

Confidential

Clinical Studies Report - Quality of life section



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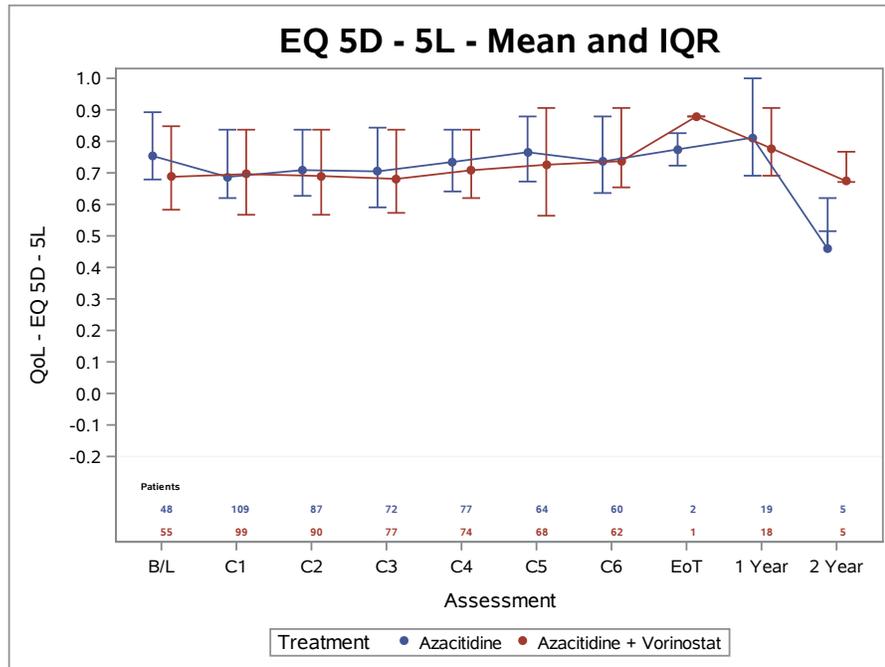
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1 Quality of Life EQ5D-5L

A higher EQ5D-5L index score represents a higher quality of life.

Figure 1: EQ5D-5L index score



EQ VAS is measured between 0 and 100, a higher score represents a better quality of life.

Figure 2: EQ5D-VAS

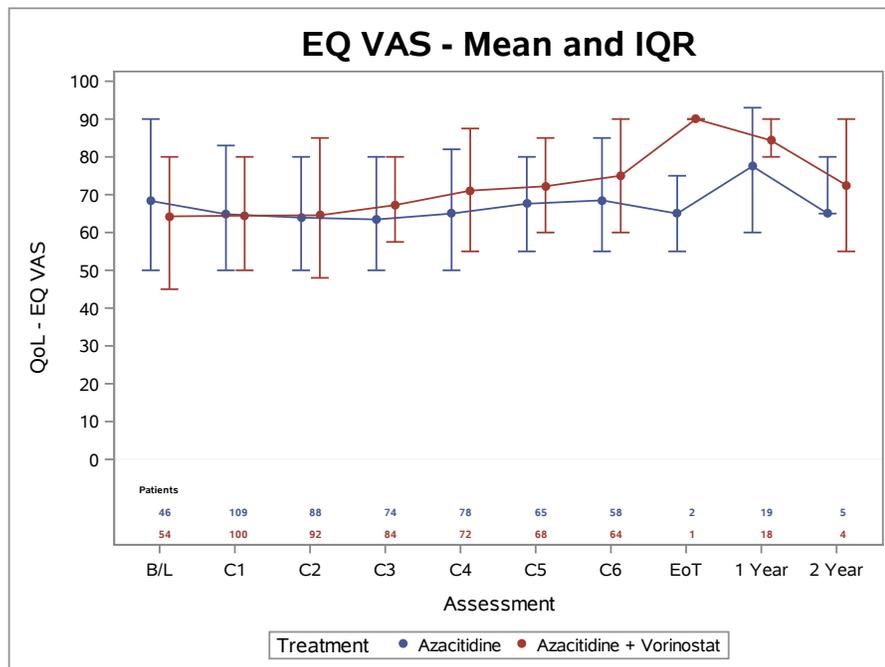


Table 1: Repeated measure model for EQ 5D quality of life

Scale	P value
EQ5D-5L	0.7241
EQ VAS	0.3440

2 Quality of Life EORTC QLQ-C30

All scales are based on a scoring system graded between 0 and 100. A high global health score represent high quality of life, a high functioning score represents a high level of functioning and a high score on the symptom scale represents a high level of symptomatology.

