Is No Surgery Feasible in Gleason 9 and 10 PCa?

For prostate cancer patients with aggressive, Gleason 9-10 disease, treatment with radiotherapy (RT) plus androgen deprivation therapy (ADT) was at least as effective as surgical strategies in a retrospective study published online ahead of print in the journal JAMA Oncology.

“In terms of prostate cancer-specific mortality (PCSM), outcomes were similar between the 50 men treated with an aggressive surgical approach, so-called MaxRP, compared with 80 men on aggressive RT or MaxRT (adjusted hazard ratio [HR] 1.33, 95% confidence interval [CI] 0.49-3.64, P=0.58, not a statistically significant difference),” reported Anthony V. D’Amico, MD, PhD, of Dana-Farber Cancer Institute in Boston, and colleagues. All-cause mortality was also similar between the two groups (adjusted HR 0.80, 95% CI 0.36-1.81, P=0.60).

The researchers also found that men treated with surgery alone or with ADT appeared to have worse PCSM compared with the MaxRT group.

MaxRP consisted of radical prostatectomy (RP) plus adjuvant external beam RT (EBRT), and ADT, while MaxRT included EBRT plus brachytherapy and ADT.

The retrospective study from D’Amico and colleagues examined outcomes in 639 men with clinical stage T1-4 Gleason score 9-10 non-metastatic prostate cancer without lymph node involvement. From 1992 to 2013, there were 80 men treated with MaxRT and 559 men treated with RP and pelvic lymph (Continued on page 4)

Prostate Cancer Risk Lower in Long-Term Users of Lipid-Lowering Drugs

Men who use lipid-lowering medication long term have a lower risk for prostate cancer than nonusers, suggests a new study published online ahead of print in Cancer Prevention and Research.

Alison M. Mondul, PhD, MSPH, of the University of Michigan in Ann Arbor, and her colleagues prospectively examined 6,518 black and white men without prostate cancer at baseline in the ARIC (Atherosclerosis Risk in Communities) study. Of these, 21% of white and 11% of black men received lipid-lowering medication, typically statins. During follow-up, prostate cancer developed in 541 white and 259 black men, and 56 and 34, respectively, died.

Compared with men who never used lipid-lowering medications, those who used the drugs for 10 or more years had a significant 32% decreased risk for prostate cancer in adjusted analyses. Current users of lipid-lowering drugs had a nonsignificant 33% decreased risk of dying from prostate cancer than nonusers, according to results. The investigators found no differences in outcomes between racial groups, possibly due to small sample sizes. Health care access and competing causes of death did not fully explain results, according to the investigators.

The findings generally corroborate previous studies on the subject. “Taken together, this literature provides
YouTube Videos Often Mislead on Prostate Cancer

Misinformation, Bias, and Lack of Balance in Content

YouTube videos about prostate cancer often miss the mark in terms of balanced and reliable information, according to a review of the most popular videos on screening and treatment. Videos about prostate cancer were almost 50% more likely to mention the potential benefits vs. harms associated with screening or treatment, and half of the videos did not promote shared decision-making, as recommended by current clinical guidelines. Three fourths of the videos contained “potentially misinformative and/or biased content” in the video itself or in viewer comments.

“The analysis revealed a significant negative correlation between the quality of a video and audience interest,” Stacy Loeb, MD, of NYU Langone Medical Center in New York City, and co-authors reported online ahead of print in European Urology. “I guess the main point, at least from this sample of videos, is that you are more likely to find a rosy picture.”

Loeb told MedPage Today. “It is important for patients to be aware of both the pros and cons of screening and treatment decisions. Online sources do not necessarily make you better poised to participate in the shared decision-making process.”

The message for physicians is that “we should be directing our patients to high-quality content,” she added. “A lot of what’s out there does not provide a balanced view or even recommend treatments that are guideline supported. Also, to create more content, to be involved in social media and support the high-quality content that is out there and, in the process, can help raise the signal above the noise.”

