INSIDE THIS ISSUE

Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

July 2009

SIGNPOSTS BROCHURE NOW AVAILABLE

Us TOO is pleased to announce the release of a valuable new resource, ***Signposts Along the Pathway of Prostate Cancer - Understanding Diagnostic Tests and Procedures to Monitor Prostate Disease.***

This booklet, an Us TOO original brochure, is designed to demystify the diagnosis process, packed with vital information on the many tests and tools you and your loved ones could encounter along the way, no matter where you are in the prostate cancer journey.

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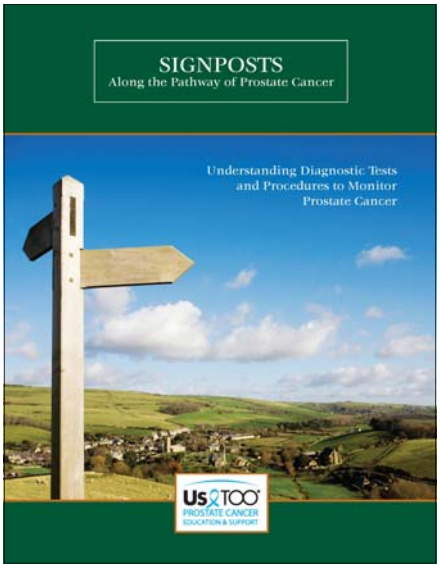

YOUNG MEN WITH ADVANCED PROSTATE CANCER HAVE WORSE PROGNOSIS

Advanced prostate cancer appears to be of a more aggressive type when it occurs in young men, leading to dramatically higher cancer-specific mortality as compared with older men, according to study findings reported in the July 1st issue of the journal *Cancer* published ahead on print.

"These data provide a strong argument for the need to consider multimodality therapy for young men with high-risk disease," the researchers conclude.

Generally speaking, younger cancer patients have better outcomes than their older counterparts, independent of comorbidity or performance status. However, few studies have focused on survival outcomes in a wide age range of men with prostate cancer.

To fill in these gaps, Dr. Bruce Montgomery and co-authors at the University of Washington, Seattle, used the Surveillance, Epidemiology, and End Results (SEER) Program database to identify roughly 320,000 prostate cancer patients ages 35-74, "the age range during which active treatment typically is considered."

(Continued on page 8)

FALSE-POSITIVES IN PROSTATE CANCER SCREENING GREATLY REDUCED BY NEW BLOOD TEST

A new blood test used in combination with a conventional PSA screening sharply increases the accuracy of prostate cancer diagnosis, and could eliminate tens of thousands of unneeded, painful, and costly prostate biopsies annually, according to a study led by researchers at Dana-Farber Cancer Institute in Boston, MA.

At the annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, FL, William K. Oh, MD, and Robert W. Ross, MD, reported that the 6-gene molecular diagnostic test, when combined with a PSA test, accurately detected prostate cancer more than 90 percent of the time.[1] Earlier studies suggest that the conventional PSA test is 60-70 percent accurate in detecting cancer.

Men who are found to have elevated levels of PSA in routine screening tests are often referred for a biopsy of the gland to check for tumors. Nearly two-thirds of biopsies performed – a painful procedure with some risk of complications – do not find any cancerous cells. This high rate of "false positive" PSA test results underscores

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PREDICTING PROSTATE CANCER RECURRENCE

US researchers have linked low oxygen levels in prostate tumors to cancer recurrence

Using a statistical model that accounted for such risk factors as tumor grade, prostate-specific antigen level and tumor size, researchers at the Fox Chase Cancer Center in Philadelphia, PA found low oxygen – hypoxia – in the tumor before treatment to be a significant independent predictor of an increase in PSA levels.

In other words, even after accounting for PSA value, Gleason score, tumor size, age, and other prostate cancer risk factors, tumor hypoxia alone could predict the likelihood of increased PSA levels, and potentially tumor recurrence.

The findings were presented at the American Society of Clinical Oncology (ASCO) annual meeting in Orlando, FL.

