

A3.2: Number of patients with grade 0-4 intestinal LENT SOMA by toxicity at 2 weeks

			Control N=28		HBO N=50		Total N=78	
			N	%	N	%	N	%
Subjective	Stool frequency	0	6	21.4%	13	26.0%	19	24.4%
		1	18	64.3%	26	52.0%	44	56.4%
		2	4	14.3%	9	18.0%	13	16.7%
		3	0	0.0%	2	4.0%	2	2.6%
	Stool consistency	0	25	89.3%	42	84.0%	67	85.9%
		1	0	0.0%	2	4.0%	2	2.6%
		2	3	10.7%	5	10.0%	8	10.3%
		3	0	0.0%	1	2.0%	1	1.3%
	Pain	0	16	57.1%	22	44.0%	38	48.7%
		1	4	14.3%	10	20.0%	14	17.9%
		2	5	17.9%	14	28.0%	19	24.4%
		3	3	10.7%	3	6.0%	6	7.7%
		4	0	0.0%	1	2.0%	1	1.3%
Constipation	0	27	96.4%	49	98.0%	76	97.4%	
	1	1	3.6%	1	2.0%	2	2.6%	
Objective	Melena	0	26	92.9%	47	94.0%	73	93.6%
		1	2	7.1%	3	6.0%	5	6.4%
	Weight loss	0	26	92.9%	49	98.0%	75	96.2%
		Missing	2	7.1%	1	2.0%	3	3.8%
	Stricture	0	25	89.3%	49	98.0%	74	94.9%
		Missing	3	10.7%	1	2.0%	4	5.1%
	Ulceration	0	25	89.3%	49	98.0%	74	94.9%
		Missing	3	10.7%	1	2.0%	4	5.1%
Management	Pain	0	22	78.6%	35	70.0%	57	73.1%
		1	3	10.7%	11	22.0%	14	17.9%
		2	3	10.7%	3	6.0%	6	7.7%
		3	0	0.0%	1	2.0%	1	1.3%
	Stool consistency / frequency	0	10	35.7%	12	24.0%	22	28.2%
		1	11	39.3%	13	26.0%	24	30.8%
		2	6	21.4%	24	48.0%	30	38.5%
		3	1	3.6%	1	2.0%	2	2.6%
	Bleeding	0	25	89.3%	48	96.0%	73	93.6%
		1	3	10.7%	2	4.0%	5	6.4%
	Stricture	0	25	89.3%	50	100.0%	75	96.2%
		1	1	3.6%	0	0.0%	1	1.3%
		Missing	2	7.1%	0	0.0%	2	2.6%
	Ulceration	0	26	92.9%	50	100.0%	76	97.4%
Missing		2	7.1%	0	0.0%	2	2.6%	

A3.3: Number of patients with grade 0-4 intestinal LENT SOMA by toxicity at 12 months

			Control N=26		HBO N=46		Total N=72		
			N	%	N	%	N	%	
Subjective	Stool frequency	0	7	26.9%	8	17.4%	15	20.8%	
		1	12	46.2%	24	52.2%	36	50.0%	
		2	5	19.2%	11	23.9%	16	22.2%	
		3	2	7.7%	3	6.5%	5	6.9%	
	Stool consistency	0	22	84.6%	32	69.6%	54	75.0%	
		1	1	3.8%	3	6.5%	4	5.6%	
		2	3	11.5%	11	23.9%	14	19.4%	
	Pain	0	14	53.8%	20	43.5%	34	47.2%	
		1	3	11.5%	6	13.0%	9	12.5%	
		2	6	23.1%	15	32.6%	21	29.2%	
		3	2	7.7%	5	10.9%	7	9.7%	
		4	1	3.8%	0	0.0%	1	1.4%	
	Constipation	0	26	100.0%	46	100.0%	72	100.0%	
	Objective	Melena	0	25	96.2%	45	97.8%	70	97.2%
			1	0	0.0%	1	2.2%	1	1.4%
2			1	3.8%	0	0.0%	1	1.4%	
Weight loss		0	26	100.0%	46	100.0%	72	100.0%	
Stricture		0	26	100.0%	45	97.8%	71	98.6%	
		Missing	0	0.0%	1	2.2%	1	1.4%	
Ulceration		0	26	100.0%	45	97.8%	71	98.6%	
	Missing	0	0.0%	1	2.2%	1	1.4%		
Management	Pain	0	22	84.6%	36	78.3%	58	80.6%	
		1	2	7.7%	6	13.0%	8	11.1%	
		2	1	3.8%	2	4.3%	3	4.2%	
		3	1	3.8%	2	4.3%	3	4.2%	
	Stool consistency / frequency	0	11	42.3%	19	41.3%	30	41.7%	
		1	10	38.5%	8	17.4%	18	25.0%	
		2	5	19.2%	18	39.1%	23	31.9%	
		3	0	0.0%	1	2.2%	1	1.4%	
	Bleeding	0	26	100.0%	44	95.7%	70	97.2%	
		1	0	0.0%	2	4.3%	2	2.8%	
	Stricture	0	26	100.0%	46	100.0%	72	100.0%	
	Ulceration	0	26	100.0%	46	100.0%	72	100.0%	

