Celebrating The Premier Cares Foundation's 2nd year

Minimally invasive options for Benign Prostatic Hyperplasia

Endoscopic ultrasound gives a new view of the GI tract

PremierHealth

The experience you need... the compassion you deserve

WINTER 2012/2013

Expert care that spans the Hudson Valley

Premier Medical Group

Leading the way to a healthy Hudson Valley

The planning committee for the Premier Cares Foundation 2nd Annual Celebrity Dinner was rewarded with the satisfaction of a job well done. They helped provide a fabulous meal for those in attendance and, most important, raised $65,000 to further the Foundation's efforts to provide health care to Valley residents in need.

Premier Cares Foundation is ending its second year with a spate of growth and new initiatives on the horizon. Its annual Prostate Cancer Walk is the only men's health fundraiser in the Hudson Valley. The urology and gastroenterology education days it supports bring the latest medical information to our region's doctors. Learn about what the Foundation does and how you can be part of it, beginning on page 6.

• Our region has added a new Robotic Surgery System and Premier's Dr. Paul Pietrow has played a significant role in getting it up and running *(page 4)*. • Dr. Elmi explains how an endoscopic technology has significantly improved the ability to stage GI cancers *(page 5)*. • Dr. Scott Kahn describes the two most prevalent minimally invasive procedures for easing the symptoms of BPH *(page 10)*. • Helicobacter pylori is among the most widespread bacteria in the world. Dr. Khurana explains why you (and your doctors) need to be aware of it *(page 11)*. • About 15 percent of couples are considered "infertile," but there's hope for many of them. Dr. Krumholtz takes you through the treatment process *(page 12)*. • Long-term GERD increases the risk of cancer of the esophagus. Dr. Dean tells us about a protective procedure *(page 15)*. • Dr. Goldfischer describes how we measure the outcomes of our kidney stone treatments (page *17)*. • There' a diet that promises to be of significant help to patients with irritable bowel syndrome, and Dr. Muslim has the details (page *18)*. • Dr. Walter Parker explains the messages your body sends via scrotal pain (page *19)*.

Premier Medical Group's multiple offices reduce the travel time needed to get the specialty care you deserve.

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Sunil K. Khurana, MD, FACG
Peter M. Varunok, MD, FACG
Salvatore M. Buffa, MD
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Khurram I. Ashraf, DO
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Jaspreet Singh, DO
Praneeth Vemulapalli, MD

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Frances Traver, ANP-C
Marylu Williams, FNP

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Northern Dutchess Hospital
St. Francis Hospital
St. Luke's Cornwall Hospital
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PREMIER *medical group*

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Premier Medical Group Editor: Sinikka Sherwood [ssherwood@premiermedicalhv.com]

Report from the Scientific Meeting

Every day sees further development in the science of medicine. Dr. Salvatore Buffa attended this year's American College of Gastroenterology Annual Scientific Meeting and Postgraduate Course, bringing home news of the latest findings.

• Good news for users of proton pump inhibitors (PPIs)

1) A large study of the drugs prescribed for gastric reflux and ulcers has shown that long-term use is not related to loss of bone mineral density, osteoporosis or hip fractures. When tested at 5- and 10-year intervals, the study subjects showed no accelerated bone loss over their baseline levels. The study concludes that the "weight of the evidence suggests the absence of an association between PPI use and BMD change over time. Further supporting our finding is the lack of a definitive physiologic mechanism through which PPI use would negatively affect BMD."

2) Clopidogrel (Plavix) is considered state of the art medical treatment for reducing cardiovascular risk, while PPIs are considered essential for patients at risk of gastrointestinal bleeding. A 2009 FDA statement, however, warned that the two drugs were a dangerous mix—reducing the effectiveness of clopidogrel. New studies discussed at the 2012 Scientific Sessions found that there is no increased risk of any of cardiac events in patients concurrently taking PPIs and clopidogrel.

Articles detailing these results are available for patients at our offices.

• Hidden faces of celiac disease (CD) — The common symptoms of celiac disease include gastrointestinal complaints and malabsorption, but recent studies confirm other possible markers for the disease. Five to eight percent of anemia cases can be traced to celiac disease. And, in the absence of discernible causes, celiac disease should be considered in the presence of abnormal liver function tests or pancreatitis. Antibody testing or HLA genotyping can be used to aid in the diagnosis.

• The new colonoscopy standard — The preferred approach to preparing for colonoscopy is now a split dose prep, that is, one dose taken in the evening and one in the morning. Not only is this method more tolerable for patients, the quality of cleansing leads to improved polyp detection. Patients of Premier Medical Group's GI division will see this new approach reflected in their pre-colonoscopy prescriptions.

• Vaccination safety for the immunosuppressed — Vaccinations are very important in the medical management of patients who are on immunosuppressants, such as Humira, Remicade, 6MP, Imuran or Cimzia. Patients taking Prednisone, as little as 20mg for two weeks, are also considered to be in the immunosuppressed category. Bear in mind, however, that vaccines containing live virus are dangerous to those with a weakened immune system. Such patients need to avoid MMR, varicella, zoster, and any live virus vaccine. However, immunosuppressed patients need to keep up with other vaccines, so they will not be susceptible to those diseases. Diphtheria-tetanus, human papilloma virus, influenza, pneumococcus, Hep A, and Hep B are all inactive vaccines that are safe and recommended.

• Attacking C. difficile — Clostridium difficile (C. difficile) is a bacterium that causes diarrhea and more serious intestinal conditions such as colitis. In most cases, the infection can be resolved with antibiotic therapy, but some patients will suffer multiple, long-term relapses. For these refractory cases, fecal microbiota transplantation has been shown to be highly effective. Patients who meet the criteria are given a donor's engineered fecal fluid through colonoscopic infusion, nasogastric tube or other means. The transfusion is delivered to either the small or large intestines where it replenishes and fortifies the good bacteria to overgrow the bad bacteria of C. difficile. Positive results of this procedure may be seen in a matter of days.

PSA Testing UPDATE

Questions raised by the recent U.S. Preventive Services Task Force (USPSTF) recommendation against routine PSA screening tests are far from settled. A spate of new studies published over the last few months point out its major negative implications.

• A study in the journal *Cancer*—extrapolating from pre-PSA era incidence rates— finds that the elimination of routine PSA testing would likely triple the number of men having advanced prostate cancer at first diagnosis.

• Following up at 11-years, with two years of additional data, the European Randomized Study of Screening for Prostate Cancer found that PSA testing reduces a man's risk of dying from prostate cancer by 29 percent. An accompanying editorial in the *New England Journal of Medicine* posits that such data shows "more information on the balance of benefits and adverse effects, as well as the cost-effectiveness, of prostate-cancer screening is needed before general recommendations can be made."

"Our sense all along," says Premier's Dr. Naeem Rahman, "is that the initial studies that received so much attention really didn't follow the disease process enough to show that PSA testing makes a difference. I think as the 15 and 20 year data starts coming out we will see PSA screening reduces cancer death rates significantly and the pendulum will shift back to screening."

