Shared decision-making when considering hyperbaric oxygen therapy: a systematic review

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Keywords
Evidence; Policy; Risk management; Theory-based advice; Treatment sequelae

Abstract
(Meijering JR, Risvanoglu N, Nederhoed JH, Hoencamp R, van Hulst RA, Ubbink DT. Shared decision-making when considering hyperbaric oxygen therapy: a systematic review. Diving and Hyperbaric Medicine. 2025 30 June;55(2):180–185. doi: 10.28920/dhm55.2.180-185. PMID: 40544146.)
Introduction: Hyperbaric oxygen therapy (HBOT) is a treatment modality used for various non-acute medical conditions, ranging from ischaemic diabetic ulcers to late post-radiation damage. Despite its wide application, HBOT is often time-consuming, requires multiple sessions, and can be physically and psychologically challenging for patients, contributing to high drop-out rates. In addition, treatment results can vary significantly. These challenges suggest the need for more patient-centred approaches, such as shared decision-making (SDM), to improve patient engagement, satisfaction, and adherence to treatment. SDM, which involves patients in the decision-making process, could potentially improve outcomes and reduce dropout rates. This systematic review presents currently available evidence on the extent of SDM in patients eligible for HBOT.
Methods: A comprehensive literature search was conducted in the Medline, Embase, TRIP and Cochrane Central databases, from inception up to 29 August 2024, to find all studies with original data on SDM when considering HBOT as a treatment option. Study selection was conducted by two reviewers independently. Desired study outcomes were the application and observed levels of SDM.
Results: The search yielded 988 articles of which 24 appeared eligible. After assessing the inclusion criteria and outcomes in the full text articles, zero remained for inclusion: none reported on patient involvement in the decision-making process regarding HBOT. However, six articles did mention that SDM should be an important element when developing clinical practice guidelines for HBOT.
Conclusions: Despite the obvious need for preference-sensitive decision-making in HBOT, there is no scientific evidence available on this topic. Possibly, physicians and patients consider HBOT as a last-resort or even the only treatment option. Consequently, involving the patient's preference regarding HBOT in the decision-making process is rarely documented. Hence, more awareness of the need for SDM is advocated when considering HBOT, which should be corroborated by research in this area.

Introduction

Hyperbaric Oxygen Therapy (HBOT) is a treatment modality used for various non-emergent medical conditions, ranging from ischaemic diabetic ulcers to late post-radiation damage.[1–4] HBOT is provided in a hyperbaric chamber where the air pressure is raised above normal atmospheric pressure (200–250 kPa) and in which patients breathe 100% oxygen administered through a mask.

For non-emergent conditions, the HBOT regimen typically consists of five sessions per week. Each session takes approximately two hours. The total number of HBOT sessions varies per indication, ranging between 10 and 60 sessions.[2]

This therapy implies that patients need to commute almost daily to the treatment centre. Therefore, HBOT is often perceived as time-consuming and exhausting, especially among patients who are elderly, have difficulty walking, or suffer from multiple comorbidities.

Shared decision-making (SDM) has been recognised as an essential method of care in modern healthcare and in some countries even legally required.[5] SDM can be defined as an interactive process in which healthcare professionals

and patients collaborate to make informed decisions about the patient's health that best fit the patient's situation and preferences.[6] SDM has been shown to increase patient satisfaction as well as treatment adherence.[7] SDM is particularly relevant when considering intensive treatment modalities where patient preferences and expectations are even more relevant. The application of SDM in other medical fields, such as surgery, cardiology and paediatrics, has highlighted its importance in improving both patient reported outcomes and treatment experiences.[8–10]

As HBOT is an intensive treatment that requires continuous patient commitment, SDM is particularly useful to ensure that patients understand the demands and benefits of the therapy. Through SDM, patients can assess whether the intensive schedule and potential health benefits align with their personal circumstances and expectations. Therefore, the goal of this systematic review was to give an overview of existing literature to appreciate whether and how SDM is applied in patients eligible for HBOT.

Methods

PROSPERO

Prior to performing this systematic review, the Prospero database was checked for similar studies, either past or current. The systematic review was then entered into the Prospero database on 8 January 2024 (CRD42024493698).

SEARCH STRATEGY

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and checklist were used as reporting guideline aimed at improving the transparency and completeness of reporting this systematic review.[11] A comprehensive search strategy was developed with the aid of a medical librarian. The Medline, EMBASE, TRIP and Cochrane Central Register of Controlled Trials databases were searched using the primary keywords 'Shared Decision Making', 'patient participation', and 'Hyperbaric Oxygen Therapy' (see *Appendix A for the complete search strategy in each database). The literature search was performed on 14 February 2024, and repeated on 29 August 2024. No language restrictions were applied. Reference lists from relevant articles were also considered to further identify potentially relevant articles.

