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Original article

Safety of recreational scuba diving in type 1 diabetic patients: The Deep Monitoring programme

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Abstract

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Aim. – To verify whether, with thorough practical and theoretical training, well-controlled, non-complicated diabetic patients can safely go diving underwater with no additional medical or metabolic risks.

Methods. – Twelve diabetic patients participated in the study after undergoing training focused on their diabetic status. Two dives per day were scheduled during two five-day stays on the island of Ventotene (Italy). Capillary blood glucose (BG) was checked at 60, 30 and ten minutes before diving, and corrective measures adopted if necessary, based on BG absolute levels and dynamics. A device for continuous subcutaneous glucose monitoring (CGM), expressly modified for the purpose, was worn during each dive.

Results. – Data were gathered from 90 dives; mean BG at 60, 30 and ten minutes before diving was 205.8 ± 69.6 mg/dL, 200.0 ± 66.4 mg/dL and 200.5 ± 61.0 mg/dL, respectively. In 56 of the 90 dives, supplementary carbohydrates or insulin were necessary, but only one dive was interrupted on account of hypoglycaemic symptoms. Mean post-dive BG was 158.9 ± 80.8 mg/dL. CGM recordings showed that glucose levels gradually decreased during the dives (nadir: -19.9%).

Conclusion. – Experienced, well-controlled, complication-free young diabetic patients can safely go scuba diving, provided that they apply a rigorous protocol based on serial pre-dive BG measurements. The specific variables of underwater diving do not appear to involve significant additional risks of hypoglycaemia.

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Keywords: Scuba diving; Continuous glucose monitoring; Physical activity; Diabetes and sports

Résumé

Sécurité de la plongée sous-marine pour les personnes diabétiques de type 1 : le programme Deep Monitoring.

Objectif. – Le but de cette étude est de vérifier si, après avoir reçu une formation spécifique, des jeunes diabétiques bien équilibrés, sans complications, peuvent plonger en conditions de sécurité, sans sur-risques médicaux et métaboliques.

Méthodes. – Douze jeunes diabétiques de type 1 ont participé à l'étude, après un cours de plongée dont le programme était ciblé sur la condition diabétique. Pendant deux stages de cinq jours sur l'île de Ventotene (Italie), deux plongées par jour ont été programmées. La glycémie capillaire (GC) était mesurée 60, 30, et dix minutes avant la mise à l'eau, et des mesures de correction étaient adoptées en cas de nécessité, en fonction des niveaux absolus de GC et de leur dynamique. Un dispositif portable de mesure en continu du glucose subcutané (CGM), expressément modifié à cette fin, a été utilisé aussi en immersion.

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Résultats. – Nous avons obtenu des données valides de 90 plongées ; la GC moyenne mesurée 60, 30 et dix minutes avant immersion était 205,8 ± 69,6 ; 200,0 ± 66,4 et 200,5 ± 61,0 mg/dL. En 56 des 90 plongées des carbohydrates ou des injections d'insuline supplémentaires ont été nécessaires. Une seule plongée a dû être interrompue à cause de symptômes d'hypoglycémie. Après la plongée, nous avons relevé une GC moyenne 45 Q1 à 158,9 ± 80,8 mg/dL. Les résultats du CGM ont montré des niveaux de glucose subcutané modérément diminuant pendant les plongées d'une façon progressive (nadir : -19,9%).

Conclusion. – Après une formation spécifique, et appliquant rigoureusement un protocole de prévention basé sur contrôles sériels de la GC avant l'immersion, un jeune diabétique expert, bien équilibré, libre de complications chroniques, peut pratiquer en raisonnable sécurité la plongée avec scaphandre autonome. En particulier, en ces patients les variables directement liées à l'immersion sous-marine ne semblent pas comporter une augmentation signifiante des risques d'hypoglycémie.

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Mots clés : Plongée sous-marine ; Mesure en continu du glucose ; Exercice physique ; Diabète et sport

1. Introduction

Type 1 diabetes mellitus (T1DM) is commonly considered a contraindication for scuba diving, mainly because of the risk of hypoglycaemia [1,2]. In recent years, however, several reports have suggested that this total prohibition should be reconsidered [3–5], and the Divers Alert Network (DAN) has recently proposed a change in current policies [6,7] to allow a specific group of diabetics to participate in scuba diving. However, it is well known that many patients with T1DM dive without declaring their condition [8–10], thereby exposing themselves to risks as a consequence of a lack of specific training.

