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ADDENDUM: (comment on feedback)
**Continuous Glucose Meters in the Management
of Diabetes**

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INTRODUCTION

Following distribution of *Review: Continuous glucose meters in the management of diabetes (John P Hampson & Dr Philip Weston March 1st 2014)*, the following articles have been highlighted as additional information which might change some of the findings:-

1. Battelino, T., Nimri, R., Phillip, M., and Oskarsson, P. Effect of continuous glucose monitoring on hypoglycaemia in type I diabetes. *Diabetes Care* 2011; **34**:795-800.¹
2. Murphy, H. R., Rayman, G., and Lewis, K. Effectiveness of continuous glucose monitoring in pregnant women with diabetes :randomised controlled trial. *BMJ* 2008; **337**:a1680.²
3. Petrovski, G., Dimitrovski, C., and Bogoev, M. Is there a difference in pregnancy and glycemc outcome in patients with type I diabetes on insulin pump with constant or intermittent glucose monitoring? *Diabetes Technology & Therapeutics* 2011; **13**:1109-1113.³

The original review took, as its starting point, a Cochrane systematic review⁴ which looked at published data on continuous glucose monitoring up to 2011. A total of 22 randomised controlled trials (RCTs) were examined and the review concluded there is limited evidence for continuous monitoring in children, adults and patients with poorly controlled patients. The 22 reviews considered by Cochrane included article 1 (Battelino)¹ above.

PREGNANCY

The section on pregnancy appeared as follows:

In pregnancy, a systematic review (2013) [Voormolen] could find only two relevant randomised controlled trials.⁵ These had conflicting results and further trials are required. Although written in 2008, NICE guidance on diabetes in pregnancy could find no evidence to assess the effectiveness of ambulatory continuous blood glucose monitoring and further research was required.⁶

Voormolen's systematic review (2013)⁵ above focused on the effectiveness of continuous glucose monitoring during pregnancy. It considered 11 separate studies. Articles 2 (Murphy)² and 3 (Petrovski)³ were included within Voormolen's review of these 11 studies.

COMMENT/CONCLUSION

The 3 additional articles cited above have, therefore, already been included in the original review via tertiary reference sources. A closer inspection of these studies (see appendix) further suggests that they add little to the body of evidence already discussed.

The findings regarding pregnancy are confirmed in a 4th article (2013) which was a randomised controlled trial of 154 pregnant women with diabetes who received standard therapy or continuous glucose monitoring.⁷ The authors concluded that intermittent, real time CGM use did not improve glycaemic control or pregnancy outcome with pregestational diabetes.

APPENDIX

Summaries of Additional Studies

Effectiveness Study

Battelino, T., Nimri, R., Phillip, M., and Oskarsson, P. Effect of continuous glucose monitoring on hypoglycaemia in type I diabetes. *Diabetes Care* 2011; **34**:795-800

This was an RCT of 120 adults and children with type I diabetes. Patients were included if HbA1c was < 7.5% and randomly assigned to either the intervention (continuous monitoring) or control group. After 6 months, the mean difference in HbA1c was -0.27% which was statistically significant (P =0.008).

The number of hours in hypoglycaemia (<3.5 mmol/l) was less (by about half an hour per day) in the monitoring group than in controls (P= 0.03). There was no statistical difference in the rate of hypoglycaemic attacks. None of the participants in either group reported an event of severe hypoglycaemia during the study period.

The authors concluded that more meaningful reduction of hypoglycaemic events remains to be demonstrated. The study was sponsored by Abbott.

Studies on Pregnancy

The remaining two studies examined the effectiveness of continuous glucose monitoring during pregnancy.

Murphy, H. R., Rayman, G., and Lewis, K. Effectiveness of continuous glucose monitoring in pregnant women with diabetes :randomised controlled trial. *BMJ* 2008; **337**:a1680

Murphy randomly allocated pregnant women to standard care (n= 33) or continuous glucose monitoring (n= 38). Statistically significant lower HbA1c values were not obtained until 32-36 weeks of gestation (a reduction from 6.4% to 5.8%).

The odds ratio for reduction in macrosomia was 0.36 which barely reached statistical significance (P=0.05). However, the intervention group included babies who were very low birth weight (x 4) and three sets of twins. This would tend to skew the mean birth weight of the intervention group.

Petrovski, G., Dimitrovski, C., and Bogoev, M. Is there a difference in pregnancy and glycemic outcome in patients with type I diabetes on insulin pump with constant or intermittent glucose monitoring? *Diabetes Technology & Therapeutics* 2011; **13**:1109-1113

In the second study, Petrovski investigated the effect of continuous versus intermittent monitoring in 25 pregnant women and observed a 0.3% reduction in HbA1c. However, this advantage was only observed during the first and none of the other trimesters. Only one episode of severe hypoglycaemia was observed in the continuous group and two in the intermittent group. It has to be stressed that one of the two episodes in the intermittent group occurred when continuous monitoring was not being used.

In this second study, there was no observed difference in macrosomia (in contrast to the above). Taken together, these two studies are of low quality

owing to low patient numbers with lack of proper controls (2nd study) and give conflicting results in terms of the timing of impact on HbA1c and prevalence of macrosomia.

ADDITIONAL REFERENCES

- (1) Battelino, T., Nimri, R., Phillip, M., and Oskarsson, P. Effect of continuous glucose monitoring on hypoglycaemia in type I diabetes. *Diabetes Care* 2011; **34**:795-800.
- (2) Murphy, H. R., Rayman, G., and Lewis, K. Effectiveness of continuous glucose monitoring in pregnant women with diabetes :randomised controlled trial. *BMJ* 2008; **337**:a1680.
- (3) Petrovski, G., Dimitrovski, C., and Bogoev, M. Is there a difference in pregnancy and glycemic outcome in patients with type I diabetes on insulin pump with constant or intermittent glucose monitoring? *Diabetes Technology & Therapeutics* 2011; **13**:1109-1113.
- (4) Langendam M, Luijf YM, Hooft L, DeVries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database of Systematic Reviews* 2012; **1**.
- (5) Voormolen DN, DeVries JH, Evers IM, Mol BW, Franx A. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. *Obstetrical & Gynecological Survey* 2013; **68**(11):753-763.
- (6) Diabetes in pregnancy: Management of diabetes and its complications from pre-conception to the postnatal period. **63**, 1-42. 2008. London, National Institute for Health and Care Excellence. Clinical Guideline.
- (7) Secher, A. L., Ringholm, L., and Andersen, H. U. The effect of real-time continuous glucose monitoring in pregnant women with diabetes: A randomized controlled trial. *Diabetes Care* 2013; **36**(7):1877-1883.