HIGHLIGHTER

Special Edition **April, 2003**

From the Secretary

As of this writing, three of the town meetings have occurred and the dates of two others have been confirmed. The feedback from participants has been very positive. We encourage you to take advantage of these informative sessions; it's a benefit of your membership in the Section. If you have any suggestions for future topics, please send them to me or Aurelie Alger. We welcome your ideas and comments.

In future issues of the Newsletter we will be adding a new feature – New England Urology Job Search. This will be a free service where Section members can post job opportunities in their practices and where residents within the Section can express their interest in urology positions. Detailed information appears on page 3.

As you can see from this edition of the Highlighter, we have asked Section members to compose articles that we think would be of interest to the membership. If you would like to contribute to future issues, or have topics that you would like discussed, please let us know.

Finally, Grannum Sant and the Scientific Program Committee are putting together what promises to be a wonderful meeting in Quebec. Mark September 11-13, 2003 on your calendar and join us at the Fairmont Tremblant Hotel.

Kevin R. Loughlin, M.D.

Upcoming TOWN MEETINGS

April 8 MAINE
Portland Marriott, South Portland, Maine
"Cryotherapy of the Kidney and Prostate"
Daniel Rukstalis, MD
Hahnemann – MCP Medical School, Philadelphia, Pennsylvania

April 2 NEW HAMPSHIRE
The Common Man Restaurant
Concord, New Hampshire
"Negotiating Managed Care Contracts in New Hampshire"
Michael A. LaFond, Esq.

Tentative Meetings - Watch your mail for details!

Date To Be Announced
WESTERN MASSACHUETTS
Sturbridge, Massachusetts
Topic and
Speaker To Be Announced

Date To Be Announced
VERMONT
Burlington, Vermont
"Health Policy Issues"
Speaker To Be Announced

To register for any Town Meeting, please contact Michelle Baker, NE-AUA Administrative Offices, (978) 927-8330 / E-mail: michelle@prri.com

HIPAA —— COMPLIANCE —— FRAUD AND ABUSE

David H. Kauder, M.D.

I have recently attended an AUA Compliance Seminar and would like to share some of the concepts with the NE AUA membership. This seminar was very worthwhile; unfortunately, the AUA is not planning to offer them in 2003. If you should ever have the chance to attend, I think the information is very valuable.

The AUA will be offering coding seminars in 2003. These are also helpful for proper compliance though the approach is different. I believe that all urologists could benefit from a coding seminar; I have always found it helpful and rewarding.

HIPAA. COMPLIANCE. FRAUD AND ABUSE.

These are all terms that are becoming very familiar. We instinctively wish to ignore them, but this is not reality.

COMPLIANCE

I suspect that all of you have heard the term "compliance" being used more frequently, but you may not know its true meaning. Essentially, compliance means avoiding fraud and abuse by billing and coding in an ethical and legal manner. Urologists receive more than 50% of their income from the federal government when you consider Medicare and Medicaid, so we will have a big red circle on our chests for the foreseeable future.

The fines for errors in billing are prohibitive; it could be $11,000 for an error, whether it involves an $8 urinalysis or a $1,600 chemotherapeutic agent. If you are billing fraudulently or erroneously, you should stop it before the Office of Inspector General (OIG) does. If an employee is upset about your billing or a patient receives an erroneous bill you should encourage them to report it directly to you, rather than to the OIG. The guidelines for this mechanism are a **compliance program**. The report to you may assure that more expensive problems can be prevented. A complaint to the OIG from Medicare can be very troublesome.

There are several services that CMS (Center for Medicare and Medicaid Services - the new name for HCFA) are concerned about. One is service *"Incident to"*. This may mean services *incident to* LHRH medications. For example, if your nurses are routinely billing for a 99211 (nurse visit) with LHRH medication - this is an unapproved visit. Unless there is a distinct service or complaint that the patient is voicing and that can be **documented**. If there is a documented complaint you may bill for the service.

Many urologists believe that the examination of urine is an integral part of a urological examination. Few would argue this point. Unfortunately, CMS feels that this would be screening and the Medicare charter prohibits it. You cannot bill for urine unless there is a **specific, documented complaint** that would require the urine to be done. Medicare is prohibited, except in special approved circumstances, from screening. Of course, this only applies if you are billing for these services. In addition, you must be careful that a physician or Medicare licensed practitioner is in the office for you to bill Medicare for any services.

