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Research Article

Comparison Of HbA1c Levels in Type II Diabetes Mellitus Patients Receiving A Combination of Oral Hypoglycemic Drugs and Insulin Degludec-Aspart Versus Insulin Degludec-Aspart Monotherapy

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ABSTRAK

Diabetes melitus tipe II merupakan penyakit kelebihan glukosa yang disebabkan oleh menurunnya kinerja insulin dalam tubuh. Kriteria utama dalam manajemen glukosa darah adalah kadar HbA1c. Penelitian ini bertujuan mengevaluasi perbedaan kadar HbA1c pada pasien diabetes melitus tipe II yang mendapatkan terapi kombinasi obat hipoglikemik oral dan insulin degludec-aspart dibandingkan dengan pasien yang menerima monoterapi insulin degludec-aspart. Metode yang digunakan dalam penelitian yaitu cross-sectional secara retrospektif pada bulan Januari-Desember 2023 dengan jumlah sampel sebanyak 66 pasien yang dibagi menjadi 2 kelompok. Nilai HbA1c yang diperoleh dari bulan pertama hingga bulan ketiga dianalisis secara statistik menggunakan **independent sample t-test** ***dengan uji SPSS versi 21. Hasil penelitian menunjukkan penurunan kadar HbA1c pada kombinasi terapi obat hipoglikemik oral + insulin degludec-aspart sebelum dan sesudah dengan selisih nilai ± SD sebesar (1,565 ± 1,10)% dan penurunan nilai HbA1c ± SD pada monoterapi insulin degludec-aspart sebelum dan sesudah dengan selisih nilai (1,05 ± 0,74)% dengan nilai p (<0,05). Kesimpulan penelitian ini adalah terdapat perbedaan penurunan nilai HbA1c pada kedua kelompok dengan nilai p (<0,05). Hal ini menunjukkan bahwa penggunaan kombinasi oral lebih efektif daripada monoterapi.***

Kata Kunci: Diabetes Mellitus Tipe II, HbA1c, Insulin Degludec-Aspart, Obat Hipoglikemik Oral, Kombinasi Terapi.

ABSTRACT

Type II diabetes mellitus is a condition marked by hyperglycemia due to reduced effectiveness of insulin within the body.The main criterion in blood glucose management is HbA1c level. The objective of this research was to assess the difference in HbA1c levels between type 2 diabetes patients treated with a combination of oral hypoglycemic agents and insulin degludec-aspart versus insulin degludec-aspart alone. This research method uses a retrospective cross-sectional research design in January-December 2023 with a total sample of 66 patients divided into 2 groups. HbA1c values collected from the first to the third month were analyzed using the independent sample t-test in SPSS version 21. The Medical Research Ethics Commission of Ulin Banjarmasin Regional General Hospital South Kalimantan has approved this study. HbA1c levels in the combination of oral hypoglycemic drug therapy and insulin degludec-aspart pre- and post- with a difference in ± SD value of (1.565 ± 1.10)% decrease and a decrease in HbA1c ± SD value in insulin degludec-aspart mono-therapy pre- and post- with a difference in value (1.05 ± 0.74)% with a p-value (<0.05).This study concludes that the reduction in HbA1c levels between the two groups differs significantly, as indicated by a p-value of less than 0.05. This implies that the use of oral combination is more effective than mono-therapy.

Keywords: Type II Diabetes Mellitus, HbA1c, Insulin Degludec-Aspart, Oral Hypoglycemic Drugs, Combination Therapy

