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Validation of decompression schedules for the Polish Navy

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ABSTRACT: Research on the validation of decompression tables is one of the common subject areas of the co-operation undertaken between the DR-DC Toronto, Canada, and The Naval University of Gdynia, Poland. For several years now, a systematic survey of diving technologies has been conducted among the target projects financed by the Polish State Committee for Scientific Research and the Polish Navy. Among the most important problems discussed have been various aspects of decompression safety. The following is a study carried out to standardise and unify validation procedures for decompression in the Polish Navy.

1 INTRODUCTION

1.1 *Studies on decompression*

The systematic study of the phenomena accompanying decompression is difficult because of a lack of precise measurement methods to monitor the processes taking place in body tissues. The mathematical models used to describe the decompression process reflect only a fragmentary part of the total phenomena taking place. They usually consist of trying to fit experimental data by means of relatively simple mathematical functions. Such mathematical models, however, should be treated as calculation methods for deriving decompression procedures, not as mathematical models of the physiological processes taking place during decompression.

1.2 *Process of validation of decompression tables*

The validation process is to verify the assumptions made in the decompression model by establishing a decompression sickness (DCS) risk function based on experimental dive data.

The purpose of this work is to recommend and standardise the statistical procedures to validate decompression tables (schedules) for Polish Navy.

1.3 *Collecting data*

Figure 1 shows recommended methodology for decompression table validation and the implementation of new decompression schedules described earlier in detail [Kłos R., Nishi R. and Olszański R.: 2002], that is why it does not presented here.

1.4 *Statistical presentation of DCS occurrence*

The onset of DCS symptoms may be treated as a statistical phenomenon since it seldom happens that

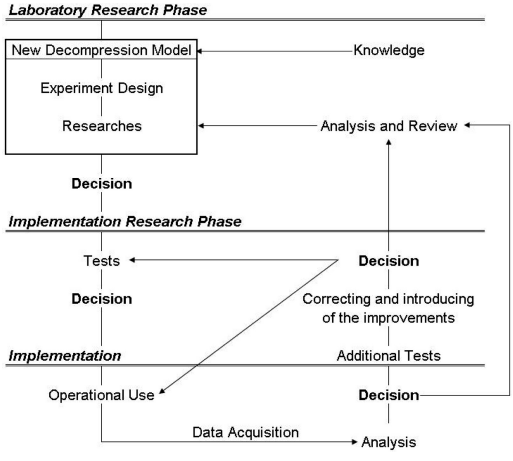

Figure 1. The flow chart showing implementation of the new methods of decompression in the Polish Navy.

divers subjected to the same decompression procedure all show the same reaction or symptoms. Because of the variability in the biological processes underlying the reactions to decompression stress that are observed, it is most convenient to acknowledge a formal statistical correlation between the results obtained from experimental dives, and the results expected to confirm the safety and adequacy of the mathematical model used to describe them. The use of statistical methods sometimes produces simple and relatively easy to interpret results. However verification of decompression tables from a small number of experimental dives is statistically unfavourable, because it is difficult to clearly prove their safety. For decompression tables, a statistical verification of the decompression for each depth and bottom time should

be the aim. A contradiction appears at this point: on the one hand, we aim at acquiring the highest possible number of experimental results (providing a solid base for statistical deduction); on the other hand, this procedure is very costly and risky.

2 METHODS AND RESULTS

2.1 *Binomial distribution model of DCS occurrence*

Assuming that the results of the decompression performed may be described by a binomial distribution (Bernoulli's trials), the probability of the occurrence $\Phi(n,N)$ of n events of DCS symptoms in a random sample of general population N, where the underlying probability of DCS is ρ, is given by:

$$\Phi(n,N) = \frac{N!}{n!(N-n)!}\rho^n(1-\rho)^{N-n} \qquad (1)$$

where Φ = probability function; n = number of DCS events; N = number of random samples from general population; ρ = probability of DCS events (decompression risk).

Using the above formula, we can then produce a table of the probability of selected joint events occurring in some number of dives at a given probability of DCS symptoms [Weathersby P.K. 1990].

