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Insulin Glargine U-300 in Type 1 Diabetes Mellitus: Single-Center Experience

Tip 1 Diabetes Mellitus'ta İnsülin Glargin U-300: Tek Merkez Deneyimi

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ABSTRACT

Aim: This study aimed to evaluate the clinical outcomes of switching from first-generation basal insulins to insulin glargine U-300 (Gla-300) in individuals with type 1 diabetes mellitus (T1DM) under real-world conditions.

Materials and Methods: A retrospective analysis was conducted on 46 adult patients with T1DM who switched to Gla-300 due to frequent hypoglycemia or inadequate glycemic control. HbA1c, fasting plasma glucose (FPG), daily injection frequency, insulin dose, and hypoglycemia rates were evaluated over a 12-month period.

Results: A significant reduction in HbA1c (from 8.45±1.27% to 7.83±1.01% at 3 months, p<0.001) and FPG levels was observed. Injection frequency decreased, particularly in patients previously on detemir or neutral protamine hagedorn. Despite a statistically significant increase in basal insulin dose over time, the frequency of all hypoglycemia subtypes declined, with the most prominent reduction in nocturnal hypoglycemia (p<0.001). No severe hypoglycemia occurred after the third month. No cases of ketosis or hospitalizations were reported. The majority of improvements occurred within the first 3 months and were maintained throughout the follow-up.

Conclusion: In real-life clinical practice, switching to Gla-300 provided improved glycemic control and reduced hypoglycemia risk in adults with T1DM, particularly in those previously using multiple daily injections. Considering the limited national data and frequent use of older basal insulins in Türkiye, these findings support the potential value of Gla-300 as an alternative option in individualized treatment planning for T1DM.

Keywords: Type 1 diabetes mellitus, glargine U-300, hypoglycemia, basal insulin, real-world evidence

ÖZ

Amaç: Bu çalışmanın amacı, birinci nesil bazal insülinlerden insülin glargin U-300 (Gla-300)'e geçiş yapılan tip 1 diabetes mellitus (T1DM) hastalarında, gerçek yaşam koşullarında klinik sonuçları değerlendirmektir.

Gereç ve Yöntem: Hipoglisemi atakları ya da yetersiz glisemik kontrol nedeniyle Gla-300 tedavisine geçiş yapılan 46 erişkin T1DM hastası retrospektif olarak analiz edildi. HbA1c, açlık plazma glukozu (APG), günlük enjeksiyon sıklığı, insülin dozu ve hipoglisemi oranları 12 aylık takip süresince değerlendirildi.

Bulgular: HbA1c düzeylerinde anlamlı bir düşüş izlendi (%8,45±1,27'den %7,83±1,01'e; 3. ayda, p<0,001) ve APG düzeylerinde de belirgin bir azalma gözlendi. Özellikle daha önce detemir veya nötr protamin hagedorn kullanan hastalarda enjeksiyon sıklığı azaldı. Bazal insülin dozunda istatistiksel olarak anlamlı bir artış olmasına rağmen, tüm hipoglisemi alt tiplerinin sıklığında azalma görüldü; en belirgin düşüş ise gece hipoglisemilerinde saptandı (p<0,001). Üçüncü aydan sonra şiddetli hipoglisemiye rastlanmadı. Ketozis ya da hastaneye yatış gerektiren bir durum izlenmedi. İyileşmelerin büyük bölümü ilk 3 ay içerisinde gerçekleşmiş olup takip süresince korundu.

Sonuç: Gerçek yaşam koşullarında, Gla-300'e geçiş yapılan erişkin T1DM hastalarında glisemik kontrolde iyileşme ve hipoglisemi riskinde azalma sağlanmıştır. Bu fayda, özellikle günde birden fazla enjeksiyon uygulanan hastalarda daha belirgindir. Türkiye'de eski nesil bazal insülinlerin yaygın kullanımı ve ulusal veri eksikliği göz önüne alındığında, bu bulgular Gla-300'ün bireyselleştirilmiş tedavi planlamasında potansiyel bir alternatif olarak değerlendirilebileceğini desteklemektedir.

