Toujeo®
insulin glargine 300U/mL

The Right Beat for Reassuring Diabetes Control

After a long journey on oral drugs, your patients need a right start to build confidence in the long run

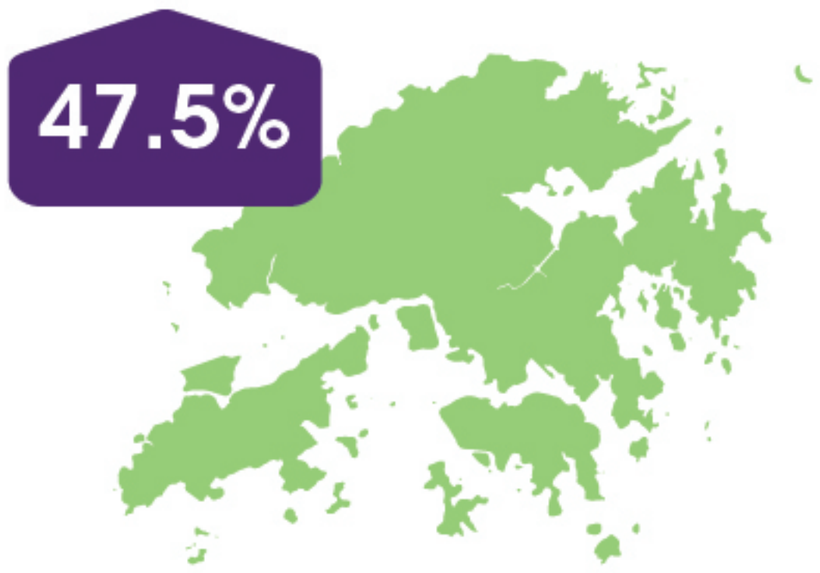
Give your patients power to control diabetes with reassuring confidence

All day and all night with Toujeo®

sanofi

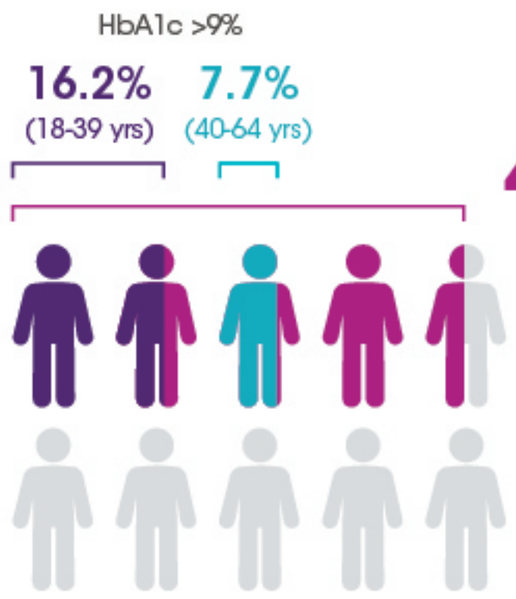
Diabetes and insulin use in Hong Kong

The number of DM patients in HA sector increases annually[1]



- **490,400** patients in HA sector, with **47.5%** increase since 2011/12
- **>50%** of patients were aged **≥65 years**

Many patients are not achieving glycaemic targets[1]



- **~1 in 2** patients cannot meet the HbA1c target of **<7%**
- **16.2%** of young patients aged 18-39 years and **7.7%** aged 40-64 years had HbA1c >9%
- **~1 in 8** DM patients were prescribed with insulin in 2019/2020

Insulin has the highest efficacy in reducing blood glucose level

Endorsed by

- ADA Guideline[2]
- HK Reference Framework for Diabetes Care for Adults 2018
  Insulin therapy should be added if glycaemic target is not attained with combination of oral blood glucose lowering drug[3]

ADA=American Diabetes Association. DM=diabetes mellitus. HA=Hospital Authority. HbA1c=haemoglobin A1c.

Considerations for insulin use

Benefits of insulin use

~50% of β-cells function has deteriorated at time of diagnosis, hence insulin use can allow β-cells rest and protection[4,5]

35–76% reduction in rates of development and progression of microvascular complications (retinopathy, neuropathy, and diabetic kidney disease) with better glycaemic control[6]

5-year sustained HbA1c reduction[7]

3 Important factors when selecting a basal analogue

Effective glycaemic control

3.7x less likely to reach glycaemic target within 2 years for patients not meeting the target within 3 months[8]

Low hypoglycaemia risk

6x increase in risk of long-term hypoglycaemia if experienced within 3 months of basal insulin initiation[8]