New at St. Francis Hospital

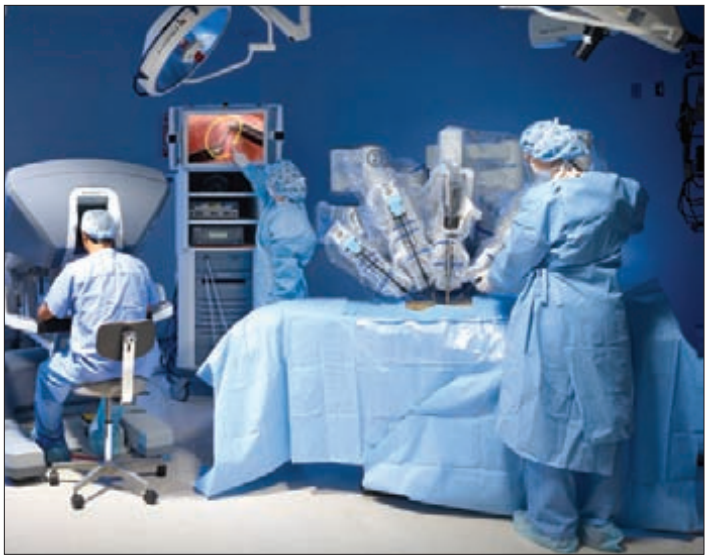
When SFH decided to invest in the area's most advanced da Vinci® Surgical system, it turned to Dr. Paul Pietrow, its long-term director of minimally invasive surgery, to expand his role and provide leadership for the hospital's new Center for Robotic Surgery.

Premier Medical Group's Dr. Paul K. Pietrow has been named the hospital's co-director of minimally invasive and robotic surgery. In this position Pietrow has helped devise and implement the standards and procedures governing use of the da Vinci® Si Surgical System that's at the heart of The Center for Robotic Surgery at Saint Francis Hospital.

"Robotic surgery is not new to the area," says Dr. Pietrow, "but the technology has evolved. St. Francis has purchased the newest generation robotic platform." The vision system of the da Vinci Si delivers high definition 3D video, providing surgeons with visual sharpness that is greater than anything previously available along with true perception of depth. This and other mechanical differences "makes it easier and more comfortable for the surgeon, and allows us to move the instruments more intuitively," says Pietrow.

The hospital's first robotic surgery was performed in June and the da Vinci is already being used in numerous surgical applications. Gynecologists use it extensively for hysterectomies while general surgeons use it in procedures on the GI tract. Urologists—including Premier physicians Naeem Rahman, Walter Parker, and Pietrow—use it for cancer surgeries and some reconstructive work. Premier's Dr. Dan Katz is employing the robot for some types of pelvic prolapse repair.

As St. Francis prepared for this new technology, the administrators wanted to provide for physicians to be directly involved in the launch. "There's a credentialing committee to make sure that we are bringing people in who have the proper training," says Pietrow. "There was a training period to get the staff comfortable with using the da Vinci. We put followup measures in place to make sure the cases are proceeding properly and the outcomes are appropriate. We review charts to ascertain that certain post-op parameters are within expectations. We're going above and beyond the normal review to be sure we're launching The Center for Robotic Surgery safely."



The da Vinci Si Surgical System (top), the LithoGold lithotripter (right), and Dr. Paul K. Pietrow (above).

In May of 2012, Premier Medical Group purchased a new LithoGold lithotripter and installed it at St. Francis Hospital. Lithotripsy is a relatively old non-invasive medical procedure—introduced to general clinical practice in the early 1980s—that uses shock waves to break up stones in the kidney, bladder, or ureter (tube that carries urine from the kidneys to the bladder). After the lithotripsy procedure, the tiny pieces of stones pass out of the patient's body in urine.

The newest lithotripter on the market, the LithoGold incorporates 20 years of NIH research in its design. "It really focuses the energy to allow for excellent stone fragmentation with minimal damage to collateral tissues," says Dr. Evan Goldfischer, co-managing partner of Premier Medical Group.

The enormous focal zone and expanded penetration depth of the LithoGold allows it to engulf and implode the kidney stone. This eliminates the need to chase stone fragments through the kidney which, in turn, reduces the number of re-treatments that might be required. The LithoGold is considered by many to be the most versatile and efficient lithotripter in the industry.

Now that the LithoGold is permanently installed at St. Francis—replacing a mobile unit—"it would be rare to have to wait more than a couple of days to have your stone treated," says Dr. Goldfischer.

EUS: a recent and invaluable tool

Once available only in academic centers, endoscopic ultrasound has become an essential tool for any good GI practice.

Endoscopic ultrasound is a procedure in which gastroenterologists use a specialized scope with an ultrasound camera installed at its tip. The procedure was developed in the 1980s, specifically for the detection of pancreatic cancer. Physicians needed to overcome the obstructions of fat, bone, and air, which compromised the image they were able to obtain through transabdominal ultrasound.

The early units—cumbersome, expensive, and difficult to operate—were available only in academic surroundings and a few regional centers. "Doctors weren't sure as to what the place of EUS would be," says Dr. Sunil Khurana. "Now, we are at a stage where we can't do without it. It's become an essential part of any good GI practice."

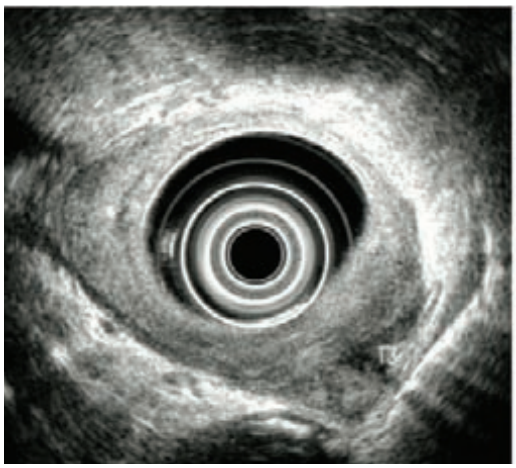
"Using the ultrasound camera, we are able to see deeper layers of intestine, stomach, esophagus and also some structures located immediately outside the GI tract," explains Dr. Farshad Elmi, one of Premier's EUS subspecialists (who took a fourth year Advanced Endoscopy Fellowship at Yale University focusing on EUS and ERCP). "The GI tract consists of three layers: the superficial layer or mucosa which can be seen directly during routine endoscopy, the fat layer which is underneath the mucosa, and the muscle layer. EUS allows the endosonographer to examine each of these layers and determine whether there are any pathologic changes in them."

Putting the technology to work

EUS is a very important tool in local staging of various GI cancers. "The procedure allows for local staging of gastrointestinal tumors to see how deeply the tumor has invaded through the deeper layers of the GI tract, or if it has invaded any surrounding structures outside the GI tract," says Dr. Elmi. "This helps the surgeon or oncologist to tailor the appropriate surgical and medical treatment."

Other key indications for employing EUS include:

- To evaluate any submucosal bumps (subepithelial lesions) in the GI tract which are covered with normal appearing mucosa. The endosonographer can also take a deep sample of the lesions using needle aspiration for diagnostic evaluation.
- To visualize the bile duct. EUS provides a very clear picture of the bile duct, revealing the presence of a stone or other obstructive process.
- To obtain tissue biopsy (fine needle aspiration) of any abnormal growth in the pancreas, lymph nodes, or other organs adjacent to the GI tract.
- To evaluate various cystic or solid mass lesions arising from the pancreas. In this regard, EUS can be used for both diagnostic and therapeutic purposes. "If there is a large pancreatic cyst causing mechanical obstruction in the stomach or small bowel, we can go in with EUS to aspirate the cyst and place a small stent to provide ongoing drainage and relieve the obstruction," says Dr. Elmi.
- Diagnostic EUS is a very safe procedure and the risk of complication is comparable to that of a routine endoscopy. EUS with fine needle aspiration has a small increased risk of complication but it is still a much safer modality than conventional surgical biopsy.



