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Insulin Glargine 100 Units/mL Alone or in Combination with Short-Acting Insulin in the Management of Uncontrolled Type 2 Diabetes Mellitus: A Prospective Real-Life Study from Egypt (DIAMOND)

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Abstract

Background: Recent reports reveal growing evidence of the effectiveness of insulin glargine (Lantus®), a long-acting human insulin analogue, in the management of poorly controlled type 2 diabetes mellitus (T2DM). In the present real-life study.

Aim of the Study: To investigate the safety and efficacy of insulin glargine in treating patients with T2DM that are poorly controlled on oral anti-diabetic drugs (OADs).

Subjects and Methods: In this prospective observational study conducted in Egypt from 2014 to 2016, a total of 1008 people with poorly controlled T2DM were enrolled, and for whom the investigator decided to prescribe insulin glargine with or without short-acting insulin. The decision of adding-on OADs or short-acting insulin was left to the investigators to reflect the "in-practice" approach. Patients were followed up for six months and efficacy and safety outcomes were measured throughout the study period. The primary efficacy endpoint was the change in HbA1c levels from the baseline to the final visit.

Results: At the end of follow-up, the mean HbA1c levels decreased significantly from 9.6±1.3% at the baseline to 7.3±0.9% (p<0.00 1). After three months of treatment, 10.2% of the patients achieved the targeted HbA1c ≤7%, and 1.6% of the patients achieved HbA1c ≤6.5%. At sixth months, 34.8% of the patients achieved the targeted HbA1c ≤7%, and 10.7% of the patients achieved HbA1c ≤6.5%. The differences between patients receiving insulin glargine, with or without OADs, and patients receiving insulin glargine plus short-acting insulin were not statistically significant (p>0.05). A total of 17 hypoglycemia events (11 categorized as serious) and one hyperglycemic event were recorded.

Conclusion: Under real-world clinical practice insulin glargine 100U/ml as add-on to OADs, or in combination with prandial insulin, demonstrated a good efficacy and safety profile in people with T2DM uncontrolled previous on OAD therapy.

Key Words: *Insulin glargine – Hypoglycemia – T2DM – Add on Therapy.*

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Introduction

WITH the recent increase in the prevalence of risk factors like obesity and aging, the prevalence of type 2 diabetes mellitus is increasing globally [1]. Although the main lines in the management of T2DM consist of lifestyle modification and oral antidiabetic drugs (OADs), a recent clinical trend of adding insulin to OADs, or even replace OADs with insulin, in poorly controlled T2DM patients has emerged recently [2,3]. Early introduction of insulin therapy can significantly reduce the rate of decline of pancreatic islet B cells and minimize the risk of complications [4]. However, the associated risk of hypoglycaemia with insulin therapy remains a major challenge in managing T2DM; in particular, nocturnal hypoglycaemia due to plasma insulin peaks was previously described with NPH insulin [5,6].

Insulin glargine 100U/mL (Lantus®) is a long-acting basal human insulin analogue which reportedly shows no remarkable plasma insulin peaks, and physiologically mimics the normal basal insulin concentrations [7]. In previous reports, insulin glargine was an effective agent in controlling the hyperglycemic status and achieved a target HbA1c level of less than 7.0% in patients with poorly controlled T2DM [8]. In addition, insulin glargine reduced the risk of hypoglycaemia, especially nocturnal hypoglycaemia [9]. Compared to NPH insulin, insulin glargine was superior in controlling

glycemic status and reducing the risk of hypoglycaemia among insulin-naïve patients with T2DM [10]. Insulin glargine showed the same effect of the long-acting insulin detemir in controlling the glycemic status of patients with T2DM, as well [11].

Despite the worldwide consensus recommendations, the published literature lacks real-life data about the safety and effectiveness of insulin glargine in the management of poorly controlled T2DM patients in Egypt. In this regards, the present study aimed to evaluate the safety and efficacy of initiating insulin glargine in Egyptian patients with poorly controlled T2DM on OADs or switching T2DM patients uncontrolled on premixed insulin to insulin glargine plus short-acting insulin, with or without OADs.

Subjects and Methods

We followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology Statement) guidelines (Supplementary file no. 1) during the preparation of this prospective cohort study [12].