Figure 3: Global Health scale

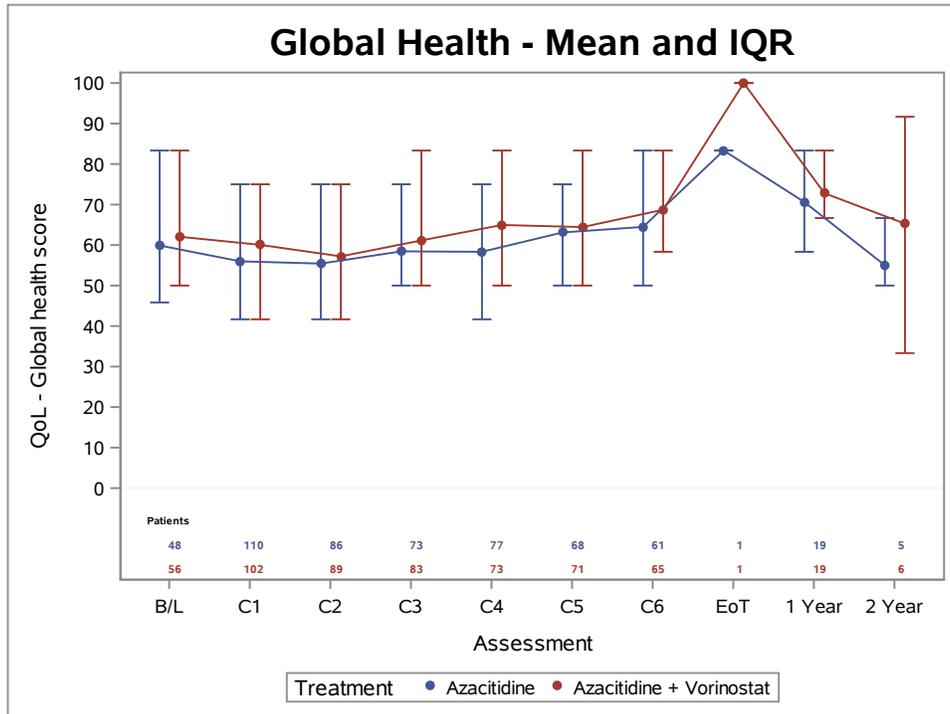


Figure 4: Physical functioning

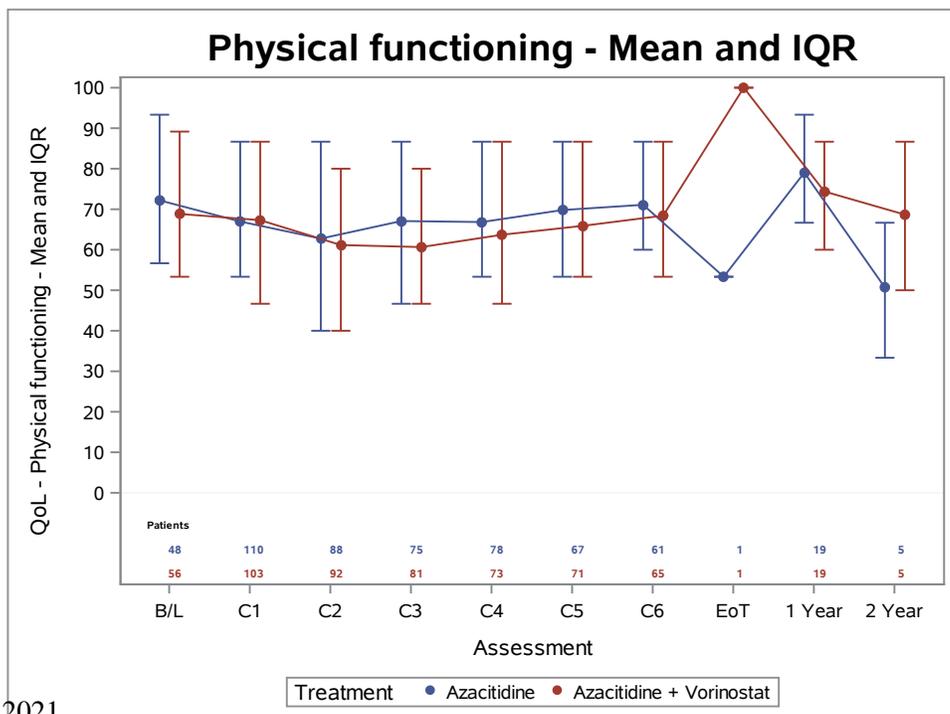


Figure 5: Role functioning

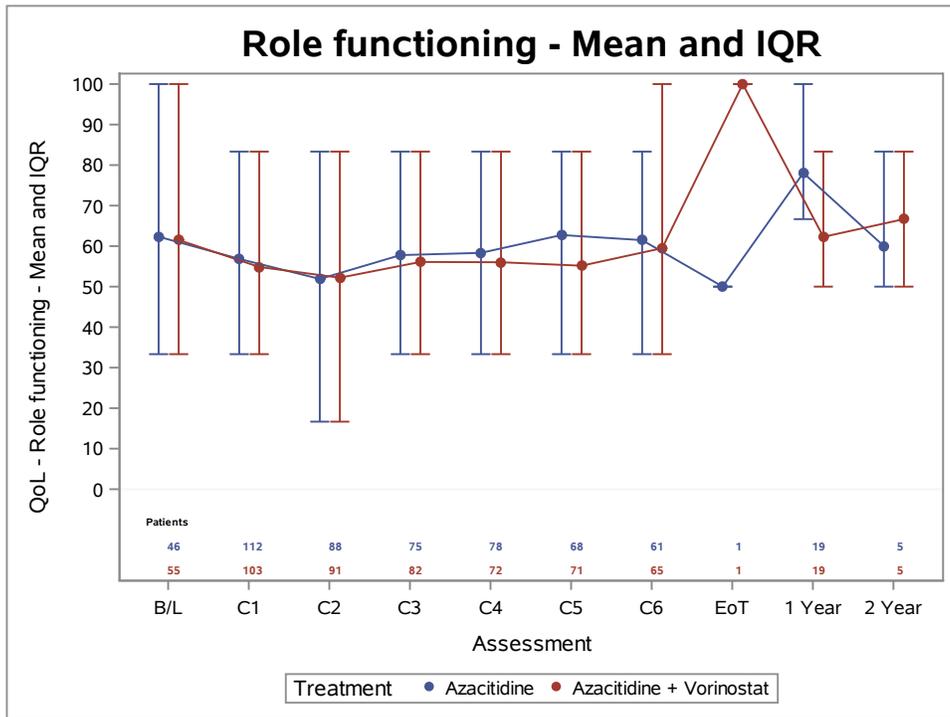


Figure 6: Emotional functioning

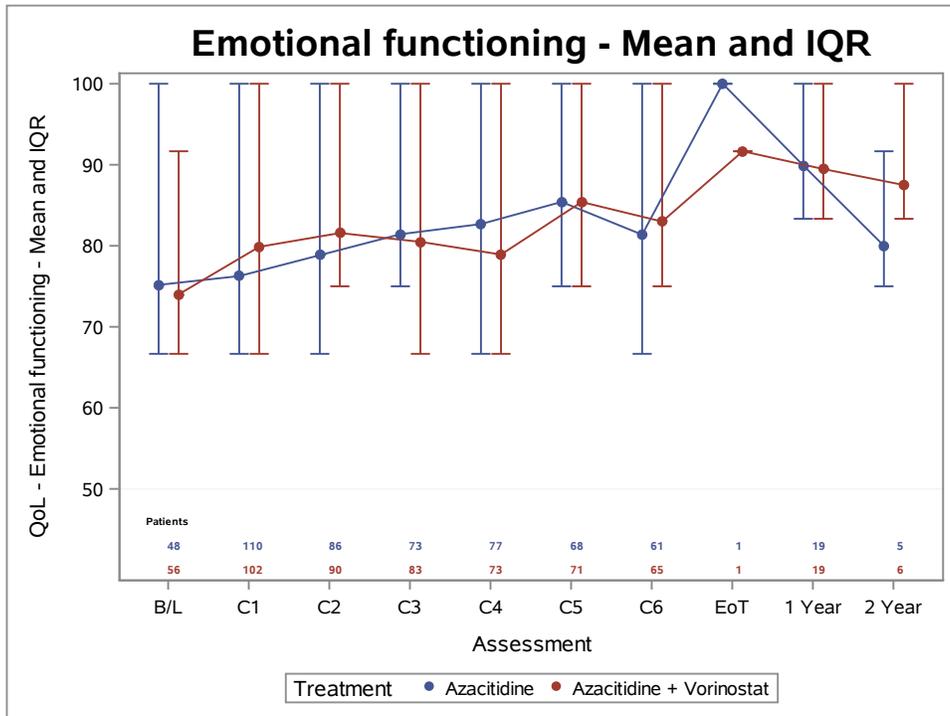


Figure 7: Cognitive functioning

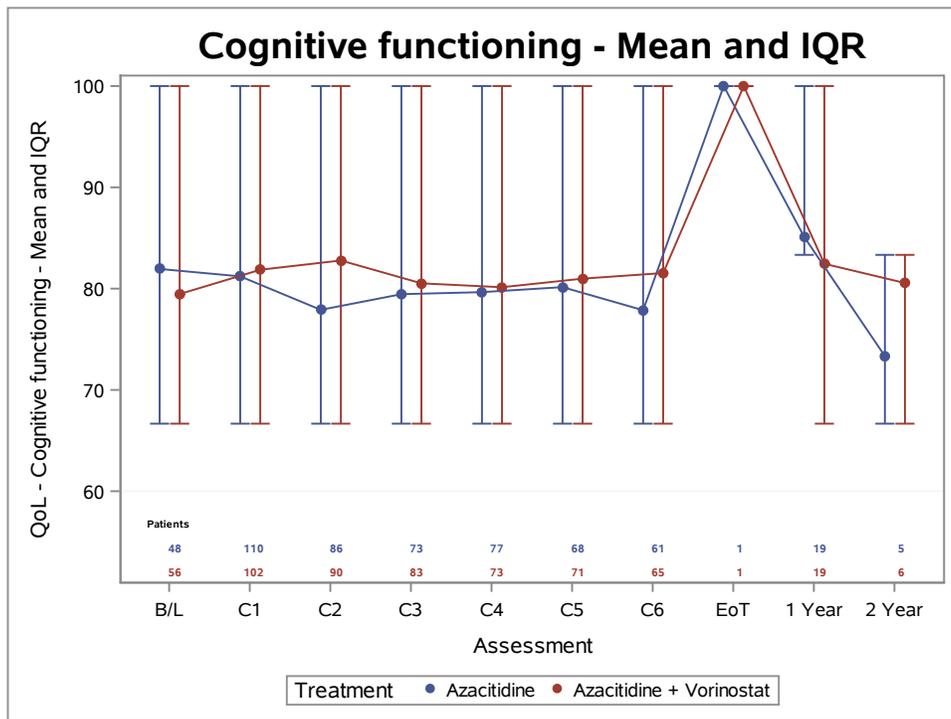


Figure 8: Social functioning

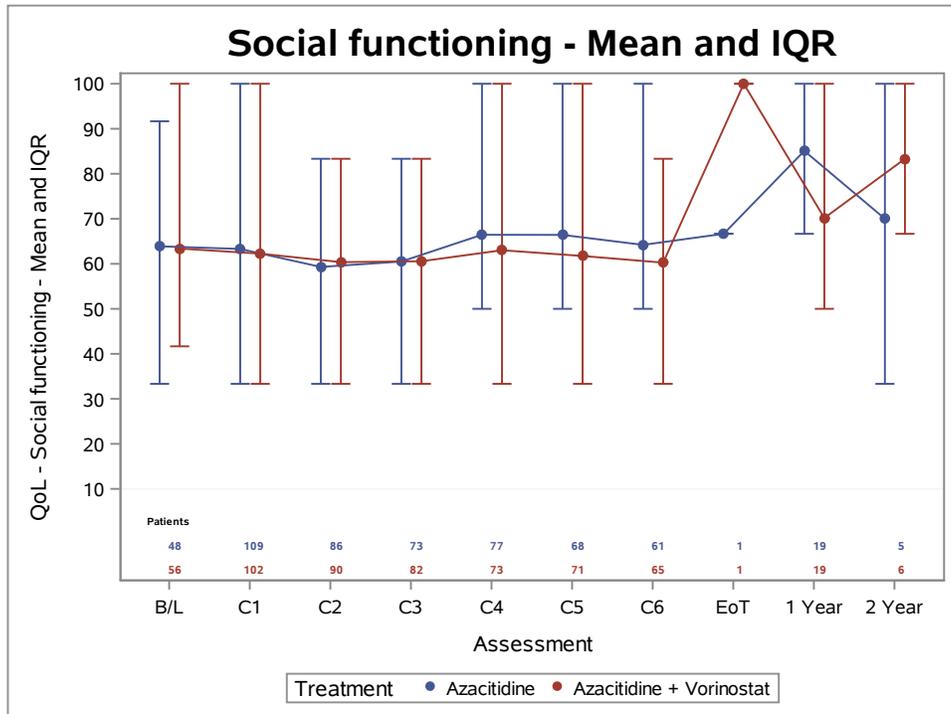


Table 2: Number of patients reporting fatigue

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	41 (84)	49 (88)	90 (86)