HIPAA

HIPAA is another program that will involve all aspects of our practice. It will be part of all patient interactions. I assume all of you have filed for the computer extension in October. The computer extension involves HIPAA compatible exchange of information; most of our computer providers are not yet compatible. As for the rest of HIPAA, this is a very complex system that will affect all transfer of information. If you have not purchased the AUA program on HIPAA implementation, it is one of the best programs the AUA has offered. It is only $99 and will have online updates periodically avai1able.

Essentially, compliance means avoiding fraud and abuse by billing and coding in an ethical and legal manner.

The most important aspects of HIPAA are that it attempts to control patient privacy. It allows the patient controlled access to where their records are released, to whom, and for how long. In addition, the patient has the right to ask for a log of where their records were sent. The primary aspect of HIPAA is patient privacy and to that end we must all have written privacy statements signed by patients. In addition, any business associates (office cleaners, ultrasound providers, transport personnel, etc.) must sign an agreement with the practice regarding the privacy of records. Essentially, anyone that has access to patient records must sign a Business Associates contract. The patient will have the right to request their records be amended. You may not agree and may refuse but you must document it in specific ways. The news is not all bad. If your patient signs the privacy statement, when another treating doctor requests records, you can send them without a release for each time.

However, the forms from insurers and attorneys may not be valid after April 14, 2003. These cannot be the typical "send all records". You will have to receive, from the attorney, a specific request for specific records. The request will have to have a self-destruct time after which it will not be valid. In addition, we will have to keep a log of where records were sent and to whom. It must be in the chart and the patient has the right to inspect it.

These are issues that we would prefer not to have to deal with, but the reality is that the sooner we adjust to them and learn what is needed, the easier it will be.

BRACHYTHERAPY

Liam J. Hurley, M.D.

Radical Prostectomy, conformal external beam radiotherapy, and brachytherapy are the most common curative modalities in the treatment of early stage prostate cancer.

Brachytherapy is a form of high dose radiation therapy in which radioactive materials are placed in intimate proximity to the malignancy. Because of the short range of this form of radiation, high doses can reach well into a cancer with relative sparing of normal surrounding tissue. Radioisotopes used include Iodine-125 (I -125) and Palladium- 103 (Pd-l 03). More high dose isotopes are limited to Iridium-192 (Ir-192).

Older forms of brachytherapy were introduced by Whitmore and placed retropubicly. The dose was inhomogeneous and coupled with bulky, advanced stages of prostate cancer that were common in that era, led to frequent and often unacceptable local failure rates. Regardless, there were some cures suggesting that future modification would be helpful.

Many institutions are using brachytherapy for lower volume (T2-A, T2-B) cancers and lower Gleason scores (less than 7) where expectantly the best results would be seen. We have been following Northwest Tumor Institutes Program in Seattle under John Blasko and Peter Grim. We confine Iodine-125 to low stage, well to moderately differentiated malignancies with modest PSA levels. Dose rates per hour are lower for Iodine-125 compared to Pal1adium-103 which lasts substantially longer (about 5 months versus 2.5 months) to treat slower dividing tumors. Palladium-103 is used for larger volume tumors with poorly differentiated, but rapidly dividing cell lines. As stage, grade, or PSA rises, both the volume of the disease and the risk of extra prostatic extension increases. In this setting, the combination approach of external beam radiation plus brachytherapy may be considered.

Blasko's most recent data with Iodine-125 monotherapy demonstrates a high rate (87%) of biochemical and clinical control in patients with low risk disease of 10 years. Our most recent data from North Andover, MA included almost 300 patients with T2-A - T2-C cancer and Gleason grades of 2-9 and a PSA range of 2-100. The PSA post-treatment was less than 1 ng/ml in 93% of the patients and less than 0.5 ng/ml in 77% of patients. There were 7% who had biochemical failures over a six-year period. Side effects include radiation related urinary symptoms in 59% of patients, urinary retention requiring a TURP in 12% of patients, radiation proctitis or diarrhea in 11% of patients and a 40% impotency rate.

Recently many studies have commented on the adjunctive treatments of hormones and radiation. While interest in neoadjuvant hormone and surgery appears to be fading at least with three months preoperative therapy, many publications have shown an increase in apoptosis using hormones before and after radiation therapy. Progressive data have shown an improved disease specific survival in patients with locally advanced and metastatic prostate cancer treated with combined neoadjuvant androgen deprivation and external beam radiation. This has resulted in an increase in local disease free survival and a decrease in the incidence of distant metastasis. We currently use hormone treatment if the pubic arch volumetric study shows interference or if prostate volume is greater than 60 grams.

