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"LIFE AFTER PROSTATE CANCER: EFFECTIVE TREATMENTS FOR ERECTILE DYSFUNCTION"

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(A summary of a presentation to the WRAMC Us TOO Chapter on May 7, 2008)

INTRODUCTION

Remember when ED was a "secret?" Well, not anymore! Nowadays, anyone who doesn't know about erectile dysfunction – ED – simply has not been paying attention! Who hasn't seen the ubiquitous TV ads with expectant couples smiling knowingly at each other? Actually, this pervasive awareness makes a urologist's job much easier. It used to be that men were reluctant to talk ED. But the advent of Viagra changed all that, and it's all to the good, even if it makes watching TV with your grandchildren a little dicey!

I realize I have a sophisticated audience tonight. All the men here likely have been diagnosed and treated for prostate cancer. Many of you have experienced to some degree the side effects of your primary therapy, including erectile dysfunction. So my plan is to present a general overview of ED treatment in order to leave more time to address your questions and concerns during the Q & A period.

THE ED PROBLEM

Erectile dysfunction is very common; one in every five men (over 30 million Americans) is affected by it, but it is a condition we can manage. Most frequently it is caused by a physical problem such as a nerve or vascular condition, perhaps due to pelvic surgery or trauma. Psychological anxiety is another major cause. I see this psychological aspect more in younger men. And as you might expect, age is another major factor in men who present with erectile dysfunction. But other issues are at work as well: diabetes, high blood pressure, alcoholism, smoking, and, of course, the co-morbidities associated with the primary therapies for prostate cancer.

It is often said with a smile that the brain is the largest sexual organ. Sexual function actually starts in the brain. The nerve impulses move down the spinal cord affecting the pelvic nerves and eventually the penis. These neurovascular bundles on either side of the prostate are absolutely essential to preserve erectile function and they are susceptible to damage during a radical prostatectomy or radiation therapy. Both the surgeon and the radiation oncologist do their best to preserve sexual function. Unfortunately, sexual dysfunction of varying degrees can still occur. **(Continued on page 6)**

♦ ***INSIDE THIS ISSUE*** ♦

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♦ FROM THE EDITOR'S DESK ♦

Wanted: A Few Good Men! No, not for the Marine Corps – for the Center for Prostate Disease Research (CPDR) at WRAMC. The CPDR provides considerable assistance to our support group, and over the years, we have reciprocated by providing volunteers to work within the CPDR. **If you live within reasonable proximity to WRAMC, you can help.** See page 12 for more information.

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♦ MAY SPEAKER'S REMARKS ♦

Dr. Robert C. Dean, Director of Andrology, WRAMC, was our speaker for Wednesday, May 7, 2008. His topic was "Life after Prostate Cancer: Effective Treatments for Erectile Dysfunction." A summary of Dr. Dean's remarks begins on page 1. We also were fortunate to have a related presentation by David and Sarah Roberts. They shared with us their personal experience in coping with erectile dysfunction. Their remarks are on page 13.

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♦ MEETING SCHEDULE FOR AUGUST 6, 2008 ♦

Our speaker for August 6, 2008, is B.J. Reid Czarapata, CRNP, CUNP. She is a Certified Registered Nurse Practitioner and a Certified Urology Nurse Practitioner who has specialized in the treatment of urinary incontinence since 1986. She is the Coordinator, Pelvic Floor Center, Medical Faculty Associates, George Washington University. Previously, she has practiced in the Division of Urology at Georgetown University Medical Center; Fairfax Urology, Ltd; and she founded and served as CEO of the Urology Wellness Center. She has spoken and written widely on urinary incontinence. Her topic is "Managing Incontinence after Prostate Cancer Therapy." Join us on Wednesday, August 6, 2008, at 7 PM in Joel Auditorium. Your guests are always welcome.

"Blue Water" Navy and Agent Orange. "Blue Water" sailors and Coast Guard veterans of the Vietnam War suffered a setback to their claim for disability compensation from illnesses they say resulted from shipboard exposure to Agent Orange. On May 8, the U.S. Court of Appeals reversed a 2006 ruling by saying that the Department of Veterans Affairs (VA) acted lawfully and reasonably in 2002 when it ended Agent Orange-related disability payments and began to deny new claims from veterans who served on ships off the coast of Vietnam but never actually "set foot" in the country.

Until early 2002, the VA paid Agent Orange-related claims filed by Navy and Coast Guard personnel who only served off the coast of Vietnam if sea service veterans had received the Vietnam Service Medal. The medal had been awarded to all military members who served from July 3, 1965 through March 28, 1973, in Vietnam, its contiguous waters or even in its airspace. The VA then reinterpreted the Agent Orange Act of 1991 to require at least a brief visit on land to be considered exposed to Agent Orange and eligible for disability pay for herbicide-related ailments such as prostate cancer.

The appeals court rejected the 2006 veteran claims court findings that the VA had applied its regulations inconsistently and that its tighter interpretation of law and regulation was both erroneous and unreasonable. Lawyers for the plaintiffs are likely to appeal this new decision, and the case could eventually reach the Supreme Court. Interested persons can learn more about the lawsuit on line at www.nvlsp.org or at www.bluewaternavy.org.

Barbers as Prostate Cancer Educators. Barbers against Prostate Cancer is a 1-year joint research project by Moffitt Cancer Center, the Tampa Bay Community Cancer Network, and the Community Health Advocacy Partnership. The neighborhood barber shop always has been a traditional community center for African-American men. Researchers are exploring whether community-based efforts by the lay public could help bridge the communication divide and increase screenings among African-American men.

