Newsletter

Prostate Cancer 101, Inc.

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The Prostate Cancer Information and Support Group of the Mid-Hudson

Value As A Decision Driver In Cancer Care: Are We There Yet?

By Lynne Lederman, PhD

The official theme of this year's American Society of Clinical Oncology (ASCO) Annual Meeting was Illumination and Innovation: Transforming Data into Learning. However, a prominent theme that quickly emerged was "value." For the first time at ASCO, value was the subject of two presentations during the Plenary Session1, 2 as well as an education session3 and a health services research and quality of care session.4

With the topic of value so prominent at the meeting, we saw and heard many discussions on the value of incremental gains in cancer care. In particular, we sat in on a discussion between Maria Whitman, Managing Principal, Specialty Therapeutics and Oncology, ZS Associates, a global firm focused on improving business performance through sales and marketing solutions, and Michael Kolodziej, MD, National Medical Director, Oncology Solutions, Aetna, about value as a decision-driver in cancer care. Ms. Whitman also commented on a survey conducted during ASCO by M3 Global Research of 94 medical or hematologic oncologists practicing in community or academic settings who attended the annual meeting.

Value Includes Clinical Benefit Plus Therapeutic and Financial Toxicities

Dr. Kolodziej said that having a conversation about value in cancer care is a big step in the right direction because the cost of cancer care needs to be addressed. "I think we want to recognize that there is a budget. We've unfortunately gotten in a groove where every innovation is a wonderful innovation. I think what we really should be focusing on is how do we pay for things that really, really make a difference? And the thing about immunotherapy is, it is clear for some patients it really, really makes a difference."

In his plenary presentation,1 Leonard B. Saltz, MD, of Memorial Sloan Kettering Cancer Center, discussed the value of therapy—what is gained in efficacy but at what toxicity and how much the regimen costs. The most prominent example at the meeting was the nivolumab plus ipilimumab regimen, which showed terrific efficacy, but which is estimated to cost about $300,000 (a patient with typical co-pays of 20% would have to pay out-of-pocket $60,000). If all patients with any metastatic cancer in the US received 1 year of a similarly priced drug, Dr. Saltz said, this could translate into $174 billion in drug costs. This price tag doesn't include adjuvant therapy, surgery, or other treatments. With the cost of pembrolizumab, estimated to be even higher, this could run up to $1M per patient per year.

Dr. Saltz said prices do not seem to reflect innovation, efficacy, or development costs. "Cancer drug prices are not re-

lated to the value of drugs, but rather are based on what has come before and what the market will bear. This," he said, "is unsustainable." He suggested a starting point in the value conversation, involving the pharmaceutical and biotechnology industries, payers, government, patients, and oncologists, should include considering an upper limit to the cost of care of each patient with cancer.

Whereas sometimes, "less [therapy] is more," Dr. Saltz observed that sometimes "more is more." For example, elective neck dissection in early stage oral cancers.5 He noted the study of nivolumab plus ipilimumab in metastatic melanoma,6 emphasizing that the median progression-free survival of 11.5 months for the combination is impressive for a disease once thought incurable. However, he said, "I have a major problem: these drugs cost too much. We can't discuss value unless we include benefit and toxicities as well as cost."

According to M3 survey respondents, drug therapy is the biggest driver to unnecessary costs in patient treatment, followed by hospitalization (Figure 1). Ms. Whitman commented, "At ASCO, there was an unprecedented level of conversation around the rising cost of cancer care overall, which includes balancing choices and eliminating waste. The shifting focus on outcomes can help reduce expense items across the value equation, which includes drug therapy selection, but also includes hospitalizations and excess diagnostic testing, which increase the total cost of care."

Cost was a deciding or influencing factor in treatment decisions in the past 6 months for most of the surveyed physicians (Figure 2). "A few years ago, cost was discussed as an 'all else being equal' consideration. Today we see cost – and in particular drug cost – more top of mind for oncologists and entering the discussion in a more deliberate way, for example through pathway guidance or more direct discussions around costs to patients. But is value a consistent driver yet? There are a number of initiatives underway to address cost transparency to enable more effective decision making at the physician-patient level." Ms. Whitman said.

