SWITCHING TO A NEW ADVANCED HYBRID CLOSED-LOOP SYSTEM: IMPROVED TIME IN RANGE, SUSTAINED AUTO-MODE AND BETTER AVERAGE GLUCOSE LEVELS

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Disclosures

- I have and I am participating in clinical research and -trials and have been member of scientific boards and serve as consultant for:
  - Medtronic, Novo Nordisk, Dexcom, Eli Lilly.

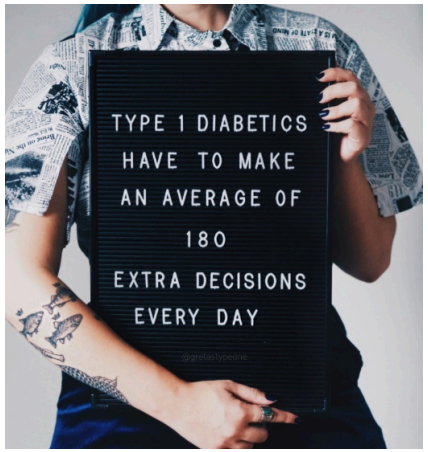
- My institution currently receives researchfunding from JDRF, Diabetes Fond Netherlands, Friends of Diabeter foundation.

- My employer (Diabeter Nederland B.V.) contracts for these services/ research, and I receive no personal income from these activities.

- Diabeter is a focussed VBHC-clinic owned by Medtronic, but with brand-agnostic/independent prescription (under Dutch healthcare laws).

Background

- Many patients with type 1 diabetes (T1D) do not reach appropriate outcomes
  - *(McKnight 2014, T1D exchange 2014,2019)*
- Appropriate management of T1D is difficult:
- Automated insulin delivery (AID) allows for a significant outcome improvement incl. quality of life
  - *(Bergenstal 2021, Beato-Vibora 2021)*
- Limitations in persisting of improvements in some studies (technical and limited ‘automated modus time)
  - *(Lal,2019)*



McKnight 2014 Diab Med 2014, T1D Exchange 2016, 2019, Bergenstal *Lancet* 2021; 397: 208–19, Beato-Vıbora DTT 2021;9;1, Lal 2019 doi.org/10.2337/dc19-0855

Advanced Hybrid Closed-Loop: Medtronic-Minimed 780G

- Improved outcomes
  - Improved auto-modus (Smartmode) + Algorithm (smart guard, autobolus)
    - *(Beato-Vibora, Collyns, Bergenstal, Bode)*

- Diabeter: 33 users in a technical evaluation started with 780G in August 2020 (Covid -19: partial lock-down)
  - previous 670G users (> 3 mo, average 1.4yr)
  - appropriate knowledge/experience in automode
  - virtual/remote training / follow-up
  - Continued the use after evaluation (Covid -19: complete lock-down / limited access clinic)

- Follow-up by their regular care-team incl. virtual group consultations/meetings

- First group to reach 1, 3 and 6 month user-timepoints (currently n=405 780G-users)

Beato-Vibora DIABETES TECHNOLOGY & THERAPEUTICS 2021;23 (9) ; Collins, Diabetes Car, 2021
https://doi.org/10.2337/dc20-2250 ; Bergenstal *Lancet* 2021; 397: 208–19 : Bode 2021 ADA

Aim

- What is the outcome in glucometrics of the 780G use in this (selected) group after 6 months use? Does it improve and remain?
- Are there important aspects/learning points in starting AID through remote training and remote care after start-up period?
- Learning points from person with T1D/ HCP?