Eight barbers in the Tampa area underwent 10 hours of training in basic prostate cancer concepts and 40 of the barbers' clients were interviewed to estimate their willingness to discuss prostate cancer with a healthcare provider after receiving educational information from the barbers. In the pilot study, barbers ask their male clients over the age of 40 years if they have ever been screened for prostate cancer. A client who responds negatively is educated about prostate cancer and made aware that he is a candidate for prostate cancer screening. If successful, this novel approach to prostate cancer awareness could be expanded to other medical issues within the African-American community. (Source: Cancer, Culture & Literacy: 6th Biennial Conference: Abstract 17, May 16, 2008, via Medscape Medical News, May 19, 2008)

New Data on Finasteride. A new look at the Prostate Cancer Prevention Trial (PCPT) has confirmed the study's main finding that finasteride reduces the risk for prostate cancer. It also found that patients taking the drug do not have an increased risk for high-grade disease, as was earlier suspected. The original PCPT study involved more than 18,000 men 55 years of age and older. It was discontinued early in June 2003 because researchers noted that although finasteride reduced prostate cancer by up to 25%, men taking the drug appeared to have more aggressive prostate tumors if and when they developed the disease. This caused concern that finasteride was triggering higher-grade cancers. The new analysis by researchers from New York Presbyterian Hospital/ Weill Cornell Medical Center should allay those fears. Finasteride has long been used by physicians to treat benign enlarged prostates. This new research found a significant reduction in the incidence of prostate cancers, even the higher-grade cancers, in men taking finasteride, compared with a placebo. Some experts cite the need for additional research to confirm this new information about finasteride. (Source: Medscape Medical News, May 22, 2008)

Vitamin D and Low Prostate Cancer Risk. Men with a high blood concentration of vitamin D don't

have a reduced risk of prostate cancer, according to researchers at the National Cancer Institute. The study also found evidence of a slight link between higher concentrations of vitamin D and aggressive disease. Previous laboratory studies had suggested that high doses of vitamin D may decrease prostate cancer risk, but epidemiological studies of that association have yielded mixed results. In this new study, researchers compared blood concentrations of vitamin D in 749 prostate cancer patients and 781 men without the disease. They found that increased vitamin D concentrations weren't associated with a statistically significant difference in prostate cancer risk. There was some evidence of a link between higher concentrations of vitamin D and increased risk of aggressive prostate cancer, but that trend wasn't statistically significant either. (Source: Journal of the National Cancer Institute, May 27, 2008, via HealthDay News, May 27, 2008)

Cancer Recurrence and African-American Men. Researchers at the Duke Prostate Center, Duke University Medical Center, Durham, NC found that African-American men are more likely than Caucasians to have their prostate cancer return after treatment, but when their disease does return, it is no more aggressive than that of their white counterparts. African-American men tend to have higher PSA levels at initial diagnosis of prostate cancer as well, despite being diagnosed at younger ages.

The researchers studied the medical records of 953 white and 659 black men who underwent radical prostatectomies were treated for prostate cancer between 1988 and 2006 at five medical centers. The team examined the relationship between race and the amount of time that lapsed between surgery and recurrence, as well as the level of PSA found in the blood of the patients. They found that African-American men were 28 percent more likely to experience a disease recurrence. However upon comparing the men who did experience recurrence, the researchers found that the aggressiveness of the disease was similar across the racial groups. They concluded that the study points to a trend toward better screening and earlier detection among black men. (Source: Science Daily, October 10, 2007)

PSA Testing and Obesity. Doctors may be missing cancers in obese men because their PSA scores can be falsely interpreted as being low. Freedland, et al, Duke University Medical Center, compared the medical records of almost 14,000 patients who had undergone radical prostatectomies for the treatment of prostate cancer between 1988 and 2006. They found that a higher body mass index directly correlated with higher blood volume and lower PSA concentrations. Men in the most obese group had PSA concentrations that were 11 to 21 percent lower than those of normal weight men. They said that obese men have more blood circulating throughout their bodies than normal-weight men, and as a result, the concentration of PSA in the blood can become diluted. Accordingly, the study indicated a need to adjust the interpretation PSA scores that will take body weight into account. Furthermore, the later detection of prostate cancer due to the dilution of PSA may help explain, in part, why obese men tend to have more aggressive cancers. The researchers say the implications of the study are serious because one in three Americans is obese, and a man who is 5'11" and weighs 215 pounds is considered obese. (Source: *JAMA*: 2007; 298(19):2275-2280 via Science Daily, November 24, 2007)

Medicare Reimbursement and Prostate Cancer Treatment Decisions. Are Medicare reimbursement rates affecting treatment decisions? Researchers are trying to explain a major shift in prostate cancer treatment, and they are wondering whether factors other than evidence-based medicine are influencing treatment decisions. The case in point is a dramatic change from medical castration to surgical castration (orchiectomy) that cannot be explained by disease demographics or changes in clinical practice. Weight, et al., the Cleveland Clinic, say the shift is due to changes in Medicare reimbursement. Physicians prescribing lutenizing hormone-releasing hormone agonist actually would lose money by administering these medications after enactment of the Medicare Modernization Act. The issue also involves ethical problems if choice of treatment is influenced by economic considerations. An observer notes the irony that shortcomings in the previous Medicare legislation actually had the opposite effect, i.e., physicians then had an economic incentive to favor medical castration. The

new Medicare Modernization Act swings the pen-

dulum in the opposite direction. Total allowed charges for medical castration peaked in 2003 at $1.23 billion, and in 2005 dropped 65% from that peak. The researchers identified an increase in the use of orchiectomy and a simultaneous decrease in the use of almost all lutenizing hormone-releasing hormone agonist. They warn that variables other than evidence-based medicine and patient preference can influence treatment decisions significantly. (Source: Medscape Medical News, April 11, 2008)

