

## New Frontiers in Imaging and Focal Therapy

*Highlights From the Third International Symposium on Focal Therapy and Imaging of Prostate and Kidney Cancer, February 24-27, 2010, Washington, DC*

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The Third International Symposium on Focal Therapy and Imaging of Prostate and Kidney Cancer explored new frontiers in imaging and focal therapy (FT) for prostate and kidney cancer. It has become an annual event for all researchers using an interdisciplinary approach to develop further the concept of FT. A cadre of clinicians and scientists gathered that included approximately 200 experts in prostate and kidney imaging and urologic pathology, basic scientists and molecular biologists, medical and radiation oncologists, urologists, and industry leaders. Presentations, didactic lectures, and panel discussions comprised this three-day meeting, which also included four poster sessions and

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Reviewed by Vladimir Mouraviev, MD, PhD, Thomas J. Polascik, MD, Division of Urology, Department of Surgery, Duke University Medical Center, Durham, NC.

video presentations. The program featured experts who provided insight into image-guided diagnosis and minimally invasive focal, organ-preserving treatment for patients with prostate and kidney cancer.

### Pathologic and Molecular Basis of FT

At the first session, Dr. Peter Carroll analyzed data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) database of 10,835 patients with localized prostate cancer (PCa), and suggested a current stage migration driven by the lowering of serum prostate-specific antigen (PSA) cutpoints, frequent re-screening, and extended-pattern biopsy schemes.<sup>1</sup> As a rationale for FT, Dr. Carroll provided the following statements: patient risk of undergrading is approximately 30% to 35% and understaging is approximately 10%; a subset of men with PCa have a dominant focus of prostate cancer amenable to ablation; ablative energy

sources are available; FT is less morbid than whole-gland therapy; and surveillance alone may not be favored by the patient, even when counseled well. As to limitations of FT, he outlined the following challenges:

- Identification and targeting of focal lesions is currently not accurate enough
- Refinement of current and identification of new forms of imaging are critical to the safe and effective utilization of such approaches
- Current experience is limited, generally anecdotal, and poorly reported

Such approaches should not discourage/replace the use of active surveillance for early stage PCa.

In his presentation, David Bostwick paid particular attention to quality assurance in prostate biopsy sampling and processing that may be a crucial factor in selecting candidates for FT.<sup>2</sup> He concluded that there is a variance in pathologists' and urologists' results in cancer yield on biopsies, and not all biopsies are created equal. Mean

core length is an important quality indicator of biopsies.

Dr. Thomas Wheeler presented a large Baylor series indicating that the number of cancers has slightly increased as the tumor volume has decreased from the pre-PSA era to the current era.<sup>3</sup> In this series of 947 radical prostatectomy specimens excised by a single surgeon, unifocal tumors were found in 22% of all cases versus 78% identified with multifocal disease, a mean of cancer foci of 2.24. The mean index tumor volume was 2.42 cc and the mean total accessory tumor volume was 0.61 cc. The frequency of multifocal lesions increased from 71.5% (1983-1988) to 77.9% (1989-1993) to 80.8% (1994-1998), and was not age dependent. Most interestingly, when the authors analyzed the Kaplan-Meier plot of biochemical disease-free survival (bDFS), the difference was significant between unifocal and multifocal disease but insignificant between groups within the latter according to the number of foci. Several study limitations must be mentioned. The definition of number of cancer foci that was used was very conservative. The authors used the written record of the mapping data that, for most cases, would have resulted in only four foci possible according to the zonal distribution (right peripheral zone [RPZ], left peripheral zone, right transitional zone, or left transitional zone). The only way to record more than one focus in a given zone (eg, two foci in RPZ) would require an intervening whole-mount specimen without tumor in this location separating the two foci in the same zone. Definitions of multifocality that rely on separation of discrete foci by a few millimeters of non-neoplastic prostate tissue can produce numbers much greater than in the study presented.

In his presentation, Hashim Ahmed pointed out that the index lesion is

likely to be responsible for disease progression in PCa.<sup>4</sup> However, to determine the definition beyond all reasonable doubt, prospective studies linking pathobiological characteristics of individual foci are necessary. Ultimately, selective ablation of all clinically significant areas of cancer using cutpoints 0.2 cc or 0.5 cc and/or Gleason pattern 4 lesions with careful follow-up in prospective trials will be necessary.

