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Platinum Priority – Position Paper

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Focal Therapy in Primary Localised Prostate Cancer: The European Association of Urology Position in 2018

Henk G. van der Poel [a,*], *Roderick C.N. van den Bergh* [a], *Erik Briers* [b], *Philip Cornford* [c], *Alex Govorov* [d], *Ann M. Henry* [e], *Thomas B. Lam* [f,g], *Malcolm D. Mason* [h], *Olivier Rouvière* [i], *Maria De Santis* [j,k], *Peter-Paul M. Willemse* [l], *Hendrik van Poppel* [m], *Nicolas Mottet* [n]

[a] *Department of Urology, Netherlands Cancer Institute, Amsterdam, The Netherlands;* [b] *Patients Advocate, Hasselt, Belgium;* [c] *Royal Liverpool and Broadgreen Hospitals NHS Trust, Liverpool, UK;* [d] *Department of Urology, Moscow State University of Medicine and Dentistry, Moscow, Russia;* [e] *Leeds Cancer Centre, St. James's University Hospital, Leeds, UK;* [f] *Academic Urology Unit, University of Aberdeen, Aberdeen, UK;* [g] *Department of Urology, Aberdeen Royal Infirmary, Aberdeen, UK;* [h] *Division of Cancer & Genetics, School of Medicine Cardiff University, Velindre Cancer Centre, Cardiff, UK;* [i] *Hospices Civils de Lyon, Radiology Department, Edouard Herriot Hospital, Lyon, France;* [j] *Clinical Trials Unit, University of Warwick, UK;* [k] *Department of Urology, Medical University of Vienna, Vienna, Austria;* [l] *Department of Urology, University Utrecht, Utrecht, The Netherlands;* [m] *Department of Urology, University Hospital K.U. Leuven, Leuven, Belgium;* [n] *Department of Urology, University Hospital, St. Etienne, France*

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Abstract

Radical treatment of localised prostate cancer is recognised to be an unnecessary intervention or overtreatment in many men. Consequently, there has been a rapid uptake in the use of focal ablative therapies. However, there are several biological and practical concerns about such approaches as they have yet to be proved as robust treatment options. In particular, the multifocal nature of prostate cancer argues against unifocal treatment, while limitations in imaging can preclude the accurate identification of the number, location, and extent of prostate cancer foci. To date, a number of ablative options have reported results on mainly low-risk disease. Most series are relatively immature, with a lack of consistent follow-up, and the morbidity of retreatment is often not considered. The authors consider focal therapy to be an investigational modality, and encourage prospective recording of outcomes and recruitment of suitable patients.

Patient summary: Focal therapy of prostate cancer is the targeted destruction of cancer within a specific part of the prostate gland, sparing the rest of the prostate and nearby tissue. This procedure could potentially reduce side effects when compared with established standard treatments, such as surgery or radiotherapy, which treat the entire prostate. Studies show that for most men with low-risk cancer, active surveillance is the preferred treatment option. However, the available data regarding all forms of focal therapy are still poor and inconclusive. Consequently, due to both the lack of clear results associated with focal therapy and the difficulties in detecting all cancerous areas of the prostate, focal therapy should be considered an investigational modality only.

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* Corresponding author. Department of Urology, The Netherlands Cancer Institute Antoni Van Leeuwenhoek Hospital, Plesmanlaan 121, Amsterdam 1066CX, The Netherlands. Tel. +31205122553; Fax: +31205122554.
E-mail addresses: h.vd.poel@nki.nl, h_vanderpoel@hotmail.com (H.G. van der Poel).

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1. Introduction

Whole-gland treatment is currently considered the optimum treatment for localised prostate cancer (PCa). However, since treatment of the entire prostate gland results in damage to surrounding tissue such as urinary sphincter, neurovascular bundle, bowel, and bladder, focused treatment for PCa lesions only, should they be accurately identified, would be of interest. Focal therapy (FT) of the prostate can be defined as treatment of specific areas of the prostate to minimise treatment-related morbidity and is facilitated by improvements in PCa imaging. The options for FT are numerous, and focal ablation may reduce complications associated with whole-gland treatment provided that the same oncological efficacy is maintained [1,2].

