Quality of reporting in hyperbaric medicine clinical trials: a cross-sectional study

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Abstract
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Introduction: Research in hyperbaric oxygen (HBO) medicine is growing, but the quality of HBO studies is variable. Low study quality may compromise evidence-based decision-making and clinical translation.
Methods: This cross-sectional study examined the adherence of 50 randomly selected HBO clinical trials (25 randomised controlled trials [RCTs] and 25 observational studies) to relevant core reporting guidelines: consolidated standards of reporting trials (CONSORT), non-pharmacologic treatments (NPT), and strengthening the reporting of observational studies in epidemiology (STROBE). Studies published in peer-reviewed journals between January 2018 and May 2023 and indexed on PubMed were analysed. Reporting quality was classified as 'excellent' (> 85% of guideline items adequately reported), 'good' (50–85%), or 'poor' (< 50%).
Results: The sample represented 29% of RCTs and 16% of observational studies for the timeframe assessed. No study was rated as 'excellent' for completeness, 28 (56%) were rated as 'good', and 22 (44%) as 'poor'. In RCTs, only one study (4%) adequately reported protocol adherence and eight studies (32%) reported blinding procedures. The NPT checklist showed that key items, including care provider adherence (0 studies) and participant adherence (one study; 4%), were frequently not reported. For observational studies, basic design elements were adequately reported, but with significant gaps in bias management (nine studies; 36%) and missing data handling (13 studies; 52%). Only six studies (12%) mentioned the use of reporting guidelines.
Conclusions: Our results showed that quality of reporting of HBO studies is suboptimal. These findings highlight the need for increased awareness and implementation of reporting guidelines, as well as the potential development of HBO-specific guidelines.

Introduction

Clinical decision-making and public health policy should rely on scientific evidence.[1] Randomised controlled trials (RCTs) are considered to be the most robust study design to inform clinical decisions, but other designs such as cohort, case-control, or cross-sectional also provide evidence.[2] Even when well-designed clinical trials are conducted, evidence can only be translated into practice when reporting of study methods and results is appropriate.[3] Unfortunately, poor reporting is common across many fields.[3–6] Poor quality reporting can lead to bias and research waste, and can impair critical appraisal and appropriate replication of studies, compromise future evidence, and ultimately decrease the value and impact of research.[7]

Since the mid-2000s, an international initiative - the enhancing the quality and transparency of health research (EQUATOR) network – has worked to improve the reporting of healthcare research and aid in research optimisation.[8] More than 550 reporting guidelines have been developed to guide authors, editors, and peer-reviewers to improve reporting quality.[9] Some of the guidelines are dedicated to specific study types, such as consolidated standards of reporting trials (CONSORT) for RCTs,[10] preferred reporting items for systematic reviews and meta-analyses (PRISMA)

for systematic reviews,[11] and strengthening the reporting of observational studies in epidemiology (STROBE) for observational studies.[12] Others are specific to a clinical area with specialised considerations, such as surgery,[13] interventional radiology,[14] or medical education.[12,15] Recent evidence demonstrates that reporting guidelines associated with adoption from journals may improve the reporting quality.[16,17]

Hyperbaric oxygen therapy (HBO) has been used for a number of elective and urgent indications for decades, and there has been a growing number of publications in the field.[18] HBO is a complex intervention with special considerations to report, such as pressure levels, session durations, frequencies, types of healthcare professionals in charge, and equipment type (e.g., monoplace or multiplace chambers, masks or head tents). Poor reporting of clinical HBO trials has been a point of concern in a number of previous systematic reviews.[19–22] However, most of the included studies of those systematic reviews considered older trials, some published before the development and implementation of current best practice reporting guidelines. There is a need to analyse the quality of reporting in recent HBO trials. In addition, no reporting guidelines specific to hyperbaric medicine have been incorporated as part of the EQUATOR Network. Given the evidence of poor reporting across healthcare disciplines, the implications for patient care, and the existence of solutions to improve reporting, we elected to explore the comtemporary quality of reporting in hyperbaric medicine trials.

Methods

This study was reported in accordance with the STROBE guidelines for cross-sectional studies.

Ethics review was unnecessary given that our study only involved publicly available data. We addressed the following research question: '*How do hyperbaric medicine clinical studies published in peer-reviewed journals currently adhere to core reporting standards*?' Our primary outcome was completeness of reporting as assessed by the core set of reporting standards suggested by the EQUATOR Network, i.e., CONSORT and non-pharmacologic treatments (NPT) or STROBE checklists, as appropriate. We did not assign weights to perceived deficiencies.

We included a sample of clinical trials in which HBO was the primary intervention investigated. Inclusion and exclusion criteria are summarised in Table 1. We elected to search references after 2018 because we were interested in recent adherence to reporting guidelines relevant to the field of HBO published in 2017.[23]

The search strategy was designed by the research team with the help from an information specialist (VL). We chose to focus only on PubMed since it is free and readily accessible to most clinicians and researchers around the world, which means that the quality of reporting of these studies is most prone to impact practice. The search strategy was peer-reviewed by a second information specialist using the peer review of electronic search strategies (PRESS) tool.[24] We conducted the search on 19 May 2023. We used observational wording adapted from the SIGN Observational Studies filter[25] and the RCT wording adapted from Cochrane search strategies for identifying randomised trials in PubMed: sensitivity- and precision-maximising version.[26] For logistical reasons and ease, we chose to conduct two separate searches, one for RCT and another for observational studies, and then import all references into a single distiller project for screening.

