**INTRODUCTION**

- Relative risk of hypoglycemia was analyzed using the Cochran–Mantel–Haenszel method.
- Statistical analyses:
  - Participants:
    - Most participants (56%) had baseline eGFR ≥60 to <90 mL/min/1.73 m²,
    - Post hoc analyses have shown these benefits were maintained regardless of age, BMI and diabetes duration.

**OBJECTIVE**

To investigate the impact of renal function on HbA₁c reduction and hypoglycemia benefits with insulin glargine 300 U/mL (Gla-300). Statistical analyses:

- **Methods**
  - Design:
    - Post hoc patient-level meta-analysis of EDITION 1, 2 and 3 (NCT01499905, NCT01676920) at 6 months.
    - EDITION 1: 2 and 3 were multicenter randomised (1:1), open-label, two-arm, parallel-group, phase 3a studies.

- **Participants**:
  - Adults (21-80 years of age) with previous diagnosis of T2DM:
    - EDITION 1: on basal insulin therapy.
    - EDITION 2: on basal insulin therapy in combination with oral antihyperglycaemic drugs (OADs) for 24 weeks.
    - EDITION 3: insulin naive on OADs for 26 weeks.

- **Participants with severe, unstable or end-stage renal disease (estimated glomerular filtration rate <15 ml/min/1.73 m²) were excluded from the EDITION trials.

**Treatment**:

- Once-daily evening injection of Gla-300 or Gla-100 followed a fasting state and monitored plasma glucose (SMG%) of 80-100 mg/dl (4.4-5.6 mmol/l).

**Subgroups**:

- The effects of Gla-300 vs Gla-100 were assessed in renal function subgroups based on baseline eGFR (ml/min/1.73 m²).

**Outcomes**:

- Mean change from baseline HbA₁c was assessed together with the percentage of participants achieving HbA₁c target <7.0 % and <5.7 %, respectively.

**Hypoglycemia** was assessed according to the following guidelines:

- Cumulative number of events, relative risk (1 event) and rate per participant-year of confirmed (≥70 or <54 mg/dl, ≥9.9 or 2.9 mmol/l) or severe nocturnal (00:00-05:59h) or anytime (24 h) hypoglycemic events.

**Statistical analyses**:

- Change in HbA₁c was analyzed using Mixed Effect Model Repeated Measurement Model (MMRM).

**Results**:

- Most participants (78%) had baseline eGFR ≥60 to <90 mL/min/1.73 m².

**SUMMARY**

- This patient-level meta-analysis of pooled 6-month data from the EDITION 1, 2 and 3 studies of participants with T2DM by eGFR subgroups (normal (≤60), mild and moderate renal impairment) at baseline demonstrated:
  - Consistent and comparable HbA₁c reductions for both the Gla-300 and Gla-100 groups, regardless of renal function subgroups.
  - Hypoglycemia rates at night and at any time were consistently lower for participants treated with Gla-300 vs Gla-100 and were not affected by eGFR subgroups at baseline.

**CONCLUSION**

Gla-300 provided comparable glycaemic control and consistently reduced the risk of nocturnal hypoglycemia vs Gla-100 in participants with T2DM regardless of renal function, with no increase in any time hypoglycemia.