THE MANITOBA PROSTATE CANCER SUPPORT GROUP NEWSLETTER

Prostate Cancer Canada Network Winnipeg

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Survival Better with Continuous ADT

John Schieszer *June 03, 2012*

CHICAGO—Intermittent androgen deprivation therapy (ADT) has some quality-of-life (QOL) benefits for men with metastatic prostate cancer (PCa), but overall survival times are inferior to those seen with continuous ADT, according to the findings of a 17-year study (SWOG9346) presented at the American Society for Clinical Oncology 2012 annual meeting.

"Some doctors recommend intermittent hormonal therapy to men with metastatic prostate cancer, believing it will reduce their risk of side effects without compromising their outcome, but these findings demonstrate a downside to this approach for certain men," said lead researcher Maha Hussain, MD, Professor of Medicine and Urology at the University of Michigan Comprehensive Cancer Center in Ann Arbor. "The findings clearly demonstrate that intermittent hormonal therapy is not as effective for all patients with metastatic prostate cancer. These findings are likely practice changing for many doctors in the U.S. and abroad who routinely use intermittent therapy; specifically, physicians must counsel interested patients regarding the potential negative impact on survival with intermittent therapy."

The study enrolled 3,040 men with hormone-sensitive, metastatic prostate cancer between 1995 and 2008. All men received an initial course of

(Continued on page 2)

Medical Advisors

Paul Daeninck M.D.
Pain Management

Darryl Drachenberg
M.D. Urologist

Graham Glezerson
M.D. Urologist

Ross MacMahon
M.D. Urologist

John Milner
M.D. Urologist

Jeff Sisler M.D.
Family Practitioner

Thanks!

September 20, 2012
Prostate Health Awareness Evening
Cohen Auditorium
St. Boniface Hospital Research Center
351 Tache Avenue, 7 – 9 p.m.

No meeting at Seven Oaks Hospital on September 20, 2012

SHARING IS CARING

The Manitoba Prostate Cancer Support Group does not recommend treatment modalities, medications, or physicians.

"Maybe it's true that life begins at fifty.
But everything else starts to wear out, fall out, or spread out."
~ Phyllis Diller

(Continued from page 1)
androgen-deprivation treatment for seven months. The 1,535 eligible men whose PSA level dropped to 4 ng/mL or less by the end of those seven months were then assigned at random to stop therapy (the intermittent therapy group) or continue therapy (the continuous therapy group).

Those randomized to the intermittent therapy arm had their treatment suspended until their PSA rose to a predetermined level, at which time they started another seven-month course of ADT. The patients cycled on and off therapy in this way as long as their PSA levels continued to respond appropriately during the "on" cycle.

The 1,535 eligible patients had a median age of 70 years; 48% had extensive disease and 12% had received prior neoadjuvant ADT. A total of 765 were randomized to continuous therapy and 770 patients were randomized to the intermittent arm. Men on continuous therapy had a median overall survival time of 5.8 years from the time of randomization, with 29% of these men surviving at least 10 years. Those on intermittent therapy had a median overall survival time of 5.1 years, with 23% surviving at least 10 years from randomization. Men with minimal disease (disease that had not spread beyond the lymph nodes or the bones of the spine or pelvis) did significantly better on continuous therapy, whereas men with extensive disease seemed to do about as well using either treatment approach.

"In the past when it came to using hormone therapy in this disease, doctors viewed the disease as one entity and adopted a 'one size fits all' approach," Dr. Hussain said. "Based on this study's findings, it seems that one size does not necessarily fit all."
Intermittent hormonal therapy appeared to be safe in prior studies, but those studies generally included either men whose only evidence of prostate cancer progression was an increase in PSA level (as opposed to radiographic evidence of disease spread), or men with wide-ranging stages of disease (not just metastatic cancer).

Additional exploratory subgroup analyses of these new data indicated that after a median follow-up of 9.2 years, the median overall survival time for those with minimal disease was 7.1 years on continuous ADT compared with only 5.2 years on intermittent treatment.

Patients with extensive disease had median overall survival times of 4.4 years on continuous therapy and 5.0 years on intermittent therapy. There was no evidence that the treatment effect differed by race. The study showed that Grade 3/4 related adverse events were similar for intermittent and continuous treatment (30.3% vs. 32.6%).With respect to QOL measures, which were compared during the first 15 months following randomization, more men receiving intermittent rather than continuous therapy had significant improvements in the level of sexual functioning.

"There is some improvement in aspects of quality of life, but the durability is the issue," Dr. Hussain told *Renal & Urology News*. "Our study demonstrates that what may appear safe may not be completely so and it sometimes takes a large study to determine this. It's important to look beyond PSA responses when evaluating hormone therapy approaches and also it's important to have a control group in performing the trials."

