INSIDE THIS ISSUE

Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

JANUARY 2012

US TOO BOARD LEADERSHIP CHANGES ANNOUNCED

During the Saturday December 3, 2011 Board meeting, the Us TOO Board of Directors accepted the results of its earlier voting to unanimously appoint three of its members to serve a three year term on the Board effective January 1, 2012. James L. Rieder, Dexter C. Rumsey III and Ridge Taylor will serve as members of the Board through December 31, 2014. Board member Rick Lyke and Chairman Fred Mills chose to retire from the Board after their years of service.

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Kay Lowmaster, MSW, LCSW, Chairman, Us TOO Board of Directors

MRI CAN IDENTIFY METASTATIC LYMPH NODES

Diffusion-weighted magnetic resonance imaging (DWI) can be used to detect pelvic lymph node metastases even in normal-sized lymph nodes. DWI is non-invasive, has a high negative predictive value, and might improve the staging of bladder and prostate cancer.

The research was presented during a prostate imaging session at the Radiological Society of North America (RSNA) 97th Scientific Assembly and Annual Meeting. Evis Sala, MD, PhD, from the University of Cambridge, United Kingdom, who moderated the session, described the work on pelvic lymph nodes as "the best talk of the session."

Harriet C. Thoeny, MD, from the University Hospital Inselspital in Bern, Switzerland, presented the results of the prospective study and discussed the implications with Medscape Medical News. She explained that if bladder lymph nodes are larger than 1 cm and prostate lymph nodes are larger than 8 centimeters, they are typically flagged for biopsy. However, her team found that approximately 25% of patients with normal-sized lymph nodes have micrometastases.

The study involved 87 patients who underwent conventional magnetic resonance imaging and DWI. Forty lymph

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TREATMENT IDENTIFIED FOR LETHAL PROSTATE CANCER

A report suggests that a treatment may be on the horizon for neuroendocrine prostate cancers, the most lethal subtype of the disease.

Although fewer than 2% of men have prostate cancer present with neuroendocrine prostate cancer, the more common prostate adenocarcinoma can also evolve into a neuroendocrine prostate cancer, with a grim prognosis

Mark Rubin, MD, professor of pathology and laboratory medicine at Weill Cornell Medical College and colleagues used next-generation RNA sequencing to profile samples of seven neuroendocrine prostate cancers, 30 prostate adenocarcinomas and five benign samples of prostate tissue.

They found that the genes AURKA and MYCN were overexpressed and amplified in 40% of neuroendocrine prostate cancers and in 5% of prostate adenocarcinomas. The research was published in Cancer Discovery.

Moreover, the researchers found that treatment with the investigational aurora kinase (AURKA) inhibitor PHA-739358 inhibited the growth of these neuroendocrine tumors.

Rubin says that PHA-739358 has been studied in prostate cancers before with-

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CONTEMPORARY PATHOLOGIC CHARACTERISTICS AND ONCOLOGIC OUTCOMES OF PROSTATE CANCERS MISSED BY 6- AND 12-CORE BIOPSY AND DIAGNOSED WITH A 21-CORE BIOPSY PROTOCOL

Ouzaid I, Xylinas E, Campeggi A, et al

World J Urol, Epub ahead of print

Purpose: To assess the pathological and the oncologic outcomes of the prostate cancer (PCa) missed by 6- and 12-core biopsy protocols by using a reference 21 -core scheme.

Materials and methods: Between 2001 and 2009, all patients who had PCa detected in an initial 21-core TRUS biopsy scheme and were treated by a radical prostatectomy (RP) were included. Patients were sorted in 3 groups according to the diagnosis site: sextant (6 first cores; group 1), peripheral zone (12 first cores; group 2) or midline/transitional zone (after 21 cores; group 3). Demographics, pathological features in biopsy and RP specimens and follow-up after RP were analyzed. The 5-year progression-free survival (PFS) was studied in the 3 groups.