For RCT: ((((“*hyperbaric oxygenation*”[MeSH Terms] OR (“*hyperbaric**”[Title/Abstract] OR “*hyper baric**”[Title/Abstract])) AND (“*randomized controlled trial*”[Publication Type] OR “*controlled clinical trial*”[Publication Type] OR “*clinical trials as topic*”[MeSH Terms:noexp] OR (“*Randomized*”[Title/Abstract] OR “*randomised*”[Title/Abstract] OR “*randomly*”[Title/Abstract] OR “*placebo*”[Title/Abstract] OR “*Trial*”[Title]))) NOT

Table 1
Inclusion and exclusion criteria; HBO – hyperbaric oxygen treatment; RCT – randomised controlled trial

Parameter	Inclusion	Exclusion
Population	Human	Animal, cell, healthy volunteer, simulated human
Intervention	HBO as the main variable investigated	HBO as part of the intervention but not the main variable tested
Design	Original research: RCTs, observational studies (cohort, case-control studies, cross-sectional studies)	Editorials, commentary, letters to the editor, reviews, conference abstracts, preclinical studies, and pre-print publications
Recency of publication	Appearing in print or final form e-publications from 1 Jan 2018 through 19 May 2023	Publications appearing before 1 Jan 2018 or after 19 May 2023
Language	English	Non-English

("*animals*"[MeSH Terms] NOT "*humans*"[MeSH Terms])) AND 2018/01/01:3000/12/12[Date – Publication]) AND (english[Filter])

For observational studies: (((("*hyperbaric oxygenation*"[MeSH Terms] OR "*hyperbaric**"[Title/Abstract] OR "*hyper baric**"[Title/Abstract]) AND ("*cohort studies*"[MeSH Terms] OR "*cross sectional studies*"[MeSH Terms] OR "*case control studies*"[MeSH Terms] OR "*epidemiologic studies*"[MeSH Terms:noexp] OR "*case control*"[Title/Abstract] OR "*cohort study*"[Title/Abstract] OR "*cohort studies*"[Title/Abstract] OR "*cohort analy**"[Title/Abstract] OR "*follow up study*"[Title/Abstract] OR "*follow up studies*"[Title/Abstract] OR "*observational study*"[Title/Abstract] OR "*observational studies*"[Title/Abstract] OR "*longitudinal*"[Title/Abstract] OR "*retrospective*"[Title/Abstract] OR "*cross sectional*"[Title/Abstract])) NOT ("*animals*"[MeSH Terms] NOT "*humans*"[MeSH Terms])) AND ((2018/1/1:3000/12/12[pdat]) AND (english[Filter])

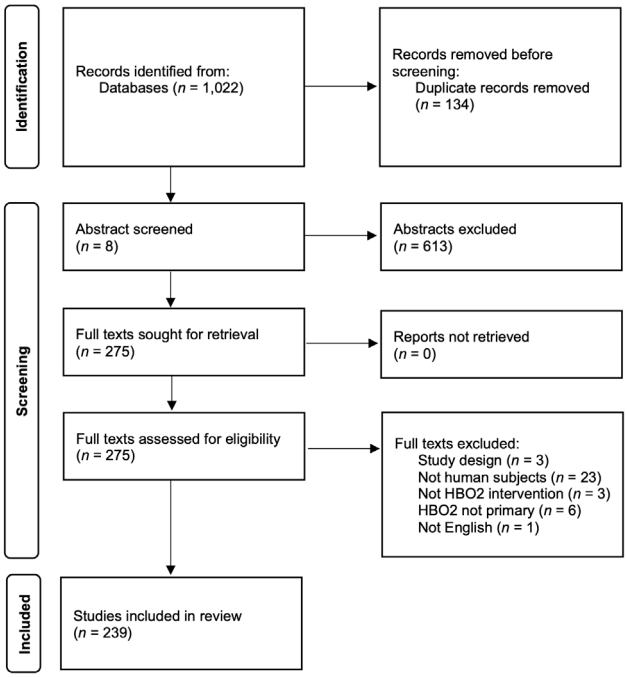
Identified articles were uploaded to DistillerSR (Evidence Partners, Ottawa, Canada), and eligible studies were identified after a two-step screening process, completed in duplicate by independent reviewers. Disagreements were resolved by consensus, or a third party as needed. To ensure feasibility, we elected to analyse a random sample of relevant studies, 25 RCTs (CONSORT) and 25 observational studies (i.e., cohort, case-control studies, or cross-sectional) (STROBE). The number was chosen as a convenient and manageable sample that was expected to capture a range of clinical indications, countries, and journals. We proceeded to the random selection of the sample from the eligible references identified after the two-step screening process described above. We exported the list of eligible studies from Distiller to Microsoft Excel (version 16.36, Microsoft Corporation, Redmond, Washington, USA) and then associated a random number (using the function "= *RAND()*") to each. The records were sorted by ascending random numbers and the first 25 for each included design (i.e., RCT or observational) were selected.