A basic problem in developing decompression procedures is finding the number of experimental dives needed to prove that the decompression profiles that were tested are sufficiently safe. In order to answer this question, it is necessary to establish the definition of "safe decompression". A 5% risk of DCS may be acceptable for some military diving purposes. On the other hand, for recreational diving, the risk should be less than 1% at a confidence level of 95% [Huggins K.E. 1992]. The estimation error of the probability limits $P_l < \Phi < P_r$ is α. Hence the confidence level of this estimate is $1-\alpha$. In order to find the number of dives necessary to verify a decompression profile within a specified limit, a low probability of error α must be assumed. Then we can calculate, from the binomial distribution, the number of experimental dives and the incident rate that will give us the confidence interval, which has a probability equal or less than the limit value assumed. Figure 2 shows the maximal probability for 0, 1 and 2 incidents of DCS as a function of the number of dives.

Before start testing decompression tables, ideally, if the validation procedure has the following characteristics: the number of the experimental dives required to be small, the experiments to involve a relatively small risk of DCS, and the final result to provide a simple and clear answer about the safety of the decompression model tested.

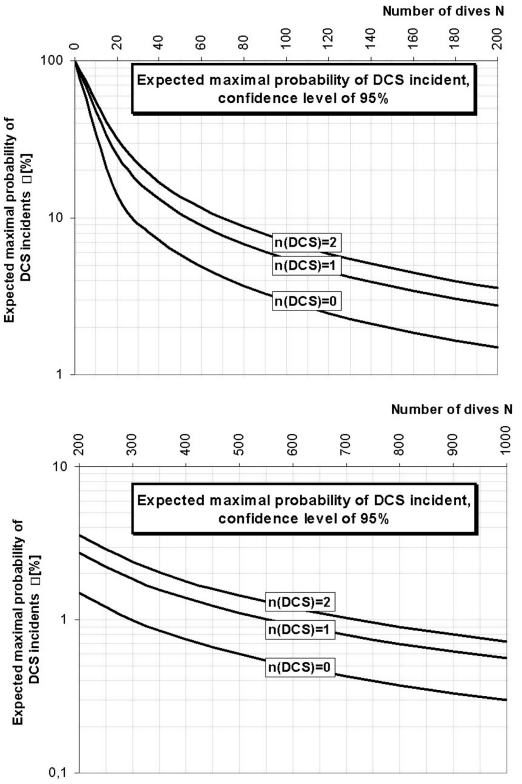

Figure 2. Expected maximal probability of DCS incident, confidence level of 95%.

The above expectations are obviously contradictory. As shown in the example above, if we aim at reducing the number of dives and at minimal DCS risk, we cannot, as a rule, achieve a clear answer about the safety of the decompression profile tested. A simple and clear answer requires a relatively high number of tests.

Because the use of confidence intervals to validate the entire decompression table would require an extremely large number of experimental dives (Fig. 2), some researchers prefer to assume that the DCS risk is constant for the whole range of depth and bottom times generated by the mathematical model. In this case, the expected probability of DCS is applied to a whole population of events, regardless of the decompression profile tested. This relies on a division of the profiles tested into certain groups (selection criteria for the groups are decided by the researcher) and then running statistical tests for these groups. The representative quality of such tests depends on the quality and variety of the selected profiles. Such procedures are justified when the experimental dives making up the groups are comparable to bottom times and depths. But when this selection is spread over a whole range of depths, for dive duration from several minutes to

dive times leading to saturation of the body, such procedures could be wrong.

Despite this the validation method based on binomial distribution is the most clear, but it is an extremely costly and time consuming process. In order to develop more practical decompression validation procedures to fit within financial and time constraints, it will be necessary to investigate other strategies for reducing the number of required dives while still keeping in mind the statistical considerations.

2.2 *Sequential analysis*

Generally there are two reasons for introducing sequential methods into statistical analysis. One is to solve more efficiently a problem which has a fixed sample solution. The other is to deal with problems for which no fixed sample solution exists. Here only the first is taken into consideration.

In the reference literature various methods of statistical inference (validation) are to be found. One of the simplest methods is that developed at the Naval Medical Research Institute (NMRI) [Huggins K.E. 1992]. It limits the number of experimental dives to a maximum of 40 for one schedule checking Figure 3.

