EC PAEDIATRICS
Thematic Article

Real Time Continuous Glucose Monitoring in Young People Affected by Type 1 Diabetes Approaching to Scuba Diving

Riccardo Schiaffini[1]*, I Rabbone[2], M Pieri[3], N Rapini[1], D Tinti[2], S Cianfarani[1], A Marroni[3] and D Cialoni[3]

[1]Diabetes Unit, Bambino Gesù Children's Hospital, Rome, Italy

[2]Diabetes Unit, Regina Margherita Children's Hospital, Turin, Italy

[3]DAN Europe Research Division, DAN Europe Foundation Continental Europe Office - Roseto degli Abruzzi, Italy

***Corresponding Author:** Riccardo Schiaffini, Diabetes Unit, Bambino Gesù Children's Hospital, Rome, Italy.

Received: May 21, 2019; **Published:** June 12, 2019

Abstract

People with diabetes, especially children and adolescents, have been usually discouraged to dive due to the specific risk of hypoglycemia. In order to prevent hypoglycemia and dive safely, Continuous Glucose Monitoring System (CGMS) seem to be a valid option to manage children with diabetes approaching to diving.

The aim of the study was to evaluate performance of a "suited" CGMS in Type 1 Diabetic adolescents during a three days diving session.

Four Type 1 diabetic patients, 12 to 16 years old, intensively insulin treated and previously patented for scuba diving were enrolled in a three days diving performance test. The CGMS receiver was kept in a waterproof case, specifically made for scuba diving activities.

No significant differences between CGM and SMBG glucose values have been reported, both before and after diving; all dive sessions didn't cause a glucose fall and no significant differences in glucose levels measured before and after diving have been reported, both by CGM (226 ± 67 mg/dl vs 205 ± 75 mg/dl) and SMBG (214 ± 55 mg/dl vs 220 ± 77 mg/dl). Referring to hyperbaric exposure, all patients resulted with a Gradient Factor between 0.2 and 0.4, identifying a very low risk for Decompression Sickness.

Our experience, the first with Real Time-CGM in children with Type 1 Diabetes (T1D), demonstrated that a waterproof cased CGMS is essential in order to allow children with diabetes diving safely, avoiding hypoglycemia when underwater. The waterproof cased CGM was accurate and safe.

Keywords: *Type 1 Diabetes; Scuba Diving; Continuous Glucose Monitoring; Hypoglycemia; Paediatric Diabetes*

Introduction

Recreational Scuba Diving is a widespread activity, but, even at innocuous depths, it puts divers through relevant physiological adaptations, especially due to effects on cardiorespiratory systems.

Minor incidents occur in 1.3% of all dives and decompression accidents occur in 2/10000 dives [1], even if the exact incidence of decompression illness (DCI) is controversial. The 30th DAN Annual Diving Report is a summary of recreational scuba diving fatalities, injuries and incidents between 2010 and 2013. Worldwide, DAN received notification of 561 deaths involving recreational scuba diving during 2010 - 2013. The most common injury involved ear or sinus barotrauma and 250 cases of DCI are described. Incidents most commonly occurred on the first day of diving, and more than half of the divers were certified for less than two years. In the majority of cases, the victims were males and over 40 years of age [2].

Some authors [3] identified risk factors (prevalently sex, age and fat mass) for DCI.

For all such reasons a medical evaluation for fitness to dive is a prerequisite for diving for all practitioners [1].

In recent years the practice of recreational Scuba Diving is increasing also in children and adolescents and it is estimated that 5 to 10% of divers is actually in the pediatric age [4]. Some physiological aspects need therefore to be considered in children and adolescents engaging in scuba diving, especially in order to prevent and avoid health incidents. Young divers are indeed exposed to a major risk of barotrauma and decompression sickness, otic injuries and hypothermia, respectively due to physiological reduced pulmonary compliance, higher incidence of otoiatric infections and reduced body surface:weight ratio [4,5].

For those reasons, general recommendations for children engaging scuba diving are absolutely needed (age < 12 years, a maximum depth of 10 meters, short immersions, absence of pulmonary and otoiatric infections) and some diseases, such as respiratory and cardiovascular disease, inner ear and sinus diseases and some psychiatric disorders, are considered an absolute contraindication for diving [4,6,7].

Also, diabetes has been included in the diseases usually considered at risk for scuba diving and, independently from age, type of diabetes, therapy and grade of glycometabolic control, people with diabetes have been usually discouraged to dive [8-10].

