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HOTSHEET

JANUARY 2015

OPTING FOR PROSTATE CANCER SURVEILLANCE DOESN'T IMPAIR QUALITY OF LIFE

Men who opt for active surveillance (AS) of their prostate cancer tend to have physical and mental well being equal to or better than men who opt for immediate treatment, a new analysis suggests.

"The men in our study did not appear to suffer from any major negative psychological impacts, including anxiety and depression," said Dr. Lara Bellardita, the study's lead author from the IRCCS Foundation's National Cancer Institute in Milan, Italy.

"Many men with prostate cancer will never need treatment for it, while about a third will get treated after an average of two to three years of AS," said Dr. Marc A. Dall'Era, who wasn't involved with the new study but is a urologist at the University of California, Davis.

While the side effects of prostate cancer treatments may affect quality of life, questions remain over how men fare while on AS, the researchers wrote October 31 in *European Urology*. For example, they say, some people question whether living with untreated cancer could make men more anxious.

Bellardita and her colleagues reviewed previous studies and found 10 reports published between 2006 and 2014 that looked at quality of life and other psy-

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ASCO ENDORSES GUIDELINES ON ADJUVANT RADIOTHERAPY IN PROSTATE CANCER

The American Society of Clinical Oncology (ASCO) has endorsed guidelines from the American Urological Association (AUA)/American Society for Radiation Oncology (ASTRO) on the use of adjuvant and salvage radiotherapy after prostatectomy, with a few caveats.

An ASCO guideline endorsement panel determined that the guideline recommendations, which were published last year, are clear and thorough, and are based on the most relevant scientific evidence. The guidelines were published online in the *Journal of Clinical Oncology* on 3 November 2014.

"Overall, the prognosis with radiation therapy when given postoperatively is quite good," said Howard Sandler, MD, chair of the Department of Radiation Oncology at the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center in Los Angeles. "Overall, the treatment is well tolerated, and so the use of radiation therapy in the postoperative setting is now being endorsed by ASCO and other professional organizations," he explained in an ASCO podcast.

However, ASCO has added one qualifying statement to the guidelines: that not all men who are candidates for adjuvant or salvage radiotherapy have the same

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ANDROGEN DEPRIVATION LINKED TO HEART DEATHS IN MEN WITH PROSTATE CANCER AND PRIOR HEART DISEASE

A new study published online October 29 in *BJU International* shows that androgen deprivation therapy (ADT) is associated with an increased risk of cardiac-specific death in prostate cancer patients with established cardiovascular disease.

"There is a small subset of men for whom the risks of ADT may outweigh the benefits," lead author David Ziehr of Harvard Medical School in Boston told Reuters Health. Retrospective research has linked ADT to increased cardiovascular morbidity, Ziehr and his colleagues note in their report.

To better understand the risks associated with ADT based on a patient's degree of cardiovascular morbidity, the researchers looked at more than 5,000 men with cT1c-T3N0M0 prostate cancer who had been treated with brachytherapy with or without adjuvant ADT.

During follow-up, which lasted a median 4.8 years, there was no association between receiving ADT and cardiac–specific mortality (CSM) in men with no risk factors for cardiovascular disease. Men with diabetes mellitus, hypertension, or hypercholesterolemia were also not at increased risk of CSM if they received ADT.

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OBESITY INCREASES THE RISK FOR HIGH-GRADE PROSTATE CANCER: RESULTS FROM THE REDUCE STUDY

Vidal A, Howard L, Moreira D, et al

Cancer Epidemiol Biomarkers Prev 27 September 2014 Epub

Background: Studies suggest obesity is associated with lower risk of prostate cancer (PC) but cancers that do occur are more aggressive cancers. As obesity lowers PSA levels, these observations may be influenced by detection bias. We examined the association between obesity and risk of low– and high–grade PC in REDUCE, where biopsies were largely independent of PSA.

Methods: The REDUCE study tested dutasteride for PC risk reduction in men with a PSA of 2.5-10.0 ng/mL and a negative biopsy. Study participants included 6,729 men who underwent at least one on-study biopsy. The association between baseline body mass index (BMI <25 kg/m^2-normal weight; 25-29.9 kg/m^2-overweight; ≥30 kg/m^2-obese) and risk of high-grade (Gleason >7) or low-grade PC (Gleason < 7) vs. no PC was examined using multinomial logistic regression.

Results: Overall, 1,739 men (27%) were normal weight, 3,384 (53%) overweight, and 1,304 (20%) were obese. Obesity was associated with lower risk of low-grade PC in both univariable (OR 0.74, p=0.001) and multivariable analyses (OR 0.79, p=0.01). In univariable analysis, obesity was not associated with high-grade PC (OR 1.08, p=0.50). However, in multivariable analysis, obesity was associated with increased risk of high–grade PC (OR 1.28, p=0.042). The current analysis was not able to address how obesity may influence prostate cancer progression.

