MEDICARE WILL PAY FOR PROSTATE CANCER DRUG

Provenge extends survival; it costs $93,000 per individual

The cost of Provenge, an expensive and newly approved therapeutic prostate cancer vaccine, will be covered by Medicare for men with metastatic prostate cancer, the agency announced late June. The vaccine, made by Dendreon, costs $93,000 per patient and extends survival an average of four months, according to results from clinical trials. A panel of experts convened by Medicare gave the nod for coverage last November, but the agency has only now announced it would cover the treatment nationwide.

“We are optimistic that innovative strategies may improve the experience of care for our beneficiaries who have cancer,” Dr. Donald Berwick, administrator of the Centers for Medicare & Medicaid Services (CMS), said in a news release. “CMS is dedicated to assuring that these patients can seek the treatments they need in accordance with their wishes.”

Research suggests the vaccine can extend men’s lives with cancer that has spread beyond the prostate. One study, published in the New England Journal of Medicine in July 2010, found that the vaccine extended survival in men with castration resistant prostate cancer

LONG TERM EFFICACY RESULTS FROM THE PHASE 1-2 STUDY OF MDV3100 IN PRE- AND POST-DOCETAXEL ADVANCED PROSTATE CANCER

This study provided an evaluation of MDV3100, a novel androgen receptor (AR) antagonist with activity against prostate cancer over-expressing AR. MDV3100 induces cell death in bicalutamide-resistant tumors via three actions on AR: direct antagonism, inhibition of nuclear translocation of the AR complex, and inhibition of the AR from binding to DNA. MDV3100 has no AR agonist activity in laboratory studies.

In patients, preliminary antitumor activity and adverse events was reported in advanced prostate cancer from a phase 1-2 study of MDV3100. Dr. Mohammad Hirmand presented the long-term follow-up for time to PSA and radiographic progression at the 26th Annual European Association of Urology (EAU) Congress in Vienna, Austria.

Patients with progressive castration-resistant prostate cancer (CRPC) were enrolled in sequential cohorts of 3 to 6 patients of MDV3100 doses of 30, 60, 150, 240, 360, 480, and 600 mg/day. After confirming dose tolerability, enrollment was expanded for doses ≥60
OncoGenex Pharmaceuticals, Inc. announced new data showing how the company’s lead investigational compound, custirsen (OGX-011/TV-1011), may work with innovative therapies MDV3100 and heat-shock protein 90 (Hsp90) inhibitors to suppress prostate cancer cell survival and improve treatment outcomes. These preclinical data were presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO), June 3-7, 2011.

Cancer cells can develop resistance to treatment over time, leading to treatment failure and disease progression. Custirsen is the only compound in development designed to inhibit the production of the protein clusterin, commonly overproduced in cancer cells and a cause of treatment resistance. In preclinical models custirsen has enhanced the activity of hormone ablation therapy, radiation therapy and chemotherapy.

“As new treatments become available for castrate-resistant prostate cancer (CRPC), these types of data can help clinicians understand when and in what combinations to use them,” says Dr. Martin Gleave, Director of The Vancouver Prostate Centre at The University of British Columbia. “It’s important to support academic partnerships that will help us understand the best way to optimize treatment and minimize drug resistance in late-stage prostate cancer patients.”

Data evaluating custirsen in combination with second generation antiandrogen therapy MDV3100 in a CRPC model was presented as part of an oral session, “Translational Science Advancing AR Targeting in Prostate Cancer” [Abstract #4502]. The study found that combining custirsen with MDV3100 more potently suppressed prostate cancer cell growth rates than either drug alone. The combination showed a synergistic effect in combining custirsen and MDV3100, down-regulating androgen receptor (AR) level and activity and suppressing androgen-sensitive prostate cancer cell growth in vitro and in vivo. In castrated male athymic mice, the combination significantly delayed castrate resistant tumor growth progression compared to control (scramble antisense oligonucleotide + MDV3100) at 12 weeks.