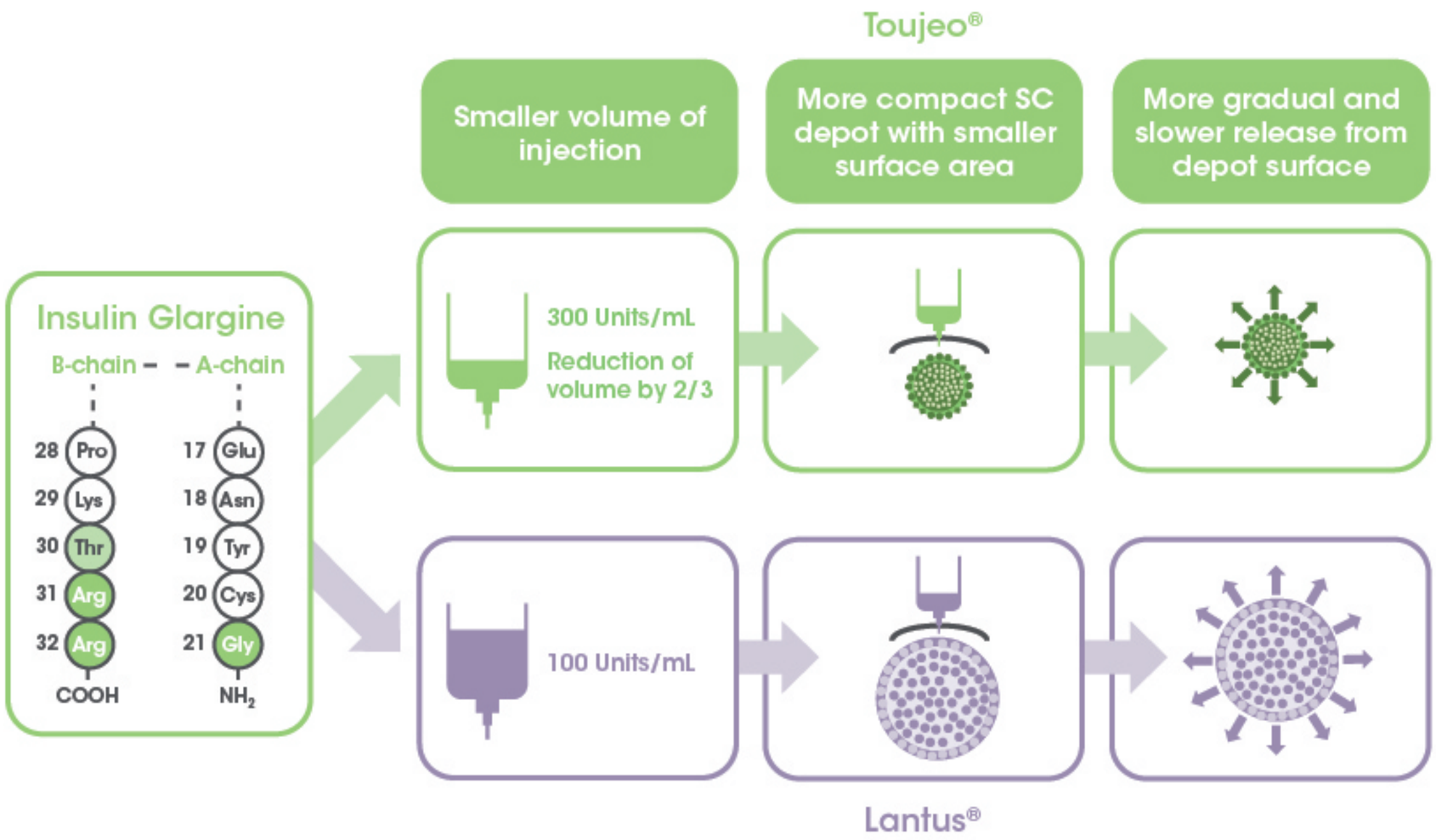
Stable glycaemic profile

36% increase in MACE for patients with high day-to-day fasting glycaemic variability[9]

HbA1c=haemoglobin A1c. MACE=major adverse cardiovascular events.

What is Toujeo®?

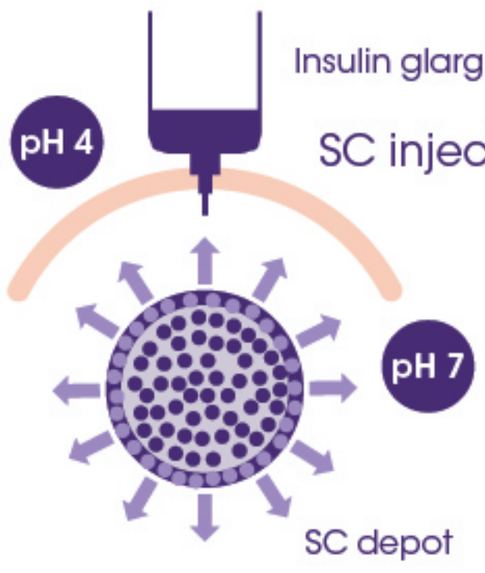
Injecting the same units of Lantus® but at 2/3 less volume



Adapted from Cheng AYY, et al. (2019)

Toujeo® delivers the same dosage of insulin as Lantus®, but in one-third of the volume. This results in reduced surface area of injection depot, ultimately resulting in a slower and more gradual release of monomers of Toujeo® as compared with Lantus®[10].

Glargine adopts a pH-dependent precipitation[11-13]



For illustrative purposes only

- Following SC injection, insulin glargine precipitates amorphously creating an SC depot at physiological pH
- Enzymatic maturation forms the active metabolite, 21A-Gly-human insulin, that is released slowly from the depot to the circulation

SC=suboutaneous.

