

DIABETES SELF-MANAGEMENT DEVICES MEDCAC MEETING (May 21, 2024)

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Presenter Disclosure Information

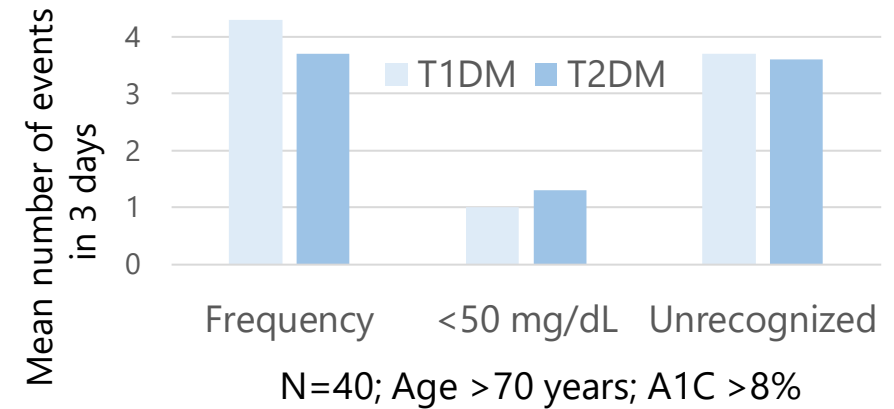
- Institutional grants: NIH, Dexcom
- Consultant/ scientific advisory board: Sanofi, Medtronic
- Educational writing and editing royalties: UpToDate
- Education seminars : MJH life sciences

Clinical endpoints considered important for older adults

Hypoglycemia

Time spent in hypoglycemia (level 1 and 2) is of primary concern

- Older adults have hypoglycemia unawareness
 - Lack of adrenergic warning symptoms
 - Lack of recognition, reporting, and prompt treatment.
(Munshi et al, Arch Int Med 2011)
- Catastrophic consequences of hypoglycemia
 - Falls, fractures,, cognitive decline, cardiac events, emergency room visits, hospitalizations long-term care facility admissions
 - Even type 1 hypoglycemia can contribute to these consequences



Thus, recognition of asymptomatic hypoglycemia by CGM has significant clinical implications in this population

Clinical endpoints considered important for older adults

Hypoglycemia

- Hypoglycemia should be considered as a health outcome of interest
- Goal for hypoglycemia duration should be 0%
 - The risk of any amount of hypoglycemia will outweigh benefits of controlling hyperglycemia in this population
- Thus the MICD will depend on sample size and characteristics of the study cohort

Clinical endpoints considered important for older adults

Time-in-Range and Hyperglycemia

- Time in Range: usually 70-180 mg/dl may need to be adjusted based on overall health status (*Toschi E et al, in press JDST 2024*)

