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Article

Long-Term Patient-Reported Outcomes of Hyperbaric Oxygen Therapy for Haematuria Due to Radiation Cystitis Secondary to External Beam Radiotherapy for Pelvic Malignancy

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Abstract

Background/Objectives: To determine long-term patient-reported outcomes for patients undergoing hyperbaric oxygen therapy (HBO2) following external beam radiotherapy. **Methods**: A retrospective cohort study of all consecutive patients who underwent HBO2 for radiation cystitis in South Australia from September 2017 to March 2023 was performed. Patient-reported symptom severity, anxiety, healthcare use and transfusion requirements pre- and post-treatment were collected through telephone interview. Readmission data and procedural data was collected through both telephone interview and a state-wide electronic medical record. Jamovi was used to perform paired sample *t*-tests for statistical analysis. **Results**: There were 89 patients who underwent HBO2 for radiation cystitis with 54 completing the questionnaire. There were 85% of patients alive at the time of follow-up, with 61% of the total cohort and 74% of survivors completing the questionnaire. For those completing the questionnaire, 96% were male with all of them having prostate cancer. Median age was 74 (interquartile range [IQR] 69–78). The mean reduction in patients' perceived symptom severity after HBO2 on a scale out of 10 was 7.9 to 2 with a difference of 5.9 (95% confidence interval [CI] 5.1–6.7, $p < 0.001$) and the mean reduction in perceived anxiety was 6.9 to 2.1 with a difference of 4.7 (95% CI 3.6–5.8 $p < 0.001$). Patients reported a reduction in family doctor visits from 2.7 to 0.76 with a mean reduction of 2 (95% CI 0.8 to 3.2, $p = 0.003$), emergency department presentations from 3.3 to 0.57 with a mean reduction of 2.7 (95% CI 1.4–4.1, $p \leq 0.001$) and blood transfusions from 0.67 to 0.31 with a mean reduction of 0.34 (95% CI −0.44 to 1.1, $p = 0.017$). Ongoing haematuria was reported in 21 of the 54 patients (39%). Further treatment was required for 20 patients (25%). No patients reported any severe or ongoing adverse effects from HBO2 via the questionnaire. **Conclusions**: HBO2 is a safe option for recurrent haematuria due to radiation cystitis with high patient satisfaction and reduction in patient-perceived symptom severity, anxiety and healthcare utilisation. Level of evidence: 4.

Keywords: hyperbaric oxygen therapy; radiation cystitis; prostate cancer

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1. Introduction

External beam radiotherapy (EBRT) is a common treatment for pelvic malignancy, particularly for prostate cancer [1]. EBRT has comparable cancer-free survival rates for the treatment of prostate cancer as radical prostatectomy and has the benefit of not requiring invasive surgery [1]. However, the long-term effects of radiotherapy can lead to collateral damage to surrounding structures, such as the urinary bladder, leading to radiation cystitis that poses a complex challenge to manage for urologists [2].

Radiation cystitis is a long-term adverse effect of radiotherapy that may affect patients many years after having radiotherapy [2]. There have been advances in radiotherapy to allow more targeted radiation; however, the incidence of radiation cystitis is still 5–10% [2]. The radiation-induced damage to tissue can result in recurrent haematuria, as well as other lower urinary tract symptoms like urinary incontinence, dysuria, urgency, urinary frequency and suprapubic pain [3]. This is due to progressive endarteritis causing ischaemic and hypoxic tissue injury changing the integral structure of the tissue. The reduced integrity of surrounding tissue and vasculature in the bladder may result in chronic intractable haematuria [3]. Another putative mechanism is the chronic inflammation induced in the urothelium and associated vasculature, with replacement of muscle fibres by fibroblasts also limiting body homeostatic mechanisms to control bleeding [4,5]. Finally, radiation-induced nerve damage can damage nerves that control bladder emptying and cause incontinence [6]. Though in less severe cases the disease can remain stable, in many patients it is progressive and the severity of symptoms can increase with time [7].