In the present observational, multi-center, prospective study, we included randomly selected consultant physicians according to their specialties (Diabetologists or Internists). Physician was asked to include ten consecutive patients (5 uncontrolled on OADs & 5 uncontrolled on premixed insulin) during a six months recruitment period. Adult patients with poorly controlled T2DM were included if they fulfilled the following criteria: (1) Poorly controlled patients on OADs or premixed insulin with previous stable treatment of at least 3 months, (2) Patients whose physicians decided to add insulin glargine to OADs (basal insulin only regimen) or to switch patients on premixed to basal-bolus regimen with insulin glargine and short-acting insulin, and (3) Patients who did not have any permanent contraindications insulin glargine. We excluded patients with previous treatment with basal insulin (insulin Glargine or NPH insulin) and patients with severe hepatic or renal disorders.

The dosing regimens and the need to add insulin or other medications were left to the investigators to reflect the real-life practice.

For every participant, demographic characteristics and medical history were collected. The primary efficacy endpoint was the change in HbA1c from baseline to six months after the introduction of insulin glargine 100U/mL.

Safety outcomes were measured throughout the course of treatment. All adverse events, whether related to insulin glargine or not, were recorded from the first day of insulin administration. The seriousness of the adverse events and corrective medications needed were also monitored. The study was conducted in full accordance with the guidelines for Good Clinical Practice and the Declaration of Helsinki, and data for each patient were collected only after obtaining that patient's signed written data release forms.

Data entry, verification, and validation were carried out using standard computer software. A double-entry method was used to ensure that the data were transferred accurately from the case report forms to the database. Data were analyzed using the software, Statistical Package for Social Science (SPSS Inc. Released 2009, PASW Statistics for Windows, version 18.0; SPSS Inc., Chicago, Illinois, USA), then processed and tabulated. Frequency distribution with its percentage and descriptive statistics with mean and standard deviation were calculated. Chi-square, *t*-test, correlations were done whenever needed. *p*-values of less than 0.05 were considered statistically significant.

Results

At the study entry, a total of 1008 patients from Egypt with T2DM, for whom the investigator decided to prescribe insulin glargine with or without short-acting insulin, were included. Out of the 1008 enrolled patients, 14 patients were excluded due to maintenance therapy on premixed insulin, three patients were excluded as they were already treated with basal insulin at study entry, and one patient was excluded due to missing data for baseline insulin. Eventually, the statistical analysis consisted of 990 participants; 518 patients received insulin glargine (basal insulin only regimen) with/without OADs, and 472 patients received insulin glargine plus short-acting insulin (basal-bolus regimen), with or without OADs.

The mean age of the included patients was 52.7 ± 9.8 years with a BMI of $31.8 \pm 5.5 kg/m^2$. Slightly more than half (52.8%) of the patients were males and only 4.8% were illiterate. The mean duration of disease was 9.7 ± 5.9 years with less than half (42.7%) of patients reported a positive family history of diabetes. About 63% of the patients had complications associated with T2DM; these complications were mainly nervous system disorders (53.3%), cardiac disorders (41.7%), renal disorders (22.3%), and eye disorders (17.7%),

while 55.5% of the patients had medical or surgical complications rather than diabetes. Only 0.8% of patients were prescribed to short-acting insulin prior to their enrollment in the present study, while a high half of the patients were instructed to premixed insulin. Prior to the baseline visit, metformin was used by 453 (45.8%) patients, and glimepiride was used by 408 (41.2%) patients (Table 1).

Table (1): Baseline characteristics of the participating patients.

Characteristics	Frequency, (%)
Age (Mean ± SD) years	52.7±9.8
Sex:	
Male	523 (52.8)
Female	467 (47.2)
BMI (Mean ± SD) kg/m2	31.8±5.5
Residence:	
Rural	100 (10.1)
Urban	83 1 (83.9)
Suburban	59 (6.0)
Educational Level:	
Illiterate	48 (4.8)
Elementary Education	384 (38.8)
Higher Education	558 (56.4)
Duration (Mean ± SD) years	9.7±5.9
Positive Family History	423 (42.7)
Diabetes-related Complications	627 (63.3)
Prior Hypoglycemia	103 (10.4)
Medical or Surgical History	574 (58.0)
Prescribed to Short/Rapid-acting Insulin before the Baseline Visit	8 (0.8)
Prescribed to Premixed Insulin before the Baseline Visit	445 (44.9)
Prescribed to Glimepiride before the Baseline Visit	408 (41.2)
Prescribed to Metformin before the Baseline Visit	453 (45.8)
Smoking Habits:	
Never	612 (61.8)
Current	213 (21.5)
Former	165 (16.7)