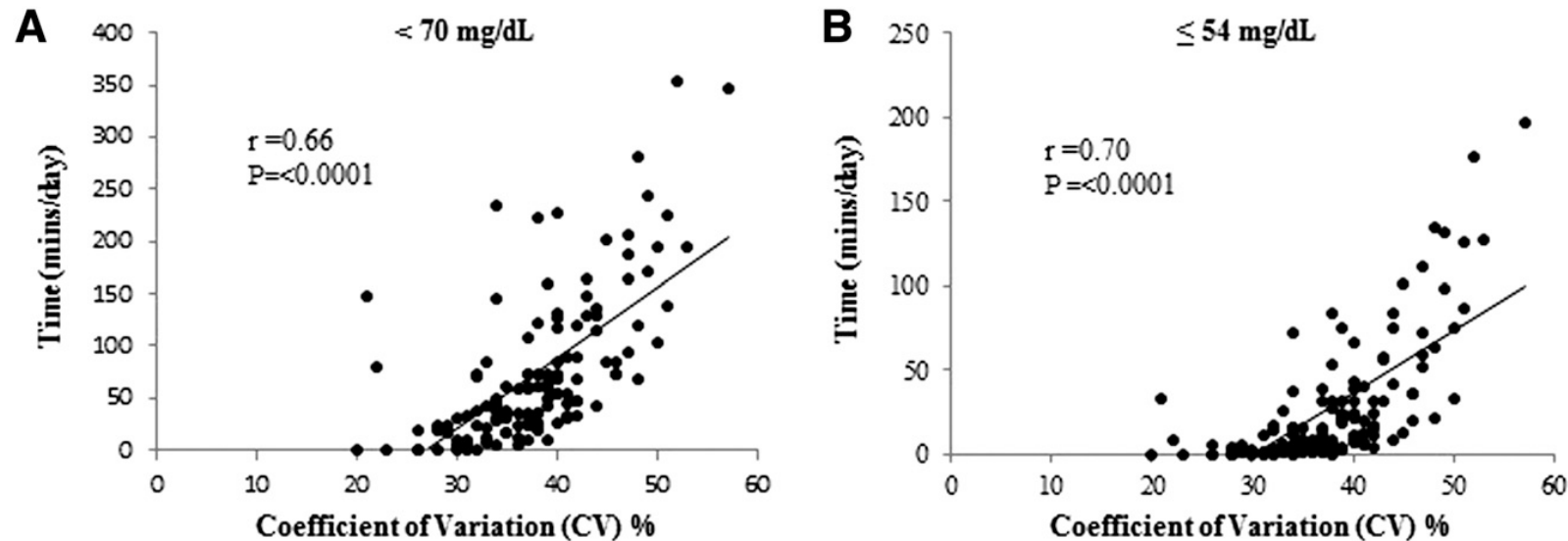
CGM target	Current	Healthy	Intermediate	Poor Health
Time-Below-Range TBR %/min	<70mg/dL; <1% (<60min/day)	<70mg/dL; 0 min/day	<70mg/dL; 0 min/day	<70mg/dL; 0 min/day
Hypoglycemia Buffer Zone %/min	N/A	70-90mg/dL <4% (<60 min/day)	70-100mg/dL <4% (<60min/day)	70-100mg/dL <4% (<60min/day)
Time-in-range TIR %/min	70-180mg/dL; 70% (> 16 hr/day)	90-180mg/dL; 70% (> 16 hr/day)	100-200mg/dL; 70% (> 16 hr/day)	100-250mg/dL; 70% (> 16 hr/day)
Time-above-range TAR %/min	>180mg/dL; <50% (<12hr/day) >250mg/dL; <10% (<2.5hr/day)	>180mg/dL; <25% (<6hr/day) >250mg/dL; <10%(<2.5hr/d)	>200mg/dL; <25% (<6hr/day) >250mg/dL; <10%(<2.5hr/d)	>250mg/dL; <25% (<6hr/day)

- Time spent in hyperglycemia (level 1 and 2) needs to be adjusted based on overall health, QoL concerns with treatment complexity