In another preclinical study presented [Abstract #4573], custirsen was shown to work synergistically with Hsp90 inhibitors PF-04928473, 17-AAG, and PF-04929113 to inhibit tumor growth. While several small molecule Hsp90 inhibitors are showing efficacy in CRPC and other cancers, most also trigger the elevation of compensatory survival mechanisms that result in the production of clusterin, leading to cancer cell survival and treatment resistance. In vitro, custirsen enhanced the activity of both PF-04928473 and 17-AAG on cancer cell growth and cell death. In vivo, custirsen combined with both PF-04929113 and 17-AAG significantly inhibited tumor growth by 80% and prolonged survival in a CRPC model compared with each agent alone.

These preclinical data further support the ongoing, Phase 3 custirsen development program in prostate cancer:

- The Prostate Cancer SATURN trial, evaluating a durable pain palliation benefit for custirsen in combination with docetaxel re-treatment as second-line chemotherapy in approximately 300 patients with CRPC
- The SYNERGY trial, evaluating a survival benefit for custirsen in combination with first-line docetaxel treatment in approximately 800 patients with CRPC

In Phase 2 trials of patients with metastatic CRPC, custirsen combined with docetaxel showed a 6.9 month improvement in overall survival over docetaxel alone. Additionally, 50 percent of patients experienced durable pain palliation for a duration of 12 weeks or longer. Custirsen has received Fast Track designation from the US FDA. More information is available at <www.OncoGenex.com> and <www.tevapharm.com/research>.

PRNewswire, 6 June 2011
advanced prostate cancer – information that can’t be found anywhere else on the Internet,” explained Us TOO President and CEO Tom Kirk. “So we assembled an advisory team of nine people who’ve been directly affected by advancing prostate cancer to offer insight and advice based on what’s worked well for them or for someone they’ve known personally. They cut to the chase and shared their wisdom and experience specific to the issues faced by someone with advancing disease.”

The new brochure, The Advanced Prostate Cancer Resource Kit provides an interactive table of contents with links to all new and existing Us TOO content specific to advanced prostate cancer. Topics include charting and assessing disease state, evaluating treatment options, developing a treatment plan, and anticipating side effects. Additional topics cover the eventual need for an end-of-life plan along with the importance of being empowered daily through diet, exercise, spirituality and humor.

The other new brochure, Principles for Managing Advanced Prostate Cancer, outlines “The 7 Principles of Empowerment,” to provide the direction and knowledge necessary for people to self-manage their care. The comprehensive content from Us TOO specific to advanced prostate cancer can be used as a tool to help individuals seeking information and answers independently. It also serves as the framework to facilitate in-depth discussions at Us TOO support group meetings.

“Much can be done to manage advancing prostate cancer and maintain a high quality of life regardless of the disease state. But you have to take control of managing your disease,” noted Russ Gould, leader of the Mets Mavericks support group in Palatine, Illinois, that was formed to help those battling advanced prostate cancer. “Many of the men who attend our meetings have been successfully managing the treatment of their advancing disease for ten or 15 years; and a few for more than 20 years.”

The new Us TOO brochures emphasize the importance of empowering advanced prostate cancer patients to ask the right questions, to seek the opinion of more than one physician, and to never blindly trust the treatment recommendation from any single doctor. The materials feature treatment charts and graphs that can be personalized along with quotes, tips, and even some humor.

“The greatest benefit from this new information is the positive impact it will have on the lives of countless men and their caretakers who are battling advancing disease,” added Us TOO International Chairman of the Board Fred Mills. “After reading this material, many people will have new information that will inspire them to develop a more effective approach to managing their prostate cancer treatment. That’s the bottom line. That’s why we’re here.”

Advisory team members included: Fred Gersh, Russ Gould, Shirley Grey, RN, MSN, Jerry Hardy, Jim Kiefert, EdD, Kay Lowmaster, MSW, LCSW, Fred Mills, Charles “Snuffy” Myers, MD, Paul F. Schellhammer, MD, Kathy Scortino, RN, MA, LCPC, Chuck Strand, Us TOO staff Tom Kirk and Pam Barrett, and designer Charlie Sauer.

PROVENGEE COVERED BY CMS
(Continued from page 1)

CRPC), compared to no treatment with less toxicity than chemotherapy.

