

# THE LANCET **Oncology**

## **Supplementary appendix**

This appendix formed part of the original submission and has been peer reviewed.  
We post it as supplied by the authors.

Supplement to: Glover M, Smerdon GR, Andreyev HJ, et al. Hyperbaric oxygen for patients with chronic bowel dysfunction after pelvic radiotherapy (HOT2): a randomised, double-blind, sham-controlled phase 3 trial. *Lancet Oncol* 2015; published online Dec 15. [http://dx.doi.org/10.1016/S1470-2045\(15\)00461-1](http://dx.doi.org/10.1016/S1470-2045(15)00461-1).

## Supplementary Tables and Figures to be added to the internet

**Table S1: IBDQ raw scores at baseline and 12 months**

	Control		HBO		Total		
	N	%	N	%	N	%	
<b>Baseline</b>	More than ever before	3	10.70%	8	14.50%	11	13.30%
	Extremely frequently	3	10.70%	6	10.90%	9	10.80%
	Very frequently	4	14.30%	8	14.50%	12	14.50%
	Moderate increase in frequency	3	10.70%	6	10.90%	9	10.80%
	Some increase in frequency	1	3.60%	5	9.10%	6	7.20%
	Slight increase in frequency	5	17.90%	7	12.70%	12	14.50%
	Not at all / normal	9	32.10%	15	27.30%	24	28.90%
	Total	28	100.00%	55	100.00%	83	100.00%
<b>12 months</b>	More than ever before	1	4.00%	4	8.30%	5	6.80%
	Extremely frequently	2	8.00%	1	2.10%	3	4.10%
	Very frequently	4	16.00%	3	6.30%	7	9.60%
	Moderate increase in frequency	3	12.00%	2	4.20%	5	6.80%
	Some increase in frequency	2	8.00%	4	8.30%	6	8.20%
	Slight increase in frequency	4	16.00%	12	25.00%	16	21.90%
	Not at all / normal	9	36.00%	22	45.80%	31	42.50%
	Total	25	100.00%	48	100.00%	73	100.00%

N.B. table includes all patients in ITT population

**Table S2: Exploratory endpoints of rectal bleeding. 2 sample tests of proportion of patients with improvement in symptoms between baseline and 12 months**

	<b>Control</b>	<b>HBO</b>	<b>Absolute difference</b>	<b>P-value</b>
	<b>n (%)</b>	<b>n (%)</b>	<b>% (95% CI)</b>	
IBDQ rectal bleeding question	10/15 (66.7%)	26/35 (74.3%)	7.6% (-20.3%, 35.5%)	0.58
Rectal LENT SOMA (objective)	12/16 (75.0%)	14/23 (60.9%)	-14.1% (-43.3%, 15.0%)	0.36
Rectal LENT SOMA (management)	5/5 (100.0%)	4/13 (30.8%)	-69.2% (-94.3%, -44.1%)	0.0085
CTCAE rectal bleeding	12/17 (70.6%)	13/22 (59.1%)	-11.5% (-41.4%, 18.4%)	0.46
EORTC QLQ-CR38 question 59	8/18 (44.4%)	17/29 (58.6%)	14.2% (-14.9%, 43.3%)	0.34

N.B. includes all patients included in the ITT population for whom rectal bleeding was present at baseline (according to each of the scales separately)

**Table S3: Recruitment by centre**

<b>Hyperbaric treatment centre</b>	<b>n</b>
London Diving Chamber, Hospital of St John and St Elizabeth, London	<b>24</b>
Hyperbaric Medicine Unit, St Richard's Hospital, Chichester	<b>15</b>
Whipps Cross University Hospital, Leytonstone, London	<b>11</b>
South Wales Hyperbaric Medical Centre (DDRC), Cardiff	<b>7</b>
North of England Medical and Hyperbaric Services, Spire Hull & East Riding Hospital, Kingston-upon-Hull	<b>6</b>
DDRC Healthcare, Plymouth	<b>6</b>
The Diver Clinic, Poole	<b>5</b>
Midlands Diving Chamber, Hospital of St Cross, Rugby	<b>4</b>
East of England Hyperbaric Unit, Lowestoft Road, Great Yarmouth	<b>3</b>
North West Emergency Recompression Unit, Murrayfield Hospital, Wirral	<b>3</b>
<b>Total</b>	<b>84</b>