There are several management options for radiation cystitis that vary in efficacy and invasiveness. The treatment options include intravesical instillation of prostaglandins, hyperbaric oxygen therapy (HBO2), prostatic artery embolization, cystoscopy and fulguration, bladder instillation of formalin and urinary diversion with or without cystectomy [2]. There is no agreed upon algorithm for the management of radiation cystitis and clinician preference certainly plays a role in which management option is chosen. A logical approach would be a graded approach, using less invasive treatment options in the first instance and escalating to more invasive options if required.

Although the mechanism of HBO2 in the treatment of radiation-induced toxicity is not completely understood, it is thought to be related to the increased oxygen supply to damaged tissue to promote wound-healing. The increased oxygen supply to neighbouring healthy tissue promotes angiogenesis and microvascularisation which replaces the damaged tissue. These changes occur over several HBO2 sessions and may explain the long-term reduction in haematuria for these patients [8].

HBO2 is usually well-tolerated; however, some of the common potential side effects are barotrauma-related, with otalgia occurring in 33% of patients and pain in the paranasal sinuses, teeth and lungs also described [9]. A rare but serious complication of HBO2 is seizures as a result of brain oxygen toxicity, which occur in 0.03% of cases but can have catastrophic consequences [10]. Finally, ocular complications can occur, either secondary to the high oxygen concentrations overwhelming normal defences against free radicals, or via direct toxic effect on the lens [11].

The Royal Adelaide Hospital has been using HBO2 for the treatment of various conditions since 1985. The use of HBO2 for radiation cystitis makes up a considerable proportion of the patients receiving treatment. This aim of this study was to determine the safety and efficacy of HBO2 for the treatment of radiation cystitis by using patient-reported outcomes, with a focus on the effect on symptom severity and patient anxiety due to recurrent haematuria.

2. Patients and Methods

We conducted a retrospective, cross-sectional cohort study that included all consecutive patients who underwent HBO2 for radiation cystitis at the Hyperbaric Medical Unit at the Royal Adelaide Hospital from September 2017 to March 2023. The Hyperbaric Medical unit keeps a database that includes all the patient details which was used to find patients for this study. All patients who had had HBO2 for radiation cystitis were screened for inclusion in the study. At our institution, prior to being offered HBO2, all patients underwent clinical evaluation with a triple-phase computed tomography (CT) scan and cystoscopy to exclude any other cause of haematuria. If no other cause was found and symptoms due to radiation cystitis were persistent, patients were offered HBO2. Patients in our cohort were all treated with reference to the same protocol which is 40 sessions of hyperbaric therapy at 100% oxygen at 10-90-30, meaning 90 min of treatment at a pressure of 100.7 kPa with 30 min of subsequent decompression. The 40 sessions were administered for eight weeks from Monday to Friday.

For each of the patients, their age, gender, primary diagnosis, time between completing radiotherapy and commencing HBO2, time between completing HBO2 and completing the questionnaire, the number of HBO2 sessions, and their HBO2 treatment regime were determined using the electronical medical records. All the patients were contacted to complete a patient questionnaire over the phone. Patients were contacted twice on two separate occasions and were excluded if they did not respond. The questionnaire, although not previously validated, was designed collaboratively by the authors to determine the patients pre- and post-HBO2 subjective symptom severity scores, anxiety scores and utilisation of the healthcare system. The symptom severity and anxiety scores were out of 10. As well as the questionnaire, the electronic medical records were used to determine if any additional treatment was required after HBO2. Patients were excluded from the study if they did not complete the questionnaire. The questionnaire used in the study is attached as Appendix A.

Paired sample *t*-tests calculated with Jamovi (The Jamovi project, open source software, version 2.6) were used to test for association between HBO2 and difference in pre- and post-treatment patient-reported outcomes.

Ethics approval for this project was given by the Central Adelaide Local Health Network (CALHN) Human Research Ethics Services (approval number: 20252). Patient consent for participation was obtained over the phone at the time of the interview.

3. Results

There were 89 patients who underwent HBO2 for radiation cystitis of which 54 completed the questionnaire. For those that did not complete the questionnaire, it was due to either being deceased (13 patients) or not being able to get in contact with the patient (22 patients). The electronic medical records showed that there were 85% of patients alive at time of follow-up, with 61% of the total cohort and 74% of survivors completing the questionnaire. Those that did not complete the questionnaire were excluded from the study. The median age was 74 (interquartile range [IQR] 69–78). Fifty-two patients (96%) were male and had a primary diagnosis of prostate cancer. Two female patients were included with primary diagnoses of cervical cancer and endometrial cancer. The median number of hyperbaric oxygen sessions per patient was 40 (IQR 38–40). The time between completing radiotherapy and commencing HBO2 was 7 years (IQR 4–10) and patient data was collected a median of 571 days (IQR 357–966) following completion of hyperbaric treatment. The patient demographics and results are shown in Table 1.