The *Diabete Sommerso* ('Submerged Diabetes') Project was launched in 2004 by our Center in close collaboration with the Milan Association of Diabetic Patients; in 2005, it was approved as a special project by DAN Europe.

The project's rationale was that, provided that appropriate security conditions are met, success in a sport requiring physical efficiency, precision, reliability and self-control in an 'alien' environment can be invaluable for boosting self-esteem and personal image. This can even shift the patient's general attitude toward the illness, with positive consequences for its clinical course.

Our aim was, therefore, to verify whether or not—after a thorough, dedicated training programme—well-controlled, complication-free diabetic patients could safely dive without incurring additional medical or metabolic risks.

In cooperation with a team of certified scuba instructors, we helped a group of young adults with well-controlled T1DM to obtain first-level Professional Association of Diving Instructors (PADI) Open Water Diver (OWD) certification. This authorizes people to dive within the safety curve (with no decompression stops during ascent). All patients were selected in advance to exclude hypoglycaemia unawareness, chronic micro- or macrovascular diabetic complications and any other medical situations usually considered contraindications for underwater diving. In the OWD course, the standard PADI teaching schedule was combined with additional theoretical and practical modules dealing with the diabetes status, with special attention paid to the prevention and management of acute metabolic complications. The protocol was partially adapted from the camp Diabetes Association of the Virgin Islands (DAVI) guidelines developed by Steve Prosterman, diving supervisor for the University of the

Virgin Islands at St Thomas, Virgin Islands, himself a diabetic [11].

The next step was to verify the efficacy and safety of the protocol outside of the protected setting of 'confined waters' during normal recreational diving. For this reason, in 2005 and 2006, we organized two five-day stays on the Island of Ventotene (Italy), during which previously trained diabetic divers took part in Deep Monitoring, an intensive programme of consecutive dives in which technical, physiological and metabolic parameters were closely followed using innovative techniques.

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2. Material and methods

2.1. 2004–2006: the OWD courses

Fourteen young diabetics were certified in three OWD courses in 2004, 2005 and 2006. To be admitted to the course, all patients had to undergo a series of multispecialist clinical and instrumental investigations to ensure that they had no clinically important chronic diabetic complications (microalbuminuria: > 20 mg/day, retinal involvement beyond background retinopathy, sensorimotor or autonomic neuropathy, macroangiopathic lesions) or other clinical conditions commonly considered contraindications for scuba diving (cardiopathy favouring arteriovenous shunt, epilepsy or disorders of the primary airways, paranasal sinuses and ears).

As regards metabolic control, candidates were allowed to participate only if they satisfied the following criteria:

- HbA_{1c} less than 8.5% at the last examination (within two months);
- no episodes of acute metabolic complications requiring hospitalization in the last 12 months;
- absence of 'hypoglycaemia unawareness', defined as asymptomatic hypoglycaemic episodes (glucose concentrations less than 60 mg/dL for at least ten minutes) during 72-hour continuous glucose monitoring (CGM). This turned out to be the most selective criterion as, in the experience of our Center, this situation occurs in almost half of T1DM patients with HbA_{1c} < 8.5%.

The extra teaching modules for the prevention of acute hypoand hyperglycaemic complications comprised a set of nutritional

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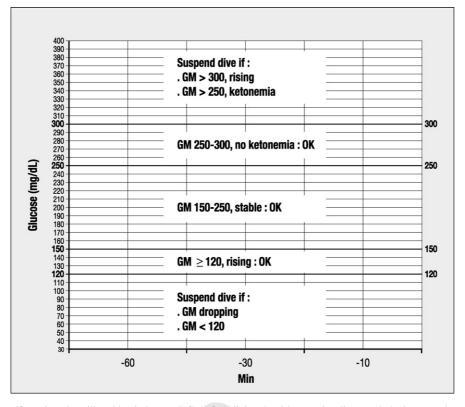


