The Use of Venous Gas Emboli to Validate Dive Computers

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Many decompression models use decompression sickness (DCS) as a measurable endpoint, but often it is not practical to commit the time or money to the large number of dives necessary for validation, nor is it always ethical to provoke DCS. Venous gas emboli (VGE) nearly always accompany DCS, although their presence does not have a direct relationship with clinical symptoms. However, VGE are an accepted indicator of the level of decompression stress that a diver is subject to. There are benefits in using VGE as a predictor for decompression stress. Unlike DCS, which may be misdiagnosed or underreported, the presence of bubbles is an objective measure. As VGE load may be graded, a smaller sample size can be used, as opposed to the endpoint of DCS or no-DCS. Further, the ethical limits of human studies do not have to be reached, as DCS is not the measurable endpoint. This increased sensitivity of measuring VGE allows us to use statistical methods such as the Bayesian approach, a method that employs a priori information, i.e., takes a known outcome sample and combines it with new observations, to produce a risk estimate for DCS. However, the number of dive profiles needed for validation of a dive computer (DC) is infinite. Therefore, a more simple approach is to tailor test to an envelope of the most common profiles used by the target diving population. This method may be used in order to find the optimal DC model for adoption. DCs can be tested against one another, and the DC producing the lowest decompression stress (in terms of VGE produced), then chosen. The DC could then be further validated across a range of other profiles using predictive modeling.

INTRODUCTION

Although the world-wide incidence of decompression sickness (DCS) is remarkably low at around 0.03% in the recreational diving community (Pollock et al., 2008) and the risk of DCS in U.S. commercial divers was approximately 0.1% (Brubakk et al., 1993), there still remains a duty of care for employers to ensure that the risk of DCS remains at the lowest possible level For the Norwegian Labour Inspection Authority, this means that "the use of dive computers (DCs) should be as safe, or safer, than use of the Norwegian Tables". To validate DCs for commercial inshore diving use, we are guided by the methods of testing and validating dive tables and algorithms.

There are numerous decompression models that are used to attempt to determine or predict the outcome of dive profiles, using DCS as a measurable endpoint. The U.S. Navy has rigorously tested and verified their tables with manned dives in this way (Doolette, et al., 2012). They used the outcomes to derive a probability of DCS that is contained in the Thalmann algorithm that drives the U.S. Navy DC (Thalmann et al., 1980; Thalmann, 1984). Testing tables or algorithms in this way is a very lengthy and expensive process, requiring many hundreds of dives. Therefore, it is often not realistic to carry out such testing and it may also be seen as unethical to push human subjects to the point at which DCS occurs.

RELATIONSHIP OF VGE TO DCS

The presence of a large load of venous gas emboli (VGE) in the body following decompression, as investigated with ultrasound techniques, is recognized to be associated with an increased risk of DCS, with a large VGE load increasing the risk (Spencer and Johanson, 1974). In extensive studies carried out by Sawatzky (1991) of 3234 human exposures to either air or heliox dives, in one case only was DCS not accompanied by the presence of VGE in either the pre-cordial or sub-clavian sites.

However, a close relationship between the number or load of VGE present and DCS cannot be derived. One might expect that the highest measurable bubble loads would guarantee the occurrence of DCS, but this is not the case. The Sawatzky (1991) data, which reports fairly conservative profiles, shows an incidence rate of 11% DCS associated with a relatively high, but still sub-maximal Kisman Masurel (KM) grade of III. Only three measurements reaching the highest grades on the scale (KM IV) were noted and none of these were associated with DCS. Herein lies the problem: in order to obtain grades at the highest level to determine the true relationship between the maximal bubbles loads and DCS, the test profiles need to be far more provocative.

When profiles do push towards limits of safety, then a greater incidence of DCS is seen with higher grades. In two such studies (Spencer and Johanson, 1974; Neuman et al., 1976) a DCS incidence rate of 80% and 32% respectively was associated with the highest grade of KM IV. Therefore, although the relationship between bubble grade and DCS occurrence cannot be said to be completely defined, it is clear that there is an increased risk of DCS with increasing bubble load. Although the occurrence of VGE might be a relatively poor predictor of DCS, the absence of VGE is a good indicator of decompression safety, and can be used to estimate a level of decompression stress.

PHYSIOLOGICAL ENDPOINTS

Using DCS as an endpoint might seem straightforward, but in reality, this is not always the case. To quote Ed Thalmann (1989) on the validation of decompression tables, “Careful clinical observation is the best method of evaluating decompression table adequacy as long as all symptoms, no matter how minor or trivial, are recorded and evaluated first hand by trained and experienced medical personnel. Minor symptoms such as fatigue or transient niggles must be considered as they probably indicate a higher level of decompression stress than completely asymptomatic tables”. It is very likely that in past and present studies DCS has been underreported and misdiagnosed, given that divers often do not report symptoms. In light of this observation, the presence of VGE is a far more objective measure of decompression stress, provided that well-trained operators record ultrasound data.

