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Tips for successful use of commercial automated insulin delivery systems: An expert paper of the Italian working group on diabetes and technology

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Keywords:										

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ABSTRACT

In recent years, automated insulin delivery (AID) systems have transformed diabetes care with demonstrated benefits in glucose control, hypoglycemia risk, and psychosocial outcomes. Given that different systems show peculiarities in terms of components, approved indications of use, type of algorithm, modifiable settings, and additional features, with this expert paper, we aim to provide healthcare professionals with device-specific recommendations for the optimization of insulin therapy and diabetes self-management with the five commercial AID systems most commonly used in Italy. In detail, we provide educational tips and suggestions for adjustment of insulin dosing parameters to address specific glucose patterns as depicted by continuous glucose monitoring data and effectively manage physical activity or exercise.

1. Background

1 diabetes in high-income countries [7,8].

In recent years, automated insulin delivery (AID) systems, providing real-time regulation of basal and/or bolus insulin in response to changes in interstitial glucose levels, have transformed diabetes care with demonstrated benefit on glucose control, hypoglycemia risk, and psychosocial outcomes [1-6], becoming the standard of treatment for type Despite the unprecedented levels of automation in insulin dosing, all available systems still require user intervention to initiate meal boluses, anticipate physical activity, react to alerts, treat hypoglycemia or severe hyperglycemia [9,10]. Besides these behavioral challenges, physiological (e.g., time lag in sensor glucose (SG) values, delayed absorption of insulin from subcutaneous depot, and different pharmacokinetics/

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pharmacodynamics of applied insulin) and technological (e.g., loss of communication between system components, infusion set or Pod failure, and need for regular update of software or apps) limitations have also been described [11]. To ensure patient empowerment and autonomy, together with the long-term achievement of glycemic goals with AID systems, involved healthcare professionals (HCPs) are required to put into play psychosocial, technical, medical, and educational skills [12]. Clearly establishing expectations for AID therapy is critical for long-term usage and optimal outcomes. High-quality training is also required. Patient therapeutic education should focus on basic diabetes tasks, how insulin delivery is regulated, the parameters that can be adjusted, and how to manage hypoglycemia, hyperglycemia and other situations of daily life (e.g., exercise, alcohol, meals with high fat/protein content, illness, etc.). Following the initiation of AID therapy, regular follow-up should be provided to facilitate optimization of adjustable settings based on CGM and insulin data [13].

To date, five commercial AID systems (Medtronic Minimed 780G with SmartGuard, Tandem T:Slim X2 with Control-IQ, Accu-Chek Insight with DBLG1, Mylife Ypsopump with CamAPS FX, and Omnipod 5 with SmartAdjust) are commonly used in Italy, each of them showing peculiarities in terms of components, approved indications of use, type of algorithm, modifiable settings, and additional features (Table S1).

The aim of this expert paper is to provide the HCPs with practical

recommendations for optimizing insulin therapy and diabetes selfmanagement with the different AID systems. Starting from a careful consideration of the peculiarities of each system, we provide educational tips and suggestions for adjustment of insulin dosing parameters to address the following glucose patterns, as depicted by continuous glucose monitoring (CGM) data: i) postprandial hyperglycemia (Table 1a; Fig. S1); ii) postprandial hypoglycemia (Table 1b; Fig. S1); iii) interprandial hyperglycemia (Table 2a; Fig. S1); iv) interprandial hypoglycemia (Table 2b; Fig. S1); v) nocturnal hyperglycemia (Table 3a; Fig. S1); vi) nocturnal hypoglycemia (Table 3b; Fig. S1).

For the purposes of this paper, glucose patterns are defined as trends in glucose levels that recur on most days over a 2-week period. Specifically, hypoglycemic patterns are defined as actual episodes of hypoglycemia or frequent and/or prolonged (>30–45 min) suspensions of insulin delivery in CGM reports, while hyperglycemic patterns as the occurrence of high readings that are not adequately addressed by the algorithm-driven insulin delivery. Moreover, postprandial, interprandial, and nocturnal patterns are defined as glucose patterns developing <3 h from the beginning of the meal, persisting or developing ≥ 3 h after the meal, and persisting or developing from 12 a.m. to 6 a.m., respectively.

