

Safety and Quality of Life of Various Artificial Pancreas Systems in Patients with Type 1 Diabetes Mellitus: A Systematic Review of Real-World Evidence

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Background and Objective

Background: Type 1 diabetes mellitus (T1DM) is caused by the autoimmune destruction of the islet β -cells and results in absolute insulin deficiency¹. It requires continuous glucose monitoring and intensive insulin therapy. Artificial pancreas (AP) may offer ideal treatment option improving QoL and minimizing safety risks^{2,3}.
Objective: This systematic review assessed the real-world evidence on the safety and QoL of various AP systems in the management of T1DM.

Methodology

- A systematic search in accordance with PRISMA guidelines was conducted in the biomedical databases (Embase® and PubMed®)
- Observational studies published in English language between 01 January 2018 and 31 May 2023, reporting safety of various AP systems, and its effect on the QoL of patients living with T1DM were included
- Screening of title/abstracts (TI/AB) and full texts were performed by two independent reviewers (Figure 1)
- Conflicts relating to eligibility were resolved by a third independent reviewer
- Data was extracted and then quality checked by another independent reviewer

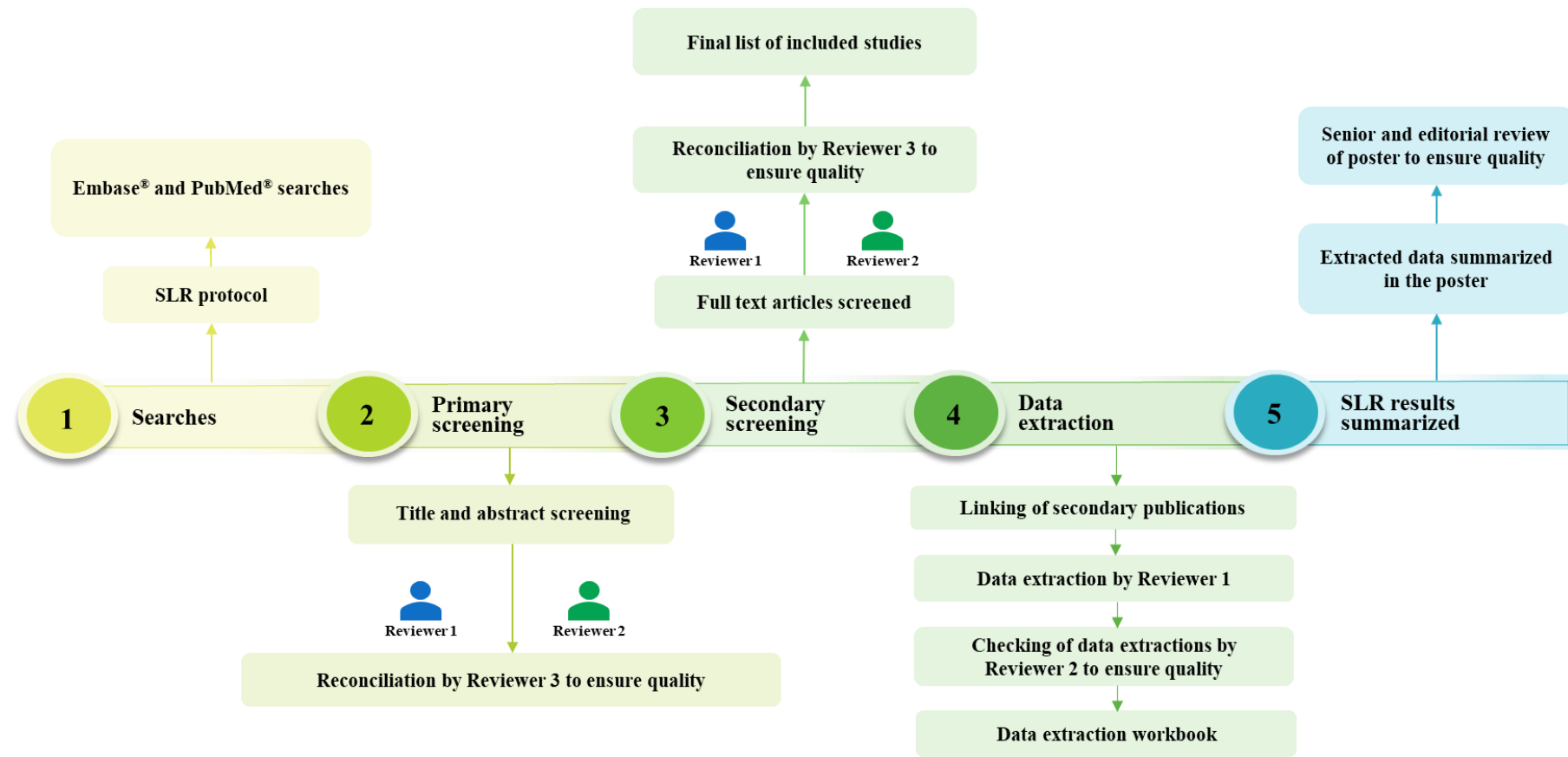


Figure 1: SLR methodology

Results

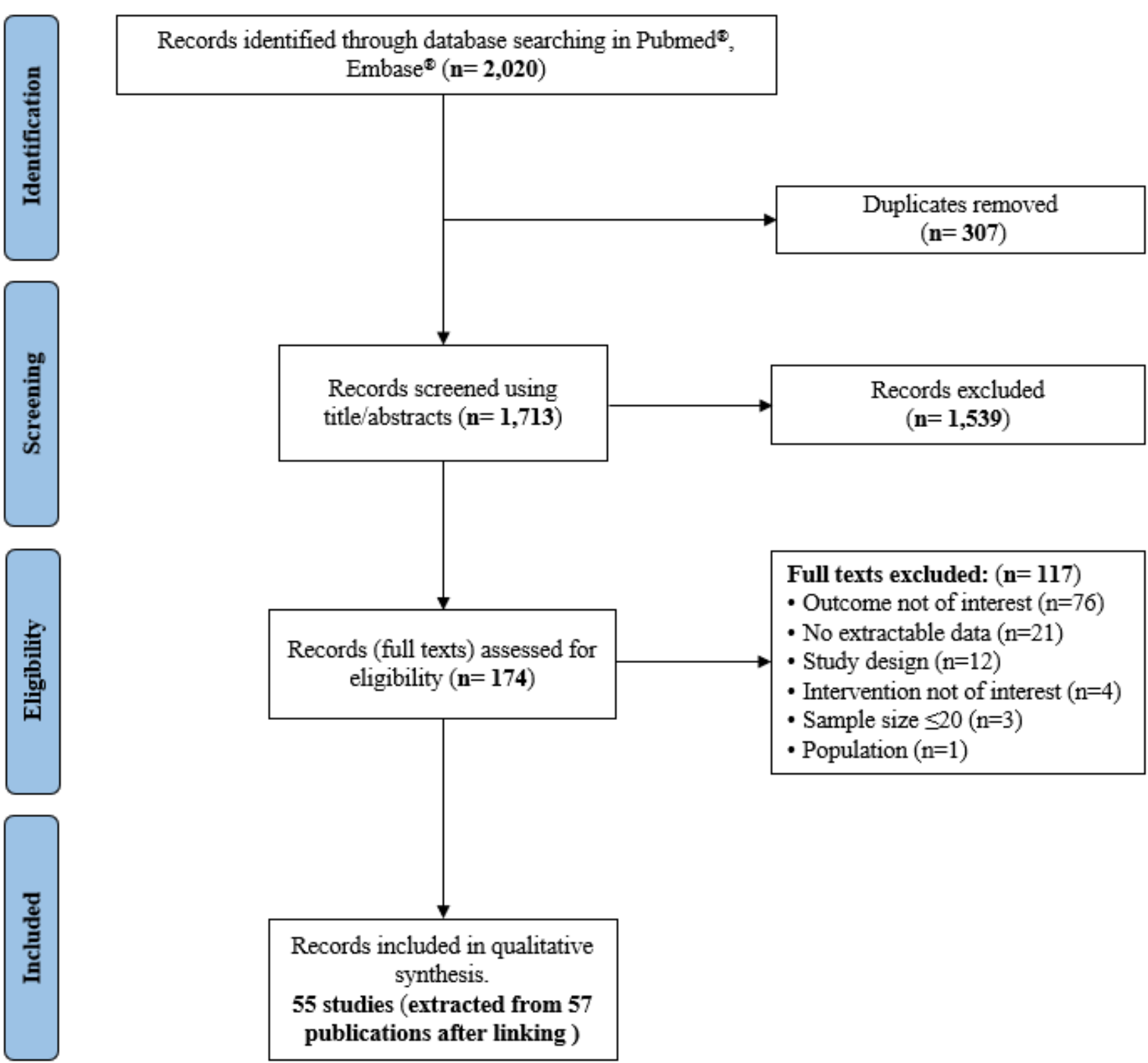


Figure 2: PRISMA diagram

- A total of 2,020 records were retrieved from Embase® and PubMed®
- After removing duplicates, 1,713 records were screened for TI/AB, followed by full-text screening of 174 records
- Finally, 57 publications were included which after linking led to extraction of 55 unique studies. (Figure 2)
- Most of the included studies were retrospective observational (43.6%), followed by interviews/surveys (27.3%) (Figure 3)