Dr. G. Steven Bova reported the results of a unique multi-institutional study utilizing high-resolution, genome-wide, single-nucleotide polymorphism and copy number survey of 94 anatomically separate cancer sites in 30 men who died of metastatic PCa.<sup>5</sup> They showed that lethal metastatic PCa had a monoclonal origin that

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#### **Biopsy and Targeting of PCa**

At the second session, J. Stephen Jones, MD, FACS, demonstrated his approach at The Cleveland Clinic, whereby a two-stage biopsy is employed: the first is diagnostic and the

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second serves as the staging evaluation with an extended schema up to 8 to 14 lateral and apical cores to select patients for active surveillance or a FT strategy.<sup>6</sup> False-negative rates still remain very high.

In his presentation, Dr. Samir Taneja reviewed the results of 200

patients from a four-institution trial to test a novel, computer-based, three-dimensional transrectal ultrasound (TRUS) biopsy technique (TargetScan™; Envisioneering Medical Technologies, St. Louis, MO).<sup>7</sup> Furthermore, he showed the advantage of a TRUS-magnetic resonance imaging (MRI) fusion system (Artemis™; Eigen Corporation, Grass Valley, CA) for targeted prostate biopsy. A computerized template likely improves the mapping ability over the standard 12 cores. These systems are promising for creating simplified methods of transrectal sampling in the selection of candidates for PCa focal therapy.

Arnauld Villers presented impressive pictures of dynamic contrast-enhanced MRI for targeted prostate

biopsy with high sensitivity and specificity to detect tumor foci more than 0.5 mL as 86% and 94%, respectively.<sup>8</sup> Dr. Daniel Stoianovici developed the first robot-assisted TRUS biopsy that was successfully tested on the phantom.<sup>9</sup> Missed cancers generally represent a daily problem for urologists managing the

disease, create uncertainty and emotional stress for patients, and initiate a cascade of repeat testing and biopsies. Reducing unnecessary repeat biopsies requires a technique with a high negative predictive value (NPV) as well as biopsies of higher sensitivity.

### Functional and Molecular Imaging

At the third session, Jean de la Rosette, MD, introduced the concept of advanced ultrasound imaging that can significantly improve diagnosis, staging, biopsy, and therapy guidance, as well as monitor treatment.<sup>10</sup> For example, a quantitative, microbubble-enhanced TRUS can be safely used as a tool for intra- and postablation changes.

Dr. John Kurhanewicz updated the advances in MRI/MRSI spectroscopy (MRSI).<sup>11</sup> He suggested that higher field MR scanners (3 Tesla) with improved coils can facilitate more sensitive MRI/MRSI images. The addition of other functional data such as diffusion-weighted imaging can reveal changes in tissue microstructure and dynamic contrast-weighted imaging in angiogenesis providing quantification ( $T_2$  maps, metabolite maps, apparent diffusion coefficient of water maps). Hyperpolarized  $^{13}\text{C}$  MRSI is a faster, more sensitive and specific spectroscopic imaging technique.

In his presentation, Dr. Martin Pomper demonstrated the role of small molecules such as urea-based prostate-specific membrane antigen (PSMA) that can detect small tumor foci by ProxiScan™ compact  $\gamma$  camera (Brookhaven National Laboratory [Upton, NY] and Hybridyne Imaging Technologies, Inc. [Toronto, Ontario, Canada]) for high-resolution imaging of PCa.<sup>12</sup> Excellent spatial resolutions were achieved in preclinical tests. Clinical measurements are the next steps to confirm the efficacy of the technology.

Omid Farokhzad, MD, highlighted the latest developments in nanotechnology for PCa diagnosis and treatment.<sup>13</sup> Combined therapeutic and imaging vehicles are the path for a real translation. Targeted delivery becomes a tool to detect and treat

prostate cells, especially at the very beginning of their development, and a new generation of nanoparticles may be an ideal messenger to do this job (eg, optimized nanoparticles

false-negative rate (5%) and high sensitivity (95%). If these results are validated, it suggests 30% of men could avoid repeat biopsy. Finally, Dr. Partin demonstrated that the urine PCA3

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[BIND-014] exhibit an exquisitely long circulation half-life for penetration inside the tumor cells).

The long-term results of the National Cancer Institute program in

assay provides additional utility to the PSA test. The presented data suggest that PCA3 expression is more specific and a useful adjunct to the serum PSA test.

