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Original Research Article

## Comparative observational study between Atorvastatin and Rosuvastatin based on HbA1c levels of patients diagnosed with acute coronary syndrome and heart failure

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### ABSTRACT

**Background:** Our study aims to compare HbA1c levels in hospitalized acute coronary syndrome and heart failure patients treated with atorvastatin versus rosuvastatin

**Methods:** This is a retrospective, prospective observational study in which the study population includes ACS and HF Hospitalized patients, the study subjects are divided based on patients prescribed with Atorvastatin and Rosuvastatin based on the medication chart, and those patients' previous history of statin use is collected from history chart, patient casenotes, doctors notes, laboratory data is collected and documented in data collection form, lab data includes HbA1c, finally compared Atorvastatin and Rosuvastatin using excel and JASP descriptive analysis.

**Results:** Overall, we collected data for 132 cases, of which 55% are males and 45% females, 59.10% are above 61 years of age, 39.39% are diagnosed with ACS and 23.48% are diagnosed with HF, among 67 patients who are using Atorvastatin, there was a significant mean decrease in HbA1c% from 8.359% to 7.901%, and among 65 Rosuvastatin users there was an increase in mean HbA1c% from 8.386% to 8.389%. Additionally for non-diabetic individuals, there was an increase in HbA1c% from 6.339% to 6.387%.

**Conclusions:** We concluded that Atorvastatin is a more effective statin than Rosuvastatin which will reduce the risk of new-onset Diabetes Mellitus in non-diabetic individuals and reduce the risk of increasing complications of diabetes mellitus in patients who are Diabetic.

**Keywords:** ACS, HF, HbA1c, Diabetes Mellitus, Statins

### INTRODUCTION

Statins, a group of drugs that were introduced in the 1970s to manage high blood cholesterol levels, have become increasingly important due to their ability to reduce cardiovascular morbidity and mortality.<sup>1</sup> Several trials, including the AACE, ADA, and IDF, have studied the use of Statins in diabetic patients to manage dyslipidaemia. The Heart Protection Study (HPS) and Collaborative Atorvastatin Diabetes Study (CARDS) have cited these trials.<sup>2</sup> According to European guidelines for cardiovascular disease prevention and lipid management, Statins are the preferred first-line

treatment option for hypercholesterolemia and combined hyperlipidemia.<sup>3</sup> During 2002 and 2018, an annual average of 21.35 million (95%CI) Statin prescriptions were purchased nationally, with a mean total cost of \$24.5 billion (95%CI) according to a study conducted on increasing expenditure of generic name Statins from 2002-2018 found that the total annual expenditure for Lipitor dropped to \$4.02 billion in 2012 and \$0.48 billion in 2013 with a moderate increase to \$1.45 billion in 2016, spending on Lipitor decreased by 96.5% to \$0.05 billion in 2018, The total annual expenditure for generic atorvastatin increased from \$4.02 billion in 2012 to \$5.76 billion in 2014 and then stabilized at around \$6

billion throughout 2018. Upon analysing different race/ethnicity-based subgroups, it was observed that there were varying patterns of cost savings after the end of market exclusivity. The highest cost savings were observed in the Asian population, followed by White and African American/Black populations<sup>4</sup>. Statin cost-effectiveness increases with the risk level of the population. Using the \$50,000 per QALY threshold, treatment of patients at relatively higher risk (25% over 10 years) was cost-effective at higher drug prices than for patients at lower risk.<sup>5</sup> Our current research on Statins was conducted at a tertiary care hospital with approximately 300 beds and an average of 8 CCU admissions per day. We observed that around 70% of inpatients were prescribed low-dose, moderate-dose, or high-intensity Statins, with Atorvastatin (Avas, Aztor ASP, Atorva, Ecosprin-AV, Avas-CV, CAAT) and rosuvastatin (Lipirose, Rozalet, Stapure gold etc) being the most commonly prescribed brands. Taking HbA1c as our monitoring factor, we selected Atorvastatin and Rosuvastatin for our study and compared their effectiveness. Statins are the most commonly prescribed agents for the treatment of hypercholesterolemia because of their efficacy in reducing LDL and their excellent tolerability and safety.<sup>6</sup> The use of high-intensity Statins or prolonged use of Statins, particularly Lipophilic Statins like Atorvastatin, have been linked to the most common adverse effects of Rhabdomyolysis and Myopathy. As an added concern, other unfavourable effects such as heightened liver enzymes have also been reported. Despite numerous articles discussing these findings, our study focused specifically on the potential for increased HbA1c levels to contribute to uncontrolled diabetes mellitus or the development of new diabetes mellitus.<sup>1,7</sup>