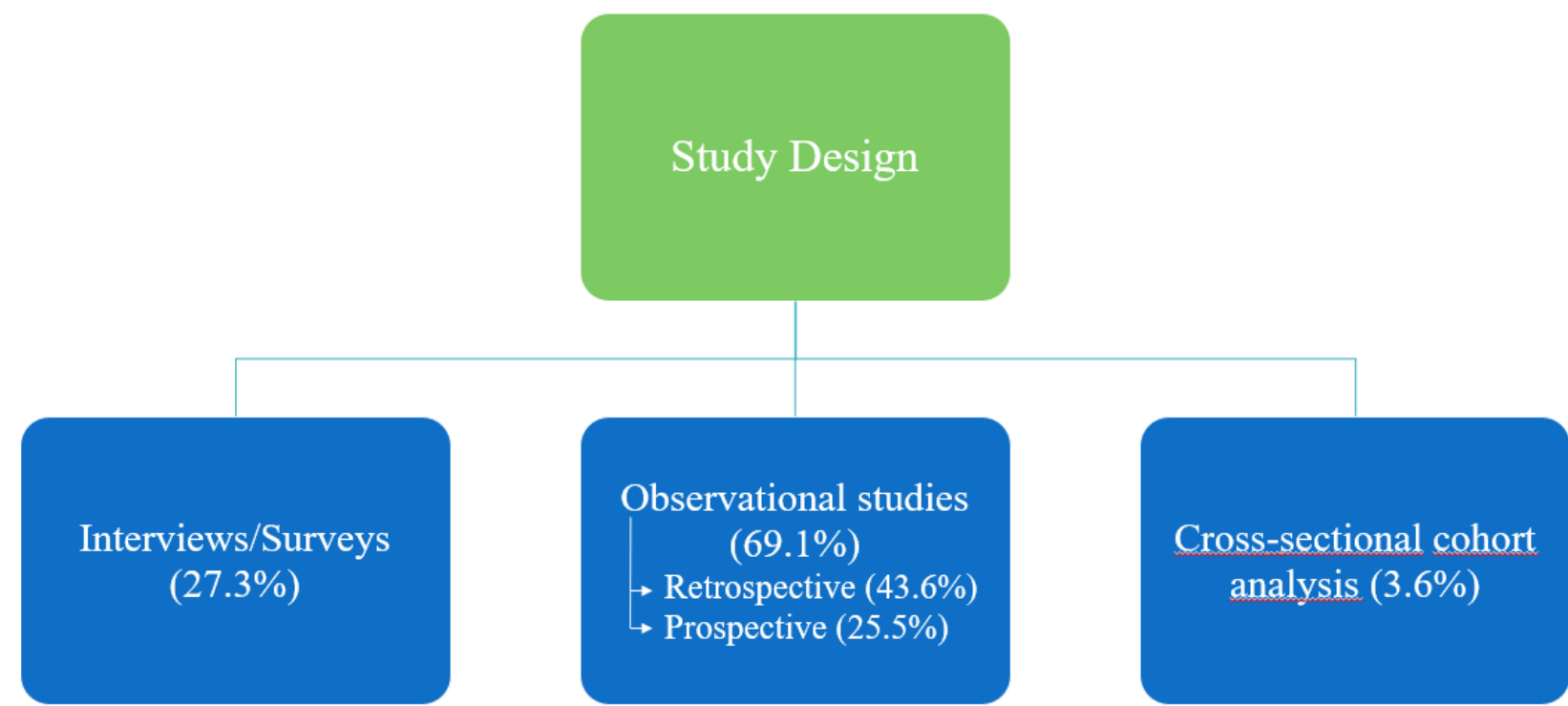


Figure 3: Types of study