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molecular imaging of PCa were summarized by Peter L. Choyke, MD.<sup>14</sup> He concluded that molecular imaging is feasible for PCa and may be useful in detection, localization, staging, and follow-up. A wide range of agents are available with more to follow. The choice of agents awaits trials to determine sensitivity for primary and secondary lesions.

### New Concepts in FT

To lead off Session IV, Dr. Alan W. Partin presented a keynote lecture on novel biomarkers for PCa detection.<sup>15</sup> Among these, he noted early PCa antigen-2 (EPCA-2) as a nuclear matrix protein found specifically in the blood of men with PCa. EPCA-2 can differentiate men with organ-confined disease from those with disease outside the prostate. Other attractive tools that were tested in the first prospective clinical study were the methylation markers APC and GSTP1 for prediction of repeat biopsy outcome. Both APC and GSTP1 improved NPV compared with initial histology. APC gave a high NPV with a low

Daniel George pointed out the need for a cell-specific strategy as an obligatory adjunct for FT.<sup>16</sup> It can be implemented in different forms and directions, such as antibodies (ie, PSMA), small molecules (ie, imatinib), anti-inflammatory agents (ie, celecoxib), nutritional supplements (ie, flaxseed, selenium), vaccines, antisense (ie, clusterin), and chemotherapy (ie, docetaxel). He also proposed a novel, cancer tissue-specific type of therapy as an intraprostatic injection of the PSMA Aptamer-Plk1 siRNA chimera that was found to result in pharmacodynamic and pathologic changes in preclinical PCa.

In his presentation, Dr. Cary N. Robertson delivered the critical endpoints for FT study design.<sup>17</sup> Ablative technology trial design success is dependent on the concept of “nothing ventured, nothing gained” on the part of the trial subject. Psychology of trial design may outweigh the structure of the trial design. Endpoints should match the technology and favor detection of treatment

effect. Imaging and biopsy are critical components of endpoint design for future trials.

John Baust, PhD, invented CryoFib™ LEM Console Technology (CPSI Biotech, Owego, NY) with supercritical cryogens as a novel tool for focal-targeted cryoablation.<sup>18</sup> The advantages of this modality are as follows: about four-fold more cooling power, deeper lesions, more uniform isothermal gradients, instantaneous cryogen transport, instant ON-OFF, reliable dosing, scalability, cryoprobe/catheter design, miniaturization, and low-cost operation (needle, flexible, catheter, etc). *Reviews in Urology* Contributing Editor Arie S. Beldegrun, in his presentation, opened the door for other combined modalities such as immunotherapy as an adjunct to FT.<sup>19</sup> He focused on variable sonication strategies plus drug or vaccine (eg, continuous high-intensity focused ultrasound [HIFU], low-intensity focused ultrasound [LOFU], LOFU + HIFU) for PCa. For kidney cancer there are targeted agents (sunitib, pazopanib, etc) adding to ablation therapy or cancer

vaccine (eg, GM-CAIX/G250) ± HIFU/LOFU.

**Focal Ablative Techniques**

During Session V, Aaron Katz, MD, presented his series of 77 cryohemiablation treatments for unilateral PCa.<sup>20</sup> Overall biochemical and pathologic recurrence-free survival for his patients was 72.7% and 87%, respectively (Figure 1). These survival rates are consistent with those reported from prior focal cryosurgery series. He disclosed some limitations, such as the use of Phoenix and American Society for Therapeutic Radiology and Oncology (ASTRO) definitions established for radiotherapy patients (whole-gland treatment). No data describe the accuracy of such definitions on predicting failure in focal cryotherapy patients.