Even though these data showed potential QOL improvements with intermittent therapy, the primary findings of the study demonstrate that intermittent therapy is inferior with regard to overall survival, which should be the primary consideration when counseling all patients interested in intermittent therapy, particularly those with minimal disease, she said.

"This clinical trial will change the use of intermittent therapy," said study co-investigator E. David Crawford, MD, Professor of Surgery/Urology/ Radiation Oncology at the University of Colorado in Denver. "This is the largest study to date and one we have all been waiting for. It shows that intermittent therapy is inferior to standard continuous androgen ablation. There were flaws in other trials such as not powered to show equivalence or even slight but significant differences."

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Fisher River Cree Nation Health Fair

On August 2, 2012 PCCN Winnipeg Board member, Pat Feschuk and his grandson Mathew, represented our Prostate Cancer Support Group at the Fisher River Health Fair, 230 km. north of Winnipeg.

We were one of 15 exhibitors with 235 people in attendance.

Pat talked to 33 people at his table while many others just came by to pick up the literature. Not surprisingly, it was the women who commented and asked the most questions.

Pat said, " One young fellow said he just turned 40 the previous week and the Prostate Cancer Canada ads on TV encouraged him to get checked."

Many thanks to the Gold Wing Riders and their donors.

This is the 11th year the Gold Wing Riders have made the commitment to fund raise for our Prostate Cancer Support Group. It is with great admiration and appreciation that we recognize the work done by Grant Ubell and Bruce Zilkowski. Their efforts have assisted us in raising awareness of prostate cancer in Manitoba.

Manitoba Prostate Cancer Support Group
presents

Prostate Cancer Canada Network Winnipeg

Dr. Jeff Sisler
Family Physician

Dr. Graham Glezerson
Urologist

Brian Sprott
Chair

PROSTATE HEALTH Awareness Evening

Thursday, September 20, 2012 | 7:00pm to 9:00pm
Cohen Auditorium - St. Boniface Hospital Research Centre
351 Tache Avenue **FREE ADMISSION**

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Consider Curative Therapy for High-Risk PCa

Jody A. Charnow July 16, 2012

Curative treatment for men with high-risk prostate cancer (PCa) is associated with decreased cancer-specific mortality and should be considered even when serum PSA levels are higher than 20 ng/mL, researchers concluded.

Treatment of men with high-risk PCa is controversial, they noted in an online report in *BJU International*, because of a lack of conclusive well-controlled or randomized studies comparing outcomes with palliative treatment, radiotherapy (RT), and radical prostatectomy (RP).

A team led by Sam Ladjevardi, MD, PhD, of University Hospital, Uppsala, Sweden, analyzed data from 11,380 men diagnosed with high-risk PCa who had PSA levels of 20-100 ng/mL and no evidence of distant metastases. A total of 7,476 patients received palliative treatment and 3,904 had curative treatment, most commonly RP and external beam RT. The 10-year PCa-specific mortality for patients with a PSA level of 20-50 ng/mL was 36% for patients who received palliative care compared with 13% for those who had curative treatment, according to the investigators. For subjects with PSA levels of 51-100 ng/mL, the 10-year PCa-specific mortality was 55% and 20%, respectively.

Among patients with PSA levels of 20-50 ng/mL at diagnosis, those treated with curative intent had a 77% decreased risk of PCa-related mortality compared with patients who received palliative care, after adjusting for age, comorbidities, disease stage, PSA level, and Gleason score. Among patients with PSA levels of 51-100 ng/mL, patients who had curative treatment had a 78% decreased risk.

The researchers noted that androgen deprivation therapy (ADT) frequently is the first line of treatment for men with PSA levels above 20 ng/mL, but their results show that ADT is not sufficient for these patients. “Either RP or RT in combination with ADT should therefore be considered for men without evidence of distant metastases, even with PSA levels close to 100 ng/mL,” they wrote.

Dr. Ladjevardi's group said they believe their study is the second largest to analyze cancer-specific mortality among men with high-risk PCa. They pointed out that the risk of selection bias when assessing outcomes after treatment is well known and should not be neglected. Even when adjusting for age, comorbidities, disease stage, PSA level, and Gleason score, residual bias that cannot be accounted for may remain.