Dr. Aruna Turaka and colleagues custom-built a probe to monitor the amount of oxygen that prostate tumors and non-cancerous muscle tissue were receiving on 57 patients with low or intermediate risk of cancer – just before the patients received a form of localized radiation therapy known as brachytherapy.

The researchers tracked the patients. Eight of the 57 patients experienced an increase in PSA levels following prostate cancer treatment. Overall, average muscle oxygenation was 12.5-times higher than that of the tumor.

"Now the goal is to apply the results to the clinic," Turaka said in a statement.

"We already knew that there are hypoxic regions within cancers," she said. "The future goal is to interpolate that to relate to the expression of molecular markers [such as hypoxia-inducible factor-1-alpha] and attack those tumors with dose escalation radiation oncology strategies and targeted agents."

Poster presented at the 2009 Annual meeting of ASCO, abstract #5136, 31 May 2009

United Press International
23 May 2009

FERUMOXTRAN-10 AND MRI HELP DETECT METASTASIS OF PROSTATE CANCER TO LYMPH NODES

In patients with prostate cancer, MRI with the experimental imaging agent ferumoxtran-10 (known as Combidex® in the US) appears to be effective in detecting lymph node metastases outside of the routine surgical area, Dutch researchers report in the May issue of the journal *Radiology* (Vol. 251, pp. 408-14, 2009).

"With Combidex MRI, small – 2 mm – lymph node metastases can be detected with high accuracy," senior investigator Dr. Jelle O. Barentsz told Reuters Health.

Dr. Barentsz of University Medical Center Nijmegen and colleagues employed the method in 296 men who were at intermediate-to-high risk of

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US TOO SEEKS BOARD MEMBER APPLICATIONS

Us TOO is pleased to announce the annual public call for nominations to the Us TOO International Board of Directors. The Board Membership Committee, chaired by Carl Frankel, will review and evaluate nominees and submit recommendations to the full Board for approval at its December 2009 Board meeting.

Selection criteria includes items such as the candidate's relationship to Us TOO's purpose, its membership criteria ("…any man diagnosed with prostate cancer, a member of such a man's family or significant other, or any person involved in or interested in support or treatment of any such patients…"), familiarity with an Us TOO chapter, ability to think globally, skills or experience deemed beneficial to the work of Us TOO and commitment to Us TOO's purpose and mission.

Letters of nomination with a vita or resume should be sent by August 31, 2009 to Thomas Kirk, President/CEO, Us TOO International, 5003 Fairview Avenue, Downers Grove, IL 60515 or e-mail <tom@ustoo.org>.

PROSTATE CANCER YET ANOTHER WORRY FOR WOMEN

Women worry about a lot – their children, relationships, jobs, health, hair and so on. But new research out of Mount Sinai Medical Center in New York has found that some women are worrying about something rather unexpected: prostate cancer. The wives and partners of men with prostate cancer actually worry more about the cancer's recurrence than the men themselves, according to a study presented at a recent meeting of the Society of Behavioral Medicine in Montreal.

The study, which focused on 96 men and their long-term spouses or girlfriends, found that at the time of prostate cancer diagnosis, male patients described themselves as "moderately worried" about the chance of their disease recurring, while female spouses and partners described themselves as "very much" worried.

After treatment, the men's worry went down. The spouses', on the other hand, stuck around.

"What surprised me is that after treatment, the patients' worry went down in an even slope," said Dr. Michael Diefenbach, associate professor of urology and oncological sciences at Mount Sinai and a lead researcher on the study. "At 12 months, they were really only slightly worried about recurrence. But for the spouse, the decline was not as pronounced. It seemed to flatten out a little bit, but there is this continued moderate worry about cancer recurring."

Feeling frustrated and out of control may be part of the reason partners seem to worry more than patients, said Diefenbach. "If you are a patient, then you do something through your treatment, you have control," he said. "You think, 'I've been treated, I've done everything I can do and hopefully, it's gone now'. But the partners don't go through the actual treatment. There's less of a perceived control and that, in my mind, seems to be connected with this continued worry."

Different attitudes about health may be another factor contributing to the "anxiety-gap."

