Table F-11. Progression to metastasis (randomized controlled trials)

| **Study Outcomes** | **Treatment Group 1** | **Treatment Group 2** | **Analyses; p-Values** |
| --- | --- | --- | --- |
| Wilt et al. 201225Prostate Intervention Versus Observation Trial (PIVOT) | RP: 364 patients | Observation: 367 patients | — |
| Number of patients with bone metastases (%) at median followup 10 years | 17 (4.7) | 39 (10.0) | HR, 0.40; 95% CI, 0.22–0.70; p<0.001. |
| Bill-Axelson et al. 201133Same study as Holmberg et al. 201234, and Bill‑Axelson et al. 200815Scandinavian Prostate Cancer Group-4 (SPCG‑4) Trial | RP: 347 patients | Watchful waiting: 348 patients | — |
| Total number of distant metastases, cumulative incidence (number (%),at followup of 12 years | 67 (19.3) | 96 (27.6) | — |
| All ages at 8 years followup | 11.5 (8.6–15.4) | 18.7 (15-23.3) | ARR, 95% CI: 7.2 (1.8–12.5) |
| All ages at 12 years followup | 19.3 (15.3–24.2) | 26 (21.6–31.2) | ARR: 6.7 (0.2–13.2)RR: 0.65 (0.47–0.88)p=0.006 |
| Age <65 years at 8 years followup | 10.8 (6.9–17) | 22.9 (17.3–30.3) | ARR: 12.1 (4.0–20.1) |
| Age <65 years at 12 years followup | 20.7 (15–28.6) | 30.3 (23.8–38.5) | ARR: 9.6 (-0.3–19.5)RR: 0.52 (0.34–0.81)p=0.006 |
| Age ≥65 years at 8 years followup | 12.1 (8.2–17.8) | 14.8 (10.5–21) | ARR: 2.7 (-4.2–9.7) |
| Age ≥65 years at 12 years followup | 17.9 (13–24.6) | 22 (16.5–29.3) | ARR: 4.1 (16.5–29.3)RR: 0.80 (0.51–1.27)p=0.28 |
| Total number of distant metastases (number (%) at 15 years followup | 81 (23.3) | 123 (35.3) | — |
| All at 15 years followup | 21.7 (17.6–26.7) | 33.4 (28.6 to 39.0) | ARR: 11.7 (4.8–18.6)RR: 0.59 (0.45–0.79)p<0.001 |
| Low risk cancer at 15 years followup | 9.9 (5.8 - 17.1) | 21.4 (15.4 to 29.6) | ARR: 11.4 (2.6–20.2)RR: 0.43 (0.23–0.79)p=0.008 |
| Age <65 years at 15 years followup | 21.5 (15.9–29.2) | 39.8 (32.6 to 48.5) | ARR: 18.3 (8.0–28.5)RR: 0.47 (0.32–0.70)p=0.001 |
| Age <65 years and low risk cancer at 15 years followup | 9.5 (4.4–20.4) | 20.6 (12.8 to 33.0) | ARR: 11.1 (-1.0–23.2)RR: 0.41 (0.18–0.95)p=0.06 |
| Age ≥65 years at 15 years followup | 22.1 (16.6–29.4) | 27.5 (21.5 to 35.1) | ARR: 5.4 (-3.9–14.6)RR: 0.77 (0.51–1.15)p=0.14 |
| Age ≥65 years and low risk cancer at 15 years followup | 10.5 (4.8–23.0) | 21.8 (13.9 to 34.3) | ARR: 11.3 (-1.6–24.1)RR: 0.46 (0.19–1.11)p=0.06 |
| Jones et al. 201143 | EBRT: 992 patients | EBRT plus ADT: 987 patients | HR (95% CI) |
| Distant metastases at 10 years (% reaching end point) | — | — | — |
| All patients | 8 | 6 | 1.45 (1.03–2.06), p=0.04 |

**Abbreviations:** 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.