Cabazitaxel Does Not Prolong Overall Survival vs. Docetaxel in Metastatic Prostate Cancer

Cabazitaxel does not prolong overall survival (OS) in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) compared with the first-line chemotherapy agent docetaxel, according to a trial published in The Journal of Clinical Oncology.

Data from previously conducted studies demonstrated that cabazitaxel may significantly improve OS once administered after initial docetaxel therapy. The authors investigated the potential of cabazitaxel as a first-line chemotherapeutic agent for patients with mCRPC.

In the phase 3 FIRSTANA trial (ClinicalTrials.gov Identifier: NCT01308567), researchers randomly assigned 1,168 chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) patients to receive intravenous (IV) cabazitaxel 20 mg/m² (C20), cabazitaxel 25 mg/m² (C25), or docetaxel 75 mg/m² (D75) every three weeks with daily prednisone. Patient characteristics at baseline were well balanced across the various treatment arms. The primary end point of the study was OS.

The study showed that median OS was 24.5 months for C20, 25.2 months for C25, and 24.3 months for D75. The hazard ratio (HR) for C20 vs. D75 was 1.01 (95% confidence interval [CI], 0.85-1.20; P = 0.997, difference not significant). The HR for C25 vs. D75 was 0.97 (95% CI, 0.82-1.16; P = 0.757, difference also not significant).

Treatment-related grade three to four adverse events (AEs) (Continued on page 8)
Treatment Regret Not Common in Prostate Cancer Survivors

"Long-term survivors of localized prostate cancer don’t often express regret over how they chose to be treated, but informing men better upfront about their treatment options, especially the option of active surveillance (AS), may help mitigate what regret they have over time," say investigators reporting long-term data from the Prostate Cancer Outcomes Study (PCOS).

"Men being diagnosed today with a low-risk cancer should be informed about the option of AS to avoid the harms of overtreatment and because there is no survival benefit for active treatment, as we’ve learned from the ProteCt study," lead author Richard Hoffman, MD, MPH, professor of internal medicine and epidemiology, University of Iowa Carver College of Medicine, told Medscape Medical News.

“Our findings also suggest that informed decision making might also reduce regret, particularly if it leads more men to select AS,” he added.

The findings on treatment regret come from a survey completed by men 15 years after they had received treatment for prostate cancer. The findings were published online May 11 in the Journal of Clinical Oncology.

The survey involved 934 men with newly diagnosed prostate cancer who had been enrolled in the PCOS between October 1994 and October 1995. Participants were younger than 75 years at the time of their diagnosis.

“Most respondents had undergone radical prostatectomy (RP), only 10.8% were treated conservatively,” the study authors note. Specifically, 696 men underwent initial RP, 146 received radiation therapy (RT), and the remaining 92 participants were treated with either watchful waiting or androgen deprivation therapy within a year of diagnosis, they add.

Men were contacted at multiple time points after initial enrollment and were asked to comment on a variety of health-related quality-of-life outcomes, including treatment regret 15 years after receiving their diagnosis. Some 14.6% of the overall cohort expressed regret over their treatment decision, the investigators report.

The likelihood that a man would regret his treatment decision was lowest, at 8.2%, for those who underwent conservative treatment; it was 15% for those who underwent RP. The highest rate, at 16.6%, was seen in men who received RT.

“The amount of reported urinary or sexual bother did not vary significantly by initial treatment,” the researchers note. "More men, at 39%, expressed ‘moderate’ or ‘big’ bother with sexual dysfunction compared with only 16.6% for urinary dysfunction.”

The authors note that the men in their study might have been expecting changes in urinary function as they aged and so did not report that they were bothered by these changes or associate them with treatment regret.

Medscape, 3 August 2017

Radium-223 Dichloride Safe Long-Term in Men with Prostate Cancer and Bone Metastases

Radium-223 dichloride shows good long-term safety for treating men with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases, according to final results from the ALSYMPCA trial.

In the phase 3 ALSYMPCA trial, radium-223 plus best standard of care prolonged median overall survival by 3.6 months over that with placebo plus best standard of care (from 11.3 to 14.9 months) and was well tolerated, with a low incidence of grade 3 or 4 myelosuppression, in men with CRPC.