Statins are medications that inhibit the rate-limiting step of the conversion of HMG-CoA to mevalonate, which in turn reduces the synthesis of cholesterol. The reduction in hepatic cholesterol levels leads to an increase in the expression of LDL receptors in liver cells, which results in increased clearance of LDL particles from the blood. As a result, lowering plasma LDL-cholesterol by statins reduces the synthesis and increases the catabolism of apo B 100. It's worth noting that the mevalonate pathway generates products such as coenzyme Q10, heme-A, and isoprenylated proteins, which play a significant role in cell biology and human physiology. Although the role of statins has been assumed to be widespread in areas such as inflammatory markers, nitric oxide (NO), polyunsaturated fatty acids, immunomodulation, neuroprotection, and cellular senescence.<sup>7</sup> A recent consensus has established a target glycosylated haemoglobin level of less than 7.0% for most people with type 2 diabetes. The goal of this target level is to reduce morbidity. A Chinese study conducted in 2022 on Diabetes Mellitus suggested that obesity is the main contributing factor for the disease. The study recommended that tackling obesity can help reduce the burden of diabetes across all education levels and genders. Another study highlighted the importance of

understanding the causes of diabetes and its related complications, which include cancer, dementia, psoriasis, atherosclerotic cardiovascular disease, non-alcoholic fatty liver disease, and non-alcoholic steatohepatitis.<sup>9</sup>

**How do statins increase HbA1c levels?**

Statins work by inhibiting HMG-COA reductase, which in turn inhibits the conversion of Mevalonate to Cholesterol. Additionally, Statins produce isoprenoid metabolites that result in the inhibition of small GTP-binding proteins (such as Ras, Rac, and RhoA). These proteins are responsible for various non-lipid-mediated activities, including anti-inflammatory, antithrombotic, and antioxidant effects. Statins also increase nitric oxide (NO) production, improve endothelial dysfunction, and cause insulin resistance due to the inhibition of isoprenoid biosynthesis and down-regulation of C/EBP $\alpha$  production. Decreased synthesis of isoprenoids can lead to the downregulation of GLUT4 expression on adipocyte cells, which can decrease insulin-mediated cellular glucose uptake and lead to glucose intolerance. Another mechanism of Statins is an increase in the production of NO, which can induce cytokines causing  $\beta$ -cell apoptosis.

**Table 1: Drugs that alter HbA1c.<sup>12</sup>**

Mechanism	Falsely low HbA1c	Falsely high HbA1c
<b>Increased erythrocyte destruction</b>	Dapsone, Ribavirin, Antiretrovirals, Trimethoprim, Sulphamethoxazole	-
<b>Altered haemoglobin, altered glycation</b>	Hydroxyurea Vitamin C Vitamin E Aspirin (small doses)	
<b>Interference with assays</b>	-	Aspirin (large doses), Opiate chronic use

**Other factors that influence HbA1c levels**

**Hypothyroidism:** Thyroid hormones significantly regulate carbohydrate metabolism, impacting insulin-dependent glucose uptake and generating free glucose through increased gluconeogenesis and glycogenolysis. These hormones have long been recognized as key regulators of glucose homeostasis, with research revealing a high prevalence of co-occurring diabetes and thyroid disorders in patients. study indicates that 15% of hypothyroid patients should be included in result analyses to ensure accuracy. **Steroids:** The use of corticosteroids is critical to treating patients experiencing exacerbation related to chronic obstructive pulmonary disease (COPD). However, it's important to note that corticosteroids can cause hyperglycemia, a

known adverse effect of glucocorticoid treatment. This effect can occur in both diabetic and non-diabetic patients and is particularly prevalent among hospitalized patients. The primary cause of this effect is increased insulin resistance. Therefore, our study carefully examined the potential impact of steroid usage on HbA1c levels in patients.<sup>11</sup> Other Drugs that alter HbA1c: Drugs that alter HbA1c are given in the below table, we checked for any of these drugs involved in altering HbA1c in our study.