An EUS image of esophageal cancer with T3 Staging. The tumor has invaded through the muscle layer of the esophagus (arrow).

Farshad Elmi, MD, MSc

"EUS provides a clear picture of all three layers of the GI tract and other surrounding structures.

In the old pre-EUS days, evaluating a subepithelial lesion in the GI tract took a combination of guesswork plus CT or MRI scans that did not yield a clear picture. EUS provides diagnostic information these modalities could not.

EUS has become the standard of care for preoperative evaluation of any GI cancer involving the esophagus, stomach, rectum and pancreas. In the case of a tumor, for example, we can get a sample of an adjacent lymph node through EUS to see if the cancer has already spread to the lymphatic system, something not previously possible except through surgery.

There are numerous studies being conducted on further utilization of EUS technology with the promise of significant therapeutic developments in the future."

PREMIER CARES FOUNDATION

The Second Year

Three years ago, the physicians of Premier Medical Group decided that it was time to establish a foundation that would maximize their contributions to their Hudson Valley neighbors. The process took a while but, with the help of a cadre of committed board members recruited from the Valley community, the Premier Cares Foundation was incorporated in March, 2011.

"One thing about Premier that, perhaps, differentiates our doctors from others," says Dr. Evan Goldfischer, "is that all of us live, work, worship and raise our families here in the Hudson Valley. So we always thought we should give back, and we all did. As the idea of a foundation began to crystallize, we wondered if we could formalize what we do, find out who needs the care, what kind of care they need, and develop a way to provide it to them."

"We also thought," says Dr. Sunil Khurana, "that we might be able to raise additional funds from businesses and develop alliances with hospitals and insurance companies. We knew that people who had the means to get screening tests were health-aware and likely to get those screenings. But we felt that if we could create some big, attention-getting events, folks sitting on the sidelines or unable to afford the procedures would now be both motivated and able to receive care."

Initially, the Foundation focused on prostate and colon cancer. Now, in its second year, the Foundation has expanded its reach and contributions to include most areas of urology and gastroenterology, plus everything from aiding patients who need help paying for transportation to their chemotherapy or radiation therapy to assisting with end-of-life hospice care.

SIGNATURE FUNDRAISER

1st Annual Challenge Your Colon Chili Festival

March 25, 2012

Funds raised — $37,000+

Over 300 people gathered at the Poughkeepsie Grand Hotel on March 25, 2012, to attend Premier Cares Foundation's first annual "Challenge Your Colon Chili Festival: Celebrating the Local Culinary Flavors of the Hudson Valley."

The Festival is slated to be a regular observance of Colon Cancer Awareness Month. By the time this first event was over, a lot of great chili and local food and beverages had been consumed, some important messages about health and community had been brought home to the Hudson Valley, and more than $36,000 had been raised to help the Foundation carry on its work.

This family friendly event was made possible by the generous contributions of local restaurants, bakeries, breweries, vintners and vendors who gave of their time and talent. Stolen Heart, the Dutchess-County-based country music band, performed while the kids enjoyed pasta tastings and a variety of crafts and activities and the adults savored tasting portions of prize chili recipes and other local delicacies.

"This was a great event, bringing even more public awareness to the importance of early screenings in the fight against colon cancer," said Dr. Sunil Khurana, Co-Chief Executive Officer of Premier Medical Group and a Premier Cares Foundation Board Member.

SAVE THE DATE

Colon Cancer Awareness Day

March 10, 2013

Challenge Your Colon Chili Festival

Join us for this country-fun afternoon as local restaurants serve tasting portions of their prize chili recipes and all the fixings.

To register on-line, please visit www.premiercaresfoundation.org
For information on sponsorship, contact Monica Metty at mmetty@premiercaresfoundation.org

SIGNATURE FUNDRAISER

3rd Annual Prostate Cancer Walk

September 29, 2012

Funds raised — $90,000+

Despite the overcast weather, 600 walkers showed their support for the battle against prostate cancer by turning out to traverse the Walkway Over the Hudson, raising money to provide screenings, education and treatment for the disease.

The Prostate Cancer Walk is the only fund-raising event in the Hudson Valley specifically devoted to men's health. Participants—there were twice as many as attended our first annual event—came from as far away as Long Island, Pennsylvania, and New Jersey. Dennis O'Hara, founder of the Man2Man Prostate Cancer Support Group in Poughkeepsie and a prostate cancer survivor, served as Grand Marshal of the Walk and shared his moving story of survival with the crowd.

The Walk, says Dr. Evan Goldfischer, "is a chance for survivors of the disease to come out and share their triumph; for people who have lost friends or relatives to the disease, it's a chance to remember together and for those who have been diagnosed and may be undergoing treatment right now, the Walk may be a opportunity to get questions answered and talk to people who have beaten the disease."

The Prostate Cancer Walk is a chance for survivors of the disease to come out and share their triumph; for people who have lost friends or relatives to the disease, it's a chance to remember together...

SAVE THE DATE

September 28, 2013

4th Annual Prostate Cancer Walk

For information, please visit www.premiercaresfoundation.org

SIGNATURE FUNDRAISER

2nd Annual Celebrity Chef Fundraising Dinner

November 10, 2012

Funds raised — $60,000+

Featuring former White House Executive Chef Scheib, the Premier Cares Foundation "White House State Dinner" drew 201 people for a sold-out affair at the Poughkeepsie Tennis Club. The event raised more than $60,000.

Chef Scheib, a 1979 graduate of the Culinary Institute of America, cooked for Presidents Bill Clinton and George W. Bush, as well as for countless heads of state and foreign dignitaries, during his 1994-2005 tenure at the White House. In addition to serving a delicious, multi-course, White House-style state dinner Chef Scheib delighted and fascinated guests with White House insider's tales and culinary insights. David Roosevelt, grandson of Franklin and Eleanor, joined in to share memories of visiting his grandparents in the White House as well as dining experiences with other U.S. presidents.

The Foundation received generous sponsorship and support from many community organizations, businesses, and patrons. Major sponsors for the event included Ashworth Creative, North American Partners in Anesthesia (NAPA), Pathline, Watson, Premier Medical Group, Health Quest, Northern Dutchess Hospital, Putnam Hospital Center, Vassar Brothers Medical Center, Cosimo's Restaurant Group and Arlington Wine and Liquor.

Eve Ashworth Foundation Board Member

In my teens, the father of one of my closest friends died of pancreatic cancer. It had such an impact on my life and I still recall the event with such sadness. When Dr. Evan Goldfischer contacted me about becoming a member of the Premier Cares Foundation board I thought it a great opportunity to give back and help be an agent of change in the community.

At the outset, and common to every newly formed non-profit organization, it was necessary to get businesses and individuals acknowledging our presence. We have overcome this challenge by hosting interesting public events, geared toward both fundraising and education. We have also shown transparency regarding how the money raised is being used and how it is benefiting the community.

I feel honored to be part of a Foundation that strengthens its community. The core team, led by Julie Goldfischer, is truly the engine behind the Foundation and I am thrilled to serve with them.

