In a high-risk group of patients with type 1 diabetes and hypoglycemia unawareness, hypoglycemic CGM profiles can clearly discriminate people with and without severe hypoglycemia. The screening performance of this hypoglycemic CGM profile is significantly better than three cut-off values by chance. There is also a high concordance of different parameters of the hypoglycemic profile. The choice of the hypoglycemic cut-off values does not play a decisive role, since the screening performance of all indicators of the hypoglycemic profile are rather similar. However, the sensitivity and specificity, respectively the precision of the hypoglycemic events ≤55 mg/dl predict the occurrence of SH. ROC areas suggest meaningful cut-off values for the duration of hypoglycemic episodes, respectively the number of hypoglycemic events ≤55 mg/dl for at least 20 minutes as hypoglycemic CGM profiles. We used Receiver Operating Characteristics curves (ROC) to evaluate the ability of the above mentioned parameters to identify people with SH. We calculated sensitivity, specificity as well as the positive and negative predictive values to determine the screening performance of these parameters.

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The ROC and the area under the ROC curve in figures 2 and 5. The ROC was clearly above the 0.5 diagonal line (figure 2), indicating better screening performance than a classification by chance. The area under the ROC curve does not cut the 0.5 line (figure 5), which indicates that the mentioned parameters of the hypoglycemic CGM profile can significantly better identify people with SH as compared to a chance distribution by chance.

Sensitivity and specificity as well as positive and negative predictive values are shown in figures 4 and 5. Although sensitivity and specificity are reasonable high, there is still room for improvement. In figure 6, the hazard rate of SH is shown. The risk of SH is roughly doubled if one of the parameters show an increase compared to baseline standard deviation.