Provenge is a therapeutic (not preventive) vaccine made from the patient’s own white blood cells. Once removed from the patient, the cells are treated with the drug and placed back into the patient. These treated cells then trigger an immune response that in turn kills cancer cells. The vaccine is given intravenously in a three-dose schedule delivered in two-week intervals.

“The strategy of trying to harness the immune system to fight cancer has been something that people have tried to attain for many years; this is one such strategy,” stated study lead researcher Dr. Philip Kantoff, a professor of medicine at Harvard Medical School and a medical oncologist at the Dana-Farber Cancer Institute in Boston.

Speaking at the time of the drug’s CMS approval, Dr. Elizabeth Kavaler, a urologist at Lenox Hill Hospital in New York City, said that “in this unfortunate category of [CRPC] patient, we have very little to offer. Adding months to a man’s life is better than doing nothing, especially if the treatment involves minimal morbidity, as this vaccine promises.”

In his team’s study, Kantoff’s group randomly assigned 512 men to receive Provenge or a placebo. All of the patients had advanced CRPC. On average, men receiving Provenge lived 4.1 months longer – 25.8 vs. 21.7 months, respectively, than men receiving placebo. He contends that if the vaccine were used by men with less severe disease, survival might be extended even longer.

Compared with other treatments, such as chemotherapy, radiation and hormone therapy, Provenge has been touted as having fewer and less severe side effects. In this trial, the most common side effects were chills, fever and headache.

Kantoff said that “this is a treatment given over a four-week period, as opposed to other treatments that are given over many months, where the costs can be high as well, if not comparable to or more expensive [than Provenge].”

HealthDay News, 30 June 2011
Kyphon® Balloon Kyphoplasty Beneficial For Treating Spinal Fractures In Cancer Patients

Study showed minimally invasive procedure provided better back function, more rapid back pain relief and improved quality of life compared with non-surgical care

Medtronic Inc. announced the results of the first randomized, controlled trial comparing Kyphon Balloon Kyphoplasty with non-surgical care in treating spinal fractures in cancer patients.1 The study found that Kyphon Balloon Kyphoplasty provided cancer patients better back-specific function, more rapid back pain relief and improved quality of life (QOL) compared with non-surgical care one month after treatment.

The study was published in the online edition of The Lancet Oncology on 17 February 2011. It involved 134 patients with vertebral compression fractures who also had various types of cancer such as breast, lung, and prostate or had multiple myeloma. The study, Cancer Patient Fracture Evaluation or CAFE took place at 22 sites in the US, Europe, Australia and Canada.

“The results of this landmark study should be welcomed news to cancer patients across the world suffering from the debilitating effects of painful vertebral compression fractures,” said Dr. James Berenson, the study’s first author and Medical and Scientific Director of the Institute for Myeloma and Bone Cancer Research in West Hollywood, CA. “It is documented that nearly one-fourth (24 percent) of patients with multiple myeloma, 14 percent with breast cancer, 8 percent with lung cancer and 6 percent with prostate cancer suffer painful vertebral compression fractures.”

Patients in the CAFE study were randomized to either a surgical group (n=70) or a non-surgical control group (n=64). Members of both groups were able to receive non-surgical care, such as pain medications, bed rest, bracing, walking aids and radiation therapy, as medically necessary.

Multiple outcomes relating to QOL, physical function and back pain were evaluated in 129 patients (68 surgical and 61 non-surgical). The primary outcome was the change in back-specific function from baseline to one month between the groups as measured by the validated Roland-Morris Disability Questionnaire (RDQ) score, with 0 equal to no disability and 24 equal to maximum disability.

Key study findings were as follows:

- **Functional status**
  The kyphoplasty group’s functional status as measured by the RDQ at one month showed clinically and statistically significant improvement, with a mean improvement from baseline of -8.3 points (p<0.0001). The control group showed no statistically significant change in RDQ score (0.1 points; p=0.83). At one month, more surgery patients (51/63, 81%) had clinical improvement compared with control patients (14/50, 28%) based on the smallest change needed for clinical meaning (p<0.0001).

