Automated closed-loop insulin delivery for the management of type 1 diabetes during pregnancy: the AiDAPT RCT

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Plain language summary

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Plain language summary

Pregnancy in women with type 1 diabetes is associated with complications for both mother and baby. Recent improvements in diabetes technology have not been sufficient to help most women achieve and maintain recommended pregnancy glucose targets. Hybrid closed-loop technology (an insulin pump, smartphone app and continuous glucose monitor), which automatically adjusts insulin doses according to glucose measurements, is effective in managing type 1 diabetes outside of pregnancy, but its effectiveness during pregnancy was unclear.

To examine the effectiveness of hybrid closed-loop therapy compared to standard insulin therapy in pregnant women with type 1 diabetes, we conducted a randomised controlled trial in nine maternity clinics in England, Scotland and Northern Ireland. We enrolled pregnant women with type 1 diabetes and above-target glucose levels, defined as glycated haemoglobin A1c of ≥ 48 mmol/mol, in early pregnancy. Women were randomly assigned to either a hybrid closed-loop system or standard insulin delivery (insulin pump or multiple daily injections) with continuous glucose monitoring.

This study found that hybrid closed-loop therapy improved maternal glucose levels during type 1 diabetes pregnancy, resulting in higher time spent in the target glucose range and less time above range. Mothers in the closed-loop group had less weight gain during pregnancy, without additional hypoglycaemia or insulin dose. The benefits of closed-loop were consistent across maternity clinics, maternal glucose levels and previous insulin pump or injection therapy. There were no unanticipated safety problems associated with using closed-loop.

However, the study was too small to provide definite information on pregnancy outcomes, and the results cannot be inferred to other closed-loop systems with higher glucose targets. Future trials should examine the effectiveness of closed-loop started before pregnancy or as soon as possible after pregnancy confirmation. Our results support National Institute for Health and Care Excellence guideline recommendations that hybrid closed-loop therapy should be offered to all pregnant women with type 1 diabetes.

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