Conclusions: Obesity is associated with decreased risk of low–grade and increased risk of high-grade PC. These data provide further support to the hypothesis that obesity is associated with aggressive PC.

Impact: Obesity is linked with aggressive PC. Avoiding obesity may prevent the risk of developing high-grade PC.

PHOTODYNAMIC DIAGNOSIS OF SHED PROSTATE CANCER CELLS IN VOIDED URINE TREATED WITH 5-AMINOLEVULINIC ACID

Nakai Y, Anai S, Kuwada M, et al

BMC Urol. 2014;14(59), Epub

Background: Past attempts at detecting prostate cancer (PCa) cells in voided urine by traditional cytology have been impeded by undesirably low sensitivities but high specificities. To improve the sensitivities, we evaluate the feasibility and clinical utility of photodynamic diagnosis (PDD) of prostate cancer by using 5-aminolevulinic acid (5-ALA) to examine shed prostate cancer cells in voided urine samples.

Methods: One hundred thirty-eight patients with an abnormal digital rectal exam (DRE) and/or abnormal prostate-specific antigen (PSA) levels were recruited between April 2009 and December 2010. Voided urine specimens were collected before prostate biopsy. Urine specimens were treated with 5-ALA and imaged by fluorescence microscopy and reported as protoporphyrin IX (PPIX) positive (presence of cells demonstrating simultaneous PPIX fluorescence) or PPIX negative (lack of cells demonstrating fluorescence).

Results: Of the 138 patients, PCa was detected on needle biopsy in 81 patients (58.7%); of these 81 patients with PCa, 60 were PPIX-positive (sensitivity: 74.1%). Although 57 patients did not harbor PCa by conventional diagnostic procedures, 17 of these at-risk patients were found to be PPIX-positive (specificity: 70.2%). PPIX–PDD was more sensitive compared with DRE and transrectal ultrasound and more specific compared with PSA and PSA density. The incidence of PPIX–PDD positivity did not increase with increasing total PSA levels, tumor stage or Gleason score.

Conclusions: To our knowledge, this is the first successful demonstration of PPIX in urine sediments treated with 5-ALA used to detect PCa in a noninvasive yet highly sensitive manner. However, further studies are warranted to determine the role of PPIX–PPD for PCa detection.

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

"Why Do Rabbits Have Perfect Vision and Never Get Prostate Cancer or Heart Disease?!"

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

Editor's note: Us TOO has invited certain physicians and others to provide information and commentary for the *HotSheet* to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Bottom Line:

The first fairly well done meta-analysis of carrot consumption and prostate cancer risk from 10 different studies shows that they may have anti-prostate cancer effects! And, carrots may be a cheap way to get really low-dose aspirin?![1]

Okay, the holiday parties are over and hopefully you did not drink too much super spiked eggnog and say something silly like "If I were single I would really be having much more fun" with your spouse standing right behind you or "I can't stand my boss because [fill in the blank]" and your boss was right around the corner listening! Hopefully, you are just excited to lose that extra weight you gained over the holidays and exercise more! And, you are getting excited about all the new research coming out in late 2014 and early 2015 like the new research showing that carrot consumption might have anti-prostate cancer effects! I guess this makes sense because I have never seen a rabbit with prostate cancer or with poor eyesight.

So, what is the magic ingredient(s) in carrots? The authors of this article mention all sorts of nutrients like beta-carotene/vitamin A but they did not list many other important components! How about aspirin? What the heck is Moyad talking about? Few folks realize that carrots have some of the highest concentrations of salicylic acid, which is basically identical to aspirin and it is what the drug aspirin is converted into in the body for effectiveness. Now, the amount of "natural" aspirin in carrots (and other foods) are still low compared to the drug, and you would be lucky to get a few milligrams but over time perhaps this is the reason carrots are so healthy (getting low amounts of aspirin over time). And, we know that aspirin reduces the risk of heart attacks and has recent good evidence to suggest it has anti-prostate cancer effects.[2] In addition, carrots are a good source of fiber as long as the peel is left on, and fiber is heart healthy and may also have anti-cancer effects. Perhaps it is also the fact that carrots are high in potassium, low in sodium, associated with lower blood pressure and are low in calories, which might help with weight loss. Who knows!

