Virginia Prostate Center Newsletter

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Quality of Life

By Paul F. Schellhammer, M.D.

Quality of life has assumed a great deal of importance in assessing the risk/ benefit ratio of a therapeutic intervention. Urologists and physicians in general have not been educated in the relatively new science and art of measuring quality of life issues. Indeed, the methodologies of data accrual, the so-called instruments, are still in the process of development and refinement. This is especially so for the disease specific quality of life instruments appropriate for measuring outcomes for patients with prostate cancer. Some of the hurdles include the development of questions that a) give consistent and reproducible responses, b) are brief and include language that is precise and understandable, and c) can be applied across a wide spectrum of cultural, economic and language differences. The following definition of quality of life illustrates the wide spectrum of response that can be anticipated within a similar clinical scenario: "Patients' appraisal of and satisfaction with their current level of function as compared to what they perceive to be possible or ideal." Because of this individual variation, I have taken the following position regarding information delivery about the treatment options for localized prostate cancer.

In discussing localized prostate cancer with patients who by age, stage of disease and general health have the option to pursue any of the treatment modalities (i.e. surgery, radiation, surveillance or androgen deprivation), my philosophy is to discourage an immediate and precipitous decision. I feel a waiting period is appropriate. The patients most disillusioned with regard to outcome, despite the fact that the outcome might be indeed quite successful, are those who pursue immediate treatment, specifically surgical treatment. A patient who quickly subjects his psyche and body to the most aggressive and invasive treatment in hopes of improving his chances for a favorable outcome, and, thereby, avoids investigation and consideration of all options, is doing himself a disservice. After surgery, the patient will be continuously exposed by way of the media, friends, and further inquiry to the alternative options, and will face the unsettling question "how might the outcome and quality of my life have been different if I had chosen another option?" This question should be addressed as completely as possible before the final decision to proceed with initial therapy. I think this requires at least one to two months of education and deliberation, requires a minimum of two visits, each ideally with the patient's significant other, so that full disclosure of expectations and complications is ensured and the patient can "live" for awhile with each option. A visit with other subspecialists especially a radiation oncologist is encouraged. Reading material is supplied and attendance at a support group function is also encouraged. This waiting period will solidify the initial decision as appropriate or will permit a change of mindset to some other direction.

Sexual Function

Do you have any difficulty achieving an erection?	Surgery #223 ■	Surgery #223 ●	XRT #257
No difficulty	11%	11%	14%
Some difficulty	22%	29%	27%
No erections	67%	60%	59%

■ = patient response by questionnaire
● = urologist assessment on chart review

In an effort to document the patient reaction to radiation therapy (XRT) or to surgery, we conducted a patient-directed questionnaire of 257 patients receiving XRT and 233 patients receiving surgery by radical retropubic prostatectomy. All respondents had therapy at least one year earlier. We supplemented the questionnaire with a phone interview to maximize patient response. We also analyzed a subset of patients who answered the same questionnaire six months after the first to determine consistency of response. Response was actually quite consistent and patients responding by phone interview gave similar answers to those responding through written questionnaire.

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Viagra Update
See page 3
New drugs for the management of erectile dysfunction

Surgery or Seeds: A significant question

by Paul F. Schellhammer, M.D.

A recent article in a urologic journal compared the results of interstitial brachytherapy with 1-125 seeds to radical prostatectomy. The significance of the comparison rests in the fact that both series were from respective centers of excellence (brachytherapy from Seattle, radical prostatectomy series from Johns Hopkins), both series had extended follow up, and both used biochemical or PSA criteria to identify failure. A major effort was made to compare patients with similar stage and grade of disease so as to ensure as accurate a comparison as possible. At the five-year mark, approximately 97 percent of the radical prostatectomy and approximately 79 percent of the interstitial therapy patients were considered free of disease by PSA criteria. It was concluded that radical prostatectomy might be more effective therapy in men with localized prostate cancer. Not measured in this comparison, and not available for either subgroup, were quality of life evaluations. We have mentioned in this issue the importance of quality of life. While quantity of life is important, quality of life is also important and there is only a limited decrement in quality of life that patients will accept in exchange for defined treatment benefits. So the real question that remains unanswered is not so much "is radical prostatectomy better than interstitial therapy but the extent or degree of advantage that will be necessary to offset the quality of life advantages that may reside with brachytherapy." A benefit of 20 percent might significantly offset any quality of life disadvantages associated with surgery; however, a five-percent difference between the two modalities may not, for some individuals, be deemed worthy of sacrifice of quality of life.

