Glycaemic outcomes associated with do-it-yourself artificial pancreas systems (DIYAPS): Initial insights from the Association of British Clinical Diabetologists (ABCD) DIYAPS audit programme

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Introduction

Use of DIY APS (a patient/community created closed-loop system) is increasing internationally with several thousand users worldwide. Although users report high levels of safety and efficacy they are currently unapproved and unlicensed. Randomised control trial data is limited. Thus, objective real-world glycaemic and safety data is needed to reassure clinicians and potential future users of their safety.

The ABCD DIYAPS audit programme launched in 2020 with the aim of providing clinically validated data. We report preliminary findings.

Methods

Clinicians were asked to enter user' data as captured in routine clinical encounters into a bespoke online audit tool and for this data analysis.

Changes from baseline for HbA1c and weight were assessed using paired t-tests. Where baseline data was not available due to the retrospective nature of the audit (e.g. time in range), we have reported outcomes at follow-up only. Analyses were conducted in Stata 16 SE, expressed in mean ±SD unless stated otherwise

Results

One-hundred and five users were included, 83.8% White British or Irish, 66.4% female, median duration diabetes 26 years (IQR 17-33.3), with mean baseline HbA1c 55.9mmol/mol±10.3, weight 82.2kg±24.3 and BMI 28.6kg/m^{2}SD±9.5.

Over a median follow-up of 0.7 years (IQR 0.4-1.8) HbA1c reduced by -7.7mmol/mol (95% CI: 5.4-10.0, P<0.001). Weight increased by 1.2kg (95% CI: 0.2-2.2, P=0.02). At follow-up, mean time in range (TIR, glucose 3.9-10mmol/L) was 74.2%±19.6 with a mean time below range (TBR, glucose <3.9mmol/L) 3.1%±2.3. 69.4% achieved the recommended TIR>70% and 77.6% achieved TBR<5%.

Changes in weight and HbA1c are demonstrated in **figures 1 and 2** respectively (across).

