**Table 1: Updated characteristics of the study population (modified intention-to-treat population)\***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **TOSCA (N=2391)** | **SCOT (N=3983)** | **IDEA France (N=2010)** | **CALGB/SWOG 80702 (N=2452)** | **HORG (N=708)** | **ACHIEVE (N=1291)** | **Total (N=12835)** |
| **Tumor stage**, no. (%) | | | | | | | |
| T1 | 76 (3.2%) | 128 (3.2%) | 78 (3.9%) | 140 (5.8%) | 1 (0.1%) | 75 (5.8%) | 498 (3.9%) |
| T2 | 236 (10.0%) | 333 (8.4%) | 161 (8.0%) | 298 (12.3%) | 60 (8.5%) | 119 (9.2%) | 1207 (9.4%) |
| T3 | 1763 (74.5%) | 2347 (58.9%) | 1399 (69.6%) | 1623 (66.8%) | 549 (77.8%) | 734 (56.9%) | 8415 (65.8%) |
| T4 | 290 (12.3%) | 1174 (29.5%) | 372 (18.5%) | 368 (15.2%) | 96 (13.6%) | 363 (28.1%) | 2663 (20.8%) |
| Missing data | 24 | 0 | 0 | 23 | 2 | 0 | 49 |
| **Nodal stage,** no. (%) | | | | | | | |
| N1 | 1745 (73.2%) | 2749 (69.0%) | 1501 (74.8%) | 1792 (73.8%) | 472 (67.2%) | 959 (74.3%) | 9218 (72.0%) |
| N2 | 640 (26.8%) | 1233 (31.0%) | 506 (25.2%) | 637 (26.2%) | 230 (32.8%) | 332 (25.7%) | 3578 (28.0%) |
| Missing data | 6 | 1 | 3 | 23 | 6 | 0 | 39 |
| **Risk group,** no. (%) | | | | | | | |
| Low risk (T1, T2, or T3 N1) | 1545 (65.3%) | 2032 (51.0%) | 1245 (62.0%) | 1551 (63.9%) | 416 (59.1%) | 718 (55.6%) | 7507 (58.7%) |
| High risk (T4, N2, or both) | 820 (34.7%) | 1950 (49.0%) | 764 (38.0%) | 878 (36.1%) | 288 (40.9%) | 573 (44.4%) | 5273 (41.3%) |
| Missing data | 26 | 1 | 1 | 23 | 4 | 0 | 55 |
| **Primary tumor sidedness,** no. (%) | | | | | | | |
| Proximal | 934 (40.8%) | NA | 750 (42.6%) | 1278 (53.7%) | 313 (44.5%) | 491 (38.5%) | 3766 (44.8%) |
| Distal | 1358 (59.2%) | NA | 1012 (57.4%) | 1102 (46.3%) | 390 (55.5%) | 784 (61.5%) | 4646 (55.2%) |
| Missing data | 99 | 3983 | 248 | 72 | 5 | 16 | 4423 |
| **Chemotherapy regimen,** no. (%) | | | | | | | |
| CAPOX | 833 (34.8%) | 2649 (66.5%) | 201 (10.0%) | 0 (0.0%) | 412 (58.2%) | 969 (75.1%) | 5064 (39.5%) |
| FOLFOX | 1558 (65.2%)† | 1334 (33.5%) | 1809 (90.0%) | 2452 (100.0%) | 296 (41.8%) | 322 (24.9%) | 7771 (60.5%) |
| **Median follow-up time**,  months (Q1, Q3) | 84.3  (83.0-85.8) | 75.2  (74.2-76.1) | 79.5  (78.4-81.0) | 66.2  (65.1-67.1) | 79.7  (74.7-81.7) | 61.8  (61.3-62.7) | 72.3  (72.2-72.5) |

\* Percentages may not total 100 because of rounding. TOSCA Three or Six Colon Adjuvant, SCOT Short Course Oncology Treatment, IDEA International Duration Evaluation of Adjuvant, CALGB/SWOG Cancer and Leukemia Group B/Southwest Oncology Group, ACHIEVE denotes Adjuvant Chemotherapy for Colon Cancer with High Evidence , and HORG Hellenic Oncology Research Group, Therapy.

† Patients in this trial received FOLFOX4; those in the other trials received modified FOLFOX6.

**Table 2: Treatment effects comparing disease free survival and overall survival between 3 months and 6 months of therapy with 6 months group as reference group**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Cohort** | **Disease Free Survival with 5 years of follow up** | | | **Overall Survival** | | |
| HR (95% CI) \* | One-sided FDRadj p-value† for non-inferiority of 3 months therapy | Two-sided FDRadj p-value¥ for superiority of 6 months therapy | HR (95% CI) \* | One-sided FDRadj p-value† for non-inferiority of 3 months therapy | Two-sided FDRadj p-value¥ for superiority of 6 months therapy |
| Overall | 1.08 (1.02 to 1.15) | 0.25 | 0.044 | 1.02 (0.95-1.11) | 0.058 | 0.64 |
| CAPOX | 0.98 (0.88 to 1.08) | 0.027 | 0.67 | 0.96 (0.85-1.08) | 0.033 | 0.62 |
| FOLFOX | 1.16 (1.07 to 1.26) | 0.80 | 0.0061 | 1.07 (0.97-1.18) | 0.34 | 0.38 |
| Low Risk | 1.04 (0.94 to 1.15) | 0.16 | 0.58 | 0.95 (0.84-1.08) | 0.033 | 0.58 |
| High Risk | 1.13 (1.03 to 1.22) | 0.63 | 0.031 | 1.08 (0.98-1.19) | 0.39 | 0.29 |

HR denotes hazard ratio, CI confidence interval, FDRadj false discovery rate adjusted, mITT modified intention-to-treat

\* Two-sided 95% CI without adjustment of multicity; † If the observed one-sided FDRadj p-value is less than 0.025, then 3 months of therapy is declared statistically non-inferior to 6 months of therapy after adjusting for multicity. ¥ If the observed two-sided FDRadj p-value is less than 0.05, then 6 months of therapy is declared statistically superior to 3 months of therapy after adjusting for multicity.