"Women know more about health than men do, they're used to dealing with the medical system, they're the gatekeeper for the family's health," said Diefenbach. "They oftentimes make the appointment for their husband and tell them to go to the doctor and get screened. They're much more intimately involved with health and seem to think about it more than men do."

Men, on the other hand, often take a less active role, which can be problematic when it comes to prostate cancer since it requires a considerable amount of personal decision-making with regard to treatment. "I think a lot of men, particularly with prostate cancer, will say, 'Tell me what to do, doc, and I'll do it,'" says Diefenbach. "They're much more likely to follow a physician's advice, which reinforces that notion that they want to have an action plan, follow it and be done with it."

Diefenbach hopes that his recent findings will help health care providers move forward when it comes to dealing with partners and spouses of prostate cancer patients.

"There's very little attention paid to the emotional reaction of the patient but less so for their spouses," he says. "I think what this study suggests is that the clinician or health care providers need to pay attention to that. It's been said that cancer is a disease of the family, but when you look at how it's treated, it's really just for the patient."

MSNBC, 27 May 2009

SIGNPOSTS BROCHURE

(Continued from page 1)

Whether you are seeking information about tests to diagnose and stage prostate cancer, or seeking clarification about follow up tests to monitor the disease process, ***Signposts*** provides straight-forward and easy-to-understand information.

Signposts is made possible through charitable contributions from Aureon Laboratories, EUSA Pharma and Medrad — special thanks to each of them for their support!!

Like ***Pathways*** and nearly all Us TOO's educational resources**, *Signposts*** is now available in two formats, print and downloadable from Us TOO's website, **<www.ustoo.org/freematerials>**.

FUTURE OF CANCER INCIDENCE IN THE UNITED STATES: BURDENS UPON AN AGING, CHANGING NATION

Smith BD, Smith GL, Hurria A, Hortobagyi GN, Buchholz TA

J Clin Oncol 27: 2758-65, 2009

Purpose

By 2030, the United States' population will increase to approximately 365 million, including 72 million older adults (age > 65 years) and 157 million minority individuals. Although cancer incidence varies by age and race, the impact of demographic changes on cancer incidence has not been fully characterized. We sought to estimate the number of cancer patients diagnosed in the United States through 2030 by age and race.

Methods

Current demographic-specific cancer incidence rates were calculated using the Surveillance Epidemiology and End Results database. Population projections from the Census Bureau were used to project future cancer incidence through 2030.

Results

From 2010 to 2030, the total projected cancer incidence will increase by approximately 45%, from 1.6 million in 2010 to 2.3 million in 2030. This increase is driven by cancer diagnosed in older adults and minorities. A 67% increase in cancer incidence is anticipated for older adults, compared with an 11% increase for younger adults. A 99% increase is anticipated for minorities, compared with a 31% increase for whites. From 2010 to 2030, the percentage of all cancers diagnosed in older adults will increase from 61% to 70%, and the percentage of all cancers diagnosed in minorities will increase from 21% to 28%.

Conclusion

Demographic changes in the United States will result in a marked increase in the number of cancer diagnoses over the next 20 years. Continued efforts are needed to improve cancer care for older adults and minorities.

6-GENE BLOOD TEST

(Continued from page 1)

the need for a more accurate method for detecting prostate cancer, said Oh, who is the clinical director of the Lank Center for Genitourinary Oncology at Dana-Farber.

The two-year study involved 484 participants. The group comprised 204 men with known prostate cancer, 110 men with benign prostatic hypertrophy (BPH), and 170 healthy men in a control group. (BPH can elevate PSA levels in the blood, which often leads to a biopsy to rule out prostate cancer.) These groups were split into age-matched training and validation sets.

The researchers sought to measure the accuracy of the 6-gene whole blood RNA transcript-based diagnostic test both in terms of its sensitivity (the ability to detect prostate cancer) and specificity (the ability to identify people who don't have prostate cancer). The test was developed by Source MDx, based in Boulder, CO.

The study found that "the 6-gene model was more accurate than PSA alone at predicting cancer if you had it and no cancer if you didn't," said Oh. The test's accuracy improved even more when PSA measurements were added. Combined, the two tests achieved a diagnostic accuracy of more than 90 percent in specificity and sensitivity and eliminated most of the false-positives yielded by the PSA test.