“YouTube’s position as a leader among social media platforms speaks for itself. More than seven billion videos with a linked social networking interface that permits viewers to add feedback to each video, more than one billion registered users, and more than five billion videos watched daily. The website has a vast potential for obtaining and sharing health information,” Loeb and co-authors noted in the introduction to their study.

“Studies examining health-related content on YouTube often demonstrated poor quality, biased content, and commercially supported content, with an associated potential for harmful consequences,” the authors continued. “For example, a review of YouTube videos that had a negative portrayal of immunizations showed high ratings among YouTube users, even though almost half of the videos contained misinformation.”

YouTube’s health information collection includes >600,000 videos about prostate cancer, many of which have >100,000 views. Few studies have examined the quality and accuracy of YouTube videos related to prostate cancer.

A decade-old analysis of 51 prostate cancer videos showed that 73% of the videos provided fair-to-poor information, and 69% exhibited a clear bias in favor of screening or treatment. A more recent analysis of 100 YouTube videos about prostate cancer identified commercial and/or biased information in many of them. Previous studies of prostate cancer videos did not use validated instruments to evaluate the content, and none examined user interactions with the videos, according to another recent review.

Using default search results, Loeb and co-authors sought to perform a comprehensive contemporary review of YouTube content related to prostate cancer. They reviewed the top 150 English-language videos (according to audience engagement) about prostate cancer screening (75 of ~173,000) and treatment (75 of ~444,000). The review included user comments related to each video.

As part of the review, the researchers applied the DISCERN quality criteria for consumer health information. Using the DISCERN questionnaire, the investigators rated each video with regard to quality of information presented, discussion of both risks and benefits (or harms) of a treatment or test, evidence of bias in the presentation, definitions/explanations of medical terms, references to information provided in the video, and other quality-related factors. The team also calculated two engagement metrics for each video: number of views per month and the ratio of total viewers to the number of viewers who gave the video a “thumbs up” rating.

For a subset of 50 videos, Loeb and colleagues evaluated the reading level of written transcripts and computed scores for videos by means of the Agency for Healthcare Research and Quality Patient Education Materials Tool, which addresses understandability and actionability.

The 150 prostate cancer videos had an average of 45,000 views, and total views for

(Continued on page 4)
Doc Moyad’s What Works & What is Worthless Column – Also Known as “No Bogus Science” Column
“VITAL Part-2 – Are Fish Oil Results a Little Fishy?!”

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

Editor’s Note: Us TOO invites certain physicians and others to provide information and commentary for the Hot SHEET to enrich its content to empower the reader. This column contains the opinions and thoughts of its author and are not necessarily those of Us TOO International.

Yes, I unfortunately attended “the game” (Michigan = Good vs. Evil = Ohio State) in Columbus, OH a few months ago and it actually felt worse than the time I got dumped at my senior prom. They should change the name of “the game” to “the ugly scrumage” because it never seems that we (good people) can beat them (the bad people) anymore. The good news is that this is why God invented beer. Anyhow, congratulations for ruining my holidays Ohio State while simultaneously increasing the number of emergency visits to my therapist.

Let’s get to the fishy story of VITAL (we talked about the vitamin D results in the last issue). This trial of healthy folks also found (similar to vitamin D) 1,000 mg per day of fish oil (Omacor) for 5.3 years did not reduce the risk of major cardiovascular events or cancer, including prostate cancer.3 Yet, like the vitamin D part of this clinical trial, the results whispered and did not shout. When I did further analysis, there appeared to be a hint of a reduction in the risk of heart attacks and death from heart attacks, and even a potential reduction in the need for a conventional cardiovascular procedure.

However, since these were subgroup findings (aka secondary and not primary endpoints) from the trial and not specifically the objective of the trial, it is possible these findings were the result of chance and not attributable to fish oil, but simply due to luck! When you throw a bunch of data against a wall some things will have to stick. Also, fish oil has not been found to consistently lower the risk of heart attack in other studies.