**Objectives**

Primary objective was to compare HbA1c of patients treated with Atorvastatin and Rosuvastatin who are Diagnosed with ACS and HF, Secondary objectives were to compare HbA1c For newly Diagnosed Diabetic patients and patients who are already diabetic and on medication, to compare age and gender that may influence HbA1c levels, to compare dose dependant changes in HbA1c, to compare HbA1c based on Hypothyroidism and to check any drugs that may alter HbA1c.

**METHODS**

**Study type, location and duration**

This is an Observational study, being conducted in Bangalore Baptist Hospital, Bangalore, Karnataka, India from January 2022 to October 2022.

**Study design**

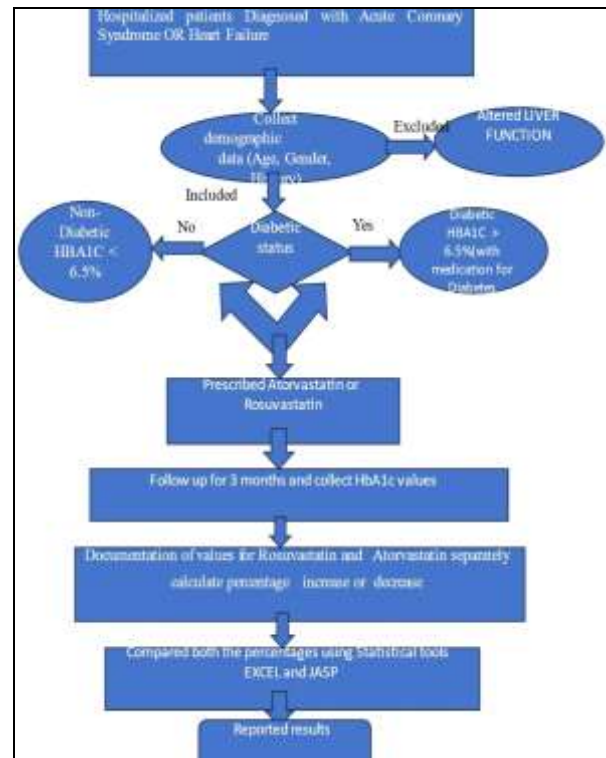
This is a retrospective, prospective observational study that took place in the inpatient wards of a tertiary care hospital. Patients were chosen based on their diagnosis of ACS, HF, CAD, or IHD and their treatment with Atorvastatin and Rosuvastatin. The initial HbA1c levels were recorded, and the cases were followed up for a period of 3 to 6 months. Follow-up HbA1c levels were noted in data collection form and further statistical comparisons were made.

**Source of data and materials**

Source of data were inpatient prescription, Medication Chart, Medication History Chart, Medicine Strips and Laboratory Data

**Inclusion criteria**

Inclusion criteria were patients who are under treatment with atorvastatin and rosuvastatin for atleast 3 months. All hospitalized acute coronary syndrome patients with or without diabetes mellitus and all hospitalized heart failure patients with or without diabetes mellitus.



**Figure 1: Flowchart of methodology.**

**Exclusion criteria**

Exclusion criteria were; patients with altered LFT may alter the enzyme activity and pregnancy and lactating Women.

**Procedure**

The study population includes ACS and HF Hospitalized patients, this data is obtained from a preliminary diagnosis chart, The study Subjects are divided based on patients taking Atorvastatin and Rosuvastatin based on patient case notes, and doctor's notes, Quantitative Variables like Age, Gender, HbA1c, LFT'S are collected from Nurse's notes and documented in data collection form, all Variables including HbA1c, LFT'S and all these data are analysed using proper Literature and references, and applying Statistical tools like JASP descriptive analysis.

**RESULTS**

The study collected data from individuals admitted to ICCU with ACS and HF who were treated with Atorvastatin and Rosuvastatin. The sample size totalled 132, with 73 (55%) males and 59 (45%) females. The population was categorized into four groups: 30-40 years old (3.79%), 41-50 years old (11.36%), 51-60 years old (25.76%), and over 61 years old (59.10%) (Table 2). Based on Statistical data, for non-diabetic patients there was a Mean increase in HbA1c from 6.339% to 6.387%, for Diabetic patients there was a mean decrease in HbA1c from 8.801% to 8.511% (Table 3).