Neglected Factors Influence Prostate Cancer Treatment Satisfaction. Men with prostate cancer and their partners face difficult decisions regarding treatment, and they need accurate information regarding expected outcomes. Outcomes after primary therapy are highly individualized and depend not only on age, but also on factors previously overlooked, such as the size of the prostate and whether a man has urinary symptoms due to prostate enlargement before treatment. Previous studies about patient satisfaction focused mostly on problems with sexuality, bowel problems, and urinary incontinence after prostate cancer treatment. These are important issues, but Sanda, et al., Beth Israel Deaconess Medical Center and nine other institutions, found that other symptoms are equally as important in determining overall patient satisfaction. The study of 1,201 men and 625 spouses also showed that overall satisfaction with treatment was lower among African-American men, despite their having received care at the same centers as their white counterparts.

The study examined many facets of quality of life, including not only sexual function, bowel function and urinary incontinence -- but also concerns that are common, yet have been previously neglected by researchers, including weak or frequent urination due to prostate enlargement as well as a man's "vitality" or hormonal function. Patients and their partners placed greater level of importance on a patient's vitality, which includes concerns expressed by patients and their partners about the patient's energy level, weight and mood. Researchers report that hormonal therapy, when combined with brachytherapy or with external radiation, worsened multiple aspects of quality-of-life, and had particularly profound effects on men's vitality and sexuality. Patients receiving radioactive seed treatment experienced problems with weak or frequent urination which lasted longer and had greater effect on overall satisfaction than previously appreciated. Nerve-sparing techniques reduced the sexual side effects of the surgical procedure but did not eliminate them.

The study was the first multi-center effort to focus on satisfaction with overall outcome of cancer care and to include partners in the evaluation. It found that changes in quality of life played a significant role in determining whether patients and their partners were satisfied overall. The researchers conclude that “partners matter,” and satisfaction with overall outcome, from the perspective of the patient and partner, should be the bottom line in health care. (Source: *ScienceDaily*, March 3, 2008)

Magnolia Tree Extract and Prostate Cancer. Lycopene, green tea and pomegranate juice as cancer fighters – what next? It’s magnolia tree extract! Singh, et al., University of Pittsburgh, found that honokiol, a substance extracted from the magnolia tree, may help treat—or even prevent—prostate cancer. Honokiol has been an important component of traditional Japanese and Chinese medicine. The researchers gave male nude mice 1, 2, or 3 milligrams of honokiol three times a week. The researchers then implanted prostate cancer tumor cells into the mice, and measured tumor growth. Tumors in mice given the 2-milligram dose were significantly smaller than tumors in mice that had not received the drug. Also, mice treated with honokiol didn’t show any side effects. The researchers say that honokiol has great promise as a prostate cancer therapy, and perhaps for other types of cancers, such as lung cancer and colorectal cancer. As expected, the researchers emphasized the need for additional research. (Source: *Cancer Monthly*, April 25, 2008)

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(“Life after Prostate Cancer” – Continued from page 1)

The other mechanism that is very important to an adequate erection is good vascular flow. It's here that the diabetic man and men with hypertension will have trouble. These tiny cavernosal arteries must dilate to engorge the penis with blood to cause and sustain the erection. The nerves tell those arteries to do that, and then the arteries have to be able to respond. So it's both the nerve and vascular functions that are important if you are having trouble getting an erection.

HAVING A DIALOGUE

I deal with male sexual health within the WRAMC Urology Clinic. The concerns cover a broad spectrum; however, a good portion of my practice involves men with erectile dysfunction associated with pelvic surgery and radiation therapy. As I noted at the outset, there used to be discomfort on the part of the patient and the physician when discussing sexual matters such as ED. Both parties were reluctant to broach the topic, and frank, informed dialogue was difficult. The situation is much improved, but we still need to work on it.

ORAL THERAPIES

No doubt everyone here tonight is familiar with the PDE-5 inhibitors--Viagra, Cialis, and Levitra. Perhaps some of you rely on one or the other of them. Levitra is the oral therapy available within the military healthcare system. What can we expect from the oral therapies? Following radical prostatectomy, our experience is that 34-37% of men with ED will respond to Levitra; in other words, they achieve an erection satisfactory for intercourse. By no means are we helping everyone. This is not the 100% success we all hope for, but the pills can help many men.

OTHER OPTIONS

What to do when the pills don't work? What are the options out there? Well, there's the vacuum erectile device. It's been around for a long time on both a prescription and non-prescription basis. A cylinder placed over the penis creates a vacuum which draws blood flow to engorge the penis. A special band placed at the base of the penis traps the blood in place to maintain the erection.