However, there was another major clinical trial of another type of fish oil (prescription known as “Vascepa”) that also showed potential benefits in a major trial called “REDUCE-IT” that was published around the same time as this VITAL trial.2 In the REDUCE-IT trial, fish oil treatment seemed to provide a similar cardiovascular benefit (reduced the risk of non-fatal and fatal heart attacks, and need for conventional heart procedure...), but in people that have high triglycerides (median 216 mg/dL), the part of the cholesterol test that measures fat in the blood. There were, of course, other differences in these two trials, but it still makes you wonder doesn’t it? Does fish oil reduce the risk of a heart attack?

I guess we need to wait on more VITAL results because there was also a suggestion that people that ate less fish might have benefitted the most when taking fish oil. So, there were some “fishy” results that need to be worked out. Still, the best news about fish oil in the VITAL trial is that it was preliminarily safe (more data in the future on this), side effects were similar to a placebo and there at least appeared to be no increased risk of cancer, and no increased risk of dying younger of other causes. Still, I cannot end this column without reminding the audience of one important thing. If your triglycerides are high, then one of the fastest and most effective ways to reduce them is weight/waist loss, but no one wants to study exercise and dietary changes vs. fish oil or vitamin D pills because that would make too much sense (and no one would make cents from that study).

Congratulations Ohio State fans, and bye-bye Coach Urban Meyer – it has been really miserable getting to know you for the last seven horrible years!

Prostatectomy Beats AS (Continued from page 1)

As of December 2017, 80% of the men enrolled in the study had died. The cumulative incidence of death from all causes at 23 years was 71.9% in the RP group and 83.8% in the WW group (difference 12.0 percentage points; 95% CI 5.5-18.4). Seventy-one deaths in the RP group and 110 in the WW group were due to PCa, for an absolute difference in risk of 11.7 percentage points (95% CI 5.2-18.2).

Distant metastases occurred in 92 men in the RP group and 150 in the WW group. At 23 years the cumulative incidence of metastases was 26.6% in the RP group and 43.3% in the WW group (difference 16.7 percentage points; 95% CI 9.6-23.7). But researchers did not report mortality for either group. Adverse events such as incontinence and sexual dysfunction were also not addressed in the current report (a 2011 publication indicated similar rates of erectile dysfunction in the two groups but a nearly fourfold higher prevalence of urinary leakage in the RP patients).

References

“VITAL Part-1 – Are Fish Oil Results a Little Fishy?”

As of December 2017, 60% of the men enrolled in the study had died. The cumulative incidence of death from all causes at 23 years was 71.9% in the RP group and 83.8% in the WW group (difference 12.0 percentage points; 95% CI 5.5-18.4). Seventy-one deaths in the RP group and 110 in the WW group were due to PCa, for an absolute difference in risk of 11.7 percentage points (95% CI 5.2-18.2).

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“A mean of 2.9 years of life were gained with RP,” observed the authors. “The mean number of years gained is a crude measure, since any man who is randomly assigned to undergo the procedure either might not benefit at all or might have a much greater benefit than the mean number for the whole group indicates. However, the measure puts in perspective what is risked by delaying intervention.

“This remains the best randomized study of RP vs. observation ever done,” Mohler said. “Its follow-up is long, it did not have PSA early detection bias, and even with the problems with Gleason grading and the determination of clinical pathologic stage, the group of men seems to be largely devoid of who we would place on AS today.” But Mohler, who was not involved in the study, said that because of the way that PCa diagnosis and management has changed since 1989, it’s unclear what the findings mean for current PCa patients.

MedPage Today
12 December 2018
YouTube Videos on Prostate Cancer Misleading
(Continued from page 2)

individual videos went as high as 1.3 million. Key findings from the analysis included the following:
- The overall quality of the information in the videos had a rating of 3 on a 5-point scale
- 75% of the videos described benefits
- 53% of the videos discussed potential harms
- 50% of the videos promoted shared decision-making between patients and their physicians
- 54% of the videos defined the medical terms used in the videos

Loeb and colleagues determined that 77% of the videos or user comments included potential misinformation or biased content. Using engagement metrics, the team estimated that the videos had a total potential reach of 600,000 viewers.