Lastly, we aimed to offer guidance on adjusting AID therapy before, during, and after physical activity or exercise (Table 4).

threshold as appropriate

threshold as appropriate

Table 1

Proposed strategies for addressing postprandial hyperglycemia and hypoglycemia.

a) Postprandial hyperglycemia

.. . .

a) Postprantiai hypergrycenna						
SmartGuard	Control-IQ	DBLG1	CamAPS FX	SmartAdjust		
 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump Review and reinforce carbohydrate counting skills Suggest increasing the time interval between the (insulin) bolus and the meal 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump Review and reinforce carbohydrate counting skills Suggest increasing the time interval between the (insulin) bolus and the meal 	EducateReview and reinforce carbohydrate counting skillsSuggest increasing the time interval between the (insulin) bolus and the meal	 Educate Suggest considering the administration of a correction bolus through the in-built calcu- lator of the pump Suggest enabling the "Boost" function to intensify algorithm- driven insulin delivery Review and reinforce carbohydrate counting skills Suggest increasing the time interval between the (insulin) bolus and the meal 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump Review and reinforce carbohydrate counting skills Suggest tapping "Use sensor" to use sensor glucose trend for bolus calculation Suggest increasing the time interval between the (insulin) bolus and the meal 		
Adjust Reduce the ICR by 10–20 % 	Adjust Reduce the ICR by 10–20 % 	Adjust • Increase aggressiveness for breakfast/lunch/ dinner by 10–20 %	Adjust Reduce the ICR by 10–20 % Lower the GT level by 10 mg/dl Switch to ultra-rapid acting insulin analoes (faster aspart. 	Adjust • Reduce the ICR by 10–20 % • Turn reverse correction OFF • Lower the GT level by 10 mg/dl • Lower the "correct above"		

ultra-rapid lispro)

b) Postprandial hypoglycemia						
SmartGuard	Control-IQ	DBLG1	CamAPS FX	SmartAdjust		
 Educate Suggest taking 10–15 g of fast acting sugars Review and reinforce carbohydrate counting skills Suggest reducing the time interval between the (insulin) bolus and the meal For slowly absorbed meals suggest splitting the bolus 	 Educate Suggest taking 10–15 g of fast acting sugars Review and reinforce carbohydrate counting skills Suggest reducing the time interval between the (insulin) bolus and the meal For slowly absorbed meals suggest use of extended bolus feature (1–2 h) 	 Educate Suggest taking the recommended amount of rescue carbs Review and reinforce carbohydrate counting skills Suggest reducing the time interval between the (insulin) bolus and the meal For slowly absorbed meals suggest splitting the bolus 	 Educate Suggest taking 10–15 g of fast acting sugars and ticking "hypo treatment" in the "add meal" menu Review and reinforce carbohydrate counting skills Suggest reducing the time interval between the (insulin) bolus and the meal For slowly absorbed meals suggest splitting the bolus and ticking 'slowly absorbed meal' in the "add meal" menu 	 Educate Suggest taking 10–15 g of fast acting sugars Review and reinforce carbohydrate counting skills Suggest tapping "Use sensor" to use sensor glucose trend for bolus calculation Suggest reducing the time interval between the (insulin) bolus and the meal For slowly absorbed meals suggest splitting the bolus 		
Adjust Increase the ICR by 10–20 % 	 Adjust Increase the ICR by 10–20 % Reduce the basal rate by 10–20 % Increase the ISF by 10–20 % 	 Adjust Reduce aggressiveness for breakfast/lunch/dinner by 10–20 % 	AdjustIncrease the ICR by 10–20 %Raise the GT level by 10 mg/dl	Adjust • Increase the ICR by 10–20 % • Turn reverse correction ON • Raise the GT level by 10 mg/dl • Raise the "correct above"		

ICR, insulin to carbohydrate ratio; ISF, insulin sensitivity factor; GT, glucose target

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Table 2

Proposed strategies for addressing interprandial hyperglycemia and hypoglycemia.

a) Interprandial hyperglycemia

u, merekanan u/per6r/comm							
SmartGuard	Control-IQ	DBLG1	CamAPS FX	SmartAdjust			
 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus 	 Educate In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For meals with high fat and protein contents suggest ticking "high-fat meal" in the "meal" menu 	 Educate Suggest enabling the "Boost" function to intensify algorithm-driven insulin delivery Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For meals with high fat and protein contents suggest splitting the bolus and ticking 'slowly absorbed meal' in the "add meal" menu 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing a Pod change For meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus 			
 Adjust Reduce the AIT by 30–60 min Lower the GT level by 10 mg/ dl 	 <i>Adjust</i> Increase the basal rate by 10–20 % Reduce the ISF by 10–20 % 	 Adjust Increase the HA by 10 % when SG lies above the hyperglycemia threshold Increase the NA by 10 % when SG lies within the hyperglycemia threshold Lower the GT level by 10 mg/ dl 	Adjust • Lower the GT level by 10 mg/ dl	 Adjust Lower the GT level by 10 mg/dl For hyperglycemic episodes persisting despite user-initiated correction boluses, consider lowering the "correct above" threshold or reducing the ISF and/or the AIT 			
b) Interprandial hypoglycemia							
SmartGuard	Control-IQ	DBLG1	CamAPS FX	SmartAdjust			
Educate Suggest taking 5–10 g of fast acting sugars 	Educate Suggest taking 5–10 g of fast acting sugars 	Educate Suggest taking the recommended amount of rescue carbs 	Educate • Suggest taking 5–10 g of fast acting sugars and ticking "hypo treatment" in the "add meal" menu	Educate • Suggest taking 5–10 g of fast acting sugars			
Additist	Additist	Additist	Adjust	Adjust			