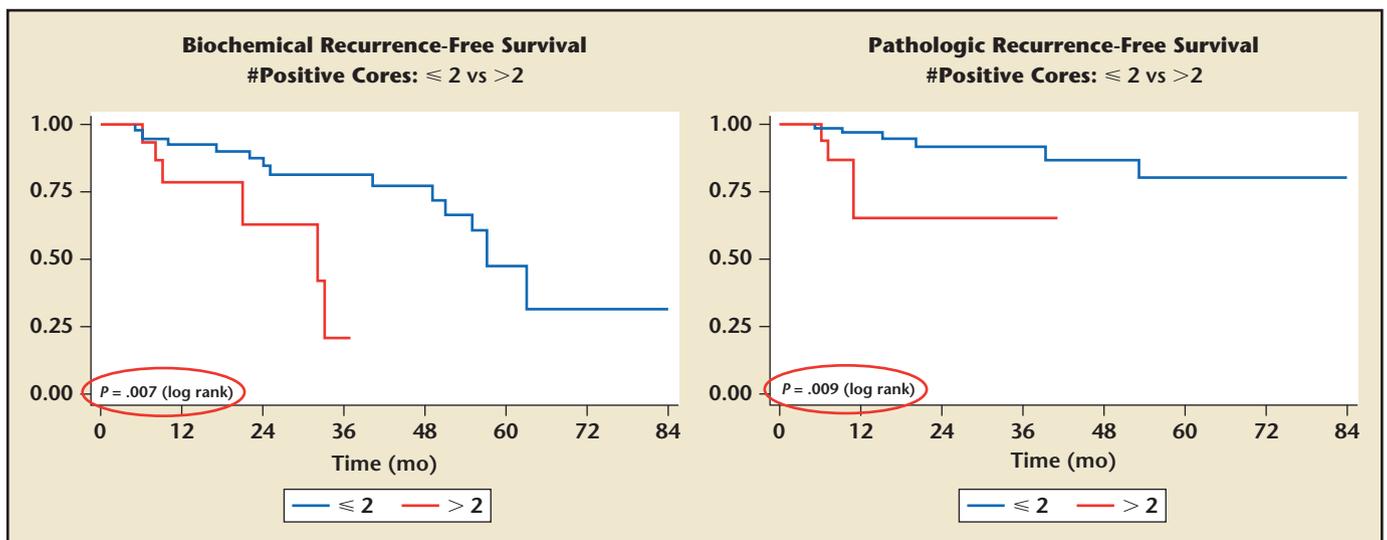
Dr. S. Jones reported results from the largest cryodatabase, The Cyro-On-Line Database (COLD; Endocare, Irvine, CA) registry, which contains 1160 men with different forms of “organ-sparing ablation.”<sup>21</sup> Although this registry has limited duration of follow-up (16.2 ± 14.5 months), bDFS rate is 75%, incontinence rate is

< 2%, impotence rate is 40%, and the fistula rate is 0.1%. More research needs to be done to specify each type of organ-sparing procedure.

During his talk, Dr. Mark Emberton presented data on phase I hemi- and focal-HIFU trials using HIFU (Sonablate® 500; US HIFU, LLC, Charlotte, NC), demonstrating encouraging short-term genitourinary function with return to baseline in the majority of men.<sup>22</sup> Early cancer control based on histologic outcomes demonstrates absence of any cancer in over 90% of men. Multicenter prospective trials addressing reproducibility and medium-term (3 to 5 years) cancer control are now required. Dr. Roland van Velthoven showed the results of his phase II study with focal HIFU ablation (Ablatherm®; EDAP TMS, Vaulx-en-Velin, France) in 24 patients, suggesting that this modality may be a valid alternative to radical treatment with curative intent for low- and intermediate-risk patients.<sup>23</sup> Targeting of HIFU must be improved with image fusion.

John Trachtenberg, MD, presented his first cases of robot-guided

Figure 1. Oncological outcomes after cryohemiablation (n = 77) from the Columbia University trial. Kaplan-Meier survival curve comparing outcomes between patients with ≤ 2 positive cores on preoperative TRUS-guided prostate biopsy versus > 2 positive cores TRUS, transrectal ultrasound.



interstitial laser therapy as a new promising modality in the FT setting.<sup>24</sup> Among other attractive techniques with initial clinical experience are vascular-targeted phototherapy and robotic partial prostatectomy.<sup>25,26</sup>

Samuel Denmeade, MD, presented a new form of chemical ablation, PRX302™ (Protox Therapeutics, Vancouver, BC) for intralesional injection, a targeted PSA-activated pore-forming toxin for the treatment of benign and malignant diseases of the prostate.<sup>27</sup> In his presentation, John Mulhall discussed the important topic of penile rehabilitation in a FT setting.<sup>28</sup> Despite an absence of evidence-based data (Level 1), results from animal and human studies are robust. Other arguments in favor of this concept are that erectile dysfunction causes depression and reduced quality of life (QoL) and that apathy leads to time-dependent changes in corpora cavernosum smooth muscle. Sexual medicine experts are including rehabilitation protocols following radical prostatectomy.

