Table F-13. Quality of life (randomized controlled trials)

| **Study Outcomes** | **Treatment Group 1** | **Treatment Group 2** | **Analyses; p-Values** |
| --- | --- | --- | --- |
| Porpiglia et al. 201345 | RARP: 60 patients | LRP: 60 patients | — |
| Survival, Continence, and Potency classification at 1 year followup | S0: 49 (98%)  S1: 1 (2%)  C0: 44 (88%)  C1: 4 (8%)  C2: 2 (4%)  P0: 3 (8.6%)  P1: 25 (71.4%)  P2: 7 (20%) | S0: 49 (92.5%)  S1: 4 (7.5%)  C0: 36 (67.9%)  C1: 6 (11.3%)  C2: 11 (20.8%)  P0: 3 (8.6%)  P1: 16 (45.7%)  P2: 16 (45.7%) | —  —  p=0.014  p=0.571  p=0.010 (C2 vs C0 to C1)  p=1.00  p=0.030  p=0.020 (P2 vs. P0 to P1) |
| Rate of continence recovery at 12 month followup | 95.0% | 83.3% | OR 3.80 (95% CI 0.99 to 14.58), p=0.04 per author and p=0.052 per ECRI calculation. |
| Rate of potency recovery at 12 month followup in the nerve-sparing cohort | 80% | 54.2% | OR could not be calculated as authors were unclear about denominator, per author p=0.02 |
| Wilt et al. 201225  PIVOT | RP: 364 patients | Observation: 367 patients | — |
| Urinary Incontinence | RP: 49/287 (17.1%) | Observation 18/284 (6.3%) | p<0.001 |
| Erectile dysfunction | RP: 231/285 (81.1%) | Observation: 124/281 (44.1%) | p<0.001 |
| Bowel dysfunction | RP: 35/286 (12.2%) | Observation: 32/282 (11.3) | p=0.74 |
| Johansson et al. 201151  Bill-Axelson et al.48  Scandinavian Prostate Cancer Group-4 (SPCG-4) Trial | WW  n/total number of patients who provided information for each question | RP  n/total number of patients who provided information for each question | Age-adjusted relative risk, RP vs. WW (95% confidence interval [CI] |
| Anxiety (moderate or high) at median followup of 12.2 years (range 7–17) | 69/161 (43%) | 77/178 (43%), mean 2.74 | 0.97 (0.76–1.24) |
| Depressed mood (moderate or high) at median followup of 12.2 years (range 7–17) | 82/159 (52%) | 85/180 (47%), mean 2.89 | 0.92 (0.74–1.14) |
| Wellbeing (high) at median followup of 12.2 years (range 7–17) | 71/161 (44%), mean 5.04 | 73 /179 (41%), mean 5.11 | 0.89 (0.70–1.13) |
| Quality of life (high) at median followup of 12.2 years (range 7–17) | 55/160 (34%), mean 5.00 | 62/179 (35%), mean 4.96 | 0.98 (0.73–1.31) |
| Sense of meaningfulness (moderate or high) at median followup of 12.2 years (range 7–17) | 79/160 (49%), mean 5.33 | 83/179 (46%), mean 5.32 | 0.92 (0.74–1.15) |
| Distress (urinary leakage at 4 – 9 years) at 8-year followup, least square means | 0.25 | 0.58 | Odds ratio (OR) 4.04 (2.33–6.92) |
| Distress (obstructive voiding) at 8-year followup, least square means | 0.18 | 0.07 | OR 0.34 (0.21–0.54) |
| Distress (difficulties with erection ) at 8-year followup, least square means | 0.83 | 0.54 | OR 4.19 (2.63–6.68) |
| Distress (difficulties with intercourse ) at 8-year followup, least square means | 0.52 | 0.81 | OR 3.97 (2.51–6.30) |
| Distress (decreased libido) at 8-year followup, least square means | 0.46 | 0.64 | OR 2.09 (1.37–3.19) |
| Distress (health-related distress) at 8-year followup, least square means | 0.22 | 0.22 | OR 1.00 (0.65–1.55) |
| Prevalence of erectile dysfunction at 4 year followup | WW: 45% | RP: 49% | OR: 0.86 (0.64–1.15), p=0.30 |
| Prevalence of urinary leakage at 4 year followup | WW: 21% | RP: 49% | OR 3.62 (2.59–5.05), p=0.00 |
| Jones et al. 201143 | EBRT: 274 patients (number/total number (%) | EBRT plus short-term ADT: 284 patients (number/total number (%) | — |