I would not go out and buy more carrots because of this study because many veggies have anti-cancer effects. However, I do want you to appreciate the carrot a bit more when you eat them as well as other healthy veggies! So, the next time you see a bunny/rabbit in your yard get as close to him or her as possible and say "Thank you, Mr. (or Mrs.) Rabbit for being you and I appreciate you even though you go number 2 in my yard regularly, and I have stepped in it many times and cursed your name, but I also realize that you went number 2 in my yard because carrots have a lot of fiber and I forgive you." Sorry, but I digress… VIVA CARROTS! VIVA CARROTS!

References:

1. Xu X, Cheng Y, Li S, et al. Dietary carrot consumption and the risk of prostate cancer. Eur J Nutr 53: 1615-1623, 2014.
2. Moyad M, Lee J. "The Supplement Handbook: A Trusted Expert's Guide to What Works & What's Worthless for More Than 100 Conditions." Rodale, New York, NY.

ADT LINKED TO HEART DISEASE

(Continued from page 1)

However, men who had congestive heart failure (CHF) or a previous myocardial infarction were at increased risk. Among these 256 men (5% of the study population), the risk of CSM was 7%, versus 2% for men with no history of MI or CHF (adjusted hazard ratio 3.28, p = 0.048). Based on the findings, administering ADT to 20 men with a past myocardial infarction or CHF could result in one cardiac death, Ziehr and his colleagues write.

"These data raise particular concern for the practice of administering ADT purely for cytoreduction before brachytherapy in men with low–risk prostate cancer and a history of CHF or MI," they add. "For these patients with low-risk disease, ADT has no prostate cancer benefit and could induce cardiac harm."

Nevertheless, the researchers add, there is strong evidence for benefit of ADT in improving survival for men with aggressive prostate cancer. Among men for whom ADT is appropriate, Ziehr noted, clinicians can focus on medical management of cardiovascular risk factors, while informing them about the cardiovascular risks associated with ADT.

"There are men for whom androgen [deprivation] therapy provides a significant benefit from the prostate cancer viewpoint," Ziehr added. "It's just a matter of knowing the risks and finding ways to abrogate those risks."

Reuters Health, 10 November 2014

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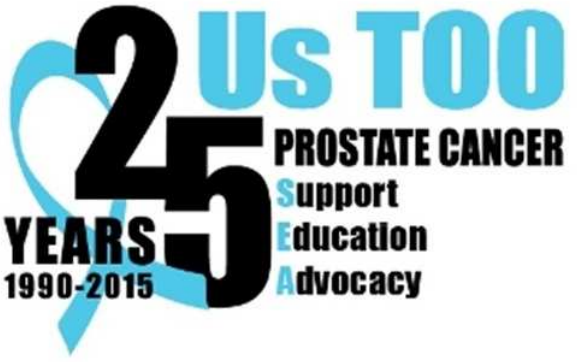

Take Action – Get Connected!

ASCO ENDORSES ADJUVANT RT GUIDELINES *(Continued from page 1)*

risk for recurrence or disease progression, and thus, not all men will derive the same benefit from adjuvant radiotherapy. The ASCO guideline endorsement panel found it "critical to highlight this point."

"As with the initial decision to undergo radical prostatectomy, deciding on adjuvant or salvage radiotherapy involves a consideration of the risk–benefit ratio," the authors write. "Although the risks are known, the benefits will vary for each patient, based on his own risk of recurrence."

The ASCO authors note that the men who are at a particularly high risk for recurrence or clinical progression, such as those with high Gleason scores (especially Gleason score 8 to 10), pathologic findings (especially seminal vesicle invasion or extensive positive margins), and an elevated postoperative PSA level, are likely to derive the greatest benefit in terms of absolute risk reduction from adjuvant radiotherapy, they note.

Conversely, for those without these high-risk factors, the absolute risk-benefit is likely to be lower, so there is a less favorable risk–benefit ratio. But, as ASCO notes, not everyone who develops a PSA recurrence has the same risk for "clinically meaningful disease progression." Thus, the risk–benefit ratio for salvage radiotherapy will likewise be different for each individual patient.

"It is important for the radiation oncologist to have a frank discussion with the patient about radiation therapy, why it's important, and also the risks," said Dr. Sandler.

"Although radiation therapy is not risk–free, the associated risks are probably lower than the surgery itself," he noted. "So if patients were willing to accept the potential risks of surgery, then the potential risks of radiation therapy are more modest, and if there is a benefit, then in our view, the benefit outweighs the risk."

Qualifying Statements

In their guidelines, AUA and ASTRO recommend that physicians discuss adjuvant radiotherapy with patients who have adverse pathologic findings at surgery (i.e., seminal vesicle invasion, positive surgical margins, extraprostatic extension), as well as salvage radiotherapy for men with detectable postoperative PSA or local recurrence after undergoing surgery.