The vacuum device has its drawbacks. It rquires some manual dexterity; the constricting band can be somewhat painful; some men experience a penile numbness attributable to the constricting band; and the mechanical process could be a turn-off for some. On the other hand, it is non-invasive and not a medication, so there are no contraindications to its use. Intracorporal injection therapy has been around since the 1980s. A very fine needle is used to inject a combination of three different medications into the side of the penis. This results in a very durable erection fairly consistently. So the user knows he is likely to get an erection each time. Of course, many potential users are simply unable to contemplate self-injecting a needle, however fine, into the penis! For men dissuaded by the self-injection, MUSE was developed in the mid-1990s. This intraurethral medication takes the form of a suppository. An applicator inserts a tiny Prostaglandin E-1 pellet about an inch into the urethra where body heat causes it to defuse into the penis to reach the corpora cavernosa, causing an erection. MUSE works well with some men who can't cope with self-injection. Unfortunately, there are reports of penile ache in about 35-40% of men relying on it. Some may say that a painful erection is probably not a good erection; on the other hand, others may say <u>every</u> erection is a good one!

PENILE PROSTHESIS

The penile prosthesis has been around for a several decades. Basically, there are two types – malleable and inflatable. The malleable prosthesis is very simple to use. The implanted prosthesis bends up when you want to have sex, it bends down when you don't. It doesn't change penis size at all; it just makes the penis rigid. The inflatable penile prosthesis has a pump placed in the scrotum which controls the transfer of fluid from a reservoir behind the pubic bone to the cylinders placed within the corpora cavernosa of the penis. An erection occurs by transferring fluid into the cylinders from the reservoir. Pressing a button on the pump automatically transfers the fluid back to the reservoir making the penis flaccid again.

WHAT DO MEN TELL US?

As we consider these various options for combating ED, what have we learned about how well

they work? We know that only about 40% of men who try intracorporal injection therapy will still be using it after one year. About 60% will simply stop using it because they don't like it or it stops working for them. As for oral therapy (Viagra, Cialis, Levitra), even if it works initially, only about 51% will still be using it at one year. The penile implant experience is more impressive. About 93% of the men who get the penile prosthesis are still relying on it one year later. Interestingly, a recent study shows that 96% of spouses like the fact that their husbands received a penile prosthesis.

Of course, we must consider timing as well. When men become serious about considering a penile implant, it is often after unsuccessful or otherwise unsatisfactory experience with the other ED therapies. The implant is often the last step. If a man selects a penile prosthesis, that's it. There are no more bridges to cross. The timing for an implant depends in large measure on when the man had his definitive prostate cancer therapy, whether surgery or radiation. The return of erectile function post-therapy takes time. For example, men who had a successful nerve-sparing radical prostatectomy still require as much as 36 months to regain potency, and about 61% of them will do so. Therefore it makes sense to defer any decision about a penile implant for about two or three years post-therapy, depending on individual circumstances. So we usually prefer to wait about two or three years before recommending a penile prosthesis.

The penile prosthesis is a good choice for men who don't do well with the other ED therapies. The device has been on the market for more than 30 years, has a proven track record, and is very safe. The most frequent questions I get about the penile prosthesis are about the implant procedure – how long does it take? And what is the recovery time? The implantation procedure takes about an hour and a half in the operating room. The patient remains overnight in the hospital with a catheter. The catheter is removed the next day and the patient goes home. He can start using the penile prosthesis in six weeks.

CONCLUSION

This concludes my quick review of ED therapy as an aspect of male sexual health. I'm looking forward to your questions, but before that I want to bring up one other topic and that's the American Revolution. I know what you are thinking, "What does this have to do with sex?" I like to make these kinds of connections so here is my connection with the American Revolution. This is a picture of the Founding Fathers of our nation. No doubt you can recognize some of them, but who is that short, stout gentleman who is the shortest of them all? It's John Adams, the second president of the United States, and the subject of a recent book by David McCullough and also the subject of an HBO series. There are wonderful stories about the deep, loving relationship between John and Abigail Adams based largely on more than 1,000 of their personal letters written during their long separations from each other. One HBO reviewer cites "the heartbreaking, beautiful love story with a wonderful love scene" in the HBO special. If you watched the HBO special or if you have read the book, you know that the connection that Abigail and John Adams had was truly amazing. After 54 years of marriage, four children, a smallpox epidemic, his extended absences in Europe, and his involvement with our War of Independence, Abigail lay on her death bed. At the very end, he tenderly called her "my friend." This term of endearment, so expressive of loving sentiment and sexual connotation, appears throughout their remarkable correspondence. If you think about it, calling a person "my lover" or "my spouse" particularly defines that person. But if you call someone "my friend" in the context of the Adams' marriage, that conveys a special relationship, indeed. So, this is a very moving story about love and sex that stood the test of time. It is a truly American love story. Now, I'll bet you never thought of John Adams as a poster boy for romantic love, did you? But it's the truth.

Now I am ready for your questions about male sexual health.

QUESTION: This is about MUSE. It comes in varying doses and the first dose prescribed for me resulted in a three hour erection and it was painful. I had read all the accompanying warn-

ings about the dangers of prolonged erection, so I didn't want to try it again. After lower doses were

prescribed, I found it was effective. It's the aching part that I don't like. Also, how long can I continue to rely on it before it becomes less effective?

DR. DEAN: Yes, that's a major complaint about MUSE. About 35-40% of men are going to complain about the ache and soreness. It's understandable that a three-hour erection concerned you (not to mention your wife!), so a lower dose was the appropriate response.