I see the Foundation becoming a major influence in shaping the medical decisions of the Hudson Valley. Better care for Hudson Valley residents will always be the primary goal of the Premier Cares Foundation.

In 2012, The Premier Cares Foundation raised a total of $187,000

FOUNDATION FAQ

The Hudson Valley community can feel assured that the funds raised by Premier Cares Foundation are not supplementing any doctor's income nor swelling the coffers of big pharmaceutical companies.

Actually, not one Foundation dollar goes to a physician. Every single physician that partners with the foundation—be it the doctors at Premier, our partners in anesthesia at Napa and Crossriver Anesthesia, or our pathology partners at Pathline—contributes his or her services for free.

And, to date, we have not had to buy any drugs to treat Foundation patients. We have been able to use our influence with the various pharmaceutical companies—some of which have also set up individual foundations—to get the drugs to the patients at no charge. All the companies we've approached have bought into the idea and said, in effect, if you guys are giving your services for free, and these patients are truly needy, then we'll provide the medication for free too.

This kind of cooperation has enabled the Foundation to apply its funds at a grass roots level, for hospitalizations and for things patients would otherwise rarely have coverage for, such as getting to their chemotherapy appointments or, if necessary, receiving end of life hospice care. In so many cases, we're filling in the gap where there is no other funding.

Men Receiving Free Prostate Cancer Testing over 2 years = 100+

People Receiving Free Colonoscopies in Year 1 =23

Grant Recipients: Premier Cares Foundation has donated funds to Vassar Brothers Medical Center, Saint Francis Medical Center, and Hospice. Donations were earmarked for patients with urological and digestive diseases with limited financial means.

New in 2013: The Premier Cares Foundation will offer grant programs designed to assist patients and families with financial challenges who are in need of ancillary services for transportation and other cancer related services. Application forms will be available on our website to make the granting process as easy and accessible to the community as possible.

Teaching Days

As part of its mission to bolster knowledge and awareness of urological and gastroenterological conditions, the Foundation helps sponsor a pair of "Teaching Days" geared toward physicians and allied health professionals.

Experts in the GI and urology fields are brought to Poughkeepsie where they deliver a kind of mini-postgraduate course on the latest developments in their respective areas. Attendees may accrue continuing medical education (CME) credits through their participation.

The target audience for Urology Teaching Day—conducted in conjunction with St. Francis Hospital—consists of primary care physicians, gynecologists, and urologists who initially diagnose the conditions under discussion. This year's event updated physicians on stone diseases, which affect over 25 million Americans each year, and on erectile dysfunction, which affects over 40 million Americans.

GI Teaching Day—in conjunction with Vassar Brothers Medical Center— is designed for gastroenterologists, hepatologists, family practitioners, surgeons, and other health care professionals who care for patients with gastrointestinal and hepatobiliary diseases. This advanced professional conference typically provides "Leading Edge" information, reviewing the latest advances in gastrointestinal disorders. Topics covered at this year's event included celiac disease, management of acute GI bleeds, and management of IBD.

Comment sheets filled out by physicians after attending these Teaching Days reveal that the information they learn leads them to change or refine their treatment practices, all to the benefit of patients in the Hudson Valley.

Minimally Invasive Surgery for BPH

The last fifteen years have seen remarkable advances in the treatment of benign prostatic hyperplasia. New medications continue to be developed along with high-tech procedures to relieve urinary problems this condition causes.

By the age of sixty, about 50 percent of American men will have developed benign prostatic hyperplasia (BPH). This enlargement of the prostate is a natural part of aging. Some men will not experience any notable symptoms from BPH, while others will have urinary problems of varying severity.

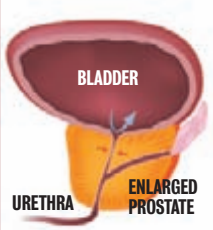
As the prostate enlarges, the gland begins to press against the urethra—the tube that transports urine out of the body—like a clamp on a garden hose. As a result of the pressure, the bladder wall becomes thicker and irritable and, eventually, the bladder begins to contract even when it contains only small amounts of urine, causing more frequent urination. Eventually, the bladder weakens and loses the ability to fully empty itself. Over time, severe BPH may cause additional problems, with urine retention and strain on the bladder leading to urinary tract infections, bladder or kidney damage, bladder stones, and incontinence.

The goal and the approach

The goal of treatment for BPH, whether medical or surgical, is reducing the size of the prostate and opening the urethra for easy passage of urine. When the use of medicine alone is unsuccessful or undesirable to the patient, we often turn to two forms of minimally invasive surgery, transurethral needle ablation (TUNA) or laser prostatectomy.

"The ideal candidate for TUNA is someone with a moderately enlarged prostate and moderate post-void residuals who hasn't responded to drug treatment," says Dr. Scott Kahn of Premier's Urology Division. "On the other hand, a patient with a greatly-enlarged prostate, severe symptoms, and large post-void residual might better benefit from a laser prostatectomy. We review the pros and cons of each approach with our patients and, together, choose the one that's right for them," he says.

The TUNA procedure was approved for clinical use by the FDA in 1996. The patient is sedated and instruments reach the prostate via the urethra. "We're able to precisely treat just the enlarged portion of the prostate with this procedure," says Dr. Kahn. "Using a pair of needles inserted directly into the prostate, we apply low level radiofrequency energy, which heats the tissue to 110 degrees Celsius, effectively destroying it."



The goal of treatment for BPH is reducing the size of the prostate and opening the urethra for easy passage of urine.

Most patient are able to return to work in two to three days after the procedure and they experience few side effects. There is no incontinence associated with the TUNA procedure and erectile difficulties are rare.

An even newer procedure, called photoselective vaporization of the prostate (PVP) was FDA approved in 2001. "Basically, as the name suggests, this procedure vaporizes the benign enlarged nodules of the prostate. There is very little bleeding involved, which makes it useful for patients who are on blood thinners," says Dr. Kahn.

Using fiber optics, the surgeon directs laser light at the prostate. The intense pulses of light are absorbed by the blood and, within moments, the temperature of the blood rises enough to cause the nearby prostate cells to vaporize. Delivery of the laser pulse is so precise that there is no damage to surrounding tissues and vessels. Recovery is quick and side effects are few.

"We have other procedures available when a patient's BPH or general health condition requires them," says Kahn. "Refinements continue to be made, but at this point these two procedures fill the bill for most men."

Scott Kahn, MD, FACS

"When a symptomatic patient diagnosed with BPH opts for treatment, we like to start with a conservative approach. The first-line treatments are medications: alpha blockers, which relax the smooth muscles of the prostate, and 5-alpha-reductase inhibitors, which actually shrink the prostate. We also employ the PDE-5 inhibitor Cialis, which has recently been approved for use in BPH.

The majority of men will respond well to some combination of these medications. However, some patients aren't keen on medications and their side effects and some have already tried medical management without their symptoms being sufficiently improved.

For these men, about 20–30 percent of our patients, we offer minimally invasive surgery. The procedures, which generally take under 45-minutes, are done in our offices, under IV anesthesia administered by a board-certified anesthetist.

Not only are the outcomes very good, side effects are minimal and recovery is easy. Most of our patients start getting back to normal activity within a week."

WHAT YOU NEED TO KNOW ABOUT

Helicobacter pylori

Eradication of this common bacterium, discovered in 1982, is the key to curing a wide range of chronic gastric conditions and some cancers.