• Increase the AIT by 30-60 min Reduce the basal rate by • Reduce the HA by 10 % Raise the GT level by 10 mg/ • Raise the GT level by 10 mg/dl • Raise the GT level by 10 mg/ 10-20 % • Reduce the NA by 10 % dl · For hypoglycemic episodes • Raise the GT level by 10 mg/ dl Increase the ISE by 10–20 % following user-initiated correcdl tion boluses, consider raising Raise the hypoglycemia the "correct above" threshold or threshold by 5-10 mg/dl increasing the ISF and/or the AIT

AIT, active insulin time; GT, glucose target; ISF, insulin sensitivity factor; HA, hyperglycemia aggressiveness; NA, normoglycemia aggressiveness

2. Suggestions for optimizing automated insulin delivery in different scenarios

2.1. Postprandial hyperglycemia

When postprandial glucose is very high, SmartGuard, Control-IQ, CamAPS FX, and SmartAdjust users are encouraged to deliver a correction bolus through the in-built bolus calculator to provide more rapid glucose lowering within the target range. SmartAdjust users should be aware that bolusing to bring down high glucose will contribute to more efficient algorithm-driven insulin delivery through the increased total daily insulin dose. For CamAPS FX users, short-term (e.g., 60 min) enabling of the Boost function, providing more aggressive algorithm-driven insulin delivery, may be considered an alternative in this scenario.

If postprandial hyperglycemia is recurrent, a review of the patient's behavior around meals, including carbohydrate counting, dietary habits, and timing of mealtime boluses, is recommended as a first step before considering adjustments of insulin-dosing parameters. Of note, while AID can partly correct for simplified carbohydrate entries, accurate carbohydrate counting is associated with more favorable changes in time in target range (TIR) and time >250 mg/dL [14]. Qualitative aspects of food intake, including glycemic load, also influence postprandial blood glucose levels. Indeed, lower carbohydrate intake and consumption of high-fiber/low-glycemic-index food may help achieve optimal glucose control in closed-loop systems users [15,16]. By contrast, delayed prandial boluses have been associated with early postprandial hyperglycemia and worse glycemic control [17,18]. When using rapid-acting insulin analogues, bolusing 10 to 20 min before a meal is recommended to match insulin action with carbohydrate absorption [7]. A review of daily reports may reveal delayed bolusing when a steep increase in SG occurs on the CGM tracing before the prandial bolus is administered; in this case, a stepwise increase in the time interval between the bolus and the meal should be encouraged. As an alternative, switching to ultra-rapid-acting insulin analogues may provide a greater lowering of postprandial glucose with no increased hypoglycaemia or glycaemic variability [19]. However, the use of ultrarapid preparations is within license only for CamAPS FX at the moment [20]. For SmartAdjust users, tapping "Use sensor" on the Bolus screen of their handset is critical to provide more calibrated bolus recommendations accounting for SG trends before the meal.

An increase in mealtime insulin doses is encouraged when

Table 3

Proposed strategies for addressing nocturnal hyperglycemia and hypoglycemia.

a) Nocturnal hyperglycemia						
SmartGuard	Control-IQ	DBLG1	CamAPS FX	SmartAdjust		
 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For dinner meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change Suggest enabling the Sleep activity mode in the sleeping hours For dinner meals with high fat and protein contents suggest disabling the Sleep activity mode in the sleeping hours 	 Educate In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For meals with high fat and protein contents suggest ticking "high-fat meal" in the "meal" menu 	 Educate Suggest enabling the "Boost" function to intensify algorithm-driven insulin delivery Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing an infusion set change For dinner meals with high fat and protein contents suggest splitting the bolus and ticking 'slowly absorbed meal' in the "add meal" menu 	 Educate Suggest considering the administration of a correction bolus through the in-built calculator of the pump In case of sustained hyperglycemia suggest measuring blood glucose (by glucometer), monitoring ketones and performing a Pod change For dinner meals with high fat and protein contents suggest adding carbohydrate equivalents for fat/proteins and splitting the bolus 		
 Adjust Lower the GT level by 10 mg/dl Reduce the AIT by 30–60 min 	 <i>Adjust</i> Increase the basal rate by 10–20 % Reduce the ISF by 10–20 % 	 Adjust Increase the HA by 10 % when SG lies above the hyperglycemia threshold Increase the NA by 10 % when SG lies within the hyperglycemia threshold Lower the GT level by 10 mg/ dl 	Adjust • Lower the GT level by 10 mg/ dl	 Adjust Lower the GT level by 10 mg/dl For hyperglycemic episodes persisting despite user-initiated correction boluses, consider lowering the "correct above" threshold or reducing the ISF and/or the AIT 		
b) Nocturnal hypoglycemia	0 1 10	DBI 61	6 A. D.C. TW			
SmartGuard	Control-IQ	DRF@1	CamAPS FX	SmartAdjust		
 Educate Suggest taking 5–10 g of fast acting sugars 	 Educate Suggest taking 5–10 g of fast acting sugars 	EducateSuggest taking the recommended amount of	 Educate Suggest taking 5–10 g of fast acting sugars and ticking 	 Educate Suggest taking 5–10 g of fast acting sugars 		