Participants

- n=33 (15male ,18female)
- Ave age: 22 ±13 yr
  - (range: 7-49 yr)
- Ave duration T1D: 12 ±11 jaar (range: 0.7 -40 yr)

- n=19 <18 yrs old (age=11.8 ± 5.9; duration =5.6 ± 3.4)
- n=14 >18 yrs old (age=35.4 ± 11; duration =21.9 ± 12)

- Lab HbA1c (Covid/available in n=22) = 6.8% ± 0.4 (51mmol/mol)
  - <18 yrs old: 6.9 (52 mmol/mol)
  - >18 yrs old 6.5 (48 mmol/mol)
  - Lab A1c average in preceding 12mo (n=31): 6.9% (52 mmol/mol)

Method

- Dataset 1: MM670G 14 days before switch (month)
- Dataset 2: 1month: preceding 14 days (mo)
- Dataset 3: 3 months preceding 14 days (mo)
- Dataset 4: 6 months preceding 14 days (mo)
- Collected from individual Carelink reports / 2 week averages
- Patients approved use of their data for these purposes

Method 2

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

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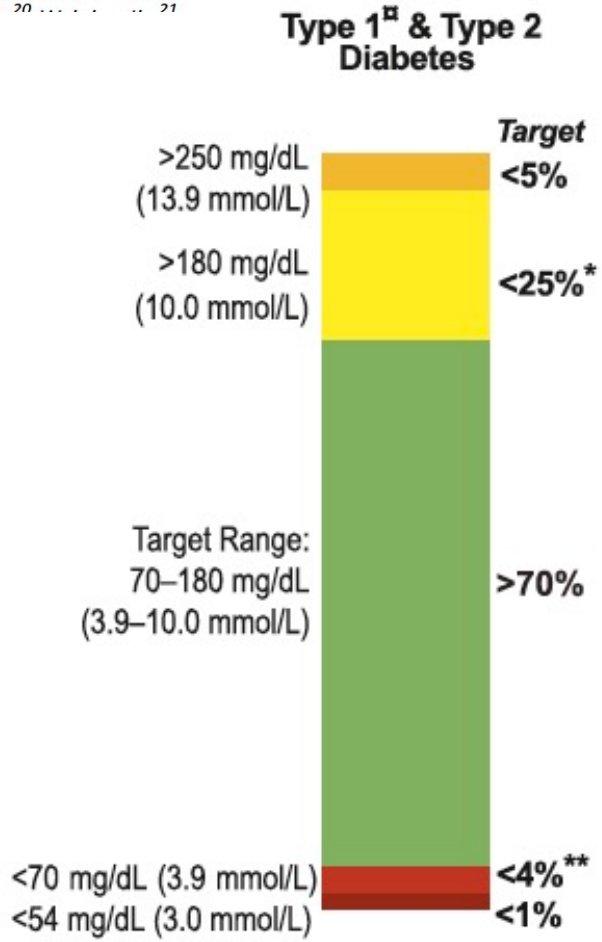
Diabetes Care 2019;42:1593–1603 | https://doi.org/10.2337/dci19-0028

