A prospective single-blind randomised clinical trial comparing two treatment tables for the initial management of mild decompression sickness

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Abstract
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Introduction: Limited evidence suggests that shorter recompression schedules may be as efficacious as the US Navy Treatment Table 6 (USN TT6) for treatment of milder presentations of decompression sickness (DCS). This study aimed to determine if divers with mild DCS could be effectively treated with a shorter chamber treatment table.
Methods: All patients presenting to the Fremantle Hospital Hyperbaric Medicine Unit with suspected DCS were assessed for inclusion. Participants with mild DCS were randomly allocated to receive recompression in a monoplace chamber via either a modified USN TT6 (TT6m) or a shorter, custom treatment table (FH01). The primary outcome was the number of treatments required until resolution or no further improvement (plateau).
Results: Forty-one DCS cases were included, 21 TT6m and 20 FH01. Two patients allocated to FH01 were moved to TT6m mid-treatment due to failure to significantly improve (as per protocol), and two TT6m required extensions. The median total number of treatments till symptom resolution was 1 (IQR 1–1) for FH01 and 2 (IQR 1–2) for TT6m ($P = 0.01$). More patients in the FH01 arm (17/20, 85%) showed complete symptom resolution after the initial treatment, versus 8/21 (38%) for TT6m ($P = 0.003$). Both FH01 and TT6m had similar overall outcomes, with 19/20 and 20/21 respectively asymptomatic at the completion of their final treatment ($P = 0.97$). In all cases where two-week follow-up contact was made, ($n = 14$ FH01 and $n = 12$ TT6m), patients reported maintaining full symptom resolution.
Conclusions: The median total number of treatments till symptom resolution was meaningfully fewer with FH01 and the shorter treatment more frequently resulted in complete symptom resolution after the initial treatment. There were similar patient outcomes at treatment completion, and at follow-up. We conclude that FH01 appears superior to TT6m for the treatment of mild decompression sickness.

Introduction

Decompression sickness (DCS) results in divers requiring lengthy treatments in a recompression chamber.[1] The current standard treatment, United States Navy Treatment Table 6 (USN TT6) commits a patient to a minimum 4 hour and 45 minute multiplace chamber treatment, although a United States Navy Treatment Table 5 (USN TT5) can be used for cases of musculoskeletal DCS where symptoms have resolved within 10 minutes of oxygen (O_2) breathing at 60 feet /18 metres of seawater depth equivalent (284 kPa).[2,3] USN TT5 is typically used where there is a short delay to recompression. A USN TT5 has a duration of approximately 2 hours and 15 minutes. Since USN TT6 was developed there has been no investigation of the optimum duration of treatment, although shorter treatment tables have been and continue to be used in some institutions (Cianci P, personal communication, 2020).

Both the USN TT5 and USN TT6 tables used in our monoplace chambers have been modified from the original published versions, with decompression from 284 kPa to 190 kPa and 190 kPa to 101 kPa ('surface pressure') over 10 minutes instead of the usual 30 minutes, as 10 minutes was the slowest decompression rate possible for the Sechrist 3200 chamber. To compensate for this, the modified TT6 (TT6m, Figure 1) and TT5 (TT5m, Figure 2) tables used in this study have an extra 20-minute O_2 breathing period at 284 kPa, as compared with standard published USN TT5 and TT6 tables.[4] The FH01 table (Figure 3) was developed by Dr Robert Wong, a previous medical director of Fremantle Hospital Hyperbaric Medicine Unit as a blend of USN TT5

Figure 1

Fremantle Hospital Hyperbaric Medicine Unit USN TT6 (modified) for monoplace chamber application; pressures are absolute pressures. The total time is 4 hours 35 minutes (275 minutes); compression rate 18 kPa·min^{-1}, decompression rate 9 kPa·min^{-1}; BIBS – built in breathing system; kPa – kilopascals; msw – metres of seawater; O_2 – oxygen; Pt – patient

