

CADTH RAPID RESPONSE REPORT: REFERENCE LIST

Hormonal Therapy and High-Intensity Focused Ultrasonography for Prostate Cancer: Clinical Effectiveness and Guidelines

Service Line: Rapid Response Service

Version: 1.0

Publication Date: October 3, 2019

Report Length: 8 Pages



Authors: Yan Li, Robyn Butcher

Cite As: Hormonal Therapy and High-Intensity Focused Ultrasonography for Prostate Cancer: Clinical Effectiveness and Guidelines. Ottawa: CADTH; 2019 October. (CADTH rapid response report: reference list).

Disclaimer: The information in this document is intended to help Canadian health care decision-makers, health care professionals, health systems leaders, and policy-makers make well-informed decisions and thereby improve the quality of health care services. While patients and others may access this document, the document is made available for informational purposes only and no representations or warranties are made with respect to its fitness for any particular purpose. The information in this document should not be used as a substitute for professional medical advice or as a substitute for the application of clinical judgment in respect of the care of a particular patient or other professional judgment in any decision-making process. The Canadian Agency for Drugs and Technologies in Health (CADTH) does not endorse any information, drugs, therapies, treatments, products, processes, or services.

While care has been taken to ensure that the information prepared by CADTH in this document is accurate, complete, and up-to-date as at the applicable date the material was first published by CADTH, CADTH does not make any guarantees to that effect. CADTH does not guarantee and is not responsible for the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials used in preparing this document. The views and opinions of third parties published in this document do not necessarily state or reflect those of CADTH.

CADTH is not responsible for any errors, omissions, injury, loss, or damage arising from or relating to the use (or misuse) of any information, statements, or conclusions contained in or implied by the contents of this document or any of the source materials.

This document may contain links to third-party websites. CADTH does not have control over the content of such sites. Use of third-party sites is governed by the third-party website owners' own terms and conditions set out for such sites. CADTH does not make any guarantee with respect to any information contained on such third-party sites and CADTH is not responsible for any injury, loss, or damage suffered as a result of using such third-party sites. CADTH has no responsibility for the collection, use, and disclosure of personal information by third-party sites.

Subject to the aforementioned limitations, the views expressed herein do not necessarily reflect the views of Health Canada, Canada's provincial or territorial governments, other CADTH funders, or any third-party supplier of information.

This document is prepared and intended for use in the context of the Canadian health care system. The use of this document outside of Canada is done so at the user's own risk.

This disclaimer and any questions or matters of any nature arising from or relating to the content or use (or misuse) of this document will be governed by and interpreted in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein, and all proceedings shall be subject to the exclusive jurisdiction of the courts of the Province of Ontario, Canada.

The copyright and other intellectual property rights in this document are owned by CADTH and its licensors. These rights are protected by the Canadian *Copyright Act* and other national and international laws and agreements. Users are permitted to make copies of this document for non-commercial purposes only, provided it is not modified when reproduced and appropriate credit is given to CADTH and its licensors.

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to requests@cadth.ca



Research Questions

- 1. What is the clinical effectiveness of hormonal therapy for early-stage or screen-detected prostate cancer?
- 2. What is the clinical effectiveness of high-intensity focused ultrasonography for early-stage or screen-detected prostate cancer?
- 3. What are the evidence-based guidelines on the use of hormonal therapy for prostate cancer?
- 4. What are the evidence-based guidelines on the use of high-intensity focused ultrasonography for prostate cancer?

Key Findings

One health technology assessment report and three systematic reviews were identified regarding the clinical effectiveness of high-intensity focused ultrasonography for early-stage or screen-detected prostate cancer. One randomized controlled trial was identified regarding the clinical effectiveness of hormonal therapy for early-stage or screen-detected prostate cancer. One systematic review was identified that compared prostate cancer treatment guidelines. Six evidence-based guidelines were identified regarding the use of hormonal therapy and high-intensity focused ultrasonography for prostate cancer.

Methods

A limited literature search was conducted by an information specialist on key resources including Ovid Medline, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were early stage prostate cancer and hormonal therapy, or high-intensity focused ultrasonography Search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, or network meta-analyses, randomized controlled trials or controlled clinical trials or guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and September 26, 2019. Internet links were provided, where available.



Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	People and individuals with screen-detected primary prostate cancer, or localized (T1 or T2) prostate cancer
Intervention	Q1,3: Hormonal therapy (e.g., androgen suppression therapy, orchiectomy surgery) Q2,4: High-intensity focused ultrasonography
Comparator	Q1,2: Watchful waiting; active surveillance; cryotherapy; radiation therapy via any technique (e.g., brachytherapy, intensity modulated, stereotactic); radical prostatectomy via any technique (e.g., open surgery, laparoscopy, robot assisted) Q1: High-intensity focused ultrasonography Q2: Hormonal therapy (e.g., androgen suppression therapy, orchiectomy surgery) Q3,4: None required
Outcomes	Q1,2: Clinical effectiveness and safety (e.g., quality of life, urinary continence, bowel function, erectile function, psychological wellbeing, prostate-specific antigen levels, adverse events, death, surgical complications) Q3,4: Guidelines on appropriate use and place in therapy
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and evidence-based guidelines

Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and evidence-based guidelines.

One health technology assessment report¹ and three systematic reviews^{2,3,5} were identified regarding the clinical effectiveness of high-intensity focused ultrasonography for early-stage or screen-detected prostate cancer. One randomized controlled trial was identified regarding the clinical effectiveness of hormonal therapy for early-stage or screen-detected prostate cancer.⁶ One systematic review was identified that compared prostate cancer treatment guidelines.⁴ Six evidence-based guidelines were identified regarding the use of hormonal therapy and high-intensity focused ultrasonography for prostate cancer.⁷⁻¹²

Additional references of potential interest are provided in the appendix.

Health Technology Assessments

 Ramsay CR, Adewuyi TE, Gray J, et al. Ablative therapy for people with localised prostate cancer: a systematic review and economic evaluation. *Health Technol Assess*. 2015 Jul;19(49):1-490.

PubMed: PM26140518



Systematic Reviews and Meta-analyses

- LBI-HTA, VASPVT et al. High-intensity focused ultrasound for the treatment of prostate cancer. (Rapid assessment of other health technologies using the HTA core model for rapid relative effectiveness assessment). Copenhagen (DK): EUnetHTA; 2018;
 - https://www.eunethta.eu/wp-content/uploads/2018/04/OTCA09_HIFU-for-prostate-cancer_v1.4.pdf. Accessed 2019 Oct 2.
- Faure Walker NA, Norris JM, Shah TT, et al. A comparison of time taken to return to baseline erectile function following focal and whole gland ablative therapies for localized prostate cancer: a systematic review. *Urol Oncol.* 2018 02;36(2):67-76.
 PubMed: PM29277585
- Lancee M, Tikkinen KAO, de Reijke TM, Kataja VV, Aben KKH, Vernooij RWM. Guideline of guidelines: primary monotherapies for localised or locally advanced prostate cancer. *BJU Int.* 2018 10;122(4):535-548.
 PubMed: PM29633514
- Valerio M, Cerantola Y, Eggener SE, et al. New and established technology in focal ablation of the prostate: a systematic review. *Eur Urol.* 2017 01;71(1):17-34.
 PubMed: PM27595377

Randomized Controlled Trials

 Thomsen FB, Brasso K, Christensen IJ, et al. Survival benefit of early androgen receptor inhibitor therapy in locally advanced prostate cancer: long-term follow-up of the SPCG-6 study. *Eur J Cancer*. 2015 Jul;51(10):1283-1292.
 PubMed: PM25892647

Guidelines and Recommendations

- National Comprehensive Cancer Network. Prostate cancer. Version 4.2019. Plymouth Meeting (PA): National Comprehensive Cancer Network; 2019: www.nccn.org. Accessed 2019 Oct 2.
- National Institute for Health Care and Excellence. Prostate cancer: diagnosis and management. (NICE guideline NG131). 2019; https://www.nice.org.uk/guidance/ng131. Accessed 2019 Oct 2.
- Alberta Health Services. Local prostate cancer. (Clinical practice guideline GU-012).
 2018; https://www.albertahealthservices.ca/assets/info/hp/cancer/if-hp-cancer-guide-gu012-local-prostate.pdf. Accessed 2019 Oct. 2
- American Urological Association (AUA) / American Society for Radiation Oncology (ASTRO) / Society of Urologic Oncology (SUO). Clinically localized prostate cancer: AUA/ASTRO/SUO guideline. 2017; https://www.auanet.org/Documents/education/clinical-guidance/Clinically-Localized-Prostate-Cancer.pdf. Accessed 2019 Oct 2.