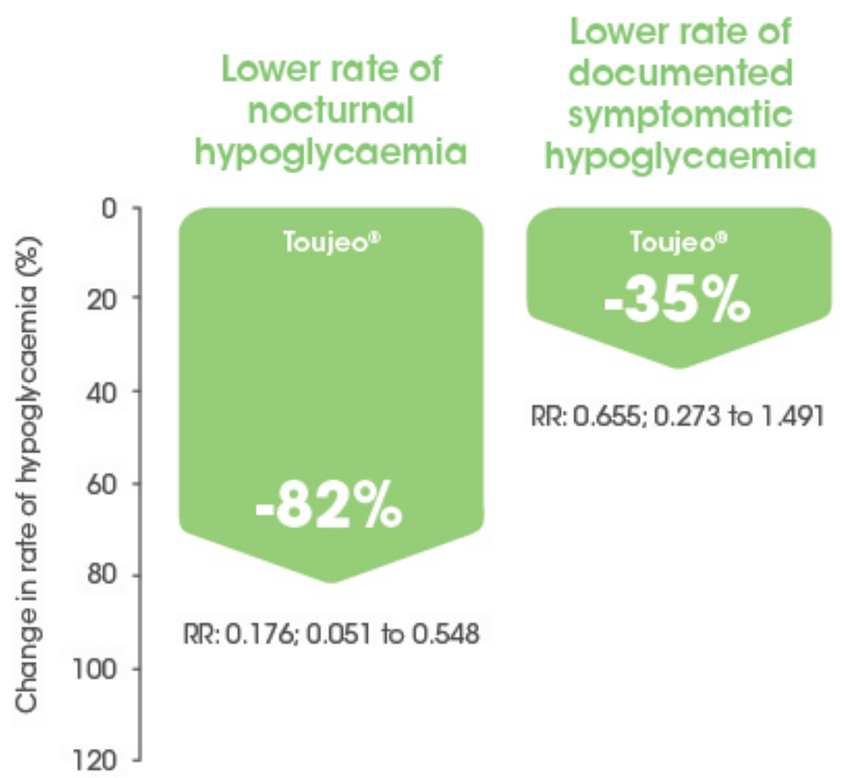
Comparison with NPH

Toujeo® insulin glargine 300U/mL

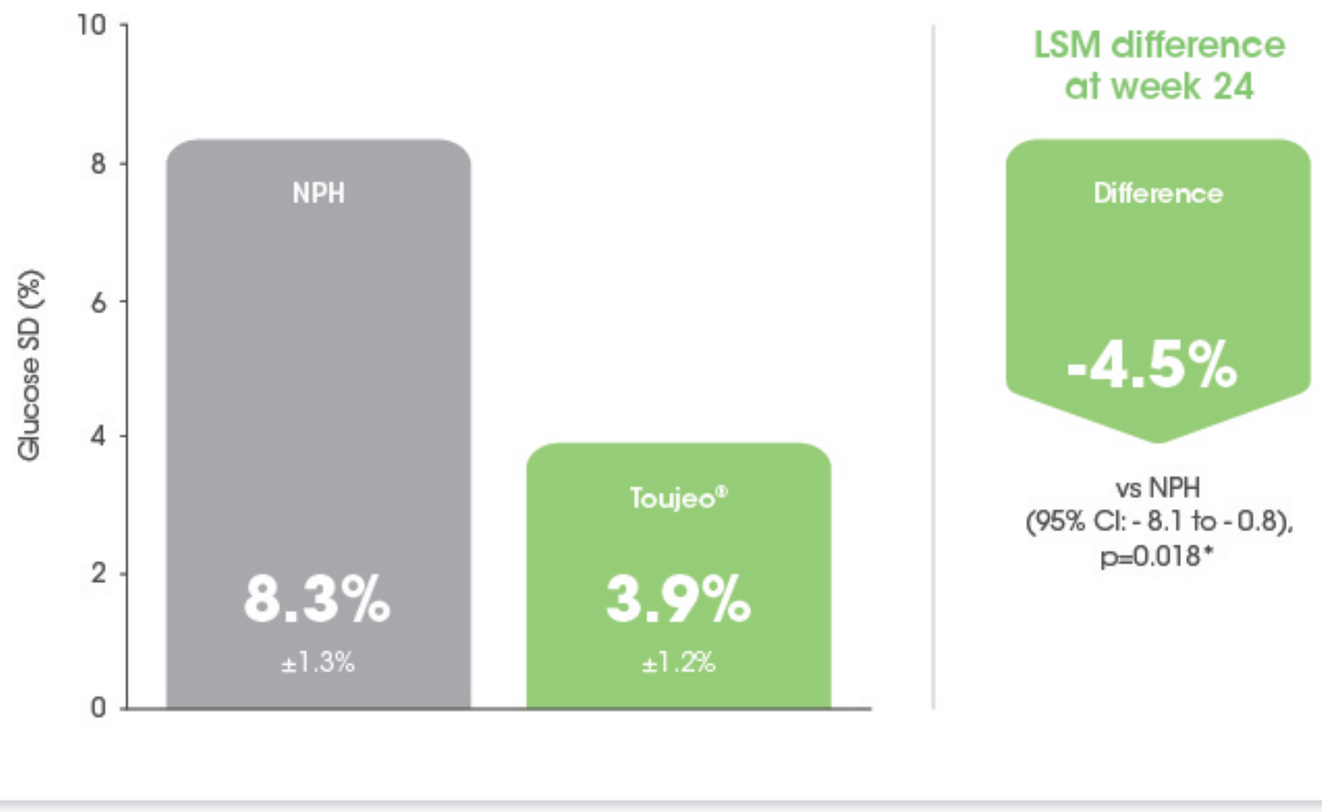
Apart from randomised controlled trials, there is abundant evidence from meta-analysis and real-world data supporting the better perfomance of Toujeo® over NPH.

Greater HbA1c reduction[14,*]

Significantly lower nocturnal and documented symptomatic hypoglycaemia[15,†]



Lower change in nocturnal GV[16,‡]



vs NPH

* The primary objective of this study was to evaluate the effectiveness of Toujeo®, defined as the percentage of participants with an HbA1c reduction of ≥0.5%, 6 months after switching from NPH insulin, in participants with T2DM. Secondary objectives included the safety assessment based on the percentage of patients experiencing ≥1 episodes and the number of hypoglycaemic episodes by category: severe, symptomatic, symptomatic confirmed, diurnal or nocturnal, change in body weight, and insulin dose. A total of 469 participants completed the 6-month observation period.

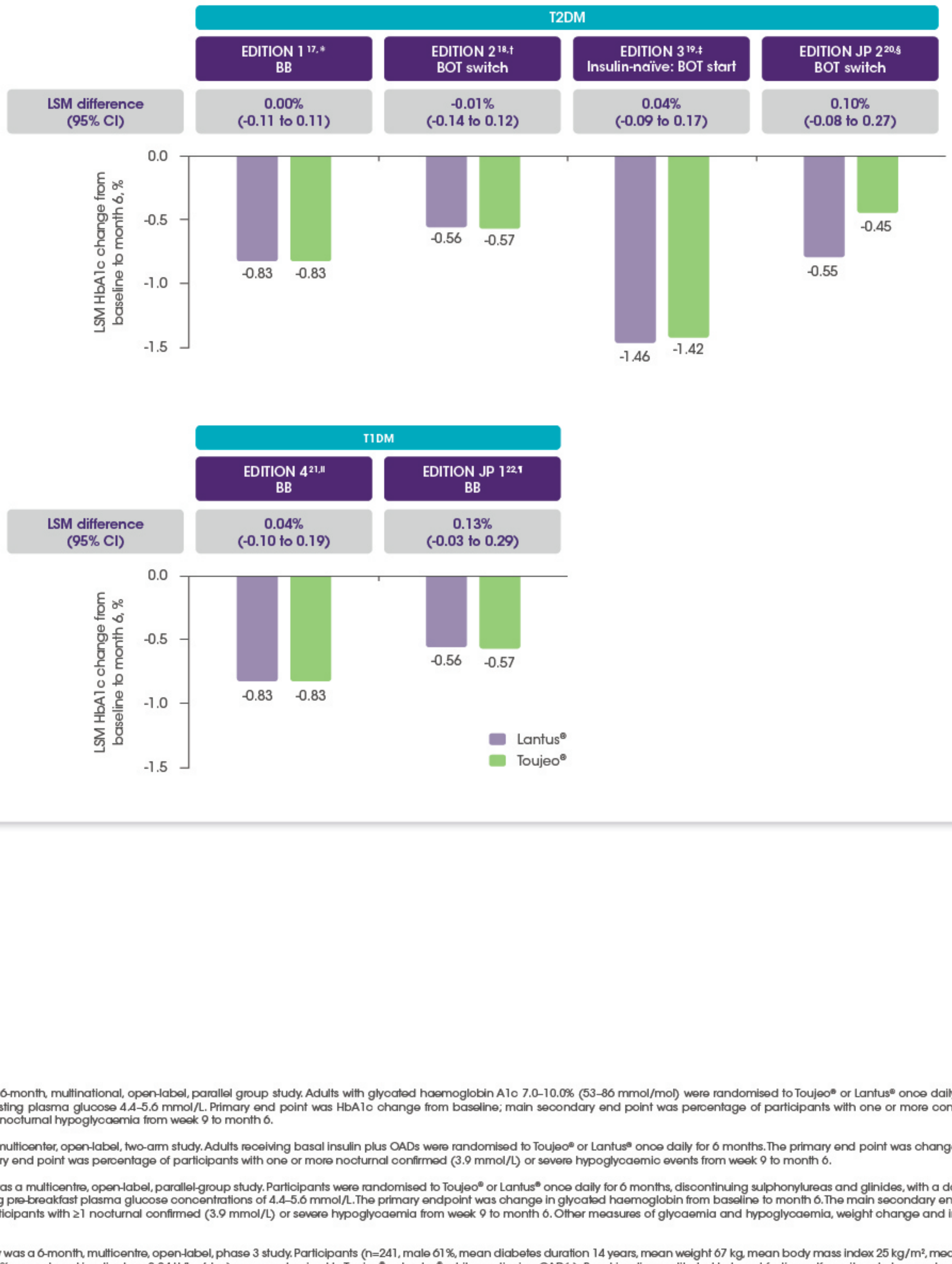
† The study was to compare the efficacy and safety of a concentrated formulation of insulin glargine (Toujeo®) with other basal insulin therapies in patients with type 2 diabetes mellitus (T2DM). This was a network meta-analysis (NMA) of 41 randomised clinical trials of basal insulin therapy in T2DM identified via a systematic literature review of Cochrane library databases, MEDLINE and MEDLINE In-Process, EMBASE and PsycINFO. The outcome measures are the changes in HbA1c (%) and body weight, and rates of nocturnal and documented symptomatic hypoglycaemia.

