

MARD range of guessing blood glucose values in people with T1DM

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Background

A majority of T1DM (76.0%) patients reported that they can distinguish whether their blood glucose (BG) is too low or too high without testing, based on what their body tells them^[1]. However, studies show that <40% guesses fall within the Clarke Zone A^[2-5]. In addition, symptomatic hypoglycemia is an unreliable indicator of biochemical hypoglycemia and the degree of glycemic control for most insulin-dependent patients^[6].

Objective

Estimate the MARD range of guessing BG in people with T1DM

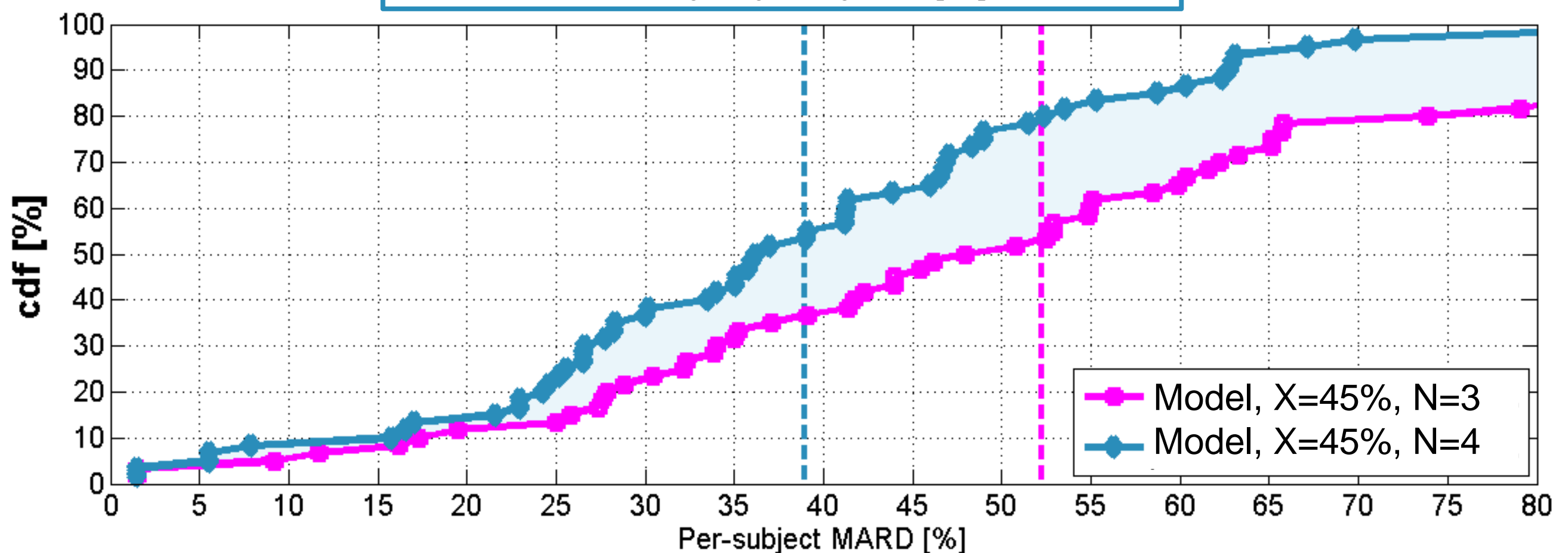


Figure 1. Estimated cumulative distribution of per-subject MARD of guessing BG

Materials and Methods

BGM data from a 40 day continuous glucose monitoring (CGM) system home use study^[8] are used to develop the model. The 6482 BGM values are taken from 60 T1DM patients during the 20 day masked CGM period of the study. The model is constructed to align with the following observations from clinical studies of guessing BG:

1. Studies suggest certain skewness in the guessing error^[9, 10].
2. A comparison of guessing with or without external cues suggest the importance of prior information^[11].
3. There are large individual differences in guessing accuracy^[11, 12].