Potential Solutions to the Cost Dilemma

Lowell E. Schnipper, MD, Chair, ASCO Task Force on Value in Cancer Care, discussed ASCO's Value Initiative: A Case-Based Approach, in an education session.7 The focus of ASCO's value framework will be to support informed, shared decision-making between doctor and patient using a tool to individualize information, including clinical benefit, toxicity, and costs. ASCO will publish a framework to assess the value of cancer treatment options in the Journal of Clinical Oncology in late June of this year.

An economic analysis was presented by Deborah Schrag, MD, MPH, Dana-Farber Cancer Institute, Boston, Massachusetts, from the CALGB (Alliance)/SWOG 80405 study in patients with KRAS wild-type colorectal cancer.8 The conclusion was that the combination of chemotherapy plus bevacizumab cost much less than the combination of chemotherapy plus cetuximab, with similar survival and quality-adjusted survival. About a 45% reduction in the average selling price of cetuximab would be required to equal bevacizumab costs as used in the clinical study. While Dr. Schrag made no recommendations, Dr. Saltz suggested adopting "pay for performance" for drugs or tiered coverage pegged to efficacy.

Dr. Kolodziej suggested that transparency ultimately will require looking at how therapeutic decision making influences total cost of care. Most survey respondents were neutral that drug therapies alone provide the number one opportunity for cost containment in cancer care, suggesting that there is more to cost containment than controlling drug costs. For example, hospitalizations also contribute to costs. Dr. Kolodziej said that in a pilot study with Texas Oncology among patients with Medicare Advantage, those over age 70 with non-small

cell lung cancer have a higher rate of hospitalization, and longer stays, which should be a part of the shared decision-making process between patient and provider. "If you don't discuss the possibility of hospitalization, you're not making an informed decision." The data that are being collected can be used to further personalize therapy, make good therapeutic decisions for patients, and make good financial decisions for everyone in the healthcare ecosystem. Ms. Whitman observed that this illustrates that value is a "holistic conversation."

Among those respondents who did have a strong opinion, more agreed than disagreed that drug therapy is the number one target for cost containment in cancer care (Figure 3). Ms. Whitman pointed out, "The pace of innovation is exciting and the clinical achievements will continue to drive us forward in the fight against cancer, and we can expect value to be a consistent part of the equation moving forward. Twenty-seven percent of oncologists surveyed strongly agree advancements like novel drugs or novel drug combinations will force considerations of cost as a decision criterion in therapy selection."

There are a number of value proposals. One of the most prominent concerns the use of biomarkers to identify patients for whom therapy will achieve the greatest outcomes. For Dr. Kolodziej, the most interesting abstract is one that discusses a marker for response. He cited in particular the presentation on the use of mismatch repair defects to predict response to the checkpoint inhibitor pembrolizumab in patients with previously treated, progressive, metastatic tumors.9 As advice to drug manufacturers, he said, "Regulatory end points are regulatory end points. They are not necessarily clinically meaningful end points, or end points that will distinguish you as this value equation is applied to your product. Think a little bit about how much an investment in a companion diagnostic or a biomarker is going to distinguish your product and give you an opportunity to have preferential placement on a therapeutic decision pathway."

The majority of respondents in the survey reported that the biggest positive impact in driving value in cancer care is the availability of biosimilars and use of biomarkers (Figure 4). Biosimilars were not mentioned in the value discussions, but Ms. Whitman noted that biosimilars are hotly debated, and that any time more options become available, there is the potential to reduce cost. For biomarkers, she said, "The availability of identifiable biomarkers enables a stronger value choice for the therapy that can really make a difference for the targeted patients they benefit."

Anthem's Payment Plan

Another value proposition involves the use of pathways to address controlling the cost of care while improving patient outcomes. Jennifer Malin, MD, PhD, Staff Vice President, Clinical Strategy at Anthem, presented a poster10 and talk11 from the payer perspective on Anthem's new payment model. This model relies on treatment pathways12 to promote quality, affordable, and accessible cancer care. The Anthem Cancer Care Quality Program based enhanced reimbursement to oncology practices on following nationally acknowledged and peer-reviewed cancer treatment guidelines and pathways. Between 63% and 72% of patients were given an approved regimen, depending on tumor type, vs. 40% to 50% before initiation of the program. Although Anthem found that their payment model was feasible, there are no data on clinical outcomes or how non-registered patients were treated. Additional interventions may be needed to increase participation and adherence to pathways.