Table 1. Characteristics of patients who had HBO2 and completed the questionnaire.

	Underwent HBO2 (*n* = 54)
Median age (years, IQR)	74 (69–78)
Male sex (*n*, %)	52 (96)
Primary diagnosis	
Prostate cancer	96% (52)
Cervical cancer	2% (1)
Endometrial cancer	2% (1)
Time between completing radiotherapy and commencing HBO2 (years, IQR)	7 (4–10)
Time between completing HBO2 and completing the questionnaire (days, IQR)	571 (357–966)
Median HBO2 sessions (IQR)	40 (38–40)
Pre-HBO2	
Symptom severity score (IQR)	8 (7–10)
Anxiety score (IQR)	8 (7–10)
GP visits (IQR)	2 (0–4)
ED visits (IQR)	2 (1–5)
Total blood transfusions	35
Post-HBO2	
Symptom severity score (IQR)	1 (0–2)
Anxiety score (IQR)	1 (0–2)
GP visits (IQR)	0 (0–15)
ED visits (IQR)	0 (0–10)
Total blood transfusions	17
Complications from HBO2	
Headache (*n*, %)	2 (4)
Change in hearing (*n*, %)	8 (15)
Change in vision (*n*, %)	7 (13)
Complete response to HBO2 (*n*, %)	33 (61)
Additional treatment required after HBO2	
Further HBO2 (*n*, %)	5 (9)
Fulguration (*n*, %)	2 (4)
Bladder formalinisation (*n*, %)	3 (6)
Prostatic artery embolization (*n*, %)	2 (4)
Urinary diversion (*n*, %)	5 (9)

Table acronyms: IQR = interquartile range, HBO2 = hyperbaric oxygen therapy, GP = family doctor, ED = emergency department.

The pre-hyperbaric treatment severity of symptoms was rated a median of 8 (IQR 7–10) with anxiety due to the symptoms rated a median of 8 (IQR 7–10). Post-hyperbaric treatment severity of symptoms was rated a median of 1 (IQR 0–2) with anxiety surrounding symptoms rated a median of 1 (IQR 0–2, Figure 1). Prior to HBO2, all patients reported haematuria, eight patients had dysuria, 10 patients had urinary frequency, and 17 patients had suprapubic pain. After HBO2, 21 patients had ongoing haematuria, two reported dysuria, five reported urinary frequency and one had suprapubic pain (Figure 2). Mean reduction in patient-rated severity of symptoms after hyperbaric treatment was 6.2 (paired t-test, $p < 0.001$) on a 10-point scale. Mean reduction in patient-rated anxiety regarding haematuria after hyperbaric treatment was 5.4 (paired t-test, $p < 0.001$) on a 10-point scale.

Patients had visited their general practitioner (GP, the family doctor in Australia) 2 times (IQR 0–4) and the emergency department (ED) 2 times (IQR 1–5) prior to commencing hyperbaric treatment. Median reported GP visits for radiation cystitis following treatment were 0 (range 0–15), but 11 patients reported at least one GP presentation. Median reported ED visits for haematuria following treatment were 0 (range 0–10) but 9 patients reported at least one GP presentation. There were 10 patients who required blood transfusions prior for a total of 35 transfusions and two people afterwards for a total of 17 transfusions.

The mean reduction in patients' perceived symptom severity after HBO2 on a scale out of 10 was 7.9 to 2 with a difference of 5.9 (95% confidence interval [CI] 5.1–6.7, $p < 0.001$) and the mean reduction in perceived anxiety was 6.9 to 2.1 with a difference of 4.7 (95% CI 3.6–5.8 $p < 0.001$). Patients reported a mean number of GP visits from 2.7 to 0.76 with a mean reduction of 2 (95% CI 0.8 to 3.2, $p = 0.003$), ED presentations from 3.3 to 0.57 with a mean reduction of 2.7 (95% CI 1.4–4.1, $p = <0.001$) and blood transfusions from 0.67 to 0.31 with a mean reduction of 0.34 (95% CI −0.44 to 1.1, $p = 0.017$). In total, 21 of the 54 patients (39%) reported ongoing intermittent haematuria.