Recent data from the ProtecT trial showed no difference in 10-yr cancer-specific survival between active monitoring, radical prostatectomy (RP), and external beam radiotherapy (EBRT) in men with mainly low- and intermediate-risk PCa, but considerable differences in functional outcomes

Table 1 – Summary of consensus reports on focal therapy

Publication	Consensus topic	Consensus set-up	Patient selection	Follow-up	Conclusion
Bostwick et al (2007) [7]	Pathobiology definition, patient selection, biopsy	Not provided	LE >5 yr, T1-3, PSA <15 ng/ml, no LUTS, bladder stones, infections excluded, 3D mapping biopsies at 5 mm interval		FT reasonable consideration in selected patients
De la Rosette et al (2010) [8]	Patient selection, imaging	Workshop, discussion group, informal	Template biopsies, LE >10 yr, cave in patients with LUTS, low–intermediate risk, <T2c, anterior/apical lesions may be difficult, long-term effects not known	Biopsy 6 and 12 mo; future: mpMRI or CEUS, 3 mo PSA in the 1st year and 6 mo thereafter, PROMs	
Smeenge et al (2012) [9]	Role of TRUS	Workshop, discussion group, informal	TRUS value limited, CEUS promising, systematic biopsy schemes needed		
Ahmed et al (2012) [10]	FT and AS	Workshop, discussion group, informal	Transperineal mapping biopsy		Suggested study sequence: proof of tumour ablation, compare FT with existing whole gland and/or AS
Langley et al (2012) [11]	Focal LDR	Consensus meeting	LE >10 yr, PSA ≤15 ng/ml, mpMRI, template biopsies, unilateral <0.5 cc, contralateral <3 mm insignificant disease(GS 3 + 3, <3 mm), index lesion ≤GS 3 + 4, <T2c, prostate size <60 cc	PSA 3 mo intervals for 1 yr and 6 mo thereafter, Phoenix criteria, mpMRI, PROMs	Distinction of ultra-FT (part of lobe), FT (hemigland), focused therapy (combining whole gland and FT)
Muller et al (2014) [12]	Role of mpMRI	Delphi method, panel meeting		Biopsy 6 mo, 12 mo	mpMRI preferred imaging, FU 6 mo, yearly mpMRI, no consensus on whether mpMRI could replace biopsies
Van den Bos et al (2014) [13]	Trial design	Delphi method, panel meeting	PSA <15 ng/ml, T1c-2a, GS 3 + 3 or 3 + 4, LE >10 yr	Biopsy 6 mo, 12 mo	
Muller et al (2015) [14]	Follow-up	Delphi method, panel meeting		Minimal 5 yr, (fusion) template TRUS biopsies after 1 yr, mpMRI (T2WI, DWI, DCE, T1WI) at 6 and 12 mo, yearly thereafter until 5 yr	
Donaldson et al (2015) [15]	Patients, interventions and outcomes	Delphi method, panel meeting	Intermediate risk, MRI-targeted or template biopsies, 5 mm treatment margin, GS 6, <3 mm can be left untreated, <20% retreatment		
Scheltema et al (2017) [16]	mpMRI	Delphi method, panel meeting	mpMRI to plan treatment	Biopsy	Use 1.5 T mpMRI only with endorectal coil, fusion MRI-TRUS when suspect lesion besides systemic biopsies
Tay et al (2017) [17]	Patient selection	Delphi method, panel meeting	mpMRI standard imaging tool, low/intermediate-risk PCa, GS 4 + 3, GS 3 + 4, foci <1.5 cc on mpMRI, <20% of the prostate, 3 cc or 25% of the prostate for hemigland treatment; Gleason 6 in one core in the nontreated region is acceptable		

AS = active surveillance; CEUS = contrast-enhanced ultrasound; DCE = dynamic contrast enhanced; DWI = diffusion-weighted imaging; FT = focal therapy; FU = follow-up; GS = Gleason score; LE = life expectancy; LDR = low-dose rate; LUTS = lower urinary tract symptoms; mpMRI = multiparametric magnetic resonance imaging; MRI = magnetic resonance imaging; PCa = prostate cancer; PROMs = patient-reported outcome measures; PSA = prostate-specific antigen; TRUS = transrectal ultrasound; T1WI = T1-weighted imaging; T2WI = T2-weighted imaging.

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