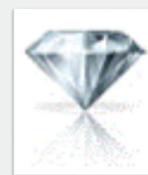


Quality Of Life Benefits Accruing From CGM Use In Patients With Type 1 Diabetes On Multiple Daily Injections: Results From A Prospective, Randomized Controlled Trial

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Background and Aims

- CGM use has been linked to improved glycemic control in adults with type 1 diabetes (T1D), but the impact on quality of life (QOL) remains uncertain (1-6). Given the recent emergence of more reliable and more accurate CGM, QOL benefits may be more likely to be observed.
- One recent trial (DIAMOND) assessed a CGM intervention (using the Dexcom™ G4 Platinum CGM System® with an enhanced algorithm; Dexcom, Inc., San Diego, CA) in poorly controlled adults with T1D using multiple daily insulin injections (MDI) over a 24-week period.(7).
- At study end, CGM participants (n=105) demonstrated significantly better glycemic control than Control group participants (who used SMBG only; n=53).
- From the DIAMOND dataset, we examined the QOL measures completed by participants at baseline and at 24 weeks, hypothesizing that this newer generation of CGM leads to greater improvements in QOL markers than what occurs in individuals using SMBG alone.

Results

- CGM subjects reported significantly greater improvement than Controls on all diabetes-related QOL outcomes, with greater reductions in DDS and HFS-W, and a rise in HSC. In contrast, there were no significant differences in the generic QOL measures (WHO-5 and EQ-5D). (Table 2)
- Among DDS subscales, CGM subjects displayed significantly larger reductions than Control subjects in diabetes-related emotional burden, regimen distress and interpersonal distress. (Table 2).
- Adjusting for participant demographic factors (age, gender, diabetes duration) did not alter the pattern of effects, with the exception of the intervention group effect for HFS-W, which did not reach statistical significance (p=.11).
- There were no consistent patterns of interactions between study arm and patient factors on change in the QOL outcomes including: age, gender, diabetes duration, ethnicity, education level, baseline SMBG frequency, baseline glycemic measures, and baseline levels of the QOL outcome.
- Reductions in total DDS [B(SE) = .42(.14), p =.004] and regimen distress subscale scores [B(SE) = .32(.09), p =.001] were significantly associated with decreases in HbA1c from baseline to 24 week follow-up.

Method

- Psychosocial self-report measures were also completed at baseline and 24 weeks: WHO-5 (overall well-being)⁸, EQ-5D (health status)⁹, DDS (diabetes distress)¹⁰, HFS-W (hypoglycemic fear, worry subscale)¹¹ and HCS (hypoglycemic confidence).¹²
- Primary analysis: treatment group comparison of the change in QOL outcomes over 24 weeks using linear regression models, adjusted for baseline levels of the outcome and clinical site as a random effect. Analyses were repeated to include potential confounding variables of age, gender, and diabetes duration as covariates and explore interactions between treatment group and patient baseline demographic and glycemic measures. We also examined associations between change in QOL with change in HbA1c from baseline to 24 weeks.

Table 1. Baseline Characteristics by Study Arm

| | CGM Group (n=102) | Control Group (n=53) |
|---|--------------------|----------------------|
| | n (%) or mean ± SD | |
| | 46 ± 14 | 51 ± 11 |
| Diabetes Duration (years) | 20 ± 13 | 24 ± 14 |
| Gender (% female) | 46 (45%) | 23 (43%) |
| Race/Ethnicity (% Non-Hispanic White) | 88 (86%) | 42 (79%) |
| Highest Education (% ≥ Bachelor's Degree) | 54 (55%) | 29 (57%) |
| HbA1c (%) | 8.6 ± 0.7 | 8.6 ± 0.6 |
| Number of Blood Glucose Tests/Day (self-report) | 3.9 ± 1.3 | 4.1 ± 1.6 |

Table 2. Quality of life outcomes by study arm from baseline to 24-week follow-up.

| | CGM Group | Control Group | CGM Group | Control Group | Controlling for baseline QOL and clinical site | | |
|---------------------------|--------------------|--------------------|--------------------|--------------------|--|--------------|---------|
| | Baseline Mean (SD) | 24 weeks Mean (SD) | Baseline Mean (SD) | 24 weeks Mean (SD) | Mean difference in change between arms | 95% CI | p-value |
| WHO-5 | 3.58 (0.73) | 3.53 (0.83) | 3.45 (0.74) | 3.37 (0.84) | -0.06 | -0.27 – 0.15 | .55 |
| EQ5D | 0.90 (0.11) | 0.89 (0.10) | 0.89 (0.11) | 0.88 (0.10) | 0.00 | -0.03 – 0.03 | .86 |
| Diabetes Distress total | 1.78 (0.65) | 1.61 (0.48) | 1.69 (0.62) | 1.78 (0.65) | 0.22 | 0.08 - 0.36 | .002 |
| Regimen | 2.09 (0.87) | 1.81 (0.68) | 2.08 (0.99) | 2.05 (0.87) | 0.25 | 0.05 - 0.46 | .02 |
| Emotional burden | 2.06 (0.90) | 1.93 (0.80) | 1.91 (0.83) | 2.03 (0.95) | 0.21 | 0.01- 0.41 | .05 |
| Interpersonal | 1.54 (0.81) | 1.43 (0.61) | 1.45 (0.70) | 1.73 (1.04) | 0.37 | 0.16 – 0.56 | .001 |
| Physician | 1.19 (0.63) | 1.09 (0.25) | 1.12 (0.25) | 1.18 (0.69) | 0.10 | -0.04 – 0.25 | .17 |
| Hypoglycemic Confidence | 3.27 (0.57) | 3.47 (0.55) | 3.15 (0.57) | 3.18 (0.63) | 0.23 | 0.06 – 0.40 | .01 |
| Hypoglycemia Fear (Worry) | 0.88 (0.68) | 0.74 (0.60) | 0.98 (0.73) | 0.99 (0.82) | 0.18 | 0.01 – 0.34 | .04 |

Conclusion

- CGM contributes to significantly greater improvement in diabetes-specific QOL measures (reductions in diabetes distress and increases in hypoglycemic confidence) in adults with T1D using multiple daily insulin injections, compared with SMBG only.
- CGM participants reported greater reductions than Control participants on 3 of the 4 DDS subscales (regimen distress, emotional burden and interpersonal distress), suggesting that CGM not only decrease diabetes-related burden and concerns, but may also attenuate interpersonal tensions with family and friends around diabetes management.
- The impact of CGM on QOL outcomes was not moderated by demographic factors (e.g., age, education), baseline glycemic indices or poor baseline QO, suggesting that QOL benefits were not limited to specific subgroups or to those with low confidence or high levels of distress at baseline.
- Reductions in diabetes distress (total distress and regimen distress) were associated with improved glycemic control over time.

References

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