‡ This was a 24-week, open-label exploratory study with 1:1 randomisation comparing patient-adjusted titration of Toujeo® (n=23) versus NPH (n=23) at bedtime in insulin-naïve T2DM patients on maximum oral glucose-lowering drugs. The starting dose was 0.2 U/kg/day and with self-titration of one unit per week to achieve a target fasting glucose of 4.4–6 mmol/L, without hypoglycaemia. Participants had masked CGM at baseline, weeks 11 and 24. The primary outcome was between treatment differences in CGM glucose standard deviation (SD) at week 24.

CGM=continuous glucose monitors. GV=glucose variability. HbA1c=haemoglobin A1c. NPH=neutral protamine hagedorn. RR=risk ratio. T2DM=type 2 diabetes mellitus.

Comparison with Lantus®

Comparable HbA1c reduction



* EDITION 1 was a 6-month, multinational, open-label, parallel group study. Adults with glycated haemoglobin A1c 7.0–10.0% (53–86 mmol/mol) were randomised to Toujeo® or Lantus® once daily with dose titration seeking fasting plasma glucose 4.4–5.6 mmol/L. Primary end point was HbA1c change from baseline; main secondary end point was percentage of participants with one or more confirmed (3.9 mmol/L) or severe nocturnal hypoglycaemia from week 9 to month 6.

† EDITION 2 was a multicenter, open-label, two-arm study. Adults receiving basal insulin plus OADs were randomised to Toujeo® or Lantus® once daily for 6 months. The primary end point was change in HbA1c. The main secondary end point was percentage of participants with one or more nocturnal confirmed (3.9 mmol/L) or severe hypoglycaemic events from week 9 to month 6.

‡ EDITION 3 study was a multicentre, open-label, parallel-group study. Participants were randomised to Toujeo® or Lantus® once daily for 6 months, discontinuing sulphonylureas and glinides, with a dose titration aimed at achieving pre-breakfast plasma glucose concentrations of 4.4–5.6 mmol/L. The primary endpoint was change in glycated haemoglobin from baseline to month 6. The main secondary endpoint was percentage of participants with ≥1 nocturnal confirmed (3.9 mmol/L) or severe hypoglycaemia from week 9 to month 6. Other measures of glycaemia and hypoglycaemia, weight change and insulin dose were assessed.

§ EDITION JP 2 study was a 6-month, multicentre, open-label, phase 3 study. Participants (n=241, male 61%, mean diabetes duration 14 years, mean weight 67 kg, mean body mass index 25 kg/m², mean glycated haemoglobin 8.02 %, mean basal insulin dose 0.24 U/kg/day) were randomised to Toujeo® or Lantus®, while continuing OAD(s). Basal insulin was titrated to target fasting self-monitored plasma glucose 4.4–5.6 mmol/L. The primary efficacy endpoint was HbA1c change over 6 months. Safety endpoints included hypoglycaemia and weight change.

‖ EDITION 4 study was a multicenter, randomised, four-arm, parallel-group, phase 3a study involving 549 participants with type 1 diabetes. Using a mealtime and basal insulin regimen, patients were randomised (1:1:1:1) open-label to Toujeo® or Lantus® and to morning or evening injection, continuing the mealtime analogue, and followed up for 6 months. The primary efficacy end point was the overall change in HbA1c from baseline to month 6, regardless of injection time. Secondary end points included percentage to HbA1c <7.0% at month 6, change in pre-injection SMPG, within-participant variability of pre-injection SMPG, FPG 8-point SMPG profile, and daily insulin doses.

¶ The EDITION JP 1 study was a 6-month, multicentre, open-label, phase 3 study. Participants (n=243) were randomised to Toujeo® or Lantus® while continuing mealtime insulin. Basal insulin was titrated with the aim of achieving a fasting self monitored plasma glucose target of 4.4–7.2 mmol/L. The primary endpoint was change in glycated haemoglobin over 6 months. Safety measures included hypoglycaemia and change in body weight.

BB=basal-bolus. BOT=basal-supported oral therapy. HbA1c=haemoglobin A1c. OAD=oral antihyperglycaemic drug. SMPG=self-monitoring of plasma glucose.