After six months of treatment, the mean HbA1C was 7.3±0.8% in basal insulin regimen group and 7.4±1% in basal-bolus regimen group. The difference between the two groups was not statistically significant (p>0 .05; Fig. 1). However, when both groups were combined, the baseline mean HbA1c levels decreased significantly from 9.6± 1.3% to 8.0± 1.0% at the third month, and to 7.3±0.9% at the end of the sixth month follow-up (p<0.001).

Notably, only 10.4% in the basal insulin regimen group and 9.9% in the basal-bolus regimen achieved the targeted HbA1c level ≤7% after three months of treatment (p=0.339). After six months of treatment, 36.4% in the basal insulin regimen group and 33% in the basal-bolus regimen achieved the targeted HbA1c level ≤7% (p=0.272); while 11.2% and 10.2% in the basal insulin regimen group and in the basal-bolus regimen, respectively, achieved HbA1c level ≤6.5%. (Fig. 1).

A total of 17 hypoglycemia (basal insulin only regimen=6 patients and basal-bolus regimen=11 patients; p=0.234) and one hyperglycemia events were recorded. Of the 17 hypoglycemia events, 11 events were categorized as serious adverse events.

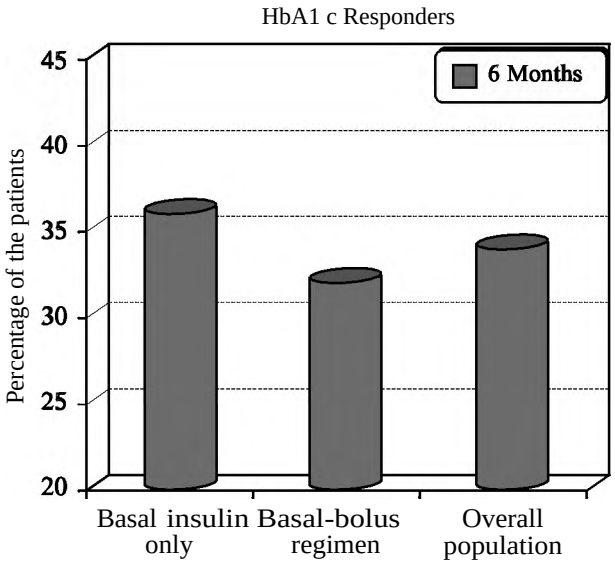

Fig. (1): Response of the participating patients to treatment after 3 and 6 Months.

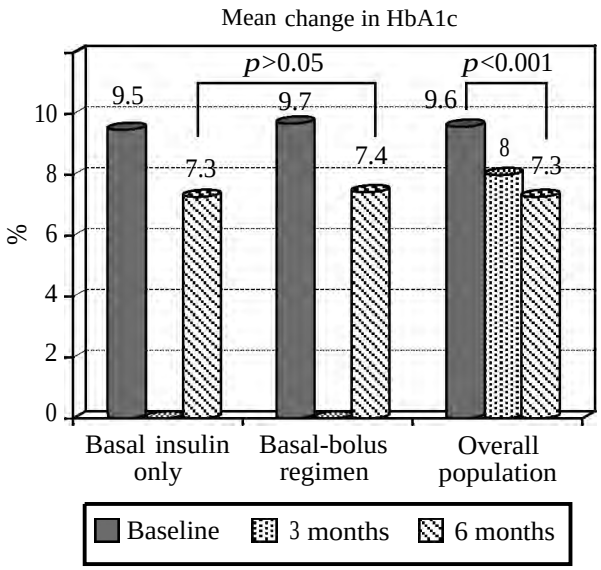

Fig. (2): Mean change in HbA1c after 3 and 6 months of treatments.