I. INTRODUCTION

Diabetes mellitus is a metabolic disorder marked by elevated blood glucose levels, known as hyperglycemia, which results from defects in insulin secretion, insulin function, or a combination of both (ADA, 2022; Kahn, 2014). In 2019, the International Diabetes Federation (IDF) estimated that approximately 463 million individuals, or 9.3% of the world's population, were living with diabetes. This number is expected to grow to 578 million (10.2%) by 2030 and 700 million (10.9%) by 2045 (IDF, 2019. The management of diabetes mellitus can be effectively achieved through pharmacological therapy, which includes both oral hypoglycemic agents (OHAs) and insulin injections. OHAs may be administered as monotherapy or in combination, depending on the patient's condition and therapeutic needs (Artini et al., 2023). As highlighted by Inzucchi et al. (2015), a patient-centered approach should be prioritized, taking into account individual patient characteristics, preferences, and treatment goals when selecting the most appropriate therapy, whether it involves oral medications, insulin, or a combination therapy, to optimize long-term outcomes. Additionally, combination oral hypoglycemic therapy is indicated when the initial HbA1c level is ≥7.5% or when blood glucose targets are not achieved after three months of monotherapy (PERKENI, 2019). Insulin therapy is given

after failure of patients using oral hypoglycemic drugs and poor blood glucose levels (HbA1c level > 7.5% or fasting blood glucose level > 250mg/dL). Insulin is a hormone formed by pancreatic beta cells that functions to convert blood glucose into glycogen in the liver.

Insulin is a natural hormone secreted by the pancreas. Insulin is needed by body cells to convert and use blood glucose (blood glucose), from glucose, cells make the energy needed to carry out their functions (ADA, 2015; Samuel & Shulman, 2016). Insulin has several types, namely rapid-acting insulin, short-acting insulin, intermediate-acting insulin, and long-acting insulin (PERKENI, 2021).

Insulin degludec-aspart is a combination of two different insulin analogs, namely insulin degludec and insulin aspart, in a ratio of 70% and 30%, which makes this insulin the first combination of basal insulin with a very long duration of action and established mealtime insulin in a preparation for patients with type 2 diabetes mellitus (Fulcher et al., 2014). A study by Franek et al. (2016) further supports this by demonstrating that twice-daily insulin degludec/insulin aspart treatment provides superior fasting plasma glucose control and a reduced rate of hypoglycaemia compared to biphasic insulin aspart 30 in insulin-naïve adults with type 2 diabetes. In the study, insulin degludec/insulin aspart showed significantly better control over fasting plasma glucose levels and resulted in fewer hypoglycaemic episodes, particularly nocturnal hypoglycaemia, compared to biphasic insulin aspart 30 (Franek et al., 2016). Preprandial insulin therapy is a critical component in achieving effective glycemic control, as it helps regulate post-meal blood glucose levels and minimizes the risk of long-term complications associated with sustained hyperglycemia. Twice-daily administration of insulin degludec-aspart significantly improved HbA1c levels, provided better control of fasting plasma glucose (FPG), and reduced the incidence of nocturnal hypoglycemia compared to biphasic insulin aspart 30 (Fulcher et al., 2014). A pan-Asian trial among type 2 diabetes patients who were not well-controlled on insulin and oral antidiabetic drugs showed that twice-daily insulin degludec-aspart led to greater reductions in FPG than biphasic insulin aspart 30 (Fulcher et al., 2014). Based on previous research conducted by Wati *et al,* (2023) at Ulin Hospital Banjarmasin concluded that the use of insulin degludec-aspart is more effective in reducing blood glucose levels compared to insulin levemir® (Rimadani and Wati 2022; Wati et al, 2023). The research conducted at the RSUD Madiun found that the use of the detemir-aspart insulin

combination accounted for 58% compared to other insulin combinations (Wulan et al., 2024). The use of insulin combination with OHO at the Tarakan General Hospital in Jakarta was observed in 19 patients, with metformin being the most commonly used OHO (Fauziah, 2025). The insulin degludec-aspart is safe and well-tolerated for long-term use, with significant clinical improvements. The multicenter design, involving 40 sites across India, strengthens the evidence of its effectiveness in real-world clinical practice, supporting its use across diverse patient populations (Kesavadev et al., 2021). The novelty of this study lies in the comparison between the combination therapy of oral hypoglycemic agents (OHO) and insulin degludec-aspart, with insulin degludec-aspart monotherapy in patients with type II diabetes mellitus at Banjarmasin Hospital. This type of research is still very limited in Indonesia, making this study a valuable source of information for optimizing diabetes mellitus treatment.