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 Raise the GT level by 10 mg/ dl

dl 10–20 % • Increase the AIT by 30–60 min • Increase the ISE factor by

AIT, active insulin time; GT, glucose target; ISF, insulin sensitivity factor; HA, hyperglycemia aggressiveness; NA, normoglycemia aggressiveness.

rescue carbs

• Reduce the NA by 10 %

Raise the hypoglycemia

• Raise the GT by 10 mg/dl

threshold by 5-10 mg/dl

Adiust

postprandial hyperglycemia is observed despite appropriate meal management. Larger meal boluses are primarily obtained through a reduction of the insulin-to-carb ratio (ICR) in one or more mealtime slots with SmartGuard, Control-IQ, CamAPS FX, and SmartAdjust and through the increase of algorithm aggressiveness for breakfast, lunch, and/or dinner with the DBLG1 system. A stepwise approach with 10–20 % changes at a time is suggested to improve postprandial glucose levels while avoiding hypoglycemia. International consensus recommends aiming for <60 mg/dL increase compared to pre-meal glucose levels [7]. Of note, numerically lower ICR settings are often needed with AID as compared with open loop systems to achieve this goal [21,22]. For SmartAdjust users, disabling the reverse corrections and lowering the glucose target (GT) and/or the "correct above" threshold around meals can also be considered for preventing postprandial hyperglycemia in selected cases.

Adiust

10-20 %

Reduce the basal rate by

2.2. Postprandial hypoglycemia

In case of postprandial hypoglycemia, possibly related to overestimation of carbohydrates or meal bolus, we suggest treatment with a greater amount of rapid-acting carbohydrates (i.e., 10 to 15 g) than is recommended during fasting and/or interprandial periods, in line with international consensus [7]. For CamAPS FX users, we advise entering these carbohydrates in the "Add meal" menu under "Hypoglycemia treatment", so that the algorithm is prevented from delivering insulin to cover the intake. Of note, the DBLG1 system proactively recommends calibrated sugaring, the so-called "rescue carbohydrates", in case of actual or impending hypoglycemia, as an adjunct to basal rate reduction/suspension [23]. Accordingly, we suggest taking the recommended amount of rescue carbohydrates and notifying the system of this decision.

Adiust

AIT

• Raise the GT level by 10 mg/dl

following user-initiated correc-

tion boluses, consider raising the "correct above" threshold or increasing the ISF and/or the

· For hypoglycemic episodes

"hypo treatment" in the "add

Raise the GT by 10 mg/dl

meal" menu

Adjust

If postprandial hypoglycemia is recurrent, a review of carbohydrate counting skills and bolus timing is suggested to rule out systematic overestimation of carbohydrate intake or undue anticipation of meal bolus. For SmartAdjust users, tapping "Use sensor" on the Bolus screen of their handset is critical to provide more calibrated bolus recommendations accounting for SG trends before the meal. Early postprandial hypoglycemia is sometimes related to delayed absorption of carbohydrates, as occurs with low glycemic index foods, high-fat foods, or diabetic gastroparesis [24–26]. In these cases, split-bolus dosing, whereby a patient announces 50 % of their carbohydrate intake before a meal and the reminder 1–2 h post meal, can be considered. Notably, Control-IQ

Table 4

Proposed strategies for management of aerobic activities.

