JOURNAL OF ENDOUROLOGY
Volume 22, Number 5, May 2008

DOI: 10.1089/end.2008.9815

Abstracts from the

First International Workshop on Focal Therapy and Imaging of Prostate Cancer

February 21–22, 2008

The Duke Comprehensive Cancer Center
and the Duke Prostate Center
Durham, North Carolina

The First International Workshop on Focal Therapy and Imaging of Prostate Cancer was hosted by the Duke Prostate Center and the Duke Comprehensive Cancer Center in Durham, North Carolina on February 21–22, 2008. The workshop was intended as a gathering of leaders in prostate imaging, urologic pathology, scientists, and cancer physicians with the intention of bringing to the forefront the perceived need to scientifically study this evolving field. The symposium was open to all interested, and included engineers, molecular biologists, radiologists, radiation oncologists, medical oncologists, urologists and industry leaders. The Workshop highlighted the latest developments in prostate cancer imaging, molecular biology/pathology, and the various techniques of focal therapy. The list of faculties included over 30 leading experts from all over the world. The two-day workshop was designed to include didactic lectures and panel discussions along with a demonstration of the actual technique through a live feed from the Duke surgical suites.

Select speaker abstracts are included below. We welcome all those interested in this topic to join us at the Second International Workshop on Focal Therapy and Imaging in Prostate and Kidney Cancer to be hosted by Professor Jean de la Rosette in Amsterdam, June 10–13, 2009.

Thomas J. Polascik, MD
Meeting Director

001 Focal Therapy: The Pathologist's Perspective

Thomas M. Wheeler
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In this 21st century it is becoming much less common to remove an entire organ as a result of cancer involving that organ. Indeed, it has been 30 years since lumpectomy for breast carcinoma has been accepted as a viable alternative to radical mastectomy in selected patients with breast cancer. Although for some organs (e.g. liver) removal of the entire organ is not compatible with life, for the major visceral cancers, prostate stands alone without a widely accepted method for treatment of a cancer focus and not the whole organ. Surgical removal of a portion of the prostate (save for transurethral resection) is not possible at present, although other forms of focal therapy (e.g. cryo, TUNA, etc.) are possible. Major impediments to the widespread application of focal therapy for prostate cancer are the multifocality of the majority of prostate cancers and the lack of highly specific and highly sensitive imaging modalities to detect them. The evolution of the field of focal therapy of prostate cancer will be due largely to increasing refinements in focal therapy (high efficacy and low morbidity) and increasing sensitivity and specificity of imaging modalities.

002 Pathologic Characteristics of Small Prostate Cancer

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Cancer volume may be the single most important factor in predicting cancer progression, and focal therapy is probably best for patients who have small volume cancer. However, the inability to accurately determine cancer volume by existing diagnostic methods and the scant knowledge of individual tumor-doubling time pose a great challenge in identifying patients who may benefit from conservative management and renders accurate preoperative determination of clinical insignificance theoretical. There is a fair (r=0.39) to good (r=O.76) correlation between amount of cancer reported in biopsies and that subsequently found in radical prostatectomy specimens. This correlation is greatest for large cancers. A high volume tumor on needle biopsy is strongly suggestive of large-volume, high-stage cancer, but the converse is not always true because of sampling issues. Umfocal cancer is present in 13–33% of radical prostatectomies, and is associated with lower grade, stage, and recurrence rate than multifocal cancer. Cases are almost always in the peripheral zone, and associated with focal rather than multifocal high-grade PIN. Age and preoperative PSA are not different from patients with two or more prostate cancer foci. As adenocarcinoma enlarges, it usually becomes less differentiated and may lose some of its capacity for PSA production. PSA concentration increases with increasing Gleason grade, but, when tumor volume is held constant, PSA decreases (PSA concentration declined as Gleason grade increased). About 80% of incidental (autopsy and cystoprostatectomy-associated) tumors are small-volume (0.5 ml or less) without elements of Gleason grade pattern 4 or 5, indicating that most multifocal tumors, other than the largest or index cancer identified preoperatively, may not be of clinical significance. Long-term clinical follow-up is warranted to determine the outcome differences among patients with small-volume prostate cancer.

003 An Analysis of 1184 Prostatectomy Specimens to Define Prostate Cancer Laterality as a Rationale for the Clinical Application of Focal Ablative Therapy

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Introduction and Objective: Effective screening and early detection of small volume prostate cancer (PCa) has led to the concept of focal therapy to treat PCa as an organ-sparing, minimally-invasive procedure [e.g. male lumpectomy]. However, traditional dogma of PCa being a heterogeneous and multifocal disease creates concern to the adoption of this approach. We sought to determine the frequency and role of tumor laterality in order to clarify the possibility of hemiablation of the prostate using focal therapy while preserving the contralateral lobe.

Methods: 1184 paraffin embedded radical prostatectomy specimens excised from patients with early stage PCa between 2002 and 2006 were sectioned at 3-mm thickness and stained with hematoxylin-eosin. Pathologic assessment had particular attention to laterality and percentage of tumor involvement (PTI) along with other routine parameters as pT-stage, pathology Gleason Score (pGS), extracapsular extension (ECE), surgical margins (SM). Based on PTI, all cancer foci were ranked from minimal (=5) to largest (=15%) PTI. Clinical and pathologic parameters were analyzed using univariate and multivariate methods.

Results: Analysis of frequency of tumors showed that a real "therapeutic window" for focal therapy sequentially decreased with increasing PTI. Completely unilateral cancers were identified in 227 (19.2%) of 1184 patients. 164 (72.2%) of them have had PTI of =5, 40 (17.6%)- PTI of $5.1 \leq 10$, 9 (4.0%)-PTI of $10.1 \leq 15$ and 14 (6.2%) -PTI of >15, respectively ($p<0.0005$). African-American men had bilateral cancers more commonly that Caucasian men, e.g. 93.3% vs. 84.2%, respectively ($p<0.0005$). Univariate analysis suggested significant variables to be race, prostate weight, pT stage, pGS, +SM. However, only race, pGS, PTI and +SM were independent predictors via multivariate logistic regression ($p \leq 0.05$).

Conclusions: This study suggests that only a select group of men diagnosed with prostate cancer have small volume, completely unilateral cancers that would be amenable to focal ablation therapy targeting 1 lobe. Further study is needed to develop predictive models forthose patients likely to have small, unilateral cancers amenable to focal therapy.

004 A Molecular Correlate to the Gleason Grading System for Prostate Cancer

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Background: Adenocarcinomas of the prostate can be categorized into tumor grades based upon the extent to which the cancers histologically resemble normal prostate glands. Since grades are surrogates of intrinsic tumor behavior, characterizing the molecular phenotype of grade is of great clinical importance.

Methods: To identify molecular alterations underlying prostate cancer grades, we used microdissection to obtain specific cohorts of cancer cells corresponding to the most common Gleason patterns (patterns 3, 4, and 5) from radical prostatectomy samples. We used microarray analysis to identify grade-associated changes, immunohistochemistry to confirm protein changes, and cell-based assays to assess the influence of altering grade-associated biochemical pathways.

Results: We identified an 86-gene model capable of distinguishing low-grade (pattern 3) from high-grade (pattern 4 and 5) cancers. This model performed with 76% accuracy when applied to an independent set of primary prostate carcinomas. Focusing on specific genes that associated with grade, we confirmed a significant correlation between protein levels of Monoamine Oxidase A (MAOA), Defender Against Death (DAD), HSD17b4 and TMPRSS2 and poorly differentiated cancers. We found that pharmacological inhibition of MAOA resulted in alterations in prostate cancer cell growth.

Conclusions: The altered expression of genes associated with cancer cell differentiation provides functional insights into tumor phenotypes that influence tissue invasion, metastasis, and therapy resistance. Further, molecular features distinguishing high-grade from low-grade carcinomas may be exploited to standardize cancer grading and possibly as biomarkers capable of identifying aggressive disease.

005 Cryo-Molecular Basis for Optimizing Thermoablation

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Clinically-based cryosurgical procedures, grounded on well-recognized scientific principles along with the use of multiprobe devices and advanced imaging techniques, support physician-managed destruction of prostate adenocarcinoma. Prostate cryoablative techniques have beneficially evolved over the past forty years with the development of successive generations of devices including cryoneedles, the advent of a urethral warmer, intraoperative ultrasound and an expanded knowledge of the mechanisms by which cancer cells are challenged by low temperatures.

The most modern cryoablative approaches to prostate cancer therapy rely on the cryoneedle placement circumferentially with additional central probes with the freezing process imaged by intraoperative ultrasound and temperature monitoring. This strategy of zonal freezing assures a near homogeneous tumor core temperature (−40 C) leaving the procedural focus on the thin (2–4 mm) freeze zone rim.

A key discovery in 1998 identified the putative role of gene regulated cell death (apoptosis) in the management of the freeze rim. Accordingly, we now recognize three modes of cell death following a freezing insult: ice-dependent cell rupture in the tumor core, necrosis (primary and secondary) throughout the tumor and apoptosis primarily in the tumor margin. The AUA 2008 Best Practice Policy Statement on Cryosurgery for the Treatment of Localized prostate Cancer recognizes that "prostate cancer cells experiencing multiple molecular-targeted stressors (cytotoxic agents) succumb more readily to low temperature exposure and that with the adoption of appropriately paired combinations, even freezing at −1 C can be totally lethal.

This presentation will focus on recent research developments that support the use of combinatorial cryoablative therapeutic strategies that may raise the ablative temperature to near −1 C and these strategies affects on androgen-sensitive and –insensitive prostate cancers.

006 Using a 3-Dimensional Transrectal Ultrasound System (TargetScan™) for Prostate Cancer Detection

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Objective: The TargetScan™ system is a novel transrectal ultrasound (TRUS) device that allows precise needle placement in a template fashion.

Methods: A retrospective analysis was done evaluating total 77 patients at Duke Prostate Center who underwent a prostate biopsy with the TargetScan™ System. Seven patients were excluded that had a previous diagnosis of prostate cancer and two patients as well who has taken chemopreventive treatment for prostate cancer before biopsy. After creation of a three-dimensional map of the prostate a computer algorithm identified an ideal biopsy scheme based on the measured dimensions of the prostate. The system then used a fixed template that allowed the physician to biopsy the prostate at specific locations and to target the same region of the prostate in the future if needed. For all patients, a 12 core biopsy pattern was used to cover medial and lateral areas of the base, mid-gland and apex.

Results: 68 patients underwent TargetScan™ prostate biopsies between April 2006 and November 2007 for the primary cancer detection. The main reason for prostate biopsy was PSA ≥4.0 ng/ml in 47 (69%) patients, abnormal digital rectal examination (DRE) in 17 (25%) and atypia on previous biopsy in 4 (6%) patients. 18 patients (26.5%) had biopsies positive for prostate cancer and 7 (10.3%) patients- atypical small acinar proliferation (ASAP), respectively. The highest cancer detection rate (55.5%) was identified when TargetScan™ biopsy was used as the initial biopsy (Table 1).

Conclusions: This pilot study demonstrates that the precision of the TargetScan™ system translates to a higher cancer detection rate among patients undergoing an initial prostate biopsy.

Table 1. Percent Cancer Detections According to the Number of Previous Biopsies

Biopsy number	*# of cancer cases detected*	*% of cancer detections*
First biopsy	10	55.5
Second biopsy	5	27.7
Third biopsy	1	5.6
Fifth biopsy	1	5.6
Sixth biopsy	1	5.6

007 3-Dimensional, Saturation, Template-guided, Transperineal Biopsy of Prostate for Selection of Candidates for Focal Targeted Ablation

Winston Barzell
Sarasota Medical Center (Sarasota, FL)

Objective: To evaluate the utility of transperineal mapping biopsies of the prostate as a staging procedure in the appropriate selection of patients considering focal cryoablation.