Future directions in brachytherapy will focus on further defining its role in the management of prostatic carcinoma, and on developing additional technical reimbursements and innovations.

In the state of Massachusetts, most insurance companies are covering brachytherapy. Important codes include:

CPT code 55859	**radioactive seed implantation**
CPT code 76965-26	**ultrasound guidance professional component**
CPT code 52310-51	**cystoscopy for seed removal**
CPT code 74480-26	**fluoroscopy**

Future directions in brachytherapy will focus on further defining its role in the management of prostatic carcinoma, and on developing additional technical reimbursements and innovations. Brachytherapy as a monotherapy is somewhat cheaper than radical surgery or external beam radiation, although radical prostectomy has relatively low technical costs. Without a clear cost advantage of brachytherapy over radical surgery, the choice of therapy should continue to be primarily influenced by tumor characteristics, treatment ethicacy, and patient preference. However, if external beam and hormonal therapy are used in addition to brachytherapy, the cost escalates quickly.

New England Urology Job Search

The New England AUA Highlighter will begin a JOB POSTINGS Section in future issues. If you have a position to fill, are looking for an associate, or are interested in a urology position, you can take advantage of this service and reach your colleagues throughout the region. And remember, the newsletter is also posted on the NEW ENGLAND AUA website: www.auanet.org/NewEngland for increased exposure. Please e-mail your "classified ad" to: Lorraine O'Grady / lorraine@prri.com

"The Current and Emerging Medical Therapies for Male Erectile Dysfunction"

Irwin Goldstein, M.D., Professor of Urology and Gynecology
Director, Institute for Sexual Medicine, Boston University School of Medicine

Erectile dysfunction (ED) is a significant and common medical problem. Recent epidemiologic studies show that about 10% of men aged 40-70 have severe or complete erectile dysfunction, defined as the total inability to achieve or maintain erections sufficient for sexual performance. An additional 25% of men in this age category have moderate or intermittent erectile difficulties. Erectile dysfunction affects an estimated 30 million men in the United States, and over 617,000 new cases are expected annually in men between the ages of 40 and 69. The disorder is highly age-dependent, as the combined prevalence of moderate to complete ED increases from approximately 22% at age 40, to 49% by age 70. Although less common in younger men, erectile dysfunction still affects 5%-10% of men below the age of 40. Findings from these studies show that ED is associated with negative effects on mood state, interpersonal functioning, and overall quality of life.

Erectile dysfunction is strongly related to both physical and psychological health. Among the major risk factors are diabetes mellitus, heart disease, hypertension and decreased HDL levels. Medications for diabetes, hypertension, cardiovascular disease and depression may also cause erectile difficulties. ED may be an important presenting symptom in many of these men. In addition, there is a higher prevalence of ED among men who have undergone radiation or surgery for prostate cancer, or who have a spinal cord injury or other neurological diseases. Life style factors, including smoking, alcohol consumption, sedentary behavior and bicycling more than 3 hours a week are additional risk factors. The psychological correlates of erectile dysfunction include anxiety, depression and anger. Despite its increasing prevalence among older men, ED is not considered a normal or inevitable part of the aging process.

Most health care providers have received little or no training in sexual medicine, nor is adequate reimbursement provided in most instances for diagnostic or treatment services. Physicians have little time available to obtain sexual histories from their patients or lack adequate training to address sexual issues and concerns. Recent studies show that the large majority of patients feel uncomfortable in discussing sexual problems with their physician, despite the prevalence and emotional distress associated with these problems. Despite the above, major changes have occurred in the physician management of ED with the advent of effective oral therapy. Many millions of patients in the U.S. have received prescriptions for sildenafil since approval of the drug in 1998. Patient education and outreach activities have increased public awareness of ED and other sexual dysfunctions. March 2003 will mark the fifth year of clinical experience with sildenafil. There have been numerous publications in peer review journal noting the safety and efficacy data of sildenafil as a treatment for men with ED. Physicians as a result are relatively comfortable prescribing sildenafil as first-line therapy for ED.

A recent study of 3291 men with ED who had used PDE 5 inhibitors, however, showed that only 51% of men with ED spoke to their physician about ED. Only 28% of them tried PDE 5 at least once. Only 14% of ED patients were still using PDE 5 inhibitors. The most common reason (42%) to avoid PDE 5 treatment for ED was concern that the treatment was dangerous. This finding emphasizes the need for continued patient and physician education, since PDE 5 oral therapy for ED has been associated with excellent safety data. The most common reasons for discontinuing use of PDE therapy was that the erection was not hard enough (34%) and the medication did not work at all (34%). In 19% of respondents, side effects were responsible for the discontinuation of treatment.