Discussion

In the present prospective, real-life, study, poorly controlled T2DM patients showed a clinically significant reduction in HbA1c levels after six months of treatment with insulin glargine (p<0.001). However, there was no statistically significant difference between basal insulin only regimen and basal-bolus regimen in terms of HbA1c reduction throughout the treatment period (7.3 ± 0.8% vs. 7.4±1%, respectively, p>0.05). Regarding safety outcomes, Only17 hypoglycemic events were reported throughout the study period, with only 11 events were categorized as serious adverse events.

In patients with poorly controlled T2DM, insulin glargine was previously reported to improve glycemic control and reduce the risk of hypoglycemic events. There is a growing body of evidence that supports the clinical and economic benefits of insulin glargine 100U/mL (Lantus®) in real-world settings **[13,14]**. Our real-life results showed a statistically significant reduction in HbA1c after six months of adding insulin glargine 100U/mL to either OADs or premixed insulin in poorly controlled T2DM patients. Thirty-four percent of the included patients achieved the targeted HbA1 c level (<7%) as well. In concordance with our findings, Chraibi and colleagues **[15]** reported a significant reduction in mean HbA1c level following six months of treatment with insulin glargine 100U/mL in Moroccan patients with poorly controlled T2DM; while 32% of the patients achieved the targeted HbA1c level (p<0.001). Another study reported that nearly 33% of T2DM reached the targeted HbA1c after 3-6 months of treatment with insulin glargine **[16]**.

Similarly, insulin glargine 100U/mL exhibited a greater reduction in HbA1c than NPH insulin among patients with T2DM, uncontrolled to NPH insulin, after 4-9 months of treatment in clinical practice in Spain **[17]**. Insulin-naïve patients showed similar results after six months of adding insulin glargine to the maximum tolerated dose of OADs **[18]**. The published literature shows the long-term beneficial effect of insulin glargine as well; Charbonnel and colleagues **[19]** reported that insulin glargine significantly increased the proportions of patients with HbA1c <7% to 39% in insulin naïve patients and 34% in insulin-treated patients, following 12 months of treatment. Another study reported that insulin glargine plus OADs significantly reduced HbA1c after 9 months of treatment **[20]**. Insulin glargine was reported to be a more cost-effective treatment option than premixed insulin as well **[21]**.

Although the basal-bolus insulin regimen is expected to achieve better glycaemic control than the basal insulin only regimen **[22]**, our findings showed no statistically significant difference between basal insulin regimen and basal-bolus regimen in terms of HbA1c at the end of follow-up. This may be attributed to the statistically significant higher HbA1c values in basal-bolus regimen group than basal insulin only group at study entry and the gradual titration of insulin dose in the basal insulin only group by a mean of 3.8 units. Siegmund and colleagues reported that the titration of the long-acting basal insulin is as safe and effective as adding a rapid-acting insulin analogue **[23]**. Another report showed no statistically significant difference between intensified insulin glargine only regimen and basal-bolus regimen in terms of HbA1c after six months of treatment **[24]**.

Hypoglycaemia is a major concern during the management of T2DM patients, especially with add-on therapies **[25]**. Both insulin and many of the OADs were reported to be associated with increased risk of hypoglycaemic events **[26]**. In the present trial, only 11 (1.1%) serious hypoglycaemic events, out of a total of 17 events, were recorded. Previous clinical trials showed that insulin glargine 100u/mL exhibited a well-tolerable safety profile with a lower risk of hypoglycaemia than intermediate-acting human insulin preparations **[27]**. In addition, insulin glargine was associated with low rate of hypoglycaemic events in the real-practice setting. Hanefeld et al., reported that only 2.45%, of the poorly controlled T2DM patients, experienced hypoglycaemic events after six months of treatment **[28]**. Another report showed a slightly higher rate of hypoglycaemic events (6. 1% of T2DM patients who received insulin glargine for six months) **[29]**.

In conclusion, the present observational study shows that insulin glargine was an effective add-on therapy in the management of Egyptian patients with poorly controlled T2DM. In addition, insulin glargine exhibited well-tolerable safety profile with a low rate of hypoglycemic events. Further studies are required to characterize the patients who were able to achieve the HbA1 c level and those who did not.

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Authors' COI:

The author has no conflicts of interest to declare.

References

1- DANAEI G., FINUCANE M.M., LU Y., SINGH G.M., COWAN M.J., PACIOREK C.J., et al.: National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: Systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2·7 million participants. Lancet, 378 (9785): 31-40, 2011.