Methods: Between October 2001 and November 2007, a total of 110 patients underwent extensive template-guided transperineal pathologic mapping of the prostate (3-DPM), in conjunction with repeat transrectal ultrasound (TRUS)-guided biopsies. Prior to 3-DPM the following clinical variables were recorded: age, prostate specific antigen (PSA), percent free PSA, total prostate volume, transition zone volume, Gleason score, TNM stage, number of cores positive, and maximum percent of cores positive. The results of 3-DPM were compared to those of TRUS-guided biopsies in determining patient suitability for focal cryoablation which served as the endpoint for this study.

Results: Of the 110 patients, 57/110 (52%) were deemed unsuitable for focal cryoablation. Repeat TRUS-guided biopsies when compared to 3-DPM in assessing patients suitability for focal cryoablation had a false negative rate of 46%, a sensitivity of 54%, and a negative predictive value of 49%. None of the pre-3DPM variables correlated significantly with patient suitability for focal ablation. Treatment selected by the 110 patients included: conformal cryoablation (27%), expectant management (22%), total gland cryoablation (16%), external irradiation (13%), radical prostatectomy (12%), brachytherapy (5%), and 5% combined external irradiation and brachytherapy.

Conclusions: In this study we demonstrated that 3-DPM effectively excluded patients with clinically significant unsuspected cancer outside the area destined to be ablated, that it seemed to do so more effectively than repeat TRUS-biopsies, and furthermore that it was able to precisely locate the site of the cancer to be selectively ablated.

008 Ultrasound-MRI Fused Image Directed Transperineal Prostate Biopsy

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Purpose: Ultrasound is a poor modality to identify areas of malignancy in the prostate. High field strength endorectal MRI with addition of perfusion imaging is superior to ultrasound in identifying suspicious areas for cancer. MRI guided biopsies cannot be performed without specialized MRI compatible equipment. We have developed software to fuse pre-operative 3 T MRI images with perfusion imaging with real time transrectal ultrasonography. Theses images are used to guide transperineal biopsies.

Material and Methods: The initial set of patients selected for fusion biopsy are men with rising PSA post external beam with suspicious areas on T2 weighted images. Image fusion was performed in real time with ultrasound images using transformations based on points detectable in the prostate in MRI and Ultrasound. More recently a tensor based method of fusing is being evaluated in patients undergo transperieneal biopsy during brachytherapy as definitive treatment in a prospective trail. A tensor based method with local warping is also being evaluated.

Results: Ultrasound-MRI fused images where used to biopsy seven patients with a rising PSA after external beam radiotherapy. Recurrent cancer was detected in six patients. Based on these results a prospective trial is currently accruing patients for Ultrasound-MRI fused image biopsy during prostate brachytherapy.

Conclusion: Ultrasound-fusion biopsy is a promising technique that permits the targeting of biopsies towards areas that are suspicious in MRI. This procedure can be performed with standard biopsy gun and needles and does not require special MRI compatible equipment.

009 Molecular Imaging in Oncology

Daniel C. Sullivan
Duke University Medical Center

A variety of imaging methods can display information about a patient's biochemistry, and no single modality is superior to all others. Collectively these methods are referred to as molecular imaging. Molecular imaging agents and methods have been developed for a variety of imaging systems. These include PET, SPECT, MRI, ultrasound, CT, and optical. These technologies have different advantages and drawbacks. For example, CT and MRI portray anatomical detail exceptionally well, whereas nuclear medicine and optical methods have very high sensitivity for detecting specific molecules. Hybrid devices, such as CT–PET, are increasingly popular.

Molecular imaging cannot provide the degree of genomic and proteomic information that obtained from in vitro assays on tissue or body fluids. However, in vivo imaging has three important advantages that complement in vitro tests. Imaging provides spatially localized information over large volumes of tissue. Imaging can give dynamic information by being obtained serially or continuously. Imaging depicts information from a tumor in its usual microenvironment.

Advances in prostate cancer imaging may help achieve earlier and more accurate diagnosis and treatment. Both ultrasound and MRI are used to improve the targeting of needle biopsy. In addition to structural features, elastography by either ultrasound or MR is proving helpful, as is color Doppler ultrasound. Elasticity imaging may also be important in assessing the progress of ablation therapy.

MRI and nuclear medicine methods are used to detect local recurrence. Advanced MRI techniques show considerable

promise. Prostate cancer can be identified based on reduced T2 signal intensity, increased choline and decreased citrate and polyamines on MR spectroscopic imaging (MRSI), decreased diffusivity on diffusion tensor imaging (DTI), and increased uptake on dynamic contrast enhanced (DCE) imaging. The best characterization of prostate cancer will likely result from a multiparametric (MRI/MRSI/DTI/DCE) exam.

FDG-PET imaging in prostate cancer is challenging because glucose utilization in well-differentiated prostate cancer is often lower than in other tumor types. Nonetheless, FDG-PET has a high positive predictive value for untreated metastases in viscera, but not lymph nodes. The use of technically improved PET/CT scanners with new tracers like C-11 and F-18 choline and acetate might offer better assessment of recurrent prostate cancer than FDG-PET or monoclonal antibody imaging with ProstaScint. Strategies using reporter genes for molecular imaging of prostate cancer are also in clinical trials.

010 Functional Transrectal Ultrasound Imaging: Tool for Prostate Cancer Detection

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Survival times of prostate cancer have considerably improved over the last years. Improvements in diagnosis and treatment may have contributed to that.

Looking at the full care-cycle that prostate cancer patients go through in developed countries, from diagnosis to therapy to follow-up, a number of gaps stand out:

- Need for an accurate screening test, to avoid unnecessary biopsies
- Need for targeted instead of blind biopsies, in order to reduce false negatives and to improve grading.
- Need for accurate grading and prognosis, in order to treat only relevant cases and avoid the side-effects involved in (over)therapy; This includes the need for reliable differentiation of local vs. regional vs. systemic disease, in order to avoid recurrence as a result of wrong staging and inappropriate treatment
- Need for targeted therapies (focal local treatment, targeted systemic therapies), in order to reduce both side-effects and recurrence.

In essence, these gaps point to two major deficiencies in the current care of prostate cancer. For one, the lack of an accurate screening test, which gives rise to concerns both about missing relevant cases and about over-diagnosis and over-treatment. Secondly, and this sets prostate cancer apart from most other cancers, there is no widely available and reliable imaging method for local tumours. Decisions on patient care are typically based on rather limited pieces of information on the localization, extent and grade of malignant tissue. Potential applications of functional transrectal imaging of prostate cancer include better diagnosis, grading and staging.

011 PSMA-based Imaging Agents for Prostate Cancer

Martin G. Pomper
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One in every six American men will be diagnosed with prostate cancer (PCa) over the course of their lifetimes, with 31,000 dying each year from the disease. Therapy for locally advanced disease remains contentious and an increasing number of options are available. More accurate staging would facilitate treatment decisions and lead to a better outcome for patients. In particularly dire need is a way to detect small lesions, ie, recurrent tumors in the surgical bed, local lymph node invasion and other subtle manifestations of the disease in men with an elevated serum prostate specific antigen (PSA) but no other obvious symptoms. The current standard of PCa staging is shifting. Metabolic imaging techniques such as magnetic resonance spectroscopy (MRS), positron emission tomography (PET) and single photon emission computed tomography (SPECT) are gaining favor over the anatomic techniques of computed tomography (CT) and MR, which merely detect enlarged tissue, revealing nothing of its underlying physiology. In particular, SPECT using the radiolabeled monoclonal antibody (mAb) 111In-capromab pendetide (Cyt-356, ProstaScint) is being used to identify candidates for salvage radiotherapy. However, intact antibodies tend to have poor pharmacokinetics for imaging. We have developed a series of low molecular weight, urea-based imaging agents for PCa. These compounds are inhibitors of the prostate-specific membrane antigen (PSMA), a marker for androgen-independent disease that is also expressed on solid (nonprostate) tumor neovasculature. We will discuss the synthesis and preclinical imaging of several such agents for PET, SPECT and optical imaging. With this new array of PSMA-targeted imaging agents we hope to provide sensitive new ways to study not only PCa, but a variety of solid tumors, *in vivo*.

012 Initial Experience with Radiotracer Anti-1-Amino-3^{18} F-Fluorocyclobutane 1-Carboxylic Acid with PET/CT in Prostate Cancer

Mark M. Goodman
Emory University

Conventional imaging techniques have serious limitations in the detection, staging and restaging of prostate carcinoma. *Anti*-3-[^{18}F]FACBC is a synthetic L-leucine analog which has excellent in-vitro uptake within the DU-145 prostate carcinoma cell line and orthotopic implanted prostate tumor in nude rats. This presentation examines *anti*-3-[^{18}F]FACBC uptake in patients with newly diagnosed and recurrent prostate carcinoma.

15 patients with a recent diagnosis of prostate carcinoma (n=9) or suspected recurrence (n=6) underwent dynamic imaging of the pelvis on a GE Discovery PET-CT after IV injection of 300–410 MBq *anti*-[^{18}F]FACBC followed by static body images.

In the 8 patients with newly diagnosed prostate carcinoma who underwent dynamic scanning, visual analysis correctly identified the presence or absence of focal neoplastic involvement. Pelvic nodal status correlated with *anti*-[^{18}F]FACBC findings. In all 4 patients in whom there was proven recurrence, visual analysis was successful in identifying disease (1 prostate bed, 3 extraprostatic). In 3 of these patients, ^{111}Indium-capromab-pendetide (ProstaScint) had no significant uptake at nodal and skeletal foci.

In this small patient sample, *anti*-[^{18}F]FACBC uptake was elevated in primary and metastatic prostate carcinoma. Malignant prostate tissue had increased SUV compared with benign regions, and visual analysis was often successful in identifying

the presence or absence of neoplasia. Malignant lymph nodes demonstrated intense persistent uptake.

013 Magnetic Resonance Imaging in Localization of Prostate Cancer

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A reliable method of localizing prostate cancer would allow for improved detection of prostate cancer by TRUS biopsy, open the door for new strategies for active surveillance and provide guidance for minimally invasive therapy without the need for saturation biopsies. Conventional T2 weighted MRI has not been adequate (sens 52%, spec 73%). Early implementations of MR spectroscopy (MRS) have long aquisition times with limited spatial resolution. New observations with 3T MRI, state of the art MRS (sens 77%, spec 84%), dynamic contrast enhanced MRI (sens 84%, spec 83%) and diffusion weighted MRI (DWI) (sens 81%, spec 84%) have suggest that the goal of prostate cancer localization is achievable for clinically significant tumors. Studies with careful radiologic-pathologic correlation, optimal combinations of various MRI methods, standardization of image aquisition methods across manufacturers and integration of MRI methods into treatment strategies are being actively pursued to define the role of MRI prostate cancer care.

014 Diagnostic Accuracy of Dynamic Contrast-Enhanced Pelvic-Phased Array MRI for Detection of Localized Prostate Cancer: Correlation with Radical Prostatectomy Findings.

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Objectives: To improve prostate cancer detection by imaging, evaluation of the accuracy of Dynamic Contrast Enhance Magnetic Resonance Imaging (DCE- MRI) was performed.

Methods: 93 patients who had a DCE MRI and a radical prostatectomy (RP) were included. The mean age was 61,5 years and median PSA was 8.5ng/ml (mean PSA: 6,9; from 1,4 to 35). MRI protocol was carried out with a Pelvic Phase Array (PPA) with T2-W and DCE T1-W sequences. MRI results were correlated with RP whole-mount step sections. The cancer detection was assessed in each of 8 regions including left and right peripheral and transition glandular zones. The studied data were cancer volume, largest surface, the glandular tumor density and % Gleason Grades 4 or 5. The sensitivity and specificity were determined with ROC curves and Youden indice (se+sp-1).