- **Back Pain Relief**
  Seven days after treatment, surgical patients experienced clinically and statistically significant improvement in back pain from baseline of -3.8 points compared with the minimal change of -0.3 points by the control group. The treatment effect for improvement from baseline was -3.5 points (p<0.0001) within seven days and -3.3 points (p<0.0001) at one month, in favor of surgery.

- **Improved QOL**
  Kyphoplasty patients experienced better improvements in QOL compared with the control group. The surgery group showed a clinically and statistically significant 8.4-point improvement (p<0.0001) in QOL compared with the control group in the SF-36 Physical Component Summary at one month. Improvement of 3.5 points is considered clinically meaningful. The surgery group also showed a mean 11.1-point QOL improvement (p<0.0001) compared with the control in the SF-36 Mental Component Summary score at one month.

- **Safety Findings**
  Medical adverse events were similar at one month between the two groups. The most common adverse events within one month were back pain (4/70 for surgery and 5/64 for control) and symptomatic vertebral fracture (2/70 for surgery and 3/64 for control). There was no difference in radiographic or clinical subsequent vertebral fractures between the two groups at one month. A subsequent vertebral fracture within a month of the index procedure observed in one surgery patient (with cement leakage to the adjacent disc) was a serious adverse event reported as related to the device.

There are risks associated with the procedure including serious complications, some of which may be fatal. Patients should consult their physicians for a complete list of indications, contraindications, benefits, and risks.

For more information on the study, go to <www.compressionfracturestudy.com>. For more information on Kyphon Balloon Kyphoplasty, go to <www.balloonkyphoplasty.com>.

Medtronic, Inc., 16 February 2011
LONG-TERM MDV3100 RESULTS
(Continued from page 1)

mg/day to include approximately 24 patients (n=12/group) per cohort who were either chemotherapy-naïve (naïve) or previously treated with docetaxel (post-chemotherapy). One hundred forty patients were enrolled and 18 (13%) continued on active treatment (naïve, n = 16; post-chemotherapy, n = 2) at a median of 131 weeks after starting MDV3100 therapy.

Long-term follow-up results demonstrate that median time to PSA progression (when defined as a 25% increase in PSA from baseline) was not reached in naïve patients and was 20 weeks in men previously treated with chemotherapy. PSA progression (when defined as Prostate Cancer Working Group 2 definition) was 56 and 24 weeks in naïve patients and men post-chemotherapy, respectively.

CTC counts were available in 128 of 140 patients of whom 91% (70/77) of patients with favorable pre-treatment CTC counts remained favorable post-treatment, whereas 49% (25/51) converted from unfavorable pre-treatment status to favorable post-treatment status.

MDV3100 is presently under evaluation in 2 ongoing global phase 3 studies in patients with advanced progressive prostate cancer: the AFFIRM study in patients previously treated with docetaxel, and the PREVAIL study in asymptomatic or mildly symptomatic chemotherapy-naïve prostate cancer patients who have progressed following androgen deprivation therapy.

Written by Christopher P. Evans, MD, for UroToday.com, 9 May 2011

PROSTATE CANCER IN MEN LESS THAN THE AGE OF 50:
A COMPARISON OF RACE AND OUTCOMES

Parker PM, Rice KR, Sterbis JR, et al
Urology 78: 110-5, 2011

Objective: To compare clinicopathologic features and survival outcomes for men 50 years of age in relation to other age groups stratified by race to further define prostate cancer (CaP) in young men. Controversy exists regarding the appropriate age to undergo CaP screening, outcomes for early intervention, and whether there is unique age-associated tumor biology. We compared clinicopathologic features and survival outcomes for men <50 years of age in relation to other age groups stratified by race to further define CaP in young men.

Methods: A multi-institutional review of 12,081 records of patients diagnosed with CaP from 1989-2009 was conducted. Patients were stratified by age group, race, and decade of treatment. Demographic and clinicopathologic characteristics were compared across age groups using chi-square tests and analysis of variance. The primary study endpoints, time to biochemical recurrence (BCR) and all-cause mortality, were compared across age groups using Kaplan-Meier estimation and univariable and multivariable Cox proportional hazards analysis.