### How to Implement FT in Clinical Practice: Debates

Session VI was one of the most exciting segments of the meeting. With an absence of established criteria and the presence of methodological limitations, presenters tried to find the truth by debating contrasting approaches. Dr. Carroll argued in favor of FT because disease is likely to be focal and of low stage, secondary cancers are not likely to present a risk, effective ablative therapy is available, the patient can be retreated if necessary, and protocols/registries will be in place to carefully monitor outcomes.<sup>29</sup> Balentine Carter, MD, defended an active surveillance (AS) strategy because overtreatment of PCa occurs with PSA screening and AS could reduce rates of overtreatment.<sup>30</sup> However, he agreed that, given the risk

of disease progression, younger individuals should be discouraged from pursuing AS.

During the debate on patient selection, Dr. Trachtenberg demonstrated that MRI can detect the majority of tumors > 0.5 cc.<sup>31</sup> Other advantages of this approach include an interrogation of the whole gland, noninvasiveness, no need for anesthesia, no danger of infection, reasonable cost, no distortion of the gland, no consequences to repeated scans, and usefulness in follow-up of treatment and the detection of new cancers. However, MRI is less sensitive than biopsy. His opponent, Dr. Taneja, noted that transperineal template biopsy currently offers the most precise tool for PCa mapping and risk stratification.<sup>32</sup> Transrectal biopsy has the potential to guide index lesion FT upon template modification and/or in combination with MRI. At present, the variability in the quality and interpretation of MRI precludes its widespread use as a selection criterion for FT. Continued improvement in the consistency of MRI and development of clear paradigms regarding the goals of therapy may allow MRI alone to select candidates for FT.

In the next debate Dr. Thomas J. Polascik stated that, to demonstrate the feasibility of FT, a conservative approach should be used for several obvious reasons: to set the stage for

following considerations: FT in moderate risk disease is deemed ethical in some jurisdictions; in this context, FT is seen as an alternative to radical therapy; it is likely that index lesion control will become the standard; imaging will continue to play an increasing role in case selection; and questions remain on the thresholds that should be applied to the untreated lesions.<sup>34</sup>

In another debate, Dr. Villers thought that using multiparametric MRI guidance (especially dynamic contrast-enhanced MRI) allows for a safe ablation of an index lesion.<sup>35</sup> Vladimir Mouraviev, MD, PhD, argued in favor of hemiablation as a historical control after conventional whole-gland therapy as a reasonable and simple anatomic-based approach for unilateral lesion therapy that can occur in 1 in 5 patients now scheduled for radical prostatectomy.<sup>36</sup>

Drs. Katz and Jones found a consensus that the PSA test has to be first used serially at follow-up, but further scientific investigation should be performed to define a cutoff for failure.<sup>37,38</sup> The criteria that are currently being used for follow-up of whole-gland cryoablation, such as the ASTRO and Phoenix definitions (originally established for follow-up after external beam radiation), cannot be used in the cryoFT setting. Additional biopsies are important in evaluating

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success, to easily demonstrate QoL outcomes in the short term, and to collect uniform data by a simple model that will be required by the American Urological Association/European Association of Urology.<sup>33</sup> In contrast, Dr. Emberton repeated the value of a liberal approach due to the

tumor location prior to considering focal ablation. Combined evaluation of PSA, biopsy, and QoL are all essential for follow-up to define failure. For focal cryotherapy to become standard, it will require a collection of postablation PSA and biopsy data to determine true cancer control.

### Small Renal Masses—Imaging, Biopsy, Selection Criteria

Session VII opened the renal segment of the symposium. Robert Uzzo introduced his R.E.N.A.L. Nephrometry Score (point system) to quantitate the complexity of renal masses that allows standardization and facilitates a proper selection of patients for FT of small renal masses (SRMs) ([www.nephrometry.com](http://www.nephrometry.com)).<sup>39</sup>

In his presentation, W. Marston Linehan, MD, highlighted the results of his long-term research in the genetics of kidney tumors as disease-specific approaches to FT.<sup>40</sup> The use of individual tumor genotyping can provide precise information about uni-versus multifocality and uni- versus bilaterality. Dr. Hessel Wijkstra demonstrated an example of how contrast-enhanced ultrasound is used during ablation procedures and how postablation changes can be efficiently monitored.<sup>41</sup> Jens Rasweiler, MD, admitted the utmost importance of an intraoperative integration of imaging in the context of an augmented reality.<sup>42</sup> Soft tissue navigation has created many challenges regarding tissue deformation. In his opinion, combined tracking methods will be the future (eg, optical plus endoscopic tracking, high-definition television technology for image to model registration, easy-to-use registration and segmentation, and optimal visualization (ie, by quasi-holography).

