Prostate

Systematic Review of Active Surveillance for Clinically Localised Prostate Cancer to Develop Recommendations Regarding Inclusion of Intermediate-risk Disease, Biopsy Characteristics at Inclusion and Monitoring, and Surveillance Repeat Biopsy Strategy

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CONTEXT

There is uncertainty regarding the most appropriate criteria for recruitment, monitoring, and reclassification in active surveillance (AS) protocols for localised prostate cancer (PCa).

OBJECTIVE

To perform a qualitative systematic review (SR) to issue recommendations regarding inclusion of intermediate-risk disease, biopsy characteristics at inclusion and monitoring, and repeat biopsy strategy.

EVIDENCE ACQUISITION

A protocol-driven, Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA)-adhering SR incorporating AS protocols published from January 1990 to October 2020 was performed. The main outcomes were criteria for inclusion of intermediate-risk disease, monitoring, reclassification, and repeat biopsy strategies (per protocol and/or triggered). Clinical effectiveness data were not assessed.

EVIDENCE SYNTHESIS

Of the 17 011 articles identified, 333 studies incorporating 375 AS protocols, recruiting 264 852 patients, were included. Only a minority of protocols included the use of magnetic resonance imaging (MRI) for recruitment (n = 17), follow-up (n = 47), and reclassification (n = 26). More than 50% of protocols included patients with intermediate or high-risk disease, whilst 44.1% of protocols excluded low-risk patients with more than three positive cores, and 39% of protocols excluded patients with core involvement (CI) >50% per core. Of the protocols, ≥80% mandated a confirmatory transrectal ultrasound biopsy; 72% (n = 189) of protocols mandated per-protocol repeat biopsies, with 20% performing this annually and 25% every two years. Only 27 protocols (10.3%) mandated triggered biopsies, with 74% of these protocols defining progression or changes on MRI as triggers for repeat biopsy.

CONCLUSIONS

For AS protocols in which the use of MRI is not mandatory or absent, we recommend the following: (1) AS can be considered in patients with low-volume International Society of Urological Pathology (ISUP) grade 2 (three or fewer positive cores and cancer involvement ≤50% CI per core) or another single element of intermediate-risk disease, and patients with ISUP 3 should be excluded; (2) per-protocol confirmatory prostate biopsies should be performed within two years, and per-protocol surveillance repeat biopsies should be performed at least once every three years for the first 10 years; and (3) for patients with low-volume, low-risk disease at recruitment, if repeat systematic biopsies reveal more than three positive cores or maximum CI >50% per core, they should be monitored closely for evidence of adverse features (eg, upgrading); patients with ISUP 2 disease with increased core positivity and/or CI to similar thresholds should be reclassified.

PATIENT SUMMARY

We examined the literature to issue new recommendations on active surveillance (AS) for managing localised prostate cancer. The recommendations include setting criteria for including men with more aggressive disease (intermediate-risk disease), setting thresholds for close monitoring of men with low-risk but more extensive disease, and determining when to perform repeat biopsies (within two years and 3 yearly thereafter).