Clinical endpoints considered important for older adults

Coefficient of variation

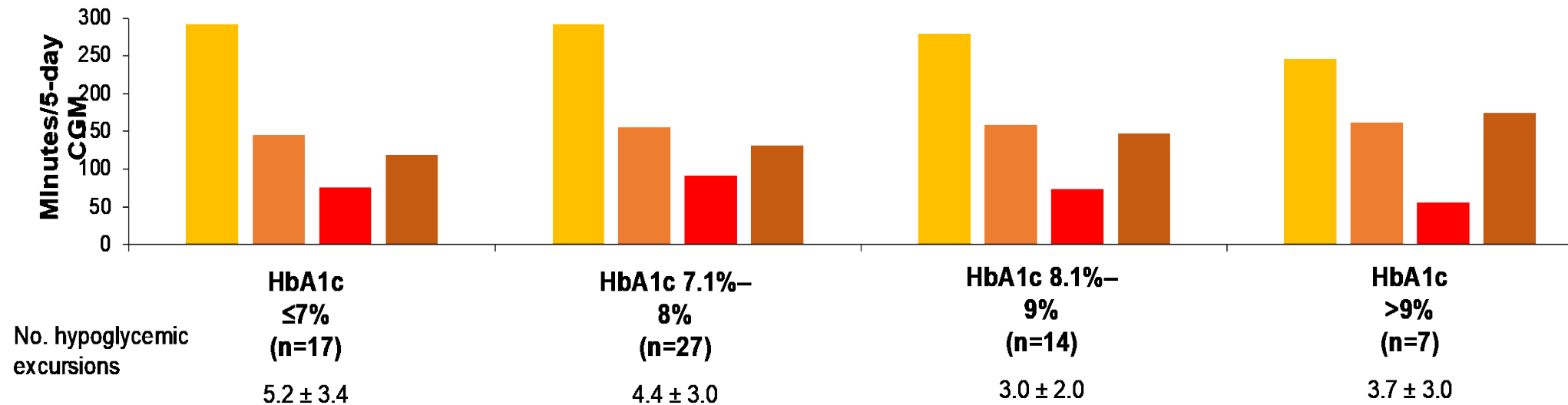
High Coefficient of variation (CV%) reflecting glycemic variability correlate with risk of hypoglycemia in older adults and is an important outcome. (Toschi E et al, diabetes care 2020)



Clinical endpoints considered important for older adults

HbA1C

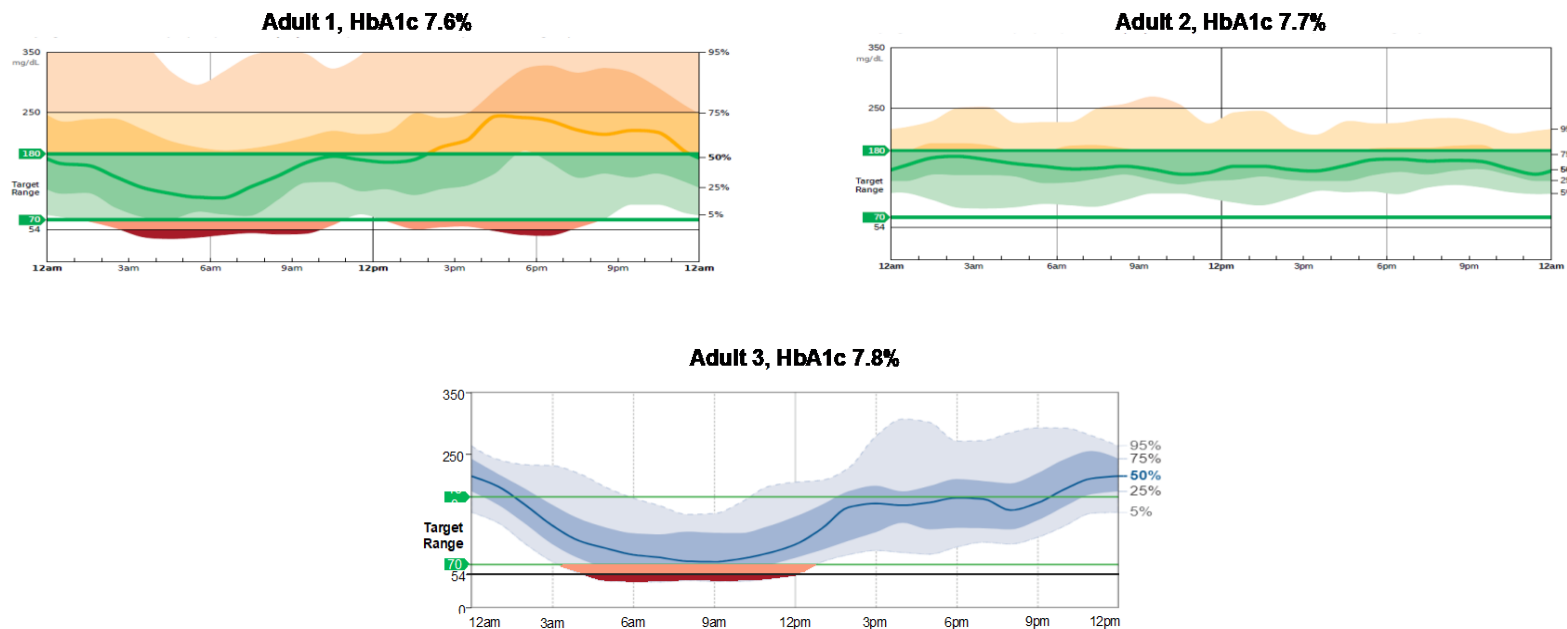
- Clinical conditions that impact RBC life-span occur frequently especially in frail older adults making interpretation of A1C unreliable
- A1C does not correlate with risk of hypoglycemia (*Munshi et al, JDC 2017*)



