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# Comparison of short-term efficacy and safety of the first generation versus second generation basal insulin analogues for inpatient management of patients with type 2 diabetes undergoing coronary artery bypass surgery: initial insight from an interim analysis of a retrospective observational cohort study from eastern India using ambulatory glucose profile data

## Abstract

**Aims:** There is paucity of data about the use of second- generation basal insulin analogues in hospitalized patients. Few studies have looked at the use of glargine U300 versus glargine U100 or glargine U100 versus degludec U100 in hospitalized patients using glucometer-based monitoring. One recent publication has also compared between two groups of type 2 diabetes mellitus (T2DM) patients in post-operative period of coronary artery bypass grafting (CABG) receiving glargine U300 as opposed to degludec U100 using multiple glucometry data. However comparative analysis between glargine U100 and the two second generation basal insulin analogues (glargine U300 and degludec U100) in similar subset of patients using continuous glucose monitoring (CGM) data is sparse.

**Methods:** As a pilot study, a retrospective analysis of retrieved ambulatory glucose profile (AGP) data of a small number of patients receiving glargine U300, glargine U100 or degludec U100 in the postoperative period after off-pump CABG was taken up for statistical analysis. AGP derived mean glucose was the primary endpoint and the glycemic metrices time in range (TIR), time below range (TBR) and time above range (TAR) were also analyzed to assess immediate glycemic control and glycemic variability. Safety data were analyzed using the discrete every 5 min data which was downloaded from the sensors. Level 2 (blood glucose less than 54mg/dl) hypoglycemia was searched for in the TBR regions and nocturnal hypoglycemia (blood glucose less than 70mg/dl) was searched for in the period from 1200 midnight to 6 AM.

**Results:** The primary outcome that is AGP based mean glucose, was similar between the 3 groups, as the p value was 0.705 that was greater than 0.05, the usual cut off value laid for significance. Similarly, the p values for the TIR, TBR and TAR were above the cut off for significance laid at 0.05 implying there was no significant difference in the immediate glucose control and the glycemic variability between the patients treated with either of the three basal insulin analogues. There were no level 2 hypoglycemic episodes or nocturnal hypoglycemic episodes noted in either of the three groups.

**Conclusion –** There was no difference between the efficacy and safety outcomes noted with the in- hospital use of glargine U100, glargine U300 and degludec U100 in this cohort of T2DM patients during the post operative period following off- pump CABG.

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## Introduction

The occurrence of hypoglycemia in diabetic inpatients is positively associated with increased risk of mortality and complications.[1–3] Improvement of glycemic control in critically ill as well as in non-critically ill medical and surgical patients have led to a reduction in short and long-term mortality, systemic infections and hospital stay.[4–6] Higher glycemic variability in the inpatients, in the course of long term follow up have shown to be associated with increased mortality.[7] It's no wonder that the recommendation and preferred approach of professional organizations towards treatment of uncontrolled hyperglycemia in the inpatient setting has always been insulin therapy. Clinical practice guidelines have recommended the use of basal bolus therapy in the management of non- critically ill patients in the hospital setting[8–10] and there is also published evidence supporting the use of the same in critically ill patients.[5] In comparison to sliding scale using regular insulin, basal bolus treatment with basal insulin glargine U100 has been effective in achieving better glycemic control and reducing the rates of in-hospital complications.[11–13]

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Both the second- generation basal insulin analogues, namely glargine U300 and degludec U 100, in general have a longer duration of action and less glycemic variability in comparison to glargine U100. Glargine U300 has a longer duration of action and a more stable pharmacokinetic and pharmacodynamic profile than glargine U100 and it exhibits better day to day reproducibility and lower within the day variability.[14,15] In ambulatory patients with type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) glargine U300 has documented efficacy and safety profile in numerous studies.[14,16–20] Yet few studies have assessed the efficacy and safety of glargine U300 in acutely ill patients admitted to the hospital.[21]

Degludec, the other second -generation basal insulin analogue has a duration of action greater than 40 hours and is virtually without a peak.[22,23] In ambulatory patients with T1DM and T2DM degludec showed similar improvements in glycemic control in comparison to glargine U100.[23–25] In randomised controlled trials (RCTs) as well as in observational real world studies degludec in comparison to glargine U100 and and other first generation basal insulin analogues has shown lower rates of overall symptomatic and nocturnal hypoglycemia[24,26,27] and also a lesser day to day and within day glycemic variability.[23,24,28] This enhanced safety profile of degludec thus poses it as a viable alternative to glargine U100 for inpatient use.[29,30] However there are only limited resources comparing the two basal insulins for inpatient use.[31]

