The Australasian Prospective Wound Care Study: Year Six Data

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Introduction

In 2004 the Medicare Services Advisory Committee (MSAC) requested that the Australian and New Zealand Hyperbaric Medicine Group (ANZHMG) produce evidence from a prospective assessment of long term wounds that are treated with hyperbaric oxygen therapy (HBOT). For government funding to continue, the ANZHMG needed to prove that the outcomes from hyperbaric oxygen therapy were better than standard treatment in a prospectively enrolled trial. Initial findings were presented at the UHMS meeting in 2005 after 18 months of data.

The current study is the data collected for the first six years of this ongoing study.

Method

All patients presenting to Hyperbaric Medicine Facilities in Australia and New Zealand were eligible for the study. Specific inclusion criteria for the study included:

1) The wound had to have been present for more than 3 months
2) The wound could not be due to malignancy or radiotherapy
3) The patient consented in writing to be part of the study under the auspices of the local ethics committee.

Prior therapy, demographic data and risk factors were all collected on a Filemaker Pro database and wound care was determined by the treating doctor at the site.

Outcome scores were assessed using a validated six point outcome scale (see below) at four time periods; at the end of HBOT, 1 month post HBOT, 6 months post HBOT and 12 months post HBOT

CLINICAL DESCRIPTION	CATEGORY	OUTCOME	DESIGNATED OUTCOME
HEALED	6	HEALED	GOOD OUTCOME
SUBSTANTIALLY HEALED	5		
IMPROVED BUT MINOR AMPUTATION	4	SOME IMPROVEMENT	POOR OUTCOME
MINIMAL BENEFIT BUT MINOR AMPUTATION	3		
NIL BENEFIT AND MAJOR AMPUTATION	2	NO IMPROVEMENT	
DECEASED	1		

Results

Currently 441 patients have been enrolled into the study. Of the 441 initially enrolled, 355 have received at least 5 hyperbaric oxygen treatments.

DEMOGRAPHIC DATA:

	HBOT (>5 TREATMENTS)			NO HBOT (≤5 TREATMENTS)		
NUMBER	355			86		
M:F RATIO	196M:159F			46M:40F		
	MEAN	*S.D.*	*RANGE*	*MEAN*	*S.D.*	*RANGE*
AGE (YEARS)	69.29	13.96	18-96	69.17	14.79	11-94
WOUND DURATION (MONTHS)	19.94	35.05	3-360	14.32	23.28	3-156
WOUND SIZE (cm^2)	18.20	31.06	0.05-216	26.90	35.40	0.09-156

Table 2: Demographic data of the two groups
(S.D. =Standard Deviation of the Mean, M = Male F = Female)

OUTCOME DATA:
Outcome data for all aetiologies combined is shown in Table 3.
Table 4 shows the percentage of those that have had a 'Good Outcome' (outcome scores of 5 or 6) at each assessment stage broken down by the four main aetiological groups. The four main aetiological groups identified as the cause of the long term wound being assessed for are: Diabetes Mellitus (DM), Peripheral Vascular Disease (PVD), Venous Disease (VEN) and Miscellaneous Causes (MISC). Miscellaneous causes include the aetiologies that have small numbers and separate analysis would not be statistically significant for that group.

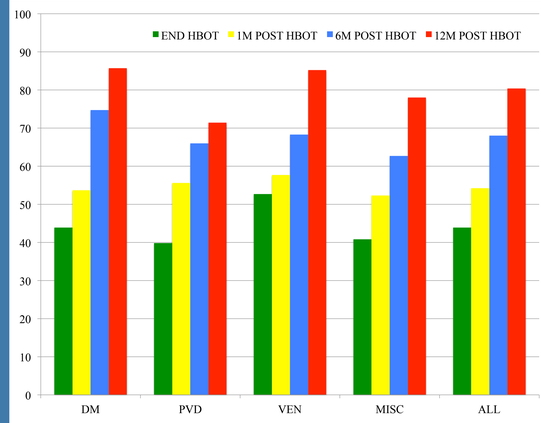
	END OF HBOT	1 MONTH POST HBOT	6 MONTHS POST HBOT	12 MONTHS POST HBOT
NUMBER FOR ASSESSMENT	346	306	241	163
GOOD OUTCOME (SCORE 5 OR 6)	152 (43.9%)	166 (54.2%)	164 (68.0%)	131 (80.4%)
POOR OUTCOME (SCORE 1-4)	194 (56.1%)	140 (45.8%)	77 (32.0%)	32 (19.6%)
MISSING DATA*	9	49	114	192

Table 3: Outcome data for all aetiologies.
**Missing data includes people lost to follow up and people who have not reached their assessment stage*

AETIOLOGY	NUMBER	PERCENTAGE WITH 'GOOD OUTCOME'			
	(n)	END HBOT	1M POST HBOT	6M POST HBOT	12M POST HBOT
DM	128	43.9	53.7	74.7	85.7
PVD	89	39.8	55.6	66.0	71.4
VENOUS	57	52.7	57.7	68.3	85.2
MISCELLANEOUS	81	40.8	52.3	62.7	78.0
ALL AETIOLOGIES	**355**	**43.9**	**54.2**	**68.0**	**80.4**

Table 4: Outcome data for all aetiologies.
**Missing data includes people lost to follow up and people who have not reached their assessment stage*

Results



Graph 1: Percentage of people with a 'Good Outcome' grouped by aetiology and assessment time period.

There were some significant differences between the group that had HBOT versus the group that was not offered or declined HBOT with the non-HBOT group having larger wounds but for a shorter duration prior to presentation. The reason for their not being offered HBOT was unfortunately not recorded and further analysis was not pursued due to the possibility that HBOT was not offered as the treatment would have been futile or the assessment determined that HBOT would not be required for the management of the wound.

Conclusion

Long term wounds impose a large cost to health funding agencies such as Medicare in Australia. They are tasked to spend limited health funds in efficient and effective ways and have assessment committees such as MSAC to evaluate new technologies or new indications for existing technologies.
An assessment for the use of HBOT for long term, non-irradiated wounds was initiated, as this prospective study, to determine the effectiveness of HBOT to substantially heal significant wounds and to follow that group out to a 12 month period to gauge long term effectiveness. The six point outcome scale is easily applied and allows us to determine a real improvement in the persons wound. In fact we deliberately had overtly strict criteria such as calling even a small amputation as a failure of treatment even though the person may heal well and have a normal life post this 'minor' surgical intervention.

Even with that strict criteria in mind, despite patients having wounds for a mean duration of nearly 20 months and being, on average 18cm^2 in area, at 12 months, 80% of those people have either totally healed or healed significantly. This is ***regardless*** of the aetiology causing the problem.

The biggest percentage of patients that improved are not surprisingly the patients with diabetes mellitus and venous disease but even the most stubborn of aetiological groups with wounds have had 40% healed or substantially healed at the immediate end of HBO treatment.

We intend to further investigate the factors that predispose people to developing chronic long term wounds and also to see what ancillary treatments and diagnostic modalities (such as transcutaneous oximetry) may be useful in determining what patients will benefit the most from HBOT and what patients may not be suitable for the initiation of HBOT.

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