SmartGuard	Control-IQ	DBLG1	CamAPS Fx	SmartAdjust
 Before exercise Suggest enabling the temporary target (150 mg/dl) one-to-two hours before starting exercise When exercising < 3 h after a meal, suggest announcing at least 25 % less carbohydrates for the meal Suggest consuming 10–20 g of carbohydrates in case SG level is below 120 mg/dL before exercise 	 Before exercise Suggest enabling the Exercise activity mode at least one hour before starting exercise Suggest switching to an alternate Personal Profile with decreased basal rates and less aggressive ICR and ISF Suggest consuming 10 to 20 g of carbohydrates in case SG level is below 120 mg/dL before exercise 	 Before exercise When exercising ≥ 3 h after a meal, suggest notifying physical activity at least one hour before the exercise start Suggest enabling the Zen mode before low-intensity activity When exercising < 3 h after a meal, suggest notifying physical activity in the "meal" menu Suggest consuming 10 to 20 g of carbohydrates in case SG level is below 120 mg/dL before exercise 	 Before exercise Suggest enabling the "Ease-off" function at least one hour before starting exercise Suggest setting a higher GT level in the hours when exercise is usually performed When exercising < 3 h after a meal, suggest announcing at least 25 % less carbohydrates for the meal Suggest consuming 10 to 20 g carbohydrates in case SG level is below 120 mg/dL before exercise 	 Before exercise Suggest enabling the Activity feature one-to-two hours before starting exercise When exercising < 3 h after a meal, suggest announcing at least 25 % less carbohydrates for the meal Suggest consuming 10–20 g of carbohydrates in case SG level is below 120 mg/dL before exercise
 During exercise Suggest maintaining the temporary target (150 mg/dl) enabled until the end of exercise If disconnection from the pump is needed, suggest stopping insulin delivery Suggest consuming carbohydrates as needed to prevent hypoglycemia 	 During exercise Suggest maintaining the Exercise activity mode enabled until the end of exercise Suggest maintaining the alternate Personal Profile until the end of exercise If disconnection from the pump is needed, suggest stopping insulin delivery Suggest consuming carbohydrates as needed to nerevent hynoelycemia 	 During exercise If disconnection from the pump is needed, suggest stopping insulin delivery Suggest maintaining the activity/Zen mode enabled until the end of exercise Suggest consuming carbohydrates as needed to prevent hypoglycemia 	 During exercise Suggest maintaining the "Ease-off" function enabled until the end of exercise If disconnection from the pump is needed, suggest stopping insulin delivery Suggest consuming carbohydrates as needed to prevent hypoglycemia 	 During exercise Suggest maintaining the Activity feature enabled until the end of exercise Suggest consuming carbohydrates as needed to prevent hypoglycemia
 After exercise Suggest restarting insulin delivery at the end of exercise, if applicable Suggest announcing up to 50 % less carbohydrates for the post-exercise meal Suggest enabling the temporary target (150 mg/dl) for up to 6 h after exercise in case of late-onset hypoglycemia 	 After exercise Suggest restarting insulin delivery at the end of exercise, if applicable Suggest maintaining the alternate Personal Profile after exercise Suggest enabling the Exercise activity mode for up to 6 h after exercise in case of lateonset hypoglycemia 	 After exercise Suggest restarting insulin delivery at the end of exercise, if applicable Suggest announcing up to 50 % less carbohydrates for the post- exercise meal Suggest enabling the Zen mode for up to 6 h after exercise in case of late-onset hypoglycemia 	 After exercise Suggest restarting insulin delivery at the end of exercise, if applicable Suggest announcing up to 50 % less carbohydrates for the post-exercise meal Suggest enabling the "Ease-off" function for up to 6 h after exercise in case of late-onset hypoglycemia 	 After exercise Suggest announcing up to 50 % less carbohydrates for the post-exercise meal Suggest enabling the Activity feature for up to 6 h after exercise in case of late-onset hypoglycemia

SG, sensor glucose; ICR, insulin to carbohydrate ratio; ISF, insulin sensitivity factor; GT, glucose target.

technology allows extended boluses to be administered at will over a specified time period, up to a maximum of two hours [27]. In our vision, extended bolus delivery is particularly beneficial for managing meals with slowly absorbed carbohydrates and in individuals with gastroparesis. The 'slowly absorbed meal' feature of the CamAPS FX system has also been designed to match delayed glucose excursions, allowing both for increased insulin delivery over a 3 to 4-hour period in response to rising glucose and for reduced/suspended insulin delivery if glucose is falling [28]. For users of this specific system, we suggest splitting the carbohydrate intake and declaring one-half of the whole amount as a "slowly absorbed meal".

Reduction of mealtime insulin doses is encouraged when postprandial hypoglycemia is observed despite appropriate meal management. Smaller meal boluses are primarily obtained through the stepwise increase of the ICR in one or more mealtime slots with SmartGuard, Control-IQ, CamAPS FX, and SmartAdjust, or a decrease of algorithm aggressiveness for breakfast, lunch, and/or dinner with the DBLG1 system. For Control-IQ users, a reduction of preprogrammed basal rates and/or an increase of the insulin sensitivity factor (ISF) around the time of meals may also be needed in selected cases. For SmartAdjust users, enabling the reverse corrections and raising the GT and/or the "correct above" threshold around meals can also be considered for preventing postprandial hypoglycemia in selected cases.