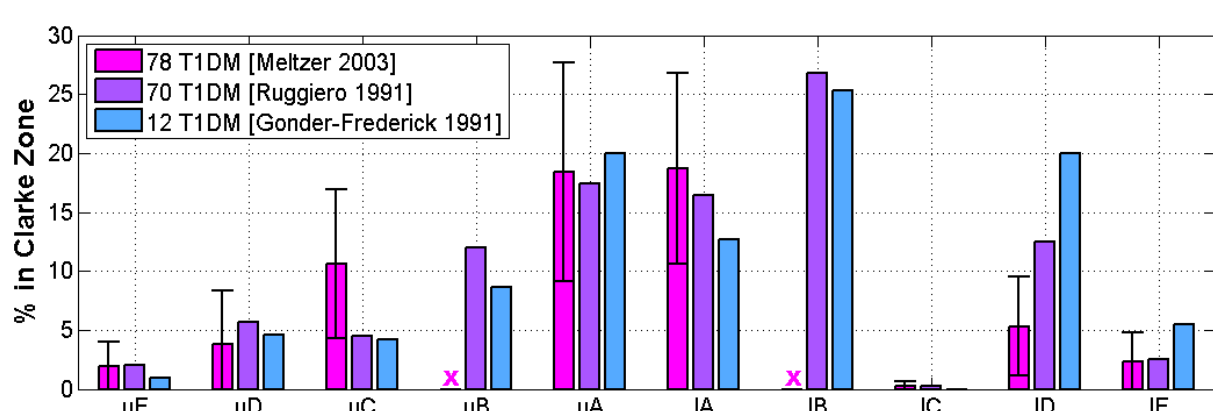


Figure 2. Average of per-subject Clarke Zone percentages from various clinical studies of BG self-estimation

Model

1. Input: Recollection of the most recent BGM measurement around each similar time-of-day from N past days. This emulates having taken past BG measurements.
 2. Output: Calculate the Xth percentile as the BG estimate.
- Set N from 1 to 9, X from 0% to 100% at 5% increments. The Nearest Rank method^[13] is used to calculate sample percentile. It allows for simple qualitative selection of a sorted set of numbers without additional arithmetic required in other percentile methods.

A recent study of blood glucose monitoring (BGM) systems^[7] calculated 6.5% as the lower mean absolute relative difference (MARD) estimate of systems whose 95% of the points fall within the main ISO15197:2013 boundaries (± 15 mg/dL for reference BG up to 100 mg/dL, and $\pm 15\%$ elsewhere). While studies on guessing BG exist, no known studies have published the MARD of guessing BG.

Results

X and N are optimized for the agreement between the model's estimate and BG self-estimation study results in terms of: (1) overall Clarke Zone A and (2) percentages in the uB and IB Zones relative to Zone A percentage. Setting X = 45% and N = 3 or 4 gave the best agreement.

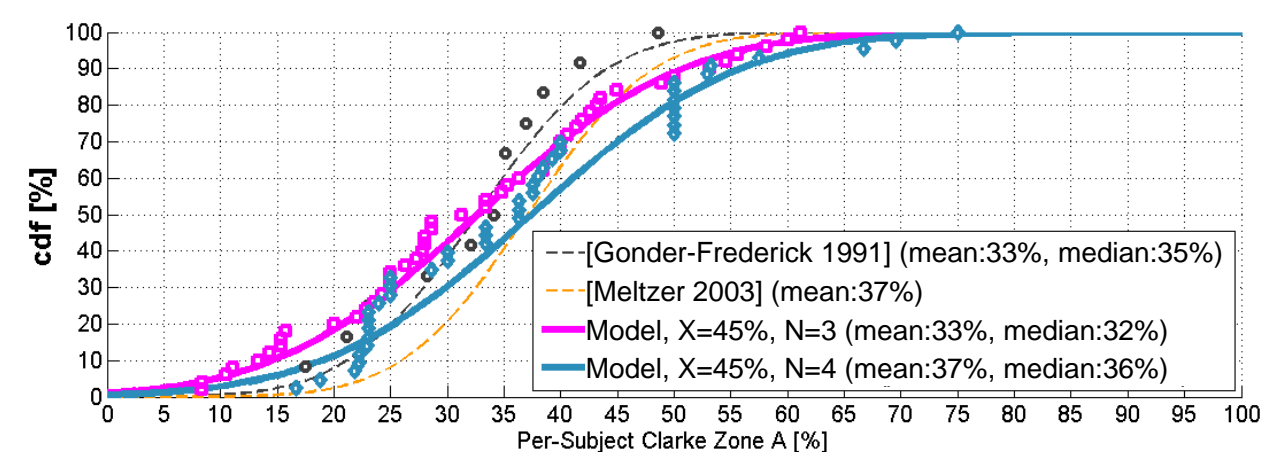


Figure 3. Per-subject Clarke Zone A comparison between results from clinical studies and the SMBG recall-based model using the most optimal parameters

Fig. 3 shows the per-subject Clarke Zone A distribution from 2 clinical studies of guessing BG, compared to the fitted models. They share similar ranges of mean and median values. The per-subject MARD distributions of the fitted models (Fig. 1) predict an average (\pm standard deviation) per-subject MARD of guessing in people with T1DM to be between 39.0% ($\pm 20.8\%$) and 52.3% ($\pm 28.5\%$). The averages are represented by vertical lines. The median values are similar to the averages, at 36.6% and 49.3%, respectively.

Conclusions

- Average MARD of guessing BG in T1DM patients: **40-50%**
- Compared to using BGM systems (whose 95% of the points are within the main ISO15197:2013 boundaries): **guessing results in 6-8 times worse MARD**

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