Looking Ahead

Ms. Whitman agreed that the value conversation "is a broad conversation, because it involves many parts, has to be linked to outcomes, and involve a collaborative solution among payers, providers, and manufacturers." And, as Dr.

Kolodziej added, patients, who matter more than anyone else, will have to be part of this discussion. The patients, Ms. Whitman concluded, are why we are all here. With ASCO and other organizations tackling the value topic, it is clear that we are only at the beginning of what will be continuing conversations about value in cancer care.

About the Contributors

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See more at: http://www.obroncology.com/obrgreen/article/Value-As-A-Decision-Driver-In-Cancer-Care-Are-We-There-Yet#sthash.ZOcgwBAe.dpuf

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The discovery of new molecular mechanisms that may link obesity and high risk prostate cancer

Obesity is a known risk factor for prostate cancer. At the 2015 Annual AACR Meeting, a study combining epidemiology and molecular pathology found that chromatin remodeling may be a mechanism involved in this relationship.

What this means for patients: Obesity is a known risk factor for prostate cancer, but the reasons for this remain unknown. This study identifies expression of chromatin remodeling genes as a likely mechanism linking these processes, and may lead to the development of therapies for obesity-related prostate cancer.

June 2, 2015 -- Obesity is known to increase the risk for prostate cancer, particularly for high-risk, lethal disease. This risk is further increased in African American men. A number of molecular mechanisms may be involved in the relationship between obesity and lethal prostate cancer including the production of tumor-promoting growth factors and metabolites by adipose cells and the accompaniment of obesity by inflammation which can abrogate the normal functions of the immune system. However, much work needs to be done to understand the cause and effect relationships between these complex biologies.
Ericka Ebot, PhD, MPH

The combination of epidemiology and molecular pathology is a powerful research methodology for identifying connections between epidemiologic measurements such as diet or lifestyle, and molecular mechanisms that contribute to disease. At the 2015 Annual AACR Meeting, held from April 18-22 in Philadelphia, PA, Dr. Ericka Ebot, of the Harvard T.H. Chan School of Public Health, presented data that implicates another molecular mechanism – chromatin remodeling –in the links between obesity and prostate cancer.

Ebot conducted a study on 402 prostate cancer patients diagnosed between 1982 and 2005 and for whom both archival tumor tissue and an average of 13-years of follow-up data on patient outcome were available. The study included 113 men who progressed to lethal prostate cancer and 289 men who had indolent cancers (defined as follow-up without evidence of metastatic disease). All of these men were participants in the Health Professionals Follow-up Study or the Physicians' Health Study, two long-term Harvard studies that include periodic surveys to follow

the lifestyle and health of participants. These surveys were used to determine self-reported BMI values prior to the diagnosis of prostate cancer. Tumor tissues and adjacent normal prostate tissues obtained during the patients' original radical prostatectomy surgeries were evaluated by whole genome transcriptome sequencing to determine gene expression levels. The top molecular pathways that were most highly expressed in the prostate tumors of obese men (BMI >27.5 kg/m²) vs. men of a healthy BMI (18.5 to 25 kg/m²) were involved in the process of chromatin remodeling. In addition, higher expression of the chromatin remodeling genes was associated with more advanced tumor stage, higher Gleason grade, and also a 5 times greater risk of lethal progression (even beyond associations with the clinical features).

Chromatin remodeling is a major mechanism regulating gene expression. In this process, the regions of chromosomal DNA surrounding a gene are modified by the additions and subtractions of various molecules that cause the DNA to alter its structure and become accessible or inaccessible for transcription factors to attach and transcribe the gene into RNA. This "epigenetic" process is heritable as a cell divides and is the primary mechanism by which the identity and functions of a cell are passed from parent to daughter when a cell divides. While tumor cells are normally thought to pass their dysfunctional state to their offspring via genetic mutations, epigenetic processes have also been shown to be important in maintaining many oncogenic activities of tumor cells. This study therefore implicates obesity in affecting epigenetic processes that promote the development of high risk and lethal prostate cancer. Future studies will aim at understanding the connections between these mechanisms in more detail and could lead to the development of new preventative measures or treatments strategies for prostate cancer.

