

Supplement

Effects of Novel Flash Glucose Monitoring System on Glycemic Control in Adult
Patients with Type 1 Diabetes Mellitus: Protocol of a Multicenter Randomized
Controlled Trial

General Diabetic Education

Version 1.0

Recommendations are based on the guideline by American Diabetes Association and the Chinese Diabetes Society.

1. Goal of glycemic control

For Adult patients:

- HbA1c<7%;
- Fasting/pre-prandial blood glucose: 4.4-7.2mmol/l;
- Postprandial blood glucose level: 5-10.0mmol/l;
- Blood glucose level during night/before sleep: 6.7-10.0mmol/L.

2. General calculation of insulin sensitivity factor (ISF): describes how much one unit of rapid or regular insulin will lower blood glucose. It is used to determine the amount of insulin to give to correct blood glucose readings that are above target

- **1800 Rule(Rapid-acting insulin analogs lispro):**

$$\text{ISF} = 1800 / (\text{total daily use} * 18)$$

- **1500 Rule (Regular short-acting insulin):**

$$\text{ISF} = 1800 / (\text{total daily use} * 18)$$

3. General insulin: carbohydrate ratio: estimation gram of carbohydrates per 1 U of insulin covering

- 500 Rule: Insulin: carbohydrate ratio=500/total daily dose

4. Recommendations when facing hypoglycemia

(1) Definition

Level	Criteria	Description
Hypoglycemia alert value (level 1)	≤ 3.9 mmol/L	Sufficiently low for treatment with fast-acting carbohydrate and dose adjustment of glucose-lowering therapy
Clinically significant hypoglycemia (level2)	< 3.0 mmol/L	Sufficiently low to indicate serious, clinically important hypoglycemia
Severe hypoglycemia (level 3)	No specific glucose threshold	Hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery

(2) **Symptoms:** Shakiness, irritability, confusion, tachycardia, and hunger (not

limited).

(3) Solutions:

- Glucose (15–20 g) is the preferred treatment for the conscious individual with blood glucose <3.9mmol/L) or any form of carbohydrate that contains glucose may be used.
- Fifteen minutes after treatment, if glucose trend shows continued hypoglycemia, the treatment should be repeated.
- Once glucose value returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia.
- Thinking back the possible factor contributing to hypoglycemia such as exercise, over-injection, diet and make adjustments before the similar situation next time.

Note: The glucose value mentioned here refers to the glucose derived from SMBG. For participants distributed to FGM group, we recommend you to have an additional finger-stick test for capillary glucose value if you are in hypoglycemia and make adjustment according to the capillary glucose value.

5. Recommendations when facing hyperglycemia

(1) **Definition:** Glucose value >10.0mmol/L(alert);

Glucose value>13.9mmol/L (immediate action required)

(2) **Solutions:**

- Take an extra dose of rapid acting insulin based on your personal ISF. And if glucose level is above 16.9mmol/L, ketone test is recommended.
- Be careful about “stacking” insulin. The rapid- acting insulin you take at meals may still be working 4 hours after your injection. Keep a careful watch on your glucose over the next hour or two.
- Thinking back the factor contributing to hyperglycemia. Consider what you would do differently the next time with your meal and/ or your mealtime insulin dose to avoid the high and rising glucose.
- If hyperglycemia is sustained the whole day, think about if you miss the

injection of insulin previously or if your additional bolus is not enough and make some additional adjustments. . If you use insulin pump, think about if there is any blockage of tube or noneffective insulin in your pump. And if hyperglycemia is sustained for more than 1 day and you cannot find the reason, we recommend you to consult your investigator.

Note: The glucose value mentioned here refers to the glucose derived from SMBG. For participants distributed to FGM group, we recommend you to have an additional finger-stick test for capillary glucose value if your glucose is higher than 13.9mmol/L and make adjustment according to the capillary glucose value.