II. METHODS

This study has been evaluated and obtained the ethical feasibility of research from the Medical Research Ethics Commission of RSUD Ulin Banjarmasin South Kalimantan with No. 16//II-Reg Research/RSUDU/24 on February 15, 2024. The design of this study is *cohort retrospective* with secondary data, namely medical records of outpatients with type II diabetes mellitus at Ulin Banjarmasin Hospital in the period January - December 2023. The research was conducted from February to April 2024 at Ulin Regional General Hospital Banjarmasin. The study population included all medical records of adult patients diagnosed with type II diabetes mellitus who had received insulin degludec-aspart therapy at the outpatient department of Ulin Regional Hospital Banjarmasin during the period of January to December 2023. Samples were taken using a *total sampling* technique, namely, *purposive sampling. The total sampling* technique is a sampling technique by taking all samples from patient medical records that meet the inclusion and exclusion criteria, namely Inclusion Criteria patients diagnosed with type II diabetes mellitus on an outpatient basis at Ulin Banjarmasin Hospital; Type II diabetes mellitus patients with or without complications of other diseases who receive OHO + insulin degludec-aspart combination therapy or insulin degludec-aspart monotherapy; Type II diabetes mellitus patients who have complete medical records of the results of examining *pre* and *post* HbA1c levels using therapy . Exclusion Criteria Patients with type I diabetes mellitus, Type II diabetes mellitus patients who did not

complete 3-month therapy or missed follow-up visits, Patients receiving other insulin types in addition to insulin degludec-aspart, Pregnant or lactating women with type II diabetes mellitus., Patients with severe comorbidities that may affect HbA1c levels. The research instruments included patient medical records The data taken were name, gender, age, diagnosis, HbA1c examination results, as well as the provision of insulin degludec-aspart and OHO therapy or insulin degludec-aspart alone. Hba1c data was taken at month 1 and month 3 then measured the difference in the decrease in Hba1c values at months 1 and 3 and data analysis was carried out using spss version 19 with independent sample t-tests.

III. RESULTS AND DISCUSSION

In Table I, the results indicate that female patients show a higher prevalence of type 2 diabetes mellitus receiving either combination therapy or insulin Ryz monotherapy. The majority of cases occur in the 55–65-year age group. This finding aligns with the study by Dayan et al (2025), which reported a significant association between age and the incidence of diabetes mellitus.

Based on this bar chart (Table I), the most common oral use in patients given oral hypoglycemic drugs + insulin degludec-aspart is metformin, with 24 patients out of a total of 33 patients given oral hypoglycemic drugs. Additionally, the distribution of gender among the patients shows that 30.3% are male, while the remaining 69.7% are female. This suggests a higher prevalence of female patients in this group, which may reflect broader trends in diabetes care or the demographic characteristics of the study population. In line with Tonolo (2021), gender differences are increasingly recognized in diabetes management, with female patients often requiring more attention due to physiological and hormonal differences that affect diabetes progression and treatment response.

Table I. Age Characteristics Of Patients With Type II Diabetes Mellitus Treated with Oral Hypoglycemic Drugs (OHO) + Insulin Degludec-Aspart vs Insulin Degludec-Aspart

Characteristics		Drug Therapy	
		OHO + insulin degludec-aspart	**Insulin deglude c-aspart**
Gender	Male (%)	30,3	24,24
	Female (%)	69,7	75,75
Age (Year)	25 - 44	12,1	3,0
	45 - 54	24,2	9,1
	55 - 65	30,3	33,3
	66 - 74	27,3	42,4
	75 - 90	6,1	12,1
Total		33	33

Description: Oral Hypoglycemic Drugs (OHO)

Table II. Use of Oral Hypoglycemic Drugs (OHO)

Radar	Drug Therapy	Difference $\bar{x} \pm SD$
HbA1c (%)	OHO + degludec -aspart	1.565± 1.10
	degludec -aspart	1.05± 0.74