During his talk, Raymond Leveillee, MD, evaluated the role of biopsy of SRM.<sup>43</sup> He addressed and answered three critical questions based on a meta-analysis of literature along with his data:

1. Should a biopsy be done on all SRMs? No.
2. If done at the time of treatment, should they be performed prior to or after ablation? Prior to ablation, because the heat especially can change tumor histology.

3. Should postablation biopsies be performed to determine success? No, SRMs favor serial imaging follow-up.

### Management of Small Renal Masses

The last session was devoted to a discussion on the management of small renal masses. Thomas Jarrett, MD, presented the pros and cons of an AS strategy.<sup>44</sup> AS, like any intervention, is a calculated risk and, as such, the risk of progression appears low for patients with small tumors. Improved biopsy techniques at a molecular level will help determine which tumors are at risk for disease progression. Life ex-

During his talk, David Albala, MD, outlined the increasing role of robotics in FT therapy of the SRMs that can facilitate a better and more targeted placement of renal thermoprobes to improve the results of ablation.<sup>47</sup> Dr. Inderbir Gill compared different types of partial nephrectomy (open, laparoscopic, robotic, laparoscopic single site).<sup>48</sup> As a take-home message, he articulated that open partial nephrectomy is not the same operation today as it was 10 years ago. Similarly, laparoscopic partial nephrectomy is not the same operation it was three to four years ago. Laparoscopy stands on the shoulders of open surgical excellence.

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### *Laparoscopy stands on the shoulders of open surgical excellence.*

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pectancy is not always apparent or easily determined. New molecular markers are necessary to differentiate who is at high risk for disease progression.

In his presentation, Dr. Bruce Shingleton discussed the data of percutaneous cryoablation in his series of 77 patients with posterior and laterally located tumors.<sup>45</sup> The rate of successful ablation was 92% (66 patients) and the retreatment rate was 4%. He concluded that computed tomography-guided percutaneous cryoablation remains an efficient minimally invasive tool for the SRM.

Dr. Leveillee demonstrated his data on radiofrequency ablation (RFA) for SRM.<sup>46</sup> RFA is effective for ablation of small and medium-sized renal masses. He stressed that there are several different choices in terms of probe design and application. We still need a better understanding of the mechanism of action that leads to success. He cautioned about enthusiasm in interpreting the preliminary results. Only longer-term follow-up can demonstrate oncological efficacy in concert with other nephron-sparing procedures.

Finally, regarding the question of whether laparoscopic techniques deliver equivalent surgical finesse and excellence as open surgery: the answer is yes.

In her presentation, Aradhana Venkatesan, MD, shared with the audience her algorithm and opinion on imaging follow-up after FT of the SRMs.<sup>49</sup> Recurrence is not uncommon after resection of localized renal cell carcinoma (RCC). No singular consensus exists, but similar guidelines do exist for surveillance after radical/partial nephrectomy for RCC. There is an emphasis in the literature on follow-up during the initial three to five years after nephrectomy. There is no consensus concerning surveillance imaging after ablative therapy, although there is an argument regarding the need for follow-up imaging and its role in assessment. Multifactorial predictive models of improvement over stage-based prognostic methods are needed because T-stage alone is likely an inadequate predictor of the diverse patterns of SRM recurrence. Risk stratification and imaging guidelines have the potential to be more

patient and tumor specific. Uniform adoption of a singular multifactorial, predictive model with links between risk level and specific imaging recommendations (consensus regarding modality, imaging frequency, duration of follow-up) are needed to obtain a single imaging surveillance algorithm for the SRMs.

In the last presentaion, Gennady Bratslavsky, MD, presented his experience dealing with FT failures.<sup>50</sup> He stated that a definition of ablative success and failure is needed. Surgical management of postablative failures is challenging and morbid. He recommended that one think twice before ablating patients with multifocal SRMs, providing informed consent to patients in terms of alternative options.

In the concluding remarks, the symposium director, Dr. Polascik, encouraged the impetus to develop the concept of FT for early-stage PCa and kidney cancer, which has been perceived by both patients and physicians to offer an effective cancer treatment without the side effects that may compromise a patient's QoL. This meeting brought together some of greatest minds in the field as we carefully move forward with the fundamental scientific study of this evolving discipline. We must pursue further efforts to develop imaging technologies capable of localizing the individual cancer foci in an effort to develop image-guided targeted FT. ■

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