Real-World Cost-Effectiveness of Insulin Degludec in Type 1 and Type 2 Diabetes Mellitus – from a Swedish Societal One Year Perspective

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Background and aims

- Randomised controlled trials have shown a lower risk of hypoglycemia in patients with type 1 diabetes (T1D) and type 2 diabetes (T2D) on treatment with insulin degludec compared with insulin glargine 100 units/mL (IGlar U100).[1,2,4] Observational studies have also shown lower risk of hypoglycemia when T1D[3,5] and T2D[3] patients switched to insulin degludec from other basal insulins.[1–5] Several of these studies have also shown an insulin dose reduction for patients treated with insulin degludec compared with IGlar U100.[1,3,4,5]
- The aim of this study was to assess the cost-effectiveness (C/E) of insulin degludec vs other basal insulin treatment before switch to insulin degludec in a Swedish societal one year perspective in people with T1D and T2D.

Materials and methods

This study used a Swedish societal one year perspective to assess C/E of insulin degludec compared with basal insulin treatment prior to switching to insulin degludec. The C/E analyses used global data from the ReFLeCT study.[5] ReFLeCT was a prospective, observational study including patients with T1D (n=566) and T2D (n=611) from seven European countries (Figure 1).[5] It comprised a four-week baseline period and a 12-month follow-up period (insulin degludec).

ReFleCT endpoints of relevance for this study, comparing baseline vs 12-month follow-up.[5]

- Change in rate of any hypoglycemia.
- Change in daily total, basal and bolus insulin dose.

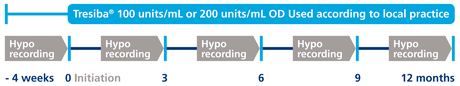
Insulin information

- Baseline basal units used to represent costs (weighted) before switch:[5]
  - T1D: IGlar U100 63.8%, insulin detemir (IDet) 22.7%, other/missing 13.5%.
  - T2D: IGlar U100 59.1%, IDet 20.8%, other/missing 20.1%.
  - If data was missing the lowest basal insulin price (insulin NPH) was used as a conservative approach.
- IGlar U100 price:
  - Base case: the Swedish original IGlar U100 price.
  - Sensitivity analyses: IGlar U100 biosimilar price.

Cost-effectiveness analyses

- C/E was analysed over a 1-year time horizon from a Swedish societal perspective.
- Only results from the ReFLeCT analyses[5] with statistical significant differences (p<0.05) were included in the analysis.
- Pharmacy selling prices in Sweden, March 2019, were used in the analyses (www.tlv.se).
- The cost per non-severe hypoglycemic event was based on data from published sources[6,7] and calculated to be SEK 27 (T1D) and SEK 159 (T2D) per event.
- Costs are expressed in 2019 Swedish krona (SEK). (€ 1 = SEK 10.47, 19MAR2019).

Figure 1: ReFLeCT study overview[5]



OD: once daily; T1D: type 1 diabetes; T2D: type 2 diabetes.
Participating countries: Denmark, The Netherlands, Spain, Sweden, Switzerland, Italy, United Kingdom

Study information

- T1D (n=566)
- T2D (n=611)
- Planned to initiate insulin degludec
- Multicentre, prospective, non-interventional

Key inclusion/exclusion criteria

- Male or female ≥ 18 years, T1D and/or T2D, insulin using, planned initiation with insulin degludec
- No previous use of insulin degludec

Results

Insulin doses

Table 1 shows the basal and bolus doses at baseline and at the 12 month follow-up. At 12 months estimated basal and bolus insulin dose ratios were 0.91 (95 % C.I. 0.83–0.91) and 0.87 (0.83–0.91) for T1D and 0.98 (0.95–1.01) and 0.96 (0.94–1.01) for T2D.

Incidence Rate Ratio (IRR) hypoglycemia

When patients with T1D switched to insulin degludec a reduced IRR for daytime, nocturnal and severe hypoglycemia was observed at 12 months follow-up (Table 2). For patients with T2D the IRR was reduced for daytime and nocturnal hypoglycemia.

Cost-effectiveness of insulin degludec

Switching to insulin degludec was cost-saving for patients with T1D compared to previous basal therapy. In T2D, insulin degludec was highly cost-effective, with a cost per quality-adjusted life-year (QALY) of SEK 15 000–24 000 (Tables 3–5). In Sweden a treatment is considered cost-effective if cost/QALY is <500 000 SEK.