Dr. Ebot is a postdoctoral fellow in the lab of Dr. Lorelei Mucci, a Prostate Cancer Foundation Young Investigator from 2008-2011. This study was also partially funded by a Prostate Cancer Foundation Challenge Award (PIs Loda and Mucci) as well as the Dana-Farber/ Harvard Cancer Center SPORE in Prostate Cancer.

Source: Prostate Cancer Foundation

http://www.pcf.org/site/c.leJRIROrEpH/b.9286715/k.F138/The_discovery_of_new_molecular_mechanisms_that_may_link_obesity_and_high_risk_prostate_cancer.htm?msource=june15np&auid=15767899

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Chemo Instead of Hormone Therapy May Be Preferred Option for Some with Advanced Prostate Cancer

Small study suggests that presence of gene variant can be used to select best treatment

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Newswise — In a small clinical trial, scientists at Johns Hopkins' Kimmel Cancer Center and James Buchanan Brady Urological Institute found that men with advanced prostate cancer and detection of androgen receptor splice variant-7 (AR-V7) respond to chemotherapy just as well as men who lack the variant.

The findings, the researchers say, may be significant for patients who carry the AR-V7 variant, because they are more likely to develop resistance to one of two hormone drugs routinely used to treat their disease. Results of the trial are published online in the June 4 issue of JAMA Oncology.

"Our study shows that men who have the AR-V7 gene variant and usually don't respond to either abiraterone or enzalutamide, are not at a disadvantage when given chemotherapy drugs," says Emmanuel Antonarakis, M.D., an oncologist at the Kimmel Cancer Center. Seven of the 17 men in the trial who carried the AR-V7 variant and received chemotherapy experienced a 50 percent reduction in their prostate-specific antigen (PSA) level.

The National Cancer Institute estimates that more than 220,000 men will be diagnosed with prostate cancer in 2015 and more than 27,000 will die from it. Approximately 5 percent (11,000) of patients with prostate cancer have advanced disease.

The AR-V7 gene variant was discovered in 2008 by James Buchanan Brady Urological Institute researcher Jun Luo, Ph.D. In a previous study, Luo and Antonarakis found that men with the AR-V7 variant were resistant to hormonal drugs, such as enzalutamide or abiraterone, which are androgen receptor-directed therapies used for treating the type of advanced cancer called castration -resistant prostate cancer.

Abiraterone and enzalutamide, says Antonarakis, aim to block the production and function of male hormones. The AR-V7 variant codes for shortened proteins that, unlike full-length AR proteins, regulate prostate cancer growth, which is not dependent on male hormones, or androgens. Therefore, men who have the AR-V7 variant are more likely to be resistant to hormone drugs, rendering them ineffective.

In the new trial with 37 men being treated with either of two chemotherapy drugs, docetaxel or cabazitaxel, at The Johns Hopkins Hospital, 17 had detectable levels of the AR-V7 variant in their blood. In comparing men with and without the gene variant, there was no statistical difference in how much patients' PSA levels declined, how long it took for their cancers to progress or their overall survival. PSA levels are markers for prostate cancer.

In a previous clinical trial of 62 patients with castraction-resistant prostate cancer, the same researchers found that 18 AR-V7-positive patients who took either enzalutamide or abiraterone showed no reduction in their PSA levels, indicating that the drugs were not effective in these patients. However, the current study showed that seven of 17 (41 percent) AR-V7-positive patients receiving chemotherapy achieved a 50 percent reduction in PSA levels.

Taken together, Antonarakis says, the findings, if confirmed in larg-

er trials, suggest that the presence of the AR-V7 variant could be used someday as a biomarker to improve treatment decision-making for patients with prostate cancer.

When some patients take either enzalutamide or abiraterone, the drug stops working, and their cancer grows and spreads, explains Antonarakis. The incidence of AR-V7 among these patients may be as high as 30 to 40 percent, he notes.