Results: Only 4.5% of the study sample was <50 years of age. A higher percentage of African Americans diagnosed were <50 compared with Caucasians (8.3% vs 3.3%, P < .0001). Positive family history was more prevalent in the <50 cohort (36.1% vs 22.0%, P < .0001). Despite these findings, both racial subgroups for men <50 years of age demonstrated improved clinicopathologic features than other age quartiles. Furthermore, both Kaplan-Meier and Cox proportional hazard analysis demonstrated the <50 cohort had a lower incidence of BCR and greater overall survival.

Conclusions: Race and family history appear to play a significant role in the incidence of CaP in younger men. Younger age at diagnosis is associated with more favorable outcomes and indicates that population-based screening at younger ages could potentially lead to improved survival for high-risk groups.
ASK DOCTOR SNUFFY MYERS
After reading your video on ADT and bone loss, I have two basic doubts if estrogen is indeed so useful and harmless (a little cleavage will do no harm!): 1. What is the long term effect of being on estrogen as we have been told that after some years hormonal therapy becomes ineffective? 2. Is it then a good idea to have an ‘estrogen light’ course in an intermittent manner for those with localized prostate cancer and on active surveillance so that the little risk of active surveillance also disappears? The strategy could be to take some estrogen until a benchmark PSA level is reached, discontinue it and if PSA starts to rise beyond a predetermined benchmark limit, start it again? This way one would have succeeded in keeping prostate cancer at bay without the rigors of other treatment/risk of overtreatment.

You seem to mix low dose estrogen for bone loss with the higher doses of estrogen used to treat the cancer. So, I will recap what we know and how it relates to your questions.

In men, some of the testosterone is converted to estradiol and then estrone. Some of this happens in the bone and it is thought that that estradiol plays a key role in normal bone health. When a patient is treated with an LHRH agonist, such as Lupron®, Zoladex®, Trelstar® or Eligard®, testosterone levels fall dramatically. Since testosterone is used to make estradiol, its levels fall as well. Low dose estradiol through the skin can be used to restore serum estradiol levels to those found in normal adult males. When you do so, bone loss is reduced and hot flashes are less intense for many patients. There is no evidence that this low dose of estradiol has any anticancer impact and thus it should also not lead to hormone resistant cancer.

High dose estradiol at levels reached during the first trimester of a pregnancy does exert anticancer effects. Of my colleagues, I think Paul Schellhammer, has written most clearly on this subject. (Continued on page 7)

DOC MOYAD’S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS “NO BOGUS SCIENCE” COLUMN

“You want another reason to lose weight? How about free vitamin D?!”
Mark A. Moyad, MD, MPH
University of Michigan Medical Center, Department of Urology

Bottom Line: Research has now demonstrated that the greater the weight or waist loss, the greater the increase in your vitamin D level! Groovy stuff!

Vitamin D is everywhere folks! And, there are all kinds of “experts” telling you how much you need to be getting daily. Heck, most pharmacies and supplement stores even sell over the counter vitamin D in 5000 IU pills! 5000 IU! Other bone (pun intended) headed “experts” are telling you to take high doses of supplements and to get more sun? Isn’t that great advice?! Overdose on vitamin D and simultaneously increase your skin cancer risk?! Who needs Monty Hall when you can get that kind of 2 for 1 deal (sarcasm alert)? And, if you wonder who the heck is Monty Hall, then shame on you for not watching more television a few decades ago!

Anyhow, what you are not hearing is that as you become healthier over time, your vitamin D level naturally increases and you do not have to spend a penny. For example, a recent clinical trial following individuals that lost weight over 1 year by reducing calories and/or exercising about 30 minutes 5 times a week found that some folks were able to increase their vitamin D levels by over 7 points (a large jump) or more with some weight loss.1 It has been known for some time that obese individuals tend to have lower vitamin D blood levels. The theory is that since vitamin D is fat-soluble, it likes to bind itself to fatty tissue and the more fat in the body, the less vitamin D able to circulate in the blood.