Analysis of engagement metrics and video quality measures also showed that, as the quality of video content increased, audience engagement decreased, and as the quality decreased, engagement improved (P=0.004 for views/month, P=0.0015 for thumbs up/views).

“Another key takeaway from this study is the need to be aware of the source of the content and the date of it,” Loeb said. “Treatment and screening guidelines change over time. Sometimes when you do a search, you might find content that is highly viewed but that is out of date. These things don’t necessarily get taken down automatically if guidelines change.”

MedPage Today
28 November 2018

No Surgery for Gleason 9-10 PCa?
(Continued from page 1)

node dissection at a tertiary cancer center.
There were 372 men (66.5%) treated with RP alone, while 88 (15.7%) also had adjuvant EBRT, 49 men (8.8%) also had ADT, and 50 (8.9%) had the MaxRP treatment with both EBRT and ADT. Median follow-up was 5.51 years in the MaxRP arm compared with 4.78 in the MaxRT arm.

With regard to patient characteristics, D’Amico noted that the two arms were very similar. “Not everybody, but in the 80%-plus range of people, had adverse pathologic findings,” he noted. “As a result you are getting much closer to apples versus oranges.” Due to their high Gleason scores, all men in the current study would be considered unfavorable from the start, eliminating a situation where favorable patients are perhaps more likely selected for surgery. “That issue of apples vs. oranges is much less so in a study of Gleason 9-10 than it would be in a Gleason 7 study,” D’Amico added.

“This does not substitute for a randomized trial, and unfortunately we don’t have one that’s going to look just at the Gleason 9-10 subset, and the ones that are completed did not stratify by Gleason 9-10,” said D’Amico. “Therefore, the data presented in this study stands as the only data, really, that will exist now and will exist in the future ... on this very important subset, which makes up most of prostate cancer deaths.”

The findings build upon an earlier retrospective study from Amar Kishan, MD, of the University of California Los Angeles, and colleagues that found EBRT plus brachytherapy was associated with significantly lower PCSM than either EBRT alone or RP. Commenting on the current study, Kishan told MedPage Today that these data confirm the findings from his group, and highlighted the new data on MaxRP/MaxRT equivalence. “We did not find this to be the case in our study, so this is a novel finding,” he said. “It underscores the importance of multimodality therapy in this disease.”

Kishan also noted that in this study the MaxRT benefit persisted despite a shorter median ADT duration (six months, with 75% of men receiving ADT for less than a year). He explained that standard of care for ADT in this setting would be 12 months at the minimum, and that, in his previous study, median ADT duration was 12 months.

“On the one hand, the new study suggests that a shorter than standard ADT duration may be sufficient to capture a benefit above RP,” he said. “But, it is unclear whether a more standard duration of 12 months would lead to outperformance of RP plus EBRT with or without ADT.”

MedPage Today
23 November 2018

Check out Us TOO web pages on maximizing quality of life after prostate cancer treatment:
- Sexual Health and Intimacy at www.ustoo.org/intimacy
- Urinary Incontinence at www.ustoo.org/incontinence
Number of studies have proposed that men take a drug to reduce their risk of PCa? A lower cholesterol in order to lower risk of death. How- ever, despite the number of supporting reports, the FDA is unlikely to give an approval to these agents. The many questions lacking answers include the proper dose, the age to begin and the incidence of side effects. Given the time needed to properly evaluate this potential indication and the fact that many of the drugs are now generic, it seems highly unlikely that a proper study will ever be conducted. For now, men on one of these drugs may consider the possible added benefit of taking it that it may also help them reduce their risk of PCa.

**The Bottom Line: Another uncontrolled study suggests that statins may help prevent PCa, but it still needs to be properly evaluated before it can be recommended.**

P2, “YouTube Videos...”

Today, more than ever, the Internet plays a huge role in men getting medical information about PCa. Unfortunately, there are no standards defining the information that needs to be included or methods to assess the level of bias. So, how good are they? Loeb and co-workers addressed this question and found many deficiencies. Only 75% described the benefits of a treatment and about half discussed potential harms and promoted shared decision-making. This is an extremely important issue that people seeking information should understand. What could help might be a consensus checklist that a group of experts develop identifying some important features for online sites and then each site would get graded A, B, C etc. That would at least provide individuals with some awareness about the quality of information they are reading.

