|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Appendix B. CTCAE v.4.0 Gastro-intestinal Morbidity** | | | | | | | | |
| **CTCAE v.4.0, grade 2+** | **Baseline (N=76-85)** | **Post RT (N=73-85)** | **3 months (N=76-87)** | **6 months (N=77-88)** | **12 months (N=75-85)** | **24 months (N=72-81)** | **36 months (N=67-78)** | **60 months (N=52-57)** |
| Overall, GI morbidity | 1(1) | 21(24)# | 9(10)# | 13(15)# | 7(8)# | 6(7) | 9(11)# | 6(11)# |
| Abdominal pain | 0 | 1 (1) | 1 (1) | 1 (1) | 0 | 1 (1) | 1 (1) | 0 |
| Bloating | 0 | 2 (2) | 1 (1) | 0 | 1 (1) | 1 (1) | 3 (4) | 0 |
| Colitis | 0 | 2 (3) | 0 | 0 | 0 | 1 (1) | 2 (3) | 2 (4) |
| Constipation | 0 | 1 (1) | 2 (2) | 1 (1) | 1 (1) | 0 | 2 (3) | 0 |
| Diarrhea | 0 | 16 (19)# | 2 (2) | 5 (6) | 1 (1) | 1 (1) | 1 (1) | 0 |
| Fecal incontinence | 0 | 1 (1) | 1 (1) | 1 (1) | 0 | 0 | 0 | 1 (2) |
| Flatulence | 1 (1) | 2 (2) | 3 (3) | 4 (5) | 5 (6) | 5 (6) | 5 (6) | 2 (4) |
| Hemorrhoids | 0 | 0 | 0 | 0 | 0 | 0 | 1 (1) | 1 (2) |
| Nausea | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Proctitis | 0 | 1 (1) | 2 (3) | 2 (3) | 1 (1) | 1 (1) | 1 (1) | 1 (2) |
| Rectal Hemorrhage | 0 | 0 | 0 | 0 | 0 | 1 (1) | 1 (1) | 1 (2) |
| Rectal pain | 0 | 4 (5) | 1 (1) | 0 | 0 | 1 (1) | 1 (1) | 0 |
| Vomiting | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| GI disorders | 0 | 0 | 1 (1) | 0 | 2 (2) | 3 (4) | 2 (3) | 0 |
| Numbers in () are percentages. # significant compared to baseline (p<0.05) | | | | | | | | |