Results: During the study period, 443 patients were included. Among them, 67, 23.7 and 9.2% were, respectively, diagnosed in groups 1, 2 and 3. Among PCa diagnosed in midline/transition zone cores, 42% were intermediate or high risk. Unfavorable disease was more frequently reported in group 1 in terms of extraprostatic extension (P = 0.001), high Gleason score (P = 0.001) and progression (P = 0.001). No significant difference was observed between groups 2 and 3 in terms of pathological features in RP specimens and oncologic outcome. The 5-year PFS was 89.7% and not significantly different in patients diagnosed with a 12-core scheme compared to those diagnosed only with 21-core scheme (P = 0.332).

Conclusions: Our findings emphasize that PCa diagnosed only in a 21-core protocol is at least as aggressive as PCa detected in a 12-core scheme. This study invalidates the widespread idea sustaining that cancers diagnosed by more than 12 biopsies are less aggressive.

CELGENE'S REVLIMID® FAILS TO HELP PROSTATE CANCER

Celgene Corp it will stop a late-stage trial of Revlimid (lenalidomide) for prostate cancer after it was determined that it would not extend survival, eliminating a potential avenue of expanded use for its flagship drug.

The US biotech company said an independent monitoring committee recommended that the pivotal Phase III Mainsail trial be halted after it determined that adding Revlimid to standard treatments would not significantly increase overall survival of patients with castrate -resistant prostate cancer.

"We have accepted this recommendation of the (monitoring committee) and following formal notification and review of the analysis, physicians and patients, internationally, will be officially advised of this action," Celgene said in a statement. The study was testing Revlimid, combined with the chemotherapy drug docetaxel and the steroid prednisone against those two drugs alone.

Independent safety monitoring committees are used to oversee blinded clinical trials in which researchers and patients are unaware of who is receiving study drugs or placebos.

These committees can halt a trial if it determines that a drug is unsafe or not likely to work. It may also stop a trial if a drug is working so well that it would be unethical not to offer it to patients in the control group.

Revlimid is approved for the treatment of the blood cancer multiple myeloma and for anemia associated with myelodysplastic syndromes.

Reuters, 22 November 2011

LETHAL PROSTATE CANCER

(Continued from page 1)

out success, but this may be due to the fact that previously studied prostate cancers were not neuroendocrine cancers.

"Prostate cancer is not a homogenous disease. We need to continue to sort out the aggressive disease from the indolent and treat accordingly," says Rubin.

Drug Discovery & Development
1 November 2011

ASK DOCTOR SNUFFY MYERS

Editors' note: This column contains opinions and thoughts of its author and is not necessarily those of Us TOO International.

I was diagnosed 1-2 years ago and have been on active surveillance (AS) ever since. My last PSA was 3.73 ng/mL, which rose from 3.53 ng/mL, and my biopsy Gleason score was 6. Do you believe it is okay for me to continue AS?

Minor changes in the total PSA of this magnitude are not significant and have no bearing on the conduct of AS. In our patients, we do the total and %free PSA. We get concerned if there is a major drop in the %free PSA as this can indicate the development of more aggressive or more extensive cancer. I think it is also very important to note that AS should not depend just on PSA measurements. Most successful AS programs include transrectal ultrasound and biopsy on some schedule. Some investigators perform these as often as every 6 months and others as long as 18-24 months.

At our center, we work closely with Dr. Bahn, who is very skilled at color Doppler ultrasound. He will usually let the appearance on the color Doppler dictate the need for a repeat biopsy. We will routinely send patients back for an examination every 18-24 months. However, if the cancer is on the aggressive end for AS, we may ask them to get a color Doppler as often as every 6 months.

Much to our surprise, in some patients we have seen a steady increase in the % free PSA up to the normal range. This has been associated with gradual shrinkage and even disappearance of the cancer as measured by the color Doppler ultrasound. Re-biopsies of the involved area have even been negative.

US TOO WANTS TO ANSWER YOUR QUESTIONS!

Dr. Myers would love to provide direct answers to questions posed by Us TOO members. Instead of printing questions answered in the *Prostate Forum*, we'd rather provide readers who subscribe to both publications with fresh content. Questions about imaging, active surveillance, and biochemical relapse would be particularly appreciated right now.