**The Bottom Line:** Men should be aware that many online websites are deficient in the info they provide.

P4, “ADT May Be Less...”

Randomized studies have proven that ADT combined with EBRT results in a higher survival compared to RT alone. Consequently, combination therapy is now the standard of care. However, in general, men with the highest Gleason scores are more difficult to treat. The study by Nguyen, et al. suggests that men with Gleason 9 or 10 cancers do not benefit by adding ADT. However, since this is not part of a randomized study and other well-done studies have not made the same conclusion, one should interpret these results cautiously. Nevertheless, their suggestion that studies incorporating the newer hormonal agents be performed is well worth considering.

**The Bottom Line:** Men with Gleason 9 or 10 PCa about to receive RT may need additional therapy besides ADT to further improve their survival, but studies are needed to make this determination.
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ADT & Benefits for GS 9-10 PCa (Continued from page 4)

given to treatment intensification for Gleason 9-10 patients through enrollment in clinical trials or potentially adding novel anti-androgens or docetaxel, which have shown efficacy in both castration-resistant and castration-sensitive settings,” Dr. Nguyen’s team suggested. They added that, in the future, genomics-based tools might help predict which GS 9 to 10 patients will respond to ADT.

Important limitations of the study include the short median follow-up (four years) and the lack of data on the type and duration of ADT. “There is clearly a need to explore better therapeutic options and, importantly, genetically profile Gleason pattern 5 disease to allow for precision medicine approaches in the hopes of improving cancer-specific outcomes,” Matthew P. Deek, MD, and colleagues from Johns Hopkins University School of Medicine in Baltimore wrote in an accompanying editorial.

Dr. Deek and his coauthors said it may be that Gleason pattern 5 disease more rapidly achieves castration resistance or the presence of GS 9-10 disease at diagnosis “is a surrogate for more rapidly progressive disease that is more likely to have disseminated microscopically.”

They also observed: “Investigation of time to castrate resistance, time to distant metastasis, stratifying men with GS 8 into 4+4 vs. 3+5/5+3 and correlation with advanced imaging modalities like prostate-specific membrane antigen-based positron emission tomography will be critical to understanding the nature of this important clinical problem.”

The editorialists suggested testing RT dose escalation to treat Gleason pattern 5 primary tumors as well as target possible metastatic clones.

Resources Address
Anxiety, Depression & Prostate Cancer

Many men who are diagnosed with prostate cancer, or are managing the disease, experience some level of anxiety and/or depression. Caregivers may also be affected. The psychosocial challenges surrounding treatment choices and side effect management can have a negative impact on quality of life.

Anxiety and depression aren’t always effectively treated, in part because the symptoms may not be recognized. We encourage you to visit the Us TOO web page for important information on recognizing and managing anxiety, depression and prostate cancer.

www.ustoo.org/anxiety-and-depression

Lipid-Lowering Drugs

(Continued from page 1)

strong evidence for a protective biologic mechanism of lower cholesterol on prostate cancer mortality,” Dr. Mondul’s team stated.

They urged researchers to conduct larger studies to determine whether results vary by type of lipid-lowering medication or by specific statin drug.

Renal & Urology News
27 November 2018

Keep up with the latest information on prostate cancer.
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US TOO INTERNATIONAL PROSTATE CANCER EDUCATION & SUPPORT
Hot SHEET – JANUARY 2019
Between the Sheets... January 2019

This column provides the platform for experts in the field to help men and women by providing answers to questions about sexual health and intimacy challenges that can result from prostate cancer treatment.