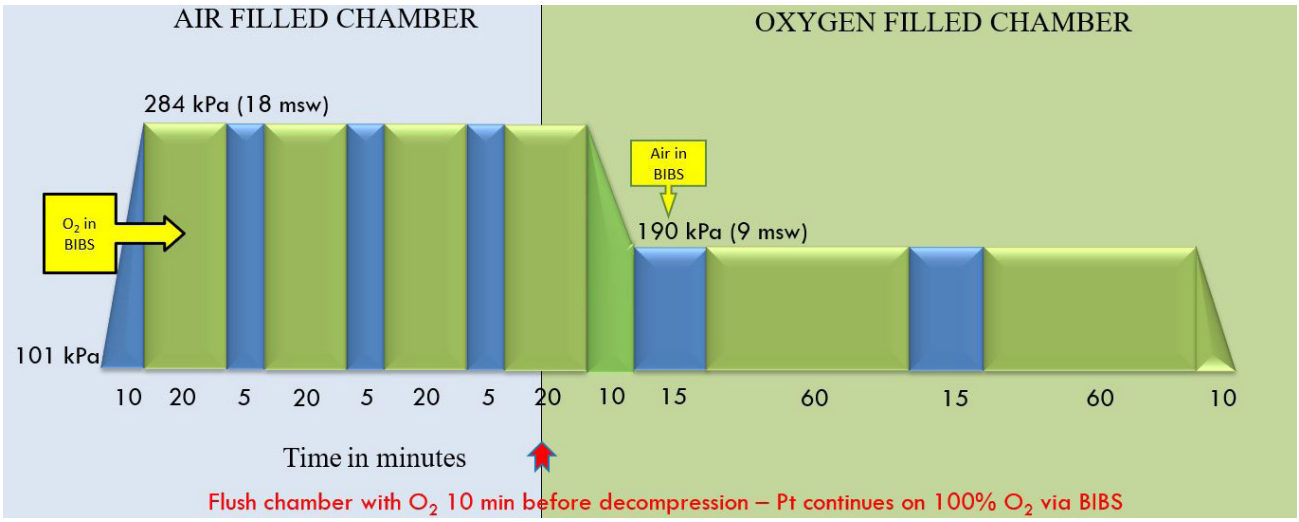
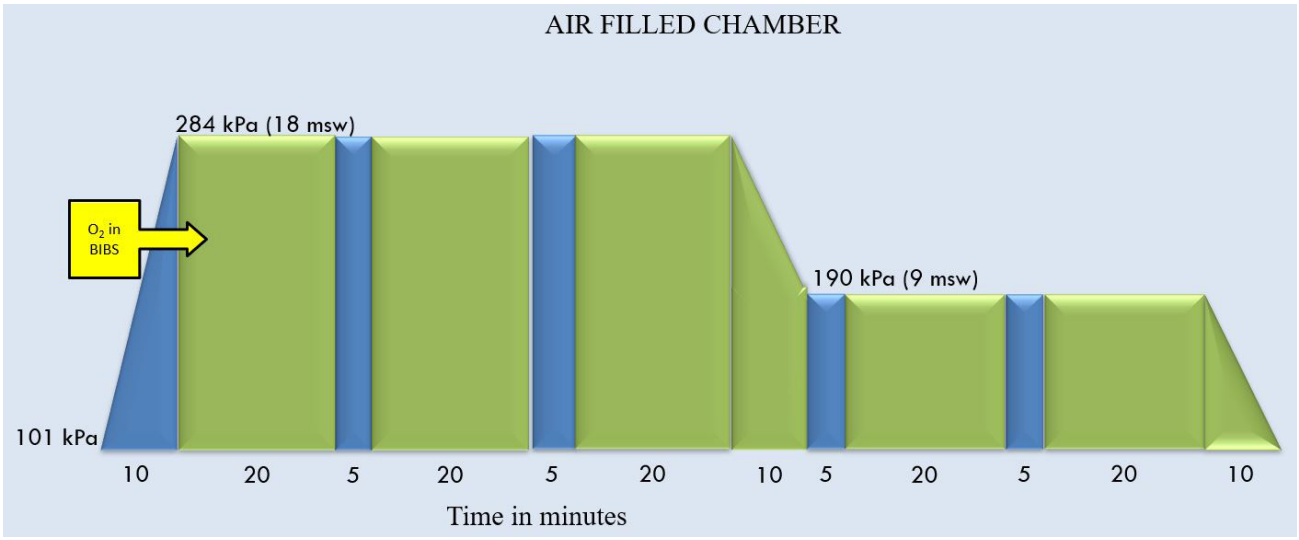


