Evaluation of Continuous Glucose Monitoring in a Rural Australian Paediatric Diabetes Program

Peter W Goss MB BS FRACP, Megan Paterson RN CDE
Gippsland Paediatrics, Victoria, Australia
ISPAD 2010 Buenos Aires

Background

Continuous Glucose Monitoring (CGM)
Continuous Glucose Monitoring is a device that measures the glucose levels of interstitial fluid on a continuous basis (every 1 - 5 minutes).

CGM systems typically consist of
- a disposable glucose sensor which may last up to 6 days
- a transmitter
- an electronic receiver which may be incorporated in an insulin pump.

CGM has become a useful adjunct to maintaining Type 1 Diabetes Mellitus (T1DM) control in children, with evidence of better glycaemic control (1, 2, 4) and reduced hypoglycaemia (3). In addition there is evidence that CGM can be associated with reducing HbA1c without increasing the risk of hypoglycaemia compared to finger stick testing alone. (4)

CGM in Rural Australia
Access to CGM in rural Australia is limited by:

- Cost of receiver/ transmitter – rural health services are loathe to spend funds on devices that business plans cannot demonstrate to be short term revenue earners. There is no Victorian Government program to coordinate quality rural paediatric diabetes services. Hence there are few CGM systems in rural Australia.

- Cost of sensors - each sensor in the Medtronic Guardian system is approximately $A75 ($US75) and there is no Government rebate on the cost of the sensor to the patient.

- Inexperience and unfamiliarity of rural diabetes teams with CGM systems.

CGM in Metropolitan Australia
Metropolitan tertiary centres have better access to CGM because of different funding arrangements.

Because of reduced access to CGM in rural Australia, rural children with T1DM are further disadvantaged compared with the known superior resources available to metropolitan children with T1DM (5, 6,) . There are no published reports of use of CGM in rural children with diabetes and no reports of patient satisfaction in rural children using CGM.

Aim

To determine whether the use of Continuous Glucose Monitoring (CGM) improves glycaemic control and provides patient satisfaction for children and adolescents with Type 1 Diabetes Mellitus (T1DM) when managed by a rural multidisciplinary diabetes team.

Methods

Gippsland Paediatrics is an independent rural paediatric practice based in South Eastern Australia. In 2007, we created a new multidisciplinary model of rural paediatric diabetes care – the RADICAL model (Rural Australian Diabetes Inspiring Control, Activity & Lifestyle). (7)

In 2009, the diabetes team managed 64 children, and adolescents with T1DM.

A local children's charitable trust, the Kate Buntine Children's Trust purchased two CGM units (Medtronic Guardian Real Time) and committed funds for local children to have access to CGM sensors free of charge.

An observational study measured glycaemic control of all Gippsland Paediatrics T1DM patients who used the CGM device during 2009.

Patient selection for CGM was on clinical need rather than randomisation. In general, CGM was not offered for use in those with stable diabetes with HbA1c in the target range (<7.0%), those with very poor compliance and those about to commence insulin pump therapy.

No patient was blinded to the real time readings on CGM, and all were encouraged to observe BGL changes with foods, treatment of hypoglycaemic episodes and exercise.

The average HbA1c for the 6 months prior to using the CGM was compared with the HbA1c between 4 and 6 months following use of CGM using t test analysis.

These results were compared to the glycaemic control over time of patients who were not offered CGM. The average HbA1C of those non CGM patients in the first 6 months of 2009 was compared with the average HbA1c in the last six months of 2009.

A CGM patient satisfaction survey was devised and applied to all patients who used CGM during 2009. The survey asked the respondent to rate on a scale of 1 to 5 the following questions:
- *The CGMS gave me confidence to avoid high blood glucose levels*
- *The CGMS reduced my fear of hypos*
- *The CGMS taught me to treat hypos more appropriately*
- *The CGMS helped me to better understand how food affects blood glucose levels*
- *The CGMS helped me to better understand how exercise se affects blood glucose levels*
- *I feel more confident and in control of diabetes since experiencing the CGMS*

Responses were requested to the following statements on CGM logistics:
- *Having the sensor inserted was a painful experience*
- *I am comfortable for the CGMS to be reapplied in the future for a 6 day period*

3. *I am comfortable for the CGMS to be reapplied in the future for a period of 4 weeks*
4. *The CGMS did not interfere with usual daily activities*

Reponses were considered negative if answered "not at all" or "a little" and the response considered positive if the response was "moderately", "very" and strongly positive if rated "extremely".