Dr. Christopher C. Parker from The Royal Marsden NHS Foundation Trust and Institute of Cancer Research, UK and colleagues reported long-term safety from 12 weeks after each patient’s last injection up to three years after their first injection.

Most of the 572 men who entered the long-term safety follow-up period had completed all six injections of study treatment (83% of men assigned to radium-223 and 71% of men assigned to placebo) according to the July 11, 2017 online report in European Urology.

During follow-up, 88% (355/405) of radium-223 patients and 92% (153/167) of placebo patients left the study, primarily due to death (70% of radium-223 patients and 63% of placebo patients).

The overall incidence of myelosuppression (depressed blood cell production) was 3% or less, and the incidence of nonhematologic adverse events was 1% or less. The few secondary malignancies reported during long-term follow-up were not considered to be related to the study drug. There were no new safety signals during

(Continued on page 6)
Some medical centers offer ONLY ultrasensitive (US) PSA tests or ONLY regular PSA tests after surgery. But why? Some men are helped by the US-PSA test and some men are hindered by regular US-PSA tests. So why aren’t men offered a choice based on their personality? Well, if you are not offered a choice then it is time to ask for a choice! It is time to get ULTRASENSITIVE about PSA choices after surgery!  

Regular PSA tests basically have a detection limit of 0.1 ng/mL, but US-PSA measures PSA levels under or around 0.01 ng/mL. The use of US-PSA tests is exciting because relapse of a cancer could potentially be found many months or years earlier than using a standard PSA test after surgery (and in other situations). Yet, many current clinical guidelines do not overwhelmingly recommend the use of US-PSA tests. Why? It is because the levels can bounce up and down like your local favorite rollercoaster ride and, more importantly in my opinion, it can cause MAJOR ANXIETY for some men!!!

I have a good friend – ahhh let’s just call him “Jack” for the sake of anonymity – and for about a decade he has watched his US-PSA test bounce up and down and with each of those bounces came incredible stress and anxiety. And, what did he get for it? He experienced a total of 10+ years of intermittent anxiety and stress for no reason. If he had a regular PSA test over that decade he would arguably have had little-to-no stress or anxiety because his PSA would simply be undetectable for 10 years! So, Jack asked me the other day, why patients aren’t offered a choice after surgery as to whether they want to have a regular and/or US-PSA after the benefits and risks of both tests are explained. And, I was nonplussed by his question. Sometimes in life common sense is not very common, for example when making lifestyle changes to improve your health. HOWEVER, this is a classic example of common sense that should be forced to become common by patients and health care professionals right now! It makes no sense that patients do not have full choice in the type of PSA they want after their prostate is removed. For someone who is at high-risk of recurrence and/or simply wants to know every little measurement or thing about his health and situation, he can choose an US-PSA test. Conversely, for those men with a lower risk of recurrence, or any type of risk of recurrence, who simply does not want to have his situation over analyzed (over analysis can lead to paralysis) and does not want to deal with this level of regular anxiety of getting a number that will be higher or lower than the previous number... well ultrasensitive PSA tests are NOT for this type of person.

Come on folks! Perhaps, over the years while many were running around arguing the pros and cons of PSA screening, we became too distracted by this single issue and missed the other relevant controversial issues when it comes to PSA testing. It is time to discuss both types of PSA tests after surgery and allow men to ultimately choose the one test that fits their situation and personality.

Please pass the Jack-Moyad PSA law of choice today! Oops, wait a second! You aren’t permitted to pass it, but rather make it clear to your healthcare professional that men should make the final decision when it comes to the type of PSA test they will receive after certain types of treatment. Patients need to get super ultrasensitive about this silly lack of option that currently exists at numerous medical centers. And, now stepping off my soapbox! THANK YOU!

References:
1. “Jack the patient” and Moyad MA. Our opinion.

With PSA Screening, Physicians Practice What They Preach

The vast majority of physicians who regularly treat prostate cancer say they are very likely to undergo PSA screening themselves or recommend it to their immediate family members, according to a survey of urologists, radiation oncologists and medical oncologists who routinely treat prostate cancer.