Based on these findings, the researchers are planning to conduct a larger, multicenter clinical trial involving approximately 1,000 men to determine if the findings remain valid.

"These findings are very encouraging and suggest that this new test could spare tens of thousands of men from undergoing an unnecessary biopsy," Oh said. "However, until we can verify our findings, it is important to recognize that the PSA test, despite its limitations, is still the best test available for diagnosing prostate cancer at this time."

1. Poster presented at the 2009 Annual meeting of ASCO, abstract 5052, 31 May 2009

<www.medicalnewstoday.com/articles/151918.php>, 29 May 2009

DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

"Flaxseed (ground/powdered) is your friend!" (& Red Wings Hockey is #1!)

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

Bottom Line or "Just the Flax, ma'am" (for you 1950s Dragnet fans): Flaxseed now has one of the largest randomized studies in the history of prostate cancer to show that it may be beneficial. Three tablespoons of flaxseed powder a day on whatever you like (cereal, yogurt, smoothie …) should be recommended before a radical prostatectomy (and perhaps before and after other cancer treatments).

Flaxseed (linseed) is a wonderful alternative remedy to reduce cholesterol, hot flashes, weight (yes, I said "weight" or "waist"), and to improve overall health. It is also high in fiber and really high in plant omega-3 fatty acids! However, its impact in prostate cancer has been controversial because over the past decade some laboratory studies and other studies that did not include flaxseed but some of the compounds in it suggested it could be harmful and encourage tumor growth.

However, over the past 10 years when flaxseed powder itself was used in men with and without prostate cancer the studies have been very, very positive! So, these researchers tried to determine the impact of flaxseed powder and/or a low-fat diet on prostate tissue and other parameters before and after radical prostatectomy in a very large and outstanding study.[1] It is one of the largest and well-done dietary studies in medical history conducted only with prostate cancer patients!

A total of 161 prostate cancer patients at least 21 days before surgery were randomized to one of 4 groups: control (regular) diet, flaxseed (30 grams/day), low-fat diet (<20% of calories from fat), or flaxseed and low-fat. Post-surgical specimens were analyzed for Ki-67 a proliferative (tumor growth) biomarker and apoptosis (cell death) before (biopsy) and after surgery.

Ki-67 rates were significantly lower ($P<0.002$) among men in the flaxseed groups ONLY compared to low-fat alone or control (that is a good thing because higher Ki-67 suggests more tumor growth and a lower Ki-67 suggests less tumor growth). So, flaxseed was found to be safe and may provide molecular changes that may ultimately discourage prostate cancer growth.

What does this mean for you and me? Few randomized trials in prostate cancer have made me happier than this one! Flaxseed has a history of being completely heart healthy, but its best feature is that any individual can afford it because it is so dirt-cheap. Gee, I wonder why you do not see any flaxseed powder commercials on TV?! How can you possibly make money from cheap flaxseed?! How about if I sell you an official (not unofficial, of course) Pure Gold Flaxseed Grinders? (dumb idea—let's move on)! Remember the study was done with ground flaxseed powder, but flaxseed pills and flaxseed oil have little to no research in prostate cancer so I would not spend my money on them.

One more important finding from this clinical trial needs to be emphasized. When researchers looked at prostate and blood levels of plant omega-3 fatty acids (the heart healthy fats found in flaxseed) they could not find large amounts of the plant form, but they did find higher levels of the fish oil form of omega-3 fatty acids! What does this mean? The body seemed to convert the plant form of omega-3 fats in flaxseed to the healthy type found in fish oil! Perhaps this is another reason flaxseed powder is so healthy. What a wonderful study filled with helpful Flax and not fiction (corny but funny don't you think)!

1. Demark-Wahnefried W, Polascik TJ, George SL, et al. *Cancer Epidemiol Biomarkers Prev* 17: 3577-87, 2008)

CARBOHYDRATE RESTRICTION MAY SLOW PROSTATE TUMOR GROWTH

Restricting carbohydrates, regardless of weight loss, appears to slow the growth of prostate tumors, according to an animal study published online in the journal *Cancer Prevention Research* by researchers in the Duke Prostate Center on 26 May 2009.