Cycle 1	100 (89)	97 (93)	197 (91)
Cycle 2	80 (91)	87 (95)	167 (93)
Cycle 3	72 (96)	80 (95)	152 (96)
Cycle 4	73 (94)	66 (89)	139 (91)
Cycle 5	64 (93)	64 (90)	128 (91)
Cycle 6	56 (92)	56 (84)	112 (88)
End of Treatment	1 (100)	1 (100)	2 (100)
12 months follow up	18 (95)	18 (95)	36 (95)
24 months follow up	5 (100)	5 (83)	10 (91)

Note: 5 patients’ (1 at baseline, 2 at cycle 3, 1 at cycle 4 and 1 at cycle 6) reported fatigue in one question but failed to answer any other questions regarding fatigue and therefore do not contribute to the overall fatigue calculation shown in the figure below.

Table 3: Fatigue of those patients reporting symptoms

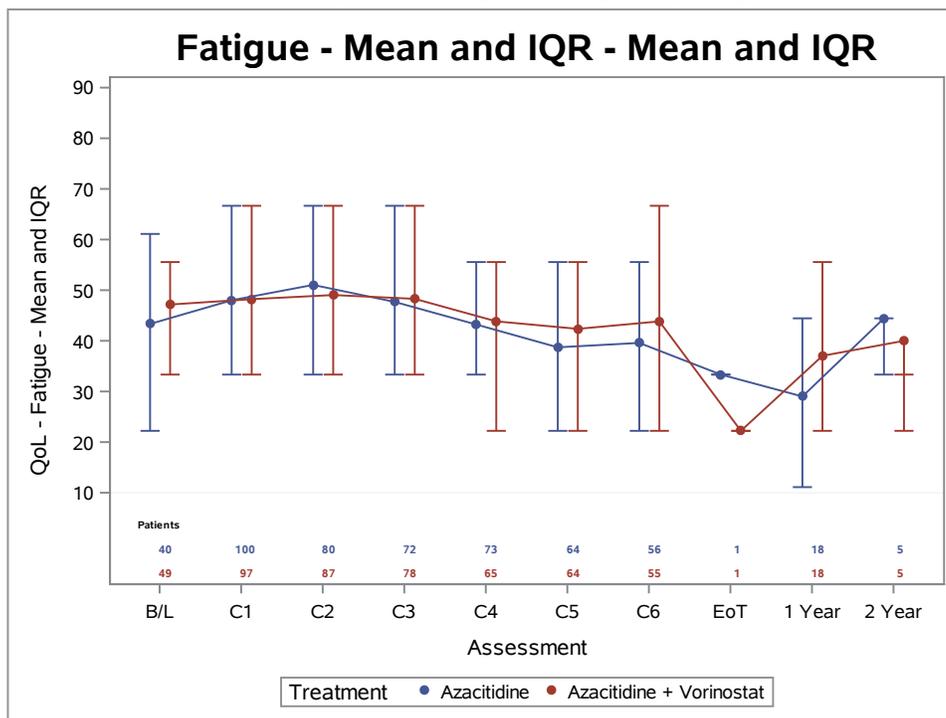


Table 4: Number of patients reporting nausea or vomiting

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	8 (16)	16 (29)	24 (23)
Cycle 1	41 (37)	31 (30)	72 (33)
Cycle 2	39 (44)	42 (46)	81 (45)
Cycle 3	32 (43)	35 (42)	67 (42)
Cycle 4	28 (36)	30 (41)	58 (38)
Cycle 5	24 (35)	25 (35)	49 (35)
Cycle 6	22 (36)	21 (31)	43 (34)
End of Treatment	1 (100)	0	1 (50)
12 months follow up	6 (32)	5 (26)	11 (29)
24 months follow up	3 (60)	2 (33)	5 (45)