Anahtar Kelimeler: Tip 1 diabetes mellitus, glargin U-300, hipoglisemi, bazal insülin, gerçek yaşam verisi

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INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a clinical condition characterized by absolute insulin deficiency resulting from autoimmune or other causes leading to β-cell destruction[1]. The cornerstone of T1DM management consists of insulin therapy combining basal and preprandial short-acting insulin[1]. In recent years, basal insulin formulations have progressively evolved from intermediate-acting to long-acting and ultra-long-acting insulin analogs, aiming to improve fasting glucose control, reduce glycemic variability, and minimize the risk of hypoglycemia[2-3].

Although there have been significant therapeutic advancements, a substantial proportion of patients with T1DM continue to struggle with achieving recommended HbA1c targets, experience frequent glycemic fluctuations, and remain at risk of severe hypoglycemic episodes[4]. Furthermore, insulin regimen complexity, frequent injections, and fear of hypoglycemia negatively impact treatment adherence and decrease quality of life[5-6]. Thus, selecting basal insulin therapies capable of effectively addressing these clinical issues continues to represent a critical aspect of diabetes management[5].

Despite recent advancements, human intermediate-acting insulins [neutral protamine hagedorn (NPH)] insulin, detemir, and insulin glargine (Gla-100) remain widely used as basal insulin options for T1DM treatment in Türkiye, primarily due to established patient-physician habits, strong clinical evidence, and lower cost. Insulin glargine 300 U/mL (Gla-300), a long-acting basal insulin with distinct pharmacokinetic properties, represents a second-generation alternative, exhibiting different absorption and distribution characteristics compared to first-generation basal insulins[1].

As an ultra-long-acting basal insulin, Gla-300 has been increasingly utilized in diabetes management due to its prolonged duration of action, stable pharmacokinetic profile, and comparable glycemic efficacy with a lower risk of hypoglycemia compared to first-generation basal insulin analogs in individuals with T1DM[7-12]. However, real-world data on Gla-300 use in T1DM remain limited due to variations in patient populations, treatment protocols, and healthcare practices, particularly in Türkiye[13-15].

This study retrospectively evaluates the long-term efficacy of Gla-300 in T1DM patients transitioning from other basal insulins, analyzing one-year data on glycemic control, insulin requirements, and hypoglycemia risk in a single-center setting.

MATERIALS AND METHODS

The medical records of patients with T1DM who attended the diabetes outpatient clinic of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine between 2020 and 2023 were retrospectively analyzed.

Patients whose treatment was switched to Gla-300 and who had been on this therapy for at least one year were included in the present study. Additionally, only those who attended regular outpatient follow-ups, demonstrated full treatment adherence, and performed routine 7-point self-monitoring of blood glucose were enrolled. Individuals with type 2 diabetes, as well as those with type 1 diabetes who were insulin-naive, using an insulin pump, or not adhering to regular insulin use were not included in the study. The patients included in the study had C-peptide levels ≤0.20 nmol/L. Additionally, patients with acute coronary syndrome, acute cerebrovascular events, chronic liver disease, cancer, or those undergoing dialysis for end-stage renal disease were not included. Patients using glucose-elevating medications such as steroids, those with a history of alcohol or drug abuse, pregnant individuals, participants enrolled in another clinical trial, and non-compliant patients were also not included in the study. All participants were following a diabetic diet, as confirmed by their medical records.

The demographic and clinical characteristics of the patients, their current basal and bolus insulin types and doses, the number of basal insulin injections, as well as the reasons for treatment modification, were recorded from medical files. The changes in the daily number of insulin injections, basal insulin dose, fasting plasma glucose (FPG), HbA1c levels, and the occurrence of hypoglycemic episodes compared to the previous basal insulin regimen were retrospectively evaluated at the initiation of Gla-300 treatment, the third month, the sixth month, and one year.

Glycemic control was considered uncontrolled if HbA1c levels exceeded 8%. Hypoglycemia was defined based on ADA criteria as a blood glucose level of ≤70 mg/dL and/or the presence of symptoms requiring treatment with fast-acting carbohydrates or adjustments in glucose-lowering therapy[16]. Hypoglycemia

was classified as "mild" when the patient could self-manage the episode without assistance and "severe" when external help or medical intervention was required.