A recent publication has compared between the two second generation basal insulin analogues for inpatient use[32] and there are data comparing glargine U100 versus glargine U300[21] and glargine U100 versus degludec[31] separately using multiple capillary glucose monitoring values. In real life, however, there is paucity of data comparing the three different basal insulins in a similar set of hospitalised patients using ambulatory glucose profile (AGP) derived metrices of time in range (TIR), time below range (TBR) and time above range (TAR) to assess not only glycemic control but also the glycemic variability, which is an important predictor of long-term mortality in hospitalised T2DM patients.[7]

## Material & methods

The retrospective analysis of data was carried from the database of the Department of Cardiothoracic and Vascular Surgery (CTVS) of a charitable Hospital in the post operative period amongst T2DM patients undergoing off pump bypass surgery. In this hospital, patients are offered insulin Aspart as the bolus insulin and after discussion about cost-benefit they are offered glargine U100, glargine U300 or degludec as the basal insulin. As a standard operating procedure, all patients who can afford are offered continuous glucose monitoring (CGM) using Freestyle Libre Pro sensor from Abbott which is applied after extubation and stoppage of inotropic support. Looking at the paucity of AGP based data on the efficacy glycemic variability and safety of basal insulin analogues glargine U300, basal insulin glargine U100 versus the second-generation basal insulin degludec U100, a retrospective database search was made for the AGP data of patients using these three basal insulin analogues from January 2023 onwards. The following inclusion and exclusion criteria were adhered to while the database search was carried out:

### Inclusion criteria

I. T2DM undergoing off pump coronary artery bypass grafting(CABG) on Freestyle Libre Pro sensor

II. Estimated glomerular filtration rate(eGFR)> 45ml/min

III. Age between 18-70 years

IV. No arrhythmia or other acute events in the post extubation period causing interruptions in normal feeding schedule

V. Must have received 500 mg of metformin sustained release tablets after breakfast lunch and dinner as the only oral anti diabetic agent (OAD) in the post extubation period

VI. Two data downloads from the Freestyle Libre sensor one just before discharge from the hospital and one at the end of the 14 days monitoring period.

### Exclusion criteria

I. T2DM patients undergoing on pump bypass surgery

II. Age greater than 70 years

III. Any additional corrective surgery such as valve replacement etc. done along with off pump CABG

IV. eGFR < 45ml / min

V. Arrhythmias or acute events in the post extubation period disrupting the normal schedule of feeding.

VI. Patients with prior history of metformin intolerance.

Insulin aspart and the basal insulins (first generation or second generation) had undergone daily titration using standard algorithm followed in the CTVS Intensive Care Unit (ICU) with the aim of keeping the blood sugars around 140mg/dl without causing hypoglycemia (140mg/dl was the goal achieved in the intensive arm of the Vanden Bergh study).

The primary glycemic control endpoint looked at was mean glucose obtained from AGP data during the hospital stay. The other endpoints looked at were average daily TIR, TBR and TAR for the duration of hospital stay. After looking at the inclusion and exclusion criteria, 5 patient's data were obtained for each of the glargine U300, glargine U100 and the degludec U100 arm and the data was analysed using Statistical Package for Social Sciences (SPSS) version 21.0. Safety was evaluated from the hypoglycemia data. Nocturnal hypoglycemia was looked for between 1200 midnight and 6.00 AM and the individual values of interstitial glucose recorded by the sensor at 5 minute interval during the aforesaid period of time were scanned for values below 70 mg/dl. These sensor derived values were also scanned for level 2 hypoglycemia (<54mg/dl during those time periods that showed TBR). Ethical consideration – As the study was investigator initiated and was based on retrospective analysis of AGP data, ethics committee approval was not sought. Bioethics related tenets of the Helsinki Declaration was meticulously adhered to and confidentiality and anonymity of data were strictly maintained.