“In contrast to earlier studies showing that physicians may recommend treatments for patients that differ from what they would choose for themselves, this study showed that these physicians undertook the same screening they recommended,” reported investigators at the 2017 Annual Meeting of the American Urological Association.

“The survey also showed that physicians who identified treatment preferences favored the treatment of their own specialty, which is consistent with a previously identified specialty bias,” said investigator Christopher J.D. Wallis, MD, PhD, a urologic resident in the Division of Urology at Sunnybrook Health Sciences Centre, in Toronto.

In the survey, 90% of physicians (n=784) endorsed past or future screening for themselves or their relatives. Of the 807 male respondents, 494 (61%) had personally undergone PSA screening and 662 (82%) planned to do so in the future. Thirty of the men (4%) had been diagnosed with prostate cancer. Of the 62 female respondents, 43 (69%) had recommended PSA testing to immediate family members.

Of the 869 physicians who received the electronic survey distributed via professional organizations mainly in the United States, Canada, Australia and New Zealand, 719 urologists (83% of 869), 89 radiation oncologists (10%), eight medical oncologists (1%) and others who did not provide their specialty responded. The median age of all respondents was 50 years, and 92.9% were men. Among physicians who identified the treatment for prostate cancer they would undertake for themselves or recommend to first-degree relatives, 65% of urologists (20/31) selected radical prostatectomy and 83% of...
The main long-term side effect from prostate cancer treatment is sexual dysfunction (SD) for both surgical removal of the prostate and radiation therapy.\(^1\) and it can adversely impact quality of life.\(^2,3\) This study examined the lived experience of men with sexual dysfunction and partners of these men to five years after prostate cancer treatment. The study was published in BMC Urology June 2017 and can be accessed at [https://bmcurol.biomedcentral.com/articles/10.1186/s12894-017-0231-5](https://bmcurol.biomedcentral.com/articles/10.1186/s12894-017-0231-5).

**Results**

Twenty seven men completed the study, mean age 61 (±8) years (range 44-77 years). Nine partners of the men also participated in the interview process. Emergent themes from the qualitative interviews were: the importance of education/comprehensive information about sex and/or sexual dysfunction throughout the prostate cancer diagnosis and treatment; frustration with sexual dysfunction; the importance of support and understanding from others; the importance of intimacy in a relationship; the psychological ramifications of sexual dysfunction including depression and anxiety; and prostate cancer treatment provider satisfaction and/or dissatisfaction.

The men spoke about the importance of education and comprehensive information before and throughout the process of prostate cancer treatment. The participants said the following:

**Man 21:** “I was not prepared for what was to follow. No doctor informed me about what I should experience, what challenges I am going to be faced with. I think everybody – all the medical staff starting with nursing and support staff and the doctors themselves, they really need to inform the patient about what’s going to happen after the surgery with complications and side effects…And I’m very, very emotionally upset because if I would have known, I think I would have been in a better place throughout the first year and following that first year if I knew.”

**Man 16:** “I was fully informed by everybody. All the doctors that were involved fully informed me that these were things that I was up against if they removed my prostate.

“So I mean there’s a lot of things that are happening to a person in my situation. So definitely – you definitely must keep everybody informed about what’s going on. It’s really – that’s extremely important. I think because she (significant other) had all the information, she read the books that I was given so she knew exactly what I was going through.”

The men spoke about their frustration with sexual dysfunction. The men described being upset with the unexpected lack of function. Many of the men talked about the impact the erectile dysfunction had on their lives and their relationship. The participants said the following:

**Man 12:** “The other thing that happened, and again I was not told to expect this, was depression. I had a very serious bout of depression, post op, when I found out the things that were going on with me physically and the time it was taking to get to what I hoped would be healing. I didn’t understand depression. I didn’t know I had it but I suffered with it for several months until I got to the point where I became suicidal.”

Intimacy, both physical and emotional, was a priority for men and their partners. Participants discussed the importance of non-penetrative sex. Most men and their partners felt that non-penetrative sex was a helpful way to maintain intimacy. Some participants felt the relationship was stronger after prostate cancer treatment. The participants said the following:

**Man 13:** “I’m in a great relationship really for the first time in my life with a woman who really doesn’t care what we do as long as we’re together. We enjoy sex a lot, not just to be active, just to have intercourse. Without her I don’t think I would be as far along in getting my sex...” (Continued on page 5)
Surgery for Early Prostate Cancer
(Continued from page 1)

tumors. These men have an excellent prognosis without surgery. This study confirms that aggressive treatment usually is not necessary. We hope the findings will steer doctors away from recommending surgery or radiation to their patients with nonaggressive early-stage prostate cancer and patients away from thinking it’s necessary.”

