

620 Final Report: Assessing the Impact of Shortened Follow-up time in Continuous Glucose Monitor Clinical Trials

Walter Williamson, Neo Kok, Will Tackett

Abstract

Introduction

Methods

Results

	CLC (N=112)	SAP (N=56)	Overall (N=168)
Age	32.7 (15.7)	32.9 (16.7)	32.8 (16.0)
Age Group			
<18	31 (27.7%)	17 (30.4%)	48 (28.6%)
>=18	81 (72.3%)	39 (69.6%)	120 (71.4%)
BMI	25.3 (34.0)	28.3 (46.3)	26.3 (38.4)
Gender			
F	54 (48.2%)	30 (53.6%)	84 (50.0%)
M	58 (51.8%)	26 (46.4%)	84 (50.0%)
Race			
Asian	3 (2.7%)	2 (3.6%)	5 (3.0%)
Black/African American	4 (3.6%)	0 (0%)	4 (2.4%)
Other	11 (9.8%)	1 (1.8%)	12 (7.1%)
White	94 (83.9%)	53 (94.6%)	147 (87.5%)
Ethnicity			
Hispanic or Latino	13 (11.6%)	5 (8.9%)	18 (10.7%)
Not Hispanic or Latino	99 (88.4%)	51 (91.1%)	150 (89.3%)
Previous CGM Use			
Current	78 (69.6%)	40 (71.4%)	118 (70.2%)
In past, but not current	26 (23.2%)	10 (17.9%)	36 (21.4%)
Never	8 (7.1%)	6 (10.7%)	14 (8.3%)
Administration Type			
Injections	22 (19.6%)	13 (23.2%)	35 (20.8%)
Pump	90 (80.4%)	43 (76.8%)	133 (79.2%)

Table 1: Demographic characteristics of trial participants, stratified by treatment group, where SAP represents the sensor augmented pump control group, and CLC represents the closed loop system treatment group. Administration type represents the personal treatment method preceding the study.