Figure 2

Fremantle Hospital Hyperbaric Medicine Unit USN TT5 (modified) for monoplace chamber application; pressures are absolute pressures. The total time is 2 hours 30 minutes (150 minutes); compression rate 18 kPa·min^{-1}, decompression rate 9 kPa·min^{-1}; BIBS – built in breathing system; kPa – kilopascals; msw – metres of seawater; O_2 – oxygen



and our 200 kPa (2 atmospheres absolute [atm abs]) no air break table (Figure 4). The decompression of FH01 from 284 kPa to 200 kPa and 200 kPa to 101 kPa is likewise over 10 minutes.

There is a recognised spectrum of DCS, ranging from mild non-specific symptoms to severe neurological or cardiopulmonary symptoms.[5] Our study focused on divers who presented at the milder end of the range (see *Appendix 1, Groups 3–6).[5] We included all divers where the presumptive diagnosis was DCS Grades 3–6. It is acknowledged that the natural history of mild DCS is toward spontaneous symptom resolution, and therefore, many such cases can be adequately treated without recompression.[6,7] However, there is also a consensus that symptom resolution is accelerated by recompression, and modern practice guidelines advocate recompression in mild cases if recompression is available without substantial logistic constraints.[7,8] It follows that the optimal approach to recompression in these patients remains a valid and

Footnote: * Appendix 1 is available on DHM Journal's website: https://www.dhmjournal.com/index.php/journals?id=295

Figure 3

Fremantle Hospital Hyperbaric Medicine Unit FH01 for monoplace chamber application; pressures are absolute pressures. The total time is 2 hours 40 minutes (160 minutes); compression rate 18 kPa·min^{-1}; decompression rate 8.4 kPa·min^{-1} from 284 to 200 kPa and 10 kPa·min^{-1} from 200 kPa to 'surface pressure'. BIBS – built in breathing system; kPa – kilopascals; min – minutes; msw – metres of seawater; O_2 – oxygen; Pt – patient

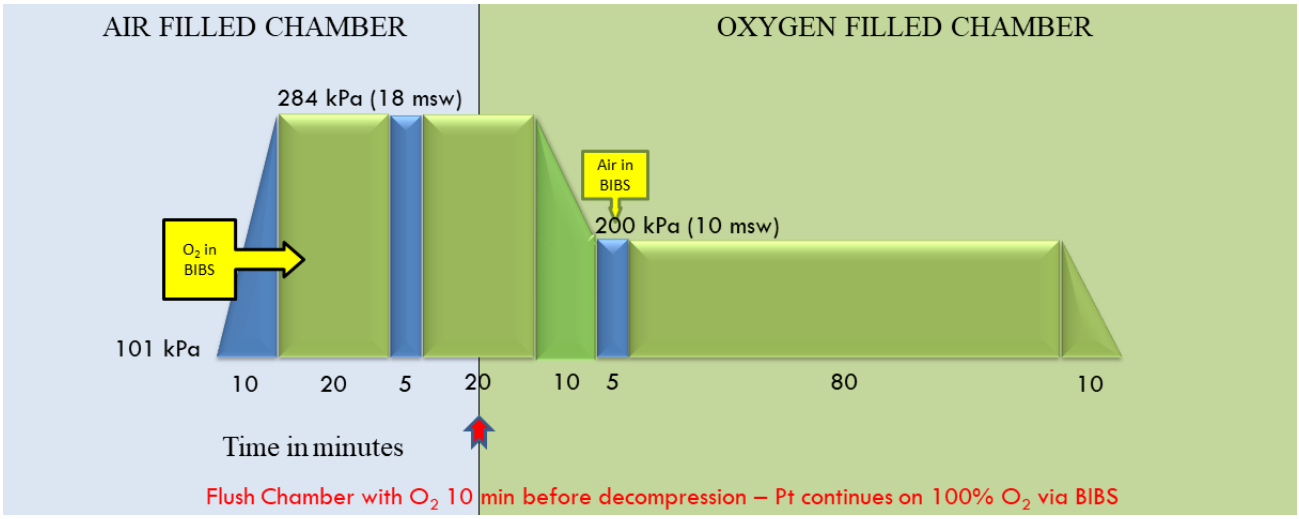
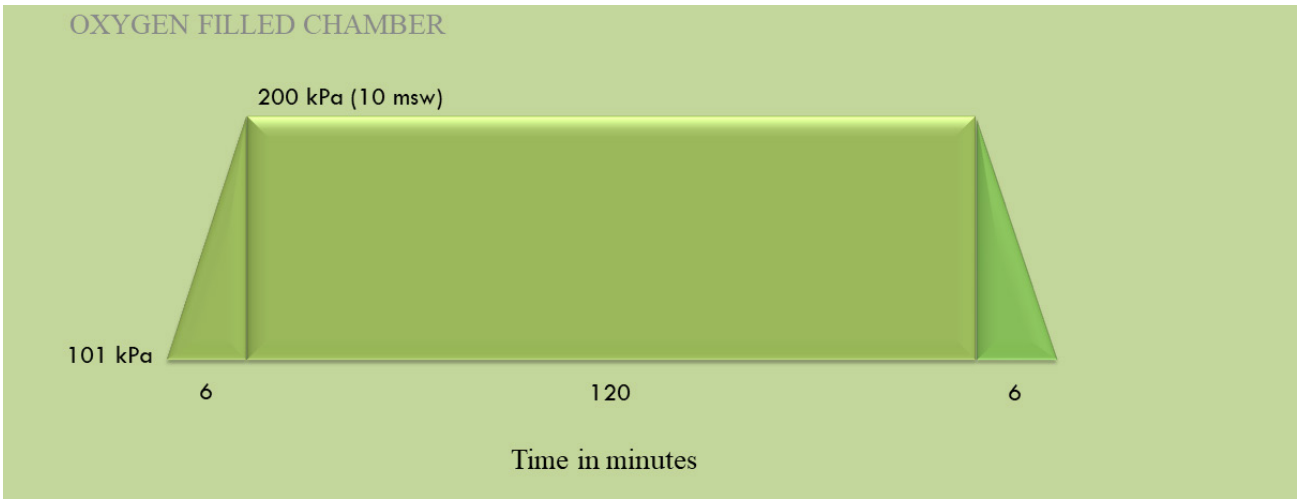