Regardless of the reason, researchers began to get more curious and wonder what would happen if someone loses weight WITHOUT getting more vitamin D from diet or supplements. Sure enough, vitamin D blood levels naturally increase as weight loss occurs, regardless of the time of year. So, now I want you to think about a few things for a second the next time you are told that you HAVE TO TAKE higher doses of vitamin D. If you lose weight, lower your cholesterol, exercise, and eat more fatty and oily fish high in omega-3 (anchovies, herring, mackerel, sardines, salmon, trout…) then you could naturally raise your vitamin D level (the other healthy changes were mentioned in previous Moyad columns).

This tip alone should save you enough money to be able to contribute to Us TOO and the Moyad Beer fund in the future (both are very worthy causes)!

Reference:

In sports, games are ON THE LINE every day...

But more importantly, so is your health.

1 IN 6 MEN WILL BE DIAGNOSED WITH PROSTATE CANCER IN THEIR LIFETIME

Know your risks and treatment options

Us TOO International is proud to be one of the featured teammates and resource partners in ON THE LINE – a groundbreaking initiative that harnesses the power of sports and celebrities to challenge men to get off the sidelines and take charge of their prostate health. Visit <www.OnTheLine.com> for videos, magazines and other resources.
a1p1c1 Any man reading page one of this month’s HOT SHEET will be relieved by the decision that Medicare will pay for Provenge. This was based on the most recent study demonstrating a four-month improvement in survival compared to placebo in men with progressive prostate cancer while on hormone therapy. As most men know, the cost of this 3-dose therapy is very high, totaling $93,000.00! Around the country, many people are concerned that increasingly costly treatments will further constrain our healthcare system.

Our country already spends more on health care than any other country. At the same time, almost everyone complains about high taxes. Eventually, we will have to cope with a difficult problem. If the total amount available for health care is not unlimited, then paying for more expensive treatments with only a small benefit may deny greater benefits to larger numbers of individuals. There is no easy solution short of finding other sources of dollars to pay the cost.

THE BOTTOM LINE:

Eventually, we may be forced to decide that there is a limit to the amount of money the government should spend to improve survival by only a few months. This challenge needs to be confronted sooner rather than later.

a4p2c1 Two new therapies under investigation provide preliminary, yet encouraging positive results combined with MDV 3100, which works on the androgen receptor, is being tested in men following progression on docetaxel chemotherapy. Early phase results discussed in this issue were positive enough to continue with phase III randomized studies that already are in progress and may be available later this year.

The second drug, Custirsin works by inhibiting production of a protein that enables cancer cells to become resistant to different treatments. Studies presented at recent meetings show this drug may help improve results with several different therapies. Phase III studies are also in progress and hopefully they will demonstrate beneficial results.

THE BOTTOM LINE:

New advances continue to offer patients new options for advanced disease. Hopefully, studies will deliver positive results that can lead to FDA approval.

a5p4c1 One consequence of aging that is increased in men on hormone therapy is spinal cord compression due to osteoporosis. The study on kyphoplasty offers patients another option. It involves injecting cement into the disc space to help stabilize the spine. The randomized study demonstrated significantly improved quality of life and reduced pain compared to a conservative approach. Although some severe side effects can occur, their incidence is low but it needs to be done by experienced clinicians.

THE BOTTOM LINE:

Kyphoplasty offers a new option to help relieve pain from vertebral compression fractures.

a6p5c2 The next paper reviewed is a retrospective look at outcomes in men under age 50. The study compares the pathological features and outcomes to older groups of men with results suggesting better outcomes. Based on the results, the authors conclude that screening in younger age groups, particularly African Americans or men with a family history of prostate cancer might have added benefit from screening for this disease. Unfortunately, there are many uncontrolled variables that prevent any reliable conclusions. There is no way to be sure that the conclusions are valid unless a better study design is used.