## Results

The analysed cohort had a male predominance with 100% patients receiving glargine U300 and degludec U100 being males and only one patient in the glargine U100 arm was a female .Their average age , eGFR and mean baseline HbA1c are enumerated in table 1 .The number of data being less than 50 , Shapiro Wilk test was done to confirm normality .Once normality was confirmed, Analysis of variance (ANOVA) was done to test for significant differences between the three types of basal insulin users with respect to-1) AGP derived mean blood glucose ( primary outcome measure) 2) Mean TIR value 3)Mean TBR value and 4) Mean TAR value . The p value for none of the four parameters compared came out to be <0.05, hence there was no statistically significant difference between the outcome parameters of glycemic control and variability. Nocturnal

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hypoglycemia and level 2 hypoglycemia was also similar between the three groups. So, all three basal insulin analogues proved to have similar efficacy and safety for inpatient use in this interim analysis of data from an ongoing retrospective cohort study. Total units of basal and bolus insulin use during the entire monitoring period were tabulated but the statistical significance was not looked for in this interim analysis as more intricate database search would be required to derive the mean unit of basal analogues and bolus insulin given per subcutaneous injection during the monitoring period.

**Statistical analysis**- Table 1, Table 2

**Table 1** Baseline characteristics (Data is presented as mean ± SD for continuous variablesand count (%) for discrete variables)

| | GLARGINE U 300 | GLARGINE U 100 | DEGLUDEC U 100 |
|---|---|---|---|
| Age, (yrs.) | 60.2 ± 2.68 | 60.2 ±7.56 | 57.6 ± 4.45 |
| Sex: Male/ Female as % | 100:0 | 80:20 | 100:0 |
| Mean HbA1c % (preoperative) | 8.7 ±1.28 | 8.28 ± 1.03 | 8.04 ±1.12 |
| Mean eGFR (ml/min) | 57.4 ± 8.3 | 65.4 ± 6.8 | 61.4 ± 2.7 |

**Table 2** Primary and Secondary Outcome

| | GLARGINE U 300 | GLARGINE U 100 | DEGLUDEC U 100 | P Value |
|---|---|---|---|---|
| Glycemic outcomes | | | | |
| Mean blood glucose ( AGP derived ) | 141.2 ±38.08 | 135.6 ± 43 | 119.8 ±42.89 | 0.705 (ns) |
| Level 2Hypoglycemic Events | Nil | Nil | Nil | |
| Mean TIR | 67 ±10 | 71.8 ± 22.2 | 71.8 ± 17.4 | 0.881 (ns) |
| Mean TBR | 9.8 ± 11.63 | 7.8 ± 9.31 | 16.2 ± 14.86 | 0.538 (ns) |
| Mean TAR | 23.2 ± 18.03 | 20.4 ± 26.01 | 12 ± 19.74 | 0.701 (ns) |
| Nocturnal Hypoglycemia | Nil | Nil | Nil | |
| Insulin dose | | | | |
| Total basal insulin requirement during the monitoring period | 69.4 ± 28.77 units | 68.4 ± 47.9units | 56.2 ±54.6units | |
| Total bolus insulin requirement during the monitoring period | 133 ± 70.3units | 110 ±101.98 units | 87.2 ± 75.7units | |

## Discussion

The present study is based on the interim analysis of retrospective data collected from the AGP sensor applied to the T2DM patients who underwent off-pump CABG. The study though small in terms of sample size looks to provide a safety and efficacy analysis between glargine U300, U100, and degludec U100 in a similar subset of patients, based on a set of AGP data wherein perhaps lies its novelty. It excluded patients with eGFR < 45 ml/min as glargine U100 has a statistically insignificant but slightly higher chance of causing hypoglycemia in such patients rather than those in higher ranges of eGFR[33]which could prove to be a confounding factor for estimating the safety issues. Metformin in a dose of 500 mg thrice after meals was continued as recommended by the American Diabetes Association (ADA) along with a basal bolus insulin regimen for enhanced glycaemic and metabolic benefits.[34]

Insulin is the cornerstone for the management of hyperglycemia in the hospital settings. A basal bolus regimen of insulin with correctional components is preferred in patients with good nutritional intake while a basal insulin plus bolus correction is preferred in those with poor oral intake.[35] Although still followed in many centers, two large multi-center RCTs proved that basal bolus regimen using glargine U100 was superior to sliding scale regular insulin in post-surgical patients.[6,36]