2.3. Interprandial hyperglycemia

Similarly to the postprandial period, when the SG is very high

5

between one meal and the other, users of SmarGuard, Control-IQ, CamAPS FX, and SmartAdjust are encouraged to deliver a correction bolus through the in-built bolus calculator of the pump to provide a more rapid glucose lowering effect. CamAPS FX users can also use the "Boost" function to intensify insulin delivery especially in case of prolonged hyperglycemia and in situations when insulin requirements are supposed to be increased (inactivity, stress, illness, certain times of the menstrual cycle, etc...). Interestingly, the safety of the "Boost" function has been recently ascertained in a retrospective analysis of 7,464 users, showing no episodes of severe hypoglycemia with Boost use over a 12-month period [29].

When SG levels are unusually high for several hours and do not respond to correction boluses, or the patient is feeling unwell, a failure of the cannula should be suspected, and the episode should be managed by changing the infusion set, checking for ketones, and eventually injecting correction doses with the insulin pen. In this regard, expert guidance to manage unexplained hyperglycaemia and avoid diabetic ketoacidosis (DKA) with AID systems has been recently made available [30].

Meals with higher fat/protein content typically result in sustained hyperglycemia that begins 2 to 3 h postprandially and lasts at least 5 h due to delayed gastric emptying and decreased insulin sensitivity [31,32], and therefore require higher doses of insulin together with prolonged bolus delivery [33–35]. Unlike conventional insulin pumps, extended boluses (also known as combo, dual-wave, or multiwave boluses) are not available with SmarGuard, DBLG1, CamAPS FX and SmartAdjust, and are limited to 2 h with Control-IQ. However, CamAPS

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FX and DBLG1 systems have dedicated features to handle meals with high fat/protein content. Specifically, the "slowly absorbed meal" feature of CamAPS FX allows additional insulin to be delivered every 30 min for the 3-4 h following the meal in response to rising glucose levels, while the "high-fat meal" feature of the DBLG1 system allows the administration of biphasic boluses with a 60-minute interval and furtherly adjust insulin delivery for several hours after the meal to compensate for delayed hyperglycemia. Accordingly, we advise that, when eating meals with high fat/protein content, i) SmartGuard, Control-IQ and SmartAdjust users increase their total carbohydrates entry by adding "carbohydrate equivalents" to accommodate the increased insulin requirements dictated by meal composition and divide the bolus by entering part of the carbohydrates before the meal and the remainder in the following hours, ii) CamAPS FX users declare some "carbohydrate equivalents" as a "slowly absorbed meal", and iii) DBLG1 users ticking "high-fat meal" in the "meal" menu screen of their handset.

When hyperglycemia recurs in the interprandial period despite appropriate meal management, adjustment of insulin delivery settings is encouraged. In this regard, our suggestions are: i) for SmartGuard users, to reduce the active insulin time (AIT) by 30 to 60 min at a time down to 2 h (first choice) or lower the GT by 10 mg/dl at a time down to 100 mg/ dL; ii) for Control-IQ users, to increase the basal rate by 10–20 % during the 3 to 4 h preceding the hyperglycemic episodes if hyperglycemia recurs on most days, in the same hours, and hypoglycemia risk is low, or reduce the ISF by 10-20 % around the time of hyperglycemia occurrence if hyperglycemic episodes are less frequent and possibly related to behavioral/social causes, and hypoglycemia risk is high; iii) for DBLG1 users, to increase the normoglycemia aggressiveness (NA) or the hyperglycemia aggressiveness (HA) by 10 % when SG lies within or above the hyperglycemia threshold, respectively, or lower the GT by 10 mg/dL at a time down to 100 mg/dL (last choice); iv) for CamAPS Fx users, to lower the GT by 10 mg/dL at a time down to 80 mg/dL in the 3 to 4 h preceding the hyperglycemic episodes. Our insights are in line with previous literature showing that reduced AIT, differently from lowered GT, increases the TIR without contributing to time below range (TBR) in SmartGuard users [36], that a higher basal rate is associated with improved TIR but also with worse TBR compared to more aggressive ISF with Control-IQ technology [37], and that increased NA, increased HA and reduced GT are associated with increased TIR in DBLG1 users, with HA, GT but not NA also being associated with increased TBR [38]. For SmartAdjust users, lowering the GT down to 110 mg/dL in the preceding 3 to 4 h is the first choice to prevent hyperglycemia in interprandial periods; however, as timely delivery of correction boluses is a key to achieve optimal glycemic control with this system, fine-tuning of bolus calculator settings ("correct above" threshold, ISF and/or AIT) is also encouraged.