"Previous work here and elsewhere has shown that a diet light in carbohydrates could slow tumor growth, but the animals in those studies also lost weight, and because we know that weight loss can restrict the amount of energy feeding tumors, we weren't able to tell just how big an impact the pure carbohydrate restriction was having, until now," said Stephen Freedland, MD, a urologist in the Duke Prostate Center and lead investigator on this study.

The researchers believe that insulin and insulin-like growth factor contribute to the growth and proliferation of prostate cancer, and that a diet devoid of carbohydrates lowers serum insulin levels in the bodies of the mice, thereby slowing tumor growth, Freedland said.

Study animals were fed one of three diets: a very high fat/ no carbohydrate diet; a low-fat/ high carbohydrate diet; and a high fat/ moderate-carbohydrate diet, which is most similar to the "Western" diet most Americans eat, Freedland said. They were then injected with prostate tumors at the same time.

"The mice fed a no-carbohydrate diet experienced a 40 to 50 percent prolonged survival over the other mice," Freedland said. Mice on the no-carbohydrate diet consumed more calories to keep body weights consistent with mice on the other study arms.

"We found that carbohydrate restriction without energy restriction – or weight loss – does indeed result in tumor growth delay," he said.

The researchers plan to begin recruiting patients at two sites – Duke and the University of California – Los Angeles – for a clinical trial to determine if restricting carbohydrate intake in patients with prostate cancer can similarly slow tumor growth. The trial should begin within a few weeks.

ScienceDaily, 28 May 2009

BROKEN HEALTH CARE SYSTEM FOSTERS TREATMENT DELAYS AND STRAINED FINANCES FOR CANCER PATIENTS

Maintaining Insurance Coverage Also a Challenge

According to a national poll released on 26 May 2009 by the American Cancer Society Cancer Action Network (ACS CAN), one in four people currently receiving cancer-related care has delayed treatment in the past year, and nearly one in three people under age 65 who have been diagnosed with cancer has been uninsured at some point since their diagnosis.

The unique poll of families affected by cancer also found that more than 40 percent had trouble affording care in the past few years. More than one in five families has used up all or most of its savings and one in seven has incurred thousands of dollars in medical debt because of high health care costs.

The survey also found that two-thirds of Americans under age 65 diagnosed with cancer who searched for coverage outside the employer-based system could not find an affordable plan. The poll was conducted by Lake Research Partners and American Viewpoint from May 1 to 11, 2009 and queried 1,057 families nationwide that are affected by cancer .

Scientific research done by the Society has shown that lack of access to care can lead to later stage diagnoses, when cancer is more expensive to treat and harder to survive. Research has also shown that people with insurance have better chances of surviving cancer than people who are uninsured — even when the uninsured are diagnosed at earlier stages of the disease.

"Cancer patients are acutely aware of the holes that exist in our current 'sick care' system and are too often forced to delay or forego lifesaving screenings and treatments because of lack of access to critical care," said Daniel E. Smith, president of ACS CAN. "If we can fix the health care system for cancer patients, we will fix it for virtually anyone who touches the system, including those who face a chronic disease diagnosis."

That's why ACS CAN is strongly pushing for health care reform this year. ACS CAN is a leading voice of patients in the health care reform debate, having worked with a broad cross-section of stakeholders for the past several years to build momentum for reform nationwide.

<http://www.acscan.org>
26 May 2009

Are you a fan of the open road, or just want to wear the t-shirt?

Make a difference & support the Rocky Mountains Prostate Cancer Awareness Ride!

<www.RockiesPCAwarenessRide.com>

You don't have to be in Chicago to participate! Register or donate today!

IMPACT OF ANDROGEN DEPRIVATION THERAPY ON CARDIOVASCULAR DISEASE AND DIABETES

Alibhai SMH, Duong-Hua M, Sutradhar R, et al

***J Clin Oncol*, e-pub, 8 June 2009**

Purpose

Androgen deprivation therapy (ADT) may be associated with an increased risk of diabetes mellitus but the risk of both acute myocardial infarction (AMI) and cardiovascular mortality remain controversial because few outcomes and conflicting findings have been reported. We sought to clarify whether ADT is associated with these outcomes in a large, representative cohort.