Now you also asked how long it would likely be effective for you. There are multiple factors that will determine how well it's going to continue to work for you. If you stay exactly the same as you are tonight, it's likely to work forever for you. But you're not going to stay the same. You are going to get older. Your blood vessels will not work as well, so the drug will be less effective. When the drug becomes less effective, you have a couple of options. We can increase the dose or move you to a different therapy. Unfortunately, when the dose is increased there could be more side effects. MUSE is available in four doses. As a practical matter in clinical practice we often end up using only the two highest doses because we find that men usually do not respond at the lower doses. This is especially true for men who had surgery or radiation as their primary therapy for prostate cancer. In short, in dealing with male sexual health, we use an appropriate therapy until it is no longer effective, or the patient indicates a preference for an alternative treatment.

QUESTION: Regarding the emotional, psychological aspect of "getting in the mood," is MUSE almost automatic, that is, it's going to provide an erection even if I am only reading the comics?

DR. DEAN: That's correct. MUSE, the injection therapy, and the penile prosthesis are going to provide an erection generally no matter what you are doing, talking about, or looking at. That's because the nerve function doesn't have to occur for MUSE to work. But Viagra, Levitra, and Cialis require sexual stimulation to cause erections.

By the way, did you know that at the outset Pfizer developed Viagra for heart disease? The men being treated for heart disease weren't getting significant cardiac benefit, but they always showed up for their appointments with smiles on their faces! It didn't take Pfizer long to know they were on to something, so, as they say, the rest is history!

QUESTION: Thank you very much for your presentation. I have one question. Is the penile prosthesis covered by medical insurance?

DR. DEAN: Yes, in most instances it is. The large majority of healthcare insurance companies will cover it for sexual health treatment. MEDICARE covers it and the healthcare insurance companies usually follow MEDICARE's lead. Insurance coverage may vary for the PDE-5 inhibitors, MUSE, and the injection therapies. For example, insurance companies may have certain limitations on the amounts they will cover on a monthly basis.

QUESTION: My question is related to MUSE in combination with other therapies. I was initially prescribed MUSE, but my new urologist has added Levitra to my treatment.

DR. DEAN: I prefer not to use combination therapy for ED. It may be beneficial in certain cases, but it can complicate matters. If MUSE is no longer working for you, my first preference would be to increase the MUSE dosage or switch you to injection therapy. I find that more patients are satisfied when they use a single therapy that works consistently for them.

Nevertheless, if the MUSE-Levitra combination is working for you and you are happy with it, I would not change it. Here's why. Male sexual health is patient-driven therapy, not doctor-driven therapy. This is a very important point that I want to leave with you. I can make the diagnosis, explain the options, and even make a recommendation, but you tell me what you want to try. As long as I think it's safe for you, I am going to let you try it.

QUESTION: You mentioned nerve-sparing during surgery, but I'm concerned about the nerves affecting the glans penis. I understand they are a different set of nerves and I certainly notice that my sensation is much diminished since my prostatectomy about five years ago. I mentioned this to a previous speaker and he said if it hasn't returned by about two or three years, I can pretty much forget about it. Can you comment on that?

DR. DEAN: You are correct that the nerves causing sensation in the glans penis are different

nerves from the neurovascular bundles at the prostate. During an erection the glans penis is hypersensitive, providing a pleasurable sensation. This brings up the broader question of penile alterations associated with surgery and radiation, particularly penis length. Some men notice a decrease in their penile length after surgery or radiation. We think this is due to smooth muscle loss as well as collagenization or fibrosis occurring in the penis. Think about it this way: if I perform shoulder surgery on you and put you in a sling for a month, then remove the sling and tell you to resume use of your shoulder, it's going to take time for the muscles and ligaments to achieve normal function, and the shoulder may never regain its former condition. The same phenomenon is true for the penis after cancer therapy. If you are not getting erections, the smooth muscles aren't being stretched and worked and atrophy occurs, making the penis smaller. The surgeon didn't reduce the size of your penis; it just starts to tighten up after the surgery. That is why early post-cancer therapy resort to the vacuum pump, the PDE-5 inhibitors, or injection therapy is recommended. It is important to keep the "system" stimulated.

So yes, the primary therapies for prostate cancer may affect the penis beyond the effect on erectile capacity. The loss of sensation you describe is one of them. We are now studying these issues much more than we did earlier. First, we wanted better erections for men with ED, and for the most part, we are doing OK on that score with the ED therapies I've described tonight. But now we are moving beyond that to the whole sexual episode of sensation and orgasm. Unfortunately, 4% of men after surgery or radiation will have dysorgasm (painful orgasm). Some men will have urine leak with orgasm, other men won't ever reach orgasm. So we must get to work on these kinds of problems.

QUESTION: If a man already has an artificial urinary sphincter in place, can he still have a penile prosthesis?

DR. DEAN: Yes, he can also have a penile prosthesis. As a matter of fact, some surgeons implant them in a single procedure for men with severe incontinence and ED. For example, one company, American Medical Systems, the sponsor this evening, makes the AMS 700, the penile prosthesis. They also make the AMS 800, the artificial sphincter. I suppose we could designate the combination as AMS 1500. (Laughter)

QUESTION: Is there an age limit to installing the penile implant?

DR. DEAN: In the practical sense there is no upper age limit. There's no younger limit either. The oldest person for whom I placed one was 84 year old. Beyond the ED associated with prostate cancer therapy, men with spinal cord injuries, pelvic fractures, and some of our Wounded Warriors from Iraq and Afghanistan require penile prostheses. It's an important quality of life factor for these men.