Table 5: Nausea and vomiting of those patients reporting symptoms

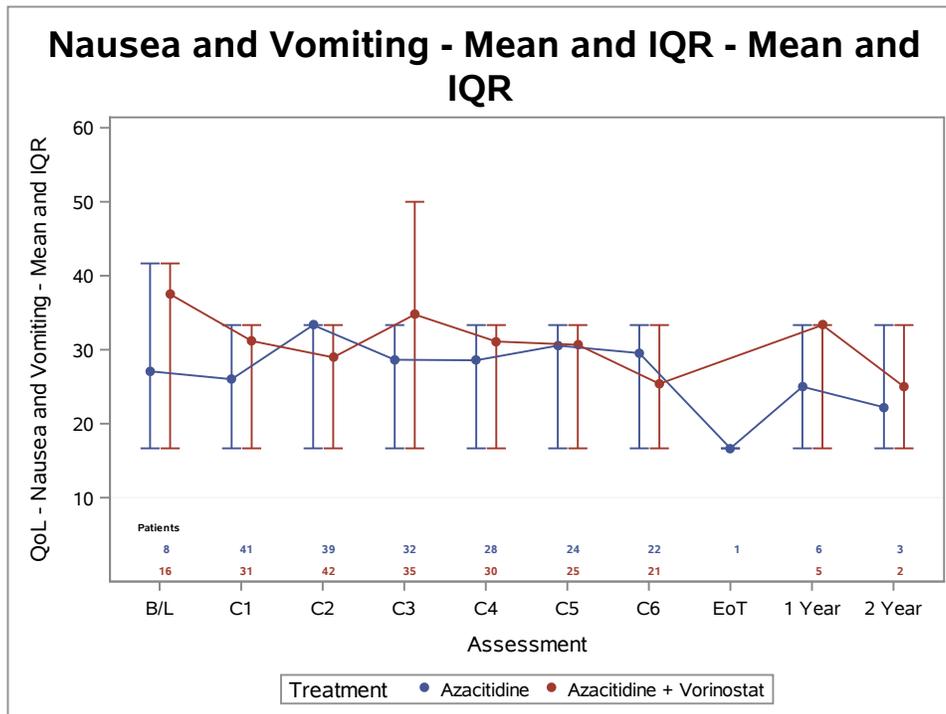


Table 6: Number of patients reporting pain

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	19 (39)	25 (45)	44 (42)
Cycle 1	57 (51)	47 (45)	104 (48)
Cycle 2	40 (45)	34 (37)	74 (41)
Cycle 3	32 (43)	35 (42)	67 (42)
Cycle 4	35 (45)	31 (42)	66 (43)
Cycle 5	32 (46)	24 (34)	56 (40)
Cycle 6	32 (52)	25 (37)	57 (45)
End of Treatment	1 (100)	0	1 (50)
12 months follow up	11 (58)	9 (47)	20 (53)
24 months follow up	5 (100)	2 (33)	7 (64)

Table 7: Pain of those patients reporting symptoms

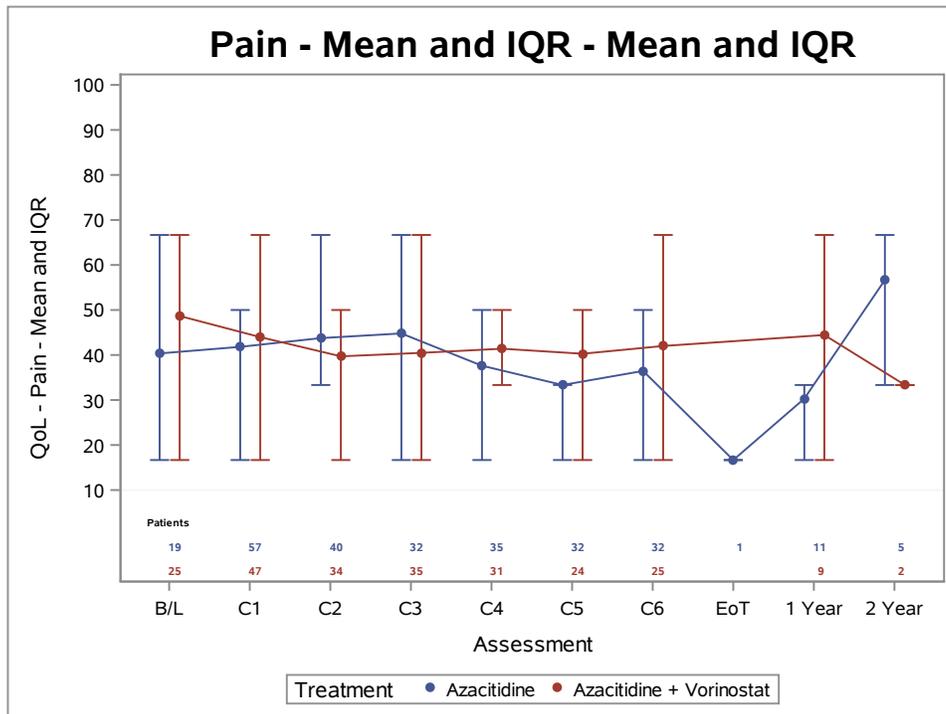


Table 8: Number of patients reporting dyspnoea

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	26 (53)	37 (66)	63 (60)
Cycle 1	72 (64)	66 (63)	138 (64)
Cycle 2	60 (68)	64 (70)	124 (69)
Cycle 3	44 (59)	58 (69)	102 (64)
Cycle 4	46 (59)	46 (62)	92 (61)
Cycle 5	31 (45)	41 (58)	72 (51)
Cycle 6	33 (54)	34 (51)	67 (52)
12 months follow up	12 (63)	10 (53)	22 (58)
24 months follow up	4 (80)	3 (50)	7 (64)