Fig. 1. Algorithm based on self-monitored capillary blood glucose (BG) before diving. Decisions on insulin or carbohydrate supplements took into consideration the absolute BG levels and their patterns. The BG was considered stable when changes from one reading to the next did not exceed 20% (or 15% on two successive readings). Blood ketones were also taken into account in cases of high BG. The safety protocol provided for an extra carbohydrate snack (15–30 g) if capillary BG at -60 minutes and -30 minutes was low in absolute terms (< 120 mg/dL) or dropping. Extra subcutaneous insulin boluses (calculated by applying the individual's 'insulin sensitivity factor') were injected at -60 minutes and -30 minutes for capillary BG > 300 mg/L or > 250 mg/dL with ketonaemia. The ultimate decision to dive was taken on the basis of the -10 minutes capillary BG: if values did not satisfy the safety protocol, the dive was temporarily suspended, corrective carbohydrates or insulin were given and the BG checked again after 30 minutes.

recommendations and a scheme for adapting insulin therapy before, during and after diving.

All participants were taught to apply a simple algorithm, based on serial capillary blood glucose (BG) measurements (Fig. 1). All patients were also taught the technique of carbohydrate counting and, for each diver, an individualized 'insulin sensitivity factor' (1800/total daily insulin dose = mg/dL glucose drop expected for 1 U of insulin) was calculated to determine the corrective insulin bolus.

To manage any hypoglycaemic episodes while in the water, divers were taught to carry two 30-mL tubes of mixed carbohydrate gel in their jacket pocket and how to eat them underwater. An additional hand signal for hypoglycaemia was introduced to alert the diver's buddy at the first sign of hypoglycaemic symptoms before the pair started a safe ascent.

The programme was overseen by expert diabetes specialists at all phases of the training. No important technical or medical problems were encountered throughout the courses in either the pool dives or the final open-sea dives.

2.2. The Deep Monitoring programme

2.2.1. Patients

Twelve well-controlled, non-complicated T1DM patients, who had obtained certification in our modified OWD courses, participated in the present study (Table 1).

2.2.2. Preliminary checks

In the two weeks before the diving programme began, all patients were admitted to our diabetes unit for a complete examination to verify metabolic control (measurement of HbA_{1c} and a three-day CGM). The complete panel of clinical and instrumental assessments required for the OWD course was also repeated if it had not been done in the previous 12 months.

2.2.3. Diving period

2.2.3.1. Self-monitoring of BG (SMBG). The BG was checked by intensified SMBG (at least eight times a day). According to the safety protocol, the BG was also checked 60, 30 and ten minutes before each dive, and corrective measures adopted if necessary. The BG was checked again as soon as they came out of the water. If the BG was more than 300 mg/dL, blood ketones were tested with a meter.

2.2.3.2. Continuous glucose monitoring. After two days of acclimatization, on days 3, 4 and 5, an external device was applied for continuous subcutaneous glucose monitoring (continuous glucose monitoring system [CGMS®], Medtronic). The device uses a needle sensor to measure glucose in the interstitial fluid every ten secondes and stores the average value in the memory at five minutes intervals [12,13]. On days 3 and 4, the device was also worn during immersions. The CGMS® devices were

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Table 1 Clinical characteristics of the patients participating in the Deep Monitoring programme.

Patient	Gender	Age (years)	BMI (kg/m^2)	Duration of diabetes (years)	OWD (year)	Therapy	Insulin (U/24-hour)	Pre-stay HbA _{1c} (%)
A.L.	M	38	21.5	10	2005	MDI	49	6.5
B.L.	M	39	21.5	11	2006	MDI	45	6.4
C.M.	F	29	20.8	8	2004	MDI	16	6.8
C.G.	F	41	23.8	19	2004	MDI	26	7.7
G.G.	M	29	23.2	18	2005	CSII	28	6.9
C.V.	M	36	23.7	13	2006	MDI	49	8.3
Q.S.	M	21	22.0	9	2004	MDI	47	8.4
R.N.	M	33	19.5	6	2004	MDI	19	6.3
R.S.	M	22	20.0	10	2004	MDI	51	7.4
S.E.	M	34	22.7	19	2005	MDI	34	6.6
V.V.	F	32	23.3	14	2004	MDI	41	7.4
Z.V.	F	33	21.7	15	2006	MDI	41	6.8
Mean		32.2 ± 6.2	22.0 ± 1.4	12.7 ± 4.4			37.2 ± 12.3	7.1 ± 0.7

OWD: Open Water Diver (year of certification); MDI: multiple daily injections; CSII: continuous subcutaneous insulin infusion.

specifically modified in collaboration with the Italian National Research Council (CNR) Institute of Clinical Physiology in Pisa. The sensor was waterproofed at the subcutaneous insertion site using a multilayered system, including:

- a direct coverage with hydrophilic vinylpolysiloxane material (Elite H-D[®], Zhermack, Badia Polesine, Italy) in contact with the skin:
- a doubled plastic adhesive dressing;
- an elastic collodion film between the two dressings.