The 2005 Nobel Prize in Physiology or Medicine was awarded to a pair of Australian physicians for what the prize committee described as a "remarkable and unexpected discovery." Working together, Drs. Robin Warren and Barry Marshall had identified a previously unknown bacterium called Helicobacter pylori (H. pylori) that eventually was proved to be the cause of most cases of gastritis and peptic ulcer disease as well as a significant factor in the development of stomach cancer.

"Before H. pylori, the thinking was that stress, lifestyle or hyperacidity was the cause of duodenal ulcers," says Dr. Sunil Khurana, co-managing director of Premier Medical Group. "In those days, we could heal ulcers with acid suppression medications, but since the underlying cause was not addressed, they would almost always return. Currently, when H. pylori is implicated, we can usually cure the problem in a matter of weeks."

Testing and treatment

The National Institutes of Health estimates that, in the U.S., about 20 percent of people under 40, and half of the adults over 60 years old are infected with H. pylori. Since most people with H. pylori will never experience symptoms or develop an illness because of the bacterium, routine screening has not been recommended. "The guidelines we follow," says Khurana, "call for testing for H. pylori in patients with peptic ulcer disease, gastric cancer, MALT lymphoma, uninvestigated dyspepsia, atrophic gastritis, or unexplained iron deficiency anemia. We also recommend testing for patients who have a first degree relative with gastric cancer."

There are several types of test available for H. pylori, both endoscopic and non-invasive. The patient's condition, symptoms, and the medications he or she is taking factor into the decision on which test should be given.

If a patient is infected with the bacterium, treatment is relatively simple. The standard "triple therapy" to eliminate H. pylori consists of a proton pump inhibitor (PPI) and the antibiotics clarithromycin and amoxicillin taken over a period of about two weeks.

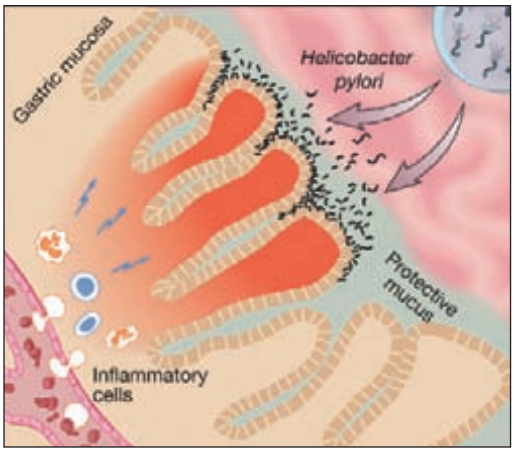


ILLUSTRATION COURTESY OF THE NOBEL COMMITTEE FOR PHYSIOLOGY OR MEDICINE

Chronic infection with helicobacter pylori is the cause of gastric inflammation that causes more than 90 percent of duodenal ulcers and up to 80 percent of gastric ulcers.

A two week course of antibiotics and acid suppressants cures most cases.

"In the last few years we've been seeing resistance developing to the antibiotics, predominantly clarithromycin," says Dr. Khurana. "When this treatment was first introduced, we could successfully treat up to 80 percent of patients with just one course of therapy, but that number has come down significantly because of the resistance factor." Alternate drugs and treatment durations are available for patients whose initial course of therapy is unsuccessful.

"The way I normally prescribe antibiotics, though it takes a little time, is by first asking my patients what antibiotics they've used in the last 5 years," says Khurana. "If someone tells me they've used Biaxin, for example, three or four times in the last few years, I may suspect they've developed a resistance to clarithromycin. In such a case, I'd want to prescribe quadruple therapy, adding an additional antibiotic. It's important to ask patients their history and not just prescribe strictly according to the guidelines."

Sunil K. Khurana, MD, FACG

"Discovery of the Helicobacter pylori bacterium and its effects has had a significant impact on the practice of gastroenterology. Twenty-five years ago, for example, a patient with a duodenal ulcer might expect to stay on a proton pump inhibitor (PPI) forever to control his or her condition. Today, such an ulcer is something we can usually cure simply by eradicating the bacteria.

Similarly, we now know that some gastric cancers may be caused by H. pylori. Not long ago, the father of one of my fellow Premier physicians came to me for treatment. I diagnosed him with MALT lymphoma in the duodenal bulb, and confirmed that he was positive for H. pylori.

Previously, the only treatment for such a cancer was surgery, radiotherapy or chemotherapy. In this case, triple-therapy to eradicate H. pylori proved effective and the tumor regressed—as it does in 60-90 percent of cases. It was quite remarkable to watch, over a period of six months, as the tumor gradually disappeared."

Overcoming Male Infertility

Helping couples realize their dreams is one of the most fulfilling things a urologist can do, professionally and personally.

After a couple has been trying to have a child for approximately a year without success, they're considered, medically, to be an "infertile couple." About 15 percent of couples fall into this category and about 50 percent of the time there is a male factor involved in the infertility.

When a man consults us on the problem the process begins with an infertility evaluation. "We take a history and do a physical examination," says Dr. Jason Krumholtz, Premier's infertility specialist, "but the cornerstone test for infertility involves a set of semen analyses." The semen analysis is typically supplemented by blood tests which yield a hormonal profile: we look for low testosterone and elevation in some other types of hormones, factors which sometimes can provide a clue to the etiology of the fertility problem.

"We see one of three things in the semen analysis," says Krumholtz. "The analysis may be completely normal, which means the patient has what is referred to as unexplained infertility. The second possibility is the presence of some moderate abnormality, such as a low sperm count or low motility or a problem with the morphology. The third possibility is that the analysis shows zero sperm, that the patient is what we call azoospermic. All three of these situations are treated differently."

The main question, at this point, is whether there is something the urologist can do to improve the semen analysis and the couple's probability of success. "We also evaluate whether, with or without improvement in the semen, the couple is a candidate for assisted reproduction, which would include intrauterine insemination or in vitro insemination," says Krumholtz.

"Infertility is different from many other conditions in the way it's treated," Krumholtz says. "When physicians treat other problems, it's very methodical. They go from answer A to answer B to answer C. In treating infertility, we often try several things at once. We give the patient and his spouse several options in terms of how to proceed: that is, we may be able to do one thing first and then try something else, or sometimes we can do both things at once. I create a list of different options the couple has depending upon how aggressive they want to be in solving the problem."

Dr. Krumholtz tries to have both parties come in for the second visit, when he goes over the results of the testing. "At that time we can say with some certainty… these are the facts and here are the ways we can deal with them. It's always easier to come to some agreement on which option is best when both the husband and wife are participating in the treatment planning," he says. "Issue one is deciding if there is something we can do, medically or surgically, to improve the semen analysis. Issue two involves deciding whether we ought to pursue, simultaneously or later, the possibility of assisted reproduction."

Assisted reproduction is a possibility for the majority of our patients with infertility. Even patients with zero sperm are able to achieve pregnancy through testicular sperm extraction (TESE). In this procedure, we remove testicular tissue and extract the sperm, sending it to a reproductive endocrinologist for in vitro fertilization. "The results have been excellent," says Krumholtz. "We have gotten sperm in the overwhelming majority of patients, even patients with severe testicular failure."

Jason Krumholtz, MD

"Our readers should realize that infertility is a very common problem, one that has personally affected some of the physicians in this practice, and we take it very seriously.