Diabeter

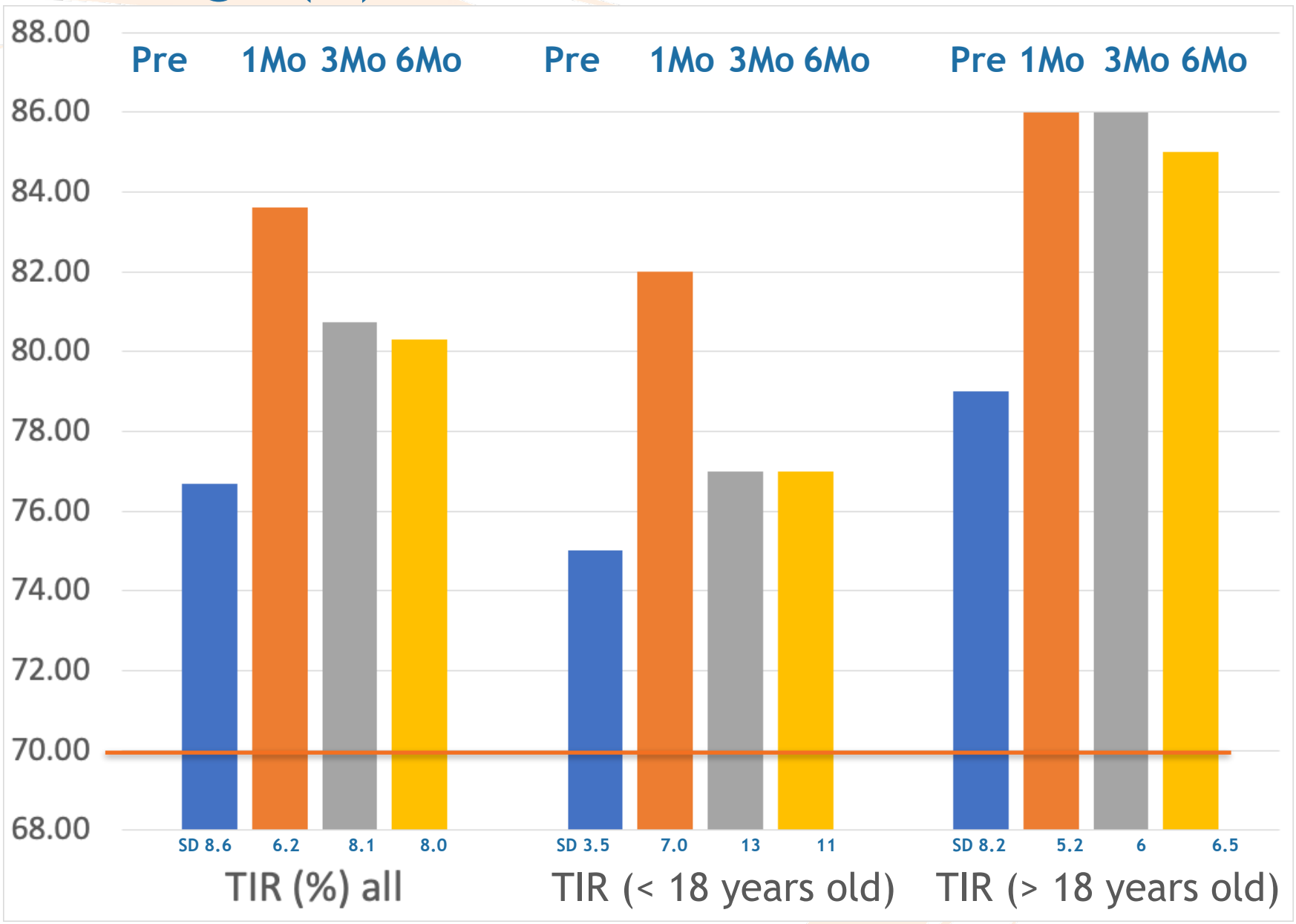
Type 1 diabetes

- TIR (3.9-10 mmol/l) : > 70% (= >16 hrs 48 min)
- TBR < 3.9 mmol/l : <4% (=< 1 hr)
  - < 3.0 mmol/l : <1% (= <15 min)
- TAR > 10 mmol/l : < 25% (= <6 hrs)
  - > 13.9 mmol/l : < 5% (= < 1hr 12 min)

