**Introduction**

- Hypoglycemia is a common adverse consequence of insulin replacement therapy, and it is a major barrier to optimal T1DM management in terms of worry and fear of that can affect the quality of life of both children with T1DM and their caregivers and in terms of accepting higher blood glucose levels in order to avoid hypoglycemia.
- That creates the need for major advancements in insulin pump technology that improves the glycemic control while it reduces the risk of hypoglycemia.
- PLGS system works through a predictive algorithms that utilizes the glucose value obtained through a subcutaneously inserted glucose sensor to suspended insulin delivery from the insulin pump if the predicted glucose is expected to reach hypoglycemia range in the next 30 minutes.

**Methods**

- The protocol was registered in PROSPERO, registration No: CRD42016118529.
- **Eligibility Criteria:**
  - Type of studies: Randomized and quasi randomized controlled trials.
  - Type of Participants: Children and adolescents age 2-18 years known to have T1DM diagnosed more than 6 months.
  - Type of intervention: SAP-PLGS
  - Type of control: Insulin pump with no continuous glucose sensor or with subcutaneous sensor with PLGS feature turned off.

**Outcomes:**

- **Primary outcomes:**
  - Percentage of time with hypoglycemia defined as sensor glucose (SG) < 3.9 mmol/l (<70 mg/dl).
  - Percentage of time with nocturnal hypoglycemia defined as hypoglycemia SG <3.9 mmol/l (<70mg/dl).

- **Secondary outcomes:**
  - Percentage of time spent with severe hypoglycemia defined as SG <2.8 mmol/l (<50 mg/dl), or altered level of consciousness or seizure.
  - Percentage of time spent with hyperglycemia based on SG >10 mmol/l (180 mg/dl) and >13.6 mmol/l (250 mg/dl).

- Two review authors independently selected trials for inclusion, assessed trial quality, and extracted the data.
- We examined heterogeneity among trials with the Chi2 and I2 statistics and used GRADE methodology to assess the quality of evidence.
- Data analysis were done through Review Manager software (RevMan version 5.3).

**Results**

- We included 5 randomized controlled trials with total sample size of 493 participants and study duration ranging between 2 weeks to 6 months.
- All the included studies have at least one domain with high risk of bias except one study with low risk of bias.
- We planned to conduct a subgroup and sensitivity analysis based on pre-specified sources of expected heterogeneity. However, there were not enough studies to conduct this analysis.

- Percentage of time with hypoglycemia defined as sensor glucose (SG) < 3.9 mmol/l (<70 mg/dl):

- Percentage of time with nocturnal hypoglycemia defined as sensor glucose (SG) < 3.9 mmol/l (<70mg/dl):

**Summary of findings for the main comparison**

**Conclusion**

- Hypoglycemia is an important patient outcome that can affect quality of life of both patients and their caregivers and can affect indirectly HbA1c as well.
- There is moderate quality evidence that PLGS is superior to SAP in decreasing hypoglycemia <3.9 mmol/l.
- There is high quality evidence that PLGS is superior to SAP in decreasing nocturnal hypoglycemia <3.9 mmol/l.
- There is low quality evidence that PLGS is superior to SAP in decreasing hypoglycemia >2.8 mmol/l.
- There is no increase in the % of hyperglycemia with PLGS use.

**Reference**