design

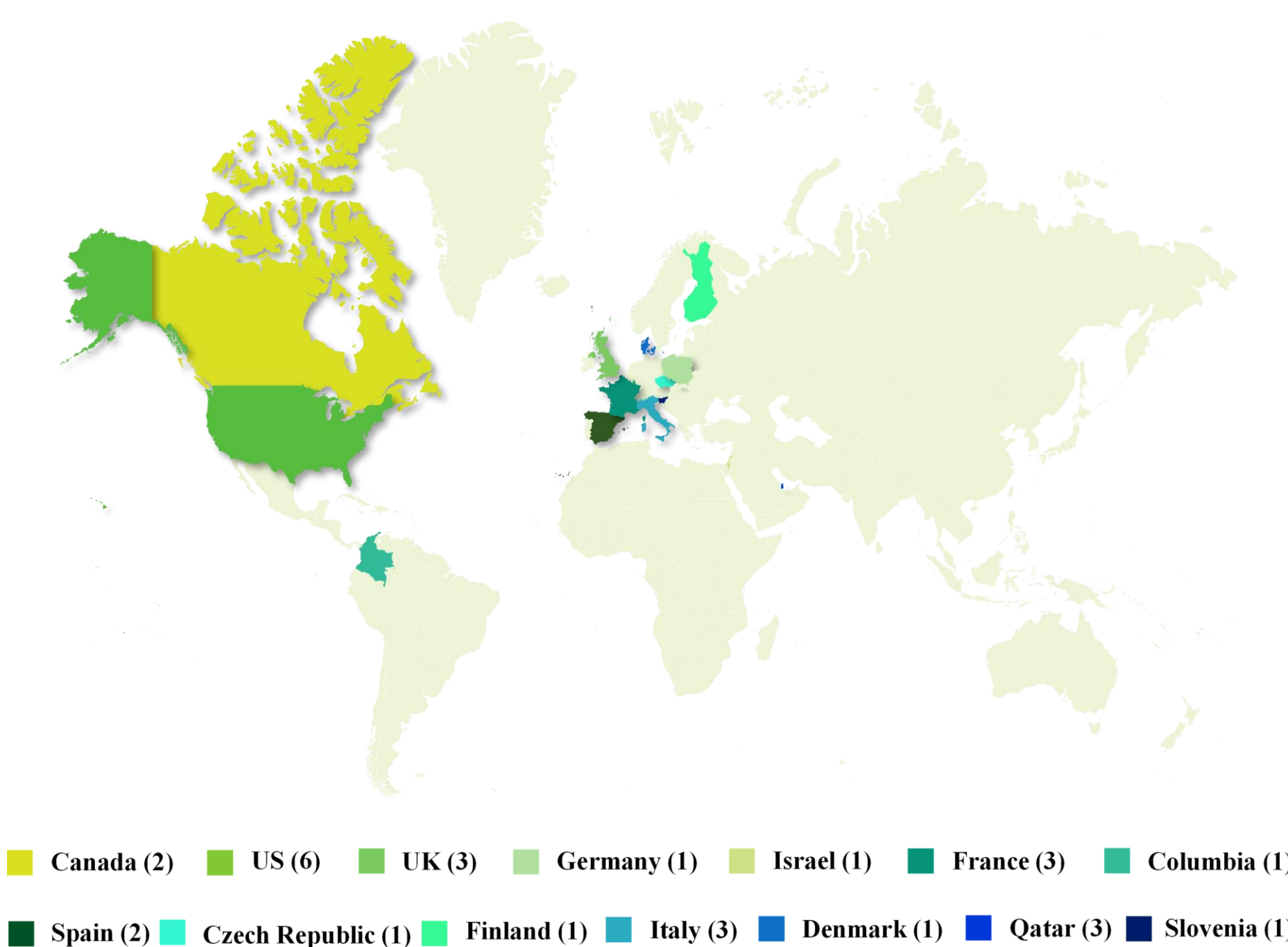


Figure 4: Geographical distribution of conducted studies

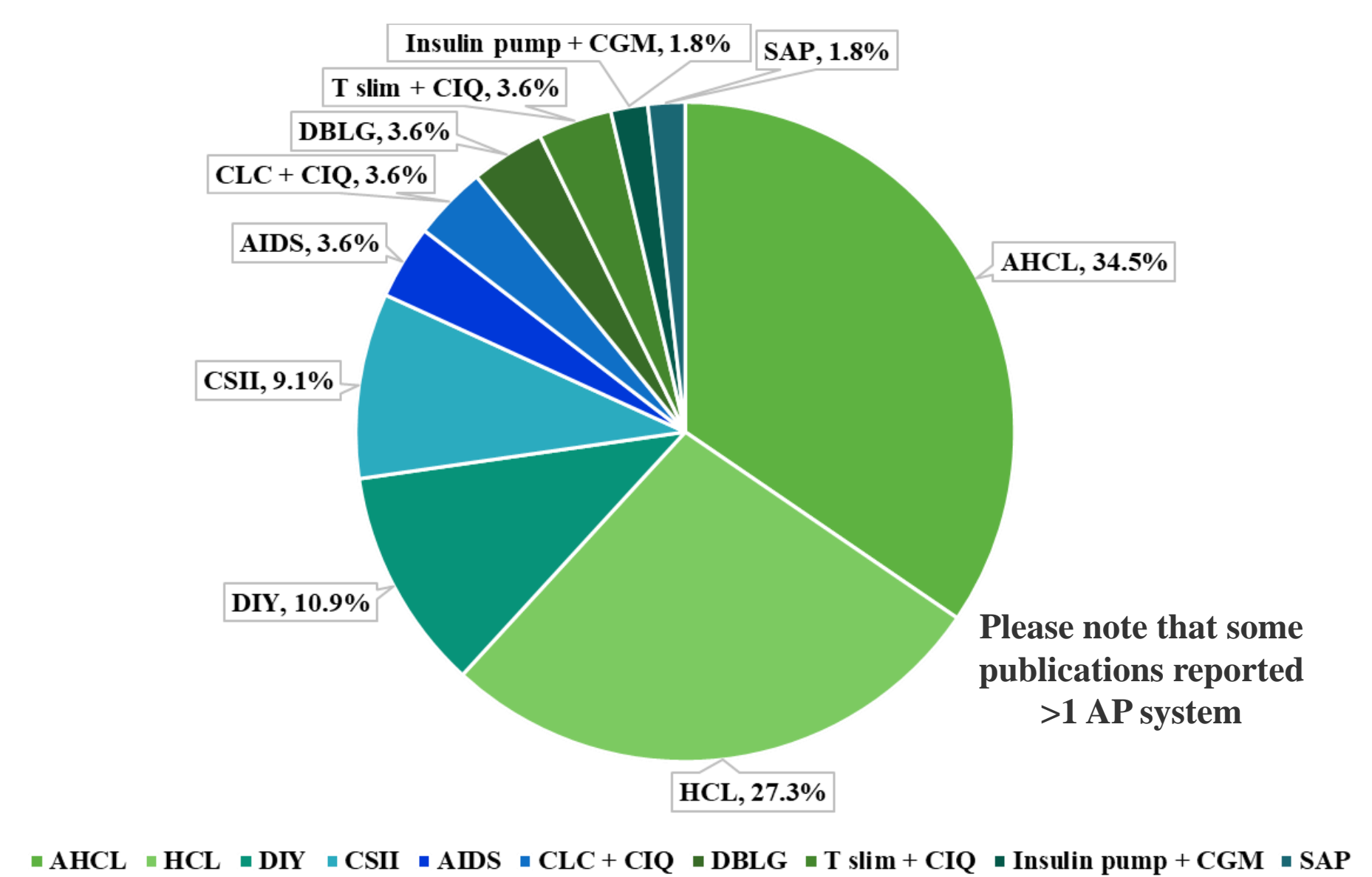
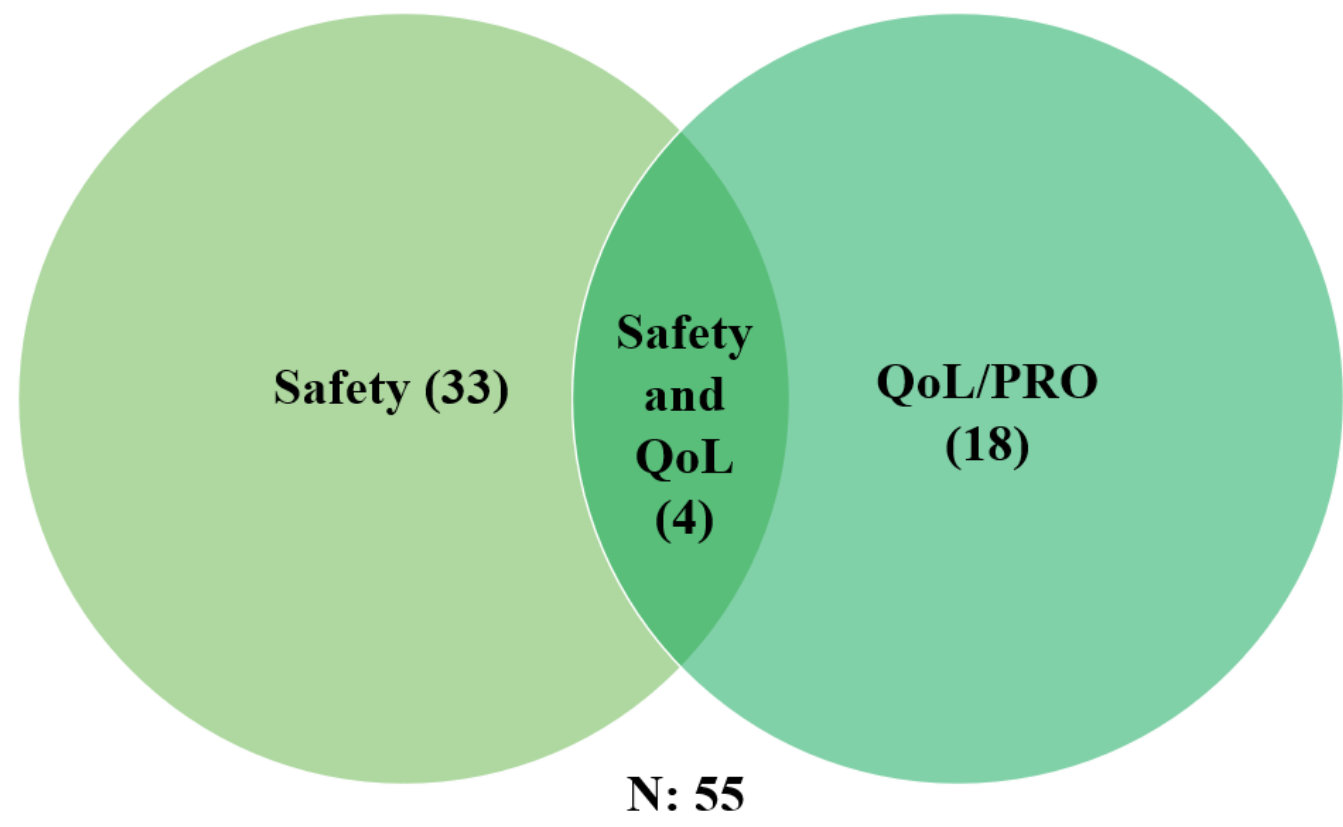