Results: The area under the curve (AUC) for combined T2-WS and T1-W DCE sequences for cancer detection was 0.957. For detection of cancer with a volume > or = 0,33cc, the sensitivity, specificity, the PPV / NPV and accuracy of the combined MRI sequences were 91%, 88%, 89%, 95% and 89% respectively. A sensitivity and a specificity of 95% for cancer detection were associated with threshold volumes of 0,26cc and 0,50cc for PZ cancers and of 0,18cc and 0,52cc for TZ cancers respectively.

The AUC for combined T2-WS and T1-W DCE sequences was of 0,819 in the detection of cancer with Gleason grades 4 or 5. The sensibility and specificity were of 81% and 82% respectively when the tumor presented at least 5% of Gleason grades 4 or 5.

Discussion: Combined T2-WS and T1-W DCE MRI is accurate for intraprostatic cancers detection in peripheral and transition zones. Possible applications are guidance of targeted biopsies, selection and monitoring of patients without treatment of treated by focal therapies.

015 Magnetic Resonance Anatomic and Spectroscopic Imaging of Prostate Cancer

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Published 1.5T magnetic resonance imaging and magnetic resonance spectroscopic imaging studies of prostate cancer patients have indicated significant clinical value in detecting and characterizing prostate cancer prior to and after therapy. Commercial combined 1.5T MRI/MRSI exams are currently available and a growing number of published studies have indicated its utility in the selection of the most appropriate therapy for individual patients, planning focal therapies and for providing early imaging biomarkers of therapeutic success and failure. Prior to therapy, prostate cancer can be discriminated from benign tissues based on a combination of reduced signal intensity on T2 MRI, increased choline and reduced citrate and polyamines on MRSI. After therapy, the loss of all metabolites (metabolic atrophy) has been associated with effective therapy, while residual prostate cancer has been identified based on the presence of 3 or more voxels having Choline/Creatine > 1.5 with an accuracy of 80%.

Recent studies have demonstrated limitations in detecting small volume (< 0.5 cc) low grade (= 3+3) prostate cancer and distinguishing prostate cancer from other benign prostatic pathologies such as prostatitis and benign prostatic hyperplasia. However, the use of higher field MR scanners (3T), addition of other functional information (diffusion and dynamic contrast weighted imaging), new spectroscopic biomarkers, and more sensitive spectroscopic imaging techniques (hyperoplarized ^{13}C MRSI) have demonstrated the potential to overcome current limitations. In this lecture, the potential and limitations of 1.5T MRI/MRSI for planning and monitoring focal therapies, and the improvements obtainable using a multi-parametric imaging approach at 3T will be presented.

016 Correlation of Raman Spectral Imaging of Prostate Cancer with Patient Outcome after Radical Prostatectomy

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Raman molecular imaging (RMI) combines digital imaging and analytical spectroscopy to produce images where each pixel contains a Raman spectrum. RMI has the potential to supplement current histopathological evaluation of prostate cancer to provide more information about potential disease course. In this study, RMI was evaluated as a tool to predict disease outcome

in patients diagnosed with Gleason Score 7 prostate cancer. Our objective was to determine if Raman imaging can differentiate between Gleason 7 cases that progress to metastatic disease and those that do not. The analysis shows a distinction between progressors and those with NED, most notably within the Gleason 3 regions when evaluating the epithelium and stroma as separate histological elements. A two-sample t-test yields a p-value < 0.05 for both the Gleason 3 and 4 epithelium and stroma classes. In Gleason 7 disease, RMI shows a distinction between patients that progress to metastatic disease and those that do not in both Gleason pattern 3 and 4 regions. There is potential for RMI to predict disease outcome in patients with Gleason 7 prostate cancer through the visualization and molecular information not seen in current methodologies. This preliminary work lays the foundation for further study of RMI in evaluation of prostate tissue.

017 Lymphotrophic Nanoparticle Enhanced MRI in Prostate Cancer Staging

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Accurate pretreatment localization of metastastic lymph nodes is important to ensure optimal therapy in primary prostate cancer. Conventional cross sectional imaging relies on anatomical nodal morphology and size as the primary yard stick for differentiating benign from malignant lymph nodes. Using these nodal parameters it is challenging to detect minimal tumor burden in normal sized nodes. Lymphotropic nanoparticle-enhanced magnetic resonance imaging (LNMRI) has been recently evaluated and has proven to be an accurate technique to reliably determine nodal status in patients with various primary genitourinary cancers. LNMRI relies on the use of highly optimized MRI pulse sequences (dual echo gradient echo sequences), the administration of lymphotropic magnetic magnetic nanoparticles (e.g., ferumoxtran-10; Advanced Magnetics Inc., Cambridge, MA; Sinerem; Guerbet, Paris, France), and sophisticated image analysis and comparison to enhancement databases. The strength of this imaging technique lies in its ability to provide high sensitivity (detecting minimal tumor burden) without compromising on the specificity. Owing to its ability to reliably detect metastastic nodes independent of their size, LNMRI has shown to be an effective presurgical and pretreatment planning tool. Information from patients scanned with LNMRI can allow one to create a comprehensive and composite map of nodal locations to define pelvic nodal regions at highest risk for harboring occult disease.

018 New Developments n Molecular Imaging: From Physics to Clinical Applications

Warren S. Warren
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Molecular imaging-resolving biologically important chemical targets with high spatial resolution-is an exploding field which will likely be a critical enabler of the next generation of drug design and molecular medicine. Physics research plays an important role in extending the applicability of this field. For example, advances in laser technology make it possible to surmount many of the limitations of conventional optical imaging methods; we use rapidly updatable, femtosecond pulse shaping and multidimensional spectroscopy to make new targets accessible by nonlinear optical imaging, including vasculature with high resolution in scattering tissue. As another example, almost all of conventional magnetic resonance imaging (MRI) relies on the theoretical framework established by physicists in the 1940s. Recently, however, it has become apparent that technological developments that were unanticipated half a century ago (very high magnetic fields, hyperpolarization) can dramatically the simple physical picture of magnetic resonance in new, useful and nonintuitive ways. In this lecture I will describe the range of these phenomena characterized over the last few years (for example, in five Science papers by my group) and show applications to enhanced spectroscopy and imaging of structured tissue.

019 Patient Selection for Hemi-ablative Focal Therapy for Prostate Cancer: Variables Predictive of Tumor Unilaterality in 538 Radical Prostatectomy Specimens with Low-risk Disease

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Objectives: The development of the concept of focal therapy for low-risk prostate cancer (PCa) depends on the proper selection of candidates for treatment. To date, no definitive criteria have been introduced to define those patients who may potentially benefit from an organ-sparing approach. We evaluated pre-treatment clinical parameters that may predict unilateral PCa amenable to hemi-gland thermoablation.

Methods: Five hundred thirty eight patients with complete data from the Duke Prostate Center Outcomes database who had low-risk PCa (PSA$<$10mg/ml, biopsy Gleason score $\leq$7 and clinical stage T1c-T2b) and underwent radical prostatectomy (RP) were included in the dataset. Patients underwent prostate biopsy at Duke or community hospitals from 1996 to 2005. Clinical parameters were validated with final pathology data after RP conducted at Duke. The following clinical covariates were included in the initial model with pathologic PCa laterality (unilateral vs. bilateral) as the outcome variable: race (African-Americans vs. non-African-Americans), age, family history of PCa, diagnostic PSA (logarithmically transformed), clinical stage, prostate weight as the surrogate for prostate size measured by transrectal ultrasonography (logarithmically transformed), number of positive prostate biopsy (PBx) cores, biopsy Gleason primary and secondary grades, biopsy Gleason 3/4 versus 4/3 versus 2 to 6, highest percent tumor involvement per core, clinical PBx laterality (unilateral versus bilateral). Backward stepwise logistic regression methods were used with a significance level of 0.05. Statistical analysis was performed with univariate (Chi-square) and multivariate logistic regression analysis using program R, version 2.5.1 (www.r-project.org) and SPSS, version 15 (Chicago, IL).

Results: In the final logistic regression model, 538 patients were entered with all known variables. Covariates that had a predictive role in the final model are included in Table 1. Negative family history of PCa and greater prostate weight had a higher probability of having unilateral disease. The strongest predictor of pathologic unilaterality was PBx unilaterality.

Univariate Regression Analysis

Covariate	*Odds ratio*	*Confidence interval (95%)*	P-*value*
Family history	1.74	1.06–2.29	0.029
PBx unilaterality	3.95	2.18–7.14	**<0.0005**
Prostate weight	1.34	1.02–1.77	0.038

Multivariate Regression Analysis

Covariate	*Odds ratio*	*Confidence interval (95%)*	P-*value*
Family history	1.83	1.09–3.05	0.021
PBx unilaterality	3.88	2.14–7.05	**<0.0005**
Prostate weight	1.28	0.97–1.70	0.084

Conclusions: Two pre-treatment clinical variables were significantly predictive of pathologic unilateral PCa: negative family history of PCa and clinical unilaterality based on PBx. The strongest predictor was biopsy unilaterality. These variables can be used to assess men with low-risk PCa prior to selection for hemi-ablation.

020 Methodological Considerations in the Design of Trials Addressing Focal Therapy

Mark Emberton
University College London

The idea of treating less than the whole prostate when considering curative therapy for a man with localized prostate cancer has, until very recently, been best described as heretical. However, with advances in technology that enable better characterization of disease and therapies that permit tissue preservation the notion of focal or zonal therapy has now become the subject of serious debate and early scientific study.

In the first of two presentations, the methodological challenges that await researchers who are considering engaging in clinical research programs addressing focal or zonal therapy will be addressed. These include the issues of patient selection, characterization of disease, treatment verification, outcome measures and follow-up regimens.

021 Partial Salvage Cryoablation: UCSF Experience

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Introduction: Recent publications suggest partial cryoablation can preserve oncologic control and lower morbidity compared to complete gland ablation. We sought to determine the efficacy of partial cryoablation in the salvage therapy setting.

Methods: We identified all patients who were treated between April 2004 and September 2007 for recurrent prostate adenocarcinoma after failure of primary radiotherapy by means of partial cryoablation.

Results: 19 patients met inclusion criteria; 15 had greater than 6 months follow-up. Mean age was 71 years. Men were received salvage therapy a mean of 6 years after primary radiotherapy. Median follow-up was 18 months (6 to 33). Biochemical free survival rate by the ASTRO definition was 89%, 67%, and 50% at 1, 2, and 3 years respectively. 1/10 patients harbored residual carcinoma on routine follow up biopsy at one year, while 50% harbored residual benign prostate tissue. Complications included incontinence 7%, urethral stricture 7%, and urethral ulcer (7%).

Conclusions: In properly selected patients with a unilateral focus of disease recurrence after radiotherapy, acceptable oncologic results can be achieved with low morbidity.

022 Focal Cryoablation: A Promising Organ-Sparing Primary Therapy For Low-Risk, Unifocal Prostate Cancer

Ravi Kacker and Aaron E. Katz
Columbia University College of Physicians and Surgeons

Introduction: Low-risk patients with a single detectable focus of cancer face a difficult choice between the risk of morbidity from radical prostatectomy or radiation therapy and the risks and anxiety of watchful waiting. Focal cryoablation is a promising minimally invasive therapy that may satisfy the need for an organ sparing therapy that definitively treats the largest tumor, achieves excellent oncologic outcomes, and preserves of patient quality of life. Here we report clinical and oncologic outcomes of cryoablation of primary, unifocal prostate tumors.

Methods: Clinical outcomes, follow-up PSA and surveillance biopsy data were recorded for 32 low-risk patients treated by cryoablation of a unilateral tumor.