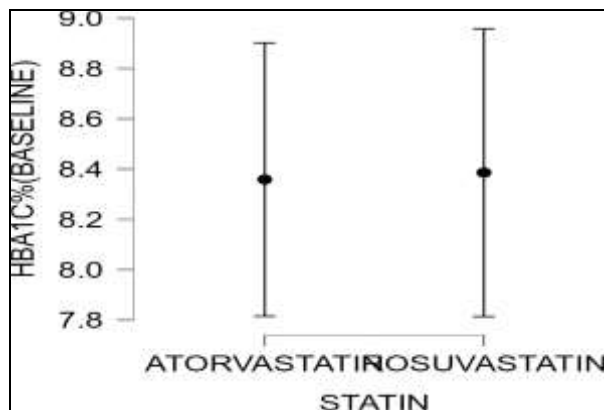
**Table 2: Patient demographic details (n=132).**

Criteria	Category	N	%
<b>Gender</b>	Male	73	55
	Female	59	45
<b>Age group (yrs)</b>	30-40	5	3.79
	41-50	15	11.36
	51-60	34	25.76
	>61	78	59.10
<b>Diabetes status</b>	Diabetic	104	78.79
	Non-Diabetic	28	21.21
<b>Other significant diagnosis</b>	HTN	81	61.36
	Hypothyroidism	20	15.15
	Dyslipidaemia	14	10.60

**Table 3: Comparing HbA1c for non-diabetic and diabetic patients**

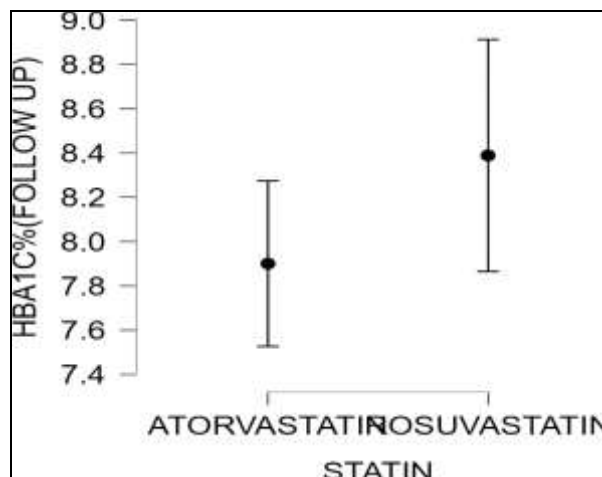
HbA1c%	HbA1c (baseline)		HbA1c (follow up)	
	Non-diabetic	Diabetic	Non-diabetic	Diabetic
<b>Valid</b>	23	109	23	109
<b>Missing</b>	0	0	0	0
<b>Mean</b>	6.339	8.801	6.387	8.511
<b>SD</b>	1.215	2.250	0.857	1.836

According to statistical data obtained by comparing the mean baseline and follow-up HbA1c levels for Atorvastatin, there was a decrease of 0.46% from 8.359% to 7.901% among 67 users.



**Figures 2: Comparison of Atorvastatin and Rosuvastatin based on HbA1c baseline.**

When comparing the mean baseline and follow-up HbA1c levels for Rosuvastatin, there was a slight increase of 0.003% from 8.386% to 8.389% among 65 users (Figures 2-3). Based on the data, we compared HbA1c with Gender, we observed in Males and females there is a decrease in HbA1c, so gender doesn't have much influence on our project. We found that from the age group 30 to 50, there was a decrease in HbA1c, and from the age group 51 and above there was an increase in HbA1c.



**Figures 3: Comparison of Atorvastatin and Rosuvastatin based on HbA1c followup.**

Based on Statistical data comparing different doses of Statins and HbA1c, for a 10mg dose, there was a decrease of HbA1c from 8.021% to 7.949%, for a 20 mg dose there was a decrease of HbA1c from 8.464% to 8.025%, for 40 mg dose there was a decrease from 8.542% to 8.497% (Table 4). Based on the data Patients are categorized into with Hypothyroidism and without Hypothyroidism, we have 20 Hypothyroid patients and 112 non-hypothyroid patients, when we checked the HbA1c baseline and follow-up, in Hypothyroid patients there was a slight increase in HbA1c i.e., 0.1% and non-Hypothyroid patients it is decreasing in mean HbA1c% i.e., 0.33% decrease.