Table 9: Dyspnoea of those patients reporting symptoms

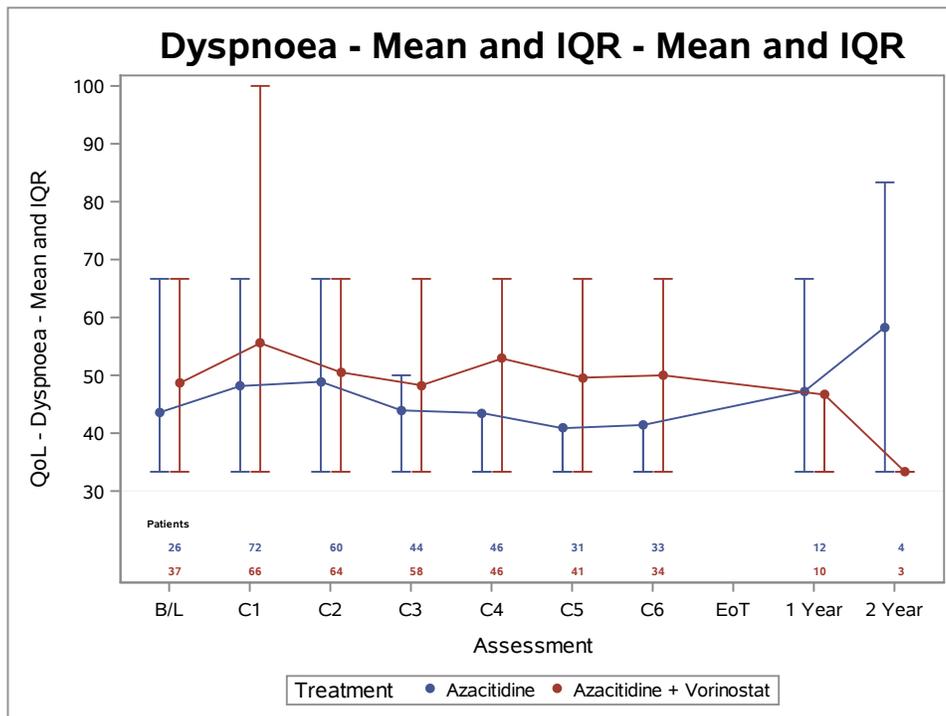


Table 10: Number of patients reporting insomnia

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	19 (39)	31 (55)	50 (48)
Cycle 1	61 (54)	55 (53)	116 (54)
Cycle 2	51 (58)	47 (51)	98 (54)
Cycle 3	41 (55)	36 (43)	77 (48)
Cycle 4	40 (51)	39 (53)	79 (52)
Cycle 5	32 (46)	32 (45)	64 (46)
Cycle 6	28 (46)	32 (48)	60 (47)
End of Treatment	0	1 (100)	1 (50)
12 months follow up	6 (32)	9 (47)	15 (39)
24 months follow up	5 (100)	3 (50)	8 (73)

Table 11: Insomnia of those patients reporting symptoms

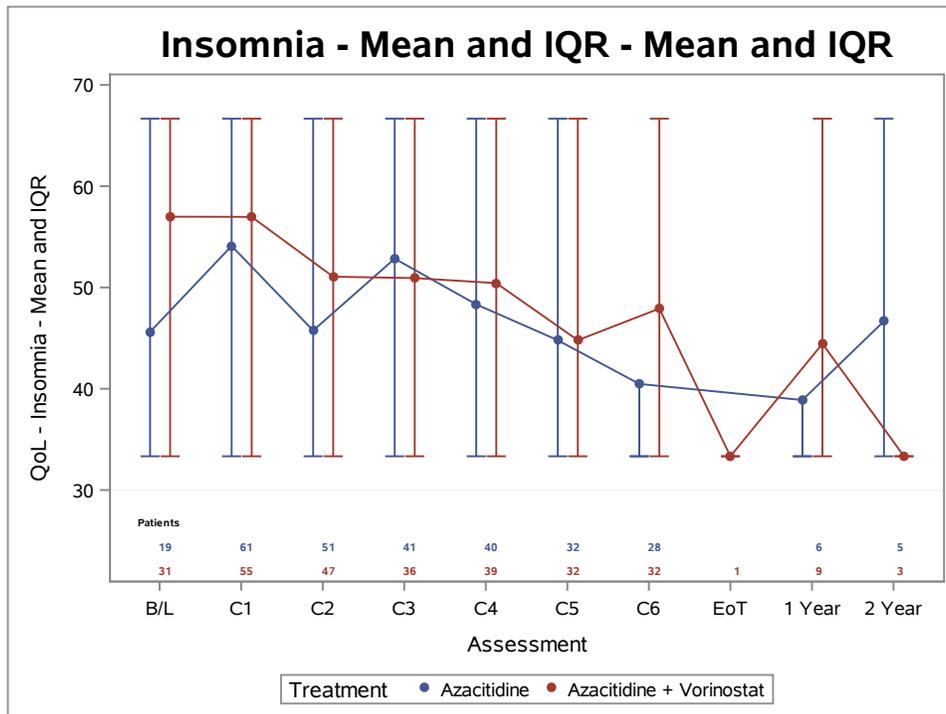


Table 12: Number of patients reporting loss of appetite

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	19 (39)	26 (46)	45 (43)
Cycle 1	62 (55)	51 (49)	113 (52)
Cycle 2	54 (61)	51 (55)	105 (58)
Cycle 3	42 (56)	56 (67)	98 (62)
Cycle 4	44 (56)	39 (53)	83 (55)
Cycle 5	37 (54)	34 (48)	71 (51)
Cycle 6	32 (52)	26 (39)	58 (45)
12 months follow up	7 (37)	4 (21)	11 (29)
24 months follow up	3 (60)	2 (33)	5 (45)