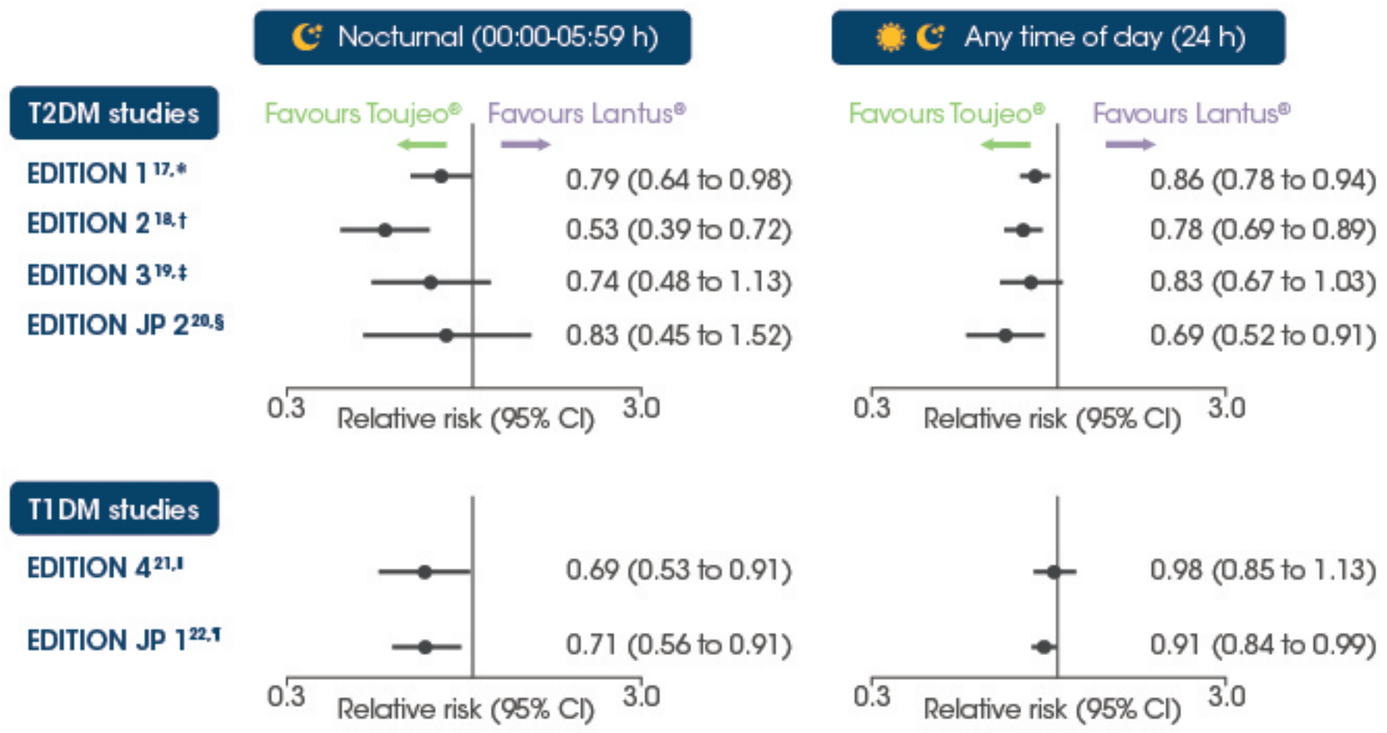
Toujeo®
insulin glargine 300U/mL

Nocturnal hypoglycaemia can cause[23]:

- Impaired cognitive function
- Convulsion
- Coma
- Cardiac arrhythmias resulting in sudden death

Lower risk of anytime and nocturnal hypoglycaemia

Confirmed (≤3.9 mmol/L) or severe hypoglycaemia vs Lantus® from baseline to week 8

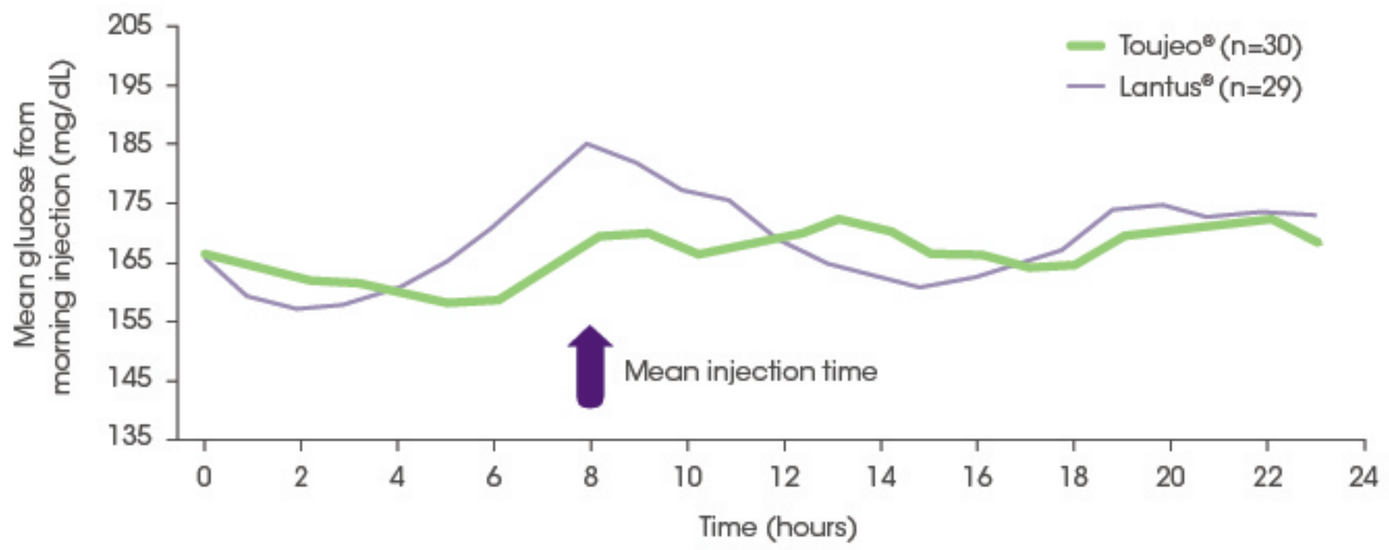


Select a basal analogue with lower risk of hypoglycaemia to avoid complications

More stable within-day glucose profile[24,**]

CGM data

Activity profile at steady state in patients with Type 1 diabetes



The mean 24-hour glucose profiles obtained by CGM were smoother with Toujeo® than with Lantus® irrespective of injection time[24]

vs Lantus®

** The study was a 16-week, exploratory, open-label, parallel-group, two-period crossover study, 59 adults with type 1 diabetes were randomised (1:1:1:1) to once-daily Toujeo® or Lantus® given in the morning or evening (with crossover in the injection schedule). The primary efficacy end point was the mean percentage of time in the target glucose range (4.4-7.8 mmol/L), as measured using continuous glucose monitoring, during the last 2 weeks of each 8-week period. Additional end points included other CGM glycaemic control parameters, hypoglycaemia (per self monitored plasma glucose), and adverse events.

CGM=continuous glucose monitors. CI=confidence interval. T1DM=type 1 diabetes mellitus. T2DM=type 2 diabetes mellitus.