Data extraction of the sample set was conducted in duplicate by a pair of independent reviewers. Any disagreements between the two reviewers were resolved by discussion and with a third reviewer as necessary. We developed a coding manual to calibrate agreement between reviewers. To optimise quality, we initially pilot-tested the data extraction form and the coding manual on a set of articles. This pilot enabled refinement of the data extraction form and coding manual to enhance inter-assessor consistency and reliability. Subsequently, the reviewers independently performed the remaining data extraction in duplicate.

Data to be collected included: publication details (e.g., first author, year, country of data collection, journal), study design, and use of reporting guidelines. Each item

Figure 1

Study selection process chart;[11] this diagram outlines the steps taken to identify, screen, and select studies for this review on HBO



of CONSORT and NPT or STROBE checklists was rated as 'adequately reported,' 'incompletely reported,' 'not reported,' or 'not applicable,' with descriptions provided by reviewers when 'incompletely reported.' We identified high-income countries (defined by the World Bank as a country with high gross national income per capita) as part of the data extraction.

Completeness and transparency of reporting in HBO for RCTs and observational studies were measured with the CONSORT, NPT, or STROBE guidelines. We calculated for each study the completeness of reporting according to the following: 'excellent' (> 85% of items rated as 'adequately reported'), 'good' (50–85% of items rated as 'adequately reported'), and 'poor' (< 50% rated as 'adequately reported'). This approach aligned with previous research that assessed the reporting quality of randomised controlled trials of massage using a similar descriptive categorisation method.[27] We also categorised and reported the frequency and nature of descriptions for items rated 'incompletely reported' or 'not reported'. Results were descriptively summarised using Excel (version 16.36, Microsoft Corporation, Redmond Washington, USA).

Results

The literature search yielded 1,022 reports from which 134 duplicates were removed. After assessment for eligibility, 239 references met our eligibility criteria for inclusion

(Figure 1). The selected sample of 50 papers[28–77] represented 29% of the RCTs and 16% of the observational studies published in the five-year timeframe assessed.

Tables 2 and 3 present the characteristics of the 50 studies, including 25 RCTs and 25 observational studies, with 27 studies (54%) from high-income countries. The studies covered a wide range of clinical indications, with sudden sensorineural hearing loss being the most frequently investigated condition. The studies were grouped by study design, with RCTs listed first, followed by observational studies. Within each study design category, studies were further ordered alphabetically by the last name of the first author, and then by year of publication for studies with the same first author. Among the 25 RCTs, only three studies explicitly mentioned using CONSORT, one study reported using another guideline, and 21 studies did not mention any structured reporting guideline. Similarly, in the 25 observational studies, one study reported using STROBE, and one study used a different guideline. There was no clear relationship between NPT adherence and the year of publication, indicating that even recent studies did not consistently follow NPT guidelines.

Overall, we found that reporting of clinical studies in HBO was suboptimal. Reporting guidelines were mentioned only in 14% of the analysed studies. None of the sampled studies correctly reported all the items recommended.

For the 50 studies assessed across all reporting items (CONSORT, NPT, or STROBE), none were rated as 'excellent', 28 (56%) were rated as 'good', and 22 (44%) were rated as 'poor'. Among the assessed studies, the completeness of reporting ranged from 35% (i.e., only 35% of the required items were adequately reported) to 82%.

Tables 4 and 5 present an aggregated view of reporting quality, showing the number and percentage of studies that adequately, incompletely, not applicable, or did not report specific checklist items across all assessed randomised controlled trials and observational studies, respectively.

Figures 2 and 3 illustrate the completeness of reporting for each individual study by showing the percentage of items adequately, incompletely, not applicable, or not reported for every single randomised controlled trial and observational study in the sample.

When analysed with CONSORT, 15 RCT studies (60%) were rated as 'good' and 10 studies (40%) as 'poor'. For each study assessed, completeness ranged from 32% to 84%. The basic study elements like structured abstracts (24 studies; 96%), scientific background (23 studies; 92%) and objectives were generally complete, but key methodological details were often incomplete or missing. For example, only one study (4%) reported changes after trial commencement. Blinding information was poorly reported, with only eight studies (32%) adequately describing who was blinded and how. Interim analyses and protocol changes were documented in two studies (8%) and one study (4%), respectively.

When analysed with NPT, the completeness of reporting of RCTs was mostly poor. For each study assessed, completeness ranged from 11% to 33%. The most adequately reported item was detailed intervention descriptions (item 5a NPT, 5b NPT, 5c NPT), but other important NPT items were often missing. Care provider adherence to protocols was not reported in any studies (0%), and participant adherence was reported in one study (4%). Additionally, clustering by care providers (Items 7a NPT and 12a NPT) and care provider descriptions (Item 15 NPT) were often marked as 'not applicable'.