Methods

Using linked administrative databases in Ontario, Canada, men age 66 years or older with prostate cancer given continuous ADT for at least 6 months or who underwent bilateral orchiectomy (n = 19,079) were matched with men with prostate cancer who had never received ADT. Treated and untreated groups were matched 1:1 (i.e., hard-matched) on age, prior cancer treatment, and year of diagnosis and propensity-matched on comorbidities, medications, cardiovascular risk factors, prior fractures, and socioeconomic variables. Primary outcomes were development of AMI, sudden cardiac death, and diabetes. Fragility fracture was also examined.

Results

The cohort was observed for a mean of 6.47 years. In time-to-event analyses, ADT use was associated with an increased risk of diabetes (hazard ratio [HR], 1.16; 95% CI, 1.11 to 1.21) and fragility fracture (HR, 1.65; 95% CI, 1.53 to 1.77) but not with AMI (HR, 0.91; 95% CI, 0.84 to 1.00) or sudden cardiac death (HR, 0.96; 95% CI, 0.83 to 1.10). Increasing duration of ADT was associated with an excess risk of fragility fractures and diabetes but not cardiac outcomes.

Conclusion

Continuous ADT use for at least 6 months in older men is associated with an increased risk of diabetes and fragility fracture but not AMI or sudden cardiac death.

PROSTATE CANCER DRUG ABIRATERONE SHOWS IMPRESSIVE NEW RESEARCH RESULTS

New UK research confirms the groundbreaking cancer drug abiraterone provides significant benefit for up to two-thirds of men with advanced and aggressive prostate cancer, according to a study published online in the *Journal of Clinical Oncology*. The drug, discovered at The Institute of Cancer Research (ICR) in the Cancer Research UK Centre for Cancer Therapeutics, made headlines in July 2008 when the first UK phase I clinical trial reported significant shrinkage of patients' tumors and reduction in pain. Scientists hailed it as one of the most significant developments in prostate cancer in 60 years.

This second publication of a phase I/II study, reporting on 54 patients, confirms the Phase I results. In addition, ICR scientists have worked out how to delay drug resistance and developed a test to identify the men most likely to benefit from abiraterone. These phase I/II studies were undertaken by the ICR and The Royal Marsden Hospital and were funded by Cougar Biotechnology Inc. The lead researchers on the study were funded by Cancer Research UK.

Lead researcher Dr Gert Attard stated "Phase I/II results showed that up to 70 per cent of men responded to the drug, abiraterone. About two-thirds of men experienced significant benefits for an average of eight months, with scans showing their tumors decreased in size and their PSA levels dropped substantially. "Our latest study also shows that by combining abiraterone with a steroid treatment when abiraterone stops working, we can reverse resistance and extend the response to this treatment by another 12 months."

"We have also noticed that the majority of patients who had very significant shrinkage of their tumors had an abnormality of a gene called ERG that was probably driving their cancer. We have developed a test for this ERG gene so we can identify the men most likely to benefit from abiraterone."

Chief investigator Dr Johann de Bono is extremely optimistic about these results: "Almost all these men had cancer that had spread to the bones, lymph glands and elsewhere. Many were in pain and not enjoying life. The patients involved in this trial remained pain-free for an average of about eight months, a brilliant result for those with aggressive prostate cancer and their families. For about a third of men – those who carried the ERG gene – the benefit lasted for more than 18 months.

"In addition, this drug has changed the way the science community looks at prostate cancer. It blocks production of male hormones, including those made by the tumor itself. The more we learn about how this drug works the more we will be able to find further ways of counteracting a patient's potential genetic resistance to it."

Mike Torr, 70, from Sheffield, was involved in the phase II abiraterone trial. He says: "Two years ago, I was in severe pain as my prostate cancer had spread to my bones. I was involved in the earlier trials and received the additional steroid treatment to combat resistance. This drug has given me over two years of life, symptom-free. I have been able to go back to fully enjoying my retirement and traveling with my wife to places such as India."