APPENDIX.1--The Chinese version of the general diabetes education

自我血糖监测及管理手册

一. 血糖控制目标:

	HbA1c (%)	空腹/餐前血糖 (mmol/l)	睡前/夜间血糖 (mmol/l)	餐后血糖
成人	<7.0	4.4-7.2	6.7-10	5-10.0
儿童和青少年	<7.5	5.0-7.2	5.0-8.3	5-10.0

在不增加低血糖发生的前提下, 尽可能做到血糖达标。

参考文献: 中国1型糖尿病诊治指南(2015年版), 2017年美国ADA指南。

二. 指尖血糖监测

①每天至少4次或以上指尖血糖监测(三餐前, 睡前, 餐后, 必要时凌晨夜间加测一次);

- ②生病、剧烈运动或有急性感染等情况时加测;
- ③没有症状+控制好≠不用监测。

三. 动态血糖监测

- ①至少每8小时扫描获取数据(≥3次/天), 扫描次数无限制, 可以随时扫描;
- ②当你发现扫描的血糖值<3.9mmol/l或>13.9mmol/l时, 加测1次指尖血糖, 以指尖血糖值为准, 进行低血糖或高血糖的处理;
- ③探头仅能用14天, 14天后需更换;
- ④做X光检查、CT(计算机断层成像)、MRI核磁共振检查时需移除;
- ⑤动态血糖监测期间请详细记录饮食、运动、治疗等生活事件。

五. 血糖偏高时怎么办?

①血糖值>13.9mmol/l;

瞬感使用者若发现血糖值高, 测指尖血糖, 并以指尖血糖值为准。

处理方法:

●目标血糖<血糖<13.9mmol/l; 根据胰岛素敏感系数(见后), 计算需要追加多少单位胰岛素, 结合自己的经验、目前情况(餐后、睡前、运动等)等, 追加合适的补充剂量, 1小时后再次复测血糖。

●血糖>13.9mmol/l; 检测血酮, 若是阴性: 同以上处理。酮体阳性: 多喝水, 补充大剂量纠正高血糖, 每小时检测血糖, 严重时医院就诊处理。

●当血糖恢复稳定30-60分钟内, 密切留意血糖变化瞬感使用者若提示“↑”葡萄糖正在迅速升高, “↗”葡萄糖正在缓慢升高, 结合你的胰岛素敏感系数追加剂量。(详细计算方法见4-6页)。

六. 追加大剂量怎么算?

掌握两个定义!

★胰岛素敏感系数: 1单位胰岛素能降低的血糖值

公式(或参考表格):

速效: 敏感系数(X)=1800/(每日总量×18)=100/每日胰岛素总量

短效: 敏感系数(X)=1500/(每日总量×18)

每日胰岛素用量	1800法则 速效	1500法则 短效
20	5	4.2

自我血糖监测及管理手册

四. 低血糖处理

★怎么知道自己低血糖?

1. 看血糖值:

- ①轻-中度低血糖 <3.9mmol/l;
- ②严重低血糖 <3.0mmol/l;

瞬感使用者提示“低葡萄糖”或“↘”(葡萄糖正在下降)、“↓”(葡萄糖正在迅速下降)时应及时预防低血糖。

瞬感使用者若监测到血糖值低, 建议测量指尖血糖, 并以指尖血糖值为准。

2. 低血糖症状: 心跳加快、饥饿、发抖、出虚汗、头晕、焦虑不安、四肢无力、抽搐、视觉模糊、头疼。

★发生低血糖时你该怎么办?

●吃15-20g碳水化合物类食物(如葡萄糖4片、半杯果汁、一汤勺蜂蜜等吸收快作用快的食物), 血糖值<2.8mmol/l时适量再增加15-20g食物;

●15分钟后测量指尖血糖, 若症状未改善重复上述步骤, 若仍未改善或出现神志不清、突发昏迷者送院就诊;

●血糖恢复后, 瞬感使用者若提示“↘”(葡萄糖正在下降)、“↓”(葡萄糖正在迅速下降)时, 可适当增加进食以预防下一次低血糖发生, 在接下来的30-60分钟内密切关注血糖的变化, 适当增加扫描次数(15分钟/间隔), 必要时予指尖血糖测准。指尖血糖组则适当加测血糖值以进一步了解血糖是否稳定。

●血糖恢复后, 回顾发生低血糖原因, 若是在饮食、运动情况不变的情况下发生血糖偏低, 考虑胰岛素注射过多所致。结合患者达标目标, 及时调整胰岛素用量。(具体方案见5-6页)

25	4	3.3
30	3.3	2.8
35	2.9	2.4
40	2.5	2.1
50	2.0	1.7
60	1.7	1.4
75	1.3	1.1
100	1.0	0.8

★碳水化合物系数: 1单位胰岛素能平衡的食物中碳水化合物克数。公式(或参考表格):

速效: 500÷每日胰岛素总量=___g/u

短效: 450÷每日胰岛素总量=___g/u

每日胰岛素用量	500法则 速效	450法则 短效
20	25	23
25	20	18
30	17	15
35	14	13
40	13	11
50	10	9
60	8	8