Hypoglycemic events occurring before and after the initiation of glargine U-300 were classified into three categories based on their occurrence in the last three months: nocturnal hypoglycemia, daytime hypoglycemia, and severe hypoglycemia. In follow-up assessments, the presence or absence of nocturnal, daytime, and severe hypoglycemia was recorded.

The study was approved by the local ethics committee of Cerrahpaşa Medical Faculty Dean's Office Clinical Research

Ethics Committee (decision no: 192547, date: 17.12.2019) the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice principles.

Statistical Analysis

Statistical analyses were performed using SPSS Version 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation for normally distributed data and median (minimum-maximum) for non-normally distributed data, while categorical variables were presented as numbers and percentages. Normality was assessed using the Shapiro-Wilk test and skewness-kurtosis values. For group comparisons, the Student's t-test was used for normally distributed data, while the Mann-Whitney U test was applied for non-normally distributed data. Categorical variables were analyzed using the Fisher's exact test or Pearson's chi-square test, as appropriate. For repeated measurements, Repeated Measures ANOVA was used, and the LSD post-hoc test was applied when needed. The median values of quantitative variables were determined as cut-off points and added into the model. A p-value<0.05 was considered indicative of statistical significance. A p-value<0.05 was considered statistically significant.

RESULTS

Forty-six patients with T1DM were enrolled in the study. The mean duration of diabetes was 20.67±7.22 (4-36) years. The demographic and clinical characteristics of participants are presented in Table 1.

Table 1. Demographic and clinical characteristics of participants (n=46)

Variable	Value
Age mean ± SD	34.22±7.98
Sex n (%)	
Female	25 (54.3)
Male	21 (45.7)
Weight (kg) mean ± SD	64.3±10.9
BMI (kg/m²) mean ± SD	24.5±7.7
Macrovascular complications, n (%)	2 (4.3)
Microvascular complications, n (%)	
Nephropathy	4 (8.7)
Retinopathy	5 (10.9)
Neuropathy	3 (6.5)
Fasting blood glucose (mg/dL) mean ± SD	217.28±77.4
HbA1c (%) (mmol/mol) Mean ± SD	8.45±1.27

SD: Standard deviation, BMI: Body mass index

At baseline, all participants were receiving a basal-bolus insulin regimen, and none were on oral antidiabetic agents. The distribution of basal insulins used at study initiation is presented in Table 2. Before the initiation of the study, 56.5% of the patients (n=26) were on once-daily basal insulin regimens, while 43.5% (n=20) used basal insulin twice daily. The most frequently used basal insulin was insulin glargine U-100 (54.3%), predominantly administered once daily (92.0%). Insulin detemir was used by 41.3% of the patients, mainly in a twice-daily regimen (84.2%). Only two patients (4.3%) were using NPH insulin, both on a twice-daily schedule. All patients in this study administered insulin glargine U-300 as their basal insulin in the evening. Regarding bolus insulin therapy, 73.9% (n=34) of the patients were using insulin aspart, and 26.1% (n=12) were on insulin lispro.

Frequent hypoglycemic episodes with the previous basal insulin regimen were the reason for switching to glargine U-300 in 28 patients (60.9%), whereas in 18 patients (39.1%), glargine U-300 was initiated due to uncontrolled hyperglycemia resulting from inadequate glycemic control. No adjustments were made to rapid-acting insulin therapy.

When patients were compared based on their baseline basal insulin type, those using insulin detemir had a significantly higher initial injection frequency than those using insulin glargine U-100 (p<0.001). Among patients using insulin glargine U-100, the prevalence of daytime hypoglycemia before switching to glargine U-300 was 64.6% (16/25), while nocturnal hypoglycemia was 72% (18/25). These rates were significantly higher compared to the detemir group [31.6% (6/19) and 36.8% (7/19), respectively; p=0.033 and p=0.020]. The incidence of severe hypoglycemia was similar in both groups. The most common reason for switching basal insulin was hypoglycemia in patients using glargine U-100 (76%) and inadequate glycemic control in those using insulin detemir (63.1%). No significant differences were found between the groups in other baseline clinical parameters. Since only two patients were using NPH insulin, this group was not statistically compared with the detemir and glargine U-100 groups.