Results: Among all patients, there were no cases of postoperative incontinence, fistulas, or rectal pain. 7 (70%) of 10 patients maintained potency after cryoablation. Of 26 patients with PSA follow-up, 22 (84.6%) were rendered biochemically disease free as defined by a PSA nadir below 50% of preoperative PSA. 10 (52.6%) of 19 patients with at least a 6 month follow-up (median 12 mo) maintained at least a 50% drop in PSA. 3 patients underwent surveillance biopsies; 2 were negative and one found high grade PIN in the contra lateral (untreated) lobe.

Conclusion: These preliminary data are encouraging that focal cryoablation can achieve good oncologic outcomes with minimum treatment associated morbidity. Further development of cryoablation technology and imaging techniques is needed to realize true organ sparing therapy with focal cryoablation.

023 Patient-Specific Modifications of Prostate Cryoablation

Daniel B. Rukstalis
Geisinger Health System

Ultrasound guided percutaneous prostate cryoablation represents a highly flexible and efficacious treatment option for men with clinically localized prostatic adenocarcinoma. In fact, this technology represents the only strategy capable of implementing a treatment individualized to the patient's cancer location, prostate anatomy and personal values.

A total of 159 men have received a prostate cryoablation procedure for prostate cancer with a computer guided treatment plan that is modified to target specific prostatic regions while minimizing injury to adjacent prostate and extraprostatic tis-

sues. This abstract represents a retrospective review of de-identified clinical data from a prospectively maintained quality improvement database.

The median patient age was 67 yrs treated in the outpatient setting with a median follow-up of 13 months. The median preop PSA was 5.4 with the postop PSA of 1.8 ng/ml. The median number of cryoprobes was 4 (2–5). There were no operative complications. A foley catheter was required for a median of 3 days. A total of 32 men developed postoperative urinary retention that required 7 days to resolve. Urinary control was excellent with 25 men complaining of immediate urge incontinence, 6 with postop stress with resolution of all symptoms by 3 months. The median preop SHIM score was 18 with an immediate postoperative median score of 5. Approximately 50% of men complained of ED that required postoperative therapy. However, 78% returned to satisfactory penetration with and without oral medications.

In conclusion, the technique of prostate cryoablation provides an opportunity to develop individualized treatment planning with the ability to tailor therapy to the specific circumstances of the patient. The procedure related toxicity is low with no long term urinary incontinence. Erectile function is maintained or recovers in the large majority of men. The oncologic efficacy must be established with follow-up protocols that include repeat prostatic biopsy.

024 Magnetic Resonance Image-Guided Salvage Brachytherapy After Radiation In Select Men Who Initially Presented With Favorable-Risk Prostate Cancer: A Prospective Phase 2 Study

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Background: The authors prospectively evaluated the late gastrointestinal (GI) and genitourinary (GU) toxicity and prostate-specific antigen (PSA) control of magnetic resonance imaging (MRI)-guided brachytherapy used as salvage for radiation therapy (RT) failure. METHODS: From October 2000 to October 2005, 25 men with a rising PSA level and biopsy-proven, intraprostatic cancer at least 2 years after initial RT (external beam in 13 men and brachytherapy in 12 men) who had favorable clinical features (Gleason score $<$ or $=7$, PSA $<$ 10 ng/mL, negative pelvic and bone imaging studies), received MRI-guided salvage brachytherapy to a minimum peripheral dose of 137 gray on a phase 1/2 protocol. Estimates of toxicity and cancer control were calculated using the Kaplan-Meier method. RESULTS: The median follow-up was 47 months. The 4-year estimate of grade 3 or 4 GI or GU toxicity was 30%, and 13% of patients required a colostomy and/or urostomy to repair a fistula. An interval $<$ 4.5 years between RT courses was associated with both outcomes with a hazard ratio of 12 (95% confidence interval [95% CI], 1.4–100; P = .02) for grade 3 or 4 toxicity and 25 (95% CI, 1.1–529; P = .04) for colostomy and/or urostomy. PSA control (nadir +2 definition) was 70% at 4 years. CONCLUSIONS: The current results indicated that MRI-guided salvage brachytherapy in men who are selected based on presenting characteristics and post-failure PSA kinetics can achieve high PSA control rates, although complications requiring surgical intervention may occur in 10% to 15% of patients. Prospective randomized studies are needed to characterize the relative cancer control and toxicity after all forms of salvage local therapy.

025 Brachytherapy-Another Focal Therapy?

W. Robert Lee

Duke University Medical Center

Given the widespread use of PSA screening in the United States a significant percentage of newly diagnosed prostate cancers are found at a very early stage, raising concerns of overdetection and overtreatment. In contemporary radical prostatectomy series the incidence of unifocal prostate cancers ranges from 13–38%. Emerging imaging techniques may allow for more precise characterization and localization of unifocal, intraprostatic cancers. These potential developments have led to growing interest in focal therapy as a method to treat unifocal prostate cancers in hopes of reducing morbidity without sacrificing efficacy. Commonly mentioned methods of focal therapy include high intensity focused ultrasound, cryotherapy, radio-frequency ablation and photodynamic therapy. Interstitial brachytherapy (high dose rate or low dose rate) should be considered as another approach for delivering focal therapy. Prospective clinical trials are required.

026 VTP in the Treatment of Localized Prostate Cancer

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Vascular-targeted photodynamic therapy (VTP) is emerging as an effective treatment option for patients with small volume, localized prostate cancer. VTP is based upon the intravenous administration of a novel photosensitizer, TOOKAD® (Padoporfin; WST09), a *bacteriochlorophyll-a* derivative, which is activated within a target tissue by using a laser light of an appropriate wavelength delivered through optical fibers. The combination of the drug and activating light in the presence of oxygen results in vascular coagulation and focal tissue necrosis in the region surrounding the optical fiber(s). STEBA Biotech is conducting the international clinical development of WST09. Trials have first been conducted in Canada, in patients affected by recurrent prostate cancer after failure of external-beam radiation therapy (EBRT). These "salvage therapy" trials collectively evaluated the combination of several doses of WST09 (ranging from 0.1 mg/kg to 2 mg/kg) together with increasing light energy doses (ranging from 100 to 360 J/cm) and the number of the light-diffusing fibers. To evaluate treatment effect, all the trials use 7-day post-treatment MR imaging, a putative surrogate endpoint that has previously been shown to highly correlate with histological findings of tissue necrosis. In brief, most patients (86%) showed decreases in PSA levels, 46% had negative 6-month biopsies, and all showed MRI changes compatible with various degrees of treatment effect (necrosis) of the tumor. More recently, a WST09 VTP trial in patients with previously untreated localized prostate cancer has been conducted in the United Kingdom. Collectively, data from this trial shows that there is a dose-response between the total light en-

ergy delivered to the prostate and the volume of the treatment effect (tissue ablation) as determined on post-treatment MRI, with optimal light parameters established at 150 mW/cm and 200 J/cm. Based on this data, STEBA is now about to launch a Phase II multicenter trial in the U.S. in patients with early stage localized cancer. The sites participating in the study include: Washington University in St. Louis, Memorial Sloan-Kettering and Columbia University in New York, the University of California at Los Angeles and San Francisco, the University of Texas in San Antonio, the Cleveland Clinic, and Midtown Urology in Atlanta. The primary endpoint of the study will be a negative repeat targeted biopsy, with as secondary endpoints: MRI findings compatible with tumor destruction, safety and quality-of-life measurements (using the IPSS and IIEF), and the prostate health-related quality-of-life questionnaire (HRQoL). We anticipate enrolling 40 subjects into this U.S. trial, which is scheduled to start shortly.

027 VTP for Men with Prostate Cancer – Early Results

Mark Emberton
University College London

The idea of treating less than the whole prostate when considering curative therapy for a man with localised prostate cancer has, until very recently, been best described as heretical. However, with advances in technology that enable better characterization of disease and therapies that permit tissue preservation the notion of focal or zonal therapy has now become the subject of serious debate and early scientific study.

In this presentation novel energy sources will be scrutinized and appraised in relation to their ability to reliably treat volumes of prostate tissue in a reliable, predictable and reproducible manner. The emphasis will be on recent, as yet unpublished, health technology assessment of a novel technique involving tissue selective injury to the endothelium of small vessels using a combination of laser light and a photosensitiser (Tookad, STEBA Biotech)

028 Vascular Targeted Phototherapy with WST09 for Recurrent Prostate Cancer after External Beam Radiation Failure

John Trachtenberg for the TOOKAD® Study Group[1]
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Objective: We report on the efficacy of WST09 (TOOKAD®)Vascular-Targeted Photodynamic therapy (VTP) as a method of salvage therapy in patients with recurrent localized prostate cancer following external beam radiation therapy (EBRT).

Methods: Patients received a fixed WST09 photosensitizer dose of 2 mg/kg and patient-specific light doses as determined by computer-aided treatment planning. Up to 6 cylindrical light diffusing delivery fibers were placed transperineally in the prostate under ultrasound guidance. Treatment response was assessed by serum PSA, lesion formation (avascular areas of tissue) measured on 7-day gadolinium-enhanced T1-weighted MRI, and 6-month biopsy.

Results: Treatment of the whole prostate gland was possible with minimal impact on surrounding organs. Increased light dose improved tissue response, with MRI-detectable avascular lesions, encompassing as much as 80% of the prostate in some patients. Complete treatment response, as determined by 6-month biopsy, required that patients received light doses of at least 23 J/cm^2 in 90% of the prostate volume ($D_{90} > 23$ J/cm^2). Of the 13 patients who received at least this light dose, 8 were biopsy negative at 6 months. In this group of 8 patients, PSA levels decreased and dropped to negligible levels for those patients with baseline PSA < 5 ng/ml. Side effects were modest and self-limited in most; rectourethral fistulae occurred in two patients, one of which closed spontaneously. The overall side effect profile was comparable or better than existing treatment alternatives at similar stages of development.

Conclusions: WST09-VTP can produce large avascular regions in the irradiated prostate with acceptable side effects, and result in complete negative biopsy response at high light doses. A response rate of greater than 50% for those patients receiving the highest light doses shows the clinical potential of WST09-VTP to manage post-EBRT recurrence of prostatic carcinoma. Further trials will more clearly define the use of WST09-VTP.

This study was funded by: StebaBiotech NV

029 High Intensity Focused Ultrasound Therapy for Prostate Cancer

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The ability to focus ultrasound waves to a specific focal point allows the creation of a definitive area of thermal injury within any targeted tissue. This principle of thermal ablation is increasingly being used in medicine for various conditions, including cardiac dysrhythmias, uterine leiomyomata, and prostate cancer. Each clinical application requires engineering designed to adapt to the organ in question. To this end devices utilized for prostate cancer treatment are transrectal, incorporating simultaneous ultrasound imaging and high intensity focused ultrasound (HIFU) therapy.

The transrectal approach allows close proximity placement of the ellipitical treatment /imaging probe adjacent to the prostate. The principle of ultrasound wave elliptoid reflection is used to produce intense heat at the F2 focal point (2 mm width). Temperatures approach 85 degrees Centigrade at the focal point with a thermal gradient extending anteriorly and posteriorly through the prostate. The depth of penetration within the prostate reaches to a prostate height (A-P dimension) of

25–30mm. Approximately 300–400 contiguous lesions are created within the gland during treatment.

Treatment times average 1–2.5 hours and are performed on an outpatient basis under spinal or general anesthesia. Due to edema of the treated tissue, urinary retention is almost universally experienced, requiring bladder drainage by urethral catheter or suprapubic cystostomy. There is minimal discomfort in the immediate postoperative period, usually characterized as urgency and a dull ache for the first 24–48 hours. Tissue effects are visible during each focal burn, evidenced as diffusion of ultrasound echoes in response to microcavitation within the tissue. The urethra is treated with the catheter temporarily removed during targeting of the central prostate, but is otherwise well visualized during treatment. The urethral catheter provides a landmark during targeting of other areas of the prostate.

