

A cost-analysis case study of radiation cystitis treatment including hyperbaric oxygen therapy

David Smart and Margaret Wallington

Abstract

(Smart D, Wallington M. A cost-analysis case study of radiation cystitis treatment including hyperbaric oxygen therapy. *Diving and Hyperbaric Medicine*. 2012;42(2):92-97.)

Aim: To undertake an economic analysis of the direct costs of treating radiation cystitis from a purchaser perspective, comparing conservative, non-operative and surgical interventions with hyperbaric oxygen treatment (HBOT).

Methods: A male in his 60s with prostatic carcinoma consented to this study. Full details of treatment costs in AUD were obtained (AUD 1.0, approx. EUR 0.6). A detailed patient diary accurately cross-referenced the consultations, investigations, admissions and treatment. Costs were recorded on a spreadsheet, dated and grouped under eight major headings related to treatment. Costs were compared for radiation cystitis treatment pre- and post-HBOT, to calculate savings or losses.

Results: The study covered three years (including 2.5 years post successful HBOT). Costs prior to HBOT (139 days) were AUD32,571.42 at an average of AUD231.09 per day, 70% from inpatient fees. Direct HBOT costs were AUD12,014.95 for 38 treatments, AUD316.18 per treatment. Post-HBOT (897 days), healthcare costs were AUD17,113.42 (AUD19.08 per day), with no emergency admissions. HBOT reduced costs of inpatient admissions, consultations, investigations and procedures and provided a projected healthcare saving of AUD187,483.96 over a 2.5 year follow up.

Conclusions: The cost of HBOT compared favourably against other costs, and HBOT may provide major health cost savings in this condition. There are significant hidden costs associated with radiation cystitis, not apparent to health funders, because the reasons for admissions and procedures are not easily captured with current information systems.

Key words

Hyperbaric oxygen therapy, soft-tissue radionecrosis, irradiation, injuries, economics, case reports

Introduction

With an ageing population and finite resources, the cost of health care has been very much in the spotlight and hyperbaric oxygen treatment (HBOT) has not escaped scrutiny.¹⁻³ Health technology assessments (HTAs) undertaken by the Federal Government's Medical Services Advisory Committee have reported on the costs of HBOT in a negative way, indicating that there was little evidence that HBOT was cost-effective for two conditions: soft tissue radiation injury and refractory non-diabetic problem wounds. The report (MSAC 1054) concluded: "*The clinical evidence was inadequate to substantiate claims that HBOT was cost-effective in the treatment of refractory soft tissue radiation injuries or non-diabetic refractory wounds*".⁴

The costs of HBOT in the Australian setting were documented from a provider perspective by Gomez-Castillo and Bennett.⁵ Despite detailed analysis of HBOT costs, the costs of 'standard care' for many of the conditions referred for HBOT is unknown. Referrals may occur after months or years of standard care. Standard care may involve dressings, bandages, lotions or antibiotics for problem wounds, and may include inpatient and more complex treatments (including surgical procedures) for wounds and radiation injury. To undertake a cost study of a population receiving HBOT compared to standard care is challenging, particularly when standard care may be spread around multiple providers and multiple geographic locations, in the community and as both outpatients and inpatients. In addition, it is not

possible to search the Medicare schedule to identify costs of treating a specific disease, because very few Medicare item numbers are linked by detailed description to a disease process or diagnosis.

Measurement of healthcare costs can be indirect or direct. Indirect measurement of costs may be derived from administrative databases or other published healthcare studies. More precise data may be obtained from direct measurement or observation.⁶ When assessing healthcare cost, it is important to document from which viewpoint the cost is being assessed. This is known as the 'perspective'.⁷ The perspective dictates the range of cost elements included in a cost analysis. Various economic perspectives have been documented: those of the provider (clinicians), the purchaser (Medicare and insurance companies), the patient and society. Provider costs involve detailed analysis of all costs associated with delivery of a service to calculate a 'per patient' or 'per treatment' cost. Purchaser costs are calculated by the amount the purchaser pays for treatment of a clinical condition during an episode or episodes of care. Patient costs may involve additional costs to those paid by the purchaser such as medications, incontinence pads, dressings, transport and loss of wages. In addition there is often a significant non-financial cost to the individual patient owing to lost quality of life.⁸ Finally, costs to society may include the need to replace or retrain individuals if they suffer poor health and are no longer able to perform their work. This may also include payment of sickness benefits.

Aim

This paper reports on a detailed economic analysis of the direct costs from the purchaser's perspective over a three-year period of treatment of a single patient with radiation cystitis, comparing conservative, non-operative and surgical interventions with HBOT.