Table 2. Basal insulin regimens before study initiation

Treatment	n (%)	Once-daily basal insulin n (%)	Twice-daily basal insulin n (%)
Basal insulin regimen	46 (100%)	26 (56.5%)	20 (43.5%)
Basal insulin			
Insulin glargine U-100	25 (54.3%)	23 (92.0%)	2 (8.0%)
Insulin detemir	19 (41.3%)	3 (15.8%)	16 (84.2%)
NPH insulin	2 (4.3%)	0 (0%)	2 (100%)

NPH: Neutral protamine hagedorn insulin

However, these patients had a long diabetes duration (mean: 16.5 years) and frequent hypoglycemia. Both experienced daytime and nocturnal hypoglycemia, which was the reason for switching to glargine U-300. Additionally, as they administered basal insulin in divided morning and evening doses, their daily injection frequency was higher.

Table 3 presents the HbA1c levels, FPG, and total daily glargine U-300 doses at baseline, as well as at the third, sixth, and twelfth months of Gla-300 treatment. The analysis of repeated measures revealed statistically significant differences in all parameters over time (p<0.001). The reduction in HbA1c levels was most pronounced during the first three months, decreasing from 8.45±1.27 at initiation to 7.83±1.01 at the third month (p<0.001). However, in pairwise comparisons, although the rate of decline slowed between the third and sixth months and between the sixth and twelfth months, the decrease remained statistically significant (p<0.001). Similarly, the decrease in FPG was most prominent in the first three months (from 217.28±77.4 mg/dL at initiation to 180.07±57.4 mg/dL at the third month, p<0.001). Pairwise comparisons showed that the reduction continued significantly between the third and sixth months (p=0.003) and between the sixth and twelfth months (p=0.006), albeit with a diminished rate of decline. Regarding total daily basal insulin dose, there was a statistically significant increase from initiation to the third month, from the third to the sixth month, and from the sixth to the twelfth month (p<0.001). However, pairwise comparisons indicated that, unlike HbA1c and FPG, the increase in insulin dose did not show a distinct difference between these periods. For the number of insulin injections, a statistically significant reduction was observed from initiation to the third month (p<0.001), while pairwise comparisons demonstrated that no further changes occurred after the third month.

Throughout the study period, no episodes of ketosis or hospitalization were observed.

Detailed data on changes in hypoglycemia rates are presented in Table 4. In this study, a statistically significant decrease was observed in all hypoglycemia categories over time (p<0.05). The most pronounced reduction occurred between baseline and the third month. The greatest decline was observed in nocturnal hypoglycemia rates (p<0.001). Severe hypoglycemia was no longer observed after the third month (p=0.041).

In the subgroup analysis based on the type of basal insulin used at baseline, changes in clinical parameters from baseline to month 12 (HbA1c, FPG, basal insulin dose, and the incidence of daytime, nighttime, and severe hypoglycemia) were compared. Except for a reduction in the number of injections, no statistically significant differences were observed in other parameters among patients using detemir. The decrease in daily injection frequency was more pronounced in the detemir group (p<0.001). Since only two patients were using NPH insulin, they were not included in the subgroup analysis. However, in both patients, reductions in HbA1c and FPG levels, as well as a decrease in the frequency of daytime, nighttime, and severe hypoglycemia, were observed, consistent with the overall patient population.

DISCUSSION

In this study, patients with type 1 diabetes who switched to glargine U-300 due to hypoglycemia or inadequate glycemic control were retrospectively evaluated over one year. Regardless of the type of previous basal insulin, treatment with glargine U-300 resulted in a significant reduction in HbA1c and FPG. This improvement was accompanied by a statistically significant decrease in the number of daily injections. Notably,

Table 3. Changes in HbA1c, fasting plasma glucose, and total daily basal insulin dose over the course of Gla-300 treatment

	Initiation Mean ± SD	3. month Mean ± SD	6. month Mean ± SD	12. month Mean ± SD	p-value
HbA1c (%)	[a]8.45±1.27	[b]7.83±1.01	[c]7.68±0.95	[d]7.45±0.8	**<0.001***
Fasting plasma glucose (mg/dL)	[a]217.28±77.4	[b]180.07±57.4	[c]170.52±49.39	[d]158.57±39.23	**<0.001***
Total daily basal insulin dose (IU)	[a]27.41±8.5	[b]30.33±8.63	[c]32.35±9.34	[d]34.54±9.46	**<0.001***
Number of insulin injection (n)	[b]4.39±0.49	[a]4±0	[a]4±0	[a]4±0	**<0.001**[+]