QUESTION: We frequently see advertisements on TV or the Internet for products to promote prostate health or enhanced sexual performance. Is this medicinal snake oil?

DR. DEAN: The quick answer is yes. If that stuff worked I'd already be giving it to my patients. Patients often bring such products or advertisements to me and ask my opinion. There's usually an 800 telephone number available. I call it. The minute I say, "Hello, I'm Dr. Dean from Walter Reed Army Medical Center and I want to talk with you about your product," then I hear a click! That tells you something right then and there. Trust me. They are banking on a placebo effect, that is, the tendency of a person taking a product to expect to improve. Remember that study about the effectiveness of Levitra after surgery? Ten percent of men who got the placebo reported good erections!

QUESTION: In a related matter, I read and hear advertisements from what appear to be reputable group medical practices offering almost guaranteed effective treatment for ED.

DR. DEAN: Yes, they seem to be a chain or franchise practice specializing in male sexual health. Men who have visited this group have appeared in our clinic. When I inquire about the experience, they say "Well, they took a history, measured my penis, and did that injection for me and they charged me $1,600." I'm not making this up! For those of you within the military healthcare system, you can be assured that we can provide you with state of the art care for male sexual

health. I do not doubt that this medical group can help men deal with male sexual health issues. They do help many men, but the men are going to have a substantial upfront cost

QUESTION: For men who have painful erections after RP, is there improvement over time?

DR. DEAN: Men with painful erections after surgery or radiation can improve over time by using the penis. It's just like physical therapy on that shoulder I spoke about earlier. The sling comes off and the physical therapist makes the patient work his shoulder. It hurts, but over time the pain is reduced or eliminated. So it's a rehabilitation process. The same principle applies to the painful erection after primary therapy for prostate cancer. There are very few medicines that are indicated for painful erections, and as far as I know, none are under development. There are some medications intended for other purposes that have proven helpful in the treatment of the painful erection. Their "off label" use in special situations is an alternative that should be considered.

QUESTION: I am interested in your comments about injection therapy with three drugs in combination. I am using just a single drug called Caverject. Are there any differences in efficacy between the single drug and the multiple drug combination that you described?

DR. DEAN: There are two single, self-injection drug products on the market, Caverject and Edex. They are neatly packaged, easy to use, and effective. The injected drug is called alprostadil. The ED therapy I prefer is a mixture of three drugs that work synergistically. They are papaverine, phentolamine, and a small amount of alprostadil. We refer to this combination as Trimix. It seems to work better and I can adjust the dose of each drug, using smaller amounts of each to achieve the same benefit. This should also result in fewer side effects. As I noted above, the single-drug products use alprostadil which can cause painful erections. Also, about 10-15% of men using it will have penile scarring (fibrosis). So if you are using the single-drug therapy, it important to see your urologist every four to six months to make sure that penile scarring is not occurring. The pain and the scarring aren't as common with Trimix. That's why I like it. Nevertheless, its users should also regularly see their urologists to be sure it is working as expected.

QUESTION: It there a relationship between a penile implant and a rising PSA?

DR. DEAN: Absolutely not. A penile prosthesis definitely does not cause a rising PSA. I have put penile prostheses in patients with rising PSAs. Here is how I operate. A man with ED comes to me, he understands the pros and cons of having a penile prosthesis, and he requests a penile prosthesis, then I am going to give him a penile prosthesis. If he has an artificial hip, if he has rising PSA, if he has high blood pressure, I am going to give him a penile prosthesis, if it is consistent with his physical condition. Now if he has uncontrolled diabetes or poorly controlled hypertension, we are going to fix his medical conditions first, and then we are going to put in a penile prosthesis. Remember, male sexual health is patient-driven, not doctor-driven.

QUESTION: Back to painful erections. How prevalent are they? And in a related question, does urine leak during orgasm clear up over time as well?

DR. DEAN: Let's take urine leak during orgasm first. There are no comprehensive studies on that topic, but we know that about 4% to 10% of men will experience it. We simply do not know if the condition improves over time. Furthermore, that 4-10% estimate is based on reports from patients and we suspect it is underreported. How many times has your primary care physician or your urologist asked whether you leak urine during orgasm? The fact is that the question goes unasked, so we don't have a great feel for the extent of the condition. The small studies done to date say it's about 4 to 10%. We surmise that if the sphincter mechanism should improve its function after primary therapy, the urine leak should also improve.

Now back to painful erections. I must rely here on my clinical experience. In my practice I estimate that about 50% show improvement. I am rather aggressive in treating men who approach me about that condition. I perform a penile ultrasound on them to see if there is any scarring that may be the problem. If I detect that this is the case, I have to treat the scar separately. If I think

there is some fibrosis (dense scarring), then I consider certain medications that may help. We also discuss certain pain medications as well as certain muscle relaxants that work on the bladder and the penis. As you can see, there are several options, none of them guaranteed.

QUESTION: Would you address the issue of starting Viagra or equivalent therapy soon after surgery in order to regain adequate erectile function sooner?