No observational study were rated as 'excellent' (> 85%). Most studies were rated as 'good' (19 studies; 76%), with 6 (24%) rated as 'poor'. Completeness ranged from 41% to 82% depending on the considered item. Similar to patterns observed with CONSORT and NPT items, basic study descriptions were generally adequately reported, while methodological details were often missing. The most adequately reported items were objectives, study design, and item data sources/measurement (items 3, 4, and 8), each with 100% completeness. Critical gaps were identified in bias management (Item 9; nine studies, 36%) and confounding control (Item 12a; 12 studies, 48%). Sensitivity analyses (Item 12e) were rarely addressed, with only one study (4%) reporting them. Key variables and confounders (Item 7) were defined in five studies (20%), and flow diagrams (Item 13c) were used in seven studies (28%).

Discussion

Based on the relevant reporting guidelines (CONSORT, NPT, or STROBE), our study indicates an overall moderate quality of reporting in both RCTs and observational studies investigating HBO. In addition, we identified significant variability in reporting quality across studies assessed from both types. No study reached 'excellent' reporting completeness, just over half fell within the 'good' category, and almost half were rated as 'poor'.

Reporting the income level of countries where patients are recruited was included with the intention to help assess generalisability, equity, and applicability of research findings across different health system contexts. Its relevance is in demonstrating that suboptimal reporting is a widespread issue in the field, even in studies from well-resourced countries where research and publication support is generally more available.

Table 2
Characteristics of included randomised controlled trials

Reference Year	Country of data collection	Clinical indication
28 – 2023	Israel	Fibromyalgia in patients with a history of traumatic brain injury
29 – 2020	Mexico	ST-elevation myocardial infarction
30 – 2022	Israel	COVID19
31 – 2022	Italy	Sudden sensorineural hearing loss
32 – 2022	China	Dog bites
33 – 2019	United States	Persistent post-concussive symptoms
34 – 2022	Greece	Idiopathic sudden sensorineural hearing loss
35 – 2019	Argentina	Type 2 diabetes mellitus
36 – 2022	China	Sudden sensorineural hearing loss
37 – 2022	Israel	Persistent post-concussion syndrome in children following traumatic brain injury
38 – 2023	Sweden	Post-COVID condition
39 – 2021	United States	Central airway stenosis after lung transplantation
40 – 2018	China	Slow coronary flow in patients diagnosed with coronary artery angiography
41 – 2019	China	Traumatic brain injury
42 – 2019	United States	Mild traumatic brain injury
43 – 2021	China	Depression
44 – 2019	Malaysia	Adjunctive treatment for non-healing diabetic foot ulcers
45 – 2019	Sweden, Norway, Denmark, Finland	Late radiation cystitis
46 – 2018	Australia	Chronic venous leg ulcers
47 – 2020	China	Idiopathic sudden sensorineural hearing loss
48 – 2020	Australia	Insulin sensitivity in men with type 2 diabetes mellitus
49 – 2022	China	Cerebral nerve function in comprehensive treatment of poststroke depression
50 – 2018	China	Epithelial-to-mesenchymal transition phenomenon in keloid tissue
51 – 2021	China	Advanced esophageal cancer using a combination of a 125I particle-integrated esophageal covered stent and hyperbaric oxygen
52 – 2022	Israel	Post-COVID condition

Table 3
Characteristics of included observational studies

Reference Year	Country of data collection	Clinical indication
53 – 2021	South Korea	Idiopathic sudden sensorineural hearing loss
54 – 2023	Croatia	Sudden sensorineural hearing loss
55 – 2022	Turkey	Carbon monoxide poisoning
56 – 2021	France	Ventilator-acquired pneumonia
57 – 2018	Taiwan	Endothelial progenitor cells with acute non-cardioembolic stroke
58 – 2018	United States	Sternal wound infections
59 – 2022	Turkey	Retina and choroid tissue
60 – 2018	Turkey	Diabetic foot ulcer
61 – 2019	Israel	Pulmonary oxygen toxicity
62 – 2020	United States	Chronic wounds
63 – 2019	Turkey	Central macular thickness, central choroidal thickness and the stage of retinopathy in patients with type 2 diabetes mellitus
64 – 2020	Turkey	Idiopathic sudden sensorineural hearing loss
65 – 2020	South Korea	Composite grafting for amputated fingertip injury
66 – 2021	South Korea	24-hour post-carbon monoxide poisoning
67 – 2021	Switzerland, France	Frostbite stage 3, 4
68 – 2021	Qatar	Avascular necrosis
69 – 2019	Japan	Carbon monoxide poisoning
70 – 2018	Italy	Autism
71 – 2020	Italy, Bosnia, Herzegovina, Spain, and Bulgaria	Aseptic tibial nonunion
72 – 2018	Turkey	Erectile dysfunction
73 – 2018	Australia and New Zealand	Central nervous system oxygen toxicity
74 – 2018	China	Sudden sensorineural hearing loss
75 – 2020	Japan	Idiopathic sudden sensorineural hearing loss
76 – 2021	Canada	Left ventricular ejection fraction
77 – 2018	Taiwan	Tuberculosis reactivation