STUDY SELECTION

The systematic screening was conducted by two reviewers independently (JM and NR), using Rayyan, software for deduplication and review of articles for systematic reviews. Titles and abstracts of all articles were screened based on relevance. Full text articles were then retrieved and further assessed for eligibility based on the in- and exclusion criteria, again by two reviewers independently. If the two reviewers could not reach consensus, a third reviewer was consulted.

INCLUSION AND EXCLUSION CRITERIA

Articles were included when meeting all of the following, broadly formulated, criteria: investigating SDM or patient involvement in the decision-making surrounding HBOT; reporting qualitative or quantitative data on the SDM-process; involving human subjects. Articles with no original data such as opinion pieces were excluded.

QUALITY ASSESSMENT

Quality assessment of the included articles was to be carried out using the Cochrane Risk of Bias tool for randomised controlled trials (RCTs), the QUIPS for cohort and case-control studies, and the ROBINS-1 for cross-sectional studies. Each article was to be systematically evaluated for potential sources of bias including selection, performance, detection, attrition, and reporting bias.

DATA EXTRACTION

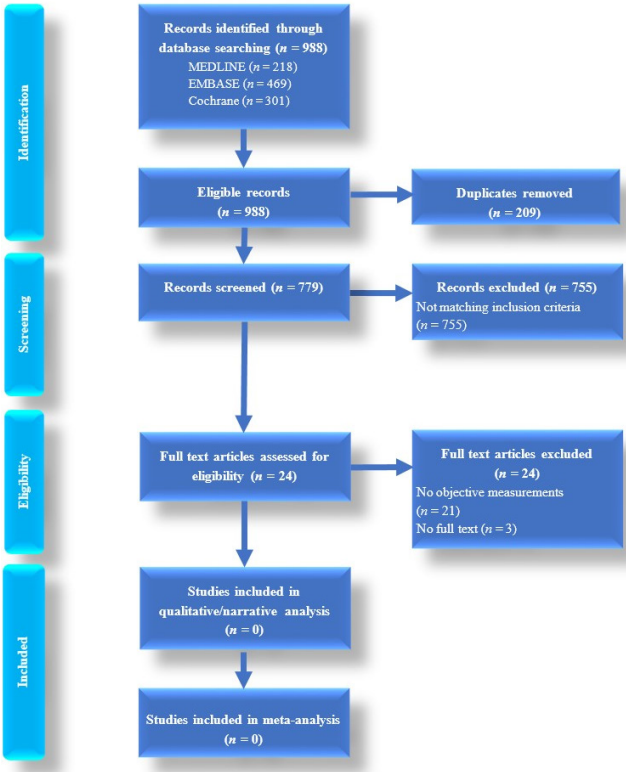
Data extraction was performed using a predefined standardised form to ensure consistency and comprehensiveness across all included studies and to avoid reporting bias. Extracted data included information on SDM observation tools and their corresponding scores, the number of HBOT sessions administered, the indication for HBOT, and patient-reported outcome measures (PROMs). Additionally, data on study characteristics such as sample size, study design, participant demographics, and the context in which SDM was implemented were also collected. This systematic extraction process aimed at capturing all relevant data necessary for a thorough analysis of the extent and impact of SDM in HBOT.

DATA ASSESSMENT

Extracted data were subjected to a detailed assessment in order to determine their suitability for inclusion in a meta-analysis. Studies were initially evaluated for qualitative soundness: considering factors such as study design, sample size, and the robustness of the findings, using the (Dutch version of the) Cochrane Collaboration's validity checklist for RCTs.[12] If the data from multiple studies were found to be methodologically sound and the data entries were homogeneous in terms of measurement tools, outcomes, and population characteristics, they were to be pooled in a meta-analysis. If meta-analysis would not be feasible due to clinical heterogeneity in the study designs, patient populations or outcomes, a narrative synthesis was to be conducted to summarise the findings.

***Footnote:** Appendix A is available on DHM Journal's website: https://www.dhmjournal.com/index.php/journals?id=355

Figure 1
Prisma flowchart of study selection



Results

The literature search, with update, yielded 988 articles: Medline (n = 218); Cochrane (n = 301) and EMBASE (n = 469). After deduplication, 779 were screened for eligibility. The flowchart of study inclusion is displayed in Figure 1.