Recovery from HIFU occurs over a 2–3 week period with resumption of normal voiding after catheter removal 10–14 days after therapy. Side effects are minimal with 10% of patients experiencing obstructive sloughing of tissue occasionally requiring endoscopic resection. Mild to moderate stress incontinence is reported in 1–5% of patients. Moderate to severe erectile dysfunction rates approach 50% and rectal fistula is experienced in 0–0.5% of cases as reported in recently published series. PSA nadirs of <0.5 ng/ml are reached within 3 months of therapy in 60–80% of patients. Follow-up prostate exams demonstrate considerable shrinkage of the prostate by 6 months.

030 Pulsed HIFU for Localized Prostate Cancer

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Introduction: High Intensity Focused Ultrasound has been utilized as a local therapy for prostate cancer for over a dozen years in Europe and has been the treatment of choice for over 13,000 patients.

Methods: The results of a Pub Med literature review in which all publications of HIFU treatment were analyzed will be reported. Clinical results in terms of efficacy (negative biopsy rates and biochemical disease free survival (BDFS) rates) and morbidity are summarized and compared to our Munich results (1900 treatments since 1996).

Results: There are no publications of randomized clinical trials which compare HIFU with other longer established treatments. The literature consists mainly of retrospective single center series with the exception of three multicenter investigations. All studies include T1-2, N0 or NX, M0 patients. Sixteen studies report negative biopsy rates ranging from 66% to 100% with a weighted average of 83%. There is an inconsistency with the biochemical failure definitions used in the literature. Three studies report five year BDFS rates for all T1,2 patients together: 78 and 76% with the ASTRO definition and 76% with the Phoenix definition. Pre HIFU TURP is responsible for a significant reduction in post treatment morbidity. Incontinence rate (Grade II or above) ranges from 2.3 to 7.0% and the impotence rate from 13–53%. Fistula occurrence is rare. Since the introduction of rectal cooling and integrated imaging the fistula rate is less than 0.5%.

Conclusions: HIFU has proven to be a promising local therapy for prostate cancer with encouraging efficacy and morbidity outcomes in the medium term.

031 Current Status and Prospects of HIFU for Focal Therapy of Prostate Cancer

Michael Marberger
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With wide spread PSA screening the incidence of organ confined low risk prostate cancer is continuously increasing. These tumors not only have lower aggressive potential but the patients diagnosed with them are frequently older and more comorbid. Active surveillance and expectant therapy protocols are a logical consequence but are poorly accepted by patients and urologists. Less invasive curative therapy therefore appears highly attractive. Using a transrectal approach ultrasound in the 3 – 4 MHz range can be focused within the prostate to achieve site intensities >1500 Wcm˜FD (High Intensity Focused Ultrasound, HIFU). This results in heat of sufficient temperature to cause immediate coagulation necrosis within the focal area. By moving the focus computer controlled with on-line imaging of the process the entire prostate or a defined segment can be ablated yet surrounding structures remain unharmed.

The two systems presently commercially available have been used clinically in several thousand patients worldwide, almost exclusively for ablation of the entire prostate. Morbidity is low and dominated by transient retention. Moderate stress incontinence is observed in $<2\%$, recto-urethral fistula in $<1\%$. Nerve sparing approaches are being promoted but so far no precise follow-up data on the preservation of erectile function are available. PSA nadirs are reached within 3 months after treatment, and if this is ≤ 0.5 ng/ml satisfactory long term results can be expected. Presently available outcome data, which unfortunately only consist of retrospective series with variable inclusion and treatment parameters, suggest that HIFU is an acceptable alternative to more aggressive treatment in older patients with low risk cancer. The main limitation comes from the fact that prostates >40 ml can not be treated sufficiently in one HIFU session, and there is a 30 % chance of the need for retreatment.

With transrectal HIFU of prostate cancer complete ablation and morbidity are inversely related to the volume of cancer to be treated. If early, but clinical significant cancer can be identified within the prostate "targeted" HIFU of the tumor bearing segment of the prostate only permits curative ablation at very low morbidity. This focal therapy ("HIFU lumpectomy") is at present only limited by the unreliable imaging modalities.

032 Management of the Contralateral Gland in Patients Undergoing Focal Therapy for Prostate Cancer

Daniel George
Duke University Medical Center

Focal therapy is currently under development as a therapeutic strategy for patients with localized, low volume prostate cancer. Several approaches, including radiation therapy, cryoablation, high frequency ultrasound and even robotic surgical resection, offer potential for subtotal treatment of the prostate gland and a decrease in the morbidity associated with total gland

treatment. In selected patients, such a strategy could theoretically control the cancer while minimizing morbidity, several challenges exist regarding long term follow up, prognosis and management of these patients. Currently there is no randomized data comparing these strategies to standard of care and even little prospective data looking at toxicity results and disease control. In this presentation we will discuss the data regarding low volume clinically localized prostate cancer and the potential for subclinical, contralateral disease. We will also discuss challenges following such patients including the role for prostatic biopsies and the interprestion of PSA changes over time. Finally, we will discuss the rationale and potential agents for prevention of a second primary in the remaining prostatic tissue.

033 Focal Therapy for Localised Prostate Cancer Using High Intensity Focused Ultrasound

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Introduction: The current choice for men with localised prostate cancer (PCa) lies between active surveillance and radical therapy. However, since whole-gland treatment causes damage to surrounding structures, significant genitourinary morbidity occurs. Focal therapy – ablation of only the areas of cancer within the prostate – has been proposed as a middle ground to balance the risk:benefit ratio. We report early results from two phase II trials in focal therapy using high intensity focused ultrasound (HIFU).

Methods: Men with confirmed localised low-intermediate risk PCa (PSA $\leq$15ng/ml, Gleason $=$7, T2cNoMo) were recruited. All underwent multi-sequence MRI (T2W, Dynamic contrast-enhancement, diffusion) and template transperineal 5mm-spaced prostate mapping biopsies to localise disease within the prostate. All treatments were under general anaesthesia using the Sonablate® 500 HIFU device. The Hemi-HIFU trial involved ablation of one whole hemisphere in unilateral PCa. Focal-HIFU involved ablation of all tumor foci (unilateral or bilateral) with 5mm margin, max 60% total tissue ablation and preservation of at least one neurovascular bundle. Suprapubic catheters were inserted. Follow-up involved contrast-enhanced MRI at 2 weeks and 6 months ; TRUS biopsy at 6 months; clinic visits at 1, 3, 6, 9 and 12 months for PSA measurment. Evaluation of toxicity was the primary objective.

Results: From April 2006, 15 men have undergone Hemi-HIFU (target 31) and 8 Focal-HIFU. Of those potent prior to treatment, 93% (14/15) and 57% (4/7) were potent within 1–3 months in the trials, respectively (4 and 2 requiring intermittent oral pharmaceutical assistance, respectively). Noen suffered incontinence or rectal toxicity. Of those reaching 6 months follow-up in the Hemi-HIFU trial, 8/8 had negative biopsies. None in the Focal-HIFU trial have reached 6 months follow-up. All men from both trials showed a consistent PSA fall of approximately 60% from pre-treatment levels.

Conclusions: These early results using HIFU for hemiablation and focal ablation are encouraging. Completion of recruitment and follow-up will demonstrate whether long term randomised trials are justified.

Acknowledgements: The focal therapy programme at University College London is funded by Pelican Cancer Foundation, Prostate Research Campaign UK, Prostate Cancer Research Centre, and the St Peters Trust. The Hemi-HIFU trial has endorsement from Cancer Research UK. Both trials have National Cancer Research Network (UK) approval.

034 Anterior Prostate Cancer: Zonal Location and Pattern of Intraprostatic Spread

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Objectives: to describe anterior prostate cancer (APC) precise location within histological zones at different stages of development and to demonstrate their pattern of intraprostatic spread from their site of origin.

Methods: APC on whole-mount radical prostatectomy (RP) specimens was found in 73 patients. APC morphometric histopathological study with mapping, modelling and 3D reconstruction was performed. Variables studied were APC number, largest surface, volume and spatial distribution within transition zone (TZ) and anterior fibromuscular stroma (AFMS).

Results: From the 73 RP specimens 91 separated APC were identified. APC volume was $<$ 0.5 cc, 0.5 to 2 cc, 2 to 4 cc and $>$ 4 cc in 58%, 18%, 11% and 13% respectively. 50% of APC $<$4 cc were located in the anterior third of TZ and/or AFMS, and 70.5% were located in the inferior (apical) half of TZ. APC $<$2 cc (n$=$69) were classified in 3 types according to their location related to histologic zones boundaries : TZ type 1 (40.6%) when cancer was confined to one TZ lobe or TZ type 2 (34.8%) when cancer volume was most represented in one TZ lobe but crossing its anterior boundary. Type AFMS (24.6%) when cancer was confined to anterior fibromuscular stroma area. These results give rationale for the hypothesis of AFMS cancers. Most anterior or medial TZ cancer foci are excluded from the TZ contours, anteriorly due to BPH enlargement, into AFMS. TZ anterior limit would act then as a posterior barrier to their extension.

Conclusion: APC arise and extend in anterior third and inferior half of TZ and AFMS. Contours and locations are predictable and conform to histologic zones boundaries. Knowledge of APC origin site and pattern of intraprostatic spread are of importance for imaging diagnosis (DCE-MRI), guidance for biopsy and focal therapy by physical agent.

035 MRI-Guided Transurethral Ultrasound Therapy for the Treatment of Localized Prostate Cancer

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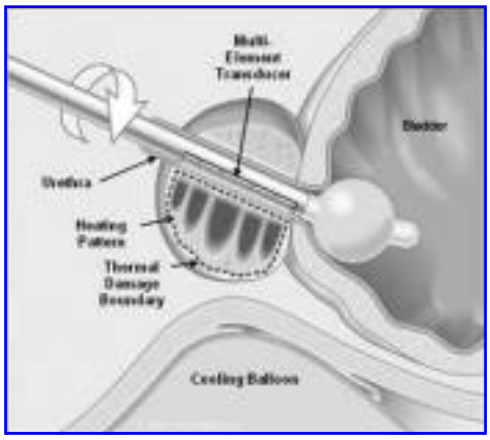
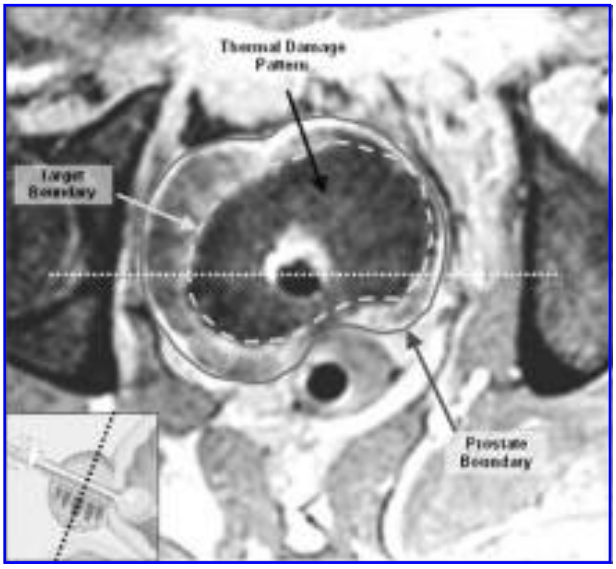


MRI-guided transurethral ultrasound therapy is a minimally-invasive treatment for localized prostate cancer performed within a standard clinical MR imager. High-intensity ultrasound energy is delivered from the urethra using rotational control to generate a precise region of thermal coagulation in the gland (Figure 1). Real-time quantitative temperature maps acquired with MRI during heating are used as active feedback to ensure a precise region of thermal damage is generated. The dual-frequency, multi-element transducer design enables a high degree of spatial control over tissue heating. This form of adaptive thermal therapy enables real-time monitoring and control over treatment delivery based on the actual energy delivered to tissue.