Case report

Mr X, a man in his 60s, was diagnosed with an early, localised carcinoma of the prostate in September 2003. He was initially treated with a radical prostatectomy in October 2003. There was evidence of slowly progressive biochemical recurrence during 2004, thought due to early local microscopic recurrence. In November 2004, radical external beam radiotherapy to the tumour bed was initiated (66 Gray in 37 fractions). Recovery from this treatment was uneventful, resulting in a complete biochemical response.

There were no other health issues until early February 2006, when Mr X required two inpatient admissions for clot retention and urethral obstruction totalling seven days. Cystoscopy demonstrated radiation cystitis, and bleeding areas were photocoagulated. Further clot obstruction occurring in late February necessitating a bladder washout and diathermy (single-day admission) and long-term urethral catheter insertion. He was referred for HBOT treatment in early March, but was unable to pressurise because of long-standing sinus blockages. This was assessed with a CT scan, then ENT referral for remedy, pending return for HBOT. While waiting for sinus surgery, he had two further admissions for haematuria with clot obstruction, two admissions for systemic sepsis (total 10 days as inpatient), and one extended emergency department visit for sepsis. Septoplasty, medial meatal antrostomies and intranasal ethmoidostomies were performed in mid-May (three inpatient days). After discharge and until mid-June, Mr X had five further visits to hospital with haematuria and urological complications, including two admissions (and one episode of sepsis for seven days). Hence, prior to HBOT, Mr X had nine inpatient admissions to treat complications from the radiation cystitis including one ICU admission. The non-HBOT admissions resulted in 26 inpatient days, and four prolonged emergency attendances out of a total of 139 days. During the active period of haematuria, Mr X's haemoglobin fell from 150 g L⁻¹ to 130 g L⁻¹; transfusion was not required.

In mid-June 2006, HBOT was commenced when Mr X still had macroscopic haematuria. Thirty-eight treatments were administered over 60 days. By Day 21, macroscopic haematuria was no longer discernible. By Day 23, the urinary catheter was removed. HBOT was completed in mid-August 2006. Admission for a check cystoscopy two weeks later demonstrated all bleeding had stopped. Post-cystoscopy, there was no further bleeding. Routine medical follow up

continued to occur, and a check cystoscopy was performed in October 2008. This showed no signs of cancer and minor remaining evidence of radiation cystitis. From October 2008 to 31 January 2009, Mr X received consultations, routine blood tests and had no admissions to hospital.

QUALITY OF LIFE ISSUES

During the 897 days of follow up on Mr X post-HBOT, he remained well with no episodes of recurrent haematuria or cystitis. His personal medical diary demonstrated that the intervention of HBOT resulted in many positive health outcomes and improved quality of life including:

- prolonged (2.5 years) freedom from haematuria;
- no admissions to hospital for complications of radiation cystitis during 2.5 years' follow up;
- no further requirement for a urinary catheter, which was possibly a permanent requirement prior to commencing HBOT, having remained in situ for 134 out of a possible 155 days from commencement of haematuria;
- no further distress with urinary retention or catheter blockage;
- no further emergency presentations or surgery with its associated risks.

Methods

The study period covered from 01 February 2006 to 31 January 2009. It commenced one week prior to onset of macroscopic haematuria, covered the duration of the illness, and extended for almost 2.5 years after completion of HBOT. Mr X provided full consent for his case history to be published including analysis of the costs of his health care. He assisted with data collection by obtaining printouts of treatment costs from Medicare and his private health fund for the study period. These records also documented gap payments made by or on behalf of the patient. As part of a life-time habit, Mr X kept a detailed diary of his symptoms and the reasons for all medical care. This diary allowed cross-referencing of his clinical status with reimbursements paid by Medicare and health funds (including gap fees), and ensured accurate assignment of treatment costs to appropriate category headings. All non-HBO treatments were delivered in the private sector in the State of Tasmania, Australia. Mr X was treated as a private patient at the Royal Hobart Hospital hyperbaric facility. The study did not include patient transport costs, medication costs or consumables purchased by the patient in the community. Actual costs directly paid by Medicare and his private health fund were included. Costs were entered into a Microsoft Excel® spreadsheet, by date and grouped under eight major headings:

- hyperbaric oxygen consultations and treatment costs;
- hyperbaric gap payments;
- hyperbaric other costs (e.g., procedures/treatments to support HBOT);
- consultations not related to HBOT;
- procedures not related to HBOT;

Table 1
Costs for cancer-related and non-cancer-related care excluding HBOT-related costs (all figures in AUD)

Time period	Consults	Procedures	Private GAP	Private pathology + X ray	Private hospital (incl. OR fees)	TOTAL
Start of study to completion of HBOT (199 days)	2,406.40	2,347.76	3,845.65	1,408.55	22,563.06	32,571.42
Post-HBOT to end of study (897 days)						
Cancer-related	2,543.75	827.65	4,337.25	2,460.89	4,662.48	14,832.22
Non-cancer-related	734.60	226.45	440.30	121.05	759.00	2,281.40

- private gap fees not related to HBOT;
- private X-ray and pathology costs not related to HBOT;
- private hospital inpatient costs.