The study, known as the Prostate Cancer Interventions Versus Observation Trial, or PIVOT, is one of the largest and longest cancer studies. It began in 1994 just as the PSA blood test for prostate cancer became routine. As more men were diagnosed with prostate cancer, the standard treatment became RP or radiotherapy (RT), with the thinking that RP or RT would increase survival. But over the next decade, reports of treatment-related complications raised concerns, as did data indicating that most early-stage cancers grew so slowly they were unlikely to cause health problems.

To evaluate benefits of surgery, the researchers randomly assigned 731 U.S. men with localized prostate cancer to RP or observation at one of 44 VA Health Care Centers or eight academic medical centers, including Washington University. The average age of men in the study was 67 years at the time of enrollment.

Of the men who had prostate cancer surgery, 223 (61%) died of other causes after up to 20 years of follow-up vs. 245 men (66%) in the observation group – a difference that is not statistically different. Further, 27 (7%) men in the surgery group died of prostate cancer, compared with 42 men (11%) in the observation group, but that difference also is not statistically significant.

However, the data show that surgery may have a mortality benefit in some men, particularly those with a long life expectancy and intermediate-risk prostate cancer.

“It would be a disservice to dismiss surgery as a viable option for patients with intermediate-risk prostate cancer,” said Andriole, the School of Medicine’s Robert K. Royce Distinguished Professor of Urologic Surgery. “For these patients, and for some men with high-risk prostate cancer, surgery is often beneficial, as are other treatments such as radiation.”

Technology has advanced since the study began, allowing physicians to more accurately classify tumors and avoid overtreating patients who have prostate cancer. Of 364 men treated with RP, 53 (15%) suffered ED, and 63 (17%) reported urinary incontinence. Another 45 developed other complications.

“The benefits of surgery also need to be balanced against the negative long-term consequences of surgery that occur early and often,” said Dr. Wilt. “Our results demonstrate that for the majority of men with localized prostate cancer, selecting observation for their treatment choice can help them live a similar length of life, avoid death from prostate cancer and prevent harms from surgical treatment.”

“Physicians can use the information from our study to confidently recommend observation as the preferred treatment option for men with early prostate cancer.”

WUSM news release
12 July 2017

Life with Sexual Dysfunction
(Continued from page 4)

Life back to where I want it to be. It’s got to do with her and she’s put up with so much.”

Man 4: “I come here shaking like a leaf, man (referring to the support group meeting). I get in here with a bunch of guys that had been where I was about to go and man, they gassed me up with that strength. And like I said, when I came in, I was shaking like a leaf. When I left, I was empowered.”

Conclusion:
This study provides personal descriptions of the journey of men & partners in terms of sex and intimacy after prostate cancer treatment. Prostate cancer survivors and their partners need for accurate information about sexual side effects before, during, and after prostate cancer treatment. Men and their partners want providers to be sensitive to their sexual activities and assist them in finding appropriate help to deal with sexual dysfunction.

Men and partners can work closely with their providers to make sure they understand their particular sexual goals and expectations with prostate cancer treatment. Sexual dysfunction after prostate cancer treatment can be very frustrating and men can find help and support if they reach out to their partner, their family and support/education groups.

Men and partners can enjoy intimacy and sex after prostate cancer treatment and some find it helpful to work together with their partner on enjoying connectedness, pleasure and orgasm regardless of erectile function. Some men may experience depression or anxiety with sexual dysfunction after prostate cancer treatment and it can be helpful to seek professional help with those issues.

Ultimately, men and their partners can enjoy life and intimacy after prostate cancer with the help and support from partner, family and/or support groups such as Us TOO, International.