Two patients (4%) reported headache during treatment. Eight patients (15%) reported changes in hearing, and seven patients (13%) reported changes in vision during treatment. Overall discomfort during treatment was rated 1/10 (IQR 0/10–2/10). A total of 47 patients (87%) had an overall positive impression of hyperbaric oxygen therapy for haematuria.

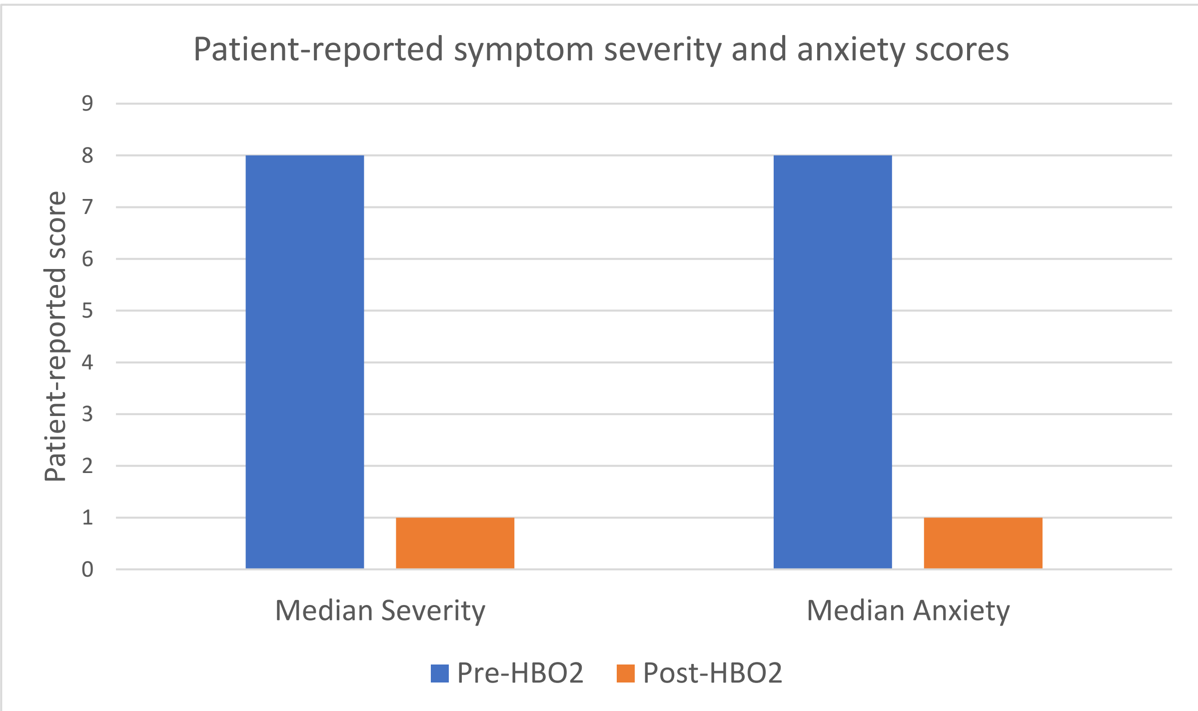

Figure 1. Patient-reported symptom severity and anxiety scores. HBO2 = hyperbaric oxygen therapy.