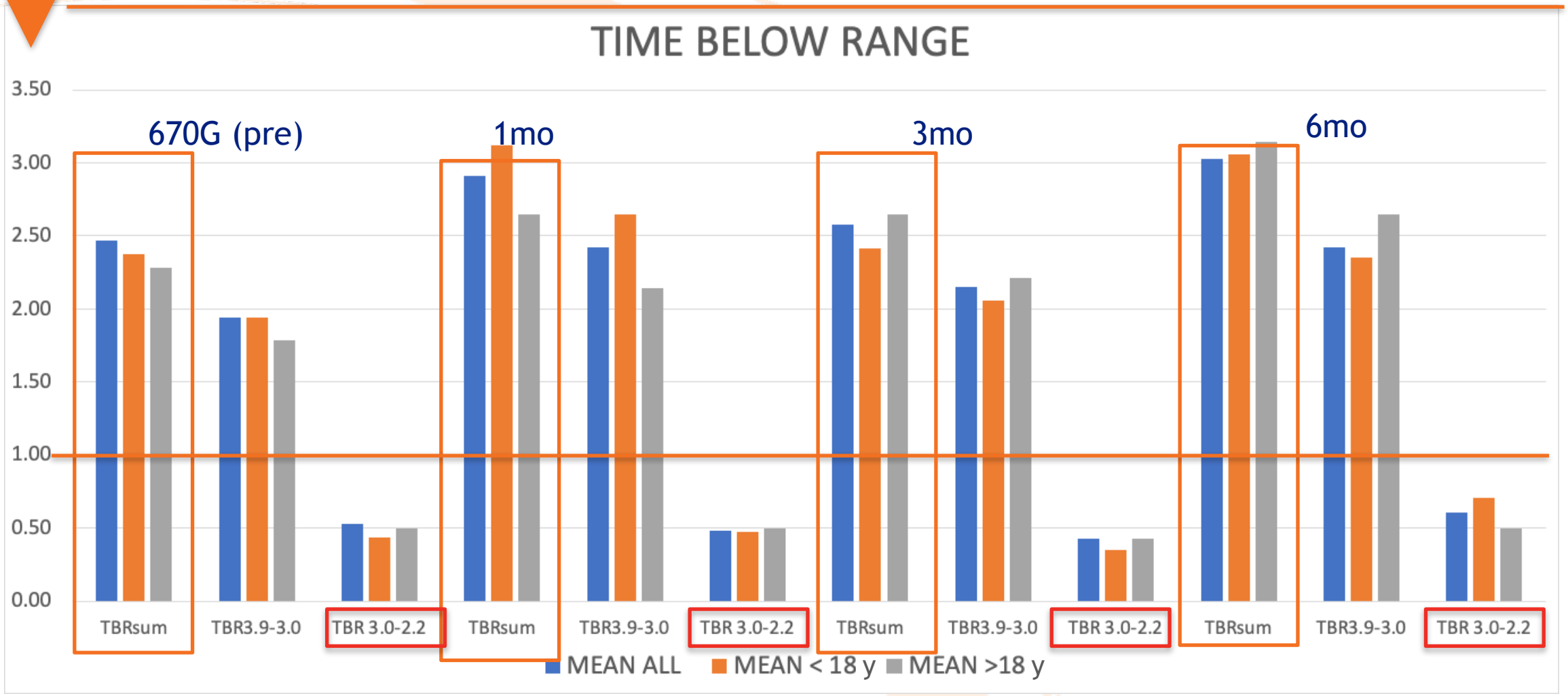
- HbA1c (lab) : < 7% (< 53 mmol/mol)
- Glucose CV : < 36%