**Table 4: Comparison of dose dependant changes in HbA1c.**

HbA1c%	HbA1c (baseline)			HbA1c (follow up)		
	10	20	40	10	20	40
<b>Dose</b>						
<b>Valid</b>	34	60	38	34	60	38
<b>Missing</b>	0	0	0	0	0	0
<b>Mean</b>	8.021	8.464	8.542	7.949	8.025	8.497
<b>Std. deviation</b>	2.236	2.261	2.448	1.811	1.761	2.131
<b>Minimum</b>	5.500	5.200	5.000	5.400	5.500	5.600
<b>Maximum</b>	14.500	16.700	16.500	11.200	12.600	15.300

**Table 5: Drug use and HbA1c comparison.**

Drug	HbA1c% (Baseline)	HbA1c% (Follow up)
<b>Aspirin</b>	9.35	10.22
<b>Prednisolone</b>	8.4	8.06
<b>Vitamin B</b>	6.8	6.9
<b>Vitamin C</b>	6.9	6.7

Based on the data obtained from our project among 132 subjects, 6 patients used Aspirin and observed a 0.87% increase in HbA1c, 4 patients were treated with prednisolone, and observed a 0.34% decrease in HbA1c, 3 patients were treated with Vit B and there is 0.1% increase in HbA1c, 4 patients are treated with Vit C, and observed 0.2% decrease in HbA1c (Table 5).

## DISCUSSION

The main objective of our Study is to compare atorvastatin and rosuvastatin in hospitalized ACS and HF patients based on HbA1c, after 10 months of our Studyperiod, we got 132 participants with follow-up HbA1c, did all Statistical analysis which is required for our study based on previous research done, and also included secondary objectives that are necessary for our conclusion and by comparing our findings with the Articles and other References and we got the following findings. Before moving on to Diabetes mellitus associated with Statins it is necessary to gain an understanding of the trials that drove Statins to the position that they currently occupy. This will hopefully lead to a balanced view of both the benefits and risks seen with this class of drugs. In a Meta-analysis Study on Atorvastatin and Rosuvastatin, Comparative Effects on Glucose Metabolism in Non-Diabetic Patients with Dyslipidemia Concluded that a significant increase in new-onset Diabetes is associated with some statins, approximately 4 extra patients for every 1000 patients can expect to develop diabetes and also in the same Meta-analysis study they concluded that patients pre-disposed to diabetes may be the individuals most at risk of new-onset diabetes following statin treatment. For every 1000 secondary prevention patients treated with a statin for an average of 4.2 years, 37 events will be postponed. is no need to change guidance on statin use. This benefit far outweighs the risk of diabetes and there they advised to Monitor Glucose levels.<sup>13</sup> In our study we included both Statins and checked for any significant increase in HbA1C in Non- Diabetic patients, yes there is an increase in

HbA1c from 6.339% to 6.387%. Next came to change in HbA1c in Diabetic patients, according to a Study Despite beneficial reductions in LDL cholesterol and apolipoprotein B, atorvastatin treatment resulted in significant increases in fasting insulin and glycated hemoglobin levels consistent with insulin resistance and increased ambient glycemia in hypercholesterolemic patients.<sup>14</sup> Our study indicated For Atorvastatin there is a Mean decrease of HbA1C from 8.359% to 7.901% in which mean HbA1C baseline is 8.359% with standard deviation 2.269 with minimum HbA1c of 5.5% and Maximum of 16.7%, that indicates there was a significant deviation from the past study and our Study. We also observed Dose-related changes in HbA1c, a previous study was done in 1049 diabetic patients and observed patients who received rosuvastatin 5 mg and atorvastatin 10 mg, there was no significant difference between the two groups in the effect of HbA1c during 12 months and after that period there was an increase, and for rosuvastatin 40 mg and atorvastatin 80 mg after 24 weeks there was a statistical increase in HbA1c% in our Study we observed for 10 mg dose of both Statins there was a decrease of HbA1c, for 20 mg dose there was a decrease of HbA1c, for 40 mg dose there was a decrease.<sup>15,16</sup> An intervention trial evaluating rosuvastatin (Jupiter) trial comparing 20 mg of rosuvastatin to a placebo, a statistically significant increase in physician-reported type 2 diabetes was noted (p=0.01). The Controlled Rosuvastatin Multinational Study in Heart Failure (CORONA) study reported a nonsignificant risk of developing diabetes while taking rosuvastatin.<sup>16</sup> Our study stated that For Rosuvastatin there is a mean increase in HbA1c from 8.386% to 8.389 these results we found that Atorvastatin is safer when compared to Rosuvastatin in reducing HbA1c thereby reducing the risk of diabetes mellitus. As a continuation of our study, we compared other cofactors like age, sex, and disease especially hypothyroidism, A previous study investigated the association between HbA1c levels and age in Taiwanese adults without a prior diagnosis of diabetes. In general, the HbA1c levels increased with aging and the levels of males