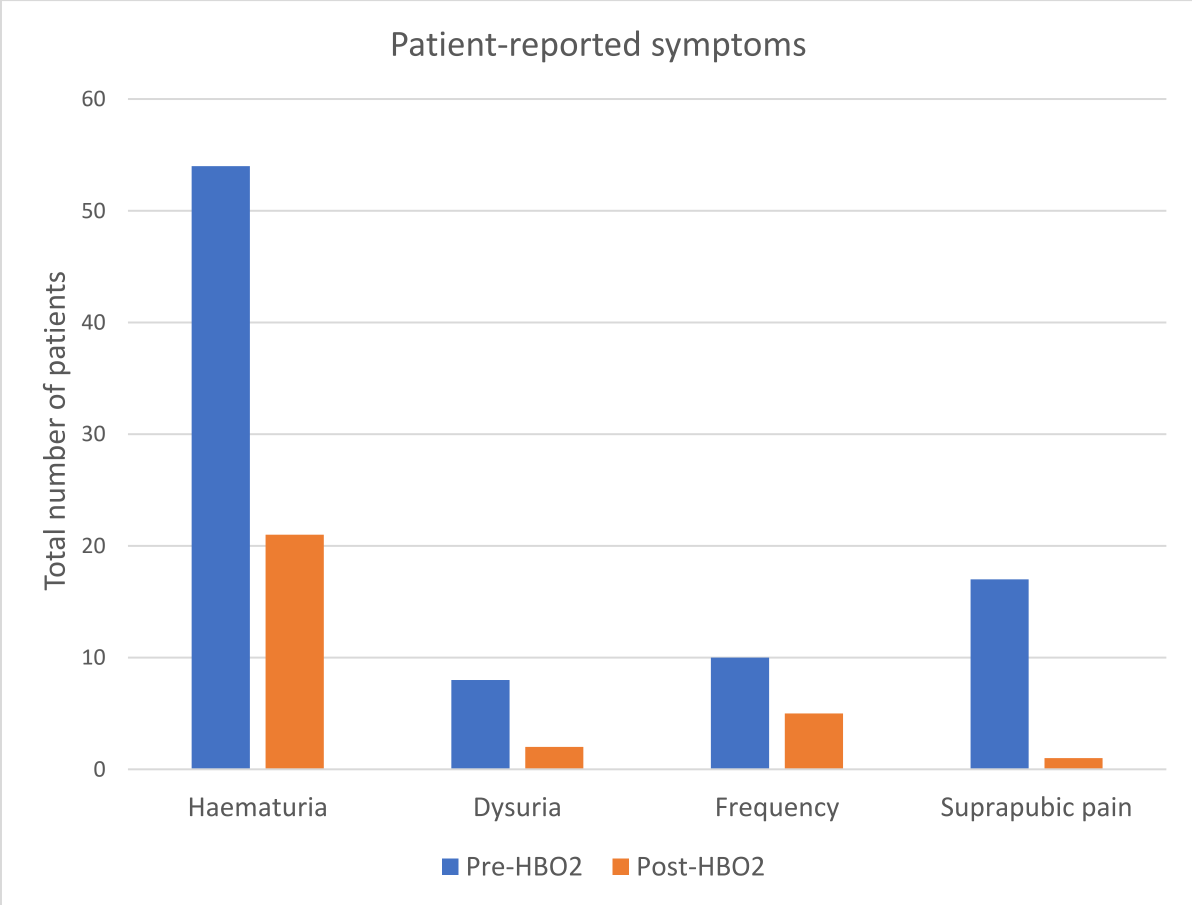

Figure 2. Patient-reported symptoms. HBO2 = hyperbaric oxygen therapy.

There was a complete response rate (resolution of haematuria) in 33 patients (61%) while 21 patients (39%) reported ongoing haematuria following hyperbaric treatment. Of the patients with ongoing haematuria, further treatment was required in 14 patients (26%). Five patients had further HBO2 (9%), two had fulguration (4%), three had formalinisation of the bladder (6%), two had prostatic artery embolization (4%) and five had urinary diversion (9%). For two of the patients who had urinary diversion, they had had additional treatment prior to urinary diversion as well. One of the patients had fulguration and formalin prior to their diversion and the second one had just fulguration.

4. Discussion

HBO2 for the treatment of radiation cystitis showed a significant reduction in symptom severity and anxiety with a complete response rate of 61%. However, it is important to note that there were seven patients (13%) that did not require any further treatment despite having haematuria, which can be considered a partial response. A partial response rate is still clinically significant for patients if they can avoid using the healthcare system and having more invasive treatment. For patients with significant symptoms after HBO2, a decision as to which further treatment was performed would have been decided by the patient and the treating clinician, which was to have further HBO2 in four of the patients.