Table 13: Appetite loss of those patients reporting symptoms

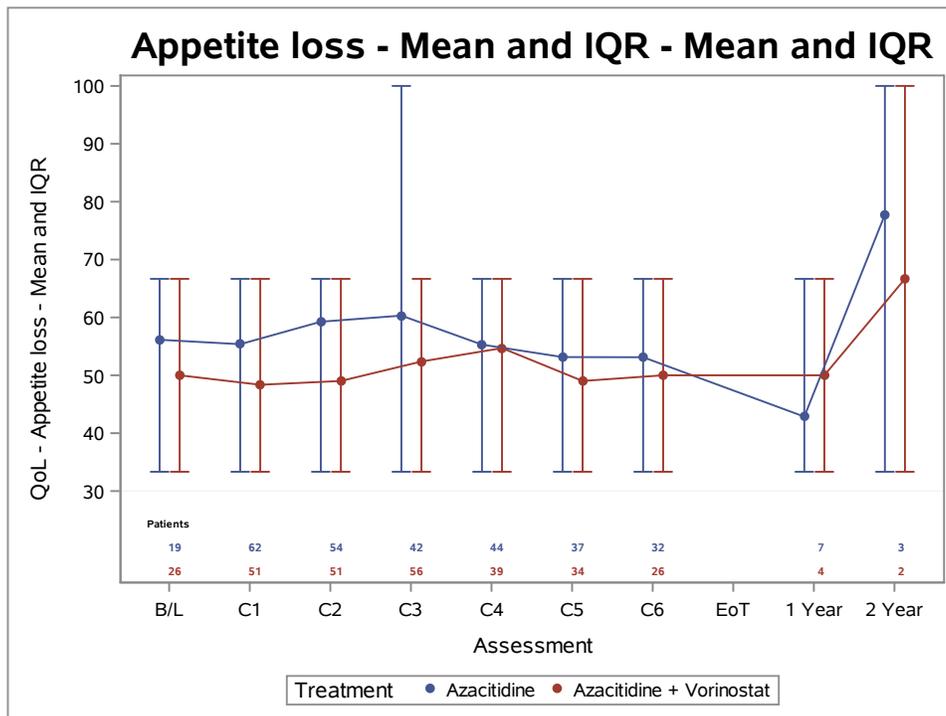


Table 14: Number of patients reporting constipation

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	12 (24)	19 (34)	31 (30)
Cycle 1	31 (28)	33 (32)	64 (30)
Cycle 2	43 (49)	39 (42)	82 (46)
Cycle 3	30 (40)	30 (36)	60 (38)
Cycle 4	30 (38)	31 (42)	61 (40)
Cycle 5	25 (36)	27 (38)	52 (37)
Cycle 6	24 (39)	29 (43)	53 (41)
12 months follow up	9 (47)	9 (47)	18 (47)
24 months follow up	4 (80)	2 (33)	6 (55)

Table 15: Constipation of those patients reporting symptoms

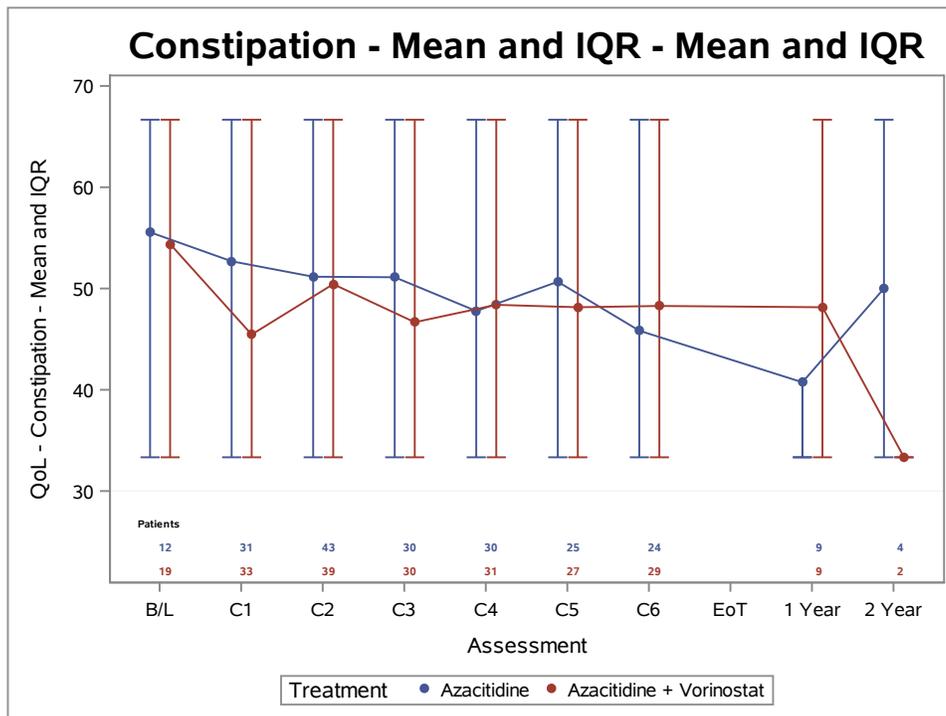


Table 16: Number of patients reporting diarrhoea

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	8 (16)	7 (13)	15 (14)
Cycle 1	20 (18)	15 (14)	35 (16)
Cycle 2	17 (19)	22 (24)	39 (22)
Cycle 3	16 (21)	19 (23)	35 (22)
Cycle 4	15 (19)	16 (22)	31 (20)
Cycle 5	10 (14)	16 (23)	26 (19)
Cycle 6	10 (16)	15 (22)	25 (20)
12 months follow up	3 (16)	3 (16)	6 (16)
24 months follow up	1 (20)	2 (33)	3 (27)