Table III. Mean Difference in HbA1c Reduction of Type II Diabetes Mellitus Patients Treated with Oral Hypoglycemic Drugs + Insulin Degludec-Aspart vs Insulin Degludec-Aspart

Type of Insulin	OHO	Number of patients
Combination Decludec+Aspart	Metformin	24
Combination Decludec+Aspart	Acarbose	5
Combination Decludec+Aspart	Gliquidone	1
Combination Decludec+Aspart	Glimepiride	3

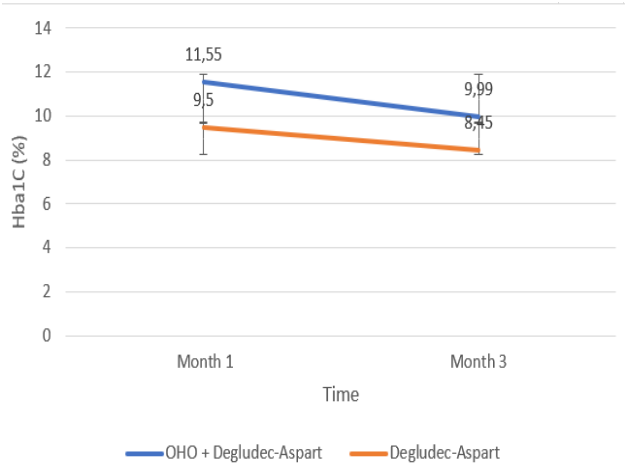

Figure 1. Graph of The Average Value of HbA1c Levels at Month 1 and Month 3

Based on the Table II, for the average HbA1c of type II diabetes mellitus patients with combined therapy of oral hypoglycemic drugs (OHO) and insulin degludec-aspart, the *pre-test* is 11.55% and the *post-test* is 9.985% with a difference of 1.565%. Meanwhile, the average HbA1c of insulin degludec-aspart for the *pre-test* is 9.5% and the *post-test* is 8.45% with a difference of 1.05%. The characteristics of type II diabetes mellitus patients based on age show that most of the samples are aged 66 - 74 years with a percentage of 34.8%. The findings of this study are consistent with those of Wikannanda et al. (2023), who reported that the majority of participants were over the age of 45. This is attributed to age-related degenerative processes, such as the decline in pancreatic beta-cell function and reduced insulin secretion. It also tends to be more prone to obesity and increased visceral fat levels which increase the risk of type II diabetes mellitus. Decreased body functions such as the pancreas in producing insulin, which can cause the risk of developing diabetes to increase 6x greater at the age of > 45 years.

In this study, the most widely used combination therapy was metformin - insulin degludec-aspart, metformin was most widely used with 24 patients compared to other oral hypoglycemic drugs such as *acarbose* (5), glimepiride (3) and gliquidone (1) to be combined with insulin degludec-aspart. This is because metformin is the most commonly

prescribed oral drug and is still the first line of monotherapy in patients with type II diabetes mellitus worldwide. Metformin is a biguanid class with a mechanism of action that increases the body's sensitivity to insulin. Metformin has minimal side effects without triggering hypoglycemia and weight gain (Wikannanda *et al* ., 2023). Similarly, Kim et al. (2014) found that the combination of glimepiride/metformin resulted in significantly better glycemic control compared to uptitration of metformin monotherapy in patients inadequately controlled on low-dose metformin, supporting the efficacy of combination therapy in improving long-term diabetes management.

Data on the average HbA1c of type II diabetes mellitus patients with combination therapy of oral hypoglycemic drugs (OHO) and insulin degludec-aspart with the *pre-test* results of 11.55% and the *post-test* of 9.985% with a difference of 1.565%. The average HbA1c *post-test* was significantly lower than the average *pre-test*. Similarly, the average HbA1c of insulin degludec-aspart for the *pre-test* was 9.5% and the *post-test* was 8.45% with a difference of 1.05%. The average HbA1c in the *post-test* was significantly lower than the *pre-test* average. The purpose of analyzing pre and post in both groups is to assess the change in HbA1c levels in type II diabetes mellitus patients after using ryzodeg insulin monotherapy or a combination of ryzodeg insulin and OHO.