References

Join Us TOO
at the 13th Annual
SEA Blue Chicago
Prostate Cancer
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Lincoln Park, Chicago
Register at
www.seablueprostatewalk.org
Can’t join us in person? You can help us raise funds to help others affected by prostate cancer by registering as a Virtual Mover.
Adverse Pathology (Continued from page 1)

5.8% in the low-risk group (relative risk [RR] 4.50, P <0.001) and 4.7% in the very low-risk group (RR 5.14, P <0.001). Clinical outcomes were not significantly changed when the low-volume intermediate-risk group was restricted to men meeting criteria for very low-risk disease (T1c, PSA density <0.15 ng/mL/cm³, ≤50% cancer in any prostate biopsy core) or low-risk disease (≤T2a, PSA <10 ng/mL).

No subgroup of the low-volume intermediate-risk group with rates of adverse pathologic findings similar to those in the very low-risk and low-risk groups could be identified on the basis of preoperative clinical or pathologic characteristics.

On multivariate analysis in the entire population, PSA density was a significant predictor of adverse pathologic findings (odds ratio [OR] per 0.01 change 1.04, P <0.001), with Gleason score having the largest effect (OR 4.30 for grade group 2 vs. grade group 1, P <0.001).

Investigators concluded: “Nearly 25% of men (150 of 608) electing immediate RP with low-volume, Gleason 3+4 prostate cancer on biopsy are found to harbor adverse surgical pathologic findings. These data do not support the presence of a ‘favorable’ subgroup among included patients and could have important implications for AS in similar patients with Gleason 3+4/7 prostate cancer.”

Content in this post has not been reviewed by the American Society of Clinical Oncology, Inc. (ASCO) and does not necessarily reflect the ideas and opinions of ASCO.

The ASCO Post 3 August 2017

Radium-223 Dichloride Safe Long-Term (Continued from page 2)

long-term follow-up.

Dr. Nicholas J. Vogelzang from Comprehensive Cancer Centers of Nevada, Las Vegas, one of the coinvestigators, told Reuters Health, “These results are comforting and thankfully not surprising. This is my experience in the over 200 patients I have treated as well.”

“I use radium in all metastatic prostate cancer patients, preferably well before they are seriously ill from the cancer,” he said in an email. “I believe it is underused, particularly in elderly men who are not good candidates for chemotherapy.”

Dr. William W. Wong from the Mayo Clinic Arizona in Phoenix, who was not involved in the study, told Reuters Health by email, “Only 12% (48/405 men) of the radium group and 7% (12/167) of the placebo group completed three years of follow-up. The small number of men in each group reduced the probability of detecting a difference in secondary hematologic malignancies. Also, three years would not be enough time to observe the development of secondary malignancies. Increased risk of secondary malignancy was seen after over five years of treatment in patients who received external beam irradiation and/or chemotherapy for Hodgkin lymphoma.”

“While the ALSYMPCA study showed the survival benefit of radium-223 for metastatic CRPC, recent trials (ECOG 3805, STAMPEDE) have shown the significant benefits of docetaxel in castration-sensitive metastatic prostate cancer, suggesting that earlier use of systemic therapy achieve more benefits than using these agents when the disease is castration resistant,” he said. “The same question should be asked about the role of radium-223. I would advocate earlier use of radium-223 in metastatic prostate cancer, before the disease develops castration resistance, and a randomized trial would be needed to evaluate this.”

“The take home message of the study is that radium-223 has an excellent long-term safety profile at three-year follow-up,” Dr. Wong concluded.

Reuters Health 26 July 2017

With PSA Screening, Physicians Practice What They Preach (Continued from page 3)

radiation oncologists (5/6) chose radiation therapy. Dr. Wallis said that among urologists and radiation oncologists, there was a significant correlation between physician specialty and the treatment selected.

Dr. Wallis said this correlation has been described previously and validated the findings in this study. He noted that the limitations of the study included the inability to identify a response rate, reliance on physician self-reported behaviors and a numerical bias toward urologists.

Earlier studies that Dr. Wallis cited relied on hypothetical scenarios, he said, and they did not capture the ways by which physicians make decisions regarding treatments in reality. The method used in the survey study – the surrogate method – avoided the bias of what physicians claim they would advise a patient and instead asked physicians what they themselves have done or would do. The investigators were not able to verify that the physicians actually behaved as they reported.