"It would be very useful to know if such patients are AR-V7 -positive," Antonarakis says, "because if they were, a better step for them might be chemotherapy rather than the alternative androgen receptor-directed hormonal therapy."

"We think AR-V7 would have the greatest utility as a biomarker to guide further treatment in men with castration-resistant prostate cancer, and not for earlier stages of the disease so far," Luo says. "But that's something we should test in further studies."

The researchers also detected what they say is an intriguing change among seven of the patients in the study who were AR -V7-positive at the start of their chemotherapy: During the course of that treatment, they converted to AR-V7-negative. "The clinical significance of this is unknown, but one hypothesis is that some of these patients could possibly become resensitized to enzalutamide or abiraterone."

There is no commercially available test yet for AR-V7, Antonarakis notes, which is detected in tumor cells circulating in a patient's blood. But Luo and Antonarakis say that they are working to develop and validate an AR-V7 test that could be used more widely.

"The ultimate goal is to address needs of patients who are failing standard therapy," says Luo. "By using the biomarker to improve patient-doctor decision-making, we could realize a therapeutic benefit without having to find a new drug."

The researchers also note that the two hormone therapies, abiraterone and enzalutamide, are considerably more expensive than chemotherapy. At more than $30,000 for a six-month treatment, the hormone-based therapies are more than double the chemotherapy costs.

Other Johns Hopkins scientists who contributed to the study include Changxue Lu, Brandon Luber, Hao Wang, Yan Chen, Mary Nakazawa, Rosa Nadal, Channing J. Paller, Samuel R. Denmeade, Michael A. Carducci and Mario A. Eisenberger.

Antonarakis has served as a paid consultant/advisor for Janssen, Astellas, Sanofi, Dendreon, Essa and Medivation and received research funding from Janssen, Johnson & Johnson, Sanofi, Dendreon, Exelixis, Genentech, Novartis, and Tokai. He is a co-inventor of a technology that has been licensed to Tokai. Luo has served as a paid consultant/advisor for Astellas, been a speaker for Sanofi and Gilead, and received research funding from Sanofi and Mirati. These arrangements are being managed by The Johns Hopkins University in accordance with its conflict-of-interest policies.

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Prostate Cancer: Optimism, Caution for Active Surveillance
Two-thirds of prostate cancer patients qualify--with caveats

by Charles Bankhead Staff Writer, MedPage Today

Action Points
Two-thirds of men with newly diagnosed prostate cancer met criteria for active surveillance, including a subset of higher-risk patients.

Note that a second study showed that men who undergo radical prostatectomy because of biopsy-confirmed progression after initiating active surveillance still have clinicopathologic features compatible with curable disease.

Two-thirds of men with newly diagnosed prostate cancer met criteria for active surveillance, including a subset of higher-risk patients, data from the National Cancer Institute (NCI) suggest.

Overall, 187 of 281 (67%) patients qualified for active surveillance. Two-thirds of the men qualified by standard assessment criteria, but 64 of the 187 qualified by expanded criteria for higher risk patients: four or fewer biopsy cores with Gleason grade 3+3 cancer and no more than one core of Gleason 3+4 cancer and 15% or less of the core with Gleason 3+4 cancer.

"In comparing the restricted group of men eligible for active surveillance with the less restricted group [expanded criteria], positive margins and upstaging were more common in the less restricted group," Ian M. Thompson III, MD, of the University of Texas Health Science Center at San Antonio, and colleagues reported in the September issue of the Journal of Urology.

"However, if upstaging or upgrading were combined as an outcome, there was no difference in the risk of this outcome between the two active surveillance groups of patients," they wrote.

"Less restricted criteria for surveillance may be appropriate based on similar rates of upgrading/upstaging at radical prostatectomy," they added.
A second study published in the same issue of the journal showed that men who undergo radical prostatectomy because of biopsy-confirmed progression after initiating active surveillance still have clinicopathologic features compatible with curable disease. Moreover, men who opted for surgery without evidence of progression had even more low-risk features, emphasizing a need to address psychological stress in men on active surveillance.