**Table S4: Per protocol analysis of the primary endpoint**

<b>Primary endpoint 1: Bowel function component of the modified IBDQ</b>					
	Median (IQR) score at baseline	Median (IQR) score at 12 months	Median (IQR) change from baseline to 12m	Mann-Whitney test U Score	P-value
Control (n=22)	51 (44, 59)	51.5 (40, 59)	3.5 (-6, 9)	0.94	0.35
HBO (n=38)	48 (42, 51)	52 (36, 62)	4 (-2, 11)		
<b>Primary endpoint 2: rectal bleeding score from the modified IBDQ</b>					
	Median (IQR) score at baseline	Median (IQR) score at 12 months	Median change (from baseline to 12m)	Mann-Whitney test U Score	P-value
Control (n=11)	3 (2, 4)	4 (2, 6)	1 (1, 2)	1.44	0.15
HBO (n=25)	3 (2, 4)	6 (3, 7)	3 (0, 3)		

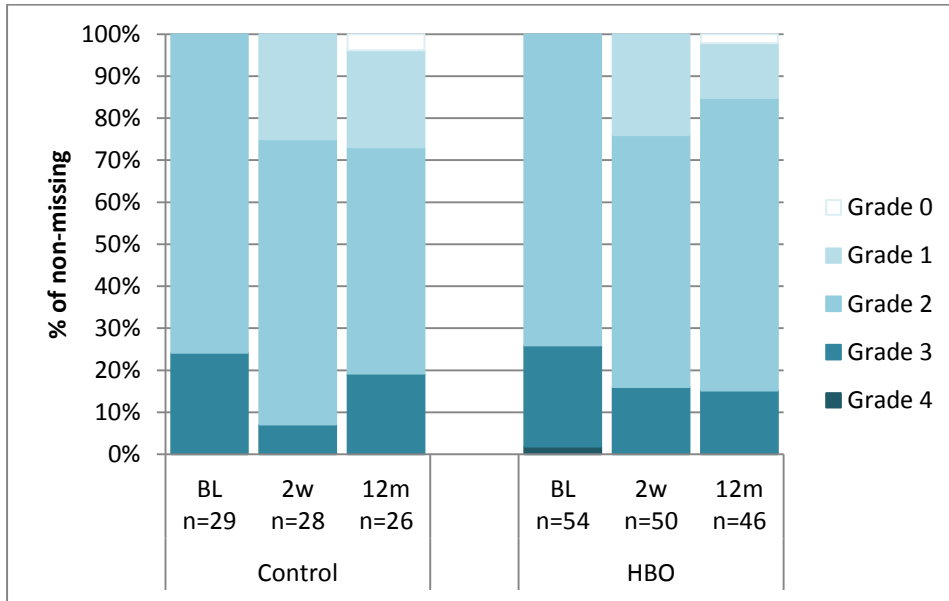
**Table S5: Exploratory analysis of LENT SOMA scales**

<b>Change in rectal LENT SOMA total score from baseline to 2 weeks</b>					
	Median (IQR) score at baseline	Median (IQR) score at 2 weeks	Median (IQR) change from baseline to 2 weeks	Mann-Whitney test U Score	P-value
Control (n=28)	<b>9.5 (8, 14.5)</b>	<b>8.5 (5.5, 14.0)</b>	<b>-2 (-3, 0)</b>	<b>0.35</b>	<b>0.72</b>
HBO (n=50)	<b>10 (7, 13)</b>	<b>8 (4, 12)</b>	<b>-2 (-3, 1)</b>		

**Table S6: Exploratory analysis of primary endpoint according to treatment with hood, monochamber or mask.**

<b>Bowel function in patients treated with a hood or monochamber</b>					
	Median (IQR) score at baseline	Median (IQR) score at 12 months	Median (IQR) change from baseline to 12m	Mann-Whitney test U Score	P-value
Control (n=14)	53 (43, 56)	54.5 (33, 59)	4 (1, 9)	-0.31	0.76
HBO (n=29)	48 (44, 54)	55 (36, 63)	2 (-7, 11)		
<b>Bowel function in patients treated with a mask</b>					
	Median (IQR) score at baseline	Median (IQR) score at 12 months	Median change (from baseline to 12m)	Mann-Whitney test U Score	P-value
Control (n=9)	51 (47, 59)	50 (47, 55)	1 (-8, 4)	1.59	0.11
HBO (n=17)	46 (35, 51)	49 (46, 55)	8 (1, 13)		

**Figure S1: Maximum CTCAE toxicities at each timepoint**



**Figure S2: CTCAE rectal bleeding grade at each timepoint**