Comparison with degludec

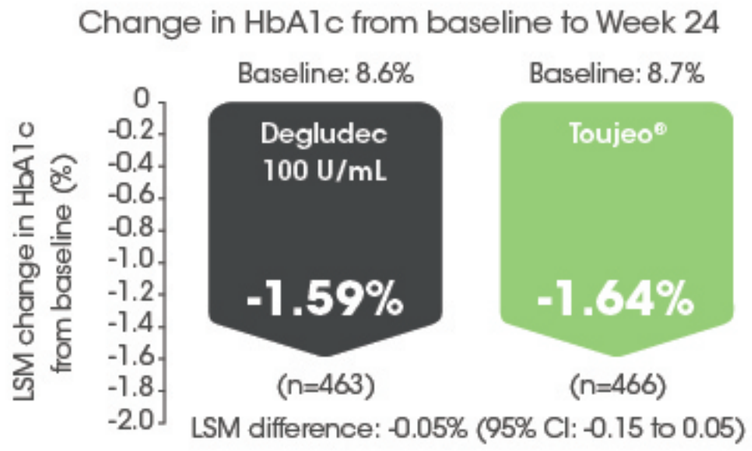
BRIGHT is the head-to-head trial comparing Toujeo® vs degludec 100 U/mL meeting the primary endpoint.

BRIGHT

Full 24-week study period

Powerful and comparable HbA1c reduction[25,*]

Change in HbA1c from baseline to Week 24



Primary endpoint met

p<0.0001 for non-inferiority of Toujeo®

Week 12 ITT population: Toujeo®, n=448; insulin degludec 100 U/mL, n=445[26]
Week 24 ITT population: Toujeo®, n=462; insulin degludec 100 U/mL, n=462

Titration period: first 12 weeks of treatment

Lower hypoglycaemia† rates during the titration period[25,*,‡]

Anytime (24h) confirmed hypoglycaemia (<3.0 mmol/L)

Lower rate§

Toujeo®

-43%

vs degludec 100 U/mL RR (95% CI): 0.57 (0.34 to 0.97); p=0.038‖

Reducing the risk of hypoglycaemia, especially during titration period, is crucial for an effective glycaemic control in the long term[27,28]. It helps:

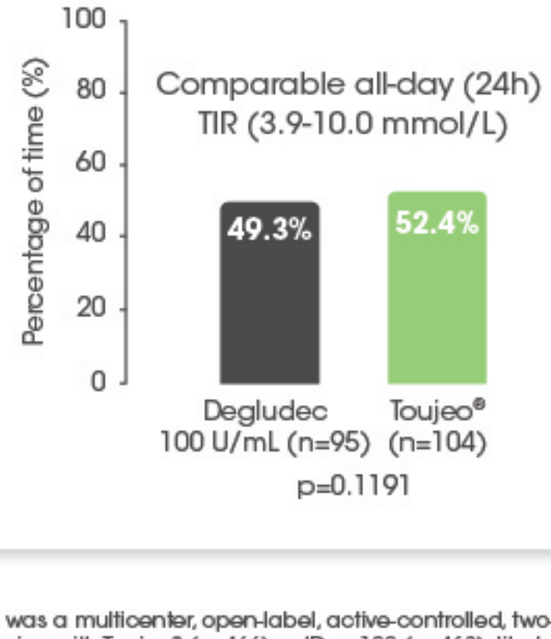
- Eliminate the fear of hypoglycaemia
- Boost confidence to properly titrate and adhere to treatment

vs degludec

oneCare ESTUDI

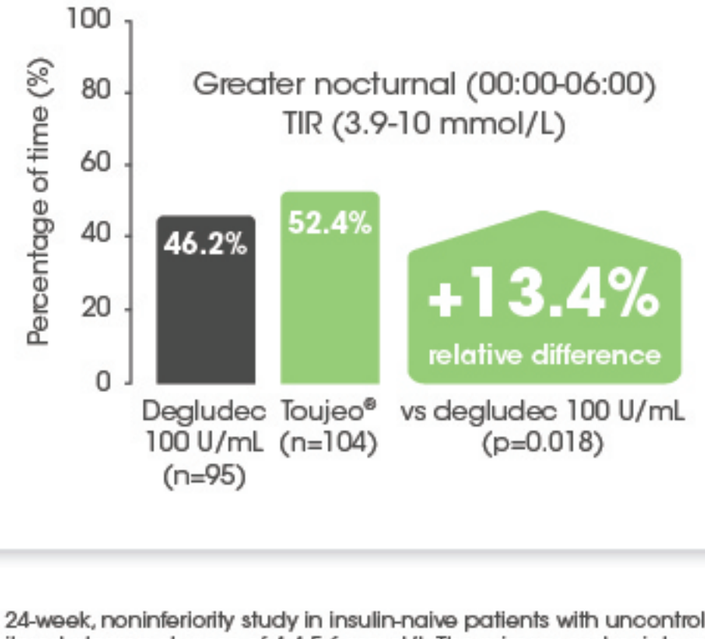
Observed with Toujeo® vs degludec 100 U/mL in a 4-week CGM study period

Comparable all-day time in range[29,¶,**]



More nocturnal time in range[29,¶,**]

Lower nocturnal glycaemic excursions[29,¶,**]



Smoother mean glucose curves at night (00:00-06:00) with Toujeo® vs degludec 100 U/mL (p<0.05)

Lower nocturnal glycaemic excursions

with comparable all-day glycaemic variability

* BRIGHT trial was a multicenter, open-label, active-controlled, two-arm, parallel-group, 24-week, noninferiority study in insulin-naive patients with uncontrolled type 2 diabetes. Participants were randomised 1:1 to evening dosing with Toujeo® (n=466) or IDeg-100 (n=463), titrated to fasting self-monitored plasma glucose of 4.4-5.6 mmol/L. The primary end point was HbA1c change from baseline to week 24. Safety end points included incidence and event rates of hypoglycaemia. Overall, 202 (43.7%) and 221 (47.8%) of participants in the Toujeo® and degludec 100 U/mL treatment groups, respectively, reported adverse events during the 24-week study period. No specific safety concerns were reported.

† Anytime (24 h) confirmed hypoglycaemia (3.9 and <3.0 mmol/L) and nocturnal (00:00–05:59 h) confirmed hypoglycaemia (3.9 mmol/L).

‡ Comparable incidence and rates of hypoglycaemia in the maintenance period (13–24 weeks) and full 24-week study period, were demonstrated.

§ Events per patient year: Toujeo®, 0.49; degludec 100 U/mL, 0.86.

‖ Nominal p-value.

¶ OneCARE study is an observational, multicenter, cross-sectional study included 199 patients with T1DM (≥3 years diabetes duration, HbA1c ≥ 7.5%) who had switched from first-generation BI to Gla-300/IDeg-100 within the past 24 months according to physician discretion. Clinical and laboratory data were obtained from clinical records and during study visit, and CGM data were collected prior to the visit. The primary endpoint was the percentage of time within the predefined CGM glucose range TIR of 3.9-10.0 mmol/L [complete day, night (24:000–05:59) or day (06:00–23-59) period] during 14 consecutive days within a 4-week period with CGM data obtained from the Free-Style Libre®.