However, the second study also questioned relaxation of criteria for active surveillance: Men who did not meet standard criteria for active surveillance because of elevated PSA density and had immediate surgery were more likely to have unfavorable-risk anterior tumors and extraprostatic extension.

"In our studies, when we try to include more patients in active surveillance and allow three, four, or five positive cores, we end up putting people on active surveillance who end up having worse disease," Jonathan I. Epstein, MD, of Johns Hopkins Hospital, told MedPage Today. "Similarly, at least on entry, we have found that they have to have a relatively low PSA value, which we measure as PSA density. If we relax that criterion, they are the ones who have worse disease when their prostate is taken out."

Patient Preferences, Expectations

The authors of an accompanying editorial argued for more individualization in the selection and follow-up of men in active surveillance.
"In the end, there may not be a single optimal set of rules to select men for active surveillance, and guidelines should be based on patient (and partner) preferences and expectations," said Marc A.

Dall'Era, MD, of the University of California Davis in Sacramento, and Peter Carroll, MD, MPH, of the University of California San Francisco.

"We know from several well-described surveillance cohorts that the risk of progression to metastatic disease and dying of prostate cancer with expectant management is low, but not zero. Novel tools will undoubtedly improve risk assessment with time and change the way we treat men with prostate cancer, but the ultimate goals of any treatment and patient priorities must be identified upfront."

"Therefore, the criteria for patient selection should be individualized instead of combined in a one-size-fits-all strategy based solely on avoiding prostate cancer mortality."

San Antonio Study

Despite support from multiple studies and in clinical guidelines, use active surveillance for newly diagnosed early prostate cancer in the U.S has lagged behind, as compared with most developed nations. Recent studies have suggested the tide has begun to turn in favor of active surveillance for appropriately selected patients.

Criteria for active surveillance have been developed, but questions have persisted about the proportion of men with newly diagnosed prostate cancer who meet the criteria. A second unresolved issue relates to undersampling prostate biopsy and the extent of higher-grade cancer in men found to have lower-risk prostate cancer.

Answers to the two questions could help determine estimates of appropriate national rates of active surveillance in men with newly diagnosed, PSA-detected prostate cancer, Thompson and colleagues noted. To address the issues, they analyzed data from the San Antonio Center of Biomarkers of Risk for Prostate Cancer (SABOR), a member of NCI's Early Detection Research Network.

Records for 3,828 men enrolled in SABOR showed that 320 had prostate cancer diagnoses, of whom 281 had complete data. The 281 men were assessed by two sets of criteria for active surveillance. Standard criteria consisted of PSA density <15%, two or fewer cancer-involved cores from prostate biopsy, Gleason score ≤6, and cancer involving ≤50 of biopsy volume. The expanded criteria comprised the second set of parameters.

The data showed that 123 patients met the standard criteria for active surveillance and 64 met the expanded criteria. Final pathologic review for 74 men who subsequently underwent radical prostatectomy showed that 14 of 42 (33%) men who met the standard active surveillance criteria were upgraded or upstaged, as were nine of 34 (26%) men who qualified for active surveillance by the expanded criteria.

Thompson and colleagues also evaluated upgrading/upstaging in a subgroup of 55 men who did not meet either set of criteria for active surveillance and underwent radical prostatectomy. Pathology results showed that 21 (38%) were upgraded or upstaged.

The rates of upgrading/upstaging in the active surveillance groups were "of some concern," Thompson and colleagues acknowledged. However, only five patients who underwent prostatectomy had seminal vesicle invasion, "perhaps the most meaningful metric of upstaging," and none of the five was from either of the active surveillance groups.
A study limitation was that men in SABOR were more likely to be closely followed compared with men in the general population, which may have led to an earlier stage and grade of disease at diagnosis.

Baltimore Study

Epstein and colleagues reported findings from a review of records for 137 men who underwent radical prostatectomy for early prostate cancer. The study population comprised 80 men in active surveillance who had biopsy-confirmed progression, 33 who opted out of active surveillance for personal reasons, and 24 who did not meet entry criteria for the Johns Hopkins active surveillance program.