The guidelines also state that the possible short– and long–term adverse effects and potential benefits of radiotherapy should also be discussed, and the decision to administer radiotherapy should be made together by the patient and the multidisciplinary treatment team.

The ASCO Endorsement Panel also added qualifying statements to help put these guidelines into clinical context. These include the following:

- The word "offer" should be interpreted as having a detailed discussion with the patient about the risks and benefits of adjuvant radiotherapy. This discussion should be heavily influenced by the additional qualifying statement and include a thorough discussion of the absolute risk of recurrence in light of exact pathologic findings and postoperative PSA levels
- The Endorsement Panel agrees that not all men are at equal risk of recurrence, but at this time, there are insufficient data to recommend different follow-up strategies based on differing risk of recurrence. Therefore, all men should be observed after surgery.
- Defining an exact cut point for PSA recurrence is challenging, and the ASCO panel acknowledges this difficulty. While they agree that 0.2 ng/mL is a reasonable cutoff and is widely used in research publications and in clinical practice, the benefits of using this cut point versus others are unclear. Therefore, they believe that the evidence to support this recommendation was clinical practice rather than clinical evidence.
- ASCO agrees with the recommendation that restaging evaluation in a patient with a PSA recurrence may be considered. However, the discussion centered on which imaging modalities to use, and they note that currently, a clear consensus is lacking. Un-

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AS AND QUALITY OF LIFE

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chological issues that men with prostate cancer might experience. The 10 studies included 966 men with prostate cancer who opted for active surveillance and were followed for up to three years. The average age was 66.

Mental health was measured with the SF-36 or SF-12 mental health subscales in four studies. Two studies measured anxiety and depression with the Hospital Anxiety and Depression Scale and one with the Patient Health Questionnaire. One study also measured depression using the Center for Epidemiologic Studies Depression Scale. Anxiety was assessed with the General Anxiety Disorder Scale and the State Trait Anxiety Inventory. Specific prostate cancer–related anxiety was measured with the Memorial Anxiety for Prostate Cancer scale in three studies.

In addition, one study assessed stress levels with the Perceived Stress Scale, another assessed decisional conflict, and another assessed coping, using the Mini-Mental Adjustment to Cancer Scale. One study used the Distress Thermometer, which specifically measures psychological burden in oncology patients.

Overall, the quality of life scores of men who chose active surveillance were similar to men who had prostatectomy. Anxiety, depression and general distress scores also didn't appear worse for the men who chose active surveillance.

Reuters Health, 19 November 2014

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

Gerald Chodak, MD, Author, *Winning the Battle Against Prostate Cancer*, Second Edition http://www.prostatevideos.com/

Editor's Note: Us TOO has invited certain physicians and others to provide information and commentary for the *HotSheet* to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

a1p1c1 As more is learned about active surveillance, one concern is the impact it has on a man's quality of life. Bellardita and coworkers attempted to address this issue by reviewing 10 studies reporting this information using several validated questionnaires. The authors found that with three years of follow-up, men on active surveillance had a similar overall quality of life compared to men undergoing radical prostatectomy (RP). One question that might be worth evaluating is whether those men who go off active surveillance without objective progression criteria have worse quality of life than men staying on this therapy. If that were true, it would offer an opportunity to develop intervention procedures to help men continue on active surveillance. Eventually, we may see formal programs aimed at helping men continue on AS until real progression occurs.

The Bottom Line: The quality of life for men on active surveillance is similar to men choosing RP.

a2p1c2 Men with pT3 disease or Gleason 8–10 prostate cancer are at increased risk for disease recurrence and mortality. A few randomized studies have assessed the benefit of postoperative radiation given within 4-6 months of surgery or at the time of a PSA recurrence. One of these found that 9 men had to be treated with immediate radiation to prevent one death from prostate cancer after 12 years. Although the risk of side effects is small, these results still mean that eight out of nine men were not benefitting. An alternative approach would be to delay radiation until the PSA recurs; however, the optimal PSA level for initiating this therapy has not been defined nor has the impact on mortality. Ongoing randomized studies are attempting to answer this question. For now, the American Society of Clinical Oncology (ASCO), has endorsed the guidelines of the American Urological Association (AUA) recommending that urologists discuss post-RP adjuvant radiotherapy in men with high-risk pathology. However, AUA acknowledges that not all men have similar risk and may need this therapy. Hopefully, these new studies will help determine the optimal approach to managing these patients.