Send questions to <Jackie@ustoo.org> or call the Helpline at 800-808-7866.

BOARD MEMBER CHANGES

(Continued from page 1)

"I am proud to have been a part of the Us TOO Board for the past five years and the past three as chairman. During that time the Board has become more accountable for the work it does through the committee's it has developed. The Board has welcomed several new members during that time and I am confident the current Board members will continue to be an excellent source of strength for the organization," reported Fred Mills.

"We held our 20th anniversary in 2010 which was a major milestone for Us TOO. Several representatives from across the US and a few foreign countries gathered to help us acknowledge this event with a symposium and celebration in Chicago. Their attendance highlighted the fact that Us TOO is an organization of Support Groups with dedicated people who care about helping men and their families through the Prostate Cancer process.

Another retiring board member, Rick Lyke will be remembered for developing 'Pints for Prostates' which is an organization that educates men about Prostate Cancer through the universal language of beer and supports Us TOO with donations from its activities," Fred added.

Ridge Taylor, chairman of the Us TOO Board Membership committee also recommended to the Board the slate of Officers for 2012 which included Kay Lowmaster Board Chairman, David Houchens, Vice-Chairman, Jack Shaff, Treasurer and Ridge Taylor, Secretary. The Board unanimously accepted the appointments which will become effective January 1, 2012.

Kay Lowmaster stated "I have mixed emotions as I anticipate serving as Us TOO Chairman in 2012. I am really excited to have an opportunity to have a continuing voice in the future of the organization. However, my becoming Chairman means saying goodbye to Fred, and I will miss him. I expected him to be a great mentor to me as Vice-chairman, but what I didn't expect was for him to become a great friend as well.

I'm really pleased that he has agreed to remain available to us as Immediate Past

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MRI HIGHLY ACCURATE IN GUIDING PROSTATE BIOPSY

Medscape Radiology Viewpoints
5 December 2011

Study Summary

The goal of this study from Germany was to prospectively compare multiparametric MRI (1H-MR spectroscopy (MRS), diffusion-weighted imaging (DWI), contrast-enhanced) and standard T2W MRI at 1.5 T for prostate biopsy planning in 54 men with at least 1 negative conventional US-guided biopsy.[1] MR-guided biopsy was performed for suspicious lesions based on a localization strategy that divided the prostate into 20 standardized areas. Prostate cancer was demonstrated in 21 of 54 men.

Detection rates were 70% for T2W imaging; 81% for combined T2W imaging and 1H-MRS; 83% for combined T2W imaging and contrast-enhanced MRI; 85% for combined T2W imaging and DWI; 91% for combined T2W imaging, 1H-MRS, and contrast-enhanced MRI; 94% for combined T2W imaging, contrast-enhanced MRI, and DWI; and 100% when all MR techniques were combined.

Viewpoint

In the post-prostate-specific antigen era, the diagnosis of prostate cancer is made using the 10-12 core transrectal US-guided biopsy procedure. However, this initial biopsy procedure can have a miss rate of 71%. In patients with initially negative biopsy results, repeat transrectal US-guided biopsy may be performed but this procedure has even higher negative rates for cancer detection at about 81%. Saturation biopsy (> 20 cores) may also be negative and is associated with increased morbidity.

This study evaluated whether multiparametric MRI provides a diagnostic ad-

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Want to learn more about local prostate cancer support group activities? Read the

CHAPTER NEWS!

at www.ustoo.org!

US TOO RECOGNIZES 2011 PROSTATE CANCER BUSINESS LEADERSHIP COUNCIL MEMBERS AND SUPPORTERS

In conjunction with the 2011 Us TOO International Board of Directors Annual Meeting, Us TOO held the annual meeting of the Us TOO Prostate Cancer Business Leadership Council (PCBLC) on Friday, December 2, 2011 in Chicago. The PCBLC fosters regular communication between the Us TOO Board of Directors and invited biotechnology, device and pharmaceutical companies working in the Prostate cancer arena to create an easier and more consistent way of sharing goals, perspectives and resources. The group discusses issues, ideas and/or concerns especially those related to patient needs and advocacy.