“These data show that urologists and radiation oncologists fundamentally believe that PSA screening is a beneficial intervention, and believe that the benefits likely outweigh the risks because they are willing to undergo it,” Dr. Wallis said.

Stacy Loeb, MD, an assistant professor of urology and population health at New York University’s Langone Medical Center, in New York City, said, “It’s nice to see that doctors who manage prostate cancer really do practice what they preach and choose PSA screening for themselves. The data showed that doctors who would recommend surgery would choose it for themselves, and doctors who recommend radiation would choose it for themselves. It suggests they know the data and the benefits and risks, and they would choose to undergo the same treatments they are recommending for patients.”

Clinical Oncology News 18 July 2017

Finding the Right Clinical Trial Can be a Challenge
Simplify the Process with the New

Us TOO Prostate Cancer Clinical Trial Finder
www.ustoo.org/HCP-Clinical-Trials
Doctor Chodak’s Bottom Line


Editor’s Note: Us TOO has invited 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.

P1, “Surgery for Early...” One of the most controversial questions about prostate cancer therapy is what degree radical prostatectomy (RP) improves survival. Most doctors have believed improvement is substantial. Unfortunately, proof has never been established. As more study data is gathered, that belief is being challenged. Such is the case with the recent report by Wilt, et al. on the PIVOT trial, a randomized study that began over 20 years ago. The most recent update shows that RP reduced death from prostate cancer by only 4%, although difference in the incidence of metastatic disease will likely change the benefit over time. Also, longer follow-up will likely show greater mortality differences, but that is just a guess and time will tell.

The study does have an important limitation: a proportion of the men assigned to surgery did not have it while a proportion assigned to watchful waiting were definitively treated. Despite any statistical limitations, it may be interesting to examine the results only for men who complied with assigned therapy to determine if different results would be detected. Nevertheless, this paper provides very important information that should be given to all men when considering their treatment options.

The Bottom Line: With 20 years of follow-up and over 50% of men followed almost 13 years, RP appears to reduce the risk of dying from prostate cancer by 4%.

P1, “Cabazitaxel Does Not...” Docetaxel was the first chemotherapy agent to improve survival in men with castrate resistant prostate cancer (CRPC). Later studies showed that a related drug, cabazitaxel improved survival in men who progressed after receiving docetaxel. A logical next step was to ask how well cabazitaxel would work as a primary agent before docetaxel. Results of the randomized study reported in this Hot SHEET found it to be equally effective in prolonging survival. However, the side effect profile of cabazitaxel differs in that the lower drug dose caused slightly lower Grade 3 and 4 toxicity than docetaxel. It still has significant side effects. But some are different and, for some patients, cabazitaxel may be a better first option than docetaxel. Patients need to be made aware of the difference when chemotherapy is to begin.

The Bottom Line: Cabazitaxel is not more effective than docetaxel as a first line chemotherapy in men with hormone refractory disease, but it may be appropriate for some patients due to differences in the potential side effects that may occur.

P1, “Adverse Pathologic...” Should men with Gleason 3+4 disease be put on active surveillance (AS)? That question is partly addressed in the report by Patel and coworkers. They studied the pathological findings in men with low-volume intermediate-risk prostate cancer who underwent RP. Low-volume intermediate-risk disease was defined as having only one or two positive cores on biopsy. Adverse pathological findings post-RP included men with at least Gleason 4+3 disease. The authors found adverse pathology post-RP in 25% of the men with intermediate-risk disease compared to much lower rates in men with low-risk or very low-risk disease. Based on their results, they conclude that AS is not appropriate for men with low-volume intermediate-risk prostate cancer.

However, that conclusion may be premature. First, the study found that 75% of the men had a less dangerous disease, so AS is still reasonable for them. The challenge is identifying those individuals. The authors found that none of their markers were helpful. But before excluding all these men from AS, more work is needed to determine if genetic testing combined with MRI could provide some insight into which men harbor the more aggressive disease and still allow the other 75% to avoid surgery, at least until there is evidence that their cancer is progressing.

The Bottom Line: More studies are needed in men with low-volume intermediate-risk disease to determine which of them are good candidates for AS.