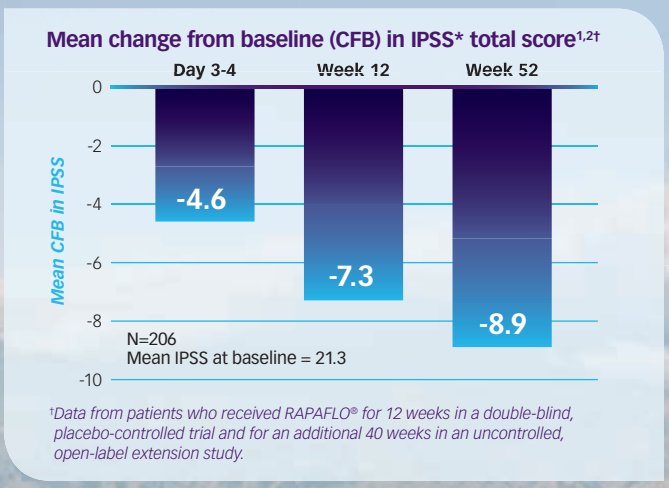
Fortunately, techniques are currently available that take even the most extreme situations and creates a scenario wherein there is a high probability of successful conception and live birth.

Of course, it is not guaranteed that we will always be able to find a way to improve a man's sperm counts. That being said, sometimes the solutions can be very simple.

For example, one of the more common things that can contribute to abnormal semen analyses is varicoceles, dilated veins that are found inside the scrotum. These can be repaired and can result in meaningful improvements in sperm counts.

Working with male infertility is one of the most fulfilling things I do, both professionally and personally: You're helping couples realize their dreams."

AVOID THE STOP AND GO OF BPH



†Data from patients who received RAPAFLO® for 12 weeks in a double-blind, placebo-controlled trial and for an additional 40 weeks in an uncontrolled, open-label extension study.

Continued BPH‡ symptom relief over 1 year†

**International Prostate Symptom Score*
‡Benign prostatic hyperplasia

RAPAFLO® is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). RAPAFLO® is not indicated for the treatment of hypertension.

Important Safety Information

RAPAFLO® is contraindicated in patients with severe renal impairment (CCr <30 mL/min), severe hepatic impairment (Child-Pugh score ≥10), and with use of strong CYP3A4 inhibitors.

Postural hypotension with or without symptoms (eg, dizziness) may develop when beginning treatment with RAPAFLO®. As with all alpha-blockers, there is a potential for syncope. Patients should be warned of the possible occurrences of such events and should avoid situations where injury could result. RAPAFLO® should be used with caution in patients with moderate renal impairment. Patients should be assessed to rule out the presence of prostate cancer prior to starting treatment with RAPAFLO®. Patients planning cataract surgery should inform their ophthalmologist that they are taking RAPAFLO®.

The most common side effects are retrograde ejaculation, dizziness, diarrhea, orthostatic hypotension, headache, nasopharyngitis, and nasal congestion.

Please see brief summary of full Prescribing Information on adjacent page.

Models are for illustrative purposes only.

www.rapaflo.com

References: 1. Marks LS, Gittelman MC, Hill LA, Volinn W, Hoel G. Silodosin in the treatment of the signs and symptoms of benign prostatic hyperplasia: a 9-month, open-label extension study. *Urology.* 2009; 74:1318-1322. **2.** Data on file, Watson Laboratories, Inc.

RAPAFLO® 8 mg (silodosin) capsules

READY. SELECT. GO.

Watson

RAPAFLO® (silodosin) capsules

BRIEF SUMMARY

For full Prescribing Information, see package insert.

INDICATIONS AND USAGE

RAPAFLO, a selective alpha-1 adrenergic receptor antagonist, is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). RAPAFLO is not indicated for the treatment of hypertension.

CONTRAINDICATIONS

- Severe renal impairment (CCr < 30 mL/min)
- Severe hepatic impairment (Child-Pugh score ≥ 10)
- Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir) [*see Drug Interactions*]

WARNINGS AND PRECAUTIONS

Orthostatic Effects

Postural hypotension, with or without symptoms (e.g., dizziness) may develop when beginning RAPAFLO treatment. As with other alpha-blockers, there is potential for syncope. Patients should be cautioned about driving, operating machinery, or performing hazardous tasks when initiating therapy [*see Adverse Reactions and Use in Specific Populations*].

Renal Impairment

In a clinical pharmacology study, plasma concentrations (AUC and C_{max}) of silodosin were approximately three times higher in subjects with moderate renal impairment compared with subjects with normal renal function, while half-lives of silodosin doubled in duration. The dose of RAPAFLO should be reduced to 4 mg in patients with moderate renal impairment. Exercise caution and monitor such patients for adverse events [*see Use in Specific Populations*].

RAPAFLO is contraindicated in patients with severe renal impairment [*see Contraindications*].

Hepatic Impairment

RAPAFLO has not been tested in patients with severe hepatic impairment, and therefore, should not be prescribed to such patients [*see Contraindications and Use in Specific Populations*].

Pharmacokinetic Drug-Drug Interactions

In a drug interaction study, co-administration of a single 8 mg dose of RAPAFLO with 400 mg ketoconazole, a strong CYP3A4 inhibitor, caused a 3.8-fold increase in maximum plasma silodosin concentrations and 3.2-fold increase in silodosin exposure (i.e., AUC). Concomitant use of ketoconazole or other strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin, ritonavir) is therefore contraindicated [*see Drug Interactions*].

Pharmacodynamic Drug-Drug Interactions

The pharmacodynamic interactions between silodosin and other alpha-blockers have not been determined. However, interactions may be expected, and RAPAFLO should not be used in combination with other alpha-blockers [*see Drug Interactions*].

A specific pharmacodynamic interaction study between silodosin and antihypertensive agents has not been performed. However, patients in the Phase 3 clinical studies taking concomitant antihypertensive medications with RAPAFLO did not experience a significant increase in the incidence of syncope, dizziness, or orthostasis. Nevertheless, exercise caution during concomitant use with antihypertensives and monitor patients for possible adverse events [*see Adverse Reactions and Drug Interactions*].

Caution is also advised when alpha-adrenergic blocking agents including RAPAFLO are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension [*see Drug Interactions*].

Carcinoma of the Prostate

Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Therefore, patients thought to have BPH should be examined prior to starting therapy with RAPAFLO to rule out the presence of carcinoma of the prostate.

Intraoperative Floppy Iris Syndrome

Intraoperative Floppy Iris Syndrome has been observed during cataract surgery in some patients on alpha-1 blockers or previously treated with alpha-1 blockers. This variant of small pupil syndrome is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents; progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs; and potential prolapse of the iris toward the phacoemulsification incisions. Patients planning cataract surgery should be told to inform their ophthalmologist that they are taking RAPAFLO [*see Adverse Reactions*].

Laboratory Test Interactions

No laboratory test interactions were observed during clinical evaluations. Treatment with RAPAFLO for up to 52 weeks had no significant effect on prostate-specific antigen (PSA).

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In U.S. clinical trials, 897 patients with BPH were exposed to 8 mg RAPAFLO daily. This includes 486 patients exposed for 6 months and 168 patients exposed for 1 year. The population was 44 to 87 years of age, and predominantly Caucasian. Of these patients, 42.8% were 65 years of age or older and 10.7% were 75 years of age or older.