2.4. Interprandial hypoglycemia

In line with international consensus, when hypoglycemia occurs during interprandial periods, we suggest treating with a reduced quantity of rapid-acting carbohydrates (i.e., 5 to 10 g), as higher amounts may be associated with rebound hyperglycemia [7]. For DBLG1 users, we suggest taking the recommended amounts of rescue carbohydrates as a first step. However, the intake of lower amounts of carbohydrates may be decided if rebound hyperglycemia occurs with the recommended amounts. In this case, users should be taught to edit the carbohydrate entry and notify the system of their decision.

When interprandial hypoglycemia is recurrent, adjustment of insulin delivery settings is encouraged. In this regard, we advise: i) for Smart-Guard users, to increase the AIT by 30 to 60 min or raise GT by 10 mg/dl at a time up to 120 mg/dL; ii) for Control-IQ users, to reduce the basal rate by 10-20 % in the 3 to 4 h preceding the hypoglycemic episodes or increase the ISF by 10-20 % around the time of hypoglycemia occurrence (especially when hypoglycemia follows automated or user-initiated correction boluses); iii) for CamAPS Fx users, to raise the GT

by 10 mg/dL at a time in the 3 to 4 h preceding the hyperglycemic episodes. For DBLG1 users, four alternative approaches are possible. While reduction of HA may be preferred when hypoglycemia follows too vigorous management of hyperglycemia by autocorrections, reduction of NA or raising of GT may be considered for fine-tuning of autobasal. Raising the hypoglycemia threshold may also be considered to enhance hypoglycemia protection. However, this will result in more frequent recommendations of rescue carbohydrates, possibly causing user fatigue. For SmartAdjust users, raising the GT up to 150 mg/dL in the preceding 3 to 4 h is the first choice to prevent hypoglycemia in interprandial periods; however, when hypoglycemic episodes mostly occur following user-initiated correction boluses, fine-tuning of bolus calculator settings ("correct above" threshold, ISF and/or AIT) is also appropriate.

2.5. Nocturnal hyperglycemia

Management of hyperglycemia during the night hours follows the same principles as the interprandial periods with few specifications. For SmartGuard users, when hyperglycemia is attributable to insufficient basal delivery and/or lower fasting glucose levels are desired, we advise lowering the GT level by 10 mg/dl down to 100 mg/dL as the first choice over reducing the AIT. Control-IQ technology includes a Sleep activity mode allowing for a tightened target range (112.5-120 mg/dl instead of 112.5-160 mg/dl) to be manually activated or scheduled by the user for their sleeping periods. As a general rule, we advise to set the Sleep activity mode ON to optimize glycemic control during the nighttime. However, we acknowledge that the effectiveness of this approach in a real-world setting is still debated [39,40]. Specifically, since no corrective boluses are delivered while the Sleep activity mode is activated, keeping SG levels within the target range might be more challenging in case of post-dinner hyperglycemia or consumption of foods with high-fat content (e.g., pizza meal). This issue may assume greater relevance for individuals from Southern Europe (e.g., from Italy), where dinner is served late in the evening and people go to sleep shortly after eating [40].

2.6. Nocturnal hypoglycemia

In our vision, management of nocturnal hypoglycemia is generally similar to that of interprandial hypoglycemia. However, given that the autobasal is often a major contributor to hypoglycemia in this scenario, we suggest, respectively in SmartGuard and DBLG1 users, to raise the GT and reduce the NA as first choices over other approaches.

Of note, patient's behaviors around the bedtime, including exercising or consuming alcohol in the evening, can elicit the occurrence of nocturnal hypoglycemic episodes. In these cases, implementation of preventive strategies (e.g., setting a temporary target in anticipation of physical activity, or eating a snack) is encouraged besides any adjustment in dosing settings.

2.7. Planned physical activity/exercise

In people living with type 1 diabetes, physical activity has been associated with increased TIR values irrespective of the type of insulin treatment; nevertheless, management of insulin delivery is often difficult due to exercise-related glycemic imbalances and fear of hypoglycemia [41]. The factors affecting the glycemic response typically include type of exercise, period of the day, exercise duration, insulin on board, timing and composition of the last meal, prior episodes of hypoglycemia, psychosocial stress (competition), temperature, site of insulin delivery, and individual hypoglycemic risk. As a general rule, aerobic activity lasting more than 30 min may have a great impact on glucose drops. This type of activity is also defined as moderate-intensity exercise (MIE), with modest counterregulatory response and significant reduction of insulin requirements [42]. Anaerobic activities, instead, usually have a lesser

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impact on glucose fluctuations and reduced drops [43]. Both highintensity (HIE) and resistance (RE) exercises are indeed associated with increased counterregulatory response and less evident increase of muscle insulin sensitivity [42]. Moreover, several studies have shown an important lack of accuracy of CGM devices with the rapid changes in glucose levels that occur during exercise, further increasing the risk of hypoglycemia [44]. Accordingly, increased vigilance with the additional utilization of self-monitoring blood glucose is recommended for people with diabetes who are exercising [45].

