
Baseline	227.4 (52.8)	228.3 (53.0)	228.3 (56.7)	0.907	One-way ANOVA
Follow up	180.9 (38.6)	189.0 (40.7)	192.7 (43.7)	<0.001	One-way ANOVA
Difference	46.5(14.2)	39.3(1.23)	35.6(13.0)		
P-Value (for Difference)	<0.001	<0.001	<0.001		
		HbA1c (Glycosylated Hemoglobin)			
	HbA1c : (%) <7	HbA1c : (%) >=7 & <9	HbA1c : (%) >=9	P-Value	Test
n=	354	2403	559		
HbA1c (Glycosylated Hemoglobin): (%), mean (SD)					
Baseline	6.5 (0.4)	7.8 (0.6)	9.7 (0.9)	<0.001	One-way ANOVA
Follow up	6.2 (0.4)	7.2 (0.6)	8.6 (0.9)	<0.001	One-way ANOVA
Difference	0.3(0.0)	0.6(0.0)	1.1(0.0)	<0.001	One-way ANOVA
P-Value (for Difference)	<0.001	<0.001	<0.001		
FBS (Fasting Blood Sugar): (mg/dL), mean (SD)					
Baseline	134.4 (25.4)	154.1 (32.7)	181.3 (41.7)	<0.001	One-way ANOVA
Follow up	118.9 (23.6)	130.8 (25.9)	147.9 (32.1)	<0.001	One-way ANOVA
Difference	15.5(1.8)	23.3(6.8)	33.4(9.6)	<0.001	One-way ANOVA
P-Value (for Difference)	<0.001	<0.001	<0.001		
PPBS (Postprandial Blood Sugar): (mg/dL), mean (SD)					
Baseline	194.3 (42.5)	224.3 (46.9)	265.5 (67.9)	<0.001	One-way ANOVA
Follow up	168.2 (32.4)	185.0 (37.4)	210.2 (51.5)	<0.001	One-way ANOVA
Difference	26.1(10.1)	39.3(9.5)	55.3(16.4)	<0.001	One-way ANOVA
P-Value (for Difference)	<0.001	<0.001	<0.001		
Table 2 : Impact on Glycemic parameters		Duration of T2DM			
		T2DM duration <= 5	T2DM duration > 5	P-Value	Test
n=		1462	975		
HbA1c (Glycosylated Hemoglobin): (%), mean (SD)					
Baseline		7.9 (0.8)	8.2 (1.2)	<0.001	Two Sample T-test
Follow up		7.2 (0.7)	7.5 (0.9)	<0.001	Two Sample T-test
Difference		0.7(0.1)	0.7(0.3)	<0.001	Two Sample T-test
P-Value (for Difference)		<0.001	<0.001		
FBS (Fasting Blood Sugar): (mg/dL), mean (SD)					
Baseline		157.1 (34.4)	164.3 (36.3)	<0.001	Two Sample T-test
Follow up		133.6 (27.5)	137.6 (28.3)	0.001	Two Sample T-test
Difference		23.5(6.9)	26.7(8.0)	<0.001	Two Sample T-test
P-Value (for Difference)		<0.001	<0.001		
PPBS (Postprandial Blood Sugar): (mg/dL), mean (SD)					
Baseline		223.0 (46.9)	241.2 (62.8)	<0.001	Two Sample T-test
Follow up		185.7 (36.4)	195.7 (45.9)	<0.001	Two Sample T-test
Difference		37.3(10.5)	45.5(16.9)	<0.001	Two Sample T-test
P-Value (for Difference)		<0.001	<0.001		

Impact on Weight: Obese Vs Non-Obese

For a sub-sample analysis comparing two cohorts of participants, one with obesity and the other without obesity, a total of 2,180 individuals with available information on obesity were included. Among these, 730 individuals were classified as having obesity, while 1,450 did not have obesity. No significant difference was noted between the two groups in terms of age, with the average age being 56 years. However, the obesity group had a higher proportion of females (39%) compared to the non-obesity group (30%). Following 3 months of Vildagliptin 100mg SR once-daily usage, there was a statistically significant difference in the drop in weight between the two groups. The obese group experienced a more substantial reduction, with a drop of 2.7 kgs, compared to the non-obese group, which had a drop of 1.5 kgs. The observed weight reduction could be attributed to the patients' adherence to recommended lifestyle changes as well.

Moreover, the drop in HbA1c levels also exhibited a statistically significant difference between the two groups. The obese group showed a reduction of 0.5%, while the non-obese group demonstrated a higher reduction of 0.7%. These findings underscore the potential impact of Vildagliptin 100mg SR OD in managing both weight and glycemic control, with notable differences observed in participants with and without obesity.