Table 4

Completeness of reporting for RCTs investigating HBO based on CONSORT and non-pharmacologic treatments (NPT); items followed by 'NPT' indicate an extension of the CONSORT guidelines specific to non-pharmacologic treatments; AR – item adequately reported; IR – item incompletely reported; NR – item not reported; NA – item not applicable

Section/Topic	**Item number and description**	**AR** ***n*** **(%)**	**IR** ***n*** **(%)**	**NR** ***n*** **(%)**	**NA** ***n*** **(%)**
Title and abstract	1a. Identification as a randomised trial in the title	11 (44%)	0 (0%)	14 (56%)	0 (0%)
	1b. Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	24 (96%)	1 (4%)	0 (0%)	0 (0%)
	1b NPT. When applicable, report eligibility criteria for centers where the intervention is performed and for care providers	0 (0%)	0 (0%)	8 (32%)	17 (68%)
	1b NPT. Report any important changes to the intervention delivered from what was planned	0 (0%)	0 (0%)	10 (40%)	15 (60%)
Introduction					
Background and objectives	2a. Scientific background and explanation of rationale	23 (92%)	2 (8%)	0 (0%)	0 (0%)
	2b. Specific objectives or hypotheses	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Methods					
Trial design	3a. Description of trial design (such as parallel, factorial) including allocation ratio	18 (72%)	7 (28%)	0 (0%)	0 (0%)
	3a NPT. When applicable, how care providers were allocated to each trial group	0 (0%)	0 (0%)	8 (32%)	17 (68%)
	3b. Important changes to methods after trial commencement (such as eligibility criteria), with reasons	1 (4%)	0 (0%)	8 (32%)	16 (64%)
Participants	4a. Eligibility criteria for participants	23 (92%)	2 (8%)	0 (0%)	0 (0%)
	4a NPT. When applicable, eligibility criteria for centers and for care providers	0 (0%)	1 (4%)	8 (32%)	16 (64%)
	4b. Settings and locations where the data were collected	22 (88%)	2 (8%)	1 (4%)	0 (0%)
Interventions	5. Interventions for each group with sufficient details to allow replication, including how and when they were actually administered	24 (96%)	1 (4%)	0 (0%)	0 (0%)
	5a NPT. Precise details of both the experimental treatment and comparator	25 (100%)	0 (0%)	0 (0%)	0 (0%)
	5b NPT. Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants	22 (88%)	0 (0%)	2 (8%)	1 (4%)
	5c NPT. Details of whether and how the interventions were standardised	24 (96%)	0 (0%)	0 (0%)	1 (4%)
	5d NPT. Details of whether and how adherence of care providers to the protocol was assessed or enhanced	0 (0%)	0 (0%)	6 (24%)	19 (76%)
	5e NPT. Details of whether and how adherence of participants to interventions was assessed or enhanced	0 (0%)	1 (4%)	24 (96%)	0 (0%)

Table 4 continued.

Outcomes	6a. Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	13 (52%)	12 (48%)	0 (0%)	0 (0%)
	6b. Any changes to trial outcomes after the trial commenced, with reasons	1 (4%)	0 (0%)	7 (28%)	17 (68%)
Sample size	7a. How sample size was determined	11 (44%)	0 (0%)	14 (56%)	0 (0%)
	7a NPT. When applicable, details of whether and how the clustering by care providers or centers was addressed	0 (0%)	0 (0%)	5 (20%)	20 (80%)
	7b. When applicable, explanation of any interim analyses and stopping guidelines	2 (8%)	0 (0%)	13 (52%)	10 (40%)
Sequence generation	8a. Method used to generate the random allocation sequence	18 (72%)	0 (0%)	7 (28%)	0 (0%)
	8b. Type of randomisation; details of any restriction (such as blocking and block size)	10 (40%)	9 (36%)	6 (24%)	0 (0%)
Allocation concealment	9. Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	13 (52%)	4 (16%)	8 (32%)	0 (0%)
Implementation	10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8 (32%)	2 (8%)	15 (60%)	0 (0%)
Blinding	11a. If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8 (32%)	6 (24%)	10 (40%)	1 (4%)
	11a NPT. If done, who was blinded after assignment to interventions (e.g., participants, care providers, those administering co-interventions, those assessing outcomes) and how	8 (32%)	6 (24%)	7 (28%)	4 (16%)
	11b. If relevant, description of the similarity of interventions	19 (76%)	0 (0%)	0 (0%)	6 (24%)
	11c NPT. If blinding was not possible, description of any attempts to limit bias	0 (0%)	2 (8%)	12 (48%)	11 (44%)
Statistical methods	12a. Statistical methods used to compare groups for primary and secondary outcomes	25 (100%)	0 (0%)	0 (0%)	0 (0%)
	12a NPT. When applicable, details of whether and how the clustering by care providers or centers was addressed	0 (0%)	0 (0%)	2 (8%)	23 (92%)
	12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses	10 (40%)	0 (0%)	5 (20%)	10 (40%)
Results					
Participant flow (a diagram is strongly recommended)	13a. For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	25 (100%)	0 (0%)	0 (0%)	0 (0%)
	13a NPT. The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	0 (0%)	1 (4%)	6 (24%)	18 (72%)
	13b. For each group, losses and exclusions after randomisation, together with reasons	18 (72%)	0 (0%)	3 (12%)	4 (16%)
	13c NPT. For each group, the delay between randomisation and the initiation of the intervention	4 (16%)	1 (4%)	20 (80%)	0 (0%)

Table 4 continued.