Figure 4

Fremantle Hospital Hyperbaric Medicine Unit Table 10:120:06 for monoplace chamber application; pressures are absolute pressures. The total time is 2 hours 12 minutes (132 minutes); compression rate 16.5 kPa min^{-1}; decompression rate 16.5 kPa/min^{-1}; kPa – kilopascals; msw – metres of seawater



open question. This study aimed to determine if divers with mild DCS could be effectively treated with a shorter initial chamber treatment table.

Methods

Ethical approval for this study was granted by the South Metropolitan Area Health Service Human Research Ethics Committee (HREC 10/477).

All patients presenting to the Fremantle Hospital Hyperbaric Medicine Unit with DCS were assessed to establish whether they met the criteria to be included in the trial. The primary outcome was the number of treatments required until resolution or plateau in recovery, with the secondary outcome being resolution of all symptoms after the initial recompression.

INCLUSION CRITERIA

Patients were included if they were 18 years or older, gave informed consent, and had one or more of the following manifestations: mild neurological symptoms, pain, lymphatic/skin, and constitutional/non-specific symptoms.

Pain was defined as musculoskeletal pain and specifically excluded girdle-type pain, a harbinger of spinal DCS. Further information of these manifestations is listed in *Appendix 1 (Groups 3–6 of the Divers Alert Network classification system). The one departure from this classification system was that patients with true vertigo were not included as this is not considered a mild symptom in contemporary practice.[6,7] Patients were excluded if they had serious neurological (including inner ear) or cardiopulmonary DCS, or any manifestation not in the inclusion criteria. The assessing physician decided on the diagnosis of 'mild DCS' based on the Appendix 1 table and was blinded to the treatment arm participants were then assigned to.