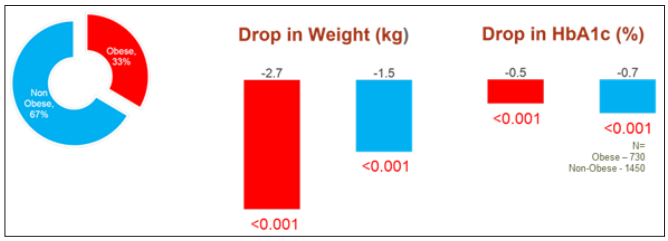

Figure 2: Impact on HbA1c and Weight among Obese Individuals

Impact on Blood Pressure

Among the total sample of individuals with T2D, 2,180 individuals had information recorded regarding Hypertension (HTN). Out of this subset, 1,579 were identified as having HTN, while 601 did not. The average age for the HTN group was 56.7 years, and for the non-HTN group, it was 54.1 years. No significant gender differences were observed between the two groups. At baseline, the HbA1c levels were 8% for the HTN group and 8.1% for the non-HTN group. Following a 3-month follow-up, the HTN group exhibited a significantly greater reduction in HbA1c levels (0.67% vs. 0.58%) compared to the non-HTN group. Regarding Blood Pressure (BP) measurements, at baseline, the HTN group showed the following distribution: 3% had Normal BP, 29% were in High BP stage 1 (130-139/80-89 mmHg), and 68% were in High BP stage 2 (>=140/90mmHg). At follow-up, these percentages changed to 5% Normal BP, 49% High BP stage 1, and 46% High BP stage 2. Notably, 36% of participants in High BP stage 2 at baseline transitioned to High BP stage 1 during the follow-up period.

Figure 3: Impact on HbA1c and Blood Pressure among Hypertensive Patients

Discussion

T2D not only elevates blood glucose levels but also exerts adverse effects on various organs within the body. The objective of oral antidiabetic drugs extends beyond merely lowering blood sugar levels; they also aim to enhance other parameters, such as body weight and blood pressure. Vildagliptin emerges as a viable option for diabetes management at all levels of HbA1c and if individuals exhibit intolerance to metformin. Furthermore, it can be seamlessly integrated into combination therapy protocols, serving as a second or third line of defense alongside other oral antidiabetic drugs [4]. In the current study, we have assessed the impact of Vildagliptin 100mg Sustained Release (SR) once-daily therapy on the reduction of weight, blood pressure, and HbA1C levels. Numerous studies have supported Vildagliptin 100mg SR once daily, portraying it as a safe, well-tolerated, and beneficial therapeutic alternative compared to the 50mg Immediate Release (IR) formulation taken twice daily [9, 11-14]. This alternative may potentially improve treatment adherence and enhance patient compliance, making it a noteworthy consideration in the management of T2D.

DPP-4 inhibitors are typically considered weight-neutral; however, studies indicate that Vildagliptin, particularly when initiated at common glycemic levels, may lead to modest weight loss [15]. Vildagliptin exhibited an antihypertensive effect by modulating serum Vascular Endothelial Growth Factor (VEGF) in diabetic hypertensive patients. The elevation of VEGF levels plays a role in enhancing physiological angiogenesis and improving vasculature [16]. Existing literature has highlighted the favorable impact of Vildagliptin on blood pressure, suggesting its potential to alleviate the Cardio Vascular Disease (CVD) burden among individuals with T2D [17-19].

In a Randomized Controlled Trial (RCT) conducted by Paul et al. it was observed that Vildagliptin 100mg Sustained Release (SR) once daily led to significant reductions in key parameters associated with diabetes [13]. Over the 12-week duration of the study, the mean HbA1c (9.0% vs. 6.5%), FBS (204 mg/dl vs. 116 mg/dl), PPBS (312 mg/dl vs. 158 mg/dl), and body weight (64 kg vs. 63 kg) were reduced. A meta-analysis of RCTs by Cai et al. has reported a reduction in HbA1c (0.77%), FBS (0.96 mg/dl), with a slight weight gain (0·95 kg) with Vildagliptin 100 mg once daily. The present study reported a reduction in all the parameters. Similar outcomes were observed in studies investigating the efficacy of Vildagliptin 100mg once daily as a monotherapy [20-22].

Conclusion

Vildagliptin, particularly in its 100 mg SR, once-daily formulation, stands out as a valuable inclusion in therapeutic alternatives, offering an effective and well-tolerated solution for attaining glycemic control. In the future, continual research and real-world evidence will enhance our understanding of the nuanced role played by Vildagliptin 100mg SR within the intricate framework of diabetes care. The ongoing exploration of its influence on patient outcomes, coupled with a deeper comprehension of its potential long-term advantages, will contribute to the continual improvement and optimization of diabetes treatment strategies.

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