Table 17: Diarrhoea of those patients reporting symptoms

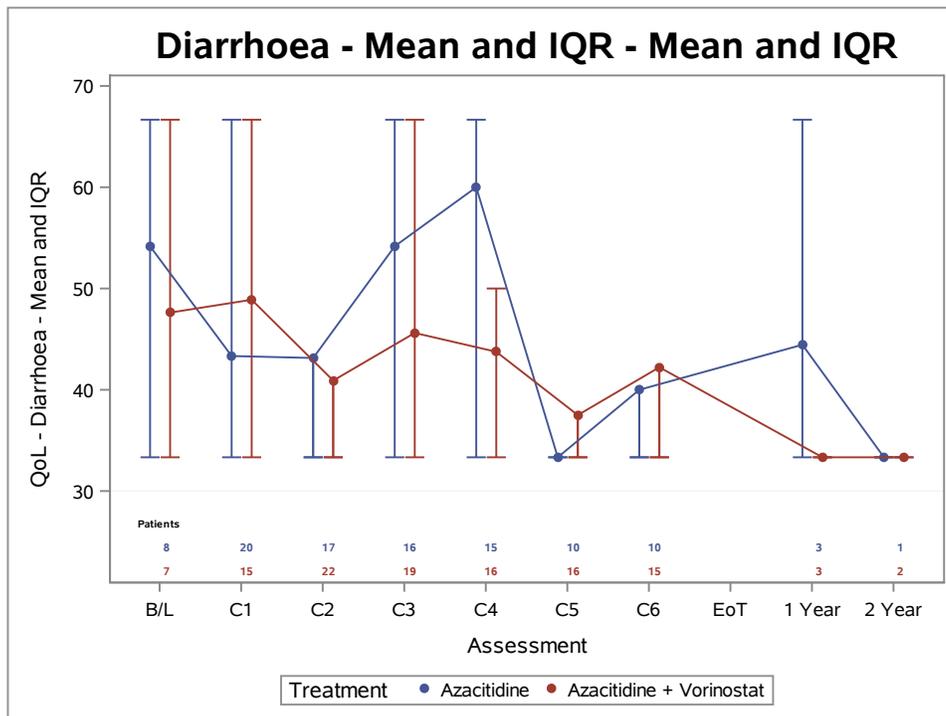


Table 18: Number of patients reporting financial difficulties

Assessment	Azacitidine N (%)	Azacitidine + Vorinostat N (%)	Overall N (%)
Baseline	12 (24)	16 (29)	28 (27)
Cycle 1	29 (26)	27 (26)	56 (26)
Cycle 2	20 (23)	20 (22)	40 (22)
Cycle 3	18 (24)	21 (25)	39 (25)
Cycle 4	21 (27)	19 (26)	40 (26)
Cycle 5	14 (20)	18 (25)	32 (23)
Cycle 6	18 (30)	20 (30)	38 (30)
12 months follow up	5 (26)	2 (11)	7 (18)
24 months follow up	3 (60)	1 (17)	4 (36)

Table 19: Financial difficulties of those patients reporting difficulties

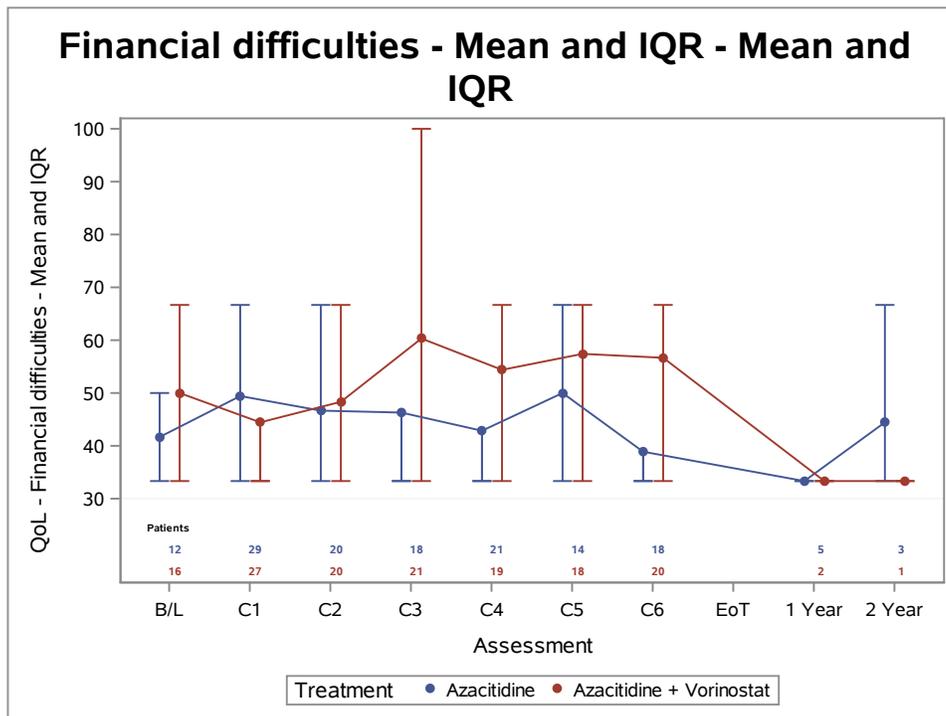


Table 20: Repeated measure model for EORTC QLQ-C30 Quality of life scales

Scale	P value
Global health scale	0.0876
Physical functioning	0.5669
Role functioning	0.3184
Emotional functioning	0.4310
Social functioning	0.5727
Fatigue	0.7281
Nausea and Vomiting	0.6689
Pain	0.8509
Dyspnoea	0.1332
Insomnia	0.4129
Appetite Loss	0.1138
Constipation	0.9389
Diarrhoea	0.7941
Financial difficulties	0.7525