Recruitment	14a. Dates defining the periods of recruitment and follow-up	20 (80%)	0 (0%)	5 (20%)	0 (0%)
	14b. Why the trial ended or was stopped	1 (4%)	0 (0%)	0 (0%)	24 (96%)
Baseline data	15. A table showing baseline demographic and clinical characteristics for each group	20 (80%)	2 (8%)	3 (12%)	0 (0%)
	15 NPT. When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	0 (0%)	0 (0%)	8 (32%)	17 (68%)
Numbers analysed	16. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	23 (92%)	0 (0%)	2 (8%)	0 (0%)
Outcomes and estimation	17a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	18 (72%)	7 (28%)	0 (0%)	0 (0%)
	17b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended	1 (4%)	0 (0%)	1 (4%)	23 (92%)
Ancillary analyses	18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9 (36%)	0 (0%)	5 (20%)	11 (44%)
Harms	19. All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	16 (64%)	0 (0%)	9 (36%)	0 (0%)
Discussion					
Limitations	20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13 (52%)	10 (40%)	2 (8%)	0 (0%)
	20 NPT. In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	1 (4%)	1 (4%)	11 (44%)	12 (48%)
Generalisability	21. Generalisability (external validity, applicability) of the trial findings	14 (56%)	4 (16%)	7 (28%)	0 (0%)
	21 NPT. Generalisability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	6 (24%)	4 (16%)	11 (44%)	4 (16%)
Interpretation	22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	24 (96%)	0 (0%)	1 (4%)	0 (0%)
Other information					
Registration	23. Registration number and name of trial registry	9 (36%)	1 (4%)	15 (60%)	0 (0%)
Protocol	24. Where the full trial protocol can be accessed, if available	5 (20%)	0 (0%)	20 (80%)	0 (0%)
Funding	25. Sources of funding and other support (such as supply of drugs), role of funders	18 (72%)	3 (12%)	3 (12%)	1 (4%)

Table 5

Completeness of reporting for observational studies investigating HBO based on STROBE (version combined for cohort, case-control, and cross-sectional studies); AR – item adequately reported; IR – item incompletely reported; NR – item not reported; NA – item not applicable

Section/Topic	Item number and description	AR *n* (%)	IR *n* (%)	NR *n* (%)	NA *n* (%)
Title and abstract	1a. Indicate the study's design with a commonly used term in the title or the abstract	14 (56%)	0 (0%)	11 (44%)	0 (0%)
	1b. Provide in the abstract an informative and balanced summary of what was done and what was found	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Introduction					
Background/ Rationale	2. Explain the scientific background and rationale for the investigation being reported	20 (80%)	5 (20%)	0 (0%)	0 (0%)
Objectives	3. State specific objectives, including any prespecified hypotheses	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Methods					
Study design	4. Present key elements of study design early in the paper	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Setting	5. Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	17 (68%)	8 (32%)	0 (0%)	0 (0%)
Participants	6a. *Cohort study* — Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study* — Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* — Give the eligibility criteria, and the sources and methods of selection of participants	24 (96%)	1 (4%)	0 (0%)	0 (0%)
	6b. *Cohort study* — For matched studies, give matching criteria and number of exposed and unexposed *Case-Control study* — For matched studies, give matching criteria and the number of controls per case	5 (20%)	20 (80%)	0 (0%)	0 (0%)
Variables	7. Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5 (20%)	20 (80%)	0 (0%)	0 (0%)
Data Sources/ Measurement	8. For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Bias	9. Describe any efforts to address potential sources of bias	9 (36%)	3 (12%)	13 (52%)	0 (0%)
Study size	10. Explain how the study size was arrived at	19 (76%)	0 (0%)	6 (24%)	0 (0%)
Quantitative variables	11. Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	25 (100%)	0 (0%)	0 (0%)	0 (0%)

Table 5 continued.