Entry criteria for the Johns Hopkins program consist of clinical stage T1c, PSA density <0.15 ng/mL, Gleason score ≤6, no more than two positive biopsy cores, and ≤50% tumor involvement in any positive core at any time during active surveillance. Most of

the 24 men who did not meet the criteria had elevated PSA density.

Findings at radical prostatectomy showed that the men who opted out of active surveillance were more likely to have Gleason 6 tumors (78.8%) than either the men who had progression on biopsy (46.2%, P=0.002) or the men who did not meet entry criteria for active surveillance (45.8%, P=0.02). Men who did not meet the active surveillance criteria were less likely to have organ-confined disease than either the opt-out group (P<0.006) or biopsy-progression group (P=0.07). Rates of positive margins did not differ among the three groups.

Men who opted out of active surveillance had significantly higher rates of insignificant tumors at radical prostatectomy (48.4%) than either the biopsy-progression group (284%, P=0.05) or the men who did not meet criteria for active surveillance (20.8%, P=0.035).
Adverse findings at radical prostatectomy included Gleason score 4+3=7 or higher, nonfocal extraprostatic extension, seminal vesicle invasion, lymph node metastases, tumor volume >2.0 cc. Men who opted out of active surveillance were less likely to have any adverse findings: 12.1% versus 31.2% of the biopsy-progression group (P=0.06) versus 37.5% of the patients who did not meet active surveillance criteria (P=0.053).

"The majority of men with biopsy progression still have tumors with features of curable disease," Epstein and colleagues concluded. "Men who opted out without without biopsy progression have even less adverse findings, which supports counseling men to stay on active surveillance while meeting follow-up criteria."

"Men who do not meet criteria for active surveillance ... had a higher incidence of anterior tumors and less organ-confined cancer, substantiating that the ideal patient for active surveillance fulfills all of our entry criteria."

Study limitations included the low number of patients and the lack of detailed data on the reasons why patients without biopsy progression elected to undergo radical prostatectomy.

The study by Thompson's group was supported by the NIH.
Thompson disclosed no relevant relationships with industry. One or more co-authors disclosed relevant relationships with Exosome Diagnostics, Oncocell MDX, Magforce, Myriad Genetics, and NanoTx Therapeutics.

Epstein and co-authors disclosed no relevant relationships with industry.
Dall'Era disclosed a relevant relationship with Genomic Health. Carroll disclosed no relevant relationships with industry.

Reviewed by Robert Jasmer, MD Associate Clinical Professor of Medicine, University of California, San Francisco
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1 comments
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Printing costs have gone up! If you do not want the newsletter or you don't wish to be on the member list given to newcomers, let me know. It costs about $1.50 to send each one of you a newsletter. I can dream, but could those of you who have never contributed find a way to send $10.00 to help cover costs?
Please make sure we have your current email address, as many come back as unknown. It's up to you.
Diane Sutkowski
dsutkowski@hvc.rr.com

Prostate Cancer 101, Inc.
8 Alcazar Avenue
Kingston, NY 12401-4302

1st	3rd
Tuesday	TBA

4:30 p.m. monthly

SEMINAR For Newly Diagnosed	**Distinguished Lecturer Series**

Hurley Reformed Church Hall, Hurley, NY

Poughkeepsie
Men to Men Group
Our brothers in support and education

Meetings are held the First Thursday of the month at the Central Hudson Auditorium on South Road in Poughkeepsie, starting at 6:30 p.m. Various doctors and speakers are on the agenda and one on one help is available after the meeting.

Contact
Paul Totta 845 297-7992
or Jim Kiseda 223-5007

If you need or want to help:

PCa 101 Seminar
First Tuesday of every month

Fred Bell 845 338-1161
Fwbelljr1@aol.com

Gene Groelle 419-5128
Gro226@aol.com

Website & Newsletters
http://prostatecancer101.org
Walt Sutkowski 331-7241
wsutkowski@hvc.rr.com

Greeters/Church Hall Setup
Bob Miggins 382-1305
GD7M37@verizon.net

Programs
Arlene Ryan 338-9229
Aryan@hvc.rr.com

Diane Sutkowski 331-7241
dsutkowski@hvc.rr.com

Membership & Administration
Diane Sutkowski 331-7241
dsutkowski@hvc.rr.com