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Testosterone Study Reveals Cancer Link

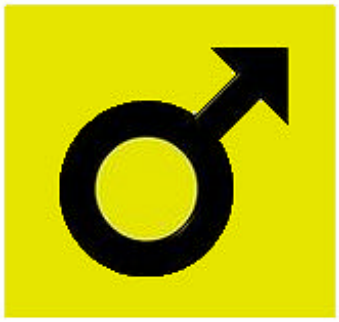
July 30, 2012 Julie Robotham
The Sydney Morning Herald

MEN whose testosterone levels remain naturally high may be more likely to develop prostate and lung cancer in old age, according to an Australian study that calls into question the growing practice of hormone supplementation to maintain energy, muscle mass and sexual potency.

The Perth research followed the medical records of men in their 70s and 80s for up to a decade, finding that among those who were diagnosed with prostate cancer the average level of testosterone circulating freely in the bloodstream was 290 picomoles per litre of blood versus 277 for those who did not develop the disease.

The picture was more pronounced for those who developed lung cancer. Their levels of free testosterone - the small proportion that is not chemically bonded to blood proteins and is therefore biologically active - averaged 317 picomoles per litre, compared with 278 for those who remained free of the disease.

The study leader, Zoe Hyde, from the Western Australian Institute for Medical Research, said prostate cancer's progression was already known to depend on testosterone, and blocking the hormone was considered the best treatment for the disease. But the hormone's role in triggering the cancer's initial development had not been firmly established.



Lung development differed between males and females, Dr Hyde wrote in the journal *Cancer Epidemiology Biomarkers and Prevention*, which might explain why testosterone appeared also to trigger lung cancer. But it was also possible the result might have been skewed by the role of smoking, which itself could raise testosterone levels, or that lung

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tumours were promoting testosterone rather than the reverse.

Dr Hyde and her team also looked for any link between testosterone and bowel cancer but found none. She said studies of testosterone-boosting drugs - sometimes given to men who report low energy or flagging libido - had so far been too small to determine any role in the development of cancer, and larger studies were now needed to enable "the detection of any carcinogenic signal".

"While some men can benefit from testosterone therapy, we still don't fully understand all of the benefits and risks of treatment," Dr Hyde said.

She said there was "no need for men who are currently taking testosterone to stop, but in light of our findings, prostate health should be monitored closely during treatment".

Pharmaceutical Benefits Scheme statistics show a nearly threefold increase in subsidised prescriptions for testosterone implants, gels, patches and tablets between 2000 and 2012, and many more are thought to be dispensed on private prescriptions.

The chief executive officer of Cancer Council Australia, Ian Olver, said the design of the West Australian study could not clearly show whether higher testosterone was a cause of prostate cancer, but its results warranted caution over supplementation.

Hormone replacement therapy could modify cancer risk in women, Professor Olver said, and "we've seen [such research] brought into the argument about risks and benefits … but population studies can't predict for any particular patient where that balance between risk and benefit lies."

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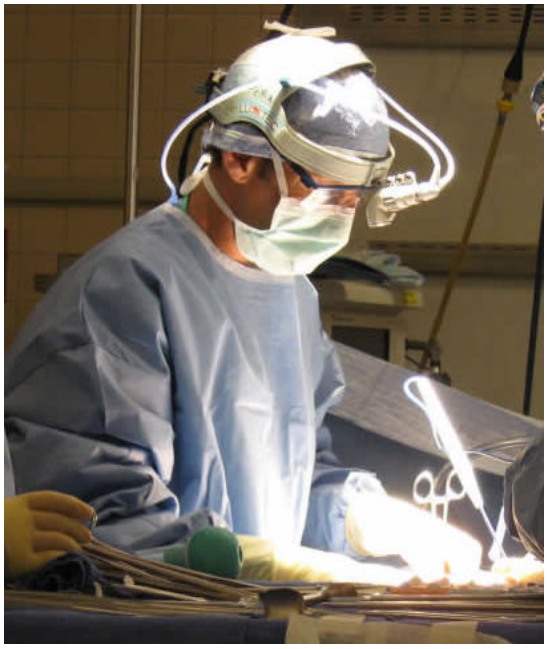
Prostate Biopsy

by Mayo Clinic Staff Sept. 4, 2010

A prostate biopsy is a procedure to remove samples of suspicious tissue from the prostate. The prostate is a small, walnut-shaped gland in men that produces fluid that nourishes and transports sperm.

Following a prostate biopsy, tissue samples from the prostate biopsy are examined under a microscope for cell abnormalities that are a sign of prostate cancer. If cancer is present, it is evaluated to determine how quickly it's likely to grow and spread, and to determine your best treatment options.



During a prostate biopsy, also called a core needle biopsy, a fine needle is used to collect a number of tissue samples from your prostate gland. A prostate biopsy is done by a urologist, a doctor who specializes in the urinary system and men's sex organs. Your urologist may recommend a prostate biopsy if results from initial tests, such as a prostate-specific antigen (PSA) blood test or digital rectal exam (DRE), suggest you may have prostate cancer.