The Bottom Line: More data are still needed to help determine which men benefit more from immediate rather than delayed radiation after RP.

a3p1c3 Several studies have addressed the question whether ADT increases a man's risk of dying from heart disease. So far, no randomized study has proven this is true. Now a new study by Ziehr and co-workers found that men undergoing brachytherapy combined with ADT had an increased risk of dying if there was a history of congestive heart disease or a previous heart attack. It is unlikely that the FDA will rely on this type of analysis to issue a definitive warning, but perhaps an additional randomized study should be initiated to define the true risk. Until then, clinicians who want to minimize patient risk when administering ADT should send men with either risk factor for a cardiac evaluation prior to starting this treatment.

The Bottom Line: Evidence from uncontrolled studies suggesting a higher risk for ADT in men with a history of congestive heart disease or a previous heart attack needs to be confirmed by a prospective, randomized trial.

a4p2c2 Does obesity increase a man's risk of having an aggressive prostate cancer? That question was partly answered by a new analysis of men participating in the REDUCE study. The authors found that weighing more than 30 kg/square meter had a slightly increased risk of being diagnosed with a Gleason 8–10 prostate cancer. The hazard ratio, however, was only 1.24, meaning the added risk was relatively small. Of course the real question is what to do with this information. Obese men are at risk for numerous health problems other than prostate cancer. Health concerns may not be important enough for obese men to alter their behavior and reduce weight but increasing public awareness of this association may prove to be helpful.

The Bottom Line: Obesity appears to increase a man's risk of developing a Gleason 8-10 prostate cancer in addition to other health problems.

a5p2c3 Could testing urine sample help diagnose prostate cancer? Nakai et al explored this question by measuring the presence of cells demonstrating PPIX fluorescence. They reported a sensitivity and specificity in the 70-75% range. Unfortunately, these values are way too low to consider for a worthwhile test but with further work, perhaps the method can be improved.

The Bottom Line: Measuring fluorescence on voided urine is able to identify some men with or without prostate cancer but both the sensitivity and specificity are currently too low and more work will be needed.

a6p8c1 Does having sex with multiple partners convey an added or reduced risk of developing prostate cancer? Spence and coworkers attempted to address this question by conducting a case control study and found that having more than 20 partners reduced a man's risk of being diagnosed with the disease. However, before we recommend that all men have at least that many sexual partners, better studies are needed. Some limitations of this one are that it is not randomized, it is unclear whether the benefit occurred in men using versus not using a condom, and whether men were routinely screened for prostate cancer in both groups.

The Bottom Line: The impact of having multiple sexual partners on the development of prostate cancer remains unclear.

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SEXUAL PARTNERS, SEXUALLY TRANSMITTED INFECTIONS, AND PROSTATE CANCER RISK

Spence AR, Rousseau MC, Parent ME

Cancer Epidemiol 29 September 2014; Epub

Background: The etiology of prostate cancer (PCa) is poorly understood. Sexual activity and sexually transmitted infections (STIs) are among factors under scrutiny, with controversial findings to date.

Methods: We examined the association between the number and gender of sexual partners, STIs and PCa risk in the context of PROtEuS, a population–based case-control study set amongst the mainly French–speaking population in Montreal, Canada. The study included 1,590 histologically-confirmed PCa cases diagnosed in a Montreal French hospital between 2005 and 2009, and 1,618 population controls ascertained from the French electoral list of Montreal residents frequency–matched to cases by age. In-person interviews elicited information on sociodemographic, lifestyle and environmental factors. Unconditional logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) between sexually related factors and PCa risk, adjusting for age, ancestry, family history of PCa, and PCa screening history.

Results: Subjects with more than 20 sexual partners in their lifetime had a decreased risk of PCa (OR 0.78, 95% CI 0.61-1.00) as did subjects who specifically had more than 20 female sexual partners (OR 0.72, 95% CI 0.56-0.94). By contrast, having had several male sexual partners appeared to confer some excess in risk of PCa. No association emerged for history of STIs and PCa but STIs prevalence was low.

Conclusion: Our findings are in support of a role for the number of sexual partners in PCa development. The gender of sexual partners should be taken into account in future studies investigating this association.

ADJUVANT RT

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fortunately, all imaging modalities have limited sensitivity and specificity in the low PSA range, where salvage radiotherapy is most effective (i.e., PSA <1 ng/mL). Thus, the authors point out that this is a rapidly evolving field with much research being performed, and it is hoped that in the future, there will be more clarity on this point.

- Although PSA control rates are best when salvage radiotherapy is administered when the PSA is <1 ng/mL, there is no guarantee of cure, because salvage radiotherapy is not curative for all men. There are many technical issues related to measuring the rate of PSA increase, typically measured as PSA doubling time.

Medscape Medical News, 3 November 2014

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