Some authors demonstrated that post-dive plasma glucose significantly fells below 70 mg/dl in 7% of type 1 diabetic divers, as compared to 1% of non-diabetic controls [11,12].

However, the prohibition to dive for young patients with diabetes risks to create more severe consequences and, especially in people without certification for diving, a positive association with diving injuries has been described. Indeed only 80.6% of divers with preexisting illness were certified and 20% of diabetic divers don't reveal to have diabetes, continuing to dive despite medical contraindications and exposing themselves to higher risks [13].

For such reasons practical guidelines are needed for diabetic patients and their caregivers, in order to decrease the extra-risk during diving and consequently prevent hypoglycemia and hyperglycemic peaks; the absolute contraindication to diving for diabetics is currently being reconsidered and recently, worldwide, it was recognized that with proper and careful management, children, adolescents and adults with Diabetes can dive safely [14].

In Spain and Australia several efforts have been made to ensure safety for diabetic people approaching diving: published studies do not describe an increased risk in children with diabetes. However, when at risk of hyper/hypoglycaemia during immersion, adequate glycaemic control and diving with a supervisor familiar with the disease must be ensured [6]. Also, in France Lormeau B., *et al*. [10] identified the following indications in order to make diving safer for people with diabetes:

- Ideal glycemic goal of 200 - 250 mg/dl (11 - 13.75 mmol/l) before immersion.
- Higher reduction of insulin requirement (-30%).
- Taking carbohydrates on board in any case.
- Dives within the «safety curve» (no decompression curve).
- Dives in above 14°C water.
- Depth limited to the median space range.
- Mandatory guidance by a diving instructor.

During the last years, new technologies for the management of T1D have been demonstrated safe and useful for both, adult and pediatric patients. Continuous Subcutaneous Insulin Infusion (CSII), Continuous Glucose Monitoring (CGM) and remote monitoring in case of Multi Daily Injections (MDI) seem to be valid options to manage children with diabetes approaching to diving. During the last ten years some papers demonstrated that pump technology and accuracy of glucose sensors are still valid even in a such extreme condition as scuba diving.

In particular, recently different models of Retrospective CGMS were adapted for immersions and used for glucose monitoring during dives [15]. Such experiences allowed authors to demonstrate a regular decrease of glucose values during dives and a good sensor accuracy; sensor data were useful in order to adjust insulin therapy and prevent hypoglycemia. Recently a CGM System (CGMS) has been developed and located in a waterproof case, in order to real-time monitor glucose profiles during diving and allow a specific control of glucose values and prevention of hypos.

Aim of the Study

The aim of the present study was to evaluate safety, accuracy and performance of a diving suited CGMS used in Type 1 Diabetic adolescents during a three days diving session. It is a pilot, thematic study, in which also bubbles formation of inert gas and the variation in hydration state after dives was investigated.

Patients and Methods

The paper, involving human subjects, complies with the Helsinki Declaration of 1975, revised October 2013. It has been prepared in compliance with ethical standards and informed consent was obtained from all patients and their parents.

Four Type 1 diabetic adolescents, M/F:3/1, 12 to 16 years old, intensively insulin treated with Multiple Daily Injections (one subject) or Continuous Subcutaneous Insulin Infusion (3 subjects), previously patented for scuba diving activities during a specific open water diving course for children and adolescents with T1D (8 lessons in enclosed water plus 3 lessons and final licence exam in open water) have been enrolled. Patients were regularly followed by two Diabetes Unit in Italy (Bambino Gesù Children's Hospital, Rome, and Regina Margherita Children's Hospital, Turin). Inclusion and exclusion criteria are reported in table 1. Patients have been continuously assisted by Specialist Instructors of DAN Europe Research Unit during the whole duration of the experiment. DAN Europe staff also followed patients for any physiological variation before, during and after each diving session.

Inclusion criteria	Exclusion criteria
Last year mean HbA1c < 7.5%	Hypoglycemia unawareness
CSII or MDI Insulin therapy	Severe Hypos during the last year
Regular physical activity (at least twice a week)	DKA episodes during the last year
	Autonomic neuropathy
	Vascular complications

Table 1: *Inclusion/exclusion criteria.*

All patients were involved in a three days diving performance test of three dive sessions, 45 minutes each, between December 27 and 29, 2016. The experiment was managed in Padua (Italy) at the "Y-40" swimming pool, the deepest pool in the world with different depths and various itineraries available in order to simulate open water activities.