As compared with open-loop configuration or multiple daily insulin injections, AID systems generally ensure good glycemic outcomes during and after physical activity, even in high-risk subgroups of patients [46]. Glucose control during the nights with antecedent afternoon exercise also appears to be strongly improved with closed-loop systems, showing increased TIR and reduced hypoglycemia [47].

However, even with AID systems, effective management of physical activity relies on preventive actions [48]. For aerobic activities that last >30 min, the cornerstones of management are the abolition/reduction of insulin on board and the setting of higher GT (also known as temporary or exercise targets) from before the exercise bout. Given the wellknown delay in the offset of insulin action, enabling the temporary/ exercise targets from 1 to 2 h in advance allows to start the activity at a higher glucose level and, therefore, have a greater buffer from falling glucose levels [49]. However, when exercise is planned 1 to 3 h after a meal, a reduction of the prandial bolus by at least 25 % is also recommended [49]. Irrespective of previous adjustments of insulin doses, if glucose levels are below 120 mg/dl just before exercise, the assumption of 10-20 g of uncovered carbohydrates should also be encouraged [7]. Further intake of uncovered carbohydrates (e.g., 30 to 60 g) may be recommended during the exercise bout in case of prolonged sessions (> 40 min) [50]. The duration of temporary targets can vary depending on individual and activity-related variables, with some users requiring the temporary target to be extended up to 6 h after exercise [7]. As an alternative, bolus dose reduction at the post-exercise meal can be considered. Some authors also suggest not to count lipids and proteins but bolusing only for carbohydrate content [51]. Instead, for anaerobic activities where a rise in glucose levels is expected, maintenance of regular prandial dose and insulin delivery settings is recommended [46]. Of note, if pump disconnection is needed during exercise (for contact sports or privacy reasons), insulin delivery should be manually suspended to avoid errors in daily insulin count. For longer periods of disconnection, the patient should be instructed to reconnect intermittently and give a small bolus (50 % of the required "correction" dose) [50].

Our suggestions are in line with the above-mentioned principles (Table 4). When aerobic exercise is planned, SmartGuard and SmartAdjust users are encouraged to enable the temporary/activity target (150 mg/dl) from 1 to 2 h before starting the exercise bout. When exercising in the postprandial periods, they can manually alter the carbohydrate entry or the suggested dose to take less bolus insulin. In Control-IQ users, the enabling of an alternate personal profile with decreased basal rates and less aggressive ISF and ICR, combined with the Exercise activity mode, may provide enhanced protection against hypoglycemia. This solution may fit especially with exercise bouts always taking place at the same hours of the day. The DBLG1 system allows notification of physical activity also via the "meal" menu, in this way providing more relaxed meal management before exercise without the need of "manual" reduction of carbohydrate entries or boluses. Of note, enabling the Zen mode may be sufficient for low-intensity activity performed at distance from meals. Finally, CamAPS FX users may act either enabling the Ease-off function or manually raising the GT up to 200 mg/ dL in the hours when the exercise takes place. While the first solution suits the best in "random" exercise, the latter may be fine for exercise bouts always taking place in the same hours of the day.

3. Conclusion

Successful management of AID therapy by the HCPs requires knowledge of specificities and options offered by different systems and long-term support to users for therapeutic education and the fine-tuning of insulin dosing parameters.

In this expert paper, we provide a structured approach for optimizing insulin therapy through commercial AID systems based on CGMinformed glucose pattern analysis.

Ethical approval

This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors.

CRediT authorship contribution statement

Sergio Di Molfetta: Writing – original draft, Methodology, Conceptualization. Antonio Rossi: Writing – original draft, Conceptualization. Roberta Assaloni: Writing – review & editing. Roberto Franceschi: Writing – review & editing. Valeria Grancini: Writing – review & editing. Vincenzo Guardasole: Writing – review & editing. Andrea Enzo Scaramuzza: Writing – original draft, Writing – review & editing, Supervision, Methodology, Conceptualization. Antonietta Maria Scarpitta: Writing – review & editing. Maddalena Trombetta: Writing – review & editing. Angela Zanfardino: Writing – review & editing. Riccardo Candido: Writing – review & editing, Supervision. Angelo Avogaro: Writing – review & editing, Supervision. Valentino Cherubini: Writing – review & editing, Supervision. Concetta Irace: Writing – review & editing, Supervision. Concetta Irace:

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Declaration of competing interest

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2025.112117.

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