The cable was extended and the monitoring device housed within a pressurized aluminium container (Fig. 2).

2.2.4. Diving parameters

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The main diving parameters (water temperature, depth, dive profiles) were recorded during all immersions by blinded 'Black Box' modified ALADIN[®] Air X dive computers.

To assess the risk of decompression illness, circulating bubbles were checked in all the diabetic divers using Doppler ultrasound (Oxford Sonicaid 121). Sixty-second precordial recordings were obtained on the vena cava window between 20 and 40 minutes after each dive. Data were analyzed using a two-level classification, adapted from the Spencer protocol [14], according to either a low bubble grade (LBG: sporadic signals, Spencer grades \leq 2) or high bubble grade (HBG: frequent-to-continuous signals, Spencer grades \geq 2).

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2.2.5. Analysis

The HbA_{1c} was measured by high-performance liquid chromatography (HPLC) by a VARIANT II instrument (Bio-Rad Laboratories GmbH, München, Germany; normal range: 4.1–6.1%). Divers used memory-based meters (Ascensia Confirm, Bayer Diagnostics) for SMBG. Capillary betahydroxybutyrate was measured using the MediSense Optium

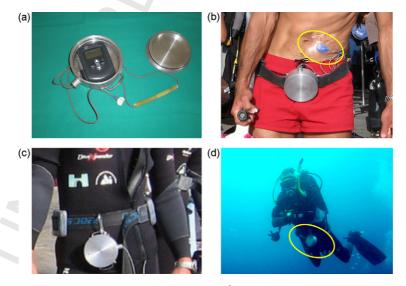


Fig. 2. Changes made to the Medtronic continuous glucose monitoring system ($CGMS^{\textcircled{@}}$) to adapt it for underwater hyperbaric use included: the monitor device was housed in a pressurized aluminium container (a); the sensor was waterproofed at the site of skin insertion (b); and the system was worn over a wetsuit (c); this is how it looks underwater (d).

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meter (MediSense/Abbott Diabetes Care, Abbott Park, IL; normal range: < 0.6 mmol/L).

The following quantitative parameters of each CGM record were considered:

- a single glucose values, at five minutes intervals, in the 40–400 mg/dL range;
- a mean 24-hour glucose concentration;
- a percentage of time glucose values were below, within or above the reference range of 65–160 mg/dL;
- an area under the curve (AUC) for glucose above the reference range (mg/dL per day).

For each CGM recording during dives, the lowest glucose level (nadir), and its percentage drop from basal level, were calculated. Sensor performance was evaluated using SMBG values as the reference. The median relative absolute difference (MRAD) and the correlation index were used as parameters of accuracy.

Dive-to-dive glucose variability on different days was evaluated by visual inspection of CGM profiles and also quantitatively measured, using the mean of daily differences (MODD) index [15,16], calculated as the absolute mean of the differences between paired glucose values on successive dives. The mean of the MODD indices was also calculated for each diver.

2.2.6. Statistical analysis

Data are expressed as means \pm S.D. or percentages. Student's t test was used to assess differences in means between groups. Categorical data were evaluated by the χ^2 test with Yates' correction. Correlation analysis was done with Pearson coefficients. The SAS statistical software package was used for all analyses, and statistical significance was set at P < 0.05.

3. Results

Data were gathered from 90 dives, all within the safety curve (maximum depth 21.5 ± 3.7 m, dive time 46 ± 5 minutes, minimum water temperature $20.8 \pm 1.6^{\circ}$ C); 30 of the scheduled 120 dives were missed for technical or organizational reasons that were not related to medical problems.

3.1. Bubbles

Doppler examination detected no significant bubble formation; all records were classified as LBG.