A3.4 Maximum grade reported for each scale at baseline

Maximum grade at baseline		Control N=29		HBO N=55		Total N=84	
		N	%	N	%	N	%
Subjective	0	2	6.9%	3	5.5%	5	6.0%
	1	13	44.8%	10	18.2%	23	27.4%
	2	10	34.5%	28	50.9%	38	45.2%
	3	4	13.8%	14	25.5%	18	21.4%
Objective	0	23	79.3%	45	81.8%	68	81.0%
	1	3	10.3%	4	7.3%	7	8.3%
	2	2	6.9%	5	9.1%	7	8.3%
	3	1	3.4%	1	1.8%	2	2.4%
Management	0	8	27.6%	12	21.8%	20	23.8%
	1	8	27.6%	16	29.1%	24	28.6%
	2	11	37.9%	23	41.8%	34	40.5%
	3	2	6.9%	4	7.3%	6	7.1%

A3.5 Maximum grade reported for each scale at 2 weeks

Maximum grade at 2 weeks		Control N=28		HBO N=50		Total N=78	
		N	%	N	%	N	%
Subjective	0	5	17.9%	7	14.0%	12	15.4%
	1	11	39.3%	17	34.0%	28	35.9%
	2	9	32.1%	20	40.0%	29	37.2%
	3	3	10.7%	5	10.0%	8	10.3%
	4	0	0.0%	1	2.0%	1	1.3%
Objective	0	23	82.1%	46	92.0%	69	88.5%
	1	2	7.1%	3	6.0%	5	6.4%
	Missing	3	10.7%	1	2.0%	4	5.1%
Management	0	6	21.4%	11	22.0%	17	21.8%
	1	12	42.9%	14	28.0%	26	33.3%
	2	7	25.0%	23	46.0%	30	38.5%
	3	1	3.6%	2	4.0%	3	3.8%
	Missing	2	7.1%	0	0.0%	2	2.6%

A3.6 Maximum grade reported for each scale at 12 months

Maximum grade at 12 months		Control N=26		HBO N=46		Total N=72	
		N	%	N	%	N	%
Subjective	0	6	23.1%	5	10.9%	11	15.3%
	1	9	34.6%	16	34.8%	25	34.7%
	2	7	26.9%	19	41.3%	26	36.1%
	3	3	11.5%	6	13.0%	9	12.5%
	4	1	3.8%	0	0.0%	1	1.4%
Objective	0	25	96.2%	44	95.7%	69	95.8%
	1	0	0.0%	1	2.2%	1	1.4%
	2	1	3.8%	0	0.0%	1	1.4%
	Missing	0	0.0%	1	2.2%	1	1.4%
Management	0	10	38.5%	17	37.0%	27	37.5%
	1	9	34.6%	9	19.6%	18	25.0%
	2	6	23.1%	18	39.1%	24	33.3%
	3	1	3.8%	2	4.3%	3	4.2%

A3.7 Maximum overall intestinal LENT SOMA grade reported at baseline

Maximum score at baseline		Control N=29		HBO N=55		Total N=84	
		N	%	N	%	N	%
	0	1	3.4%	3	5.5%	4	4.8%
	1	9	31.0%	5	9.1%	14	16.7%
	2	13	44.8%	31	56.4%	44	52.4%
	3	6	20.7%	16	29.1%	22	26.2%

A3.8 Maximum overall intestinal LENT SOMA grade reported at 2 weeks

Maximum score at 2 weeks		Control N=28		HBO N=50		Total N=78	
		N	%	N	%	N	%
	0	3	10.7%	6	12.0%	9	11.5%
	1	12	42.9%	14	28.0%	26	33.3%
	2	9	32.1%	23	46.0%	32	41.0%
	3	4	14.3%	6	12.0%	10	12.8%
	4	0	0.0%	1	2.0%	1	1.3%