This column was compiled with the help of Dr. Anne Katz, Certified Sexuality Counselor and Clinical Nurse Specialist at CancerCare Manitoba. She has educated thousands of healthcare providers and cancer survivors about cancer, sexuality and survivorship. She is the editor of the Oncology Nursing Forum, an avid blogger for ASCO Connections, and the author of 13 books on the topics of illness, sexuality and cancer survivorship. (www.drannekatz.com)

QUESTION FROM PROSTATE CANCER SURVIVOR:

Ever since my surgery (open radical prostatectomy) my orgasms are pretty non-existent. Seems they’re not really worth all the bother of taking the pills to get an erection in the first place. Hope that works and, if it does, get the ‘deed done’ and then pretty much nothing in terms of feeling. Why is this happening and why didn’t someone tell me that would happen?

RESPONSE FROM DR. ANNE KATZ:

I’m going to answer the last question first, although it may be rhetorical. I don’t know why you were not told that this could happen as it is known that, after surgery, the QUALITY of orgasms may change. For some men, they are more intense to the point of pain. For others, they remain pretty much the same as before surgery. And for some men like you, unfortunately the SENSATION of orgasm is much decreased. You seem to be in the latter group and I hear your frustration. Many men in the first group (painful orgasm) may actively avoid orgasm because it hurts so much.

It is not really clear what the cause of this is. The pelvic floor muscles seem to be the ‘culprits’ in that much of the sensation of orgasm comes from contraction of these muscles. If you have a ‘loose’ pelvic floor, the sensation of orgasm may be muted to the point of non-existence. If your pelvic floor muscles are tight (this can happen from overdoing the pelvic floor muscle exercises recommended to prevent incontinence), orgasms may be painful. In my experience, men who are overweight or obese, especially in the mid-section tend to experience loss of sensation with orgasm due to the excess pressure of their belly on the pelvic floor muscles. Internal scar tissue after radical prostatectomy may play a role in this and internal nerve damage likely has a role too.

A visit to a knowledgeable pelvic floor physiotherapist can be very helpful. The American Physical Therapy Association is the official organization for physiotherapists in the U.S. and members of the public can search for a member through their website (http://aptaapps.apta.org/findapt). However, it is important to ask if the physiotherapist you are considering visiting has expertise in pelvic floor physiotherapy, as this is not included in basic training programs. The physiotherapist will assess the tone of the pelvic floor muscles and suggest exercises and/or internal massage of the muscles to help correct the tone. Most people, including health care providers, don’t understand the importance of the pelvic floor muscles, but they hold the key to much of our daily functioning including posture, core stability, urination, defecation and yes, sexual pleasure too!

Do you have a question about sexual health or intimacy? If so, we invite you to send it to Us TOO. We’ll select questions to feature in future Between the Sheets columns.

Please email your question to: ustooBTS@ustoo.org

Or mail your letter to:
Us TOO International
Between the Sheets
2720 S. River Road, Suite 112
Des Plaines, IL 0018
2018 and the Us TOO Holiday Hope Campaign are coming to a close. But there is still time to help us give hope in the new year!

Please consider making a donation to help Us TOO International provide educational resources, support services and personal connections within the prostate cancer community through our:

- Network of more than 200 support groups across the country and abroad
- Inspire online prostate cancer communities (UsTOO.inspire.com)
- Toll-free Us TOO Prostate Cancer HelpLine (1-800-808-7866); including connecting callers with similar survivors for peer-to-peer conversations and support
- Monthly Hot SHEET newsletter and monthly News You Can Use updates and articles
- Support group meetings/services and telephone support groups including A Forum for Her
- New website content on sexual health and intimacy, erectile dysfunction, and urinary incontinence
- Clinical Trials Finder website portal
- Educational videos and printed/digital materials
- Events, physician presentations and webcasts

... all provided at no charge.

Your gift and the work we do together matters now more than ever. There are nearly 3 million men in the U.S. living with a prostate cancer diagnosis. That number is estimated to climb to 4 million by 2024 as men in the baby boomer generation age. Every one of those men and his loved ones will need access to education and support to make informed decisions on the best approach to minimize the impact of the disease and maximize the quality of life.

Please join us in giving the gift of Hope with a generous donation today.

DONATE NOW
at www.ustoo.org/donatehope

Thank you and best wishes in 2019!