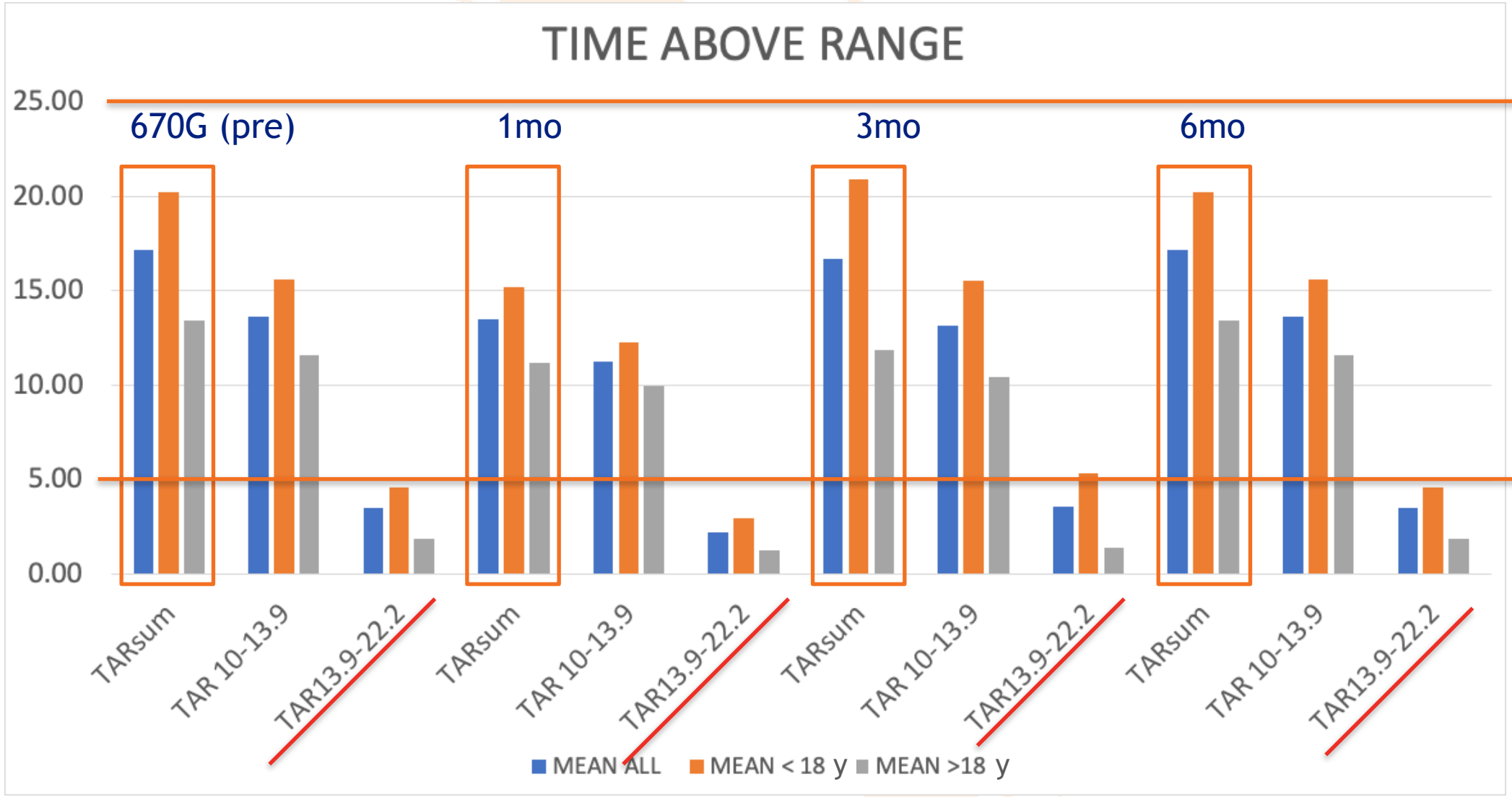
Time in Range (%)



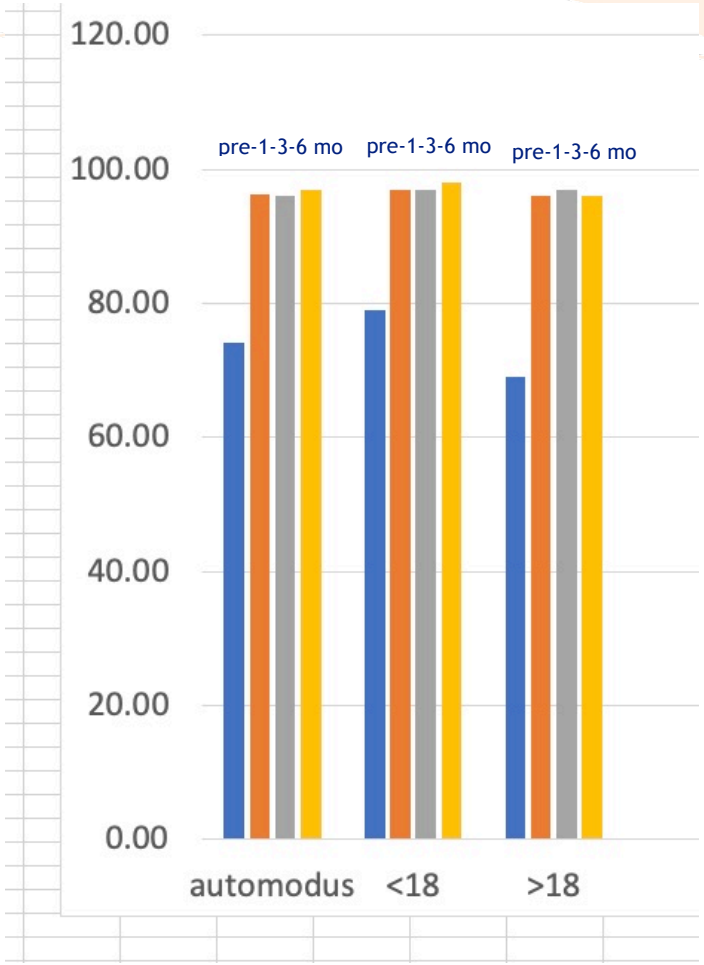
Time below range TBR (%)