Why it's done

A prostate biopsy is used to detect prostate cancer. Your doctor may recommend a prostate biopsy if:

=> Results of a prostate-specific antigen (PSA) test are higher than normal for your age

=> Your doctor found lumps or other abnormalities during a digital rectal exam

=> You've had a previous biopsy that was normal, but you still have elevated PSA levels

=> A previous biopsy revealed prostate tissue cells that were abnormal but not cancerous

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"Keep it clean, no hitting below the prostate!"

Beyond the Abstract

The language of prostate cancer treatments and implications for informed decision making by patients and their partners

by Richard Wassersug, PhD

Published on 01 August 2012
BERKELEY, CA (UroToday.com) - At any time in North America some 600,000 men are on androgen deprivation therapy (ADT) to treat prostate cancer (PCa).[1] In a series of studies, my colleagues and I have been exploring how patients understand and adapt to this therapy. In one recent paper[2] we show that PCa patients who have been prescribed ADT are poorly informed about the side effects of the LHRH agonists commonly prescribed in the industrial world for ADT.

The common name used for ADT by health care providers and patients alike is "hormone therapy." Previously we suggested that this euphemistic simplification may mislead patients about the reality of this treatment.[3] Our recent paper in the *European Journal of Cancer Care* used an anonymous online questionnaire to find out, among other things, whether our concern was valid.

Our paper was built upon surveys completed by 690 adult males and females recruited through various cancer-related websites. It was evident from these surveys that many men, including those who were actively being treated for PCa, had little understanding that "hormone therapy" entails an endocrine ablation rather than an endocrine augmentation. We found that many had no idea that androgen deprivation was tantamount to chemical castration.

An interesting finding was that the men and women in our study had very different understandings about what the side effects of ADT meant, overall. Significantly fewer women than men, for instance, were likely to consider a man on an androgen suppressing treatment (however it was labeled) as "less of a man." More men were likely to consider a male, who was castrated compared to one on "hormone therapy" as emasculated. This was true despite the fact that the physiological and psychological effects are ostensibly the same. Similarly, significantly more men said that they would be willing to accept "hormone therapy" than "castration" if their physician recommended it to treat PCa.

One might suppose that these results justify using the vague term "hormone therapy" as a proxy for ADT. Calling the treatment "hormone therapy" rather than "chemical castration" or "androgen deprivation" avoids the stigma of those other terms, which our study shows are more readily linked to the idea of emasculation.

In a separate study, recently submitted for publication, we explored what urologists and oncologists in Canada (N=75) consider essential information to tell patients, who are starting on ADT.[4] There we found an enormous amount of variation between what side effects physicians felt were essential, versus nonessential, to warn their patient about.

In addition, there was little agreement between the patients and their physicians about what constituted important side effects to be aware of. Thus, for example, from a medical perspective, the loss of body hair was of no consequence and most physicians did not consider it worth warning patients about. However from a psychological perspective, many patients found this visible marker on androgen deprivation distressing (unpubl. data).

I am hesitant to fault physicians who fear that a more precise label for ADT might stress their patients. They may be trying to avoid producing negative placebo effects. Perhaps they even worry that their patients might refuse treatment if fully informed about the side effects of LHRH agonists. Using the vague term "hormone therapy" and understating the side effects of this treatment may thus be well intended. However, my colleagues and I know of no data to show that patients commencing this treatment are indeed better off in the long run by being uninformed about ADT's side effects. In fact, in another submitted manuscript, we assessed a preemptive educational intervention for patients starting on ADT.[5] There we found that the patients favored getting as much information as possible about ADT and its side effects at the onset of treatment.

These results overall raise the concern that calling ADT "hormone therapy" and not telling patients about the majority of well-established side effects of LHRH agonists violates the ethical principle of informed consent. The big question now is how to change clinical practice so that health care providers will do more to prepare their patients starting on ADT for the physical and mental impact of this treatment.

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SPEAKERS:

September 20, 2012
Prostate Health Awareness Evening
Samuel N. Cohen Auditorium
St. Boniface Hospital Research Center
351 Tache Avenue, 7 – 9 p.m.

No meeting at Seven Oaks Hospital
on September 20, 2012

October 18, 2012
Mike Talgoy
Managing my Metastatic Castration-Resistant
Prostate Cancer

November 15, 2012
To Be Announced

All meetings are held at
Seven Oaks General Hospital Auditorium
7-9 p.m.
Everyone welcome

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