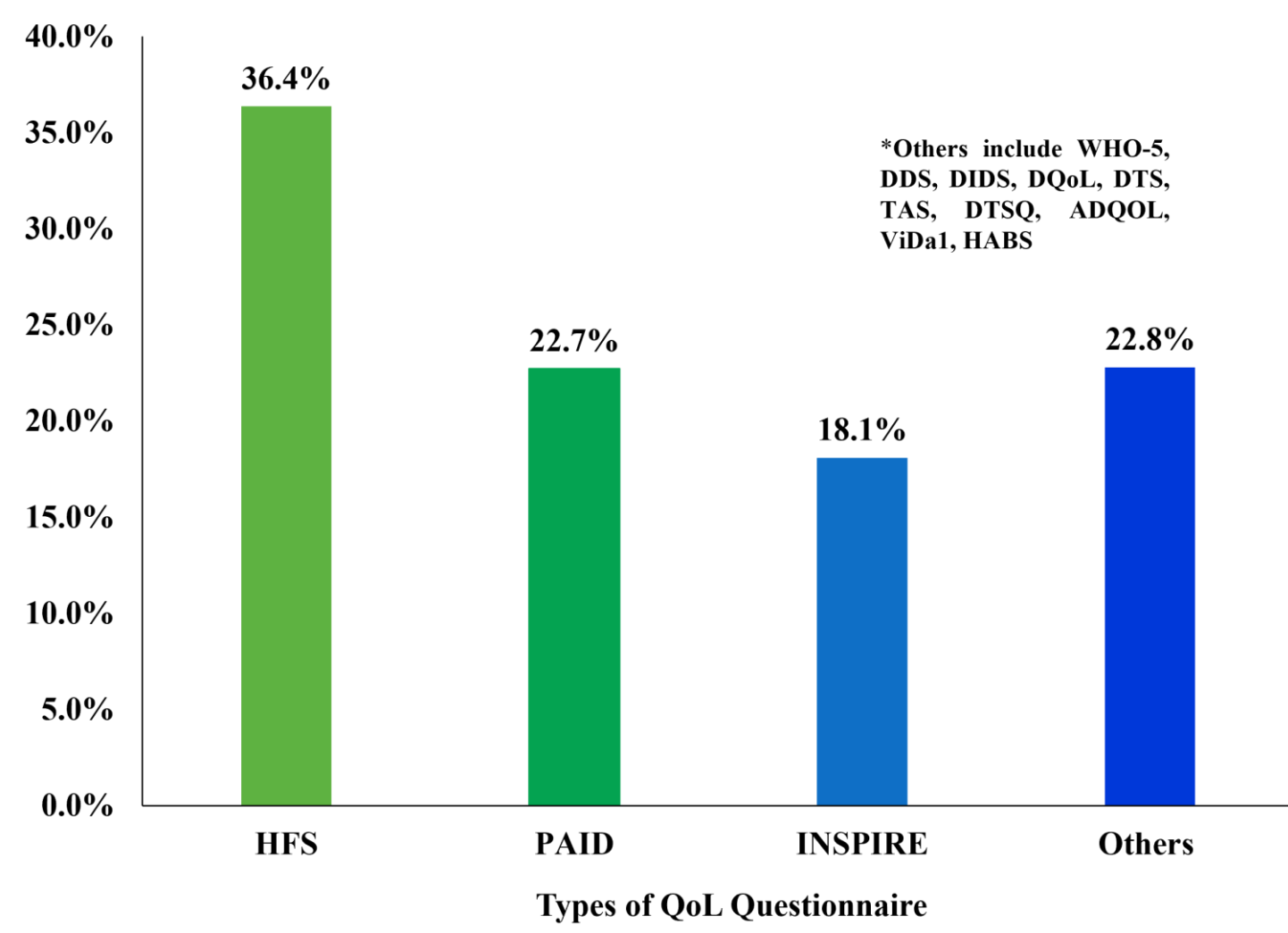
Figure 5: Types of artificial pancreas systems

