CLINICAL ASSESSMENT OF THE MARD OF A BLOOD GLUCOSE TEST-STRIP OVER A SEVEN-YEAR PERIOD

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Introduction

MARD (mean absolute relative difference) is being increasingly used to describe the performance of glucose monitoring systems (e.g. BGM and CGM), providing a single quantitative measure of accuracy, thereby allowing comparisons between different systems. This study reports MARD values for the OneTouch Verio® BGM system (Figure 1) from a clinical data-set of over 80,000 glucose values (671 unique strip batches), gathered as part of a 7.5-year self-surveillance initiative.

Methods

OneTouch Verio® test strips were routinely sampled from randomly selected manufacturer's production batches and sent to one of 3 clinic sites for clinical accuracy assessment using fresh capillary blood from diabetes patients. Verio BGM system performance was compared to a standard laboratory reference instrument (YSI 2300 STAT PLUS).

Mean Absolute Relative Difference (MARD)
Absolute relative deviation (ARD) between the meter and corresponding reference reading (test *i* and YSI reference *i* respectively) was calculated as:

$$ARD = \frac{Abs\,[\text{Difference (test } i, \text{ YSI reference } i)]}{\text{YSI reference } i} \times 100\%$$

Mean absolute relative difference (MARD) from *N* paired test and reference values was then calculated as:

$$MARD = \frac{1}{N}\sum_{i=1}^{i=N} ARD$$

Absolute difference instead of ARD may be used at low glucose;

Absolute difference $_{(glucose\ <100\ mg/dL)}$ =

Difference (test i, YSI reference i)

Thus allowing calculation of mean absolute deviation (MAD). Depending on the glucose levels present in a data-set, values may therefore be presented as MAD (<100 mg/dL glucose), MARD (either ≥100 mg/dL glucose or all levels) or combined MAD/MARD (all levels).

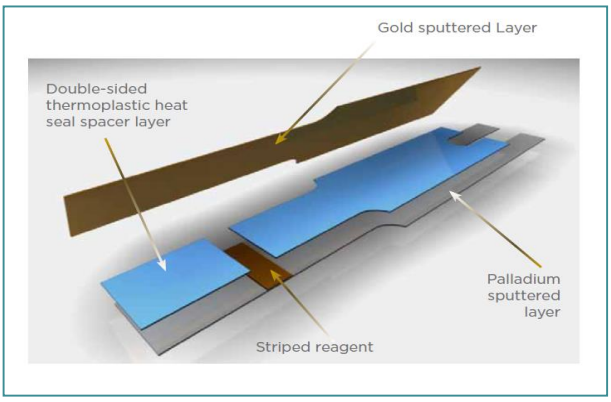

Figure 1: *Exploded image of a OneTouch Verio® Blood glucose test strip*

Results

MARD was calculated for each unique strip batch (n=671) yielding values of 3.68-6.43% (±1.96 standard deviations from the all-batch mean MARD value of 5.05%). MARD and MAD values split according to glucose ranges described within the ISO15197:2015 standard are shown in Table 1. Similar MARD values are evident across the claimed glucose range of the product. Mean MARD, by year of manufacture, ranged from 4.67-5.42%. The overall MARD for all data-points (n=80,258) was similarly 5.05%.

Conclusions

The consistency of the MARD data over the 7.5-year surveillance period provides patients with confidence in the accuracy of this BGM system when transitioning from one strip batch to another. Mean MARD, by batch, and overall MARD across all strips tested, indicates the accuracy of the product within the clinic setting and compares favourably against CGM technologies. Percent MARD should not be confused with percent accuracy as defined by the ISO 15197 standard, they are not interchangeable measures.

References

BS EN ISO 15197:2015. In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (30 June 2015). ISBN 9780580908002

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Table 1: MARD/MAD clinic dataset values split according to ISO 15197:2015 glucose 'bin' ranges

Glucose range (mg/dL)	MAD (mg/dL) or MARD (%)/MAD (mg/dL)	SD	No. paired data-points (N)	% total no. data-points
ISO #1 (≤50)	5.15[a]	4.14	360	0.45
ISO #2 (>50-80)	5.69[a]	5.17	2,738	3.41
ISO #3 (>80-120)	5.43[b]	4.42	12,048	15.01
ISO #4 (>120-200)	4.95	4.19	29,707	37.01
ISO #5 (>200-300)	4.55	3.75	24,180	30.13
ISO #6 (>300-400)	4.69	3.75	8,411	10.48
ISO #7 (>400)	4.63	3.80	2,814	3.51

[a] MAD; [b] Combined MARD/MAD