For many ED patients, sildenafil has not been the medication that has provided a safe or effective response. In the near future, two additional oral erectogenic agents will likely become available for clinical use. Vardenafil is a phosphodiesterase type 5 (PDE5) inhibitor with a pharmacokinetic profile and molecular configuration similar to that of sildenafil. Like sidenafil, vfardenafil also has selectivity to PDE 6 inhibition. Tadalafil is another PDE 5 inhibitor which has a unique chemical structure and a pharmacokinetic and pharmacodynamic profile that differs from both sildenafil and vardenafil. Tadalafil also has a selectivity to PDE 11 inhibition. The availability of these new PDE5 inhibitors will expand our treatment armamentarium for ED but also raises important questions for physicians. What criteria will be used to choose among the three PDE 5 inhibitors? How do the new PDE 5 inhibitors differ from sildenafil?

Patient education and outreach activities have increased public awareness of ED and other sexual dysfunctions.

To help select the most appropriate PDE5 inhibitor for patients with ED, it is important to examine some of the distinguishing characteristics of these agents, including biochemical potency, biochemical selectivity, onset, duration of action, and safety and efficacy data. At present, there are no carefully controlled head-to-head trials with the three PDE 5 inhibitors.

BIOCHEMICAL POTENCY

PDE 5 inhibitors are signal amplifiers. The non-adrenergic, non-cholinergic neurotransmitter nitric oxide (NO) plays a critical role in attenuating smooth muscle contraction and inducing smooth muscle relaxation and penile erection. Activation of neurogenic and endothelial nitric oxide synthases results in synthesis of NO. Released NO diffuses into smooth muscle cells and binds to the heme

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component of soluble guanylyl cyclase, stimulating cyclic guanosine monophosphate (cGMP) synthesis. Binding of cGMP to cGMP-dependent protein kinases (PKG) or cGMP dependent ion channels results in reduction of intracellular calcium, via calcium sequestration and extrusion, and activation of myosin light chain phosphatases causing diminution of smooth muscle contractility and enhancing penile erection. As long as sexual stimulation releases NO into the penile smooth muscle cytoplasm, PDE 5 inhibitors increase cGMP and faciliate penile smooth muscle relaxation.

Biochemical potency for a PDE 5 inhibitor is considered the efficency of prevention of cGMP hydrolysis. The enzyme PDE 5 hydrolyzes cGMP, therefore, PDE 5 inhibitors prevent c GMP hydrolysis. PDE 5 inhibitors have different "on-off" binding rates to the active sites of the PDE 5 enzyme. The PDE 5 inhibitor which has the longest dwell time is the most biochemically potent. Multiple studies by various investigators have independently shown that vardenafil is the most biochemically potent of the three PDE 5 inhibitors. Vardenafil has a more pronounced increase of cGMP in the presence of NO in intact cells compared to sildenafil at equivalent doses. The PDE 5 inhibitory effect of vardenafil is approximately 10 fold higher than sildenafil.and 12 -15 times higher than tadalafil. Vardenafil is the only PDE 5 inhibitor which is subnanomolar in dose required to block 50% of the enzyme activity. Comparative clinical studies will determine if there are any clinically appreciable differences, such as side effect profiles, between the three PDE 5 inhibitors based on biochemical potency. Vardenafil doses (5, 10 and 20 mg) are 1/5 those of sildenafil (25, 50 and 100 mg).

BIOCHEMICAL SPECIFICITY - BIOCHEMICAL SELECTIVITY

There are at present eleven known PDE enzymes. Selectivity is an important issue, because there are as yet no pure PDE5 inhibitors. In addition to inhibiting PDE5, both sildenafil and vardenafil also produce modest PDE 6 effects at the upper limits of the dosage range, whereas these effects are absent with tadalafil. Sildenafil and vardenafil have no significant effects on PDE's 1-4 and 7-11. All efficacy and safety attributes are likely related to PDE5/6 inhibition. PDE 6 inhibition affects the cones in the retina and results in the "blue" vision experienced by some patients taking sildenafil. In contrast, only tadalafil has definite PDE11 effects at therapeutic doses, although the clincial significance of this is not yet clear. PDE11 has only recently been described and is present in the pituitary, pancreas, skeletal muscle, heart, testes, and corpus cavernosum. However, the effects on these tissues of chronic or intermittent PDE11 inhibition are not known and require further study. In preclinical studies, tadalafil caused testicular alterations in beagle dogs characterized by degeneration of germ cell line cells in the seminiferous tubules and depressed spermatogenesis. Two studies in men, who received 10mg or 20mg tadalafil daily for 6 months, showed that tadalafil had no adverse effects on human spermatogenesis or reproductive hormones. The effects, if any, of either prolonged or intermittent PDE11 inhibition by tadalafil remain unknown