A CGMS (Dexcom G4) was worn two days before dives and continuously used during the three days of experiment, also during the three dive sessions. During dives the G4 receiver was kept in a waterproof case, specifically made for scuba diving activities (Figure 1).

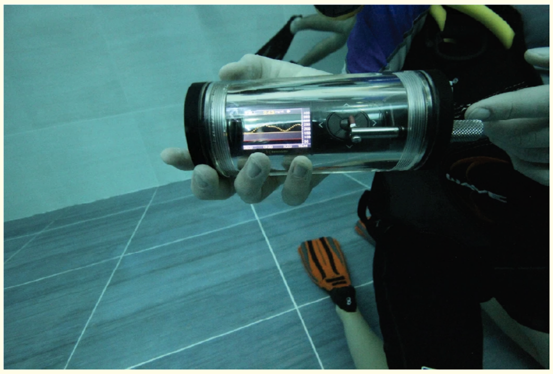

Figure 1: *Waterproof case for CGM.*

A detailed management protocol was purposely built for a safe dive and favorable results in terms of hypoglycemia prevention and glucose control.

A sensor calibration with SMBG value was performed in the ten hours before diving session and, if a persistent difference of more than 20% was reported between SMBG and CGM values, the sensor was replaced and tested again. During dives the case with the receiver was kept in strict contact with the transmitter.

Dives occurred at least 2.5 hours after meals and insulin boluses administration.

SMBG (at - 60', -30' and -15') and CGM values and trends (arrows) were considered for medical authorization for dives. The protocol performed for each dive session is reported in table 2.

	Diving not allowed	Diving allowed
BG > 300 mg/dl or CGM > 250 and any	X	
CGM AND BG 250 - 300 mg/dl and ketones pos	X	
CGM AND BG 250 - 300 ketones neg		X
CGM AND BG 150 - 250 mg/dl		X
BG < 150 mg/dl or CGM < 200 mg/dl and any	X	

Table 2: *Glucose managment protocol.*

Patients and their instructors (one to one ratio) have previously been learned to some conventional symbols in order to communicate the following important messages about glucose levels: “check your glucose - see CGM receiver”, “Low Glucose”, “High Glucose”.

If a CGM value higher of 300 mg/dl (any arrow) or lower of 150 (any arrow) was registered during diving the session was stopped, while if the CGM glucose value was maintained between 150 and 300 mg/dl the session continued regularly.

During the three days diving sessions also the Maximum Gradient Factor (GF) was calculated according to the Buhlmann ZHL16 C model. GF is a way to measure nitrogen supersaturation in the “leading tissue”. GF and is a marker for risk of Decompression Sickness (DCSs) and a value between 0.5 and 0.75 identifies a “Low Risk” profile.

We finally investigated the modifications in the state of hydration indirectly calculated by the changes in blood volume (BV), red cell volume (CV) and plasma volume (PV) after the dive series using the Dill and Costill formula [17].

Statistical analysis

Data are expressed as Mean ± Standard Deviation (SD) for parametric data. The median of CGM Blood Glucose was recorded pre-, during and post-dives. Statistical differences were tested by non-parametrical analysis of variance (Kruskal-Wallis test).

Differences in hyperbaric exposure (GF) between the four divers were evaluated using the two-sample t-test and the Mann-Whitney U test.

Results

No significant differences between CGM and SMBG glucose values have been reported, both before and after diving; moreover, all dive sessions didn’t cause a glucose fall and no significant differences in glucose levels measured before and after diving have been reported, both by CGM (226 ± 67 mg/dl vs 205 ± 75 mg/dl) and SMBG (214 ± 55 mg/dl vs 220 ± 77 mg/dl).

No hypoglycemic episodes have been registered during the three days diving performance test. Table 3 refers to CGM parameters during all dive sessions.

	Mean	SD
AUC > 180 mg/dl	44	20
AUC < 70 mg/dl	0	0
N° glucose values in target (70 - 180 mg/dl)	119 (25%)	38

Table 3: *CGM parameters.*

Referring to hyperbaric exposure, all patients resulted with a GF between 0.2 and 0.4, identifying a very low risk for DCSs (Figure 2).