3.2. Glucose control

The mean SMBG at 60, 30 and ten minutes before diving was $205.8 \pm 69.6 \,\text{mg/dL}$, $200.0 \pm 66.4 \,\text{mg/dL}$ and $200.5 \pm 61.0 \,\text{mg/dL}$, respectively. In 56 of the 90 cases, some correction was necessary according to the safety protocol: 36 were given supplementary carbohydrates (CHO) and 16 took extra insulin; four received both CHO and insulin. In eight cases, the dive had to be postponed for 30 minutes because SMBG was still not on target at $-10 \,\text{minutes}$.

Few problems arose during immersion: on three occasions, the same diver complained of minimal headache (on dives without CGM); symptoms were retrospectively attributed to hypoglycaemia, as BG levels measured a few minutes later were 45, 53 and 53 mg/dL. Only one other patient had to interrupt a dive because of asthenia and dizziness, which resolved after taking CHO at the surface; BG level after a few minutes was 50 mg/dL. Only one of the four hypoglycaemic episodes was preceded by an extra bolus of insulin.

On analyzing the dynamics of BG measurements in this phase *a posteriori*, however, it was evident that, in all of these symptomatic cases, the safety protocol had been wrongly applied. In one case, the dive was preceded by an extra bolus of insulin that was too large, given the patient's sensitivity factor; moreover, the dive was started at -10 minutes with a BG of 258 mg/dL—apparently high but, in fact, more than 20% lower than the previous measurement.

In the other three cases, the pattern of glycaemia had been incorrectly assessed. Capillary BG at -10 minutes was in the range of 120-150 mg/dL, but did not show the rising trend required by the protocol to allow the diver to begin the immersion.

The post-dive mean BG for the whole group was $158.9 \pm 80.8 \text{ mg/dL}$ (range 45-372 mg/dL) and <70 mg/dL in nine cases. The BG <60 mg/dL was seen only in the four symptomatic divers. In five cases (asymptomatic during the dive), values were between 60 and 70 mg/dL; for three of these, retrospective analyses detected inappropriate application of the safety protocol as the dive was started while the BG was dropping.

Seven patients had post-dive glycaemia of $> 300\, mg/dL$. However, blood ketones, measured when BG was $\geq 300\, mg/dL$, never exceeded 0.5 mmol/L.

3.3. Continuous glucose monitoring

Because of technical problems (one flood, one accidental cable damage, four signal 'overflows' probably because of defects in the sensor and/or cable waterproofing), CGM recordings were available for only 27 of 48 monitored dives by nine patients. The general pattern was similar for all monitored dives, with glucose concentrations falling gradually throughout the dive (Fig. 3) with a mean drop to a nadir of 19.9%; the lowest glucose value recorded during immersions was 82 mg/dL.

When consecutive monitored dives were available, the percentage changes in interstitial glucose were highly reproducible in the same subject by visual inspection. In five cases, all four scheduled consecutive dives were monitored (median MODD = 40.4 mg/dL); for technical reasons, only partial series were available in the other cases.

The CGM data from two dives in the same patient on the same day was available in 11 cases. On average, interstitial glucose levels at time 0 were similar for both morning and afternoon dives (189.8 \pm 31.4 versus 187.2 \pm 57.9 mg/dL); the mean drop at nadir was also not significantly different (17.4% versus 24.6%, P = 0.26). In addition, on dividing CGM-monitored dives according to the initial BG level (at time -10 minutes), the decrease in interstitial glucose was similar across subgroups. In

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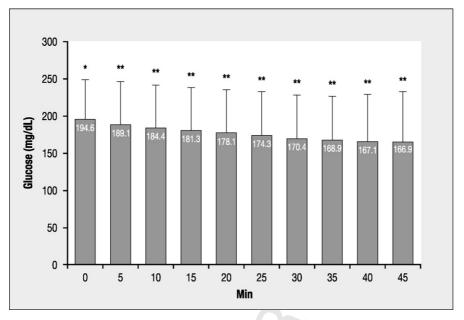


Fig. 3. Interstitial glucose values, as monitored continuously (CGMS® Medtronic) during 27 dives. *P<0.05 versus basal; **P<0.01 versus basal.

general, no correlation was found between the glucose decrease at nadir and pre-dive glycaemia, or other parameters such as maximum depth, water temperature or insulin dosage. However, there was a relationship with dive duration (r = 0.97).