ONSET OF ACTION

The median time to maximum plasma concentration of any drug is call the Tmax. The T max for sildenafil, vardenafil and tadalafil has been reported as 0.8, 0.6 - 0.9 and 2 hours, respectively. None of the PDE5 inhibitors work immediately. Onset of action is not affected by the dose of drug. Drugs with comparable Tmax should have comparable onset of action. A recent home study with active drug, vardenafil versus placebo utilized successful intercourse as the primary efficacy parameter to assess drug onset of action. A stop watch was started at 10 minutes post administration of the study medication. At 16 minutes, vardenafil (34%) was significantly more effective than placebo (22%). A similar study showed similar data for sildenafil. In a Rigiscan-based study, tadalafil (10 mg) showed significantly different response from placebo at 45 minutes after administration. A high fat meal delays stomach emptying, which delays absorption of the drug. Sildenafil's average onset is 30 minutes when taken on an empty stomach and about 1 hour if not. Tadalafil is reported to have lack of a food effect. This is most likely due to the drug's delayed metabolism. As a result, slow gastric emptying has less effect on the time to maximum concentration.

Among the three oral agents, the most clinically significant differences are found in duration of action.

DURATION OF ACTION

Among the three oral agents, the most clinically significant differences are found in duration of action. The reported half-life (T 1/2) of sildenafil, vardenafil and tadalafil is 4, 4 - 6 and 17 - 21 hours, respectively. The duration of activity that is seen with sildenafil and vardenafil appears to be suited to the average couples' patterns of sexual interaction. In a recent study of sexually active men aged 40 to 69 years both with and without ED, investigators found that the average frequency of sexual intercourse was 1 episode per week and that the average time for foreplay was approximately 14 minutes; the vast majority (> 70%) of men studied reported that they had sex only once in a 24-hour period. The duration of activity that is seen with tadalafil, however, offers ED patients a new sexual paradigm. It is possible that sexual spontaneity may be enhanced by the long half life.

SAFETY

The safety of PDE5 inhibitors is an important concern, since many men with ED also have cardiovascular disease. A careful assessment of cardiovascular status before prescribing treatments for ED and/or advising the patient to resume sexual activity is recommended. To date, there is no evidence that any of the PDE5 inhibitors has any direct adverse cardiovascular effects. In fact, the reverse may be true, as recent studies suggest that sildenafil may delay exercise-induced ischemia and angina.

Other safety issues specific to tadalafil also need to be considered. Because of the drug's prolonged duration of action (ie, approximately 17 hours in a healthy man and up to 21 hours in an

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elderly patient), it will take up to 4 days for tadalafil to be completely eliminated from the body. This could potentially extend the duration of adverse effects or delay intervention with nitroglycerin during a cardiac event. In addition, because tadalafil inhibits PDE11, additional studies examining the effects of tadalafil on cardiac function are needed.

In general, the PDE5 inhibitors are well tolerated and have similar mild to moderate adverse effects profiles. In clinical trials, the most commonly reported adverse events were vasodilation, resulting in headache, nasal congestion, facial flushing, and dyspepsia. There appears to be a greater incidence of myalgia and low back pain with tadalafil, although the etiology of the myalgia remains unclear.

None of the PDE5 inhibitors has any significant drug interactions except for an absolute contraindication for the concomitant use of organic nitrates. Sildenafil and all agents in this class potentiate nitrate-induced vasodilation. In addition, they are all metabolized by the cytochrome P450 3A4 isoenzyme system, and concomitant administration of inhibitors of this pathway (eg, cimetidine, ketoconazole, erythromycin, and protease inhibitors) will prolong duration of action and raise serum concentrations of the drugs.

CLINICAL EFFICACY

Once the safety of the drug has been established, clinical efficacy is clearly a most important factor for the clinician to consider when selecting a drug. Evidence suggests that all 3 PDE5 inhibitors improve the quality of erections and enable successful intercourse in men with ED of all etiologies, even those with severe ED. The question as to whether men with certain comorbidities (eg, diabetes, post-radical prostatectomy, and hypertension) would be more successfully treated with one particular agent awaits further study and experience. To clearly define one drug's benefit or superiority over another requires carefully designed, head-to-head studies with well-defined efficacy measures. It is hoped that more sensitive measures of drug side effects can be developed. At present, simply the presence of a side effect is recorded. In the future is hoped that data comparing the intensity and severity of the side effect will also be available.