DR. DEAN: This is what penile rehabilitation therapy is all about. It's my belief that men who undergo surgery or radiation for prostate cancer should start having erections as soon as possible. If they need help in this regard, we should offer them the vacuum pump, the PDE-5 inhibitors, or injection therapy – whatever works. Think about it as physical therapy for your penis (remember my shoulder analogy earlier?) Here at Walter Reed we are involved with a study to determine how much medicine is needed and how long is it required to rehabilitate the penis after primary therapy for prostate cancer. And even more basic, are these rehabilitative efforts effective in the first place. At the moment, we have about 45 men enrolled in that study. It's a long-term study and we are very grateful to these men who have volunteered their time (not to mention their penises!) to our efforts to better understand the penile rehabilitation process. We should have sufficient data in a year or so. Until then, we are relying on some earlier studies that show penile rehabilitation is marginally helpful. Well, if it's marginally helpful, it should be available to our patients.

QUESTION: There was some talk about a topical ED medication. What is happening here?

DR. DEAN: The topical ED medication is still a work in progress. It's basically a MUSE pellet (alprostadil**)** in cream form. You rub it all over your penis in the hope that it penetrates. There are some problems with it. It does not penetrate well or defuse into the penis well.

At this point, let me introduce another research topic - stem cell research for erections! This tries to regenerate the injured penile nerves or actual penile tissues using new active stem cells. Early testing with rats holds some promise, but obviously there is a long road ahead. Then there are ongoing clinical trials for vaccine therapy for erections. The idea is to develop a vaccine that would help neurotransmitters make the nerves work better. This is a major effort involving institutions such as Tulane University, the University of California at San Francisco, Harvard, and Johns Hopkins.

QUESTION: I often see comments touting certain herbal products for male sexual health by saying that they contain testosterone-like properties.

DR. DEAN: Testosterone does very little for erections. The male hormone testosterone helps you maintain your body mass, helps your energy level, and helps increase your sex drive. But it doesn't help your penis directly. If you read that it does, you know right then and there that the manufacturer is banking on the placebo effect. Don't buy that product. If you clip the advertisement from a magazine or copy it from the Internet, and bring it in and I'll call the 800 number and they will hang up on me as they always do!

QUESTION: Can the penile prosthesis malfunction or break?

DR. DEAN: Yes, of course. Nothing lasts forever. Our experience is that they are very reliable. At least 50% of the inflatable prostheses (the one with the pump in the scrotum) will still be working at 10-12 years. Remember, it's a mechanical device which eventually will fail to work. The malleable version is more durable, lasting as long as 20 years. The replacement process, when necessary, is relatively simple and patients tend to report less pain after this type of redo surgery.

QUESTION: What is the rate of infection with the prosthesis?

DR. DEAN: As with any surgical procedure, infection is always a major concern. It used to be as high as 5% for the prosthesis, but technological improvements have helped to reduce the infection rate to about 0.8%. For example, the new prostheses now are coated with an antibiotic. Furthermore, we take many precautions to prevent infection. For example, the patient receives preoperative antibiotics via IV before the surgeon even begins; special dressings and drapes are used; access to the operating room is restricted; and the patient remains in the hospital overnight

with continued antibiotic infusion and observation. Then upon discharge the patient receives a two-week supply of antibiotic medication. So yes, infection is a primary concern in any prosthetic implant, be it a knee replacement, hip replacement, or penile prosthesis, but we have learned how to minimize this risk. Let me add here that should infection occur, there are salvage techniques that allow us to remove the infected penile implant and replace it with a new one during the same procedure in some cases.

QUESTION: Which of the two types of prostheses, the malleable or the inflatable, is more frequently preferred?

DR. DEAN: No question about it - the large majority of men prefer the inflatable type because they feel it is a more practical and natural prosthesis. The malleable type is indicated for men with limited manual dexterity and for men who have had major abdominal surgery. Of course, we honor the preference of the patient who is suitable for either type.

QUESTION: In comparing MUSE and the penile injection options, is it fair to say that long-term physical effects would tend to favor the use of MUSE?

DR. DEAN: I would not make that statement. I don't think that comparison has been studied. We do know MUSE, Caverject, and Edex can cause penile fibrosis due to the drug alprostadil itself. We observe this in about 10-15% of the patients. You will recall that with Trimix we can adjust the alprostadil component to a lower dosage, thereby reducing the chance for fibrosis. Whatever delivery system is employed, the patient should have a regular schedule of follow-up with his urologist.

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DEALING WITH ERECTILE DYSFUNCTION

By
DAVID AND SARAH ROBERTS

Introduction

We are David and Sarah Roberts. We are not doctors. We are an average couple who have confronted prostate cancer and its side effects and we want to share our experiences with you. I am a member of the Us TOO chapter at a hospital in Baltimore. Several chapter members have developed a niche, so to speak, based on our particular experiences with the disease. I am the chapter's "implant guy" and this is my story. Sarah will present her views later.

Getting the Diagnosis

I was diagnosed with prostate cancer in 2000. My clinical results were such that I was a candidate for treatment or for watchful waiting. Our daughter died of cancer in 1989; she was thirteen. So selecting my primary therapy was easy. I had cancer in my body and I wanted it out. I was asymptomatic, i.e., no pain or distress. In fact, I felt fine, yet here I was facing a radical prostatectomy. My research made me aware of the possible side effects—incontinence and erectile dysfunction, but I was hoping for the best. My hope was that any side effects would be temporary, and I was determined to work hard to overcome them. But the cancer would be gone, I hoped.