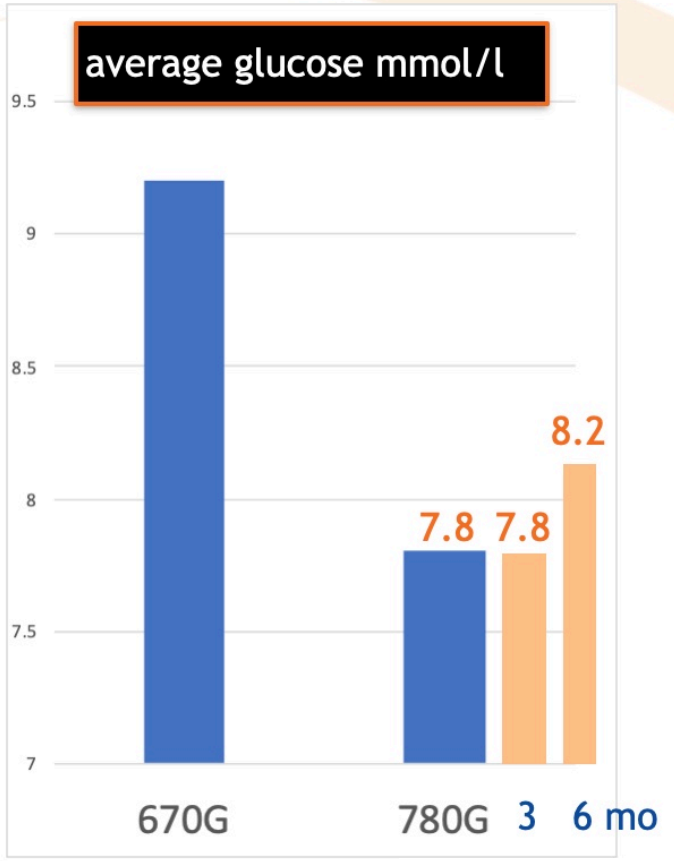


Time above range TAR



Automodus /Smartguard™ / Mean glucose / CV of glucose



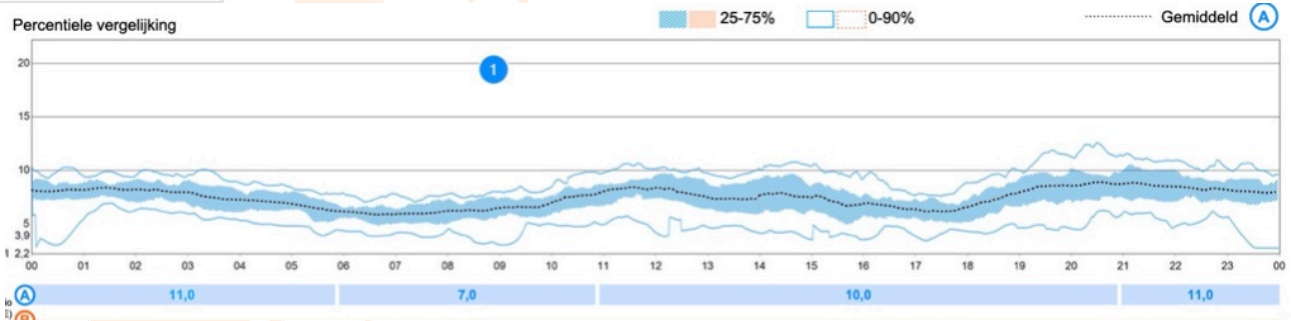


glucose CV = 41% > 34% > 33%

LabA1c:
6.8 > 6.7 > 6.5%
51> 50> 48 mmol/mol

GMI
6.9> 6.7 >6.7%
52> 50> 50 mmol/mol

Active insulin
= 2.25 (92% =2hr)



Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

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Diabeter

First time that we reach all consensus goals !!!!!!!!!!!!!