A3.9 Maximum overall intestinal LENT SOMA grade reported at 12 months

Maximum score at 12 months	Control N=26		HBO N=46		Total N=72	
	N	%	N	%	N	%
0	5	19.2%	4	8.7%	9	12.5%
1	9	34.6%	13	28.3%	22	30.6%
2	8	30.8%	23	50.0%	31	43.1%
3	3	11.5%	6	13.0%	9	12.5%
4	1	3.8%	0	0.0%	1	1.4%

NOT FOR CITATION

Appendix 4 CTCAE

The number and proportion of patients with each grade of each toxicity are shown split by treatment group at each time point

A4.1 Baseline CTCAE toxicities

		Control N=29		HBO N=54		Total N=83	
		N	%	N	%	N	%
Abdominal pain	0	15	53.6%	21	38.9%	36	43.4%
	1	10	35.7%	16	29.6%	26	31.3%
	2	1	3.6%	10	18.5%	11	13.3%
	3	3	10.7%	7	13.0%	10	12.0%
Bloating	0	17	60.7%	26	48.1%	43	51.8%
	1	8	28.6%	17	31.5%	25	30.1%
	2	4	14.3%	11	20.4%	15	18.1%
Constipation	0	26	92.9%	49	90.7%	75	90.4%
	1	3	10.7%	4	7.4%	7	8.4%
	2	0	0.0%	1	1.9%	1	1.2%
Diarrhoea	0	21	75.0%	39	72.2%	60	72.3%
	1	1	3.6%	1	1.9%	2	2.4%
	2	6	21.4%	12	22.2%	18	21.7%
	3	1	3.6%	1	1.9%	2	2.4%
	4	0	0.0%	1	1.9%	1	1.2%
Faecal incontinence	0	9	32.1%	18	33.3%	27	32.5%
	1	6	21.4%	19	35.2%	25	30.1%
	2	14	50.0%	16	29.6%	30	36.1%
	3	0	0.0%	1	1.9%	1	1.2%
Flatulence	0	9	32.1%	20	37.0%	29	34.9%
	1	11	39.3%	25	46.3%	36	43.4%
	2	9	32.1%	9	16.7%	18	21.7%
Frequency	0	11	39.3%	11	20.4%	22	26.5%
	1	6	21.4%	17	31.5%	23	27.7%
	2	11	39.3%	26	48.1%	37	44.6%
	3	1	3.6%	0	0.0%	1	1.2%
Rectal bleeding	0	10	35.7%	27	50.0%	37	44.6%
	1	7	25.0%	6	11.1%	13	15.7%
	2	11	39.3%	16	29.6%	27	32.5%
	3	1	3.6%	5	9.3%	6	7.2%
Rectal pain	0	22	78.6%	48	88.9%	70	84.3%
	1	4	14.3%	2	3.7%	6	7.2%
	2	2	7.1%	4	7.4%	6	7.2%
	3	1	3.6%	0	0.0%	1	1.2%
Tenesmus	0	6	21.4%	17	31.5%	23	27.7%
	1	13	46.4%	16	29.6%	29	34.9%
	2	10	35.7%	21	38.9%	31	37.3%
Urgency	0	3	10.7%	5	9.3%	8	9.6%
	1	3	10.7%	10	18.5%	13	15.7%
	2	21	75.0%	37	68.5%	58	69.9%
	3	2	7.1%	2	3.7%	4	4.8%
GI disorders	0	27	96.4%	47	87.0%	74	89.2%
	1	1	3.6%	6	11.1%	7	8.4%
	2	1	3.6%	1	1.9%	2	2.4%