Clinical endpoints considered important for older adults

HbA1C

A1C does not identify glycemic excursions (*Munshi et al, submitted for publication 2024*)

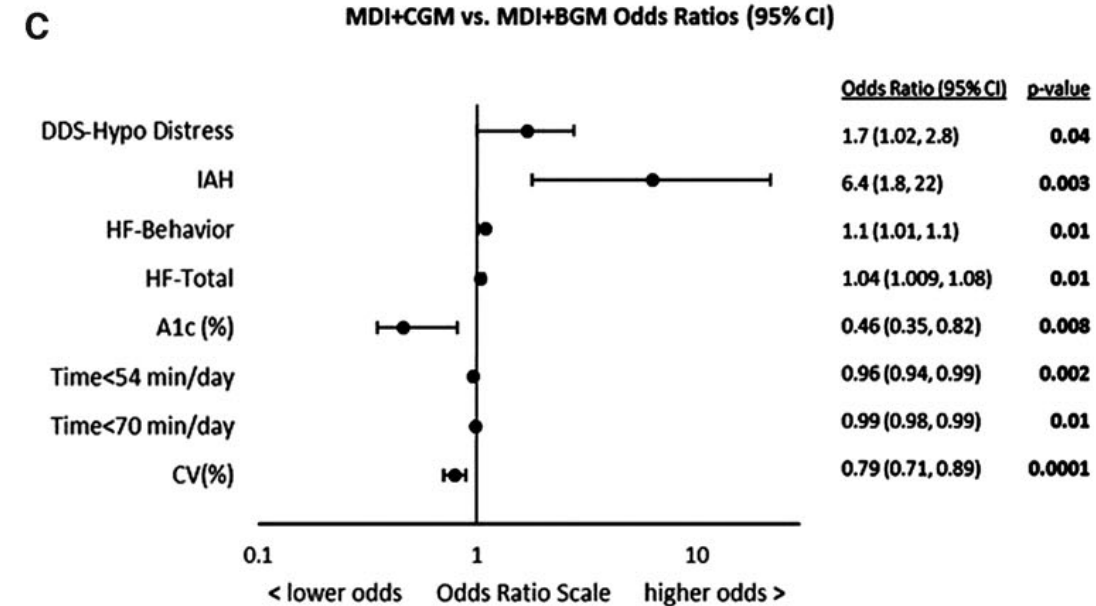


A1C should be de-emphasized as an outcome in older adults

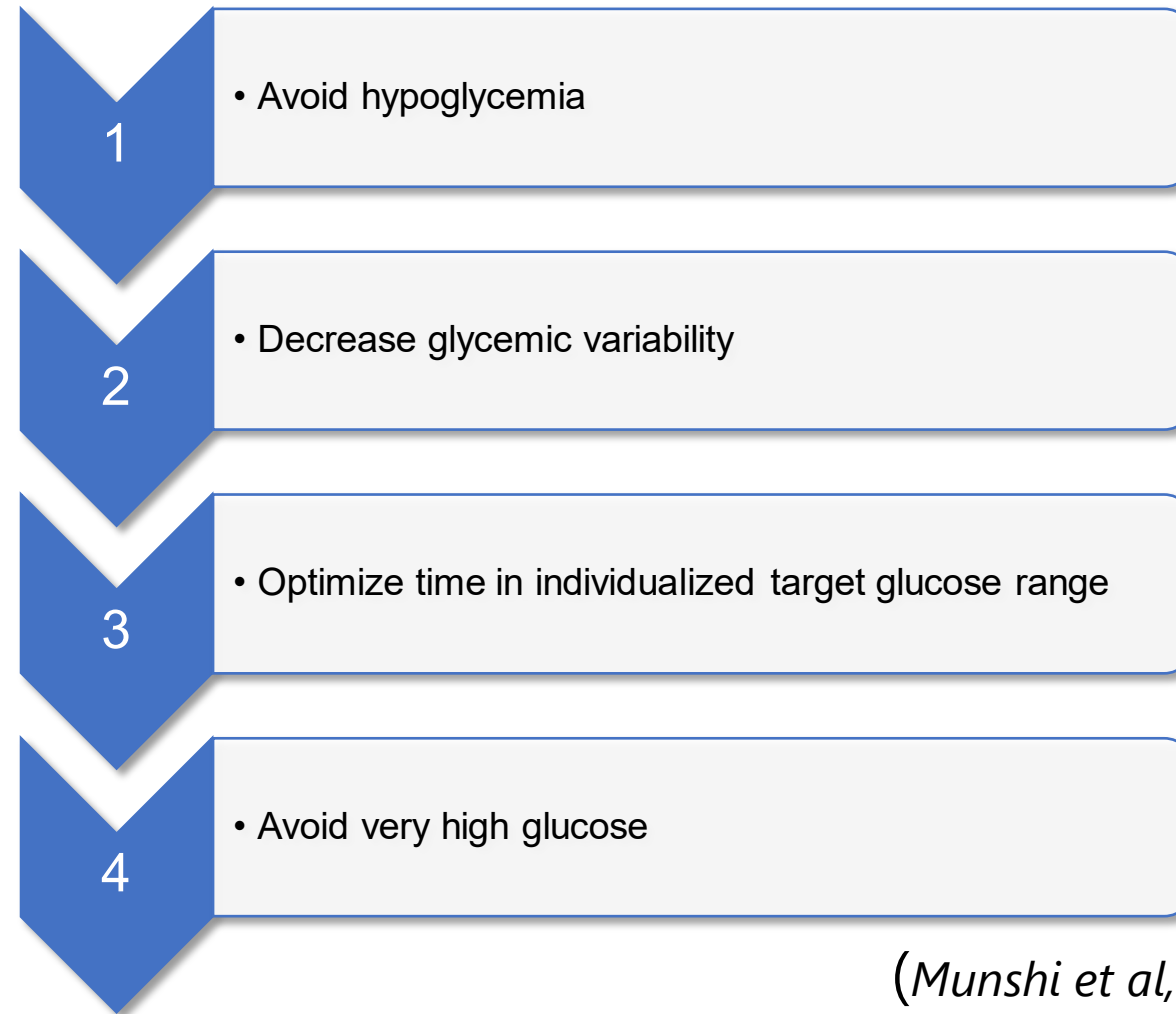
Clinical endpoints considered important for older adults

Quality of Life

- Distress about hypoglycemia and its feared consequences lead to fear of hypoglycemia - a quality of life issue as well as limiting factor for improved glycemic control
- Improves with CGM use (*Munshi et al DTT 2021*)



Priority for clinical outcomes in older adults



(Munshi et al, submitted for publication 2024)