780G

Type 1 diabetes (and type 2) - unless old/high risk or pregnant

- TIR 3.9-10 mmol/l : > 70% (= >16 hrs 48 min)
- TBR < 3.9 mmol/l : <4% (=< 1 hr)
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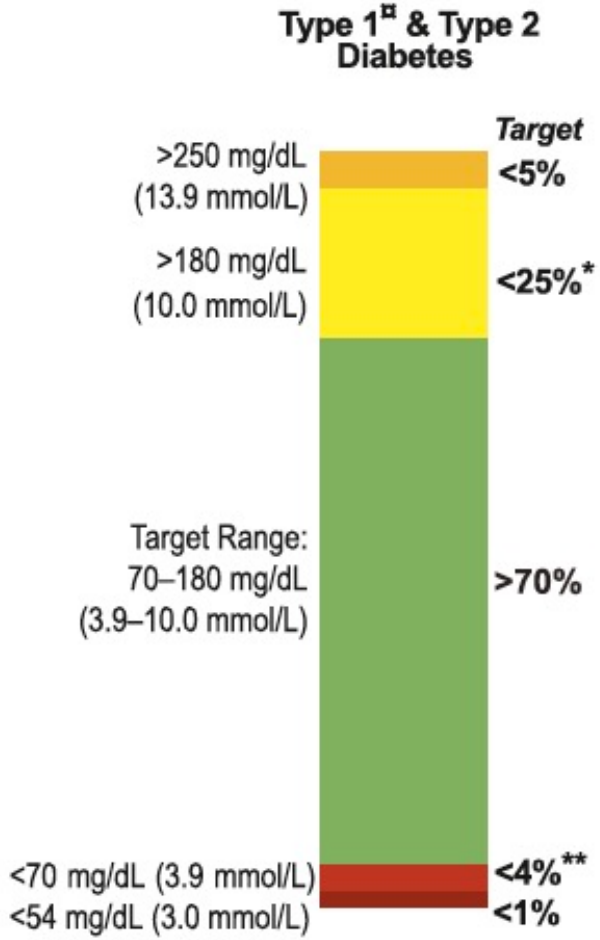

Aim

- What is the outcome in glucometrics of the 780G use in this (selected) group?

- What are important aspects/learning points in starting AID by remote training and start-up period?
  - '*A shock can change healthcare*'
  - Virtual training: very well appreciated, sometimes individual, mostly group
  - 'Zoom' sessions : continue as the group evolves
  - '*Did the patients learn faster than your HCP team*????'
- AID requires adapted diabetes-care
  - remote, on-demand, annual plan

Summary and conclusions

- **Improved TIR at t=6 months /‘CGM consensus compatible’**
  - Next step in CGM targets?
- **Less ‘hands-on’, more automation (needed!)**
- **Selected group!** What happens to the next 780G users?
- **Lower outcomes in:**
  - agegroup < 18 (in particular 7-11) (lower bolus use in teens)
  - Longer active insulin
  - Manual interference (‘*Sitting on my hands 2.0*’)
- **Quick improvement/ learning curve** (< 5 weeks) and successful education and onboarding despite limitations in visits due to Covid-19
- **‘Behavioural aspects’ remain important point for education/explanation**
  - *‘My TIR is only 78%…* /lifestyle adaptations to reach targets incl complete carb-avoidance (‘Flatliners’)
  - Improvements of the algorithm (breakfast-bolus)

- Learning points from person with T1D/ HCP? => poster