were significantly larger than females, the HbA1c levels did not increase with age for the age group of 50-70 years in males.<sup>17</sup> In our study we found that in the 30-40 age group, there was a decrease in HbA1c from 9.68% to 7.54%, in the age group 41-50 there was a decrease in HbA1c from 9.19% to 8.97%, in the age group 51-60 there is an increase in HbA1c from 7.78% to 8.1%, in age group 8.35% to 8.54%, so we can say 30 to 50 there was a decrease in HbA1c and from age group 51 and above there was an increase in HbA1c. In both males and females, there is a decrease in HbA1c, we compared HbA1c with Gender, and we observed in Males and females there is a decrease in HbA1c.

Diseases like Hypothyroidism which is related to endocrine glands also influence HbA1c, so, according to a previous study they have presented preliminary findings on, 40 long-term diabetic subjects, less than 70 years of age and under regular supervised medical management. They screened these patients, for vascular dysfunction using thermal imaging, to obtain risk scores for diabetes, hypertension, and dyslipidemia. That study shows, that at the clinically significant value of HbA1c (>6.5), the observed values correlate well, with the diabetes risk index. Now in our study, we had 20 Hypothyroid patients and 112 Hypothyroid patients, when we checked the HbA1c baseline and follow-up, in Hypothyroid patients there was a slight increase in HbA1c i.e., 0.1%, and in non-Hypothyroid-patients it is decreasing in mean HbA1c i.e., 0.33% decrease. Finally, we also did changes in HbA1c with drugs, according to a previous study High doses of antioxidant agents such as Vitamin C and E have been reported to lower the HbA1c by reducing the rate of glycation of hemoglobin, Chronic use of aspirin in large doses can lead to acetylation of hemoglobin, leading to falsely elevated HbA1c levels due to interference with some of the assays used. Patients with anemia due to deficiency of iron and vitamin B12 have high HbA1c levels. This can be reversed with the administration of the deficient factor. In some cases, administration of iron and vitamin B12 can lead to falsely lowered HbA1c due to the preponderance of young erythrocytes in circulation.<sup>41</sup> observed among 132 subjects, 6 patients used Aspirin and observed a 0.87% increase in HbA1c 3 patients were treated with Vit B and there was a 0.1% increase in HbA1c, 4 patients were treated with Vit C and observed a 0.2% decrease in HbA1c. So, so there is an increase in HbA1c in patients who are using Aspirin and VIT B, but very less patients using these drugs we can ignore the data. In another study done in COPD patients who are diabetic and non-diabetic and who are treated with Prednisolone they found that there was a significant increase in HbA1c.<sup>11</sup> In our Study we found that 4 patients were treated with prednisolone, and observed a 0.34% decrease in HbA1c.

### Limitations

All studies that are being carried out have its own limitations and boundaries. Hence, being an

observational study, this study also had its all limitations which were noted during the study period. In this Study as it is observational and not funded, HbA1c follow-ups are taken for patients who ever come for follow up and done their HbA1c voluntarily with Physician prescription, and as the patients are admitted to ICCU and most of them no able to stand, Weight and Height along with BMI are not measured at initial Diagnosis.

### CONCLUSION

In this study, we were able to draw a conclusion on the HbA1c association with diabetic, non-diabetic Patients and according to age. We conclude that Atorvastatin is the most effective statin than Rosuvastatin which will reduce the risk of new-onset Diabetes Mellitus in non-Diabetic individuals and reduce the risk of increasing complications of Diabetes mellitus in patients who are Diabetic.

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