One study compared basal bolus regime using glargine U100 versus neutral protamine hagedorn (NPH) as the basal component, where both arms showed similar glycemic efficacy but glargine users had lower hypoglycemic rates.[37] We also find another study in the literature where a combination of regular and mixed formulation was used in contrast to a basal bolus regimen using glargine U100, where again both arms reported similar glycemic control but glargine arm had lesser incidences of hypoglycemia.[38]

Looking at the novel pharmacokinetics of second generation basal insulin analogues where the steady state is achieved after second or third day of administration[25,30] there was a question mark regarding the use of the second generation basal insulin analogues in the inpatient setting. In the hospital setting the second generation basal insulin analogues required daily titration and the safety of their usage was in question keeping in mind the possibility of insulin stacking and hypoglycemia .However prospective studies using glargine U300[21]as a basal insulin and also two other studies using degludec as basal insulin[31,39] in the hospital setting showed they were safe for use in hospitalised patients and could be safely titrated on a daily basis without added risk of hypoglycemia when compared with the glargine U100 arm.

This interim analysis of our AGP based data is reassuring as it did not see any difference between the first generation basal insulin glargine U100 and the second generation basal insulin analogues glargine U300 and degludec U100 with respect to glycemic control as evidenced from the mean glucose and the time in range. More important is the fact that the second generation basal insulin analogues despite daily titration in a basal bolus regimen, had similar TBR in AGP monitoring ,similar rates of level 2 hypoglycemia and nocturnal hypoglycemia in comparison to glargine U100- which is

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usually considered to be the gold standard basal insulin for inpatient care .

The rising cost of insulin is a concern not only in developing countries like India but also in the Western world.[40] Approximately one out of every four patients in the United States of America (USA) too report cost related underuse of insulin.[41] Such India specific statistics of under usage is not available although it is not an uncommon experience with the Health Care Providers (HCPs) dealing with diabetes. Second generation basal insulin analogues are still much dearer than the first generation basal insulin glargine U100 in India. This early analysis comparing the three basal insulin analogues in terms of efficacy and safety in- hospital use, can serve as an initial data support for a judicious choice of basal insulin analogue, keeping in mind the cost, till larger studies comparing the three become available.

## Limitations

The small size of the analysed cohort is the greatest limitation of the study (adequately reflected by the large standard deviation [SD] values of the insulin dose requirements). The study also lacks the correlation of AGP data with the self monitoring of blood glucose (SMBG) values (the work on which is going on). The issue of in hospital complications, mean dose of basal / bolus insulin administered is also not reflected in the study. This study entirely includes post-CABG patients and these results should not be extrapolated to other post-surgical patients or to patients in medical ICUs.

## Conclusion

Second generation basal insulin analogues are as efficacious as glargine U100 for inpatient use. Despite skepticism from the health care fraternity, second generation basal insulin analogues can be titrated daily when used for inpatient care without increased risk of level 2 or nocturnal hypoglycemia in comparison to glargine U100. Although second generation basal insulin analogues have been known to decrease glycemic variability (both intra-day and inter-day) in comparison to glargine U100 [mainly in out-patient based studies]. However, such an impact of second generation basal insulins on glycemic variability was not seen in this study.

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## Author contribution

I. Dr Soumyabrata Roy Chaudhuri (Visiting Endocrinologist, Anandalok Hospital, Salt Lake City, Kolkata) - Conceptualization, study design, patient management and compilation of manuscript.

II. Dr (Prof) Anirban Majumder (Professor, KPC Medical College and Hospital, Kolkata) - Study design, editing of manuscript.

III. Dr (Prof) Debmalya Sanyal (Professor, KPC Medical College and Hospital, Kolkata) - Study design, editing manuscript.

IV. Ms. Susama Chuyan (Certified Diabetes Educator, Adopt Clinic, Kolkata) - Retrieval of data, preparation of XLs sheet and preparation of tables from the raw data and assistance in referencing.

V. Ms. Soma Chakraborty (Nutritionist and Research Associate, Diabetes-Obesity-Thyroid and Hormone Clinic, Kolkata) – preparation of tables and final editing of the manuscript including reference sequencing and formatting.

VI. Dr Ajoy Biswas (Consultant Physician-GD Diabetes institute, Kolkata) – Preparation of abstract.

VII. Dr Barun Chandra Roy (Consultant cardiac surgeon- Anandalok Hospital, Salt Lake City, Kolkata)- patient management and compilation of data.

## Conflicts of interest

The author declares there is no conflict of interest in this job.

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