Dealing with Side Effects

I suspect your support group is much like mine. Our members have experienced a variety of primary therapies, even multiple therapies. They have dealt with just about every possible side effect, and as you can understand, their experiences differed. So I have the benefit of their experiences, especially regarding incontinence and erectile dysfunction (ED). My bladder control returned after 4 ½ months, so that issue was taken care of.

Of course, I still didn't have erectile function, but I knew that would take longer, so we waited. Nevertheless, my wife and I were able to make love, and I was able to have orgasms, but they were "dry" ones. After a year without the ability to achieve an erection sufficient for penetration, we began to consider alternatives because we both really missed that aspect of our relationship.

Seeking Help

Viagra-type medications were not an option for me. I had a heart attack in the 1990's and must carry those little nitrate pills in my pocket at all times. So I started looking at the other alternatives. Men in my support group use the vacuum pump, but it held no appeal for me. I tried MUSE, and I had some success, but it was inconsistent. It would work, but the next time, it wouldn't. Next, I considered Caverject, the self-injected medication, but not for long! I guess I'm one of those squeamish guys who cannot even contemplate sticking a needle into his penis!

Temporary Setback

The only option left was the penile prosthesis. "Prosthesis" sounded like an artificial penis, so I prefer the term "penile implant." After more research, I decided to go for it, but my cardiologist declined to give me clearance for the operation because he detected a cardiac condition. Was he ever right! Just after Thanksgiving 2001, I had a massive heart attack that led to quintuple bypass surgery. I'm told that had the attack occurred during the penile implant surgery, I wouldn't be here tonight. After recovery and clearance from my cardiologist, I had the penile implant surgery in 2002. I selected the inflatable version because it seemed to be a more natural process. The procedure and my recovery went as expected and six weeks later, I was back in business, so to speak!

I am sometimes asked whether the penile implant results in increased penile size. No. What you have is what you have. The implants do come in different sizes and are fitted to the individual patient during the implant procedure. I am glad I was asleep during my fitting. If I had realized that my penis was being measured in front of all those people, I would have died of embarrassment!

Success Story

The penile implant is completely unobtrusive. It's totally in the body and no one knows it's there except Sarah and me, unless we care to share our experience as we are doing tonight. We find it to be almost natural in operation. When you are

completely soft, you are completely soft, just like normal. The only difference now is in my scrotum--I have three things inside of two!

I found out that I was not the first guy on my block to have a penile implant. Its use is more common than I imagined. Guys just don't sit around and talk about having it, but once you mention it, just like your prostate cancer diagnosis, some one will pipe up and say "me too." I had a CAT scan a couple of years ago and warned the technician that she was going to see a penile implant. She says she encounters them frequently.

It's better than natural because I can always have an erection. I don't have to worry about being tired or stressed. Whenever I want to have an erection I just pump it up and I am erect and I can stay erect as long as I want. Our general routine is when I think we'll be making love, I go to the bathroom, brush my teeth come back to bed, and when my wife is getting ready, I just pump it up, so when she comes back to bed we are good to go! We couldn't be more pleased. Some friends have expressed concern about a malfunction. Mine has been in place for six years without a problem. I am not worried about it. In the meantime, we are enjoying the restoration of ***all*** of our romantic love. We are so grateful for that. Now Sarah will provide her perspective.

Spouse's Viewpoint

Good evening. I am Sarah Roberts. David had an appointment with a urologist one day. Like the spouses here tonight, I was concerned. He came home to say his PSA was rising. He tried to soften the blow, but the bottom line was that he had prostate cancer. He decided on a radical prostatectomy almost immediately because he was influenced by our daughter's experience.

Now I was frightened. I went to the urology appointments with him. We learned that David would likely be incontinent and unable to have erections for a time after the surgery. I kept telling him that we could live with the outcomes, whatever they were, as long as I still had him. But I must admit that as time passed, his ED made a difference. No, there was no danger of separation. It was just that our physical relationship had been such an important part of our life together, and even though we still made love, we wanted him to be able to penetrate again.

So we were both looking forward with anticipation to the penile implant. But David's massive heart attack made his survival our sole concern. After his recovery and cardiac clearance, our hopes were restored. Frankly, we had noticed the effect of aging and cardiac problems on David's erections prior to his diagnosis for prostate cancer. But that condition is gone now that he has the penile implant. In some ways the penile implant is our fountain of youth. As David said earlier, we can share our physical love whenever we chose and for as long as we chose. And for both of us it's a very natural feeling, not artificial at all. In fact, if he had gone off and had it done without telling me — which I would not recommend — I wouldn't have known (except for an increase in the girth of the penis).

I should mention one other thing. I was very concerned about the penile implant surgery. After all, here was a man who had had one heart attack, a radical prostatectomy, another more massive heart attack, and quintuple bypass surgery. Would he be able to make it through the penile implant surgery? I need not have worried. He tolerated it well, came home the next day, recovered quickly, and was back at work within a week. The only difficult part for him (and me!) was waiting those six weeks to try out our new toy. And it worked (and works!) I am completely satisfied. We have gotten back a significant part of our life together after too long.

If anyone here tonight is enduring ED, we both encourage you to investigate the penile implant as a solution to the problem. We would do it again in a minute! Thank you.

♦ WRAMC US TOO COUNSELORS ♦ (As of August 1, 2008)

(These persons are willing to share their experiences with you. Feel free to call them.)

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Medical Faculty Associates
George Washington University Hospital

♦ TOPIC ♦

"Managing Incontinence after Prostate Cancer Therapy"