The key features of the technology are 1) the minimally-invasive transurethral approach, 2) the incorporation of real-time quantitative MR thermometry for precise control of treatment, 3) short treatment time (<30 minutes), 4) rapid recovery, and 5) the capability to perform multiple treatments in the case of recurrent disease or deliberate focal therapy. Results obtained through patient-specific modelling, gel phantoms, and canine studies have demonstrated that 3D conformal thermal therapy of targeted regions within the prostate gland is possible with a precision of 1–2mm (Figure 2). Histological evaluation of the spatial pattern of thermal damage reveals a sharp transition from thermal damage to normal tissue (<3mm) at the outer target boundary. Clinical evaluation of this technology in humans is underway.



036 Prostate HistoScanning™ (PHS) Technology and its Potential Use in Focal Therapy

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Introduction & Objective: To date mapping spatial characteristics of prostatic cancers has had little merit in diagnosis or therapy as most treatments involve the whole gland irrespective of burden or disease orientation. Considering therapies to preserve or treat with differential dosing creates demands on diagnostic platforms. We outline design and conduct of studies being undertaken in assessing a novel technology – Prostate HistoScanning(PHS) that may characterise disease uniquely and at a threshold conferring substantial clinical utility.

Methods: HistoScanning utilises ultrasound radiofrequency(RF) signals (backscatter) with data subjected to three sets of 'tissue characterisation' algorithms which discriminate between cancerous and non-cancerous tissues. The ongoing phase 2 multi-centre study, evaluates patients awaiting radical prostatectomy, by TRUS to obtain RF data . This is correlated with whole mounted prostate specimen (3mm slices). The next phase is to evaluate PHS against TRUS guided biopsy in men with raised PSA. Evaluating this technique as guidance for focal treatment is also planned.

Results: study results are to be analysed in 3 steps: the first two refining the algorithms and third the blinded trial. previously published Phase 1 study of 29 patients using calibrated grey level raw data , showed sensitivity and PPV of 95 % for cancer lesions > 0.2 c.c ; for lesions > 0.5 c.c sensitivity and PPV was 100 %.

Conclusion: High sensitivity for detection and the ability of PHS to show tumour foci in three dimensional orientations could potentially be exploited to focally direct therapies like HIFU, cryotherapy, radiofrequency ablation , photodynamic therapy etc. in real time imaging.

037 Total Prostate Embedding with Diagrammatic Reporting: An Alternative to Whole Mount Histology and Traditional "Text Only" Reporting

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Focal therapy of the prostate is predicated on the correct selection of patients with unifocal low risk prostate carcinoma. The selection process includes a critical interplay of high quality biopsy techniques, pathology interpretation, laboratory studies and imaging studies. The surgical prostatectomy specimen provides an ideal template for feedback QA data for the Urologist, Pathologist, Radiologist and Radiation Oncologist.

Diagrammatic reporting of prostate needle biopsies and totally embedded prostatectomy specimens is performed at our

institution. Diagrammatic reporting greatly facilitates biopsy/imaging/prostatectomy correlation and most importantly, enhances patient communication.

Examples of diagrammatic reporting will be presented, to include;

1) Unifocal vs. multifocal tumor patterns
2) Unifocal margin involvement or extraprostatic extension detected by enhanced total embedding
3) Discordant cases where the biopsy detected tumor is not the predominant or most clinically aggressive tumor.
4) Presumed unifocal or low volume disease with resultant high volume multifocal disease.

Misinterpretation or miscommunication of pathology findings can occur at any of stage of medical care. Diagrammatic reporting can succinctly summarize the gross, microscopic and salient reporting checklist items with dramatic impact.

The future of prostate therapy is dependent on a firm foundation of high quality biopsy, pathology, laboratory and imaging studies. Diagrammatic reporting is a vital tool for "Completing the loop", with feedback to both patients and physicians.

038 Diagnostic Accuracy of Dynamic Contrast-Enhanced Pelvic-Phased Array MRI for Prediction of Significant Volume Cancer. Correlation with Biopsy Findings

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Objectives: Evaluation of the diagnostic accuracy of Dynamic Contrast Enhance Magnetic Resonance Imaging (DCE- MRI) to detect prostate cancer. Correlation with biopsy findings.

Methods: 493 consecutive patients who had a DCE MRI before transrectal ultrasound guided biopsies for clinical or PSA abnormality were included . All patients had 10 systematic biopsies including 6 lateral and 4 midlobar biopsies and targeted biopsies in case of rectal or TRUS or MRI suspicious area for malignancy. For each biopsy site, core length, cancer length and % grade 4 and 5 were recorded. MRI protocol was carried out with a Pelvic Phase Array (PPA) with T2-W and DCE T1-W sequences. Results were recorded according to a 5 point scale : benign (1,2) equivocal (3) to malignant (4,5).MRI

Results: The mean age was 63,5 years and median PSA was 8.5ng/ml. For detection of cancer on at least one biopsy, the sensitivity, negative predictive value (NPV) of the combined MRI sequences with scores 3 to 5 were 80% and 70% respectively.

For detection of cancer on more than one biopsy, or a cancer length $>$ 3mm on one biopsy or with grade 4 or 5, the sensitivity, NPV of the combined MRI sequences scores with 3 to 5 were 89% and 87% respectively. For detection of cancer on more than 2 biopsies with length of cancer $>$ 50% on of the 2 biopsies or with grade 4 or 5, the sensitivity, NPV of the combined MRI sequences with scores 3 to 5 were 95% and 95% respectively.

Discussion: Combined T2-WS and T1-W DCE MRI is accurate for cancer detection. 95% NPV for non clinically significant cancers has important applications for diagnostic and therapeutic protocols such as rebiopsy, active surveillance and focal therapy.

039 The Utility of Transrectal Real-Time Elastography in the Diagnosis of Prostate Cancer

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Introduction: The aim of this study is to evaluate the diagnostic performance of transrectal real-time elastography (TRTE).

Methods: Conventional gray scale transrectal ultrasonography (TRUS) and power Doppler ultrasonography (PDUS) were performed in 107 men who had elevated serum PSA level above 4 ng/ml or abnormal findings on digital rectal examination. We used newly adopted five-point subjective scale for TRTE imaging based on the degree and distribution of strain in relation to hypoechoic area. All patients underwent systematic 8-cores biopsies as well as up to 4 cores of targeted biopsy from suspicious area by TRUS, PDUS and/or TRTE. The samples were diagnosed pathologically and compared with the images.

Results: Prostate cancer was detected in 40 (37%) of 107 patients. When a cutoff point of 3 (displaying focal asymmetric lesion without strain not related to hypoechoic lesion) was used, TRTE had 68% sensitivity, 81% specificity, and 76% accuracy. TRTE was comparable with PDUS (70% sensitivity, 75% specificity and 73% accuracy) and had significantly higher sensitivity than TRUS (68% vs. 50%, $p = 0.027$). Combination of TRTE with PDUS increased sensitivity to 78%. The detection rate of directed biopsy from suspicious area in either TRTE or PDUS (TRTE+PDUS directed biopsy) was 29% (31/107) by patient and was comparable with systematic biopsy (31%, 33/107, $p = 0.86$).

Conclusion: For assessing prostatic lesions, TRTE had almost the same diagnostic performance as PDUS. Although TRTE+PDUS directed biopsy detected comparable number of cancers with systematic biopsy, both techniques should be used supplementarily for minimizing the number of missing cancers.

040 Unilaterality of Early Stage Localized Prostate Cancer Cannot be Reliably Predicted by Routine Prostate Biopsy

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Objectives: With the introduction of focal therapy into clinical practice, the detection of unilateral prostate cancer (PCa) by biopsy to select candidates for unilateral thermoablation is of paramount importance. We analyzed the correlation between clinical and pathological stage for low-risk PCa from Duke Prostate Cancer Outcome Database.

Methods: Analysis included demographic, clinical and pathological characteristics of 1144 men with low-risk features according to the D'Amico classification, who underwent radical prostatectomy (RP) from 1995 to 2006. Biopsies were performed in both a community and an academic setting. Final pathology

assessment was done with particular attention to laterality and percentage of tumor involvement along with other routine parameters. Statistical analysis was performed using univariate (Chi-square test) using SPSS, version 15 (Chicago, IL).

Results: Unilateral lesions were found by biopsy in 654 (57.2%) patients, although RP pathologic assessment confirmed unilaterality in only 152 (23.2%) patients originally diagnosed with unilateral disease while the remaining 502 (76.8%) were upgraded to bilateral disease ($p<0.0005$). Bilateral lesions were diagnosed by biopsy in 377 (32.9%) and RP pathology confirmed bilateral disease in 346 (91.8%) patients, although 31 (8.2%) returned as unilateral disease ($p<0.0005$). An additional 113 (9.9%) patients not diagnosed by biopsy who underwent RP identified as 29 (25.7%) unilateral and 84 (74.3%) bilateral pathology cases.

Conclusions: Unilateral PCa biopsies are more common than bilateral positive biopsies, yet RP pathology confirms the contrary. Routine prostate biopsy cannot provide urologic oncologist with reliable information about unilaterality of PCa lesion(s). A significant increase of number of the cores coupled with precise imaging guided technique may better facilitate correlation of tissue diagnosis between prostate biopsy and RP pathology.

041 Anatomic Prostate MRI at 7 Tesla: Endorectal versus Surface Array Comparison

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The potential advantages of ultra high field (UHF) magnetic resonance imaging (MRI) include increased spatial, temporal and spectral resolution all of which would improve anatomic and functional MRI studies of prostate cancer. However, in order to make UHF imaging of the prostate a reality, many challenges must be addressed including increased local RF heating and decreased transmit RF homogeneity resulting from destructive interferences. Both of these issues preclude the use of whole-body transmit coils which are standard on lower field strength clinical scanners and necessitate the use of local transmit or transmit-receive (transceive) coils. In this abstract, preliminary results are presented comparing T2-weighted images from a 16-channel transceive external surface array (tESA) and a transceive endorectal coil (tERC) at 7 Tesla from a healthy human volunteer. The tERC produced a nearly 6-fold increase in signal-to-noise ratio (SNR) which permitted higher resolution images to be obtained. However, unlike the tESA with RF shimming, the tERC was not able to generate a uniform transmit RF field resulting in variable contrast and SNR across the prostate. Despite the lack of RF homogeneity, the tERC requires only a fraction of the total power to achieve the same average flip angle in the prostate which can reduce local RF heating when compared to the tESA. Most likely, a combination of these two coil designs will provide the optimal configuration in terms of SNR, local RF heating, and transmit homogeneity for prostate cancer studies at 7 Tesla.

Acknowledgements: This work was funded by the Minnesota Medical Foundation and BTRR-P41 RR008079.

042 Pathologic Stage T2A and T2B Prostate Cancer in the Recent Prostate-Specific Antigen Era: Implications for Unilateral Ablative Therapy

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Introduction and Objective: Early detection of small volume prostate cancer (PCa) has led to the concept of focal therapy to treat PCa in an organ-sparing, minimally invasive manner. We evaluated trends in pathologic staging among patients with localized PCa undergoing radical prostatectomy (RP) to determine the frequency of unilateral cancers during three different time periods.

Methods: Data were abstracted from the Duke Prostate Cancer Outcome database, a disease registry, selecting 3,676 men with available pathology who underwent RP. Based on surgical pathology, trends in tumor characteristics were evaluated over the eras 1988–1995, 1996–2000 and 2001–2006.