Abiraterone is currently in Phase III prostate cancer trials at more than 150 hospitals across the world, in one of the largest ever trials for end-state prostate cancer. More than 1,300 men have been treated with the drug and it is hoped that, should the trials continue to show a benefit, abiraterone may be available for general use as a prostate cancer treatment by the year 2011. The Phase III abiraterone trial in prostate cancer patients has reached full recruitment.

Professor Peter Johnson, chief clinician at Cancer Research UK, which helped fund the lead investigators on the study, said: "These early results hold great promise for treating a problem which affects many men with prostate cancer and give us real hope for the future. We are keen to see the results of the larger trials now underway, to find out whether abiraterone should be made generally available.

Medical News Today, 28 May 2009

THE DOCTOR'S NOTE

Dr. Gerald Chodak

Cautious excitement are the two words I think of as I read this month's *HotSheet*. Excitement because this issue contains a number of articles with encouraging findings from ongoing research studies. I say cautious, however, because only one is ready for prime time usage at this time, a few others are getting close and several provide interesting data that may or may not ever become clinically useful.

This plea for caution is partly the reason this column exists and is a recurring theme for several reasons. First, readers should be aware that just because a study is presented at a scientific meeting or published in a medical journal and then cited in the *HotSheet* does not mean that its conclusions are valid or applicable to men with prostate cancer. A supporting fact is less than 20% of meeting presentations actually get published in scientific journals in the ensuing five years. Reasons include that the quality of the studies are not good enough when critically evaluated by journal editors, or more extensive investigation fails to reproduce the earlier findings.

Another reason for caution is that even if a study does get published showing something works in a test tube or a mouse does not mean it will translate into a benefit when applied to patients. And even if something is observed in men, that does not mean it has useful implications. Therein lies a challenge; how should be counsel men when a study provides interesting information without the necessary proof it is really good for patient care?

The article that provides clinically useful information is based on a randomized study comparing short and long-term hormone therapy in combination with radiation therapy for men with locally advanced disease. An ongoing debate exists over the best duration of hormone therapy for men getting radiation. The problem with long-term treatment (3 years) is the potential side effects. Is three years absolutely the best choice? That cannot be determined without more studies like this one. However, this study does show that short term therapy is not as good as longer term treatment. Unfortunately, not enough doctors will become aware of this result and thus continue to use durations of hormone therapy that either are less effective or have not been properly studied. Support group members can help other newly diagnosed men by making them aware of the need to receive the extended duration of hormone therapy if tolerable.

Two other articles discuss exciting drugs getting closer to clinical utility, Abiraterone and OGX-011. A small phase II study using Abiraterone supports the earlier findings with this drug showing it is very active in men with advanced prostate cancer. The drug has a further impact on male hormone production even in men already castrated. The most important aspect of this finding is that is supports the value of conducting the vital phase III study which is needed before FDA approval is possible. This study is underway and the results will be anxiously awaited.

OGX-011 is another drug under investigation for hormone refractory prostate cancer in combination with Taxotere. Presently, even though Taxotere does improve survival, the average gain is relatively short so a large percentage of men choose not to receive it because of its side effects.OGX-011 may make men more open to chemotherapy because a recent study found a much greater improvement in survival when this drug is combined with Taxotere compared to Taxotere alone. This drug also needs to be studied in phase III to find out for sure that it works, but if confirmed could be a major step forward for helping men when hormone therapy is no longer effective.

And now onto the studies with interesting information of unknown benefit. Dr. Moyad has brought to our attention the results of a prospective study in men about to have a radical prostatectomy in which they were given a low fat diet or powdered flaxseed or both or neither. The study found a significant decrease in Ki-67, a marker associated with tumor growth in the men taking flaxseed.

Although the study is interesting and potentially valuable, I do not share Dr. Moyad's enthusiasm for the significance of the result. Although flaxseed appears to have other health benefits, there is no evidence that this observation has any real implications for men with prostate cancer. That is not to say that it does not help patients nor that it might cause harm, only that this study does not support a recommendation that all prostate cancer patients start taking flaxseed to help their cancer.