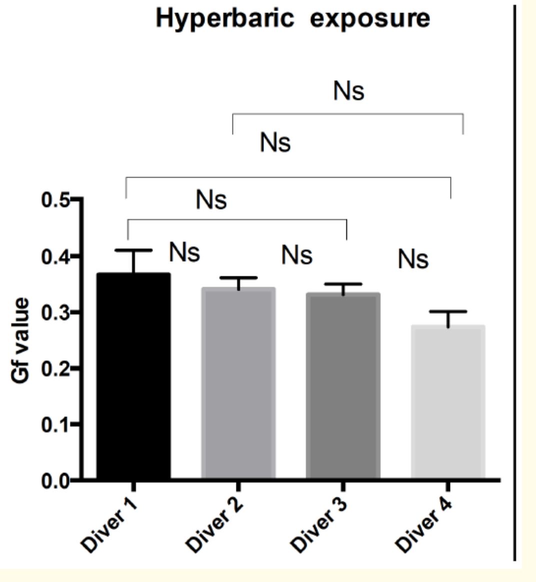

Figure 2: *GF values in all four divers.*

All divers continuously used their CGMS and no failures of the sensors or receivers occurred during the entire three days diving sessions.

We did not find any significant difference in BV before and after the dives (100 ml ± 0 vs. 99.9 ml ± 7.5; p = 0.75) as well as in PV (58 ml ± 4.2 vs. 57.5 ml ± 4.3; p = 0.95), and in RC (42 ml ± 4.2 vs 42.4 ± 5.5; p = 0.71). In particular the BV was relatively unchanged (- 0.14 ml), CV increased (+ 0.93 ml) and the PV decreased (- 0.57 ml), but without any significant evidence. Likewise, we did not find any relationship between changes in the state of hydration (in percentage) and the day of diving: first day + 1.6% ± 6.0, second day - 4.1 % ± 13.8 and last day + 1.2 % ± 4.5. Concerning bubble formation, we found two subjects that did not show any bubble, one subject showed grade 1 and one subject grade 0.5 Bubbles (all bubbles were present during the first two days and no bubbles were formed in the last day).

Discussion and Conclusion

People with diabetes have been usually discouraged to dive, due to high risk of hypoglycemia. Especially for children and adolescents with T1D Scuba Diving has been considered for years a prohibited activity. In fact scuba diving is considered as a mild to moderate physical activity; subsequently blood glucose levels can decrease rapidly increasing the risk of hypoglycemia.

However, recent progression of new technologies applied to diabetes probably let such more extreme activities more suitable for young patients affected by T1D. In particular, Continuous Glucose Monitoring has to be considered the technological progress in the management of diabetes that really could make the difference approaching to scuba diving. Especially the real-time CGM seems to be indicated, allowing patients continuously follow their glucose excursion during and after physical exercise and consequently correct their behaviors and therapies.

Glucose Sensor accuracy was tested by Adolfsson., *et al.* [16] during hypo- and hyperbaric conditions: the use of Medtronic Enlite sensor in hypo- and hyperbaric conditions demonstrated a good system performance, with a MARD (Mean Amplitude Relative Difference) Index at 15% and 7%, respectively in hypobaric and hyperbaric conditions.

The accuracy of glucose sensors for real-time use was also evaluated in a hyperbaric chamber validation test [17]; during the test the Clarke Error Grid analysis showed 93% of values in zone A and 7% in zone B.

Adolfsson., *et al.* [16] tested also the function of the CGMS at high pressures in a pressure chamber and demonstrated that CGMS can be used with good accuracy during scuba diving, providing helpful information on glucose fluctuations and potentially preventing hypoglycemic episodes.

Bonomo., *et al.* [15] demonstrated that also a retrospective use of CGM can be useful to understand glucose profiles while diving and that CGM can be used without technical problems also in non-conventional, even "extreme" conditions as scuba diving. In the "Submerged Diabetes" project, authors concluded that CGM can give a fundamental aid in order to avoid hypo- and hyperglycemic episodes, so contributing to remove a no more justified obstracism toward scuba diving for people with diabetes.

In both experiences, performances of the sensors were satisfactory, with good accuracy, both in land during a prolonged period of intermittent water sport, and in depth. This technique provides precious information on the glucose variations in T1D subjects during and after diving.

Our experience is the first one with RT-CGM in children with T1D. We demonstrated that a waterproof cased CGMS is essential in order to allow children with T1D diving safely, avoiding the risk of hypoglycemia when underwater. The waterproof cased CGMS was accurate, as we proved that no differences between SMBG and CGM values have been reported, both before and after diving. It has also been proven safe, as we didn't report hypoglycemia during all dive sessions. All our four patients reported similar CGM glucose values at the beginning and at the end of each dive session.