Participants were randomly allocated to receive recompression via either TT6m (Figure 1) or FH01 (Figure 3), in a Sechrist 3200 or 3600 monoplace chamber (Sechrist Industries Inc, Anaheim CA). The randomisation process was via a sealed opaque envelope system selected by the duty hyperbaric technician, with computer generated allocation. Participants were not informed into which arm of the trial they were assigned. Inspection of the TT6m and FH01 (Figures 1 and 3) tables used in this study show that they have identical profiles up to the end of the second O_2 period. At this point the assessing doctor, who was blinded to treatment table allocation, would make a decision as to whether the diver's symptoms had resolved sufficiently to allow completion of the table as allocated (> 75% symptom resolution), or to change the table and as such, define these participants as 'treatment failures' to allow an extended time of initial recompression treatment as a safety mechanism. For FH01 subjects this meant conversion to TT6m and for those already in TT6m arm, one or two extensions with further 20-minute O_2 breathing periods at 284 kPa.

ADJUNCTIVE THERAPY

All patients could receive normobaric oxygen whilst awaiting hyperbaric therapy where appropriate. One litre of fluid was advised to be given to all trial patients prior to recompression, either orally or as intravenous normal saline. The need for further oral or intravenous fluid and analgesia was decided by the referrer or by the assessing doctor according to clinical need. Analysis of the type and amount of adjunctive therapy was not performed.

INITIAL TREATMENT TABLE

Patients received either a TT6m or the shorter FH01 in a monoplace chamber. In this study the effect of initial treatment table (the independent variable of interest) upon both initial and eventual symptom resolution (complete or not) is reported.

FOLLOW-UP TREATMENT TABLE

All patients received a follow-up hyperbaric treatment unless they had become asymptomatic prior to the commencement of their initial recompression, (n = 1 in the TT6m arm), or did not re-attend, (n = 1 in the FH01 arm), as per our usual practice of treating to resolution of symptoms plus one. The decision as to whether a further treatment was required was made on further assessment immediately prior to commencing the next treatment. Follow-up treatments did not differ by the initial treatment arm. The protocol was that the patient would routinely receive a daily FH 200:120:06 table (120 minutes at 200 kPa [2.0 atm abs] with no air break, Figure 4) unless they had significant ongoing or recurrent symptoms where the treating clinician could opt for a TT5m (Figure 2). If there was no monoplace availability for a timely follow-up treatment, a participant could be given a 243 kPa (2.4 atm abs) treatment in the multiplace chamber (two 45-minute O_2 breathing periods separated by a 5-minute air break with a 24-minute decompression). Patients were treated to resolution of all symptoms plus one treatment or plateau (no change in symptoms after three treatments).

FOLLOW UP POST DISCHARGE

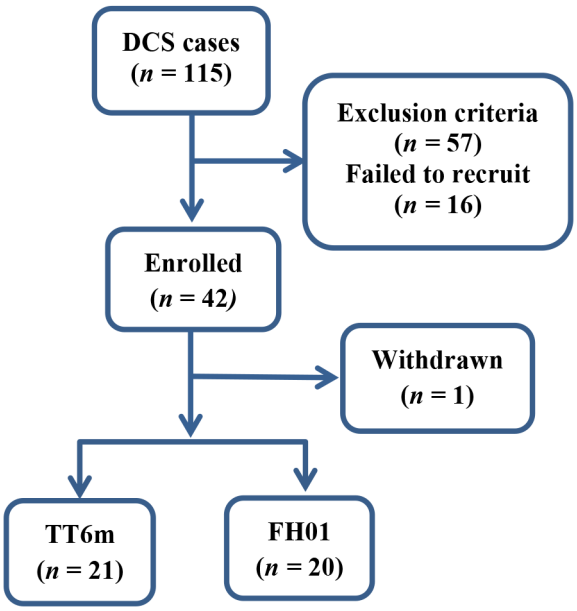
All patients were attempted to be contacted by telephone two weeks following their final treatment to assess their progress and presence of any residual or recurrent symptoms.

ANALYSIS

Data were stored in Microsoft Excel then imported in SAS (Cary, NC) version 9.4 for analysis. The initial power calculations were based upon a two-sided t-test, where the null hypothesis was that there would be no difference detected between protocols in the mean number of treatments before symptoms resolved or there was no further improvement (plateau). Asymptomatic 'plus one' treatments were not counted in this number. An initial sample size of 20 in each arm was decided as being achievable for recruitment into a study, based on the number of cases of DCS treated annually (approximately 30 per year). A sample of 20 patients in each arm would have a power of 87% to detect a mean difference of one treatment between arms. With the exception of reporting aggregated data for resolved cases, all values reported herein relate to the intention to treat (ITT) analysis. Any participants defined as failures to respond to two oxygen breathing periods at 284 kPa were included in the ITT.

