ISPOR 2019

2–6 November
Copenhagen,
Denmark

The real-world dose differences of insulin glargine 300 U/ml in Finland

Koski Lotta[1,2], Hahl Jarmo[1], Kaye Sanna[3], Pousar Katariina[3]

1 Medaffcon Oy, Espoo, Finland; 2 University of Eastern Finland, Kuopio, Finland; 3 Sanofi Oy, Espoo, Finland

INTRODUCTION

- Insulin titration protocols in randomized clinical trials have indicated differences between basal insulin doses to reach and maintain glycaemic targets.[1] In real-world, however, various factors may have significant impact on dose requirements and therefore on the societal economic burden between basal insulin analogues.
- According to the SmPC of insulin glargine 300 U/ml, a 10–18 % higher dose may be needed when switching from insulin glargine 100 U/ml to glargine 300 U/ml.
- In Finland, there are approximately 0.5 million diabetics of which 10–15 % have type 1 diabetes (T1DM) and 75 % type 2 diabetes (T2DM).[2,3] Economic burden of diabetes is substantial while its healthcare related costs are over 1,778 million euros which is approximately 10 % of the total Finnish healthcare spending.[4] The costs of drugs used in diabetes were in total 223.9 million euros in 2018.[5]

OBJECTIVE

Assess, how the real-world relative insulin doses change after switching basal insulin to insulin glargine 300 U/ml.

DATA AND METHODS

- The data was obtained from the Finnish national reimbursement registry (Finnish Social Insurance Institution, SII), which contains prescription information (patient, drugs, physician) and information on drug costs and reimbursement.[6]
- Study population consisted of diabetic patients, selected from the reimbursement registry by use of insulin glargine 300 U/ml during the time period from January to October 2016, immediately after the product entered the Finnish market.
- Insulin glargine 300 U/ml purchases were observed for 6 and 12 months. In addition, the insulin purchases were observed from 6 month period before the initiation of usage. Previous insulin purchases included insulin glargine 100 U/ml and detemir. It was also observed if patients were insulin naïve (no purchases during 6-month period). Patients using other insulins were categorised in a class of other treatment.
- All patients were divided into those who continued or discontinued treatment. Definition for treatment continuation was minimum of two purchases of insulin glargine 300 U/ml during the follow-up.
- The diabetic status, gender and age were determined from the coding based on the reimbursement statement. Patients under 18 years were excluded from the data.
- The average insulin doses were defined from purchases by dividing the amount of insulin units by the length of treatment period. The treatment period was defined as the difference between the first and last purchase to which maximum refill period 90 days was added corresponding Finnish reimbursement system.
- The data was used to assess the average real-world insulin doses of glargine 300 U/ml by compared to the dose of previously used basal insulin; insulin glargine 100 U/ml or insulin detemir.

The data was analysed at the University of Eastern Finland as a part of master's thesis in Faculty of Health Sciences.

RESULTS

Demographics

- The study population included in total 12 549 patients of which the patients (n=1 383) who discontinued insulin glargine 300 U/ml were excluded. 11 166 patients continued their treatment. Patient characteristics are presented in **Table 1**.
- 6 131 patients were included in the analysis based on previous treatment (insulin glargine 100 U/ml or detemir). Insulin naïve patients and patients whose diabetes type was other or not defined were excluded.

Table 1. Patient characteristics

	n	%
Number of patients	11 166	89 %*
Type of diabetes:		
Type 1	1 881	17 %
Type 2	5 921	53 %
Other/Not defined	3 364	30 %
Time of the diabetes diagnose (months):		
Type 1 diabetics	149	-
Type 2 diabetics	130	-
Previous treatment:		
Insulin glargine 100 U/ml	6 261	56 %
Insulin detemir	2 809	25 %
Other	52	0 %
Insulin naive	2 044	18 %
Gender:		
Man	6 460	58 %
Woman	4 654	42 %
Not defined**	52	0 %
Age:		
18–24 years	415	4 %
25–34 years	850	8 %
35–44 years	959	9 %
45–54 years	1 644	15 %
55–64 years	2 508	23 %
65–74 years	2 915	26 %
+75 years	1 787	16 %
Not defined**	52	0 %

* Rate of the total patient number including the patients who discontinued treatment (n=12 549).
** No information was collected on the patient group "other" as previous treatment (n=52).

The real-world dose differences of insulin glargine 300 U/ml after switching basal insulin therapy

- Information on average real-world doses and dose changes after the switch to insulin glargine 300 U/ml either from insulin glargine 100 U/ml or insulin detemir are presented in **Figure 1**.
- In all patients who switched (n=6 131 [6 month data]), the 6 month/12 month dose difference between insulin glargine 300 U/ml and 100 U/ml was 3 %/0 %, and between insulin glargine 300 U/ml and detemir -11/-16 %, respectively.
- The dose difference between insulin glargine 300 U/ml and 100 U/ml after 6 month/12 month follow-up was -1 %/-6 % in patients with type 1 and 4 %/1 % in type 2 diabetes, respectively.
- The dose difference between insulin glargine 300 U/ml and insulin detemir, after 6 month/12 month follow-up was -15 %/-20 % in patients with type 1 and -11 %/-15 % in type 2 diabetes, respectively.