METHOD OF CALCULATION OF COSTS

Costs were calculated in Australian Dollars (AUD); for the period of the study, AUD1.0 was approximately €0.6. Costs were split into three time periods: before HBOT, during HBOT and after HBOT. Costs were further subdivided into non-HBOT (cancer and non-cancer related), and HBOT-associated costs. This enabled any additional therapy for the radiation cystitis administered during HBOT to be detected, and costs unrelated to cancer to be separated. All costs of other treatments (for example ENT surgery) to support HBOT were included in the HBOT costs.

A further calculation was made of the cost of all treatment delivered for the period after HBOT. The point at which HBOT was completed (18 August 2006) was defined as the index date, for the purposes of calculating pre- and post-HBOT costs. For the two time periods, pre- and post-HBOT, the medical costs per day were calculated by dividing the total cost by the number of days. The predicted post-HBOT cost was calculated by multiplying the daily cost pre-HBOT by the number of days post-HBOT. Daily costs were then compared pre-and post-HBOT.

NON-HBOT MEDICARE PROCEDURE CODES

During the course of the study, procedural services were provided under 17 Medicare Procedural Item Numbers.* None of these item numbers were directly traceable to an episode of radiation cystitis, unless the admission episode and the diagnosis-related group (DRG) were also searched simultaneously. In addition, procedures required to allow the patient to receive HBOT (to correct previously undiagnosed paranasal sinus disease) were provided under six more Medicare codes.

Results

During the period before HBOT (139 days), Mr X had nine admissions totalling 26 inpatient days (one day spent in hospital every 5.4 days) as a result of his radiation cystitis. HBOT was administered as 38 treatments over 60 days. The time period from study commencement to completion of HBOT was 199 days. The study time period post-HBOT was 897 days.

COSTS PRE-HBOT

Prior to commencing HBOT, Mr X incurred AUD32,120.82 non-HBOT treatment costs (AUD231.09 per day over 139 days). While receiving HBOT, there was an additional AUD450.60 in non-HBOT related consultations (AUD157.85), pathology fees (AUD100.45) and gap fees (AUD192.30), which totalled only 1.4% of the non-HBOT costs. Total non-HBOT costs at the completion of HBOT were AUD32,571.42 (AUD163.68 per day over 199 days). Table 1 shows the non-HBOT patient treatment costs incurred before and until completion of HBOT. During this period, all costs were for treatment of radiation cystitis or cancer follow up. Figure 1 summarises the percentage breakdown by cost category. Prior to commencing HBOT, hospital admission fees made up 69% of all medical costs.

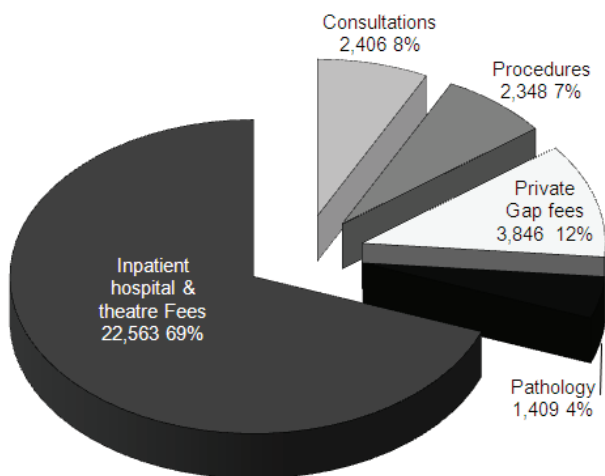
COSTS OF HBOT

HBOT costs were AUD12,014.95 in 38 treatments, spread over 60 days or AUD316.18 per treatment (Medicare AUD216.15 with private gap AUD100.03). The cost of sinus surgery (AUD7,788.82) was added to the HBOT costs, (a pre-existing condition but required in order to undertake HBOT). This increased the total cost to enable the patient to receive HBOT to AUD19,803.77. When receiving HBOT, there were no further admissions to hospital for radiation cystitis complications. Hence for the 199 days from start of study to completion of HBOT, the treatment costs for Mr X were:

* **Footnote:** Medicare Procedural Item Numbers used: 20120H, 20160H, 20810H, 20910H, 31210, 32090H, 34528H, 36800, 36812H, 36840H, 37318H, 55113H, 56507, 56507H, 58503, 58503H, 58706H.