This response rate is comparable to an average complete response rate of 65% reported in a systematic review completed by Villeirs et al. in 2019 which included 20 studies with a cohort of 815 patients [12]. However, this study had a very different population, with only 59% of this population receiving radiotherapy for prostate cancer. The largest study in this systematic review was by Oliveira et al. in 2015 which included 176 patients; however, only 32% of patients had received radiotherapy for prostate cancer [13]. As the study included patients receiving radiotherapy for other causes, the age demographic, gender, and radiation doses were more variable. Of the 20 studies included, 16 were retrospective studies, three were prospective and one was a randomised controlled trial.

A study by Liss et al. in 2013 looked only at 22 patients who had received HBO2 for prostate cancer specifically, which reflects the study of this population as it was almost entirely prostate cancer [14]. The average age was 75, which is comparable to this study's average population of 74. Their study found that 50% of men had resolution of symptoms following HBO2 with 23% going on to have urinary diversion [14]. Another study by Nakada et al. in 2012 looked at long-term outcomes of HBO2 for patients receiving radiotherapy for prostate cancer in 48 patients [15]. The average age was 67, slightly younger than the 74 in this study. This study reported a 95% rate of complete resolution following HBO2 with no one needing a urinary diversion [15]. The small sample sizes in these studies may be the reason for the variable results, as well as different radiotherapy target zones, radiotherapy dosage, variable HBO2 regimes and timing of administration of HBO2. The heterogeneity of results does highlight the lack of understanding known regarding which factors will impact the response to HBO2 and the requirement for larger, randomised controlled studies to be conducted.

Although the pathophysiology of radiation cystitis is known theoretically, it can be challenging clinically to definitively diagnose someone with radiation cystitis. Current recommendations are that it is effectively a diagnosis of exclusion in patients with intractable haematuria who are suspected to have radiation cystitis (i.e., they have had previous pelvic radiotherapy), with the use of clinical assessment, imaging and cystoscopy to exclude other causes of haematuria [16]. Similarly, this makes it difficult to determine if a treatment has been successful in treating the underlying pathology. For this reason, this study was designed to determine the subjective improvement of patients with regard to their symptoms and anxiety from those symptoms. It is difficult to determine an exact level of improvement that would suggest HBO2 had successfully treated a patient; however, a clear reduction in symptom severity, anxiety, and reduction in utilisation of the healthcare system is clinically significant.

Another reason for the heterogeneity of outcomes for HBO2 is due to lack of a standardised questionnaire or objective assessment. There are several scores that exist to evaluate haematuria, which, while they may be a useful adjunct to the assessment, have their own limitations. In the systematic review mentioned above, the RTOG (Radiation Therapy Oncology Group) score was the most used questionnaire, used in four of the studies included [14,17–19]. The SOMA (Subjective, Objective, Management, Analytic) score and CTCAE (Common Terminology Criteria for Adverse Events) score were used three times, EORTC (European Organisation for Research and Treatment of Cancer) score two times, the Expanded Prostate Index Composite score once, ASTRO (American Society for Therapeutic Radiology and Oncology) score once and a modified Parsons questionnaire once [9,13,15,20–32]. The remainder of the studies included used clinical assessment, either based off symptomatology or categorising patients into symptoms resolved, partially resolved, or not resolved. In this study, an anxiety score was included to demonstrate the psychological impact that is often associated with recurrent haematuria and clot retention. With the clear lack of agreement on the best form of assessment to use, moving forward, a standardised questionnaire would provide more robust evidence. We did not use a standardised score for this study. Our decision not to use a previously described scoring system was driven by our focus on quality of life and patient-centred satisfaction, which we thought was a significant factor that had not previously been thoroughly investigated.

Our questionnaire also included a focus on healthcare utilisation in the form of GP and ED visits, which is a novel outcome measure in the setting of radiation cystitis.