The Institute for Sexual Medicine at Boston University School of Medicine presents monthly sexual medicine information sessions free to the public and health care clinicians. You are welcome to attend and encouraged to post these meetings for you patients to attend. Each session will have an educational lecture on the topic and a presentation by a patient with the condition or the therapy followed by a question and answer period. All information sessions are held in conference room C-D, Boston Medical Center, 88 East Newton St, Boston, MA 02118. For further information call 617 638-8576 or write ism@bu.edu.

Choosing the right pill to treat your erectile dysfunction
April 15, 2003, 7:00 – 9:00 pm

Renewing your sex life after childbirth
May 13, 2003, 7:00 – 9:00 pm

Ejaculation problems: are you too fast or too slow?
June 19, 2003, 7:00 – 9:00 pm

CONCLUSIONS

New oral treatments for ED will soon be available. How physicians will choose which drug to prescribe will be much the same as electing among other classes of drugs with multiple options, such as NSAIDs, alpha-blockers, or SSRIs. The selection process will take into account physicians' previous experiences, patient satisfaction and preferences as well as the recognition that similar drugs may have significantly different effects in the same individual.

From the AACU

ALS VICTORIOUS IN STARK II CASE

Earlier this year, the American Lithotripsy Society learned that the Federal Government had withdrawn its appeal of Judge Henry Kennedy's decision in American Lithotripsy Society and Urology Society of America versus Thompson. The ALS was supported in this effort by the AACU.

For the 65% of urologists in the nation who hold some interest in lithotripsy partnerships, this represents a major victory.

Hand Access Devices for Hand-Assisted Laparoscopy

Steven Shichman, M.D., Associate Clinical Professor

University of Connecticut Health Center, Farmington and Connecticut Surgical Group, P.C., Hartford

Over the past 5 years Hand-Assisted Laparoscopy has become accepted as a new gold standard for performing extirpative renal surgery. Since 2000, over 500 urologists have taken the AUA training course making it one of the most popular post-graduate training courses given by the AUA Department of Education. With the increased popularity of this minimally invasive surgery, numerous manufactures have introduced new and improved hand access devices.

The purpose of the hand access device is to enable the surgeon to comfortably insert his/her nondominant hand into the abdominal cavity through a small incision without the loss of the pneumoperitoneum.

There is no perfect hand access device. Each device has its advantages and disadvantages. Factors determining the ideal choice of a hand access device for a specific case include the patient's body habitus and pathology, and the surgeons experience and preference using each individual device. All devices require a similar size incisions (3 to 4 inches) in the abdominal wall, but vary widely on how they and maintain a seal around the surgeon's arm and wrist. Unlike the first generation devices, none of the new products adhere to the body wall using adhesive seals. These adhesives seals were tedious and difficult to apply and were very prone to leakage.

Devices, which are currently on the market, include the following:

1. Gelport - Applied Medical, Rancho Santa Margarita, Ca.
2. Lapdisc - Ethicon Endosurgical, Cincinnati, OH.
3. Omniport – InterMed, Selling, NV
4. Handport – Smith and Nephew, Largo, Fl.

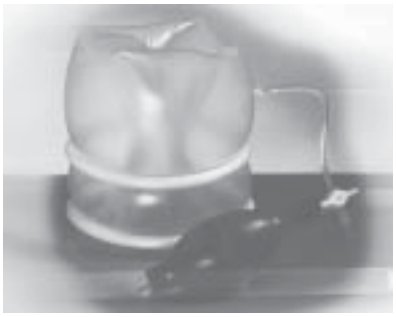
All of these devices secure to the body wall using 2 concentric rings that are attached together with vinyl or rubber. One ring is inserted on the undersurface of the abdominal wall and the other ring rests on the outside surface of the body wall. The material holding the two rings together is placed on stretch, maintaining the seal at the body wall and acting as a wound protector. These second generation devices can be directly inserted into the abdominal cavity without first insufflating, which is a definite time saver.

