Table F-1. All-cause mortality (randomized controlled trials)

| **Study Outcomes** | **Treatment Group 1** | **Treatment Group 2** | **Analyses; p-Values** |
| --- | --- | --- | --- |
| Wilt et al. 201225  Prostate Intervention Versus Observation Trial (PIVOT) | Observation: 364 patients | RP: 364 patients | HR (95% CI), p–value for interaction |
| Overall death from any cause at median followup of 10 years (number of events/total number of patients) | 183/367 | 171/364 | 0.88 (0.71–1.08)  p=0.22 |
| *Age* | — | — | p=0.85 |
| <65 years | 50/131 | 43/122 | 0.89 (0.59–1.34) |
| >65 years | 133/236 | 128/242 | 0.84 (0.63–1.08) |
| *Race* | — | — | p=0.81 |
| White | 119/220 | 117/232 | 0.84 (0.65–1.08) |
| Black | 53/121 | 46/111 | 0.93 (0.62–1.38) |
| Other | 11/26 | 8/21 | 0.85 (0.34–2.11) |
| *Charlson score* | — | — | p=0.79 |
| 0 | 86/220 | 82/224 | 0.90 (0.66–1.23) |
| ≥1 | 97/157 | 89/140 | 0.84 (0.63–1.13) |
| *Performance score* | — | — | p=0.66 |
| 0 | 146/310 | 139/312 | 0.89 (0.71–1.13) |
| 1–4 | 37/57 | 32/52 | 0.82 (0.51–1.31) |
| *Prostate specific antigen (PSA)* | — | — | p=0.04 |
| ≤10 | 101/241 | 110/238 | 1.03 (0.79–1.35) |
| >10 | 77/125 | 61/126 | 0.67 (0.48–0.94) |
| *Risk* | — | — | p=0.07 |
| Low | 54/148 | 62/148 | 1.15 (0.80–1.66) |
| Intermediate | 70/120 | 59/129 | 0.69 (0.49–0.98) |
| High | 49/80 | 42/77 | 0.74 (0.49–1.13) |
| *Gleason score* | — | — | p=0.87 |
| <7 | 125/261 | 113/254 | 0.86 (0.67–1.12) |
| ≥7 | 47/86 | 50/98 | 0.84 (0.56–1.25) |
| At 12 years (percentage of men who died). The authors did not provide subgroup data for patients at 12 years followup | 43.9 | 40.9 |  |
| Bill-Axelson et al. 201133  Same study as Holmberg et al. 201234, and  Bill‑Axelson et al. 200815  Scandinavian Prostate Cancer Group-4 (SPCG-4) Trial | WW: 348 patients | RP: 347 patients | ARR and or RR, 95% CI, p-value for interaction |
| Total number of deaths, cumulative incidence (number (% [95% CI]) at a median followup of 10.8 years | 156 (44.8) | 137 (39.5) | p=0.09 |
| All ages at 8 years followup | 22.4 (18.4–27.3) | 17.9 (14.3–22.4) | ARR with RP, % (95% CI): 4.6 (‑1.4–10.5) |
| All ages at 12 years followup | 39.8 (34.7–45.7) | 32.7 (27.9–38.4) | ARR with RP: 7.1 (-0.5–14.7)  RR with RP: 0.82 (0.65–1.03)  p=0.09 |
| Age <65 years at 8 years followup | 23.5 (17.8–30.9) | 12.1 (7.9–18.5) | ARR with RP: 11.4 (3.1–19.6) |
| Age <65 years at 12 years followup | 40.2 (33.0 – 49.0) | 21.9 (16.1–29.9) | ARR with RP: 18.3 (7.8–28.8)  RR with RP: 0.59 (0.41–0.85)  p=0.004 |
| Age ≥65 years at 8 years followup | 21.4 (16.2–28.3) | 22.6 (17.4–29.5) | ARR with RP: -1.2 (-9.6–7.30) |
| Age ≥65 years at 12 years followup | 39.3 (32.5–47.7) | 42 (35–50.5) | ARR with RP: -2.7 (-13.5–8.0)  RR with RP: 1.04 (0.77–1.40)  p=0.81 |
| Total number of deaths, cumulative incidence (number (% [95% CI]) at median followup of 12.8 years | 201 (57.8) | 166 (47.8) | p=0.007 |
| All at 15 years followup | 52.7 (47.4–58.6) | 46.1 (40.8–52.0) | ARR 6.6% (-1.3–14.5), p=0.007 |
| Low risk cancer at 15 years followup | 44.6 (36.6–54.4) | 31.4 (23.9–41.3) | ARR with RP: 13.2 (0.9–25.5)  RR with RP: 0.62 (0.42–0.92)  p=0.02 |
| Age <65 years at 15 years followup | 47.4 (40.0–56.1) | 33.9 (26.9–42.6) | ARR with RP: 13.2 (0.9–25.5)  RR with RP: 0.52 (0.37–0.73)  p<0.001 |
| Age <65 years and low risk cancer at 15 years followup | 36.2 (26.1–50.2) | 16.9 (9.5–30.1) | ARR with RP: 19.3 (4.0–34.7)  RR with RP: 00.36 (0.18–0.70)  p=0.002 |
| Age ≥65 years at 15 years followup | 57.4 (50.2–65.8) | 56.7 (49.5–65.0) | ARR with RP: 0.7 (-10.3–11.7)  RR with RP: 0.98 (0.75–1.28)  p=0.89 |
| Age ≥65 years and low risk cancer at 15 years followup | 52.9 (41.3–67.6) | 46.8 (35.1–62.3) | ARR with RP: 6.1 (-12.6–24.8)  RR with RP: 0.92 (0.57–1.49)  p=0.74 |
| Nguyen et al. 201053 | 3D-CRT: 104 patients | 3D-CRT plus ADT: 102 patients | — |
| All-cause mortality among healthy men (i.e., with mild or no comorbidity) | Adjusted HR 0.36; 96% CI, 0.13 to 0.98 | | p=0.046 |
| All-cause mortality among men with moderate or severe comorbidity) | Adjusted HR 5.2; 96% CI, 1.3 to 20.2 | | p=0.018 |
| D’Amico et al. 200835 | EBRT: 104 patients | EBRT plus ADT: 102 patients | HR (95% CI), p-value for interaction |
| Overall death in all patients at median followup of 7.6 years (range 0.5–11.0) | 44 | 30 | 1.8 (1.1– -2.9), p=0.01 |
| Overall death (No or Minimal Comorbidity) | 31 | 11 | 4.2 (2.1–8.5), p<0.001 |
| Overall death (Moderate or Severe Comorbidity) | 13 | 19 | 0.54 (0.27–1.10), p=0.08 |
| D’Amico et al. 200835 | Radiation therapy: 103 patients | Radiation therapy plus AST: 98 patients | HR (95% CI) |
| Overall mortality at a median of 4.52 years followup | 23 | 12 | 2.07 (1.02–4.20), p=0.04 |

**Abbreviations:** 3D-CRT=Three-dimensional conformal radiation therapy; ADT=androgen-deprivation therapy; ARR=absolute risk reduction; CI=confidence interval; EBRT=external beam radiation therapy; HR=hazard ratio; RP=radical prostatectomy; RR=relative risk; WW=watchful waiting.