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The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: A randomized controlled trial

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The aim of this multi-centre, randomized, controlled crossover study was to determine the efficacy of adding Continuous Glucose Monitoring (CGM) to insulin pump therapy (CSII) in type 1 diabetes. Children and adults (n0153) on CSII with hba1c 7.5–9.5% (58.5–80.3 mmol/mol) were randomized to (CGM) a Sensor On or Sensor Off arm for 6 months. After 4 months' washout, participants crossed over to the other arm for 6 months. Pediatric and adult participants were separately electronically randomized through the case report form according to a predefined randomization sequence in eight secondary and tertiary centres. The primary outcome was the difference in hba1c levels between arms after 6 months. 77 participants were randomized to the On/Off sequence and 76 to the Off/On sequence; all were included in the primary analysis. The mean difference in hba1c was –0.43% (–4.74 mmol/mol) in favor of the Sensor On arm (8.04% [64.34 mmol/mol] vs. 8.47% [69.08 mmol/mol]; 95% CI –0.32%, –0.55% [–3.50,–6.01 mmol/mol]; p<0.001). Following cessation of glucose sensing, hba1c reverted to baseline levels. Less time was spent with sensor glucose <3.9 mmol/l during the Sensor On arm than in the Sensor Off arm (19 vs 31 min/day; p00.009). The mean number of daily boluses increased in the Sensor On arm (6.8±2.5 vs. 5.8±1.9, p<0.0001), together with the frequency of use of the temporary basal rate (0.75±1.11 vs. 0.26±0.47, p<0.0001) and manual insulin suspend (0.91±1.25 vs. 0.70±0.75, p<0.018) functions. Four vs. two events of severe hypo-glycaemia occurred in the Sensor On and Sensor Off arm, respectively. Continuous glucose monitoring was associated with decreased hba1c levels and time spent in hypo-glycaemia in individuals with type 1 diabetes using CSII. More frequent self-adjustments of insulin therapy may have contributed to these effects

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