2- SINCLAIR A.J.: A Desktop Guide for the Management of Non insulin dependent Diabetes Mellitus (NIDDM) by the European NIDDM Policy Group. Vol. 12, Diabetic Medicine, p. 724-724, 1995.

3- Introduction: The American Diabetes Association's (ADA) evidence-based practice guidelines, standards, and related recommendations and documents for diabetes care. Diabetes care, 35 Suppl 1, 2012.

4- PHILIS-TSIMIKAS A.: Tolerability, safety and adherence to treatment with insulin detemir injection in the treatment of type 2 diabetes. Vol. 2, Patient Preference and Adherence, p. 323-32, 2008.

5- MCCRIMMON R.J. and FRIER B.M.: Hypoglycaemia, the most feared complication of insulin therapy. Diabete Metab., 20 (6): 503 -12, 1994.

6- WALLIA A. and MOLITCH M.E.: Insulin Therapy for Type 2 Diabetes Mellitus. JAMA [Internet], 311 (22): 23 15 . Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2014.5951, 2014.

7- LEPORE M., PAMPANELLI S., FANELLI C., PORCELLATI F., BARTOCCI L., VINCENZO A. DI, et al.: Pharmacokinetics and pharmacodynamics of subcutaneous injection of long-acting human insulin analog glargine, NPH insulin, and ultralente human insulin and continuous subcutaneous infusion of insulin lispro. Diabetes, 49 (12): 2142-8, 2000.

8- HEINEMANN L., LINKESCHOVA R., RAVE K., HOMPESCH B., SEDLAK M. and HEISE T.: Time-action profile of the long-acting insulin analog insulin glargine (HOE901) in comparison with those of NPH insulin and placebo. Diabetes Care, 23 (5): 644-9, 2000.

9- OWENS D.R., COATES P.A., LUZIO S.D., TINBERGEN J.P. and KURZHALS R.: Pharmacokinetics of 125I-labeled insulin glargine (HOE 901) in healthy men: Comparison with NPH insulin and the influence of different subcutaneous injection sites. Diabetes Care, 23 (6): 813-9, 2000.

10- ROSENSTOCK J., SCHWARTZ S.L., CLARK C.M., PARK G.D., DONLEY D.W. and EDWARDS M.B.: Basal insulin therapy in type 2 diabetes: 28-week comparison of insulin glargine (HOE 901) and NPH insulin. Diabetes Care [Internet]. 24 (4): 631-6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/11315821, 2001.

11- SWINNEN S.G., DAIN M.P., ARONSON R., DAVIES M., GERSTEIN H.C., PFEIFFER A.F., et al.: A 24-week, randomized, treat-to-target trial comparing initiation of insulin glargine once-daily with insulin detemir twice-daily in patients with type 2 diabetes inadequately controlled on oral glucose-lowering drugs. Diabetes Care, 33 (6): 1176-8, 2010.

12- ELM E. VON, ALTMAN D.G., EGGER M., POCOCK S.J., GØTZSCHE P.C., VANDENBROUCKE J.P., et al.: The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for reporting observational studies*. Int. J. Surg., 12 (12): 1495-9, 2014.

13- WANG L., WEI W., MIAO R., XIE L. and BASER O.: Real-world outcomes of US employees with type 2 diabetes mellitus treated with insulin glargine or neutral protamine Hagedorn insulin: A comparative retrospective database study. BMJ Open, 3 (4), 2013.

14- BASER O., TANGIRALA K., WEI W. and XIE L.: Real-world outcomes of initiating insulin glargine-based treatment versus premixed analog insulins among US patients with type 2 diabetes failing oral antidiabetic drugs. Clin. Outcomes Res., 5 (1): 497-505, 2013.

15- GARBER A.J., KING A.B., DEL PRATO S., SREENAN S., BALCI M.K., MUÑOZ-TORRES M., et al.: Insulin degludec, an ultra-longacting basal insulin, versus insulin glargine in basal-bolus treatment with mealtime insulin aspart in type 2 diabetes (BEGIN Basal-Bolus Type 2): A phase 3, randomised, open-label, treat-to-target non-inferiority trial. Lancet, 379 (9825): 1498-507, 2012.

