Active Surveillance for the Management of Localized Prostate Cancer (Cancer Care Ontario Guideline): American Society of Clinical Oncology Clinical Practice Guideline Endorsement
Introduction

• In order to avoid the harms associated with unnecessary treatment, Active Surveillance (AS) is an option for patients with prostate cancer that is less likely to cause mortality.

• This American Society of Clinical Oncology (ASCO) endorses the recommendations offered in the CCO guideline on Active Surveillance for the Management of Localized Prostate Cancer.
The ASCO Clinical Practice Guidelines Committee (CPGC) endorsement review process includes:

- methodological review by ASCO guidelines staff
- content review by an ad hoc endorsement panel
- final endorsement approval by ASCO CPGC

The full ASCO Endorsement methodology supplement can be found at:
www.asco.org/endorsements/activesurveillance

CCO Guideline Methodology can be found at:
Clinical Questions

1. How does AS compare with immediate active treatments (e.g., RP, RT, brachytherapy, hormone therapy, cryotherapy, or high-intensity focused ultrasound) as a management strategy for patients with newly-diagnosed localized prostate cancer (T1 and T2; Gleason score ≤7)?

2. In patients with localized prostate cancer undergoing AS, which findings of the following tests predict increasing risk of reclassification to a higher-risk disease state? What are their test characteristics (i.e., positive and negative predictive values, sensitivities, specificities, and likelihood ratios)?
   - PSA kinetics (e.g., velocity or doubling time)
   - DRE
   - Imaging (e.g., magnetic resonance imaging [MRI] or ultrasound [US])
   - Prostate cancer antigen3 (PCA3)

3. In patients with localized prostate cancer undergoing AS, how does supplementation with 5-alpha reductase inhibitors (5ARIs) (e.g., finasteride or dutasteride) compare with no supplementation?

4. In patients with localized prostate cancer undergoing AS, how do clinical outcomes differ if treatment is managed by a:
   - Single doctor versus a multidisciplinary team of clinicians?
   - Urologist versus another oncologist (e.g., a radiation oncologist)?
   - University/teaching hospital versus a community or private clinic/hospital?

5. In patients with localized prostate cancer who are candidates for or who are undergoing AS, how does the offer, receipt, or choice of treatment and patient compliance or adherence differ based on (but not limited to) the following factors:
   - AS protocol: order of and frequency of tests (PSA, DRE, imaging), and other test/clinical factors?
   - Care provider(s): single versus team of doctors; urologist versus other oncologist?
   - Care setting: clinic versus hospital?
   - Patient factors: clinical, psychosocial?
   - Social support: family or community?
   - Socioeconomic or geographic variables?

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Target Population and Audience

Target Population
Men with early clinically localized prostate cancer (stage T1 and T2, Gleason score ≤7)

Target Audience
Clinicians and specialists providing care to patients with prostate cancer (i.e. urologists, radiation oncologists, primary care physicians)
Summary of Recommendations

CCO recommendations, with original language, are listed below with qualifying statements added by the ASCO Panel listed in bold italics:

• For *most* patients with low-risk (Gleason score ≤6) localized prostate cancer, AS is the *recommended* disease management strategy

• Active treatment (RP or RT) is *recommended* for *most* patients with intermediate-risk (Gleason score 7) localized prostate cancer. For select patients with low-volume, *intermediate-risk* (Gleason 3+4=7) localized prostate cancer, AS *may be offered*
Summary of Recommendations

• The AS protocol should include the following tests:
  – a PSA test every 3 to 6 months
  – DRE at least every year
  – At least a 12 core confirmatory transrectal ultrasound (TRUS) guided biopsy (including anterior directed cores) within 6 to 12 months, then serial biopsy every 2 to 5 years thereafter or more frequently if clinically warranted. Men with limited life expectancy may transition to watchful waiting and avoid further biopsies.

• For patients undergoing AS who are reclassified to a higher risk category, defined by repeat biopsy showing Gleason score ≥ 7 and/or significant increases in the volume of Gleason 6 tumor, consideration should be given to active therapy (e.g., RP or RT)

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Discussion

• The distinction between active surveillance and watchful waiting is important for clinical decision-making.
  – Active surveillance – which carries a curative intent and involves regular monitoring with PSA, DRE, and biopsy is appropriate for patients who have sufficient life expectancy to benefit from active treatment if disease progression were detected
  
  – For patients with a life expectancy of less than 5 years, watchful waiting (cessation of routine monitoring with treatment initiated only if symptoms develop) is appropriate and further reduces the issue of overtreatment in prostate cancer – including biopsies which carry a small but non-zero risk of infection and hospitalization

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Discussion

• Active surveillance is the recommended disease management strategy for low-risk prostate cancer

• Older patients may start on active surveillance, potentially transition to watchful waiting if there is no disease progression, and be able to avoid treatment altogether

• Intensive treatments when cancer progresses need to be balanced against the benefits of active surveillance including delaying treatment and associated short-term and long-term side effects – and decisions need to take into account patient preference
Discussion

• Use of ancillary tests beyond DRE, PSA and biopsy to improve patient selection or as part of monitoring in an active surveillance regimen remains investigational

• There is no clear role for 5-alpha reductase inhibitors in a routine active surveillance regimen

• The ASCO Endorsement Panel was in agreement with the CCO guideline that currently, there is insufficient evidence to make recommendations with regard to the personnel who should be responsible for the management of AS protocols
  – However, in the opinion of the endorsement panel, a multidisciplinary team approach should be taken when a change to active treatment is considered
Reprint Permission


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Endorsement Recommendation

ASCO endorses the CCO Active Surveillance for the Management of Localized Prostate Cancer, published by Morash C et al. in 2015 in the *Canadian Urological Association Journal*, with qualifying statements.
Additional Resources

More information, including a Data Supplement with a reprint of all CCO recommendations, a Methodology Supplement, clinical tools, and resources, is available at: www.asco.org/endorsements/activesurveillance

CCO Guideline:
http://www.cancercare.on.ca/common/pages/UserFile.asp?fileId=325696

Patient information is available at: www.cancer.net
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