Special thanks go out to all the corporations who participate on the council, and those who have supported Us TOO and our patient education and support programming over this last year. We wouldn't be able to help as many men and their families as we do without them!

Corporate supporters for 2011 include:

Diamond level – Sanofi Oncology; **Platinum** – Dendreon Corporation, Novartis Oncology; **Emerald** – Millennium Pharmaceuticals, Janssen Biotech, Medivation, Astellas Pharma US, Abbott Oncology; **Sapphire** – Accuray, Genentech; **Gold** – Amgen Oncology, Veridex; **Bronze** – UroPartners Prostate Center at the Glen, American Medical Systems; **Friend** – Mediaplanet, Endocare, Mitomics, BlueCross BlueShield Association, Varian Medical Systems, GTx, Medrad Radiology, ProCure Proton Therapy Center, Sport Clips, Watson Pharmaceuticals.

Prior to the 2011 Edward C. Kaps Hope Awards presentation and dinner, Sara Campbell, RN, BSN, OCN, Oncology Community Science Liaison, US Medical Affairs with Sanofi Oncology presented the Bill Blair Memorial Lecture, "Current and Future Directions in Prostate Cancer." Thanks to Sara, and all those who were able to join us!

Standing L to R: *David Lubaroff/Us TOO BOD, David Houchens/Us TOO BOD Treasurer, Sara Campbell/Sanofi Oncology, Rick Tazioli/Sanofi Oncology, Lindsay Bohlander/Sanofi Oncology, Joel Beetsch/Sanofi Oncology, Jean Jefferies/Us TOO BOD, Kip Cross/Millennium Pharmaceuticals, Howard Kaczmarek/Us TOO BOD, Jim Rieder/Us TOO BOD, Hal Teuscher/Us TOO BOD, Scott Riccio/Dendreon Corporation, Rick Lyke/Us TOO BOD, Ellen Ivey/Janssen Biotech, Kay Lowmaster/Us TOO BOD Vice-Chair, Jack Shaff/Us TOO BOD, Melanie Jaeger/Varian Medical Systems, Jerry Hardy/Us TOO BOD, Barbara Attridge/American Medical Systems, Ridge Taylor/Us TOO BOD Secretary*

Sitting L to R: *Catherine Bonetti/Accuray, Gloria Dillard/Abbott Oncology, Tom Kirk/Us TOO President & CEO, Fred Mills/Us TOO BOD Chairman*

DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN – AKA "NO BOGUS SCIENCE" COLUMN

"It is 2012 Folks – Another Reason to Donate to US TOO!"

Mark A. Moyad, MD, MPH, University of Michigan Medical Center, Dept. of Urology

Bottom Line: It is easy to take things for granted including that Us TOO constantly produces free health care information and non-stop advocacy that changed so many lives again this year. I sent my annual check…what about you?

I cannot believe we beat Ohio State this year! I cried and acted like a spoiled baby when we won (just being honest)! And, I cannot believe another year has passed in my life!

Us TOO accomplished so much this year and not just in terms of education, but also in helping with our Early Access Program for Patients, which has and continues to allow life saving medications reach the public for very little cost. We helped desperate men and their families get Zytiga before it was officially FDA approved through their early access program, and in 2012 we plan to help many men get MDV3100.

In fact, all advocacy groups are coming together in an unprecedented way! And, all of the advocacy groups need funding like never before because the economy this year has been so _____! (fill in the blank with your favorite 4-7 letter word).

Here is the real bottom line…I get out my computer 12 times a year to write for this newsletter and so many wonderful readers write back and tell me they love this column (the ones that tell me they hate it I use as toilet paper…just kidding…my new puppy actually uses it for toilet paper), and it really is an incredible honor to be able to volunteer for Us TOO at least 12 times a year.