Because the expected number of recompression treatments required was small, we anticipated the results would not be normally distributed, and planned an analysis to explore the differences between the median total number of treatments required in each group using a two-sided Wilcoxon rank-sum test (WRS). A Fisher's exact test was calculated when

Figure 5
Modified CONSORT flow diagram; FH01 – Fremantle Hospital Treatment Table 01; TT6m – United States Navy Treatment Table 6 (modified)



comparing the number of patients resolved after their initial treatment between treatment tables. Significance was accepted when $P < 0.05$.

Results

A total of 115 patients with suspected DCS presented during the study period (17 October 2010 to 5 July 2014). Of these, 41 patients diagnosed with mild DCS were included in the study, 21 allocated to TT6m and 20 to FH01 (Figure 5). There was no difference between allocation groups in patient age or sex. Two patients allocated to the FH01 arm showed < 75% symptom resolution at the end of the second 20-minute O_2 breathing period at 284 kPa (2.8 atm abs), and their treatment table was continued as a TT6m (though not added to the TT6m arm for analysis). Likewise, two TT6m patients required a single 20-minute O_2 breathing extension. Neither of the two participants that crossed to the TT6m arm required extensions to their TT6m.

One patient was treated on two occasions, just over two years apart, and was considered in the analysis as two separate cases. Thirty-seven cases (90%) were male, mean age (years) was 35.3 (SD 6.7) for females and 36.5 (SD 9.2) for males, 36.9 (SD 10.5) for FH01 and 35.8 (SD 7.5) for TT6m. The distribution of symptoms by treatment table is presented in Table 1. There were two subjects in each group that had a lengthy delay to recompression, both of whom had been diving overseas.

The median total number of treatments to achieve symptom resolution was one (IQR 1–1) for FH01 (range 1–3) and two (IQR 1–2) for TT6m (range 0–5), (WRS $Z = -2.67$, $P = 0.01$). Of the patients receiving FH01 initially, 17/20 (85%) showed complete symptom resolution after the initial treatment, versus 8/21 (38%) for TT6m ($P = 0.003$). At the completion of their final treatment, both FH01 and TT6m had similar overall outcomes, with 19/20 and 20/21 respectively asymptomatic ($P = 0.97$). Of the 'treatment failure' patients, one of those in the TT6m arm that required an extension had resolution of symptoms at the end of their initial extended TT6m, the other had full resolution after a single follow-up treatment. For the FH01 participants changed to TT6m, neither had complete resolution after their initial treatment but both were fully resolved after a single follow-up treatment.

Table 1
Distribution of symptom severity[5] by treatment table; [a] – denotes that more than one symptom group may be present; FH01 – Fremantle Hospital Treatment Table 01; TT6m – United States Navy Treatment Table 6 (modified)

Symptoms	TT6m *n* (%)[a]	FH01 *n* (%)[a]	Total *n* (%)[a]
Mild neurology	6 (29)	7 (35)	13 (32)
Pain	16 (76)	16 (80)	32 (78)
Lymphatic/skin	2 (10)	2 (10)	4 (10)
Constitutional/ non-specific	8 (38)	4 (20)	12 (29)

In one of the cases in the TT6m arm, symptoms persisted after two recompression treatments (TT6m then one 200:120:06 table) but further treatment was declined. This patient was nevertheless assigned two as the number of treatments for the primary outcome. One FH01 participant had resolution of symptoms after the first treatment but failed to return for a follow-up treatment. The participant remained asymptomatic at follow-up telephone contact. This patient was accordingly assigned 'one' as the number of treatments for the primary outcome. For the two patients who did not achieve resolution (one in each group), both had three treatments at plateau.

All subjects received the FH 200:120:06 table (Figure 4) as follow-up treatment, except for three receiving TT5m (nil in the FH01 and three in the TT6m groups respectively) and two receiving a 243 kPa multiplace treatment (one in the FH01 and one in the TT6m groups respectively). No distinction was made between different follow-up treatment tables in our analysis.