The National Cancer Institute (NCI) under the auspices of the American College of Surgeons (ACS) is developing a comparative trial of interstitial implantation (brachytherapy/seeds) with radical prostatectomy with the intent to measure both the PSA and quality of life outcomes. The trial will give more accurate information than the comparison in the urology journal. However, studies like that reported in the journal prompt the questions that lead to the very tedious, expensive, and detailed development of a prospective randomized clinical trial. The VPC plans to participate in this trial and in other trials where there is clearly benefit to the patient and benefit to the future generation of patients with prostate cancer who will ask the same questions as now asked but hopefully will be provided with more definitive answers than is now possible. ■

Patients and Physicians hear about nutrition and supplements

Analysis by Paul F. Schellhammer, M.D.

On August 14, 1998, Mark Moyad, M.P.H., from the University of Michigan, discussed the role of nutrition with prostate cancer. The program was sponsored by the Virginia Prostate Center, Eastern Virginia Medical School and Sentara Cancer Institute. Approximately 125 individuals attended his lecture in the Brickhouse Auditorium. I summarize my intake of several highlights of his discussion as follows.

Nutritional supplements must be distinguished from natural food substances. The health food store supplement is an attempt to extract the critical compounds from the natural product. The problem in this strategy is that in the process of extraction certain of the beneficial ancillary compounds might be lost. The take home message is that the greatest advantage lies with the natural product and not with the supplement. In a word, you cannot replace nature with a capsule or a bottle.

■ Along this line of thinking, green tea capsules do not contain all of the ingredients of the green tea leaf. The benefits ascribed to green tea probably lie with the actual brewed green tea leaf. It is of interest that all tea initially is "green." It is only through the process of fermenting and drying that the "green" tea is converted to "black" tea and in this process certain ingredients are lost.

Lycopene, a strong antioxidant found in tomatoes, watermelon and guava, may be taken as an individual supplement. However, there is no specific evidence that this is beneficial and the recommendation is to obtain Lycopene through its natural environment in fruits and vegetables.

■ Beta-carotene, another antioxidant found in leafy green vegetables, has actually demonstrated undesirable effects in supplement form in some studies. Therefore, beta-carotene supplement is questioned and, again, the beta-carotene is best obtained through natural dietary sources.

■ Soy found in the soy bean has many beneficial attributes. Individuals with high consumption of soy have lowered incidence of prostate and other cancers.

■ Finally, DHEA and DHEAS have a significant conversion to testosterone. As such they should be avoided in patients at risk for or with the diagnosis of prostate cancer. ■

Volunteers Needed

The Heitzer family has graciously donated their time to organize and manage a bingo parlor (Bingo Palace) every Saturday from 1:00 to 5:00 p.m. with all proceeds going to the Foundation for Specialized Surgery to support the research programs of the Virginia Prostate Center. They need 3-5 volunteers each Saturday to help with this important fundraising effort. Won't you please consider serving as a volunteer (or come and play bingo) to help in this important support of prostate cancer research? Please call (757) 622-5900 for more information on how you can help.

New drugs for the management of erectile dysfunction

By Gerald H. Jordan, M.D. and
Paul F. Schellhammer, M.D.

Viagra appears to be the first truly effective pill for the management of erectile dysfunction. In just over 15 years, we have progressed from the options of "you will just have to live with it" or "we have this prosthesis" to a host of modalities for managing the patient with erectile dysfunction. All of this, of course, has evolved from a better understanding concerning the mechanisms of erectile function. In short, erectile function is a complex cascade, eventually leading to smooth muscle relaxation and vascular engorgement of the erectile bodies to the penis.

The pill is really nothing more than an oral preparation of one of the agents that has been used effectively via intracavernosal injection. Two other pills will almost certainly be released within the year. One of those pills is also an oral preparation of an agent that has been effectively used in injection form. The third pill, which is just beginning clinical trials, is aimed specifically at the patient with erectile dysfunction due to emotional factors. That pill will be unique to that population.