Figure 1

Actual and percentage non-HBOT costs (AUD) over 199 days in a patient with post-radiation haemorrhagic cystitis



- All alternative treatments (unsuccessful), including 9 hospital admissions, one ICU admission, long-term urinary catheterisation, multiple procedures (including surgical and diathermy), and investigations: Pre-HBOT cost = AUD32,571.42.
- HBOT (successful), including admission for sinus surgery prior to HBOT, and associated investigations and consultations: HBOT cost = AUD19,803.77.

COSTS POST-HBOT

Table 1 summarises the costs of non-HBOT care, split by cancer-related costs and other medical costs. For the purposes of the study, all treatment costs (including those not related to radiation cystitis) were included, to ensure there was no bias in data collection. The other medical costs included minor surgery for a sebaceous cyst, and routine general practice consultations. The only HBOT-related cost after completion of the course was a single review consultation a year later.

The total cost post-HBOT of AUD17,113.62 was 53% of the pre-HBOT cost for a period 6.45 times as long (897 days vs. 139 days), at an average of AUD19.08 per day, or 8.3%

of the pre-HBOT cost per day. Of the post-treatment costs, AUD14,832.22 (86.7%) was cancer related. Table 2 shows the numbers of consultations, procedures, and investigations before and after HBOT, with a significant reduction per 100 days post-HBOT ($P < 0.0001$ for all).

Discussion

These data have been derived directly from a detailed study of actual costs incurred by a single patient with radiation cystitis in an Australian setting. The authors are confident that the costs have been accurately assigned to the correct disease category, because the patient documented his life events over the course of the illness. Printouts from Medicare and his private health fund were also classified by date and provider, and contained a description of the service that had been reimbursed. Direct measurement of these raw data provided more accurate assessment of costs from a purchaser perspective than if modelling had occurred based on DRG, or per occasion of service. Previous HBOT cost-effectiveness studies have been based on modelling and hypothetical patients, or administrative databases, rather than prime source data, and they have not been linked to comparator treatments of the relevant clinical conditions.^{2,9,10}

This case study demonstrates that there may be significant hidden costs in the treatment of radiation cystitis, none of which are easily identified. The reasons for admissions and procedures are not easily captured and linked to the Commonwealth Medicare Benefits Schedule item numbers with current information systems. An admission diagnosis of haematuria or urinary retention may have multiple aetiologies. Hence it may be difficult to track a patient over the time course of their specific clinical condition. The analysis of this case was assisted considerably by the patient’s detailed personal diary.

The cost of HBOT compared favourably against costs of preceding unsuccessful treatments, which required multiple admissions. Standard treatments, including surgical diathermy, had not been successful in arresting this patient’s haematuria prior to commencement of HBOT. There was a clear cause-and-effect relationship between onset of HBOT and the cessation of bleeding (and catheter removal). This is consistent with available knowledge of the beneficial

Table 2

Comparison of pre- and post-HBOT numbers of consultations, procedures and investigations per 100 days in a patient with post-radiation haemorrhagic cystitis; * $P < 0.0001$ for pre-/post-HBOT items

Time period	Consultations	Procedures	Investigations X-rays + pathology
Before HBOT (all cancer related)	59	14	61
Number per 100 days*	29	7	31
After HBOT	64	14	67
Cancer related	49	13	59
Number per 100 days*	7	2	7

effect of HBOT in late soft-tissue radiation injury, which suggests upward of three quarters of such patients are likely to benefit from HBOT.¹¹⁻¹⁴ Most other treatments (surgical or non-surgical) are directed at symptom control and do not influence the underlying pathophysiology of radiation cystitis. In contrast, HBOT has been shown to reverse the pathophysiology of radiation tissue injury.¹¹ A Cochrane review has investigated non-surgical interventions such as alum, formalin and placental extract bladder instillations, and systemic therapies such as pentosan polysulphate, tetrachlorodecaoxide, and oestrogens and pentoxifylline.¹⁵ The review was inconclusive regarding the efficacy of any of these treatments.