Of the 20 FH01 patients, 14 (70%) could be contacted at two weeks after their final treatment. All 14 had full resolution after their final treatment and remained asymptomatic at two weeks. Similarly, for the 21 TT6m patients, 12 (57%) could be contacted at two weeks after their final treatment, and all

had full resolution after their final treatment and remained asymptomatic at two weeks.

Discussion

This study found that the median total number of treatments to achieve resolution of symptoms was significantly fewer in the FH01 arm than in the TT6m arm, and that treatment table FH01 more frequently had complete symptom resolution after the initial treatment than TT6m. However, there was no difference in the number of patients achieving resolution at the completion of treatment.

There has previously only been one randomised controlled trial on the treatment of DCS completed: a trial of a non-steroidal anti-inflammatory drug as adjunctive therapy to recompression.[9,10] Another randomised controlled trial comparing oxygen and oxygen-helium in the treatment of air-diving decompression illness was reported as underway, but final results have never been published.[11,12] The present study is only the second completed randomised controlled trial published on the treatment of DCS, and the first to compare the outcomes of short and long oxygen recompression tables. Although there have not been other randomised trials, several studies have suggested the efficacy of short treatment tables. One compared enhanced treatment tables with a variety of regular treatment tables in a non-randomised multicentre study of 327 treated scuba divers.[13] A logistic regression analysis confirmed the shorter regular treatment tables had greater successful resolution of symptoms than the enhanced tables (63% vs. 48% respectively), though the authors highlighted a potential selection bias in the study design.[13] Another study reviewed the development of these short oxygen tables and their published outcomes as well as experience with using a short no-air-break table, and reported a 98% full recovery rate.[14] On the basis of the results of these retrospective reviews it was concluded that "…*this short oxygen protocol has proven highly effective for the type of patients presenting to our hospital, a major Divers Alert Network referral center, for decompression sickness*."[14]

A retrospective review of 292 cases of Type I DCS treated with either TT5 (208 cases) or TT6 (84 cases) showed similar (4.3% versus 3.6% $P > 0.10$) rates of symptom recurrence.[3]

A possible reason for the increased efficacy of the shorter table (FH01) could be that treated divers were exposed to much less exogenous nitrogen (10 minutes versus 45 minutes) during their initial recompression, owing to the differing length of air breaks in the respective treatment tables (Figures 1 and 3). It is conceivable that nitrogen in air breathed during air breaks may diffuse into residual bubbles and expand them. The fact that FH01 table is completed at 200 kPa rather than 190 kPa in the TT6m seems less likely to be a significant contributor to the outcome difference.

One case that was withdrawn and excluded from analysis was a 37-year-old man who presented with symptoms of musculoskeletal DCS, subsequent investigation of which determined the event to be factitious. Munchausen's Syndrome presenting with DCS symptoms has been previously described.[15–17]

Regarding the ITT analysis, the two patients who discontinued FH01 were thereafter treated with TT6m, but were not added to the TT6m arm. To have counted patients who were not responding to FH01 within the TT6m arm would have introduced a directional bias. Furthermore, the two patients who were discontinued from the TT6m were treated for the remainder of their initial treatment differently (an extra 20-minute O_2 period at 284 kPa / 2.8 atm abs) to the two patients moved from the FH01 arm (TT6m). Following their initial treatment however, follow-up treatments were equivalent for all four patients.

LIMITATIONS

This was a small study prone to both Type 1 and Type 2 errors. Nevertheless, based on the present results, at the least it seems very unlikely that choosing the shorter FH01 table to treat mild DCS would constitute an inferior approach when compared to a TT6.

Another limitation was that many patients could not be contacted for post treatment follow-up, therefore it is not known with certainty if the comparable outcomes between FH01 treatment and TT6m were lasting. Another limitation may have been a form of selection bias, with just 41 of 115 (36%) potentially eligible patients recruited, although, as indicated in Figure 5, 57 patients (50%) did not satisfy the eligibility criteria, plus allocation to the treatment arms was randomised.

Conclusion

We conclude that FH01 appears superior to TT6m for the treatment of mild DCS. Although the ultimate rate of recovery was not different, which is probably to be expected in mild DCS where the natural history is toward eventual recovery irrespective of treatment modality, divers treated with the shorter oxygen table required fewer recompression treatments and were more likely to be symptom-free after the first recompression.

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