** Time-in-range was defined as the percentage of time with target blood glucose level from 3.9 to 10 mmol/L.

CGM=continuous glucose monitors. CI=confidence interval. HbA1c=haemoglobin A1c. ITT=intent-to-treat. LSM=least-squares mean. RR=rate ratio. T1DM=type 1 diabetes mellitus. TIR=time in range.

Comparison with degludec in CKD patients

Toujeo® insulin glargine 300U/mL

High-risk patients are at greater risk of hypoglycaemia

CKD patients:

2X risk of hypoglycaemia[30]

Elderly patients:

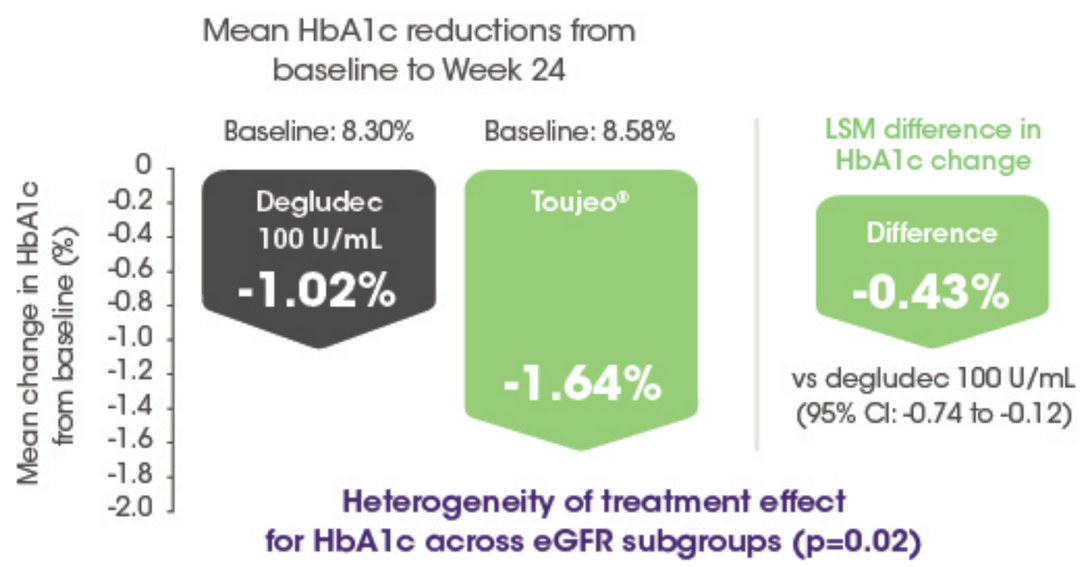
78.2% of diabetic patients attended AED due to hypoglycaemia were the elderly[31]

An insulin treatment that decreases HbA1c without increasing the risk of hypoglycaemia is clinically important

Greater HbA1c reduction with comparable hypoglycaemic risk in high-risk patients

CKD patients (eGFR<60 mL/min/1.73m²)[32,*]

61% greater HbA1c reduction



Comparable anytime confirmed hypoglycaemia rate

Anytime (24 h) confirmed hypoglycaemia rate (3.9 mmol/L)

Events per participant-year

Degludec 100 U/mL	Toujeo®
13.9	13.5

RR (95% CI): 0.93 (0.56 to 1.54)

vs degludec

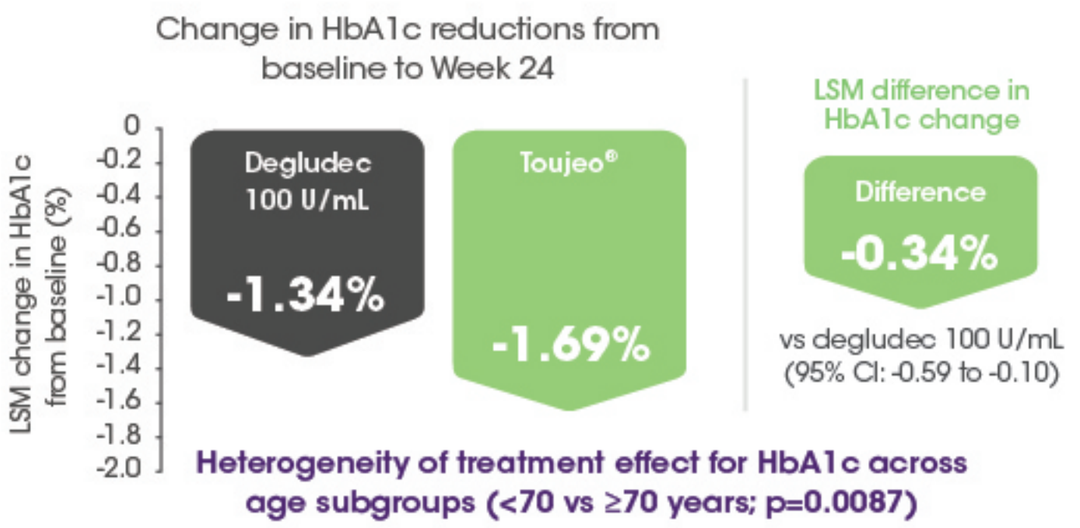
* BRIGHT trial was a multicentre, open-label, randomised, active-controlled, two-arm, parallel-group, 24-week study in insulin-naïve uncontrolled type 2 diabetes (T2D). Participants were randomised 1:1 to evening Toujeo® (n=466) or IDeg-100 (n=463) and stratified based on baseline estimated glomerular filtration rate (eGFR) for this analysis.

AED=accident and emergency department. CI=confidence interval. CKD=chronic kidney disease. eGFR=estimated glomerular filtration ratie. HbA1c=haemoglobin A1c. LSM=least-squares mean. RR=rate ratio.

Comparison with degludec in elderly patients

Elderly patients (Aged ≥70 years)[33,*]

26% greater HbA1c reduction



Heterogeneity of treatment effect for HbA1c across age subgroups (<70 vs ≥70 years; p=0.0087)

Comparable anytime confirmed hypoglycaemia rate

Anytime (24 h) confirmed hypoglycaemia rate (3.9 mmol/L)

Events per participant-year

Degludec 100 U/mL	Toujeo®
11.44	12.95

RR (95% CI): 1.14 (0.75 to 1.74)

vs degludec

* BRIGHT was the first head-to-head randomised trial comparing Toujeo® and IDeg in insulin-naïve adults with T2DM. In this subanalysis, endpoints were studied by predefined (</≥65 years, n=596/333) and post hoc (</≥70 years, n=768/161) age groups.