Advantages of the **Gelport** device include an excellent seal, flexibility, and comfort offered by the gel. The unique gel-like polymer through which the surgeon inserts his or her hand is flexible and soft around the wrist. Additionally, this polymer can be temporarily pierced by an instrument or trocar and maintain a seal at the puncture site. Instruments can even be inserted through the gel while the hand is inserted in the device. Other advantages include the fact that removal of the surgeon's hand from the abdominal cavity does not cause loss of pneumoperitoneum and rarely causes the device to become dislodged. The Gelport device has the largest template or footprint, requiring a large area for application. This is not a problem in most cases, but in small-framed patients the device may be too large to use in a right lower quadrant incision that is commonly used for a right-sided nephrectomy. In these cases the anterior iliac spine may prevent the device from sitting evenly against the body wall, thereby jeopardizing the seal. Gelport is the most expensive hand access device on the market.

GELPORT

The **Lapdisc** is the least expensive device on the market and is the easiest to use. There are no pieces that need to be assembled, and insertion of the device is quick and easy. This device has the smallest footprint, fitting almost anywhere on most abdominal walls and rarely interferes with adjacent trocars. An oversized device is available for patients with thicker than normal abdominal walls. The iris that tightens around the surgeon's wrist, to develop the seal, can alternatively be tightened around a trocar or completely closed on its self to maintain the pneumoperitoneum. This iris requires meticulous adjustment around the wrist. If it is too tight the hand will quickly tire and become painful, if too loose, the device will leak. When removing the hand from the abdomen the iris must be adequately loosened or the Lapdisc will inadvertently be removed. Pneumoperitoneum is lost when the hand is removed but can be easily be reestablished by quickly closing the iris.

LAPDISC



OMNIPORT

The **Omniport** is an inflatable device, which maintains an excellent seal and rarely becomes dislodged once it is inserted. As with the Gelport and Lapdisc, the surgeon can rapidly remove and reinsert his or her hand, which is a major advantage for resident teaching programs when the teaching surgeon must quickly take over the case to avert or manage a potential complication. The

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Hand Access Devices for Hand-Assisted Laparoscopy

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device can be insufflated to maintain pneumoperitoneum without the hand being inserted, but an accessory trocar or instrument cannot be inserted through the device. Unfortunately, the device can be difficult to insert. Additionally, care must be taken to assure that bowel or omentum is not caught under the rigid inner ring that is unforgiving and can easily damage soft tissue.

HANDPORT

The inflatable **Handport** is probably the most comfortable device as there are no rigid pieces to rub against the wrist or forearm. Unfortunately without a rigid inner ring the device can easily become dislodged. To develop a seal around the arm, the surgeon must wear a sleeve that attaches at the wrist and is covered by a second glove. This sleeve weds the surgeon to the device and makes insertion or removal of the hand and switching surgeons more complicated and time consuming. Additionally, removal of the sleeve from the device does cause immediate loss of pneumoperitoneum. This device has an available insert that can be used to maintain pneumoperitoneum without insertion of the hand and can be used for insertion of an accessory trocar or instrument.

As with all forms of minimally invasive surgery, products will continue to change and improve. It is not practical or cost effective for any one operating room to have all products available. Surgeons performing hand-assisted laparoscopy should periodically evaluate the hand-access devices available and select the one or two devices they feel are best suited for their needs.

2003 Annual Meeting NEWS

The New England Section of the AUA's Annual Meeting will be held September 11-14, 2003 at the Fairmont Tremblant in Quebec. Abstracts are now being accepted for consideration at this year's annual meeting.

To submit your abstract go to www.auanet.org/NewEngland. All abstracts must be submitted electronically.

ABSTRACT DEADLINE: May 16, 2003

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If any Section member has an issue he or she would like considered by the NEAUA Board of Directors for possible comment and action, please contact your state representative.

Case Report: Conflicting Signals in PSA Screening

Christopher J. Doyle MD

This case history illustrates the delay in diagnosis of prostate cancer that may occur when physical examination and free/total PSA percentage seem reassuring. These diagnostic tools may miss significant prostate cancer.

CASE HISTORY

A 75 year-old man presented for evaluation of an elevated PSA (4.3) and voiding symptoms. He had undergone a CABG 12 years earlier but was otherwise well. Examination showed an enlarged, smooth and firm prostate. A repeat total PSA was 4.1 with a free percentage of 23%. Biopsy was deferred and the patient was followed.

Gradually his total PSA rose to 8.2 and the free component rose to 44 percent. Examination remained consistent revealing an enlarged smooth firm prostate. The patient's voiding symptoms remained consistent (IPSS = 8-12). He experienced no problems that might have suggested either inflammation or disseminated malignancy.