There are several other limitations to this study. Unfortunately, of the 89 patients who underwent HBO2, only 54 patients completed the questionnaire, which was either due to the patient having passed away or us being unable to get in contact with the patient. We acknowledge that this may introduce a degree of selection bias to our study, but we believe the data we have provided on quality of life is a valuable addition to the literature, nonetheless. Additionally, a large proportion of patients in this cohort did not receive their radiotherapy at our institution. It was common for patients to have their radiotherapy in a private setting or interstate, meaning the data on their primary pathology, previous surgeries, comorbidities, and other complications from radiotherapy was not accessible. The time between completing the HBO2 and performing the questionnaire was variable, which has an unknown impact on these results. Whilst over time some patients may develop haematuria again, the HBO2 could still be considered a successful treatment regardless of the time period if the haematuria had improved temporarily. It would have also been useful to include a consistent timeframe for the pre- and post-HBO2 patient-reported outcomes on their GP and ED visits. This is an inherent limitation of the retrospective nature of our study and could be addressed in future by having pre-defined time points to complete the questionnaire. This was included as it was assumed the development of symptoms from radiation cystitis would lead into commencing HBO2 at a reasonably similar timeframe to the duration of time to complete the questionnaire, which was 574 days. The low number of GP and ED visits after HBO2 seems to demonstrate a positive response over a clinically significant period of time.

This study was a retrospective study, which can result in bias of the patients' answers. The fact that pre-HBO2 and post-HBO2 questionnaires were performed at the same time, with the treatment pre-dating the questionnaire by up to 6 years, this introduces an element of recall bias that could confound the findings of this study. Although this study was retrospective, it has demonstrated a positive response from patients regarding the safety and efficacy of HBO2 for radiation cystitis. With the ongoing requirement of patients at this institution requiring treatment for radiation cystitis, a prospective study and database with a pre-treatment and post-treatment questionnaire will be commenced to provide more robust evidence of the efficacy of HBO2. An additional possibility would be the implementation of a double-blind crossover study design in which the patient undergoes two sets of HBOT with half having placebo first and treatment second with the order reversed in the other half of the cohort. Surveys could be performed pre-treatment and after each set of treatments. This would help understand the normal time course of symptoms and would allow for the interrogation of a possible placebo effect.

5. Conclusions

HBO2 was a safe and effective treatment for radiation cystitis in this population. There was a complete response rate in 61% of patients. Patient-reported outcomes demonstrated a significant reduction in both severity of symptoms and anxiety. HBO2 was a safe treatment option with no patients reporting long-term adverse effects.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Human Research Ethics Committee at the Central Adelaide Health Network. Reference number: 20252, 9/10/24.

Informed Consent Statement: This was accepted as a quality improvement project and waiver of consent approved by our HREC. Formal consent was obtained over the phone at the time the interview was performed.

Data Availability Statement: The data supporting this study is available on application to the corresponding author, T.M. Data is not publicly available to protect patient privacy.

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Conflicts of Interest: The authors declare no conflicts of interest.

Appendix A. Data Collection Questionnaire

We are doing a review of patient outcomes following hyperbaric oxygen treatment for radiation cystitis. Would you be happy for me to ask you a few questions?

1. Severity of symptoms prior to HBO2 from a scale of 1–10?
2. What symptoms did you experience?
    a. Haematuria
    b. Dysuria
    c. Frequency
    d. Suprapubic pain
3. How would you rate your anxiety regarding your symptoms prior to HBO2 from 1–10?
4. Prior to HBO2, have you ever presented to your GP with haematuria? If so, how many times did you present?
5. Prior to HBO2, have you ever presented to an ED with haematuria? If so, how many times did you present?
6. Did you experience any complications from hyperbaric therapy? And if so, have they now resolved? How long did they last for?
    a. This is a list of possible side effects
    b. Middle ear barotrauma (ear pain, difficulty with ear equalisation, ruptured membrane)
    c. Sinus barotrauma (pressure over sinuses)
    d. Dental barotrauma
    e. Pulmonary barotrauma (bronchospasm)
    f. Oxygen toxicity
    g. Ocular side effects
    h. Convulsions
7. On a scale of 1–10, how uncomfortable did you find receiving hyperbaric?
8. Severity of symptoms after HBO2 from a scale of 1–10?
9. What symptoms have you experienced?
    a. Haematuria
    b. Dysuria
    c. Frequency
    d. Suprapubic pain

10. How would you rate your anxiety regarding your symptoms after your HBO2 from 1–10?
11. After HBO2, have you ever presented to your GP with haematuria? If so, how many times did you present?
12. After HBO2, have you ever presented to an ED with haematuria? If so, how many times did you present?
13. Have you required any additional treatment?

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