16- FLORENȚIU A. and DIMA I.: Lantus solostar in real life medical practice. Rom J Diabetes Nutr Metab Dis [Internet]. Mar 1 [cited 2018 Jan 12]; 21 (1): 9-15. Available from: https://www.degruyter.com/view/j/rjdnmd.2014.21.issue-1/rjdnmd-2014-0002/rjdnmd-2014-0002.xml, 2014.

17- DELGADO E.: Outcomes with insulin glargine in patients with type 2 diabetes previously on NPH insulin: Evidence from clinical practice in Spain. Int. J. Clin. Pract., 66 (3): 281-8, 2012.

18- HAJOS T.R.S., POUWER F., DE GROOTH R., HOLLEMAN F., TWISK J.W.R., DIAMANT M., et al.: Initiation of insulin glargine in patients with Type 2 diabetes in suboptimal glycaemic control positively impacts health-related quality of life. A prospective cohort study in primary care. Diabet Med [Internet]. 28 (9): 1096-102. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21845401, 2011.

19- CHARBONNEL B., ESCHWÈGE E., CHARPENTIER G., VIALETTES B., CHABRIER G., POUCHAIN D., et al.: Insuline glargine en conditions réelles d'utilisation en France: Étude observationnelle menée sur une large population de patients diabétiques de type 1 et de type 2. Med des Mal Metab., 4 (2): 169-78, 2010.

20- SCHREIBER S.A., FERLINZ K. and HAAK T.: The Long-Term Efficacy of Insulin Glargine Plus Oral Antidiabetic Agents in a 32-Month Observational Study of Everyday Clinical Practice. Diabetes Technol Ther [Internet]. 10(2):121-7. Available from: http://online. liebertpub.com/doi/abs/10.1089/dia.2007.0265, 20 08 .

21- LEVIN P.A., ZHANG Q., MERSEY J.H., LEE F.Y., BROMBERGER L.A., BHUSHAN M., et al.: Glycemic Control With Insulin Glargine Plus Insulin Glulisine Versus Premixed Insulin Analogues in Real-World Prac-

tices: A Cost-Effectiveness Study With a Randomized Pragmatic Trial Design. Clin. Ther., 33 (7): 841-50, 2011.

22- ABRAHAMSON M.J. and PETERS A.: Intensification of insulin therapy in patients with type 2 diabetes mellitus: An algorithm for basal-bolus therapy. Vol. 44, Annals of Medicine, p. 836-46, 2012.

23- SIEGMUND T., PFOHL M., FORST T., PSCHERER S., BRAMLAGE P., FOERSCH J., et al.: Titration of basal insulin or immediate addition of rapid acting insulin in patients not at target using basal insulin supported oral antidiabetic treatment - A prospective observational study in 2202 patients. Diabetes Metab Syndr Clin. Res. Rev., 11(1): 51-7, 2017.

24- PFOHL M., SIEGMUND T. , PSCHERER S., PEGELOW K. and SEUFERT J.: Effectiveness and tolerability of treatment intensification to basal-bolus therapy in patients with type 2 diabetes on previous basal insulin-supported oral therapy with insulin glargine or supplementary insulin therapy with insulin glulisine: The PARTNER observational study. Vasc. Health Risk Manag, 11: 569-78, 2015.

25- CRYER P.E.: Hypoglycemia in Diabetes. Pathophysiology, Prevalence and Prevention [Internet]. American Diabetes Association. 45-95 p. Available from: http://www. amazon.com/Hypoglycemia-Diabetes-Pathophysiology-Prevalence-Prevention/dp/1580403263%5Cnhttps: //scholar.google.co.uk/scholar?q=Hypoglycemia+in+Diabetes.+Pathophysiology%2C+Prevalence+and+Prevention&btnG=&hl=en&as_sdt=0%2C5#0, 2009.

26- CHAUDHURY A., DUVOOR C., REDDY DENDI V.S., KRALETI S., CHADA A., RAVILLA R., et al.: Clinical review of antidiabetic drugs: Implications for type 2 diabetes mellitus management. Vol. 8, Frontiers in Endocrinology, 2017.

27- RIDDLE M.C., ROSENSTOCK J. and GERICH J.: The Treat-to-Target Trial: Randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care, 26 (11): 3080-6, 2003.