CI=confidence interval. HbA1c=haemoglobin A1c. LSM=least squares mean. RR=rate ratio. T2DM=type 2 diabetes mellitus.

Flexibility to start and titrate

Toujeo®
insulin glargine 300U/mL

Toujeo® has a flexible time of injection, once daily in morning or evening[11]

6-hour injection window

Sustained glycaemic control with long duration of action

Flexibility to upgrade[11]

Insulin-naïve patients

Start: 0.2 U/kg

Dose calculated based on weight

Weight range*
50 -75 kg

Dose range
10 -15 U/day

Patients on OD basal insulin

1:1 conversion

No dose recalculation required

Patients on BID basal insulin

80% of total previous daily insulin dose

Flexibility to support various titration algorithms‡

Once weekly[16] (Hong Kong study)

- Self-titrated weekly based on average of 3 fasting SMBG readings per week, aiming for 4.4 – 6.0 mmol/L
- Dose increased by 1U per week if greater than defined target

Every 3 days[2] (American Diabetes Association)

- Increase 2U every 3 days to reach FPG target of ≥4.4 – ≤5.6 mmol/L

Every 3 to 4 days[17,18,†]

- Titrated no more than every 3 to 4 days
- Dose increased by 6U every 7 days (based on previous 3 measurements) if the median SMBG is >7.8 mmol/L, and by 3U if >5.6 and <7.8 mmol/L

Once daily[34]

- Self-titrated by 1U per day, aiming for fasting SMBG 4.4 to 5.6 mmol/L
- Dose increased by 1U per day if fasting SMBG >5.6 mmol/L

* Weight change shown is illustrative only and dose calculation is not limited to this range.

† Titration algorithm for people with type 2 diabetes is based on EDITION studies 1, 2 and 3. Insulin dose is to be increased by 6 units every 7 days and not more than every 3-4 days (based on the preceding 3 measurements) if the median SMPG is ≥7.8 mmol/L, and by 3 units if >5.6 and<7.8 mmol/L, decreased by -3 units or at investigator's discretion if <3.3 mmol/L or occurrence of ≥2 symptomatic or 1 severe hypoglycaemia episode(s) in the preceding week. Median fasting SMPG from the last 3 days. Toujeo® was always given in the evening.

‡ For illustrative purpose only; based on the titration algorithm used in EDITION 1, 2 and 3 clinical studies. If hypoglycaemia occurs, dose reduction at physician's discretion.

BID=twice daily. FPG=fasting plasma glucose. OD=once daily. SMBG=self-monitoring of blood glucose.

Toujeo® offers optimal diabetic management to your patients

Key benefits of Toujeo®

Powerful HbA1c reduction[17-22,25,32,33,*]

Lower incidence of hypoglycaemia[15-22,25,32,33,†]

vs Lantus®[17]: Up to **31%** LOWER incidence

vs degludec[25]: Up to **43%** LOWER rates

Better glucose stability[11]

vs Lantus®[24]: **50%** LOWER within-day fluctuation

vs degludec[35]: **20%** LOWER within-day fluctuation

Elderly

Renal impairments

Cater for individual needs, especially for high risk populations[32,33]

Up to **36** hours

Once daily with 36-hour duration of action[11]

*Toujeo® has a significant HbA1c reduction in patients switching from NPH and comparable HbA1c reduction with degludec and Lantus®.

† Toujeo® has lower incidence of hypoglycaemia than Lantus®, detemir, degludec and NPH insulin.

HbA1c=haemoglobin A1c. NPH=neutral protamine hagedorn.

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Abbreviated prescribing information: Presentation: Insulin glargine 300 IU/ml solution for injection. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years. **Dosage:** Once daily (preferably at the same time every day up to 3 hours before or after the usual time of administration), with adjusted individual dosage. Please refer to the full prescribing information for guidelines on switching between other insulin preparations. **Administration:** Subcutaneous injection. Toujeo is NOT INTENDED FOR INTRAVENOUS USE since it could result in severe hypoglycaemia. Toujeo must not be drawn from the cartridge of the SoloStar pre-filled pen into a syringe or severe overdose can result. **Contraindications:** Hypersensitivity to insulin glargine or to any of the excipients. **Precautions:** Toujeo has not been studied in children below 6 years of age. **Elderly:** Progressive deterioration of renal function may lead to a steady decrease in insulin requirements. **Renal impairment:** Insulin requirements may be diminished due to reduced insulin metabolism. **Hepatic impairment:** Insulin requirement may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. Perform continuous rotation of injection site to reduce risk of lipodystrophy and cutaneous amyloidosis. Blood glucose monitoring is recommended after change in injection site. Hypoglycaemia. Intercurrent illness. Combination of Toujeo with pioglitazone. Medication errors prevention. **Interactions:** Effects enhanced by oral antidiabetics, ACEI, disopyramide, fibrates, fluoxetine, MAOIs, pentoxifylline, propoxyphene, salicylates, sulfonamide antibiotics. Effects reduced by corticosteroids, danazol, diazoxide, diuretics, glucagons, isoniazid, oestrogens and progestogens, phenothiazine derivatives, somatropin, sympathomimetics, or thyroid hormones, atypical antipsychotics and protease inhibitors. Beta-blockers, clonidine, lithium or alcohol may either potentiate or weaken the effects of insulin. Pentamidine may cause hypoglycaemia, followed by hyperglycaemia. The signs of adrenergic counter-regulation may be reduced or absent under the influence of sympatholytic medicinal products such as Beta-blockers, clonidine, guanethidine and reserpine. **Fertility, pregnancy and lactation:** Animal studies do not indicate direct harmful effects with respect to fertility and reproductive toxicity. The use of Toujeo may be considered during pregnancy if clinical needed. It is unknown whether insulin glargine is excreted in human milk. **Overdose:** Insulin overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. More severe episodes with coma, seizure or neurologic impairment may be treated with glucagon (intramuscular or subcutaneous) or concentrated glucose solution (intravenous). **Undesirable effects:** Hypoglycaemia, lipohypertrophy, injection site reactions. For common, uncommon, rare and very rare undesirable effects, please refer to the full prescribing information. **Storage:** Before first use: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. After first use: Store below 30°C. Use within 42 days. Do not freeze. **Preparation:** Toujeo 5 x 1.5ml (450IU) pre-filled pens. **Legal Classification:** Part 1 Poison **Full prescribing information is available upon request.**

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Toujeo® insulin glargine 300U/mL

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