As reported in a recent paper by Lippmann J., *et al.* some divers got used to dive with their medical diseases (for example with diabetes) without inform instructors and other divers, which could potentially and negatively impact the safety of their diving. In order to modify the diving practices of children and adolescents with T1D and consequently reduce the risk connected to their disease, we are convinced that a preliminary specialist diving medical consultation, together with proper and detailed management and therapeutic protocol are needed. In our opinion CGM also should be mandatory for young people with T1D approaching to diving.

Data about hydration, even if referred to only few cases, didn't reveal statistical significant differences between divers and each single dive session. A definitive interpretation of this data is not possible, especially due to the low number of subjects evaluated, but it seems not to indicate a unique behavior in this kind of dives and in this particular condition (Thermal swimming pool).

Finally, although not expected, even if not entirely surprising, the observed bubble grades can be compatible with the achieved tissue supersaturation at the end of the dives.

Further studies are anyway needed to fully evaluate the usefulness and accuracy of CGM, especially with more recent and accurate devices, during pressure changes in children and adolescents affected by T1D.

Bibliography

1. Eichhorn L and Leyk D. "Diving medicine in clinical practice". *Deutsches* Ärzteblatt *International* 112.9 (2015): 147-157.
2. Trout BM., *et al*. "DAN Annual Diving Report 2012-2015 Edition. A report on 2010-2013 data on diving fatalities, injuries, and incidents" (2015).
3. Cialoni D., *et al*. "Dive Risk Factors, Gas Bubble Formation, and Decompression Illness in Recreational SCUBA Diving: Analysis of DAN Europe DSL Data Base". *Frontiers in Psychology* 8 (2017): 1587.
4. Cilveti R., *et al*. "Scuba diving in children: Physiology, risks and recommendations". *Anales de Pediatría* 83.6 (2015): 410-416.
5. Klingmann C., *et al*. "Otorhinolaryngologic disorders and diving accidents: an analysis of 306 divers". *European Archives of Oto-Rhino-Laryngology* 264.10 (2007): 1243-1251.

6. Vandenhoven G., *et al*. "Children and diving: medical aspects. Eight years' sports medical follow-up of the first scuba diving club for children in Belgium". *South Pacific Underwater Medicine Society (SPUMS) Journal* 33.2 (2003): 70-73.

7. Johnson R. "Insulin-dependent diabetes mellitus and recreational scuba diving in Australia". *Diving and Hyperbaric Medicine* 46.3 (2016): 181-185.

8. Edmonds C., *et al*. "Insulin-dependent diabetes mellitus - Part B: "The Cons"". In: Edmonds C, Lowry C, Pennefather J, Walker R, eds. Diving and subaquatic medicine. 4th Edition London, UK: Arnold (2002): 590-595.

9. Davis JC and Bove A. "Medical evaluation for sport diving". In: Bove A, editor. Diving Medicine. 3rd Edition Philadelphia, PA: W.B. Saunders Co (1997): 355-356.

10. Dear GdeL. "The DAN Diabetes Survey". *Alert Diver* 3 (1993): 28.

11. Lormeau B., *et al*. "Blood glucose changes and adjustments of diet and insulin doses in type 1 diabetic patients during scuba diving (for a change in French regulations)". *Diabetes and Metabolism* 31.2 (2005): 144-151.

12. Pollock NW., *et al*. "Plasma glucose response to recreational diving in novice teenage divers with insulin-requiring diabetes mellitus". *Undersea and Hyperbaric Medicine* 33.2 (2006): 125-133.

13. Taylor DM., *et al*. "Experienced, recreational scuba divers in Australia continue to dive despite medical contraindications". *Wilderness and Environmental Medicine* 13.3 (2002): 187-193.

14. Edge CJ., *et al*. "Scuba diving with diabetes mellitus - the UK experience 1991-2001". *Undersea and Hyperbaric Medicine* 32.1 (2005): 27-33.

15. Bonomo M., *et al*. "Safety of recreational scuba diving in type 1 diabetic patients: the Deep Monitoring programme". *Diabetes and Metabolism* 35.2 (2009): 101-107.

16. Adolfsson P., *et al*. "Accuracy and reliability of continuous glucose monitoring in individuals with type 1 diabetes during recreational diving". *Diabetes Technology and Therapeutics* 11.8 (2009): 493-497.

17. Pieri M., *et al*. "Continuous real-time monitoring and recording of glycemia during scuba diving: pilot study". *Undersea and Hyperbaric Medicine* 43.3 (2016): 265-272.

Volume 8 Issue 7 July 2019