Having completed 28 dives free from DCS incidents it is assumed that the profile tested is safe. But if under the tests 1 case of DCS appeared, the dives should be continued to a total of 40, on condition that no DCS incident was previously manifested. If it does then the procedure is aborted, the profile is considered to be dangerous and therefore rejected, but if during the realization of 40 expositions only one case of DCS took place, the profile gets accepted as safe enough. It is not possible to use the inference requiring a small population of experimental dives. It can be assessed by system of equation:

$$\begin{cases} \sum_{x=0}^{n}\left[\frac{N!}{x!(N-x)!}\rho_1^x(1-\rho_1)^{N-x}\right]=\beta \\ \sum_{x=0}^{n}\left[\frac{N!}{x!(N-x)!}\rho_0^x(1-\rho_0)^{N-x}\right]=\alpha \end{cases} \qquad (2)$$

where α = probability of type I error; β = probability of type II error.

For N = 28, n = 0, $\alpha = 0,05$ and $\beta = 0,2$, DCS risks are: $\rho_0 \cong 10,1\%$ and $\rho_1 \cong 5,5\%$. For N = 40, n = 1, DCS risks are: $\rho_0 \cong 11,3\%$ and $\rho_1 \cong 7,3\%$, and for N = 28, n = 1, DCS risks are: $\rho_0 \cong 15,8\%$ and $\rho_1 \cong 7,3\%$ (α and β = idem).

Solving again system of equation (2) for the sake of N, for n = 2, $\alpha \leq 0,05$, and $\beta = 0,2$, $\rho_0 \cong 15,8\%$ and $\rho_1 \cong 10,3\%$, it is N $\cong$ 40 as result. It is evident, that

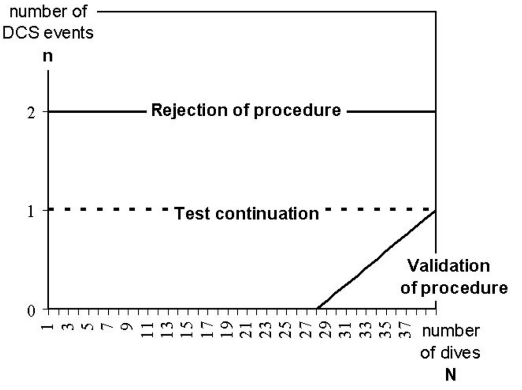

Figure 3. Chart of validation procedure used by Naval Medical Research Institute for a single decompression profile.

DCS risk for N = 40 and n = 2 ist almost identical like for N = 28 and n = 1. In other words: it is possible to assess risk on ca.15% with 95% of significance level and statistical power 80%. And it is possible to distinguish between <11% and >15% risk by means of NMRI procedure.

This answer is more accomplished than from binomial approach but is obtained by a cheaper and faster way. The above results show that it is a basis for rejection of hypothesis $H_0 > 15\%$ (for N = 40, n = 2, $\alpha = 0,05$ and $\beta = 0,2 \Rightarrow \rho_0 \cong 14,9\%$ and $\rho_1 \cong 10,3\%$) with 5% of error for NMRI procedure. Rejection of H_0 gives a basis for acceptance of DCS risk on a ca.15% level. In other words, positive passing of NMRI procedure gives a basis for the statement that the tested decompression profile can generate no more than 15% DCS risk.

This answer can appear unsatisfactory, but determination of DCS risk on 1% level by means of the binomial model needs:

$$N = \frac{\lg\alpha}{\lg(1-\rho)} = \frac{\lg 0,05}{\lg(1-0,01)} \cong 298 \Rightarrow N = 299 \qquad (3)$$

N = 299 experimental dives (see also Fig. 2) without any DCS (n = 0) for 95% confidential level, and N = 555 experimental dives for n = 1 DCS for $0,004\% < \rho < 1\%$ on 95% confidential level. These results can be obtained after numerically solving the system of equations (the same system of equation was a base for calculation shown in Fig. 2):

$$\forall_{0<n<N} \begin{cases} P(\rho \leq P_r) = \sum_{x=0}^{n}\binom{N}{x}\cdot P_r^x(1-P_r)^{N-x} = \frac{\alpha}{2} \\ P(\rho \geq P_l) = \sum_{x=n}^{N}\binom{N}{x}\cdot P_l^x(1-P_l)^{N-x} = \frac{\alpha}{2} \end{cases} \qquad (4)$$

where P_r = maximal probability of DCS onset; P_l = minimal probability of DCS onset.