- Majority of the studies were conducted in the US (20.6%) followed by UK, France, Italy, and Qatar (10.3% each) (Figure 4)
- Advanced hybrid closed-loop (34.5%) and hybrid closed-loop (27.3%) were the two most frequently utilized AP systems (Figure 5)



Please note that some publications reported >1 types of outcome

Figure 6: Types of outcomes



Please note that some publications reported >1 QoL questionnaire

Figure 7: Types of QoL questionnaire

- A total of 37/55 studies reported safety-related data, of which 18 reported AEs/complications, while ‘no adverse events’ were reported in 19 studies (Figure 6)
- Amongst those reporting AEs/complications, 50% reported severe hypoglycemic events, followed by diabetic ketoacidosis (33.3%)
- Surveys/questionnaires recording QoL of patients were administered in 22 studies, most (95%) of which suggested improvement in the QoL with usage of AP systems
- Most assessed QoL questionnaires included HFS (36.3%), PAID (22.7%), and INSPIRE (18.1%) (Figure 7)

Conclusions

- RWE identified from our review indicates that the AP systems improved QoL, thereby reducing the burden of T1DM
- Improved QoL was defined in terms of reduction of glucose variability, improved metabolic control, reduced fear of hypoglycemia, diabetes distress, and improved sleep quality
- AP systems were also preferred because of device related satisfaction
- Major limitation identified through our review was patient compliance

Abbreviations: ADQOL: Audit of diabetes dependent quality of life; AE: Adverse events; AIDS: Automated insulin delivery system; AP: Artificial pancreas; CGM: Continuous glucose monitoring; CIQ: Control-IQ technology; CLC: Closed-loop control; CSII: Continuous subcutaneous insulin infusion; DBLG1™: Diabeloop generation 1; DDS: Diabetes distress scale; DIDS: Diabetes impact and device satisfaction; DIY: Do-it-yourself; DQoL: Diabetes quality of life; DTS: Diabetes treatment satisfaction; DTSQ: Diabetes treatment satisfaction questionnaire; HABS: Hypoglycemic attitudes and behavior scale; HFS: Hypoglycemia fear survey; INSPIRE: Insulin dosing systems: perceptions ideas reflections and expectations; PAID: Problem areas in diabetes; PRISMA: Preferred reporting items for systematic reviews and meta-analyses; PRO: Patient-Reported Outcomes; QoL: Quality of life; RWE: Real-world evidence; SAP: Sensor-augmented pump; SLR: Systematic literature review; t slim: Tandem's t:slim; T1DM: Type 1 diabetes mellitus; TAS: Technology acceptance scale; TI/AB: Title/Abstract; UK: United Kingdom, US: United States, WHO-5: World Health Organization- five well-being questionnaire

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