Results

Glycaemic Control
The CGM was applied to 31 children and adolescents on 34 occasions during 2009 representing 48% of our patients with diabetes.

At the commencement of 2009 there were 26 children managed with Insulin pump therapy (IPT) and by the completion of 2009 there were 46 managed with IPT.

20 of 31 patients were on Insulin Pump Therapy (IPT) at the time of CGM and 11 were managed with injection therapy at the time of CGM.

Patients spent up to 6 days per episode on the CGM.

Overall change in HbA1c
Overall the mean HbA1c for 6 months pre CGM was 8.65% ± 1.55 (median 8.3%).

The mean HbA1c four to six month post CGM was 8.25% ± 1.47 (median 7.9%). (p = 0.004)

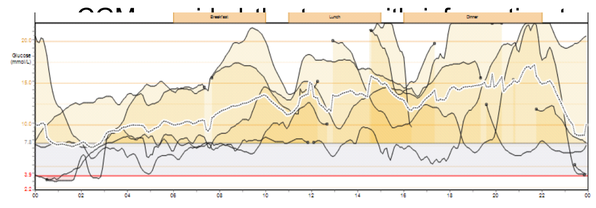
The average improvement in HbA1c was 0.4%.
Improvement in glycaemic control was evident in 25 of the 31 patients (81%).

CGM on IPT vs. Non IPT
For the 20 patients on IPT the mean HbA1c reduced from 8.43% ± 1.55 (median 7.9%) to 8.01% ± 1.12 (median 7.6%). (p = 0.04)

For the 11 patients not on IPT, the mean HbA1c reduced from 9.21% ± 1.51 (median 9.2%) to 8.60 % ± 1.98 (median 8.1%). (p = 0.09)

For those 33 patients who were not managed with CGM during 2009, the mean HbA1c for the first half of 2009 was 8.14% ± 1.57 (median 7.9) vs. 7.80% ± 1.42 (median 7.4) . p = 0.13

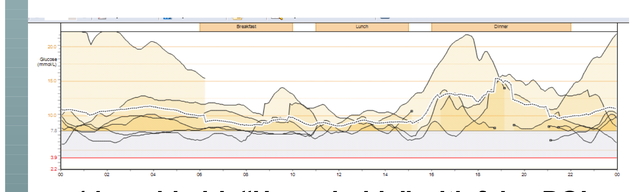
CGM clinical usefulness



16 yr boy, non-compliant to BGL testing with high HbA1c

- CGM also served as a "trial device run" for patients considering IPT.

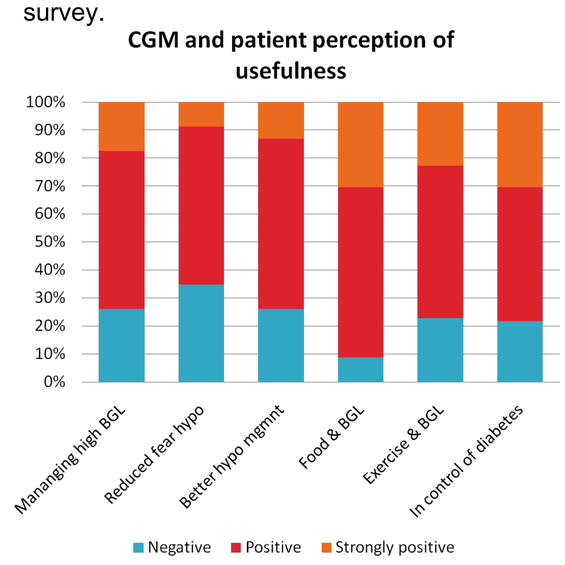
- CGM was an education tool for children and adolescents to understand the effects of exercise on BGL, hypoglycaemic episode (over)treatment, eating patterns especially high GI foods and alcohol on BGL.