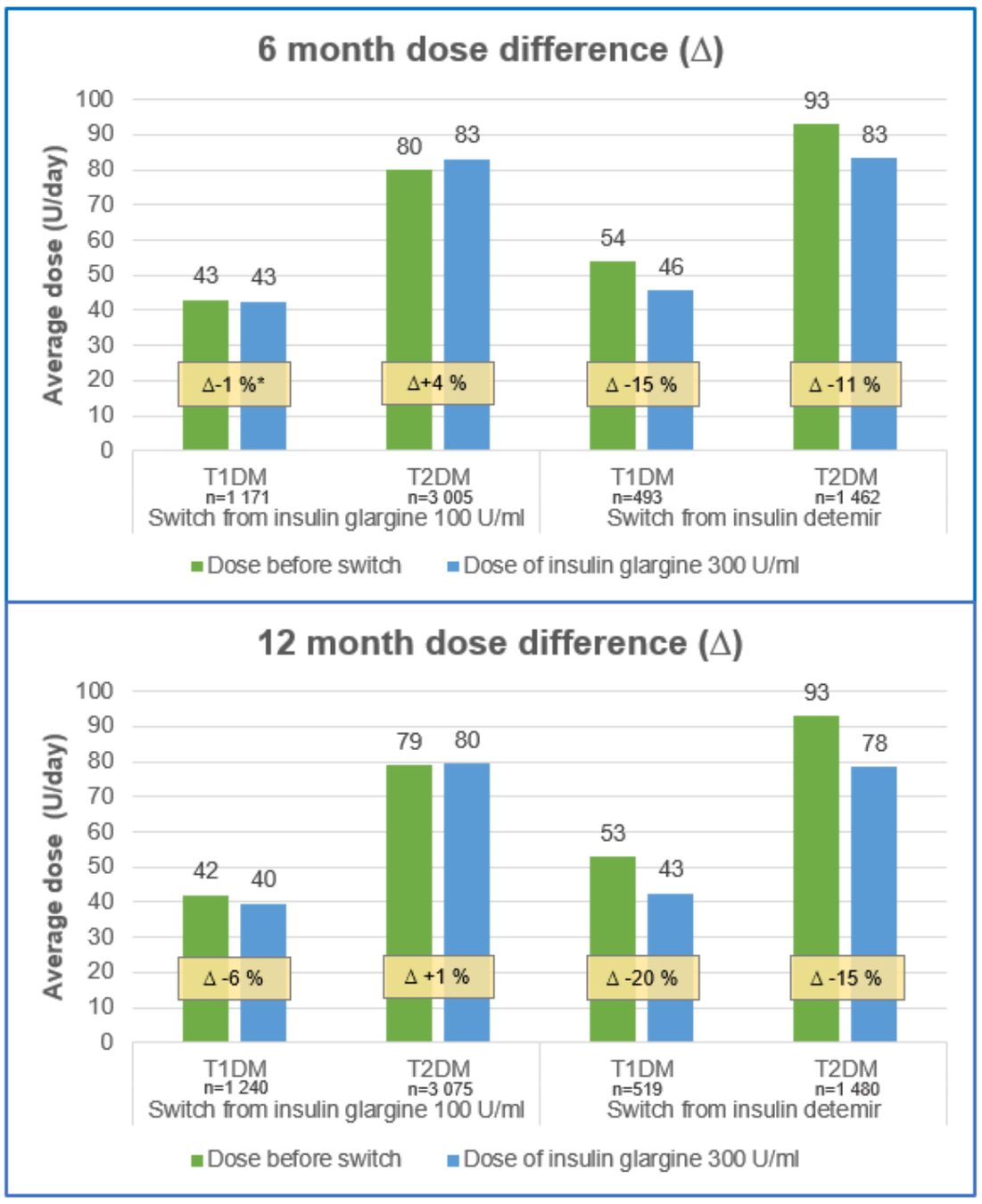

Figure 1. The real-world dose difference after switch at 6 and 12 months follow-up
*percentages are calculated from accurate numbers

DISCUSSION

- In this study, negligible differences were seen between insulin glargine 300 U/ml and 100 U/ml doses. After the basal insulin switch, insulin glargine 300 U/ml doses were lower than the ones of insulin detemir.
- Doses slightly decreased over time which may be due to the variable number of patients between 6 and 12 month data collection and the definition of treatment continuation used in the study.
- The dose difference of insulin glargine 300 U/ml to insulin glargine 100 U/ml (+10–18% in SmPC, Phase III EDITION trial program) does not correspond findings of this real-world study. This indicates that the dose differences found in RCTs may not be relevant in real-world setting due to number of overriding factors.
- As a limitation of the study, statistical significance of the results, HbA1c levels and other simultaneous treatments were not analysed. Therefore this study provides economically rather than clinically relevant information on real-world doses.

CONCLUSION

This study provides the decision makers supplementary information to clinical trial data which could be utilised in the assessment of the drug prices and future treatment costs between basal insulins in real-world setting.

REFERENCES

1. TOUJEO SmPc
2. Diabetes. Current care guidelines. Working group set up by the Finnish Medical Society Duedecim, 2018. Available online at: www.kaypahoito.fi (Accessed 2.9.2019)
3. THL 2019. Available online at: https://thl.fi/fi/web/kansantaudit/diabetes/diabeteksen-yleisyys (Accessed 2.9.2019)
4. Koski S., Kurkela O., Ilanne-Parikka P. & Rissanen P. Diabetes lukuina 2018:1. Available online at: https://www.diabetes.fi/files/9736/Diabetes_lukuina_2018_1_kustannustutkimus_A4.pdf (Accessed 2.9.2019)
5. Kela reimbursement statistics 2019. Available online at: http://raportit.kela.fi/ibi_apps/WFServlet?IBIF_ex=NIT137AL&YKIELI=E (Accessed 2.9.2019)
6. Kela website. Available online at: www.kela.fi (Accessed 2.9.2019)

DISCLOSURE

Writing and analysis of the data was done as a part of master's thesis work of L.K. at the University of Eastern Finland in the Faculty of Health Sciences. Sanofi Finland funded the costs of obtaining the reimbursement data from the KELA reimbursement registry. S.K. and K.P. are employees of Sanofi.