Tom Kirk (the fearless leader unless his football team is playing Michigan), and Pam and Jonathan and all the others that make up Us TOO (so many fabulous folks) are really a beautiful team. I think that anyone (yes, that also includes the health care professionals) reading my column this month should write a check or just send Us TOO some kind of donation.

This is all I wanted to say this month! Next month we will talk about the latest research that proves when you donate it actually improves your physical and mental health (why do you think I donate? Just kidding…I think..).

DOCTOR CHODAK'S BOTTOM LINE *(Ref Key: article #, page #, column #)*

Author: *Winning The Battle Against Prostate Cancer, 2011*

a2p1c2 One of the ongoing debates for newly diagnosed men is whether cancer has spread to the lymph nodes. No reliable test has been available thus far but the article about Diffusion Weighted MRI suggests that it might be helpful. Assessing this article is difficult since it was only presented at a scientific meeting and it has not been published yet. Although the results seem encouraging, some key information is missing. First, we do not know the clinical information associated with the men who had positive scans such as their PSA, Gleason score and T stage? Did they all have their prostate gland removed or was the lymph node removal done anyway? The accuracy of this method in the best case was 89%, which appears pretty good. But, with a positive predictive value of 80%, it means that 20% of men would be told they have cancer in the lymph nodes when they do not. This would mean that surgery might not be recommended when it could have been the best approach. Also, it remains unclear whether men still benefit from prostate removal if a small lymph node is involved with cancer. We also do not know how the results with MRI compare with predictive models that use PSA, Gleason score and biopsy results to tell men the odds they have cancer in the lymph nodes. For now, more information is needed, but ultimately the following dilemma is likely to remain. Some men with cancer in the lymph nodes will be missed and others without metastases will be told their cancer has spread. Perhaps these results will improve over time.

THE BOTTOM LINE: DW MRI is not yet ready for routine use.

a7p3c3 A second study using MRI for prostate biopsy evaluated 4 techniques and found that combining at least 3 of them yielded a high chance of finding cancer in men whose initial biopsy was negative. Unfortunately, this study did not do a comparison against conventional ultrasound guided biopsy and without it one cannot justify the added expense of putting men through the MRI. Another problem is learning about the characteristics of the tumors discovered. We continue to be faced with the challenge of deciding how accurate our biopsies should be. Many doctors agree that we do not want to find every last patient who harbors some cancer cells as that will only increase the number of men who end up with treatment for a non-life threatening tumor. At the same time we want to avoid missing those cancers that are truly dangerous.

THE BOTTOM LINE: More information is needed to know whether MRI should play a role in follow-up biopsies of men with a previously negative biopsy and whether it offers significant advantages over ultrasound guided biopsy.

a5p2c3 A commercially available drug, Revlimid, failed to improve survival for men receiving docetaxel therapy. As a result, the study was halted. This demonstrates the real difficulty in treating cancer. A drug that may be useful for some tumors may not be able to help in other cancers. Differences between cancers may be very subtle and only by gaining new understanding of what makes tumors grow and function will it be possible to identify effective treatments.

THE BOTTOM LINE: Revlimid does not appear to offer any benefit for men with metastatic prostate cancer.

NIH ACTIVE SURVEILLANCE SYMPOSIUM

Many Us TOO members may have seen some information and publicity about the recent NIH conference on active surveillance (AS) held Dec 5-7. A link to the complete report can be seen at http://consensus.nih.gov/2011/docs/prostate/Prostate%20Cancer%20Draft%20Statement%2012.07.11.am.pdf. The goal was to define the current status of this approach given that so many men are undergoing treatment for a non-life threatening tumor. This was an important first step in the process of helping improve our understanding of this approach. Sadly, much more information is needed to tell men what to expect. Long-term results are limited to at most a few thousand patients followed in most cases for less than ten years. Doctors still have not identified the best way to monitor men, decide who needs treatment or when, and what happens to those who end up delaying therapy. An equally important problem is to find out how to help men remain on this approach when fear is the only reason that they choose to have definitive treatment. Another problem is the small number of eligible men who take this approach. The panel observed that only 10% of men who are appropriate candidates for AS are choosing it, in part because of physician bias against it. The panel recommends improving education for doctors so they can present a balanced approach about this option. Additional research is clearly needed to compare the quality of life impact of AS to other treatment options. Randomized studies for selected groups of patients also will be needed to obtain some of the missing information, but one may question whether such a study will be successful in recruiting patients without having many of them abandon their assigned treatment.