Statistical methods	12a. Describe all statistical methods, including those used to control for confounding	12 (48%)	13 (52%)	0 (0%)	0 (0%)
	12b. Describe any methods used to examine subgroups and interactions	11 (44%)	1 (4%)	5 (20%)	8 (32%)
	12c. Explain how missing data were addressed	9 (36%)	1 (4%)	2 (8%)	13 (52%)
	12d. *Cohort study* — If applicable, explain how loss to follow-up was addressed *Case-Control study* — If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* — If applicable, describe analytical methods taking account of sampling strategy	3 (12%)	0 (0%)	4 (16%)	18 (72%)
	12e. Describe any sensitivity analyses	1 (4%)	0 (0%)	1 (4%)	23 (92%)
Results					
Participants	13a. Report numbers of individuals at each stage of study – e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	18 (72%)	5 (20%)	1 (4%)	1 (4%)
	13b. Give reasons for non-participation at each stage	13 (52%)	0 (0%)	0 (0%)	12 (48%)
	13c. Consider use of a flow diagram	7 (28%)	0 (0%)	18 (72%)	0 (0%)
Descriptive data	14a. Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	24 (96%)	1 (4%)	0 (0%)	0 (0%)
	14b. Indicate number of participants with missing data for each variable of interest	8 (32%)	2 (8%)	1 (4%)	14 (56%)
	14c. *Cohort study* — Summarise follow-up time (e.g., average and total amount)	12 (48%)	0 (0%)	1 (4%)	12 (48%)
Outcome data	15. *Cohort study* — Report numbers of outcome events or summary measures over time *Case-Control study* — Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study* — Report numbers of outcome events or summary measures	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Main results	16a. Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8 (32%)	10 (40%)	7 (28%)	0 (0%)
	16b. Report category boundaries when continuous variables were categorised	7 (28%)	0 (0%)	7 (28%)	11 (44%)
	16c. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	1 (4%)	0 (0%)	4 (16%)	20 (80%)

Table 5 continued.

Other analyses	17. Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	14 (56%)	0 (0%)	1 (4%)	10 (40%)
Discussion					
Key results	18. Summarise key results with reference to study objectives	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Limitations	19. Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11 (44%)	12 (48%)	2 (8%)	0 (0%)
Interpretation	20. Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	25 (100%)	0 (0%)	0 (0%)	0 (0%)
Generalisability	21. Discuss the generalisability (external validity) of the study results	9 (36%)	6 (24%)	10 (40%)	0 (0%)
Other information					
Funding	22. Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15 (60%)	3 (12%)	7 (28%)	0 (0%)

Analysis of RCTs identified significant gaps, particularly in NPT reporting. When evaluated solely against CONSORT, 15 studies (60%) were rated as 'good', reflecting moderate adherence to methodological standards. However, this adherence declined when incorporating NPT-specific items, as many items were marked 'Not Applicable' or 'Not Reported'. This may be surprising, as NPT was specifically designed to facilitate reporting of interventions that are more complex than conventional medication treatments. This could suggest these checklists items may not apply to or may not be recognised to apply to HBO-specific characteristics. For instance, items related to clustering by care providers (7a, 12a) and allocation of care providers to trial groups (3a) were frequently deemed inapplicable. This likely reflects the controlled nature of HBO, where treatment administration remains consistent, minimising variability introduced by care providers. Additionally, no studies reported monitoring of care providers' adherence to protocols (5d) or participant adherence (5e).

More importantly, significant gaps in key treatment parameters, particularly regarding chamber type, pressure levels, compression time, and decompression time were noted. Among the 25 RCTs, 19 studies (76%) did not specify the chamber type used, eight studies (32%) did not document compression time, and six studies (24%) failed to report the treatment pressure used. Additionally, 11 studies (44%) did not provide details on decompression protocols, which are essential for understanding the full pressure profile of HBO sessions.

Given that pressure level, session duration, and transition phases (compression and decompression) function similarly to medication dosing, these omissions may critically impact study reproducibility, treatment standardisation, and clinical applicability. While our initial screening rated most studies as adequately reporting intervention details, a more in-depth review suggests that essential HBO parameters were inconsistently documented. These findings underscore the need for HBO-specific reporting guidelines that better capture the distinct characteristics of an intervention.

Observational studies showed slightly better reporting rates, still with no study categorised as 'excellent', but with 19 studies (76%) categorised as 'good'. Critical elements were often omitted, including flow diagrams (18 studies; 72%), control of bias (13 studies; 52%), and missing data handling (13 studies; 52%). This reduces transparency and hinders bias identification, such as loss to follow-up. Underreporting in these domains weakens the credibility of observational findings and limits their utility in clinical guidelines.

Our findings align with prior research in other fields demonstrating persistent reporting deficiencies in both RCTs and observational studies on HBO.[27,78,79] Previous

Figure 2
Representation of completeness of reporting for RCTs investigating HBO, based on CONSORT and NPT