Just because we have a pill certainly does not mean that we have all the answers with regards to its use. Specifically, in the cancer patient, historically we have looked at the cause of the erectile dysfunction as being secondary to nerve damage. If that were the case, the modalities that we already have, intracavernosal injections and the medicated urethral system for erection (MUSE), ought to be virtually universally successful in that population. Experience has shown that they are not. This has led to the proposal that some of the problems with erectile dysfunction in the patient after radical surgery might be due to lack of erections themselves. In other words, erections are necessary to maintain the health of the vascular structures involved in erectile function. This being the case, the only real solution will lie in oral therapy, we believe. All other modalities are aimed at the "creation" of a single erection. With oral therapy, therapy can be aimed at improving the "erectile milieu."

In summary, the new pill appears to be very safe with only a few interactions with other medications that might contraindicate its use. Other troublesome side effects associated with the use of the new pill are unusual. It will be reasonable to try almost all patients who do not have other contraindications to the pill. This cannot, however, be summarized to be saying that the pill will work for everyone. Initially, the oral medications will be used as single agents. Already drug study protocols are being formulated to look at using the pill in combination with other modalities. In other words, if the pill doesn't work, will the pill and some other modality work? Over these next exciting years, doctors and patients will teach each other much about the improved management of erectile dysfunction, both as a result of radical surgery and as a result of other factors.

As an addition to the above discussion, certain Viagra facts are noteworthy.

■ Viagra-associated deaths. Elderly men who have been unable to participate in sexual intercourse for many years may, with Viagra, resume activity. This must be done slowly, cautiously and wisely and not with the vigor of youth. As with the 220-yard dash, sexual activity taxes the cardiovascular system. If an elderly man was given a new set of legs that permitted the 220-yard dash and he proceeded full bore, his heart would likely suffer and possibly cease function. Use newfound ability wisely, gradually and sensibly. Another admonition: should chest pain occur, the traditional solution in the form of sublingual nitroglycerin must be avoided. Viagra is a vasodilator (the explanation for the slight facial flush that might be experienced) and the addition of a second vasodilator, nitroglycerin, will precipitate a blood pressure drop that could be lethal. In fact, several of the Viagra-related deaths were in the situation of paramedics giving nitroglycerin to men complaining of chest pain without first questioning Viagra usage.

■ Viagra taken on a full stomach, for example with a meal, will delay absorption and therefore delay onset of effect beyond the one-hour most often recommended.

■ Viagra is not an aphrodisiac. It will not promote a spontaneous erection. It will only be effective if sexual stimulation is applied. Remember, it produces its effect by slowing the breakdown of a neurosecretory substance. That substance is released by stimulation. Without the substance, Viagra will not have the substrate upon which to act and will be ineffective. This sequence also explains the variable effect of Viagra; namely, why in some circumstances it might be more successful than in others.

■ Another oral pharmacological agent to treat erectile dysfunction is under FDA scrutiny. It acts by a different mechanism than Viagra. It does not carry the same contraindication to use in conjunction with vasodilatars as nitroglycerin. It has been approved in several other countries and is called Vasomax.

■ While most physicians, especially urologists, and industry analysts, expected that Viagra would be a "blockbuster" drug, the extent to which it has moved the foundations of pharmaceutical/ patients/ insurance relations was not anticipated by most. It will lead to an entirely new set of guidelines in healthcare coverage.

We can expect a host of new pharmacologic agents that are directed at improving quality of life. To what extent these quality of life enhancers are considered health related options will need to be investigated and determined. It is inevitable that some degree of rationing and restrictions will be applied. ■

Yes! I want to help support the Virginia Prostate Center

I want to help support the Virginia Prostate Center and its efforts to find more effective treatments and a cure for prostate and other urologic cancers. (Please also consider a $5.00 donation to support publication cost and postage for circulation of this newsletter.)

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Quality of Life

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We also compared the questionnaire results to the physician assessment of outcome. Overall, urinary incontinence was a greater problem amongst patients having radical prostatectomy when compared with those having external beam radiation therapy. The physician assessment of continence was more optimistic than the patient assessment. This emphasizes the importance of patient-directed surveys to determine quality of life impact. Sexual dysfunction was very common after either radiation therapy or surgery, but this analysis suffers from the lack of detailed and uniform evaluation of sexual function prior to the initiation of therapy. Satisfaction with treatment was high; only 10% said they would probably or definitely not select the same treatment again. Hopefully, this reflects appropriate pretreatment counseling and time for informed decision making. ■

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