28- HANEFELD M., FLEISCHMANN H., LANDGRAF W. and PISTROSCH F. EARLY study: Early basal insulin therapy under real-life conditions in type 2 diabetics. Diabetes, Stoffwechsel und Herz, 21 (2): 91-7, 2012.

29- FIESSELMANN A., WIESNER T., FLEISCHMANN H. and BRAMLAGE P.: Real-world therapeutic benefits of patients on insulin glargine versus NPH insulin. Acta. Diabetol., 53 (5): 717-26, 2016.

الانسولين جلارچين ١٠٠ وحدة/مل وحدة أو بمصاحبة الانسولين قصير المفعول فى إدارة علاج مرضى السكر من النوع الثانى غير المنضبط دراسة واقعية من المستقبل

الخلفية: تكشف تقارير حديثة عن وجود أدلة متزايدة حول فعالية أنسولين جلارجين (لانتوس®)، وهو نظير للأنسولين البشرى طويل المفعول، فى علاج مرض السكرى من النوع ٢ غير المتحكم به بشكل جيد. فى الدراسة الفعلية القائمة، كان هدفنا هو التحقق من أمان وفعالية أنسولين جلارجين فى علاج المرضى الذين يعانون من مرض السكرى من النوع ٢ غير المتحكم به بشكل جيد بإستخدام أدوية علاج مرض السكرى الفموية.

المشاركون وأساليب العلاج: فى هذه الدراسة الرصدية الاستطلاعية التى تم إجراؤها فى مصر منذ عام ٢٠١٤ إلى ٢٠١٦، تم إلحاق إجمالى ١٠٠٨ أشخاص مصابين بمرض السكرى من النوع ٢ غير المتحكم به بشكل جيد، والذين قرر الباحث أن يصف لهم أنسولين جلارجين مع الأنسولين قصير المفعول أو بدونه. تم ترك قرار أضافة أدوية علاج مرض السكرى الفموية أو الأنسولين قصير المفعول إلى الباحثين ليعكس النهج فى الممارسة العملية. تمت متابعة المرضى لمدة ستة أشهر وتم قياس نتائج الفعالية والأمان على مدار فترة الدراسة. كانت نقطة نهاية الفعالية الأساسية هى التغيير فى مستويات نسبة الهيموجلوبين السكرى من بدء الدراسة إلى الزيارة النهائية.

النتائج: فى نهاية المتابعة، انخفض متوسط نسبة مستويات الهيموجلوبين السكرى بشكل ملحوظ من ٩.٦±١.٣٪ عند بدء الدراسة إلى ٧.٣±٠.٩٪ (القيمة الاحتمالية < ٠.٠٠١). بعد ثلاثة أشهر من العلاج، وصل ١٠.٢٪ من المرضى إلى النسبة المستهدفة للهيموجلوبين السكرى ≤ ٧٪، ووصل ١٠.٦٪ من المرضى إلى مستوى الهيموجلوبين السكرى الذى يبلغ ≤ ٦.٥٪. بعد ستة أشهر، وصل ٣٤.٨٪ من المرضى إلى النسبة المستهدفة للهيموجلوبين السكرى والتى تبلغ ≤ ٧٪، ووصل ١٠.٧٪ من المرضى إلى مستوى الهيموجلوبين السكرى الذى يبلغ ≤ ٦.٥٪. لم تكن الاختلافات بين المرضى الذين يتلقون أنسولين جلارجين، مع أو بدون مضادات مرض السكرى الفموية، والمرضى الذين يتلقون أنسولين جلارجين إلى جانب الإنسولين قصير المفعول ذات دلالة إحصائية (القيمة الاحتمالية < ٠.٠٥). تم تسجيل إجمالى ١٧ حالة من حالات نقص السكر بالدم (تم تصنيف ١١ حالة على أنها خطيرة) وحالة واحدة من الإصابة بفرط سكر الدم.

الاستنتاج: فى ظل الممارسة السريرية الفعلية، أظهر أنسولين جلارجين ١٠٠ وحدة/مللى لتر كعلاج مضاف لأدوية علاج مرض السكرى الفموية، أو بمصاحبة الأنسولين أثناء الوجبات، فعالية جيدة وملف أمان جيد فى الأشخاص المصابين بمرض السكرى من النوع ٢ غير المتحكم به سابقاً بإستخدام أدوية علاج مرض السكرى الفموية.