In double-blind, placebo controlled, 12-week clinical trials, 466 patients were administered RAPAFLO and 457 patients were administered placebo. At least one treatment-emergent adverse reaction was reported by 55.2% of RAPAFLO treated patients (36.8% for placebo treated). The majority (72.1%) of adverse reactions for the RAPAFLO treated patients (59.8% for placebo treated) were qualified by the investigator as mild. A total of 6.4% of RAPAFLO treated patients (2.2% for placebo treated) discontinued therapy due to an adverse reaction (treatment-emergent), the most common reaction being retrograde ejaculation (2.8%) for RAPAFLO treated patients. Retrograde ejaculation is reversible upon discontinuation of treatment.

Adverse Reactions observed in at least 2% of patients:

The incidence of treatment-emergent adverse reactions listed in the following table were derived from two 12-week, multicenter, double-blind, placebo-controlled clinical studies of RAPAFLO 8 mg daily in BPH patients. Adverse reactions that occurred in at least 2% of patients treated with RAPAFLO and more frequently than with placebo are shown in Table 1.

Table 1 Adverse Reactions Occurring in ≥ 2% of Patients in 12-week, Placebo-Controlled Clinical Trials

Adverse Reactions	RAPAFLO N = 466 n (%)	Placebo N = 457 n (%)
Retrograde Ejaculation	131 (28.1)	4 (0.9)
Dizziness	15 (3.2)	5 (1.1)
Diarrhea	12 (2.6)	6 (1.3)
Orthostatic Hypotension	12 (2.6)	7 (1.5)
Headache	11 (2.4)	4 (0.9)
Nasopharyngitis	11 (2.4)	10 (2.2)
Nasal Congestion	10 (2.1)	1 (0.2)

In the two 12-week, placebo-controlled clinical trials, the following adverse events were reported by between 1% and 2% of patients receiving RAPAFLO and occurred more frequently than with placebo: insomnia, PSA increased, sinusitis, abdominal pain, asthenia, and rhinorrhea. One case of syncope in a patient taking prazosin concomitantly and one case of priapism were reported in the RAPAFLO treatment group.

In a 9-month open-label safety study of RAPAFLO, one case of Intraoperative Floppy Iris Syndrome (IFIS) was reported.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of silodosin. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

Skin and subcutaneous tissue disorders: *toxic skin eruption, purpura*

Hepatobiliary disorders: *jaundice, impaired hepatic function associated with increased transaminase values*

DRUG INTERACTIONS

Moderate and Strong CYP3A4 Inhibitors

In a clinical metabolic inhibition study, a 3.8-fold increase in silodosin maximum plasma concentrations and 3.2-fold increase in silodosin exposure were observed with concurrent administration of a strong CYP3A4 inhibitor, 400 mg ketoconazole. Use of strong CYP3A4 inhibitors such as itraconazole or ritonavir may cause plasma concentrations of silodosin to increase. Concomitant administration of strong CYP3A4 inhibitors and RAPAFLO is contraindicated [*see Contraindications and Warnings and Precautions*].

The effect of moderate CYP3A4 inhibitors on the pharmacokinetics of silodosin has not been evaluated. Concomitant administration with moderate CYP3A4 inhibitors (e.g., diltiazem, erythromycin, verapamil) may increase concentration of RAPAFLO. Exercise caution and monitor patients for adverse events when co-administering RAPAFLO with moderate CYP3A4 inhibitors.

Strong P-glycoprotein (P-gp) Inhibitors

In vitro studies indicated that silodosin is a P-gp substrate. Ketoconazole, a CYP3A4 inhibitor that also inhibits P-gp, caused significant increase in exposure to silodosin. Inhibition of P-gp may lead to increased silodosin concentration. RAPAFLO is therefore not recommended in patients taking strong P-gp inhibitors such as cyclosporine.

Alpha-Blockers

The pharmacodynamic interactions between silodosin and other alpha-blockers have not been determined. However, interactions may be expected, and RAPAFLO should not be used in combination with other alpha-blockers [*see Warnings and Precautions*].

Digoxin

The effect of co-administration of RAPAFLO and digoxin 0.25 mg/day for 7 days was evaluated in a clinical trial in 16 healthy males, aged 18 to 45 years. Concomitant administration of RAPAFLO and digoxin did not significantly alter the steady state pharmacokinetics of digoxin. No dose adjustment is required.

PDE5 Inhibitors

Co-administration of RAPAFLO with a single dose of 100 mg sildenafil or 20 mg tadalafil was evaluated in a placebo-controlled clinical study that included 24 healthy male subjects, 45 to 78 years of age. Orthostatic vital signs were monitored in the 12-hour period following concomitant dosing. During this period, the total number of positive orthostatic test results was greater in the group receiving RAPAFLO plus a PDE5 inhibitor compared with RAPAFLO alone. No events of symptomatic orthostasis or dizziness were reported in subjects receiving RAPAFLO with a PDE5 inhibitor.

Other Concomitant Drug Therapy

Antihypertensives

The pharmacodynamic interactions between silodosin and antihypertensives have not been rigorously investigated in a clinical study. However, approximately one-third of the patients in clinical studies used concomitant antihypertensive medications with RAPAFLO. The incidence of dizziness and orthostatic hypotension in these patients was higher than in the general silodosin population (4.6% versus 3.8% and 3.4% versus 3.2%, respectively). Exercise caution during concomitant use with antihypertensives and monitor patients for possible adverse events [*see Warnings and Precautions*].

Metabolic Interactions

In vitro data indicate that silodosin does not have the potential to inhibit or induce cytochrome P450 enzyme systems.

Food Interactions

The effect of a moderate fat, moderate calorie meal on silodosin pharmacokinetics was variable and decreased silodosin maximum plasma concentration (C_{max}) by approximately 18 - 43% and exposure (AUC) by 4 - 49% across three different studies. Safety and efficacy clinical trials for RAPAFLO were always conducted in the presence of food intake. Patients should be instructed to take silodosin with a meal to reduce risk of adverse events.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B. RAPAFLO is not indicated for use in women.

An embryo/fetal study in rabbits showed decreased maternal body weight at 200 mg/kg/day (approximately 13-25 times the maximum recommended human exposure or MRHE of silodosin via AUC). No statistically significant teratogenicity was observed at this dose.

Silodosin was not teratogenic when administered to pregnant rats during organogenesis at 1000 mg/kg/day (estimated to be approximately 20 times the MRHE). No maternal or fetal effects were observed at this dose. Rats and rabbits do not produce glucuronidated silodosin, which is present in human serum at approximately 4 times the level of circulating silodosin and which has similar pharmacological activity to silodosin.

No effects on physical or behavioral development of offspring were observed when rats were treated during pregnancy and lactation at up to 300 mg/kg/day.

Pediatric Use

RAPAFLO is not indicated for use in pediatric patients. Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

In double-blind, placebo-controlled, 12-week clinical studies of RAPAFLO, 259 (55.6%) were under 65 years of age, 207 (44.4%) patients were 65 years of age and over, while 60 (12.9%) patients were 75 years of age and over. Orthostatic hypotension was reported in 2.3% of RAPAFLO patients < 65 years of age (1.2% for placebo), 2.9% of RAPAFLO patients ≥ 65 years of age (1.9% for placebo), and 5.0% of patients ≥ 75 years of age (0% for placebo). There were otherwise no significant differences in safety or effectiveness between older and younger patients.