After applying the inclusion criteria on title and abstract, 755 articles were excluded. Thus, 24 articles remained for full text screening. Full texts could not be retrieved for three articles (two were oral presentations and one could not be found). None of the remaining 21 articles were deemed eligible for inclusion as none of these quantified or compared SDM in any way. Hence, zero studies were found addressing SDM in HBOT according to our (broad) inclusion criteria. Due to the lack of articles suitable for inclusion, the full-texted reviewed articles were revisited with the intention to get more perspective on the current status of SDM in HBOT.

This reassessment yielded six articles that mentioned the importance of SDM in HBOT without further specification or quantification. An overview of these articles can be found in Table 1. De Ru et al.[13] described the importance of SDM in patients with sudden sensorineural hearing loss (SSNHL) for whom HBOT was found to be effective.[14] Also, both Chandrasekhar et al. and Fazel et al. underlined benefits of SDM, such as better patient adherence and outcomes, in SSNHL patients.[15,16] Various key action statements were provided regarding different treatment options for SSNHL, in which the importance of SDM was considered for each statement. These included the importance of providing good information as well as suggesting that SDM is especially useful in areas where evidence is weak or benefits are unclear, as became clear from the Cochrane review regarding SSNHL treatment.[14] The notion that SDM should be used when considering HBOT for Diabetic Foot Ulcer patients was supported by a systematic review by Lalieu et al. It was mentioned that this could reduce drop-out rates in this intensive treatment modality.[17] Huang et al. described a conversation with patients eligible for HBOT to ascertain the importance and impact of provided information in their clinical practice guidelines.[18] Lastly, Jefferson and Linder also pointed out the value of SDM in the process of treating haemorrhagic cystitis after radio- or chemotherapy without describing specific benefits of SDM.[19]

Discussion

This systematic review highlights the notable absence of literature regarding SDM in patients eligible for HBOT. This lack of evidence on SDM in HBOT suggests a possible neglect of prioritising patient involvement in treatment decision-making regarding HBOT when weighing its possible benefits against the possible harms.

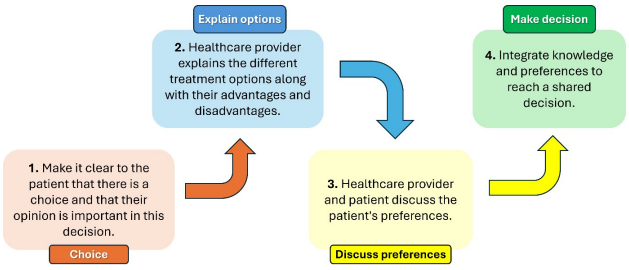
Although no studies were found that quantified the level of SDM when deciding about HBOT, some aspects of SDM may have occurred and been described that were not identified as part of SDM. Essential elements of SDM have been defined previously and are illustrated in Figure 2. When considering HBOT, this SDM-process would include the following steps: (1) Informing patients at the start of the consultation that a decision regarding possible HBOT treatment has to be made in which the patient has a decisive voice; (2) explaining to the patient the relevant and feasible treatment options, including standard care with or without HBOT, along with their pros and cons. For example, HBOT may increase the chance of wound healing, lower the risk of amputation, and reduce the patient's complaints. However, patients also face possible undesired effects, such as the burden of undergoing multiple HBOT sessions to achieve results, possible barotrauma, oxygen toxicity, or myopia; (3) explicitly asking the patients how they appreciate these options, including the possible benefits and harms, and what their personal preference would be; and (4) integrating the patients' preference into the eventual treatment decision.[20]

Some of these elements commonly occur in doctor-patient encounters, such as informing about the HBOT treatment, including the benefits and harms, but without presenting alternatives.[21] Also, informed consent is commonly asked, but may be done without any involvement of the patient in the decision-making process.[22] In addition, surgeons rarely ask patients how they would like to receive information, whether they have understood the information (for example with the teach-back method) and how they would like to be involved in SDM.[23,24] Practicing only a few of these essential

Table 1
Overview of excluded studies referring to shared decision making (SDM); HBOT – hyperbaric oxygen therapy

Title	Ref	Key points related to SDM
Sudden deafness: hyperbaric oxygen therapy should be discussed	13	Suggests that hyperbaric HBOT should be considered in sudden deafness cases, implying the need for SDM between clinicians and patients.
Clinical practice guideline: sudden hearing loss (update) executive summary	15	Discusses guidelines for sudden hearing loss treatment, including patient-centered approaches and informed discussions about treatment options.
Evaluation and treatment of acute and subacute hearing loss: a review of pharmacotherapy	16	Reviews pharmacological treatments and emphasises the importance of discussing risks and benefits with patients.
Hyperbaric oxygen treatment for University of Texas grade 3 diabetic foot ulcers: a retrospective cohort study	17	Examines HBOT for diabetic foot ulcers, noting that treatment selection should involve discussions with patients on expected outcomes.
A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers	18	Provides guidelines for HBOT use and underscores the role of SDM in patient-centered care.
Haemorrhagic cystitis: making rapid and shrewd clinical and surgical decisions for improving patient outcomes	19	Discusses decision-making strategies for hemorrhagic cystitis, highlighting the need for rapid yet informed SDM processes.