Most importantly, using VGE as a physiological measure of decompression stress meets our modern ethical constraints. Gaining approval for human experimental diving that uses DCS as an endpoint is increasingly difficult and ethically questionable. Although it cannot be guaranteed that in the process of testing even conservative profiles subjects will not present with DCS, it is far preferable that a measure be used whereby DCS does not have to be provoked to get a meaningful result.

In addition, a smaller sample size for testing may be used when measuring VGE, as the range of grades available by which to rate the bubble load gives a greater level of sensitivity. In contrast, the binomial nature of a DCS or no-DCS endpoints means that a far greater number of comparisons have to be made. For example, more than 300 exposures with no DCS are needed to confirm an incidence below 1% with a 95% confidence interval (Eftedal et al., 2007), while if only one DCS 'hit' occurs, then the figure will rise to more than 500 dives. It should be noted that even in the simplest terms, this would only take care of one depth/time combination. In reality, multiple combinations and types of profile would need to be tested in order to validate a model/algorithm/DC (Angelini, 2012).

It is apparent that a deterministic approach to validating dive computers is not feasible. Instead, an approach to test against a stress predictor model, such as Copernicus, may be helpful, and experimental efforts should be focused on the scientific consolidation of such a model (Gutvik, 2011). The use of VGE data is necessary for exciting the model through a wide diversity of exposures, with historical datasets describing DCS from a probabilistic view being of great use. The high sensitivity of VGE can most likely be exploited in a probabilistic model to better effect than DCS occurrence. This is the reasoning behind the Copernicus model that, instead of predicting the risk of DCS, predicts the amount of VGE produced after any dive exposure. The problem is viewed from a physiological approach and a model designed to predict VGE load.

AN ACCEPTABLE LEVEL OF RISK: STATISTICAL CONSIDERATIONS

Consideration has to be made as to what the acceptable level of risk of DCS is. If the physiological endpoint to be used is not DCS but VGE load (i.e., decompression stress), then despite the highly non-linear relationship between VGE and risk of DCS, a decision still has to be made as to where to draw the line. Defence Research and Development Canada (formerly DCIEM) has selected a limit of KM grade II or greater in 50% of subjects to discriminate between stressful and acceptable procedures (Nishi and Eatock, 1989). Eftedal et al. (2007) have previously suggested that by designing decompression procedures so that less than 50% of the subjects have bubble scores of III and IV, the DCS risk should be less than 5%. Pollock (2008) suggested that "VGE data should be interpreted conservatively, with an analytical focus on the most meaningful Doppler grades – III or higher – on standard scales". However, there is a danger that in defining VGE limits for decompression profiles, too high a level of conservatism may be reached, and meaningful diving will not be able to proceed. This limitation must be considered and weighted up when attempting to use VGE to validate DCs, particularly as the occurrence of DCS across dive populations, and therefore the projected risk to divers, is statistically low.

The higher sensitivity of VGE measurement versus the DCS endpoint may be exploited by using statistical techniques such as the Bayesian method to validate profiles. This technique uses *a priori* information, i.e., takes a known outcome sample (for example the Sawatzky data) and combines it with new observations, reducing the necessary sample size. The higher sensitivity of VGE data also produces narrower confidence intervals than looking exclusively for DCS. It should be noted that because the sample size is considerably reduced when designing trials using this methodology (for example, n<50) it is unlikely that there would be any incidence of DCS, so it would not be possible to use DCS as an endpoint in studies deigned in this way.

However, even if the number of dives that have to be made are reduced substantially by the use of techniques like the Bayesian method during the validation process, a huge amount would still have to be made to encompass all of the combinations of profiles and dive types that a DC could compute (Angelini, 2012). Therefore, a more simple methodology would be to use the VGE approach, but test only profiles that are commonly used by the target population. This approach reduces the complexity of the validation process to a manageable process in terms of time and economics

CONCLUSION

Once the target population has identified their need for a dive computer, then ideally their most commonly used dive profiles could be used to test different models against one another to find the optimal DC for the populations' use. It is necessary to test individual DC models, because each is driven by a specific, but usually unidentifiable, algorithm. Although this might not be ideal, it is a cost-effective approach and with objective endpoints, an eminently testable approach to take. This method obviously could not be employed if using DCS as an endpoint. Using VGE measurement, the algorithms in each DC for each specific profile can be rated for decompression stress, then paired comparisons can be made and the optimal DC (producing the lowest amount of VGE across the test population over selected profiles) chosen for use in that specific population.

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