The mean HbA1c reduction was greater in the group receiving combined oral hypoglycemic agents and insulin degludec-aspart compared to the monotherapy group, suggesting superior glycemic control with combination therapy. This finding is consistent with the results of Moon et al. (2021), who demonstrated that insulin degludec/insulin aspart therapy not only provided superior control of HbA1c levels but also significantly reduced the incidence of hypoglycemia when compared to conventional premixed insulin or basal insulin therapies, further supporting the efficacy of combination therapy in achieving better glycemic control in patients with type 2 diabetes. This may be attributed to the fact that combining insulin with oral hypoglycemic agents enhances insulin sensitivity, thereby improving its effectiveness in maintaining stable blood glucose levels.

In the data analysis Table III, using the *Shapiro-Wilk* normality test, it was found that the significance value in testing HbA1c data with combination therapy of oral hypoglycemic drugs and insulin degludec-aspart for *pre-test* is 0.060 and post-test is 0.060, each exceeding 0.05. This can be interpreted that the data from

the study were normally distributed and continued with the paired sample t-test. Analysis of the paired sample t-test using SPSS obtained results for HbA1c on oral hypoglycemic drug therapy and insulin degludec-aspart 2-tailed significance value is 0.000. The data has a 2-tailed sig value of < 0.05, which means that the use of therapy has an influence on reducing HbA1c in patients with type II diabetes mellitus. In line with the average HbA1c which decreased after using degludec-aspart insulin therapy and oral hypoglycemic drugs .

Normality testing using the Shapiro-Wilk method for the insulin degludec-aspart monotherapy group produced significance values of 0.111 (pre-test) and 0.368 (post-test), both exceeding the 0.05 threshold, indicating that the data follow a normal distribution. A paired sample t-test was subsequently performed, revealing a two-tailed significance value of 0.000 for HbA1c levels following insulin degludec-aspart therapy, indicating a statistically significant reduction in HbA1c among type II diabetes mellitus patients. In line with the average HbA1c which decreased after using degludec-aspart insulin therapy.

To assess the difference in HbA1c levels between patients receiving a combination of oral hypoglycemic agents and insulin degludec-aspart versus those receiving insulin degludec-aspart monotherapy, an Independent Sample T-test was utilized. Prior to this, a normality test confirmed that both groups had normally distributed post-test HbA1c data, with significance values of 0.060 for the combination therapy group and 0.368 for the monotherapy group. A homogeneity test was then conducted, yielding a significance value of 0.127, which exceeded the 0.05 threshold, indicating that the data were homogeneous. These conditions allowed for the application of a parametric test. The Independent Sample T-test, assuming equal variances, produced a two-tailed significance value of 0.001. This result demonstrates a statistically significant difference in HbA1c levels between the two treatment groups, suggesting that the combination therapy is more effective in lowering HbA1c levels in patients with type II diabetes mellitus compared to insulin degludec-aspart monotherapy, as observed at Ulin Banjarmasin Hospital.This is due to the ability of insulin therapy to control post-preprandial glucose while oral therapy is able to control fasting blood glucose, so that glucose is controlled at all times. Oral therapy also helps improve insulin sensitivity so that insulin works very well. This finding is consistent with prior research by Timur et al. (2024), which showed no significant difference in

glycemic profiles (HbA1c and RBG) between the metformin–insulin and metformin–vildagliptin combinations, with $p > 0.05$. Additionally, Wahyuni et al. (2019) highlighted that diabetes education interventions can play a crucial role in improving the management and treatment outcomes of diabetes.

IV.CONCLUSION

The comparison of HbA1c levels between patients with type II diabetes mellitus treated with oral hypoglycemic agents plus insulin degludec-aspart and those treated with insulin degludec-aspart alone showed no significant difference ($p > 0.05$).

CONFLICT OF INTEREST

There is no conflict of interest in this research.

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