A4.2 2 week CTCAE toxicities

		HBO N=50		Control N=28		Total N=78	
		N	%	N	%	N	%
Abdominal pain	0	27	54.0%	15	53.6%	42	53.8%
	1	12	24.0%	8	28.6%	20	25.6%
	2	7	14.0%	3	10.7%	10	12.8%
	3	4	8.0%	2	7.1%	6	7.7%
Bloating	0	27	54.0%	17	60.7%	44	56.4%
	1	20	40.0%	6	21.4%	26	33.3%
	2	3	6.0%	5	17.9%	8	10.3%
Constipation	0	47	94.0%	24	85.7%	71	91.0%
	1	3	6.0%	4	14.3%	7	9.0%
Diarrhoea	0	40	80.0%	24	85.7%	64	82.1%
	1	6	12.0%	0	0.0%	6	7.7%
	2	3	6.0%	4	14.3%	7	9.0%
	3	1	2.0%	0	0.0%	1	1.3%
Faecal incontinence	0	23	46.0%	9	32.1%	32	41.0%
	1	13	26.0%	6	21.4%	19	24.4%
	2	14	28.0%	12	42.9%	26	33.3%
	3	0	0.0%	1	3.6%	1	1.3%
Flatulence	0	20	40.0%	11	39.3%	31	39.7%
	1	19	38.0%	12	42.9%	31	39.7%
	2	11	22.0%	5	17.9%	16	20.5%
Frequency	0	27	54.0%	11	39.3%	38	48.7%
	1	11	22.0%	11	39.3%	22	28.2%
	2	11	22.0%	6	21.4%	17	21.8%
	3	1	2.0%	0	0.0%	1	1.3%
Rectal bleeding	0	23	46.0%	12	42.9%	35	44.9%
	1	17	34.0%	11	39.3%	28	35.9%
	2	8	16.0%	5	17.9%	13	16.7%
	3	2	4.0%	0	0.0%	2	2.6%
Rectal pain	0	41	82.0%	22	78.6%	63	80.8%
	1	8	16.0%	5	17.9%	13	16.7%
	2	1	2.0%	1	3.6%	2	2.6%
Tenesmus	0	21	42.0%	11	39.3%	32	41.0%
	1	17	34.0%	9	32.1%	26	33.3%
	2	12	24.0%	8	28.6%	20	25.6%
Urgency	0	10	20.0%	5	17.9%	15	19.2%
	1	20	40.0%	9	32.1%	29	37.2%
	2	20	40.0%	14	50.0%	34	43.6%
GI disorders	0	48	96.0%	27	96.4%	75	96.2%
	1	2	4.0%	1	3.6%	3	3.8%

A4.3 12 month CTCAE toxicities

		Control N=26		HBO N=46		Total N=72	
		N	%	HBO	%	N	%
Abdominal pain	0	14	53.8%	20	43.5%	34	47.2%
	1	7	26.9%	12	26.1%	19	26.4%
	2	1	3.8%	9	19.6%	10	13.9%
	3	4	15.4%	5	10.9%	9	12.5%
Bloating	0	12	46.2%	22	47.8%	34	47.2%
	1	10	38.5%	20	43.5%	30	41.7%
	2	4	15.4%	4	8.7%	8	11.1%
Constipation	0	25	96.2%	43	93.5%	68	94.4%
	1	1	3.8%	2	4.3%	3	4.2%
	2	0	0.0%	1	2.2%	1	1.4%
Diarrhoea	0	23	88.5%	39	84.8%	62	86.1%
	1	1	3.8%	1	2.2%	2	2.8%
	2	0	0.0%	6	13.0%	6	8.3%
	3	2	7.7%	0	0.0%	2	2.8%
Faecal incontinence	0	10	38.5%	18	39.1%	28	38.9%
	1	5	19.2%	14	30.4%	19	26.4%
	2	10	38.5%	13	28.3%	23	31.9%
	3	1	3.8%	1	2.2%	2	2.8%
Flatulence	0	10	38.5%	16	34.8%	26	36.1%
	1	11	42.3%	15	32.6%	26	36.1%
	2	5	19.2%	15	32.6%	20	27.8%
Frequency	0	12	46.2%	17	37.0%	29	40.3%
	1	7	26.9%	13	28.3%	20	27.8%
	2	6	23.1%	16	34.8%	22	30.6%
	3	1	3.8%	0	0.0%	1	1.4%
Rectal bleeding	0	11	42.3%	25	54.3%	36	50.0%
	1	13	50.0%	14	30.4%	27	37.5%
	2	2	7.7%	6	13.0%	8	11.1%
	3	0	0.0%	1	2.2%	1	1.4%
Rectal pain	0	20	76.9%	35	76.1%	55	76.4%
	1	3	11.5%	11	23.9%	14	19.4%
	2	1	3.8%	0	0.0%	1	1.4%
	3	2	7.7%	0	0.0%	2	2.8%
Tenesmus	0	17	65.4%	20	43.5%	37	51.4%
	1	4	15.4%	15	32.6%	19	26.4%
	2	5	19.2%	11	23.9%	16	22.2%
Urgency	0	6	23.1%	13	28.3%	19	26.4%
	1	8	30.8%	5	10.9%	13	18.1%
	2	11	42.3%	24	52.2%	35	48.6%
	3	1	3.8%	4	8.7%	5	6.9%
GI disorders	0	22	84.6%	42	91.3%	64	88.9%
	1	1	3.8%	2	4.3%	3	4.2%
	2	3	11.5%	2	4.3%	5	6.9%