Figure 2
Schematic representation of the four essential steps of shared decision-making process between healthcare providers and patients



elements is insufficient to achieve true SDM, in which the patient's preference is effectively evoked and integrated in the eventual treatment decision.

SDM seems the obvious approach, given HBOT's taxing character. Recent trials have revealed that patients eligible for HBOT often decline treatment or trial participation due to its intensity. For example, in the HONEY trial by Mink van der Molen et al.[25] conducted in patients with irradiated breast cancer, 94 patients out of 126 in the HBOT-group did not undergo HBOT. It was reported that 75 out of these 94 patients opted out or declined due to treatment-related reasons. In the HOT-2 trial, in patients with chronic bowel dysfunction after pelvic radiotherapy, significant drop-out rates were observed among patients who started HBOT (16.7%).[26] In the retrospective observational study by Ennis et al. drop-out rates were as high as 54.8%.[27] Similarly, in the DAMO$_2$CLES trial on HBOT for diabetic ischemic foot ulcers, 35% of the patients randomised for HBOT could not complete the full treatment of 40 sessions.[28]

While treatment intensity is a significant barrier to starting and continuing HBOT, Ennis et al. found that patients showed significant improvement of their diabetic foot ulcer wounds when completing their treatment versus not completing (75.2% vs 47.4%).[27] Also, patients in the DAMO$_2$CLES-trial who completed all HBOT sessions showed fewer amputations and had a higher amputation-free survival rate than those who did not.[28] This underscores the potential benefits of treatment as well as the importance of good pre-treatment counselling in order to enable patient participation in the decision-making process.

Additional barriers to applying SDM when discussing HBOT, perceived by both clinicians and patients, may include whether HBOT is covered by their health insurance or must be paid by patients themselves, and the vicinity of a HBOT facility. Other barriers may be local guidelines that may or may not recommend HBOT for the patient's affliction. Finally, clinicians' belief in HBOT as a useful therapeutic option plays a crucial role in whether it will be discussed with patients at all. Another key challenge is the perception that SDM is time-consuming, which may deter clinicians from fully engaging in the process. While SDM does require an initial investment in discussion and patient education, evidence suggests that it does not necessarily prolong consultations when integrated effectively.[29]

Furthermore, because many clinicians have not received formal training in SDM techniques, some feel uncertain about how to effectively incorporate it into their practice.

Although the search strategy was developed in collaboration with a medical librarian and repeated on a later date to capture newer publications, the possibility of missing relevant studies remains. The reliance on electronic databases and reference list screening means that unpublished studies, grey literature, or studies not indexed in the selected databases may not have been identified, despite their potential relevance.

Furthermore, three articles identified in the search could not be retrieved in full text, potentially impacting the review's comprehensiveness. Two were oral presentations, while the third was a published study that could not be located, possibly missing valuable insights into SDM in HBOT.

The use of broad search terms enhanced sensitivity but also increased the inclusion of irrelevant articles, adding to the screening burden and potentially diverting focus from highly relevant studies.

Finally, while this systematic review highlights a gap in the available research on SDM in HBOT, this does not necessarily indicate that SDM is absent in clinical practice.

Conclusions

This systematic review on SDM shows an apparent lack of patient involvement in the decision-making on HBOT. It also underscores the need to perform research in this area to explore the application of SDM in HBOT, as well as the potential benefits and challenges of integrating SDM into the decision-making process for patients undergoing HBOT for elective indications. Recommendations for future studies are to investigate the existing practice in referring patients for HBOT and the level of SDM present in these referrals, the patient perspectives on treatment intensity, the decision-making process, and perceived barriers to treatment with HBOT by both patients and healthcare workers.

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Acknowledgements

We would like to express our gratitude to Faridi Jamadulin, our medical librarian, whose expertise and dedication were instrumental in developing and executing the comprehensive search strategy for this systematic review.

Conflicts of interest and funding: nil

Submitted: 8 January 2025
Accepted after revision: 2 May 2025