11. Mottet N, Bellmunt J, Bolla M, et al. EAU-ESTRO-SIOG guidelines on prostate cancer. Part 1: screening, diagnosis, and local treatment with curative intent. *Eur Urol.* 2017 04;71(4):618-629.

PubMed: PM27568654

 Department of Health. Diagnosis, staging and treatment of patients with prostate cancer. National clinical guideline No. 8. June 2015. Updated March 2016. https://assets.gov.ie/11607/44b3edda9897415a96db8f9d9d654923.pdf. Accessed 2019 Oct 2



Appendix — Further Information

Previous CADTH Reports

13. Treatment versus active surveillance in men with low risk prostate cancer: clinical effectiveness and guidelines. (CADTH Rapid response report: summary of abstracts). Ottawa (ON): CADTH; 2015:

https://www.cadth.ca/treatment-versus-active-surveillance-men-low-risk-prostate-cancer-clinical-effectiveness-and. Accessed 2019 Oct 2.

Systematic Reviews – Unclear or No Comparator

 Bolton EM, Lynch T. Are all gonadotrophin-releasing hormone agonists equivalent for the treatment of prostate cancer? A systematic review. BJU Int. 2018 09;122(3):371-383.

PubMed: PM29438592

 Golan R, Bernstein AN, McClure TD, et al. Partial gland treatment of prostate cancer using high-intensity focused ultrasound in the primary and salvage settings: a systematic review. *J Urol.* 2017 11;198(5):1000-1009.
 PubMed: PM28433640

 Helgstrand JT, Berg KD, Lippert S, Brasso K, Roder MA. Systematic review: does endocrine therapy prolong survival in patients with prostate cancer? *Scand J Urol.* 2016 Jun;50(3):135-143.

PubMed: PM26907159

 Carneiro A, Sasse AD, Wagner AA, et al. Cardiovascular events associated with androgen deprivation therapy in patients with prostate cancer: a systematic review and meta-analysis. World J Urol. 2015 Sep;33(9):1281-1289.
 PubMed: PM25387877

18. Veereman G, Jonckheer P, Desomer A, et al. Systematic review of the efficacy and safety of high-intensity focussed ultrasound for localised prostate cancer. *Eur Urol*

PubMed: PM28723429

Focus. 2015 Sep;1(2):158-170.

 Crouzet S, Rouviere O, Martin X, Gelet A. High-intensity focused ultrasound as focal therapy of prostate cancer. *Curr Opin Urol.* 2014 May;24(3):225-230.
 PubMed: PM24710053

Randomized Controlled Trials – Alternative Comparator – Combination Therapy

 Tombal B, Saad F, Penson D, et al. Patient-reported outcomes following enzalutamide or placebo in men with non-metastatic, castration-resistant prostate cancer (PROSPER): a multicentre, randomised, double-blind, phase 3 trial. *Lancet Oncol*. 2019 Apr;20(4):556-569.

PubMed: PM30770294

21. Hussain M, Fizazi K, Saad F, et al. Enzalutamide in men with nonmetastatic, castration-resistant prostate cancer. *N Engl J Med.* 2018 Jun 28;378(26):2465-2474. PubMed: PM29949494



 Saad F, Cella D, Basch E, et al. Effect of apalutamide on health-related quality of life in patients with non-metastatic castration-resistant prostate cancer: an analysis of the SPARTAN randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2018 10;19(10):1404-1416.

PubMed: PM30213449

 Smith MR, Saad F, Chowdhury S, et al. Apalutamide treatment and metastasis-free survival in prostate cancer. N Engl J Med. 2018 Apr 12;378(15):1408-1418.
 PubMed: PM29420164

Review Articles

24. Tyson MD, Penson DF, Resnick MJ. The comparative oncologic effectiveness of available management strategies for clinically localized prostate cancer. *Urol Oncol.* 2017 02;35(2):51-58.

PubMed: PM27133953

Clinical Practice Guidelines

 Droz JP, Aapro M, Balducci L, et al. Management of prostate cancer in older patients: updated recommendations of a working group of the International Society of Geriatric Oncology. *Lancet Oncol*. 2014 Aug;15(9):e404-414.
 PubMed: PM25079103

Position Statements

 Ganzer R, Arthanareeswaran VKA, Ahmed HU, et al. Which technology to select for primary focal treatment of prostate cancer?-European Section of Urotechnology (ESUT) position statement. *Prostate Cancer Prostatic Dis.* 2018 06;21(2):175-186. <u>PubMed: PM29743538</u>