| Effect of short-term ADT on erectile function, according to responses on the Sexual Adjustment Questionnaire at 1 year [number (%)] | — | — | — |
| Always or almost always | 85 (31) | 59 (21) | p=0.004 |
| Sometimes | 62 (23) | 66 (23) | p=0.95 |
| Almost never or never | 69 (25) | 94 (33) | p=0.054 |
| Did not try | 55 (20) | 58 (20) | p=1.00 |
| Not applicable or not answered | 4 (1) | 13 (5) | p=0.04 |
| Robinson et al.52  Same study as Donnelly et al. 201047 | EBRT: 122 patients | Cryotherapy: 122 patients | — |
| Urinary function scores at 3 years | 88.6 | 93.0 | p=0.043 |
| Bowel function scores at 3 years | 84.1 | 88.1 | p=0.092 |
| Sexual function scores at 3 years | 36.7 | 16.0 | p<0.001 |
| Giberti et al. 200944 | RPP: 100 patients | BT: 100 patients | — |
| European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ)-C30 at 5-year followup | — | — | — |
| Physical function | 90 | 94 | p-value not specified |
| Role function | 90 | 94 | p-value not specified |
| Emotional function | 84 | 82 | p-value not specified |
| Cognitive function | 90 | 88 | p-value not specified |
| Social function | 89 | 94 | p-value not specified |
| Global health/Quality of life | 78 | 82 | p-value not specified |
| Fatigue | 18 | 18 | p-value not specified |
| Nausea/vomiting | 1 | 1 | p-value not specified |
| Pain | 9 | 8 | p-value not specified |
| Dyspnea | 8 | 11 | p-value not specified |
| Insomnia | 22 | 20 | p-value not specified |
| Appetite loss | 3 | 4 | p-value not specified |
| Constipation | 3 | 0 | p-value not specified |
| Diarrhea | 5 | 6 | p-value not specified |
| Financial problem | 3 | 2 | p-value not specified |
| International Prostate Symptom Score at 5‑year followup | 4.7 | 5.1 | p-value not specified |
| EORTC-QLQ-PR25 urinary symptoms | 10 | 17 | p-value not specified |
| Bowel symptoms | 2 | 5 | p-value not specified |
| Treatment-related symptoms | 8 | 8 | p-value not specified |
| Sexual function | 7 | 8 | p-value not specified |
| Sexual activity | 8 | 8 | p-value not specified |
| IIEF at 5‑year followup | 22.0 | 21.2 | p-value not specified |
| D’Amico et al. 200835 | EBRT: 103 patients at median followup of 4.52 years | EBRT plus ADT: 98 patients at median followup of 4.52 years | — |
| Urinary incontinence (complete) | Grade 1: 3  Grade 2: 1  Grade 3: 1  Grade 4: 0 | Grade 1: 2  Grade 2: 1  Grade 3: 1  Grade 4: 0 | — |
| Urinary incontinence (stress) | Grade 1: 20  Grade 2: 7  Grade 3: 0  Grade 4: 0 | Grade 1: 22  Grade 2: 6  Grade 3: 0  Grade 4: 0 | — |
| Impotence | Grade 1: 4  Grade 2: 7  Grade 3: 21  Grade 4: 0 | Grade 1: 1  Grade 2: 6  Grade 3: 26  Grade 4: 0 | — |
| Martis et al. 200746 | RPP: 100 patients | RRP: 100 patients | — |
| IIEF score at 6 months followup | 30% of the patients had an average score of 18.5±0.5 | 45% of the patients had an average score of 21.7±1.9 | — |
| IIEF score at 24 months followup | 42% had a an average score of 19.7±1.1 | 60% had a an average score of 23.1±2.5 | — |

**Abbreviations:** ADT=androgen-deprivation therapy; BT=brachytherapy; CI=confidence interval; EBRT=external beam radiation therapy; IIEF= International Index of Erectile Function; LRP=laparoscopic radical prostatectomy; OR=odds ratio; RARP=robot-assisted radical prostatectomy; RP=radical prostatectomy; RPP=radical perineal prostatectomy; RRP=radical retropubic prostatectomy; WW=watchful waiting.