Safety outcomes

Three episodes of severe hypoglycaemia were reported, two of which required admission. There was one admission for hyperglycaemia. No other admissions or paramedic callouts were recorded. Four user reported adverse events were noted including insulin over delivery due to interference from another application (n=1), excessive weight gain (n=1) and hypoglycaemia due to exercise (n=2).
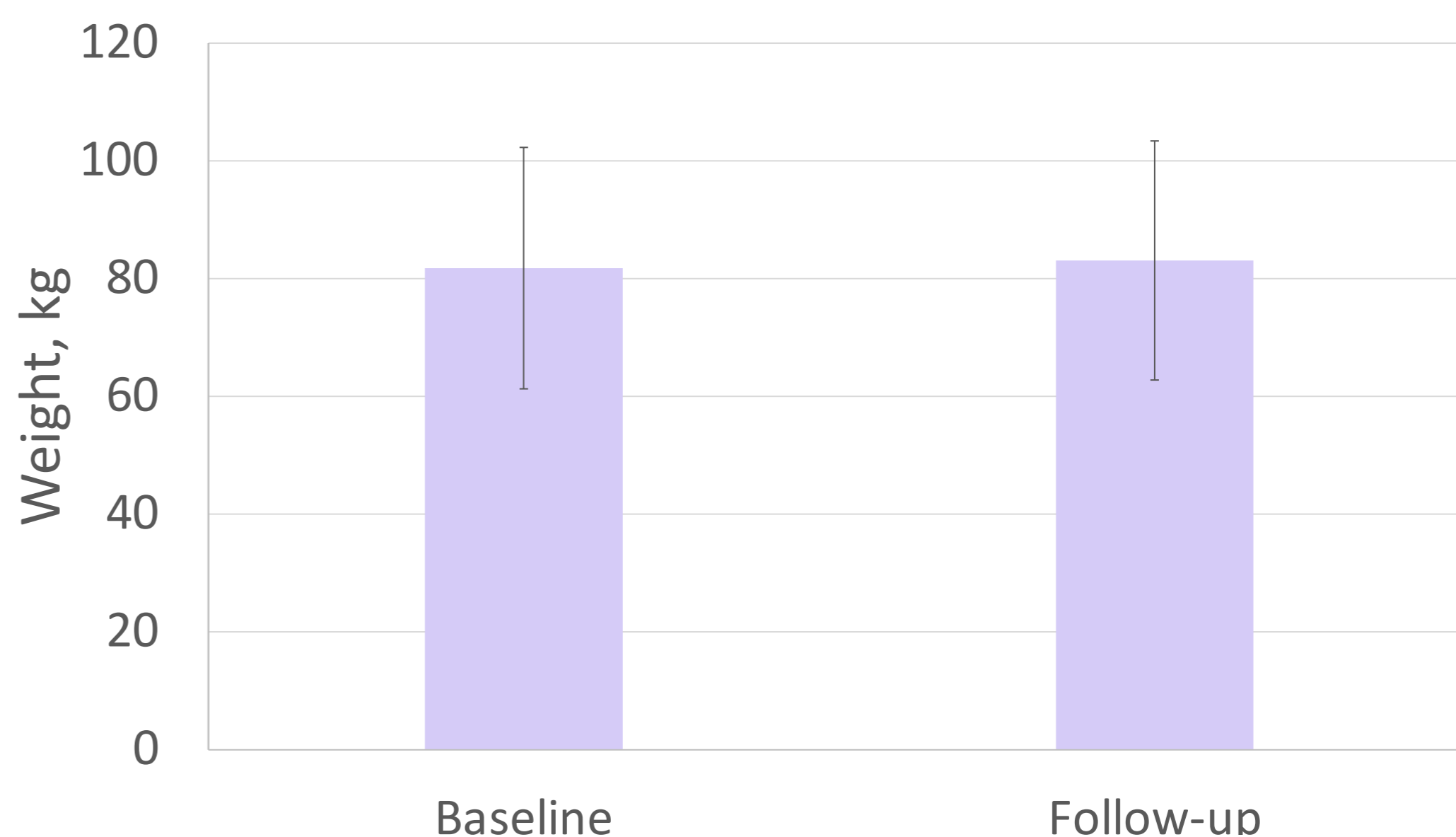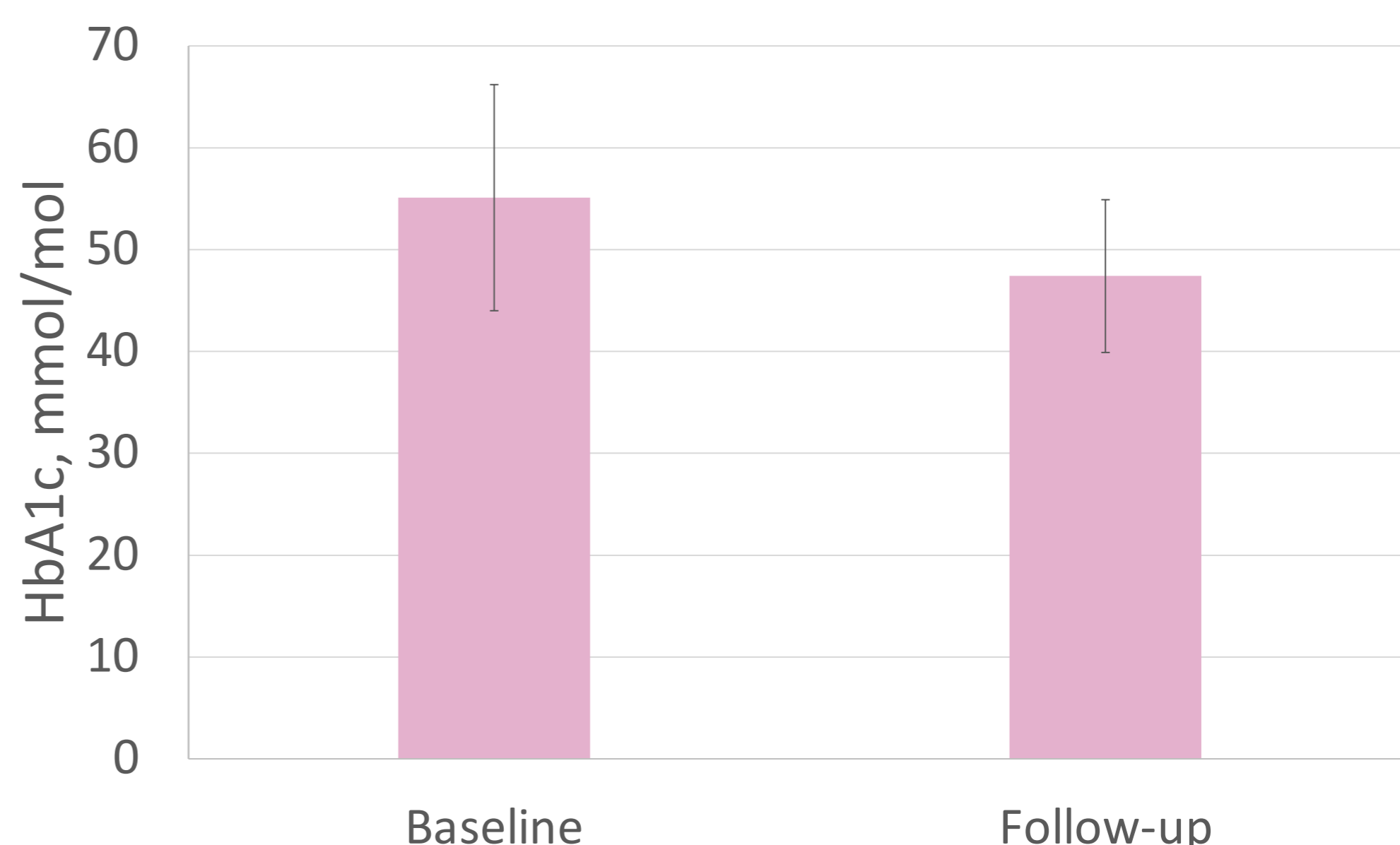

Figure 1. (above) Bar chart showing weight at baseline and follow-up, error bars showing standard deviation

Figure 2. (below) Bar chart showing HbA1c at baseline and follow-up, error bars showing standard deviation

Conclusions

Our initial analysis suggests that DIYAPS use is associated with improvements in HbA1c at follow-up, with achievement of TIR similar to commercial closed loop systems. Most users achieved the recommended % time in and below target ranges. Current safety outcomes are reassuring but continued surveillance for potential adverse outcomes is required, with ongoing healthcare professional understanding and oversight.

Comparison with commercially available alternatives such as the MedTronic 780G, Control IQ and CAM APS FX will also be needed.

References

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