THE BOTTOM LINE: AS for low risk disease is becoming increasingly recognized as a reasonable alternative to immediate therapy. Hopefully, more research will be forthcoming to help men understand the long-term results and how they compare to other forms of therapy.

MRI-GUIDED BIOPSIES

(Continued from page 3)

vantage over the standard T2W MRI in this challenging clinical situation. Although all 4 MRI techniques combined provided a perfect detection rate in this group of patients, excluding 1H-MRS from the combination was associated with a miss rate of only 6%. Interestingly, 47% of prostate cancer areas were in the central zone, an area that typically harbors 32% of all prostate cancers. The authors concluded targeted MRI-guided biopsy is a valid alternative to repeat transrectal US -guided biopsy and saturation biopsy in men with initially negative biopsy results.

Reference

1. Franiel T, Stephan C, Erbersdobler A, et al. Radiology 2011; 259: 162-72.

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BOARD MEMBER CHANGES

(Continued from page 3)

Chairman. I feel Fred's legacy is the fact he has elevated the Board to the next level by developing a highly accountable business model.

Kay also added, "I plan to keep the momentum going. We have built a very talented Board who will work in tandem with an amazingly dedicated staff to advance our mission. I have been involved with Us TOO on a variety of levels for the past 17 years, and in all that time, I have never forgotten that everything we do is all about the men and families who are dealing with prostate cancer.

All you have to do is to meet one Ed Kaps Award winner and you immediately understand how fortunate we are to have 300+ support groups and chapters led by incredible men and women who are the heart of the organization. Simply put, I love Us TOO; I'm proud to be part of it; and I plan to work to keep us moving forward while never forgetting our roots."

Ridge Taylor reported at the Board meeting that there are currently three positions available on the Us TOO Board and work is underway to seek dedicated volunteers to join the Board.

MRI CAN IDENTIFY METASTATIC LYMPH NODES *(Continued fro page 1)*

nodes were removed from each patient, for a total of 3533 lymph nodes. As Dr. Thoeny explained, "that is the really huge and really the sexy part of this presentation.... Our surgeons took out all lymph nodes."

Image analysis was performed prospectively by 3 independent readers, and the results of the DWI analysis were compared with biopsy results. On a per-patient basis, the 3 readers yielded sensitivities of 64%, 80%, and 84% and specificities of 80.6%, 91.9%, and 90.3%. This resulted in positive predictive values of 57.1%, 80%, and 77.8% and negative predictive values of 84.7%, 91.9%, and 93.3%.

Diagnostic accuracies were 75.9%, 88.5%, and 88.5% for the 3 independent readers. The kappa values between readers 1 and 2, between readers 1 and 3 and between readers 2 and 3 were 0.54, 0.65 and 0.67, respectively.

DWI has been used for many years to image the brain, particularly for the detection of acute stroke. Only recently have investigators directed the technique at the more movement-prone torso.

DWI can be quantified using apparent diffusion coefficient (ADC) values. Previous studies have shown that tumors have low ADC values, but only recently have ADC values been used to identify lymph node metastases.

Studies to date have focused on enlarged lymph nodes, and have found that they have low ADC values when they have metastatic cancer. This is the first study to show that some normal-sized lymph nodes have low ADC values and are positive for metastases.

All of the metastatic lymph nodes identified in this study were smaller than 5 mm, and many were smaller than 3 mm, suggesting that they would have been missed with conventional techniques.

Presented 28 November 2011 at the RSNA 97th Scientific Assembly and Annual Meeting: Abstract SSC06-06.

Medscape Medical News, 29 November 2011

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