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ORIGINAL ARTICLE

Benefits of Blinded Continuous Glucose Monitoring during a Randomized Clinical Trial

Douglas Muchmore, M.D., Melissa Sharp, and Daniel Vaughn, Ph.D.

Abstract

Background:

Real-time, personal continuous glucose monitoring (CGM) is a validated technology that can help patients improve glycemic control. Blinded CGM is a promising technology for obtaining retrospective data in clinical research where the quantity and quality of blood glucose information is important. This study was designed to investigate the use of novel procedures to enhance data capture from blinded CGM.

Methods:

Following a 4-week run-in, 46 patients with type 1 diabetes were randomized to one of two prandial insulins for a 12-week treatment period, after which they were crossed over to the alternate treatment for 12 weeks. Continuous glucose monitoring was implemented at the end of run-in (practice only) and during the last 2 weeks of each treatment period. Eighty percent of 288 possible daily glucose values were required for at least three days. Continuous glucose monitoring was extended for an additional week if these criteria were not met, and patients were allowed to insert sensors at home when necessary. Continuous glucose monitoring results were compared to reference eight-point self-monitoring of blood glucose (SMBG).

Results:

Higher than expected sensor failure rate was approximately 25%. During run-in, 12 of 45 attempted profiles failed adequacy criteria. However, treatment periods had only 1 of 82 attempted profiles considered inadequate (6 cases required an additional week of CGM). Using SMBG as reference, 93.7% of 777 CGM values were in Clarke error grid zones A+B.

Conclusions:

With appropriate training, adequate practice, and opportunity to repeat blinded CGM as needed, nearly 100% of attempted profiles can be obtained successfully.

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Author Affiliation: Halozyme Therapeutics, Inc., San Diego, California

Abbreviations: (CGM) continuous glucose monitoring, (SD) standard deviation, (SMBG) self-monitoring of blood glucose

Keywords: clinical trial, continuous glucose monitoring, diabetes mellitus, self-monitoring of blood glucose

Corresponding Author: Douglas Muchmore, M.D., Halozyme Therapeutics, 11388 Sorrento Valley Rd., San Diego, CA 92121; email address *dmuchmore@halozyme.com*