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Platinum Priority – Collaborative Review – Prostate Cancer

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New and Established Technology in Focal Ablation of the Prostate: A Systematic Review

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Abstract

Context: Focal therapy of prostate cancer has been proposed as an alternative to whole-gland treatments.

Objective: To summarize the evidence regarding sources of energy employed in focal therapy.

Evidence acquisition: Embase and Medline (PubMed) were searched from 1996 to October 31, 2015 following the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement. Ongoing trials were selected from electronic registries. The stage of assessment of each source of energy was determined using the Idea, Development, Exploration, Assessment, Long-term study recommendations.

Evidence synthesis: Thirty-seven articles reporting on 3230 patients undergoing focal therapy were selected. Thirteen reported on high-intensity focused ultrasound, 11 on cryotherapy, three on photodynamic therapy, four on laser interstitial thermotherapy, two on brachytherapy, three on irreversible electroporation, and one on radiofrequency. High-intensity focused ultrasound, cryotherapy, photodynamic therapy, and brachytherapy have been assessed in up to Stage 2b studies. Laser interstitial thermotherapy and irreversible electroporation have been evaluated in up to Stage 2a studies. Radiofrequency has been evaluated in one Stage 1 study. Median follow-up varied between 4 mo and 61 mo, and the median rate of serious adverse events ranged between 0% and 10.6%. Pad-free leak-free continence and potency were obtained in 83.3–100% and 81.5–100%, respectively. In series with intention to treat, the median rate of significant and insignificant disease at control biopsy varied between 0% and 13.4% and 5.1% and 45.9%, respectively. The main limitations were the length of follow-up, the absence of a comparator arm, and study heterogeneity.

Conclusions: Focal therapy has been evaluated using seven sources of energy in single-arm retrospective and prospective development studies up to Stage 2b. Focal therapy seems to have a minor impact on quality of life and genito-urinary function. Oncological effectiveness is yet to be defined against standard of care.

Patient summary: Seven sources of energy have been employed to selectively ablate discrete areas of prostate cancer. There is high evidence that focal therapy is safe and has low detrimental impact on continence and potency. The oncological outcome has yet to be evaluated against standard of care.

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1. Introduction

In the last decade, focal therapy has been evaluated as a novel strategy in selected men harboring localized prostate cancer. The aim of this tissue-preserving strategy is to maintain the oncological benefit of active treatments, while optimizing genito-urinary function. Focal therapy has as its objective the eradication of clinically significant disease, thereby conferring to the individual a transition from a moderate or high-risk status to a lower one. This process aims to preserve as much tissue as is compatible with treating the target volume plus a margin. This approach seeks to protect key structures from injury whose integrity is essential for stable genito-urinary function (neurovascular bundles, urethral sphincter, and bladder neck) [1]. Further, the bladder and the rectum, two structures that can be impaired by radiation therapy, are fully preserved. Although partial surgery and focal ablation in almost all solid cancers are accepted options in eligible patients, the legitimacy of focal therapy in prostate cancer is debated as this malignancy is multifocal in most cases [2,3].

While comparative effectiveness research against standard of care options is lacking, the rationale supporting this strategy relies on evidence-based elements. Firstly, the natural history of the disease seems to be linked to the *index lesion* in the majority of men, and secondary low-grade lesions seem to have an indolent behavior in most if not all cases [4–6]. Secondly, our ability to risk stratify men at a regional level within the prostate has significantly increased. There is growing evidence that the use of multiparametric magnetic resonance imaging (MRI) with targeted and mapping biopsy allows the detection of the index lesion with reliability over 90%, at least in expert centers [7]. Thirdly, these diagnostic tools together are able to rule out clinically significant lesions within discrete areas of the prostate with again accuracy over 90% [7].

Focal therapy has been delivered employing a number of sources of energy: (1) high-intensity focused ultrasound (HIFU), (2) cryotherapy, (3) photodynamic therapy (PDT), (4) laser interstitial thermotherapy (LITT), (5) brachytherapy, (6) irreversible electroporation (IRE), and (7) radio-frequency ablation (RFA). The aim of this systematic review was to summarize the stage of assessment and the evidence available with respect to each of these sources of energy.

2. Evidence acquisition

2.1. Search strategy and selection criteria

This systematic review was performed in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement [8]. Embase and Medline (through PubMed) were searched systematically using medical subject headings including “(<prostate cancer> OR <prostatic neoplasms>) AND (<focal> OR <subtotal> OR <hemiblation> OR <quadrant>).” The search was limited to studies reporting focal therapy outcomes between 1996 to October 31, 2015. Electronic links to related articles and references of selected articles were hand searched.

Additional relevant articles were selected from authors’ bibliographies. In addition, ongoing and recruiting registered trials were retrieved from ClinicalTrial.gov and the International Standard Randomized Controlled Trial Number registry to assess the current status of evaluation of each source of energy.

Eligible articles included meta-analyses, randomized controlled trials (RCTs) or prospective case series including a control group, prospective development studies, and retrospective case series investigating ablative techniques to treat patients with biopsy-proven prostate cancer in a subtotal manner (focal, quadrant, hemi-ablation, dog-leg, etc.) in the primary setting. Case reports were excluded, as well as review articles and congress abstracts. Studies related to *whole-gland treatment* or performed in a salvage treatment setting were excluded while studies involving focal treatment followed by radical prostatectomy were included. The search was limited to human studies and English language. Eligibility was determined by two separate reporters (MV and YC) using the Covidence software (www.covidence.org). Covidence is a web-based software platform designed to ease and improve systematic reviews by facilitating duplicates exclusion and the independent process performed by the reviewers, from screening to data extraction. It also helps with resolution of discrepancies and agreement by consensus. In case of persistent discrepancies after discussion, the senior author (ME) arbitrated. Besides the source of energy used to ablate, at least one of the following main outcome measures had to be reported: (1) oncological outcomes, (2) morbidity, or (3) functional outcomes. All studies of interest were obtained as full text articles and scrutinized thoroughly. Relevant data were extracted and documented in a data extraction form developed a priori. In cases of potential duplicated datasets, the study was excluded. If overlapping was partial (< 50% sample size) and over a limited period of time, all studies were fully reported, although the risk of duplication was highlighted.

2.2. Objectives

The primary objective of this study was to determine the stage of assessment of sources of energy currently used in focal therapy of the prostate. We employed the recommendation from the Idea, Development, Exploration, Assessment, Long-term study statement which defines the stage of assessment according to the design, the sample size, the outcome, and the outcome measures used to evaluate a novel surgical procedure [9]. Briefly: (1) Stage 1 (Innovation) refers to the first description of a procedure, (2) Stage 2a (Development) refers to the development phase in which the procedure is carried out by early adopters in well selected patients, but the intervention needs to be refined, (3) Stage 2b (Exploration) refers to the exploration of indications, quality control measures, and reproducibility in larger groups of patients, (4) Stage 3 (Assessment) refers to comparative effectiveness research of the novel procedure against standard of care, (5) Stage 4 (Long-term) refers to the implementation and monitoring of established

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