P2, “Treatment Regret...” How do men diagnosed with prostate cancer in 1994-1995 feel about their treatment choice? Hoffman, et al. addressed this question in a survey of 934 men 15 years later. Results showed that about 15% of the men on average regretted their decision. About the same percentage were dissatisfied if they chose RP or radiation. The lowest percentage was found in men treated conservatively. Unfortunately, the meaning of these findings is unclear. Someone could be dissatisfied with their choice for many reasons. One would expect that the most likely reason would be how their quality of life was affected. Also, results could be biased because participation in the survey was not selected in a random fashion and results may not reflect true results.

The Bottom Line: A relatively low percentage of men regret their decision for prostate cancer therapy 15 years after treatment.

P2, “Radium-223 Dicho...” The study by Parker and coworkers provides additional support for the use of radium-223 in men with castrate resistant prostate cancer. It showed a small but significant increase in survival compared to standard of care. Importantly the incidence of lowering blood counts and other side effects was very low. However, as pointed out in the Hot SHEET, the relatively short-term survival of the men may have limited the ability to assess for secondary cancers that might develop over time as a result of the systemic radiation. This could be an important issue warranting further evaluation if radium-223 is started much earlier in the course of the disease.

The Bottom Line: Radium-223 is another useful agent for improving survival in men with castrate resistant disease with low side effects over two years.
Bristol-Myers Squibb and Clovis Oncology will collaborate to assess the combination of Opdivo (nivolumab) and Rubraca (rucaparib) in Phase 2 and 3 clinical studies in patients with different cancer types, including prostate cancer.

The companies plan to launch a Phase 2 study to investigate the safety and effectiveness of the combo treatment in patients with metastatic castration-resistant prostate cancer (mCRPC). All studies are expected to begin before the end of 2017.

“We are very enthusiastic about studying Rubraca and Opdivo in combination, and the potential to create new treatment options for patients with multiple tumor types, as well as for patients beyond those with BRCA mutations,” Patrick J. Mahaffy, Clovis Oncology’s president and CEO, said in a press release.

“This substantial clinical collaboration in ovarian, triple-negative breast and prostate cancers represents a significant effort by Clovis and Bristol-Myers Squibb to realize that potential,” he said.

Fouda Namouni, MD, Bristol-Myers Squibb’s head of oncology, said the collaboration with Clovis “addresses areas of unmet medical need where the combination of Opdivo and Rubraca may lead to an additional treatment option for patients with difficult to treat cancers.”

“We are committed to investigating a wide range of oncology therapies and look forward to studying the combination of Clovis’ PARP inhibitor and our immunotherapy,” Namouni added.

Cancer cells are constantly multiplying, but the division process is sometimes associated with errors that may cause their death, such as DNA breaks. If cancer cells repair these breaks, they survive and keep multiplying.

Rubraca is an oral inhibitor of PARP proteins (PARP-1, PARP-2, and PARP-3), which are involved in DNA repair. By inhibiting these proteins, Rubraca prevents cancer cells from repairing their DNA. Indeed, previous studies have shown that PARP inhibition promotes inflammation, cell death, and increases the action of T-cells within tumors.

Opdivo acts upon a protein called programmed cell death-1 (PD-1), which inhibits the immune system’s ability to detect cancer cells. By inhibiting PD-1, Opdivo restores the body’s capacity to activate the anti-tumor response and fight cancer cells. Because of its potential role as an enhancer of the immune system’s response, Opdivo is under evaluation in a broad range of clinical trials across all phases in a variety of tumor types.

Medical News Today
7 August 2017

Cabazitaxel
(Continued from page 1)
occurred in 41.2%, 60.1%, and 46.0% of men in C20, C25, and D75, respectively. The treatment arm receiving C25 reported higher incidence of febrile neutropenia, diarrhea, and hematuria, and the treatment arm receiving D75 reported high incidence of peripheral neuropathy, peripheral edema, alopecia, and nail disorders.

The final results of the study show that cabazitaxel is not superior to docetaxel in improving OS. The authors concluded that the similarity between the two agents however, “may offer additional flexibility to prescribing physicians with regard to treatment choices for individual patient-specific profiles in men with neuropathy, edema, or other conditions that may be preferentially exacerbated by docetaxel.”

Oncology Nurse Advisor
31 July 2017