THE BOTTOM LINE:

Once again, caution is advised about trying to draw any conclusions from uncontrolled, retrospective studies.

a10p8c1 Lastly, an encouraging study was reported using hydro dissection as an aid during open radical prostatectomy to help improve nerve sparing. The study was done by a single surgeon and used consecutive patients. The first group did not have the hydro dissection while the second group all had it done. The results showed an earlier time to regaining sexual function and higher sexual function scores using written surveys in the men having hydro dissection.

Although the two groups appeared to be balanced, the study results must be questioned. Other factors, such as further refinements in technique over time could account for the results. Although a randomized study would be more accurate for assessing this technique, another option would be to have the same surgeon alternate cases to reduce potential biases.

THE BOTTOM LINE: This initial report is encouraging but further work is needed to determine that the improvements are not a result of a biased study.

ASK DOCTOR SNUFFY MEYERS

(Continued from page 6)

At present, I do agree with him that this appears to be remarkably well tolerated by most men.

However, some men do have problems. Some are very upset with breast enlargement and I have seen several become depressed about this. For some men, a little cleavage is indeed a big issue. Some men retain fluid and get ankle edema. This appears to be more of a problem in those on a high salt diet or who have heart or kidney problems.

We do not have clinical trials randomizing patients to transdermal estradiol versus any LHRH agonists, so we really cannot accurately compare the side effects of the two treatment options. We also do not have long-term survival data on transdermal estradiol and that is a significant gap in our knowledge. However, I have patients who are experiencing multi-year cancer control after Lupron and related drugs have failed. I would not be a fan of adding estradiol to an active surveillance program as, by definition, it would no longer be active surveillance. I must say my enthusiasm for this approach is also lessened by the fact that we are seeing prostate cancer become undetectable on a rather simple nontoxic program of a Mediterranean heart healthy diet, Avodart, and a few supplements. I discussed this in Prostate Forum Volume 11 #9 and Volume 11 #10 and this trend seems to be continuing since I made those comments.
Hydrodissection of Neurovascular Bundles During Open Radical Prostatectomy Improves Postoperative Potency

Patel MI, Spernat D, Lopez-Corona E


Purpose:
Preservation of the neurovascular bundle during radical prostatectomy (RP) is important for postoperative erectile function. We determined whether hydrodissection of the neurovascular bundle during RP would result in improved erectile function postoperatively.

Materials and Methods:
Included in the study were 253 consecutive men who underwent nerve sparing RP, as done by 1 high volume surgeon (MIP). The first 117 and the next 136 men underwent standard dissection and hydrodissection, respectively, of the neurovascular bundle. In all men erectile function was evaluated by Sexual Health Inventory for Men score pre-RP, and 6 weeks and 6 months postoperatively. Time needed to achieve successful intercourse was also determined.

Results:
In men with bilateral neurovascular bundle preservation, mean Sexual Health Inventory for Men scores in the hydrodissection group were higher than in the standard dissection group by 2.8 at 6 weeks and by 3.5 at 6 months (p <0.05). In men with unilateral partial neurovascular bundle resection, there was also significant improvement between the hydrodissection and standard dissection groups after 6 weeks and after 6 months post-RP (p <0.05).

Men with bilateral neurovascular bundle preservation who underwent hydrodissection and standard dissection required a median of 3 and 6 months, respectively, to achieve successful sexual intercourse with or without a phosphodiesterase-5 inhibitor (e.g., Viagra, Cialis) (p <0.05). A difference was also observed in men who underwent partial neurovascular bundle resection.

Hydrodissection was an independent predictor of time to successful intercourse on multivariate Cox regression analysis.

Conclusions:
Hydrodissection of the neurovascular bundle during open RP improves postoperative Sexual Health Inventory for Men scores and the time needed to achieve successful intercourse.

Editor’s note:
Hydrodissection is a surgical technique that involves injecting small volumes of fluid (“hydro”) around the surgical area, which creates a bubble. It was initially used in cataract surgery to separate the diseased lens of the affected eye from surrounding tissues to make surgical removal of the diseased lens and insertion of a prosthetic lens easier.

It has recently been used for neurosurgical repair of carpal tunnel syndrome to help isolate the nerves so that nearby diseased tissue can be removed without damaging them. Its use in nerve-sparing prostatectomy is a new application.