Results: Between 1988 and 1995, only 2.8% undergoing RP had pT2a and 4.7% had pT2b disease. Stage pT2a and pT2b increased to 4.1% and 12.8%, respectively, between 1996 and 2000. Between 2001 and 2006, pT2a increased to 13.0% while pT2b declined to 3.5% ($p<0.0005$). Percent tumor involvement (PTI) $=5\%$ significantly increased from 10% between 1988–95, to 24.8% (1995–2000), up to 37% (2001–06) due to a decline in larger-volume (PTI>15) ($p<0.005$). Of all patients with pT2a throughout 1988–2006, there was a dramatic increase in pT2a from 10% (1988–1995), up to 69.4% (2001–2006). A majority of pT2a cases, 59%, were pGS ≤ 6. The differences between pT2a and pT2b disease according to pGS distribution was insignificant ($p=0.61$). Over three eras, 65% of pT2a specimens had minimal (PTI $=5\%$) or small volume disease. Cox Hazard analysis showed four factors to be statistically significant, contributing to PSA disease-free survival in the contemporary era 2001–2006: stage pT2a vs pT2b, surgical margins, PTI, and PSA (low risk, PSA <10 vs moderate/high risk, PSA>10).

Conclusions: Increasing prevalence of unilateral pT2a and pT2b PCa characterizes a growing proportion of patients electing RP. These tumors are associated with lower PTI, lower pGS <7, and have demonstrated better PSA-free survival in the most recent 2001–2006 era. These low risk pathologic characteristics may potentially allow for unilateral focal thermal ablation procedures as a treatment option in the carefully selected patient.

043 The "Male Lumpectomy": Focal Therapy for Prostate Cancer Using Cryoablation Results in 102 Patients with 1–10 yr Follow-up

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Background: The use of breast sparing surgery, i.e., "lumpectomy," revolutionized management of breast cancer. Lumpec-

tomy confirmed that quality of life issues can successfully be addressed without compromising treatment efficacy. Complications of prostate cancer treatment, including impotence and incontinence, affects the male self image no less than the loss of a breast does a woman. Traditional thinking held that prostate cancer was multi-focal and therefore not amenable to a focal treatment approach. Recent pathologic studies, indicates however that up to 20–25% of prostate cancers are solitary and unilateral. This raises the question of whether these patients can be identified and treated with a limited "lumpectomy" or focal cancer treatment.

Methods: Focal cryoablation was planned to encompass the area of known tumor based on staging biopsies. PSA's were obtained every 3 months for two years and then every 6 months thereafter.

Results: 102 patients with at least 1 year follow-up had focal cryoablation. Follow up ranged from 2 year- 10 years with a mean of 3.5 years. 100 of 102 patients (98%) have stable PSA's (ASTRO criteria) with no evidence for cancer, despite 67 patients being medium (50) to high risk (17) for recurrence. Of the 24 patients with stable PSA's who were routinely biopsied (N=24) all were negative. Evidence for persistent local disease was ultimately demonstrated in no patient (100% local control) although 7 patients had cancer later discovered in a non treated area of the prostate and were retreated with all 7 subsequently having stable PSA's. Potency was maintained to the satisfaction of the patient in of 76 of 83 patients who were potent preoperatively. Of the 102 patients all were continent.

Conclusion: These preliminary results indicate a "male lumpectomy" in which the prostate tumor region itself is destroyed, appears to preserve potency in a majority of patients and limits other complications (particularly incontinence), without compromising cancer control. If confirmed by further studies and long term follow-up, this treatment approach could have a profound effect on prostate cancer management.

044 WST09 Vascular-Targeted Photodynamic Therapy: A Non-Thermal Focal Therapy for Prostate Cancer

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Introduction & Objectives: Vascular-Targeted Photodynamic therapy (VTP) is a new non-thermal technique that can be used in the treatment of prostate cancer. The photosensitiser WST09 (TOOKAD®) is delivered intravenously and activated by laser light whilst in the vasculature of the prostate. Tissue necrosis is limited to the area of light illumination, *via* the production of reactive oxygen species in the small vessels of the target tissue. A phase I/II clinical trial is underway at our institution to investigate the use of the WST09 VTP in localised prostate cancer.

Methods: The WST09 VTP treatment procedures used a brachytherapy approach, with trans-rectal ultrasound and brachy-template to guide the insertion of light-delivering optical fibres into the prostate. The dose-escalation phase of the trial necessitated part-gland or focal treatments. The primary outcome was the measurement of VTP-induced necrosis as seen on dynamic contrast-enhanced (DCE) MRI 1 week following treatment.

Results: VTP produced necrosis in the prostate gland, as seen on DCE-MRI at 7 days post-treatment. These non-enhancing areas corresponded to the position of the optical fibres used for the WST09 VTP treatment. In many patients, tissue-dependent selectivity was observed, with sparing of the extraprostatic structures and prostate capsule.

Conclusions: The WST09 VTP is a non-thermal ablative technique that may be used to treat primary prostate cancer. The method can produce focal tissue necrosis within the prostate with apparent tissue selectivity. WST09 VTP has potential utility in focal as well as whole-gland treatment. Further studies are required to assess its long-term oncological efficacy.

Declarations: Research supported by STEBA Biotech N.V., (Mr D Pendsé, Miss M Sahu, Mr M Emberton). Mrs C Moore was funded by The Royal College of Surgeons of England Research Fellows scheme, St Peters Trust and the BUPA Foundation.

045 Prostate Cancer Computer-Assisted Diagnosis Software Using Combined Dynamic Contrast-Enhanced MRI and Diffusion-Weighted Imaging

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We developed a computer assisted diagnosis (CAD) software dedicated to prostate MRI with multimodality visualization and analysis tools. *Methods*: Images can be sent from any PACS workstation. Simultaneous visualization of T2-w, dynamic contrast enhanced (DCE)-T1w and diffusion weighted imaging (DWI) series is available, including 3D cursor synchronization and image subtraction. Manual or semi-automatic (one-click) contouring tools allow fast delineation and volume assessment of suspicious prostate areas, and a 3D landmarking of the lesions that can be exported to any DICOM-RT compatible device. Semiquantitative and true quantitative analysis of suspicious areas, based on pharmacokinetic models, and ADC measurements can be performed and compared with built-in statistical data. A 5 points scaled reproducible enhancement score (ranging from "probably benign" to "Highly suspicious") is calculated on the basis of DCE-MRI parameters. *Results*: We present the implementation of this software in daily practice and its combination with an experimental MRI-US image fusion-based TRUS biopsy device. A simple scoring algorithm based the median w.i and w.o values of 121 benign or tumoral areas in 121 sample prostate areas was modelled to provide the highest sensitivity in our series. We found respective Se/Sp of 100/49% for peripheral zone cancers, and 100/40% for transition zone cancers characterization. *Conclusion*: This software provides useful tools for reproducible assessment of suspicious prostatic areas at diagnosis and tracking of targeted images in MRI-based prostate diagnosis or treatment devices (biopsy, robotic

surgery, HIFU or radiotherapy) thanks to the DICOM-RT standard.

046 Does Saturation Biopsy Reliably Predict Unilateral Prostate Cancer in Patients with Low-Risk Tumours?

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Introduction & Objectives: Standard treatments for localized prostate cancer (radical prostatectomy, external beam radiation therapy, brachytherapy) are associated with side effects. The interest in focal treatments of prostatic carcinoma has increased significantly with the advent of image-guided tissue ablative techniques, such as cryoablation and high-intensity focused ultrasound, which in theory could minimize tissue injury and result in fewer side effects. The patients that would benefit most from focal ablative therapies are those with unilateral prostate cancer. The aim of our study was to determine whether initial saturation biopsy can reliably predict unilateral prostate cancer in patients with low-risk tumours.

Material & Methods: From the databases of 2 clinics performing prostate biopsies and radical retropubic prostatectomies (RP) using similar techniques, we retrospectively identified 168 men with unilateral low-risk prostate cancer detected by means of 8 – 24 cores transrectal ultrasound-guided biopsies, who subsequently underwent RP between June 2001 and May 2006. All patients fulfilled the Epstein criteria for insignificant prostate cancer (clinical stage T1c, PSA < 10 ng/ml, PSA density < 0.15, biopsy Gleason score ≤ 6, 1 positive core and no more than 50% of cancer in any core). The mean age of patients was 60.2 ± 8 years (range 44 – 68 years), mean PSA level 5.8 ± 2.6 ng/ml (range 2.1 – 9.8 ng/ml), mean prostate volume 48 ± 12 cc (range 18 – 82 cc). Prostatectomy specimens were evaluated using a standardized protocol and all specimens were examined with particular attention for laterality with respect to the side of positive biopsy and number of cores. The chi-square test was used for statistical analysis and $p < 0.05$ was considered statistically significant.

Results: Overall, unilateral prostate cancer was identified in 16.6% (n=28/168) of patients. The probability of ultimately finding unilateral tumour was significantly higher ($p<0.01$) in patients with low-risk prostatic carcinoma diagnosed by initial biopsy from 18 and 24 cores (27%; n=16/59) comparing with those whose biopsy was taken from 8 – 12 cores (11%; n=12/109) (table 1).

Conclusions: In order to achieve total tumor ablation the clinician must be able to accurately localize neoplastic lesions within the prostate with a high degree of reliability. Our data suggest that an 8 – 12 cores biopsy scheme does not allow ruling out prostate cancer on the contralateral side even in low-risk patients. Saturation biopsy as an initial strategy significantly (up to 34.6%) improves the prediction of unilateral cancer in these patients, although its ability to predict in which patients a focal ablative therapy would eradicate all cancer remains insufficient. Indeed, our data shows that 65% of low risk patients predicted to have unilateral cancer on 24 core saturation biopsy actually had bilateral disease. Future studies should focus on clinical predictors identifying those with unilateral prostate cancer as well as advanced imaging that accurately locates the site of tumor foci within the prostatic lobe for selecting potential candidates for minimally invasive nerve-sparing focal therapies.

047 Focal Cryoablation Experience at Hackensack University Medical Center

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Objective: We report herein the outcomes of men treated for primary PCa at University Urology Associates, PA for Focal Cryoablation (FC); i.e., less than the entire prostate gland was ablated as a primary PCa treatment.

Methods: Biopsies, saturation as needed, were performed prior to FC. L/R pathology findings included +/- status, tumor volume and Gleason. FC was offered only to patients with no (or very) low tumor volume on one side. FC was most often a hemi-freeze. Data was collected and analyzed via the Cryo On-Line Data (COLD) Registry, a secure, de-identified online registry for prostate cryoabaltion. ASTRO and Phoenix biochemical failures were defined as three consecutive post-treatment PSA rises and PSA nadir+2, respectively. Post procedure PSA values, continence and major complications were collected for each patient. Potency was not uniformly collected.

Results: 27 patients were treated between 2004 and 2007. The longest follow-up was 36 months. To date, no biochemical failures have been observed by either definition. No patients were found to be incontinent nor experienced major treatment complications.

Conclusions: Although follow-ups are short, the biochemical and local control is encouraging and longer follow-up is

Table 1. The Probability of Unilateral Prostate Cancer after RP Depending on Scheme of Initial Biopsy

Number of biopsy cores	8	109	12	18	24
Number of patients	28	42	39	33	26
	Total n = 109			Total n = 59	
Unilateral cancer after RP					
Number of patients	2	5	5	7	9
	7.1%	11.9%	12.8%	21.2%	34.6%
	Total n = 12 (11%)			Total n = 16 (27.1%)	

needed. Potency for patients with data was similar to results published earlier by: Onik, Bahn and Katz.