Because of the gradual rise in total PSA biopsy was suggested despite the very reassuring free/total PSA ratio. Ultrasound measured the gland at 70 cc. The biopsy revealed Gleason Grade 4+ 5 adenocarcinoma bilaterally in 9 of the 10 cores submitted. Lymphovascular invasion and penetration by the tumor into periprostatic fat were documented bilaterally by the needle biopsy

Staging by MRI revealed massive bilateral pelvic lymphadenopathy consisting of a 6.5 cm metastatic nodal mass along the right iliac artery and a similar 4.5 cm mass on the left. Needle biopsy confirmed that the new disease was prostatic in origin. Bone scan and chest CT scan did not show additional disease.

Twenty-seven months elapsed between the patient's initial presentation and definitive diagnosis.

DISCUSSION

Screening for prostate cancer by PSA testing produces many false positives that cause excessive financial and psychological burden. Because the percent of free PSA is lower when cancer is present percent free PSA can be incorporated into screening protocols to reduce unnecessary biopsies. Dr. William Catalona and others have recently written that using a percent free PSA cutoff of 20 percent decreased false positives and preserved cancer detection. (J. Urol. 2002 June; 16 (6): 2427-34). Other investigators have confirmed his data and commonly this information is incorporated into decisions regarding the necessity of prostate needle biopsy in many patients. And a favorably high percent free PSA does not rule out the presence of cancer. In the most favorable group of Dr. Catalona's population, patients with a percent free PSA of > 25% cancer was present in eight percent of the patients.

Other work has shown that percent free PSA does not reliably predict the aggressiveness of prostate cancer although in several ways a high percent free level suggests a more favorable circumstance. Investigators have found that in patients with metastatic disease undergoing hormonal therapy the percent free PSA often increases if patients respond to treatment (J Urol. 1999 Jan; 161 (1): 176-81).). But, although percent free PSA tends to decrease with increasing Gleason score the association is variable. The test is not useful as a staging tool. As an independent predictor it does not predict organ confinement or PSA recurrence in patients undergoing radical prostatectomy (J. Urol. 2002 Mar; 16(3): 1306-9.

As with any of the parameters used to predict the aggressiveness of prostate cancer percent free PSA adds information to the description of a given tumor but the information is not completely reliable and cannot be the sole guide to management.

In this particular patient it seems likely that the poorly differentiated character of his disease caused discordance between the extent of his disease and PSA production. Perhaps his malignant tissue did not make PSA and his benign prostatic tissue did. His physicians were only able to observe the benign side of his PSA production which took the form free PSA.

How can a clinician avoid such a pitfall? Can other guidelines such as PSA velocity, age-specific PSA or PSA density help? In this case the PSA density at the time of initial presentation was probably 0.06 and rose to 0.10. The PSA velocity over that time was 1.55, higher than 0.75/year, By age-specific PSA criteria initially his PSA was considerably below the level of 6.5 that has been suggested as acceptable for a man 70-80 years old. But at the end of the observation his PSA had surpassed that milestone. So in this case PSA density was not helpful. Measures based on total PSA levels suggested an abnormality but dramatically underestimated the magnitude of the problem. And percent free PSA was strongly misleading.

PSA screening, even when incorporating PSA velocity, density and age-specific ranges and percent free PSA remains an imperfect science. A high level of suspicion and early resort to increasingly safe and thorough biopsy technique remain crucial in importance.

FUTURE MEETINGS OF THE NE AUA

September 11-14, 2003
Fairmont Tremblant Hotel / Quebec, Canada

September 8-13, 2004
Ritz Carlton Resort / Amelia Island, Florida

November 2-6, 2005
Joint Meeting with
Northeastern Section, AUA
The Southampton Princess / Bermuda

September 28-October 1, 2006
Rhode Island Convention Center and the
Westin Providence / Providence, Rhode Island

UPCOMING UROLOGY MEETINGS OF INTEREST

Massachusetts Association of Practicing Urologists
ANNUAL MEETING
Tuesday, May 13, 2003
Westin Hotel, Waltham, Massachusetts
"Treatment Options for BPH: Clinical and Economic Implications."

Registration - 5:00 p.m. Reception - 5:30-6:15, followed by dinner and the speakers
For additional information: Ginny DuLong, MAPU, P.O. Box 9132, Waltham, MA 02454-9132, 781-434-7313, Fax: 781-893-2105 / E-mail: vdulong@mms.org

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If you would like to list your meeting in this section of the NE AUA Newsletter, please e-mail or fax to Michelle Baker: michelle@prri.com / Fax: (978) 927-8890.

In addition to the meeting specifics, please include a contact person.