In this way, the NMRI procedure appears to be an enough efficient, from a practical point of view, method.

2.3 *Monte Carlo simulations*

The Monte Carlo technique is an important numerical tool for studying the relationship of variables in complex systems of equations. The general idea behind the Monte Carlo techniques is to generate random variations in the variables, which are then inserted into the appropriate equations to arrive at some result. The starting point is the pseudo-randomisation function supplied with most computers, or use mathematical formulas. In most situations, the pseudo-random numbers generator generates every value between 0 and 1, which has an equal probability of being hit. For generating pseudo-random number L from an a to b interval, with the use of generator G, which generates pseudo-random numbers from 0 to 1, it is possible to use the formula:

$$L = G \cdot (b - a) + a \tag{5}$$

For 1000 repetitions of NMRI procedure with DCS probability accuracy $\Delta\rho = 0{,}001$, the result of one dive simulation can be written, as:

$$\begin{cases} n = 0 \quad for \quad int(1000 \cdot G) \le int[1000 \cdot (1 - \rho)] \\ n = 1 \quad for \quad int(1000 \cdot G) > int[1000 \cdot (1 - \rho)] \end{cases} \tag{6}$$

Figure 4 shows an average result of 3 times repetition of 1000 NMRI procedure simulations. In Figure 4, points represent the result of simulations but curves show the result of smoothing the data. A solid line represents average probability of NMRI procedure acceptance but a broken line represents the average number of required experimental dives. A horizontal lines show two thresholds of NMRI procedure and 5% significance level (probability of a type I error).

3 DISCUSSION

The Polish Navy cannot accept a verification procedure for testing tables that meets rigorous statistical standards such as achieving 0 cases of DCS at a confidence level of 95% with the expectation that the actual probability of DCS will be only 1%. In such a case, about 300 dives without any incidence of DCS would be required to test each depth and bottom time entry in the set of tables (Fig. 1). Financial and time constraints will not allow the high numbers of dives required.

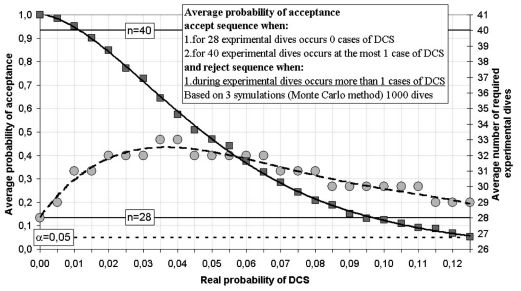

Figure 4. An average result of 3 times repetition of 1000 *NMRI* procedure simulations.

It is necessary to adopt some strategies for reducing the number of dives while still providing some clear answers on the safety of the dives. The goal would be to obtain dives that are "reasonably safe".

The NMRI procedure of accepting a dive profile if no cases of DCS are observed in 28 dives is a reasonable strategy. If one case of DCS occurs in the first 28 dives, then diving is continued until 40 dives are attained or a second case of DCS occurs. This strategy reduces the trial size significantly.

If the dives are safe and no DCS occurs, we stop at 28 dives for each profile. If the dives are very risky and produce 2 cases of DCS quickly, then the trials would be terminated early.

Further analysis of this procedure, including Monte Carlo simulations, is warranted to obtain clearer enough answers on the safety with acceptable power level of inference based on these dive trials.

4 DEFINITIONS AND SYMBOLS

DCS = decompression sickness; H_0 = null hypothesis (hypothesis of no experimental effect or change); H_1 = alternative hypothesis (hypothesis of experimental effect or change); $1 - \alpha$ = confidence level (probability of failing to reject H_0 when H_0 is true); $1 - \beta$ = power (probability of correctly rejecting H_0 when H_0 is false); α = type I error (erroneous rejection of H_0); β = type II error (erroneous failure to reject H_0).

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