This case also demonstrates the positive impact on patient wellbeing and quality of life after successful HBOT, to a follow-up of 2.5 years. However, there are some limitations to the report. The economic perspective is that of a purchaser of healthcare services (Medicare and private insurers + gap fees), and does not include patient-related costs such as transport, medications and other consumables. Despite the detailed analysis, this is a single case, and the results cannot be generalised. However, the methodology should provide the basis to undertake more detailed study of a larger series in a prospective manner. Mr X suffered a high number of complications from his disease, and may have experienced a severe form of radiation cystitis. However, this story is fairly typical of such patients referred for HBOT, and who have often failed a variety of other treatments before their referral.¹³ Radiation cystitis may affect 5 to 10 per cent of individuals receiving pelvic radiotherapy for cancer and, once established, tends to be progressive.¹⁵

The patient's HBOT course was also atypical. Sinus barotrauma occurred in only 11 cases in 24,731 Australian hyperbaric patient treatments in 2008 (unpublished data). The need to undertake surgery for his pre-existing problem is even less common. Even inclusive of sinus surgery, the cost of HBOT was 60.8% of all other preceding treatment for radiation cystitis, and it succeeded in stopping the bleeding when other treatments had failed.

Before HBOT was instituted, Mr X was incurring an average daily treatment cost of AUD231.09. There was no sign that his disease process was being controlled. If this had continued, the total cost for the 897 days of follow up this patient received after cessation of HBOT would have been AUD207,287.73. Therefore, the expenditure of AUD19,803.77 for HBOT provided a potential (theoretical) saving of AUD187,483.96, and resulted in successful remission of manifest disease symptoms for a 2.5 year period, with a leveraged cost-advantage factor of 9.5. The success of HBOT was supported by a significant reduction in the number of consultations, procedures and investigations required post treatment. Without the successful intervention provided by HBOT, it is likely that Mr X may have suffered major complications from radiation cystitis, or required

radical surgical intervention such as total cystectomy, with a severe negative impact on his quality of life. Although cost-effectiveness cannot be calculated from a single case, there was a cost saving of AUD12,767.65 when comparing cost of HBOT with preceding treatments, which had been ineffective. The average cost of HBOT of AUD316.18 per treatment, compares closely to that of AUD311.00 calculated from a provider as opposed to a funder perspective using a comprehensive modelling technique.⁵

The major costs of standard treatment for Mr X prior to HBOT resulted from hospital bed fees and theatre charges (69%, Figure 1). Post-HBOT no further hospital admissions were required for complications of radiation cystitis, and costs of inpatient cancer-related follow up fell to 31% of all costs (Table 1). Despite the considerable reduction in healthcare costs post-HBOT following successful remission of radiation cystitis, 87.1% of all Mr X's healthcare costs, and the majority of consultations, procedures and investigations were still attributable to his original cancer. This demonstrates that even in remission, cancer has a major impact on healthcare costs. It is also noteworthy that, with a greater amount of care delivered in the outpatient setting, Mr X had a higher percentage of out-of-pocket gap fees (29%) in the follow-up period.

In 2009-10, there were 1,355 separations in Australia for diagnosis N30.4-irradiation cystitis, occupying just under two bed days per separation.¹⁶ This may be an underestimate because presentations due to urosepsis, haematuria and bladder obstruction due to clots may not be linked to radiation cystitis. HBOT has potential to reduce requirements for hospital admission, leading to major cost savings for health services and improvement in quality of life for patients.

Conclusions

This study demonstrates the complexity of calculating healthcare costs for late soft-tissue radiation injury. The cost of standard treatment for soft-tissue radiation injury has not been previously studied, and may be much higher than generally appreciated. In this patient, HBOT was clinically effective in resolving complications from radiation cystitis, and had lower costs than other unsuccessful treatments. Further investigation in a prospective study of multiple patients is warranted.

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Submitted: 01 September 2011

Accepted: 10 April 2012

David Smart, BMedSci, MBBS(Hons), MD(UTas), FACEM, FIFEM, FAICD, FACTM, Dip DHM, Cert DHM (ANZCA), is a Clinical Associate Professor in the University of Tasmania and Co-Director of the Department of Diving and Hyperbaric Medicine, Royal Hobart Hospital. Margaret Wallington, BSc, MBBS, FRANZCR, MRCP(UK), PGCertGerMed, is retired Senior Specialist in Radiation Oncology, WP Holman Clinic, Royal Hobart Hospital.

Address for correspondence:

David Smart

*C/- Department of Diving and Hyperbaric Medicine
Royal Hobart Hospital
Liverpool Street, Hobart, Tasmania 7000
Australia*

Phone: +61-(0)3-6222-8193

Fax: +61-(0)3-6222-7268

E-mail: <david.smart@dhhs.tas.gov.au>

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