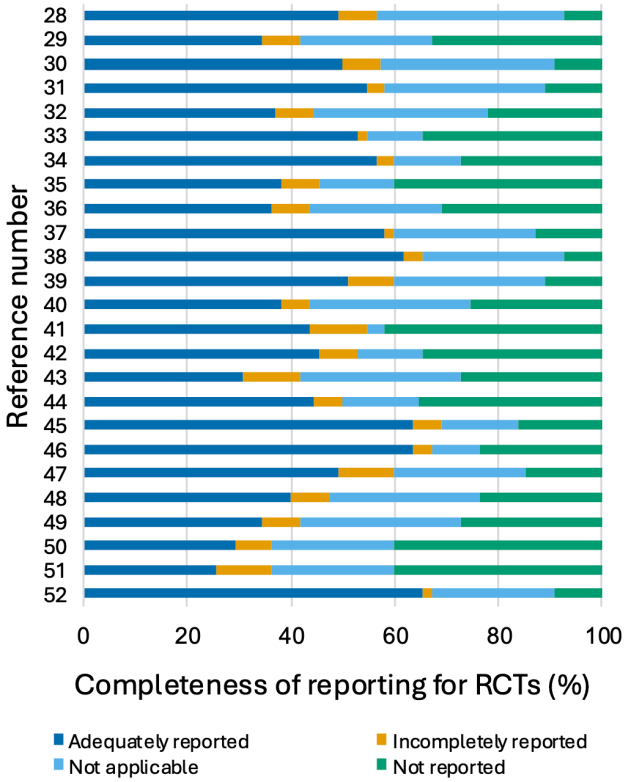
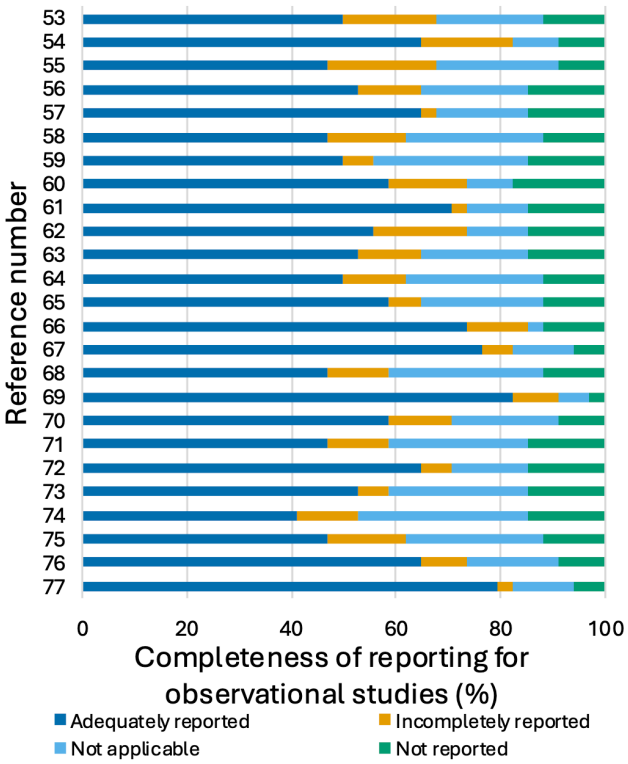


Figure 3
Representation of completeness of reporting for observational studies investigating HBO, based on STROBE



studies suggest that adherence to reporting guidelines improves reporting quality, but widespread endorsement and enforcement remain aspirational.[78,79] Notably, many HBO studies published in journals that endorse CONSORT or STROBE still lacked key methodological details, reinforcing the need for mandatory adherence to these guidelines.[78,79] This suggests that implementation strategies are key to promote adherence to reporting guidelines – a call shared by others previously.[78,79]

One distinctive aspect of HBO is the specialised role of the chamber operator, who 'drives' the chamber, managing pressurisation and a large portion of patient safety, setting it apart from conventional treatment administration in healthcare. Unlike other interventions, HBO requires a trained operator, which is not typically addressed in standard reporting checklists. Incorporating this role into future HBO-specific guidelines may enhance reporting completeness. Additional operational parameters specific to HBO are also important. Details on pressure levels and treatment schedules are important to evaluate protocol adherence. Additionally, the challenges of implementing sham-controlled trials complicate adequate blinding and control.[80,81] Environmental factors within the hyperbaric chamber may influence participant perception and interaction, further affecting blinding and study integrity. Addressing these issues requires the development of HBO-specific reporting guidelines that provide explicit instructions on reporting key aspects, including pressure ('dive') profiles, randomisation procedures, and bias management. Such guidelines would enhance transparency and strengthen the validity of HBO research.

The role of the peer reviewers is critical in improving reporting quality. Studies indicate that structured peer review, particularly when reviewers utilise CONSORT checklists, significantly enhances RCT reporting adherence.[24,82] Given the complexity and specificity of HBO studies, peer reviewers should be engaged in the design and creation of HBO-specific reporting guidelines, and receive specialised training to evaluate reporting quality effectively. Strengthening peer review processes could contribute to promoting more rigorous and transparent HBO research.

This study has limitations. Firstly, we only assessed a sample of recent peer-reviewed reports of clinical trials in HBO. We also did not consider articles accessible only through other literature databases or in languages other than English. This constrained the comprehensiveness of our sample, and thus the generalisability of our findings. Our decision to not assign weighting to missing or incomplete elements weakens the assessment of 'deficiencies'. For example, it is possible that authors did not comment on 'important changes' when there were none. The absence of such a statement may not

necessarily constitute a true reporting deficiency. Finally, our evaluation did not evaluate journals where the articles were published, which can contribute to differences in both quality and completeness of reports.

Conclusions

In a randomly selected sample of 50 clinical trials in HBO, reporting guidelines were not used by the vast majority of HBO trials and, when used, the reporting details were typically incomplete. Future efforts are required to ensure a high degree of relevance for all checklist items and to improve the quality of reporting in HBO trials in order to strengthen the quality of evidence in the field.

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