Unfortunately, studies like this one are frequently cited by companies marketing herbs, vitamins and other supplements as 'scientific evidence' that these things work in order to get people to buy their products. Although men want quick answers to help their disease, caution is needed otherwise men will be taking a long list of potentially helpful agents without ever knowing they work and without knowing if there is a negative interaction with other medications that actually could have an adverse health impact.

Other studies needing much more work include the 6-gene blood test for prostate cancer, the restriction of carbohydrates in the diet, the implications of finding low tissue oxygen levels in prostate cancers for predicting recurrence and the use of Ferumoxtran-10 for distinguishing if lymph nodes do or do not have metastatic prostate cancer.

The latter has been under investigation for a number of years and the question is how useful it might be for patient care. What are the concerns about this report? First only 20% of the men tested showed positive tests and it is unclear how many tests were falsely negative. Secondly, there were 14 possible false positives and only 18 showing positive nodes exclusively outside the normal dissection area which is almost a coin flip (50:50). Thirdly, there is no evidence that radiating those lymph nodes outside the normal dissection area is beneficial, and lastly, it is unclear whether these men should have had surgery in the first place.

So, we must be patient while more work is done in these areas that provide the necessary information to determine if they can be helpful for men with prostate cancer.

COMBIDEX®

(Continued from page 2)

lymph node metastases.

Findings were positive in 58 patients and were histopathologically confirmed in 44 patients. In 18 (41%) of men, the approach showed nodes that were exclusively outside of the routine dissection area. In another 18 (41%) of men, positive nodes were seen both inside and outside of the routine dissection area. In the remaining 8 (18%) of patients, MRI findings showed positive nodes only within the routine dissection area.

"With Combidex, in 41% of patients with positive nodes, metastatic nodes which are missed by surgery are detected," said Dr. Barentsz in summary. "Because of its high negative predictive value – greater than 97% – a negative Combidex MRI result obviates a diagnostic pelvic lymph node dissection, which saves costs and morbidity," he added.

"Potentially positive Combidex lymph nodes," Dr. Barentsz concluded, "can be treated with selective radiotherapy."

Reuters Health, 11 May 2009

YOUNGER MEN

(Continued from page 1)

During the 1988 through 2003 study period, the median age at diagnosis fell from 72 to 68 years. For those with intermediate grade disease (Gleason score 5-7), the report indicates that advancing age was associated with decreased overall survival compared with the youngest men.

"Unexpectedly," the physicians report, "the youngest men (35-44 years of age) were at least 5 times more likely to die of prostate cancer than any of their older counterparts with high-grade, stage III disease."

"The paradoxical effect of very young age and high-grade disease suggests that the biology of prostate cancer in young men may be inherently different and may provide new insights into the development and behavior of the disease."

There is a critical need to investigate systemic therapies that will improve the efficacy of local therapy, because these young men "will remain at risk for the greatest period of time."

Reuters Health, 26 May 2009

OGX-011 PROVIDES SURVIVAL BENEFIT

OncoGenex Pharmaceuticals, Inc. announced the final results of a randomized phase 2 trial in a presentation at the 2009 ASCO annual meeting.

The trial enrolled 82 patients at 12 sites in Canada and the US from September 2005 to December 2006. Patients were randomized to receive either OGX-combined with docetaxel and prednisone or docetaxel and prednisone alone. The primary endpoint of the trial was a 50% reduction in PSA from baseline in over 50% of the patients treated with OGX-011 plus docetaxel.

The median overall survival in patients treated with OGX-011 plus docetaxel was 23.8 months compared to 16.9 months for patients treated with docetaxel alone – a 6.9 month survival advantage for the OGX-011 arm. The unadjusted hazard ratio (a comparison of death rates between the 2 groups) was 0.61, representing a 39% lower rate of death for OGX-011 patients.

Scott Cormack, president and CEO of OncoGenex stated "These data clearly justify advancing to Phase 3 development, and we expect these data will be key in our partnering discussions ..."

PRNewswire-FirstCall, 30 May 2009

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