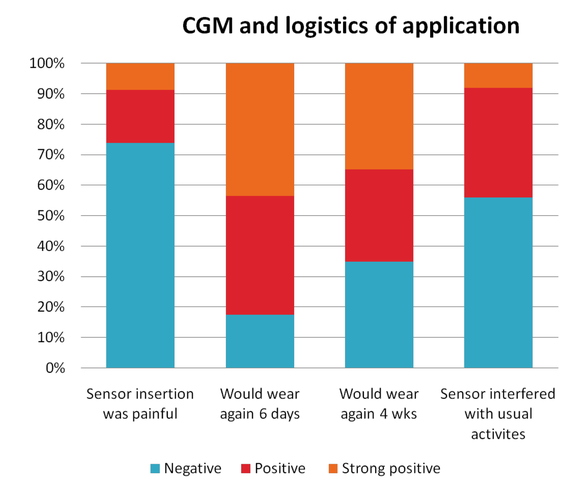


14 yr old girl, "Hypophobia" with false BGL entries and high HbA1c

Patient Satisfaction with CGM

25 of 31 patients or parents completed the survey.





The patient satisfaction survey demonstrated a high percentage of respondents indicating they gained confidence from CGM to avoid high blood glucose levels (74%). There were also positive responses to perceiving reduced fear of hypos (65%) and feeling that they could treat hypos more appropriately (74%). Most stated they had better understanding of how food affects BGL (91%), better understanding of how exercise affects BGLs (77%) and feeling more confident and in control of diabetes after CGM. (78%)

Approximately 26% found the insertion of the sensor painful. 83% of respondents were willing to wear the device again for 6 days but only 65% indicated they wear it for 4 weeks. The sensor was reported to interfere with usual activities 48% of the time.

Conclusions

- CGM can improve glycaemic control in rural children and adolescents with T1DM - particularly for those managed with IPT.

- CGM is a valuable tool in the management of diabetes in a rural setting when managed by an appropriate multidisciplinary team.

- CGM is educational to patients on many aspects of diabetes management and is generally well tolerated but about a quarter of children still find insertion painful and almost a half of respondents found CGM interfered with daily activities.

- Currently CGM is underutilised because of cost and inexperience in rural areas. Coordination of quality rural diabetes programs and subsidy of CGM systems and sensors by Government would improve access to CGM and benefit those with T1DM, particularly those disadvantaged by living in rural areas.

REFERENCES

1. Boland E Monsod T, Delucia M, Brandt CA, Fernando S, Tamborlane WV. Limitations of Conventional Methods of Self-Monitoring of Blood Glucose, Diab Care 2001: 24:1858-62
2. Kaufman FR, Gibson LC, Halvorson M, Carpenter S, Fisher LK, Pitukcheewanont P. A Pilot Study of the Continuous Glucose Monitoring System. Diabetes Care 2001; 24: 2030-4
3. Schiaffini R Ciampalini P, Fierabracci A, Spera S, Borrelli P, Bottazzo GF, Crino A. The Continuous Glucose Monitoring System (CGMS) in type 1 diabetic children is the way to reduce hypoglycaemic risk., Diabetes Metab Res Rev 2002; 18:324-9
4. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *N Engl J Med* 2008;359(14):1464-1476.
5. Handelsman P, Jackson L. A national needs assessment of children and adolescents with diabetes in Australia 1999. Juvenile Diabetes Foundation Australia, Sydney 1999
6. National Health and Medical Research Council Clinical practice guidelines: Type 1 diabetes in children and adolescents. Prepared by the Australasian Paediatric Endocrine Group for the Department of Health and Ageing. March 2005
7. Goss PW, Paterson MA, Renalson J. A 'radical' new rural model for pediatric diabetes care. Pediatric Diabetes 2010:11:296-304

This study was supported by Medtronic Australia