Examining the complete 24-hour CGM profiles, gly-caemic indices were clearly higher during the diving period than in the pre-stay control period—mean glucose: 194.3 ± 50.3 versus 144.8 ± 41.5 mg/dL (P < 0.03); time spent within 65-160 mg/dL reference limits: $30.4 \pm 22.4\%$ versus $65.3 \pm 17.6\%$ (P < 0.01); time spent above 65-160 mg/dL: $63.5 \pm 26.3\%$ versus $28.7 \pm 19.8\%$ (P < 0.01); AUC above 65-160 mg/dL: 55.0 ± 44.6 versus 21.6 ± 22.7 mg/dL per day (P < 0.05). The comparisons were done on the second of the three days of glucose monitoring.

As for the accuracy of glucose readings, MRAD was $13.1 \pm 5.4\%$, and the coefficient of correlation r was 0.95 ± 0.02 .

4. Discussion

Other studies in recent years have examined the metabolic effects and general safety of scuba diving in patients with diabetes mellitus [3–7]. All have reported only modest changes in BG and no additional medical risks due to the diabetes.

A first novel factor in our study was that we intervened in the training phase, modifying the traditional teaching programme for a first-level OWD course by introducing extra theoretical and practical modules aimed at specific aspects of the diabetic condition. This was to ensure a further safety element, especially in the prevention of acute metabolic complications and their management during immersion, if necessary.

The true innovative aspect of the present study, however, was the CGM at depth, obtained in a sufficient number of immersions via a modified CGMS[®]. It is important to recall that any evaluation based only on perceived symptoms and on BG values obtained at the surface—of necessity, either before or

immediately after immersion—does not exclude the possibility of erroneous identification of hypoglycaemia during dives. This may be due to 'hypoglycaemia unawareness' or confounding elements related to environmental conditions. Also, confusion can arise with pathological states caused by high pressure such as nitrogen narcosis.

The glucose data during immersions provided important findings. Previously, to our knowledge, this technique was used underwater only occasionally [5]. The underwater monitoring profiles showed a slight, progressive lowering of glucose concentrations throughout the dive, and no hypoglycaemic episodes. This is similar to the pattern encountered in well-controlled diabetic patients during other types of prolonged aerobic exercise on land, and does not appear to be influenced by any features of the underwater environment. The reproducibility of glucose changes documented by this innovative method should make it a useful means of preventing hypoglycaemia: CGM could serve as another valuable tool for implementing safety protocols in well-trained patients.

Our data did, in fact, confirm and reinforce previous reports of safety and well-being in diabetic divers, highlighting the rarity and ease of control of hypoglycaemic episodes during or after immersions. Indeed, most of the few cases of low BG levels after the dive could have been prevented by more rigorous application of the safety protocol.

On the other hand, our algorithm inevitably involves the acceptance of high BG levels during diving days; however, this transient glucose derangement, in the absence of ketonaemia, should pose no major problems underwater, and is too short lasting to have any serious clinical consequences on global metabolic control and chronic complications. The 120 mg/dL (low) and 300 mg/dL (high) BG thresholds we adopted therefore appear to be sufficiently safe as a basis for authorizing diving by well-trained diabetics. However, this assumption does not preclude the advisability—whenever possible—of

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aiming for more reassuring BG concentrations (in the range of 150-250 mg/dL).

Another reassuring finding is the limited amount of bubble formation, evidenced by Doppler transthoracic examination immediately after the divers emerged from the water. This apparently excludes any increase in the tendency towards decompression illness, suggested in the past for diabetic patients [17].

In conclusion, in selected, well-controlled, complication-free diabetic patients, scuba diving can be considered a safe sport as long as the divers have received specific training and strictly adhere to a specific protocol that prevents acute metabolic complications. If confirmed, these results could contribute to reconsidering the long-standing general belief that diabetics should not take part in this sport, an idea that continues to persist among the diabetological community. Indeed, as has recently been seen with other 'extreme' sports, scuba diving may well offer positive psychological benefits in addition to contributing to a more responsible attitude toward the patient's and doctor's management of diabetes.

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