*Repeated measures were analyzed using ANOVA test, [+]Friedman test, different superscript letters [(a, b, c, d)] in the rows indicate statistically significant differences according to the LSD post-hoc test, SD: Standard deviation, IU: International unit

Table 4. Changes in hypoglycemia episodes over time (*)

Hypoglycemia type	Baseline n (%)	3rd month n (%)	6th month n (%)	12th month n (%)	p-value
General hypoglycemia	24 (52.2)	12 (26.1)	9 (19.6)	11 (23.9)	**0.017**
Nocturnal hypoglycemia	27 (58.7)	6 (13.0)	6 (13.0)	2 (4.3)	**<0.001**
Severe hypoglycemia	4 (8.7)	0 (0.0)	0 (0.0)	0 (0.0)	**0.041**

[*]All hypoglycemia episodes refer to events occurring in the last 3 months, p-value were obtained using Pearson's chi-square test

nearly half of the patients had previously required twice-daily basal insulin regimens particularly those on detemir or NPH contributing substantially to the overall injection burden. The most pronounced changes were observed within the first three months. Despite a statistically significant increase in basal insulin dose during follow-up, a significant reduction was observed in all categories of hypoglycemia, including daytime, nocturnal, and severe hypoglycemia, with the most evident decrease occurring by the third-month follow-up. The reduction in nocturnal hypoglycemia was particularly prominent, and no severe hypoglycemia events were reported after the third month. No cases of ketosis or hospitalizations were reported during the study period.

Our findings are largely consistent with three major prospective, open-label, randomized studies evaluating the efficacy of insulin glargine U-300 (Gla-300) in patients with T1DM - EDITION 4, EDITION JP1, and its 12-month extension study[8,9,17]. These studies showed that Gla-300 was non-inferior to Gla-100 in reducing HbA1c levels, although this effect was achieved with higher basal insulin doses. Significant reductions in nocturnal hypoglycemia were reported, especially in the first 8 weeks, and the JP1 study also showed a statistically significant decrease in daytime hypoglycemia. In the extension phase, hypoglycemia continued to decline even with stable insulin doses, and HbA1c non-inferiority was maintained. None of these trials showed a significant difference in severe hypoglycemia incidence. Similarly, our study showed the most prominent reduction in HbA1c at the third month, which was maintained throughout one year. This early response may be attributed to the pharmacological properties of Gla-300. Long-term glycemic control might also be associated with regular dose titrations despite the retrospective design. Furthermore, a significant reduction in nocturnal hypoglycemia was observed despite increasing basal insulin doses, and daytime hypoglycemia also decreased, consistent with JP1 and its extension. Unlike the previous studies, we observed a statistically significant decline in severe hypoglycemia. These results align with the long-acting and stable pharmacodynamic profile of Gla-300. In support of this, Becker et al.[18] demonstrated that Gla-300 had a flatter and longer action profile compared to Gla-100, and Bergenstal et al.[10] showed that Gla-300 provided a more stable 24-hour glucose profile with reduced glycemic variability in patients with T1DM. Therefore, the improvements observed in our study are compatible with the known pharmacodynamic advantages of Gla-300.