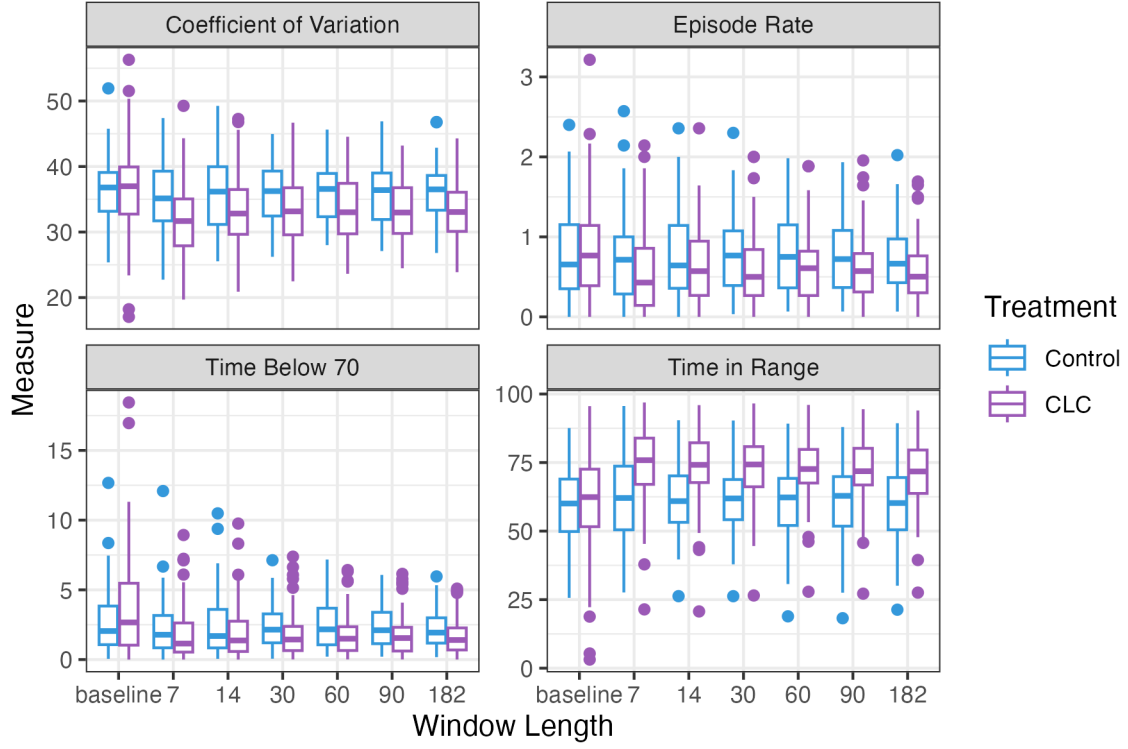


Figure 1: Metric distribution at baseline and with various intervention follow-up windows. Distributions of treatment and control group metrics are represented by purple and blue boxplots, respectively. Window length is in days.

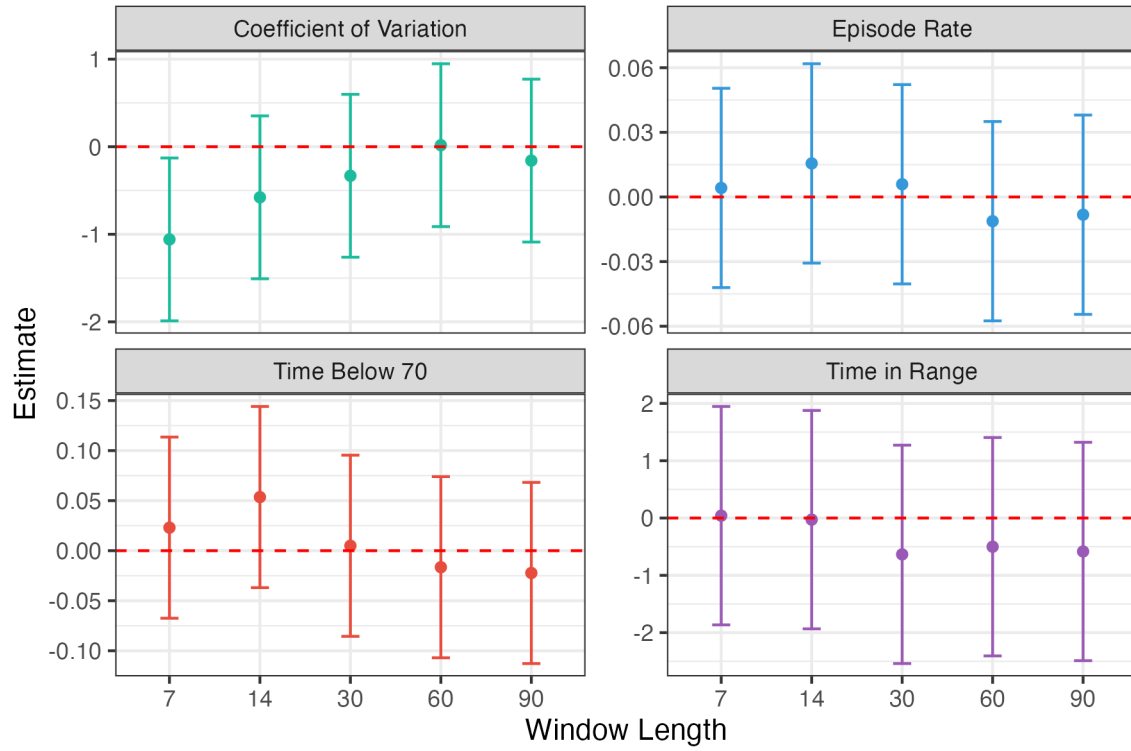


Figure 2: Estimated difference in treatment effect between full length follow-up period and a series of shortened follow-up periods, across CGM metric endpoints. 95% confidence intervals containing the red dashed line indicated a lack of significant difference. Estimates derived from linear mixed effects model.

Discussion

Appendix