Sensitivity analyses showed that the results were robust to changes in efficacy and cost parameters in both T1D and T2D.

Table 1: Insulin doses at baseline and at one year follow-up

Dose	Before	After	Difference	%	
T1D					
Basal insulin	25.0	22.8	-2.2	-9%	
Bolus insulin	27.3	23.8	-3.5	-13%	
Total dose	52.3	46.6	-5.7	-11%	
T2D					
Basal insulin	37.5	35.9	-1.6	-2%	(NS)
Bolus insulin	38.9	38.3	-0.6	-4%	(NS)
Total dose	76.4	74.2	-2.2	-3%	(NS)

NS: Non-significant in T2D, and therefore NOT included in analysis

Table 2: Incidence Rate Ratio (IRR) hypoglycemia

	T1D RR (95% CI)	T2D RR (95% CI)
Non-severe daytime hypoglycemic event	0.85 (0.78, 0.93)*	0.56 (0.46, 0.69)*
Non-severe nocturnal hypoglycemic event	0.63 (0.52, 0.76)*	0.38 (0.22, 0.64)*
Severe hypoglycemic event	0.28 (0.14, 0.56)*	N/A

* p<0.001

Table 3: Cost-effectiveness of insulin degludec vs treatment before switch of basal insulin (SEK)

Diabetes type	Scenario	Cost Difference (SEK)	QALY Difference	Cost (SEK)/ QALY
T1D	IGlar U100 price: original	-1 249	0.079	Dominant
T1D	IGlar U100 price: biosimilar	-995	0.079	Dominant
T2D	IGlar U100 price: original	560	0.038	14 911
T2D	IGlar U100 price: biosimilar	912	0.038	24 259

SEK: Swedish kronor; QALY: Quality-Adjusted Life Years; T1D: Type 1 Diabetes; T2D: Type 2 Diabetes; IGlar U100: Insulin Glargine U100. (€ 1 = SEK 10.47, 19MAR2019).

Table 4: Cost distribution in T1D (SEK)

Costs	Insulin Degludec	IGlar U100 (Original)	Δ Costs	IGlar U100 (Biosimilar)	Δ Costs
TOTAL	**12 582**	**13 830**	**-1 249**	**13 577**	**-995**
Basal insulin	3 680	3 065	614	2 812	868
Bolus insulin	1 466	1 685	-219	1 685	-219
Hypoglycemia	1 853	3 044	-1 191	3 044	-1 191
Production loss	804	1 257	-453	1 257	-453
Needle & SMBG*	4 779	4 779	0	4 779	0

*SMBG:Self Monitoring Blood Glucose (lancet and strip). (€ 1 = SEK 10.47, 19MAR2019).

Table 5: Cost distribution in T2D (SEK)

Costs	Insulin Degludec	IGlar U100 (Original)	Δ Costs	IGlar U100 (Biosimilar)	Δ Costs
TOTAL	**13 633**	**13 073**	**560**	**12 722**	**912**
Basal insulin	6 039	4 418	1 621	4 066	1 973
Bolus insulin	1 506	1 506	0	1 506	0
Hypoglycemia	556	996	-440	996	-440
Production loss	753	1 374	-621	1 374	-621
Needle & SMBG*	4 779	4 779	0	4 779	0

*SMBG:Self Monitoring Blood Glucose (lancet and strip). (€ 1 = SEK 10.47, 19MAR2019).

Discussion

- The switch to insulin degludec was cost-saving for patients with T1D relative to previous basal therapy with IGlar U100 priced as original or biosimilar independent of changes in efficacy and cost parameters.
- Switching to insulin degludec was highly cost-effective for patients with T2D compared with previous basal therapy with IGlar U100 priced as original or biosimilar independent of changes in efficacy and cost parameters.
- The C/E of insulin degludec was driven by lower insulin doses in T1D and reduced risk of hypoglycemia in T1D and T2D.
- Patients with T1D had more hypoglycemic events than patients with T2D. However, the cost per event is higher in T2D, mainly due to a larger proportion of health care visits after the event.

Conclusion

Compared to previous basal insulin therapy, with IGlar U100 priced as original or biosimilar, the switch to insulin degludec is cost-saving in patients with T1D and highly cost-effective in patients with T2D after one year from a Swedish societal perspective when using real-world data from ReFLeCT.

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