Although the findings of prospective randomized trials are valuable, real-world data provide additional insight into the effectiveness and safety of treatments in routine clinical settings. In a study by Oriot et al.[19] including 116 patients with T1DM, switching from Gla-100 to Gla-300 led to similar glycemic control in the short term, with a significant reduction in nocturnal hypoglycemia and a modest but significant HbA1c reduction after six months. In our study, although the baseline basal insulin types were more heterogeneous, a similar improvement was observed with higher doses of Gla-300. Unlike Oriot's study[11], the most evident improvements in HbA1c and hypoglycemia frequency occurred by the third month and were maintained throughout follow-up. The SPARTA study is a large, multicenter real-world study in T1DM patients. As in our study, patients had previously used various basal insulins, and many were on twice-daily regimens. In SPARTA, HbA1c decreased by 0.4% overall and 0.6% in the twice-daily group ($p<0.001$), consistent with our results. In both studies, Gla-300 was used at higher doses compared to previous basal insulins. Although the proportion of patients switching due to hypoglycemia was lower in SPARTA (19%) than in our study (60.9%), this may reflect differences in patient selection and referral reasons. However, both studies showed a significant reduction in hypoglycemia rates and treatment burden due to injection frequency. Gla-300's ability to provide similar or better glycemic control with fewer injections supports our findings. A single-center retrospective study from Türkiye reported HbA1c and hypoglycemia improvements in 35 younger T1DM patients who switched to Gla-300 solely due to hypoglycemia, without dose adjustments. However, hypoglycemia subtypes were not specified, and HbA1c improvement appeared later. In contrast, our study included a more diverse population and showed early and consistent improvements with dose titration. Therefore, our findings offer a more comprehensive contribution to national real-world evidence.

The most recent real-world data on Gla-300 use in T1DM come from the TOP1 (n=123) and COMET-T (n=94) studies, published in 2024 and 2025, respectively[7,20]. In the COMET-T study, patients were monitored using continuous glucose monitoring (CGM), and a significant improvement was observed in time in range, especially among those who had previously used insulin detemir. A reduction in hypoglycemia frequency was also reported across the entire study group[7]. The TOP1 study evaluated patients switching from twice-daily basal insulin to once-daily Gla-300. It showed reductions in injection frequency and hypoglycemia, along with improved patient satisfaction[20]. In both studies, Gla-300 was associated with clinical and patient-centered benefits, particularly in those who had been using first-generation basal insulins. In our study, which retrospectively included 46 T1DM patients, similar findings were observed. Switching from detemir or NPH to Gla-300 led to a decrease in the number of daily injections, a significant early reduction in hypoglycemia rates, and improved HbA1c levels. Although patient satisfaction could not be assessed through structured questionnaires due to the retrospective design, high follow-up adherence may reflect overall treatment acceptability.

Although first-generation basal insulins such as NPH, detemir, and glargine U-100 have similar glycemic efficacy in type 1 diabetes treatment, pharmacodynamic differences especially with NPH and detemir often require more frequent injections[21]. This increases injection burden and may negatively affect patient comfort, treatment adherence, and quality of life[5]. Our study reflects how these pharmacological differences translate into clinical practice and adds to the current real-world evidence in this area.

Study Limitations

This study has several limitations. First, the retrospective design and relatively small sample size may limit the generalizability of the findings. Hypoglycemic episodes were assessed based on patient self-reports, as CGM was not used due to its high cost and lack of reimbursement. Additionally, body weight data were missing in many patient records, so the effect of Gla-300 on weight could not be evaluated. Finally, since all patients in this study received Gla-300 in the evening, the effectiveness of morning administration could not be assessed.

CONCLUSION

Type 1 diabetes is a unique patient population that requires long-term and intensive insulin therapy, with a direct impact on quality of life. Therefore, choosing basal insulin should be evaluated not only in terms of glycemic control but also treatment sustainability, patient profile, healthcare delivery, and quality of life. In Türkiye, first-generation basal insulins are still widely used, creating a treatment burden both for patients and physicians due to multiple daily injections. Our study provides updated real-world data on basal insulin preferences and clinical outcomes in T1DM management in our country. These findings suggest that Gla-300 may be considered as a treatment option in individualized care plans, especially when factors like patient comfort, hypoglycemia safety, adherence, and quality of life are taken into account.

Ethics

Ethics Committee Approval: The study was approved by the local ethics committee of Cerrahpaşa Medical Faculty Dean's Office Clinical Research Ethics Committee (decision no: 192547, date: 17.12.2019), the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice principles.

Informed Consent: The medical records of patients with T1DM who attended the diabetes outpatient clinic of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine between 2020 and 2023 were retrospectively analyzed.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Ö.P.K., Z.O.S., Concept: Ö.P.K., Design: Ö.P.K, Z.O.S., Data Collection or Processing: Ö.P.K., Analysis or Interpretation: Ö.P.K., Z.O.S., Literature Search: Ö.P.K., Writing: Ö.P.K.

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