Disclosure: The COLD registry is supported through an educational grant from Endocare, Inc.

048 On-Board Platform to Monitor Freezing and Quality Control of Prostate Cryosurgery

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Introduction: Cryoablation of prostate cancer (PCa) is a low morbidity option in the treatment of localized prostate cancer. However, due to the flexible nature of the cryogenic needles and frequent requirement of cryoablation avoidance for patient specific regions, parallel orientation of the probes is rarely achievable. As a consequence, ice ball formation within the prostate volume and neighboring organs may follow a different route than what might be predicted during pre-treatment planning.

Materials and methods: The platform for cryodose analysis based on the real intraoperative room prostate geometry was built around 3D ultrasound imaging of the target volume. The prostate volume was segmented, and accurate 3D orientation and position of the cryoneedles, thermosensors and urethra were reconstructed based on the greyscale images of the scan. The time-dependent equations for temperature distribution were then solved in the volume of the treatment target (prostate, seminal vesicle) and in the organs sensitive to freezing risk. At first, Pennes' bio-heat framework was used to calculate time-dependent radial temperature distribution due to a single cryo- needle. Then the temperature distribution within the prostate volume and beyond was evaluated with respect to the closest needle neighboring a given point. Cryoprobes were modeled as volumes with constant negative power. The computed data were compared against thermocouple readings during the freezing cycle.

Results: The platform was evaluated on data obtained from the analysis of primary whole gland cryosurgery performed on 3 patients. The computed temperature profile agreed reasonably with the recorded thermosensor data. The thermal distribution coverage (0 and -20°C isotherms) as computed in 3 patients was achieved.

Conclusions: The platform has good time performance, as the solution of Pennes' equations can be parameterized and tabulated. Therefore it can be used as guidance for needle repositioning if the predicted isotherms are not satisfactory. Furthermore, this approach can be potentially used for planning of conformal cryoablation in order to preserve the remainder of the prostate gland that is free of cancer.

049 Selective Prostate Cancer Thermal Ablation with Laser Activated Gold Nanoshells

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Purpose: Laser activated gold nanoshell (GNS) thermal ablation represents a new, minimally invasive technology that offers focal thermal ablation of malignant tumors. We evaluated this technology as a prostate cancer treatment in a subcutaneous tumor model.

Methods: 110nm GNS with a 10nm thick gold shell are designed to act as intense near infrared (NIR) absorbers. PC-3 cells were injected on the dorsum of nude mice in three groups: 1) GNS +NIR laser 2) Saline alone 3) NIR laser alone. Animals received either a 7.0μl/gram (low dose) or 8.5μl/gram (high dose) tail vein injection of nanoshells. Control animals received saline. A 810nm NIR laser, with a 200micron laser fiber and an energy setting of 4W/cm^2 was aimed at the tumor bed for three minutes. Tumors were measured at day 0, 7, 14 and 21. Tissue temperature was monitored during laser activation. Tumors were harvested at day 21, stained with H&E, and for nicotinamide adenine dinucleotide (NADH) diaphorase activity.

Results: We observed 93% (14/15 tumors) total tumor necrosis and regression in the high dose treated group. NADH staining corroborated this finding. The zone of ablation was sharply limited to the laser spot size. There was no difference in the size or tumor histology of the control groups indicating a benign course for NIR laser treatment alone. Temperatures up to 65.4°C were reached in the treated group.

Conclusion: Laser activated gold nanoshell ablation holds promise as a future treatment for focal ablation of Pca. Further studies are underway.

050 In-Field/Out-Field Prostate Cancer Foci: Multifocality and Considerations for the Application of Focal Prostate Therapy

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Introduction and Objective: Sub-total prostate ablation with controlled energy devices (cryotherapy, high intensity focused ultrasound and brachytherapy) strives to minimize prostate cancer treatment morbidity, while achieving cancer control. By definition, a portion of the prostate gland is left viable following these procedures. We evaluated the histologic findings outside a prescribed focal treatment field in prostatectomy specimens from men who pre-surgically met eligibility criteria for focal prostate cancer therapy.

Methods: Records of 180 patients (1997—2006) with unilateral, multisite positive prostate biopsy cores (10–13 cores) who subsequently underwent radical prostatectomy were retrospectively reviewed. Clinical and biopsy features were correlated with the prostatectomy specimens assessed for the location and characteristics of individual tumor foci. Tumor foci were considered in-field or out-field by comparing detailed prostate maps created from histologic sections to treatment plans commonly employed in focal prostate cancer therapy (ipsilateral "hemispheric" versus 3/4 "hockey stick" templates).

Results: A single biopsy core was positive in 60% of men (108/180), 40% having multiple (range 2–5) ipsilaterally positive cores. The median number of tumor foci within the prostate was 3 (range 1–8). Median total tumor volume and dominant

tumor volume were 0.727 cc and 0.501 cc, respectively. 26% (47/180) of men had dominant tumors considered low-volume/low-grade cancer (LV/LG Ca; volume < 0.5 cc, Gleason score ≤ 6). The dominant tumor focus was ipsilateral to the unilaterally positive biopsy site in 66% (118/180). Bilateral disease (dominant and non-dominant tumor foci) was present in 83% (157/180) of prostate specimens. A hockey stick treatment plan increased in-field capture of all tumor foci from 17% to 47% (55% if a single core was positive). There were no statistically significant predictors of in-field disease when applying either hemispheric or hockey stick treatment plans. Contralateral tumors not within treatment field were LG/LV in 64% of specimens.

Conclusions: Undetected multifocality of prostate cancer persists even using an extended, laterally directed biopsy scheme in the PSA era. Focal treatment plans, will leave untreated prostate cancer in the majority of men. However, these untreated tumors are predominantly LG/LV. The clinical significance of these untreated foci remains unknown.

051 Fusion of Pre-Acquired MRI with Real Time Transrectal Ultrasound for Targeted Prostate Biopsy Guidance

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Background and Objective: Most prostate biopsies are performed under transrectal ultrasound (TRUS) guidance with limited resolution of prostate cancer. MRI may provide more accurate cancer depiction and improved lesion-target guidance. However, procedures in the MR-suite are time-consuming and costly. Fusing pre-acquired MRI with TRUS brings valuable information to biopsy guidance at low cost and with minimal impact on standard workflow, allowing for lesion-targeted prostate biopsy.

Methods: Preoperative MRI scans are performed on a Philips 3T scanner using endorectal and body coils. Suspicious regions are identified on the T2-weighted, spectroscopy, diffusion-weighted, and dynamic contrast-enhanced images. A TRUS probe is spatially tracked using an electromagnetic tracking system to enable MRI/TRUS registration. Real-time TRUS imaging displays the current ultrasound frame fused with the corresponding T2-weighted MRI and the identified targets that can be color-coded. The TRUS images are also processed to account for prostate motion during the biopsy procedure. The technique was used to guide targeted biopsies in 30 patients, 17 for feasibility and 13 for comparison of targeted biopsies to conventional systematic biopsies. Histopathologic examination of specimens was performed.

Results: The registration accuracy between the TRUS and MRI was about 3 mm on average. Prostate overlap between MRI and TRUS without and with motion compensation was $75\% \pm 19\%$ and $94\% \pm 5\%$, respectively. Positive lesion targeted biopsies were obtained in patients with prior false negative systematic TRUS biopsies.

Conclusions: Fusion of MRI with real-time TRUS is feasible for lesion-targeted biopsy and has potential to enable localized therapy of prostate cancer.

052 Prospects of Acoustic Radiation Force Impulse (ARFI) Imaging in the Diagnosis of Localized Prostate Cancer: Ex-vivo Experience with Prostatectomy Specimens

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Objectives: McNeal's zonal anatomy of the prostate has been the standard anatomical model for the human prostate for about 30 years. However, it was not well visualized by current ultrasound techniques especially regarding a spatial distribution of organ-confined prostate cancer (PCa). In this study, 3D Acoustic Radiation Force Impulse (ARFI) imaging has been tested in order to better visualize PCa lesion(s) within a zonal distribution of excised human prostates.

Methods: Prostate specimens from 7 patients with localized PCa were obtained immediately after radical prostatectomy and put in an isotonic saline bath at room temperature. ARFI data were acquired from the posterior side of the prostate using a modified Siemens Antares^{TM} scanner and a VF10-5 linear array, whose imaging plane is the axial/lateral view of normal anatomy. The position of the imaging transducer was controlled by a 3D translation stage. The scanner and the translation stage were programmed to scan the entire prostate specimen automatically with 1 mm spacing between elevation planes. 3D ARFI images with high spatial resolution were acquired for each specimen.

Results: Different zones and structures within the prostates have been well visualized using 3D ARFI images, which are in agreement with McNeal's zonal anatomy. PCa lesion(s) were accurately visualized in peripheral zones while benign prostatic hyperplasia was also detected in some transitional zones. In cases where alignment between the histological sections and ARFI data were obtained, structures portrayed in the ARFI images were in good agreement with the histopathological results.

Conclusions: This pilot trial demonstrated that ARFI imaging is capable of visualizing internal structures and detecting PCa lesion(s) in the prostate. ARFI imaging could be potentially used to guide prostate biopsy of suspicious lesions and focal targeted thermoablation of a single focus or unilateral PCa lesions.

Locally Recurrent Prostate Cancer. Radiation: HDR Brachytherapy. Phase 1 Phase 2.Â With focal HDR brachytherapy, the investigators can treat the isolated areas of disease, while avoiding normal prostate tissue, with the goal of further improving toxicity rates. The investigators hypothesize that using single fraction, focal HDR brachytherapy performed with one single implant for the treatment of LRPC is feasible and without excess toxicity, and can be safely delivered.Â Biopsy proven locally recurrent adenocarcinoma of the prostate after the completion of definitive radiation therapy for initially diagnosed prostate cancer. Biopsy must be performed within 182 days of trial registration. The International Symposium on Focal Therapy and Imaging in Prostate and Kidney cancer takes place every year rotating between the North America, Europe and Asia. History. The early beginning of the society was initiated in 2008 and is addressed to urologists, radiation oncologists, medical oncologists, pathologists, radiologists, researchers, biomedical engineers and anyone from the cancer community with an interest in prostate and kidney cancer. RESOURCES.Â Read the latest combined resources from members of the Focal Therapy Society. Become a Society Member. Our members have an interest in the latest treatments involving prostate and kidney cancer. View the benefits of joining the Focal Therapy Society. Learn More. Focal therapy offers a middle ground therapy for men with localized prostate cancer. The cancer is traditionally treated either with "watchful waiting" or radiation and surgery. Focal therapy uses ablation to target the index lesion, the largest tumor with the highest grade.Â What is focal therapy for localized prostate cancer? Localized prostate cancer is cancer that has spread (metastasized) no farther than the tissue surrounding the prostate gland. Focal therapy is a treatment for this type of prostate cancer. For many years there have been two main approaches to treating localized prostate cancer. The first is active surveillance or â€œwatchful waiting.â€ Prostate Consensus 2: Biomarkers in prostate focal therapy. Closed session - participation by invitation only Chairs: Rafael Sanchez Salas (France). Room: Ashlawn South. 1:30pm - 3:30pm.Â > Focal therapy for intermediate-high risk prostate cancer: expanding indications - Andre Luis de Castro Abreu (USA) > Rationale for the high-risk primary patient - Mark Emberton (UK) > Rationale for salvage focal therapy - Aaron Katz (USA) > PT selection for renal ablation - Thomas Jarrett (USA) > Tissue-based genomic classifiers for prostate cancer: Can they help identify candidates for AS or FT [Oncotype, Prolaris, Decipher] is there. an impact on outcomes? - Peter Carroll (USA) Q&A. 9:45am - 10:15am.Â Imaging Panel 1: Engineering and Imaging News Panel.