Renal Impairment

The effect of renal impairment on silodosin pharmacokinetics was evaluated in a single dose study of six male patients with moderate renal impairment and seven male subjects with normal renal function. Plasma concentrations of silodosin were approximately three times higher in subjects with moderate renal impairment compared with subjects with normal renal function.

RAPAFLO should be reduced to 4 mg per day in patients with moderate renal impairment. Exercise caution and monitor patients for adverse events.

RAPAFLO has not been studied in patients with severe renal impairment. RAPAFLO is contraindicated in patients with severe renal impairment [*see Contraindications and Warnings and Precautions*].

Hepatic Impairment

In a study comparing nine male patients with moderate hepatic impairment (Child-Pugh scores 7 to 9), to nine healthy male subjects, the single dose pharmacokinetics of silodosin were not significantly altered in patients with hepatic impairment. No dosing adjustment is required in patients with mild or moderate hepatic impairment.

RAPAFLO has not been studied in patients with severe hepatic impairment. RAPAFLO is contraindicated in patients with severe hepatic impairment [*see Contraindications and Warnings and Precautions*].

OVERDOSAGE

RAPAFLO was evaluated at doses of up to 48 mg/day in healthy male subjects. The dose-limiting adverse event was postural hypotension.

Should overdose of RAPAFLO lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by maintaining the patient in the supine position. If this measure is inadequate, administration of intravenous fluid should be considered. If necessary, vasopressors could be used, and renal function should be monitored and supported as needed. Dialysis is unlikely to be of significant benefit since silodosin is highly (97%) protein bound.

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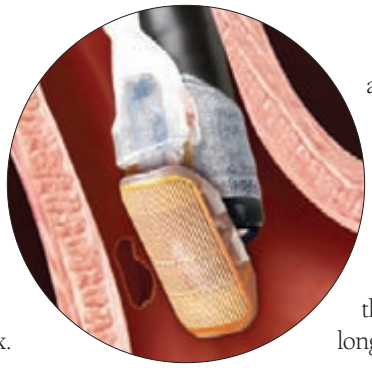
Rx Only Revised: November 2011 173761-3

WHAT YOU NEED TO KNOW ABOUT

Barrett's esophagus

Often the result of GERD, this condition can be a precursor to America's fastest growing type of cancer. A new treatment helps lower the toll.



The endoscopic HALO system employs radiofrequency ablation, providing a new paradigm for how we treat Barrett's.

Barrett's esophagus is a condition in which the lining of the esophagus, the tube that connects the mouth to the stomach, is replaced by tissue that is similar to the lining of the stomach, most often in response to the effects of chronic acid reflux.

The ends of the esophagus are normally pinched together by sphincter muscles. The sphincters relax to allow food or drink to pass from the mouth into the stomach, and then close rapidly to prevent the food or drink, and stomach acids, from leaking back into the esophagus and mouth.

When the lower sphincter fails to close, however, stomach acid washes back and touches the lining of the esophagus. This is called gastroesophageal reflux (GER), and can cause the burning sensation in the chest or throat called heartburn or acid indigestion. Occasional GER is common, but can progress to the more chronic condition known as gastroesophageal reflux disease, or GERD.

Reflux that occurs more than twice a week is considered GERD. With about 20 percent of Americans experiencing GERD symptoms every day, it is one of the most common medical conditions. GERD can eventually lead to more serious health problems, including Barrett's. "Because the environment of the esophagus is now acidic, the cells evolve to be more like stomach lining cells in order to withstand that acid exposure," says Robert S. Dean, M.D., of Premier Medical Group's Gastroenterology Division.

Diagnosis and Treatments

Typically, there are no signs or symptoms associated with Barrett's esophagus—which affects about one percent of adults in the U.S.— and most of the time the condition is harmless. "But between 0.13 percent and 0.5 percent of Barrett's patients are at risk of developing esophageal adenocarcinoma," Dr. Dean says. "It's not that common, but this is the fastest growing cancer in the U.S., and most of it has to do with acid reflux."

The American Gastroenterological Association recommends that persons over 40 with longstanding chronic GERD, the at-risk population, receive endoscopic examinations and biopsies to look for early warning signs of cancer. Typically, precancerous cells appear in the Barrett's tissue first. This condition is called dysplasia and can be seen only through biopsies. Detecting and treating dysplasia may prevent cancer from developing.

"There is a sequence of cellular changes as it progresses from Barrett's to cancer," Dr. Dean says. These progressions are graded as low-grade and high-grade dysplasia. "With low-grade dysplasia, we historically just watched and waited, with periodic endoscopy and biopsy," he says. "But with new technologies like the HALO System we are more aggressive in removing even low-grade dysplasia. With high-grade, the possibility of cancer is more imminent, and interventional therapy is needed."

Therapies include endoscopic or surgical treatments to treat the disease. During these therapies, the Barrett's lining is destroyed or the portion of the lining that has dysplasia or cancer is cut out. The goal of the treatment is to encourage normal esophageal tissue to replace the destroyed lining. Surgical removal of most of the esophagus is recommended if a person with Barrett's esophagus is found to have severe dysplasia or cancer and can tolerate a surgical procedure. Surgery soon after diagnosis of severe dysplasia or cancer may provide the patient with the best chance for a cure.

The key, though, is early diagnosis. When this potentially deadly cancer is not detected until its later stages, treatments may not be effective. "The more Barrett's we diagnose, the fewer cases we see turning into cancer," says Dean.

Robert S. Dean, MD

"The newest and best treatment we have for Barrett's esophagus is radiofrequency ablation (RFA) using the HALO System. There have been many treatments over the years that attempted to halt the Barrett's-to-cancer sequence, all of which have been either ineffective or very invasive, or both. This is the first treatment that appears to have excellent results with minimal patient trauma.

The HALO System is an endoscopic procedure, performed under 'twilight' sedation on an outpatient basis. Most patients can go to work the next day and have no discomfort. The RF probe is attached to the endoscope and is inserted, under direct visualization, to the diseased tissue. The probe applies a predetermined RF current to the tissue that kills the abnormal cells, allowing normal cells to regenerate in their place. Typically two or three sessions are needed to fully eradicate the diseased tissue.

Barrett's is a pretty common diagnosis these days. This new system gives us an actual treatment as opposed to watchful waiting. It has changed the paradigm of how we treat this condition."

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Measuring Outcomes

How does a physician know that his or her patients are in compliance and responding to the treatment plan as well as they should be?

Were a patient to pass a kidney stone and then get no additional treatment nor adjust diet and fluid intake, he or she would have a 50 percent chance of forming another stone within the next two years.

Yet, once we have identified the type of stone a patient is prone to forming, we have the ability to help them significantly reduce that risk. We advise our patients that drinking sufficient water and other fluids—enough to produce about 2 quarts of urine daily—will impede formation of all types of stones. We tell them that consuming foods with high levels of oxalate increases the risk of forming calcium oxalate stones; that too much animal protein in the diet increases the risk of uric acid stones; that a diet high in salt increase the risk of forming calcium containing kidney stones.

"You can tell a patient to take a medication, or follow a particular diet," says Dr. Evan Goldfischer, "but the question remains… do they go out and do it? The process is very patient dependant and some doctors seem to be more persuasive than others."

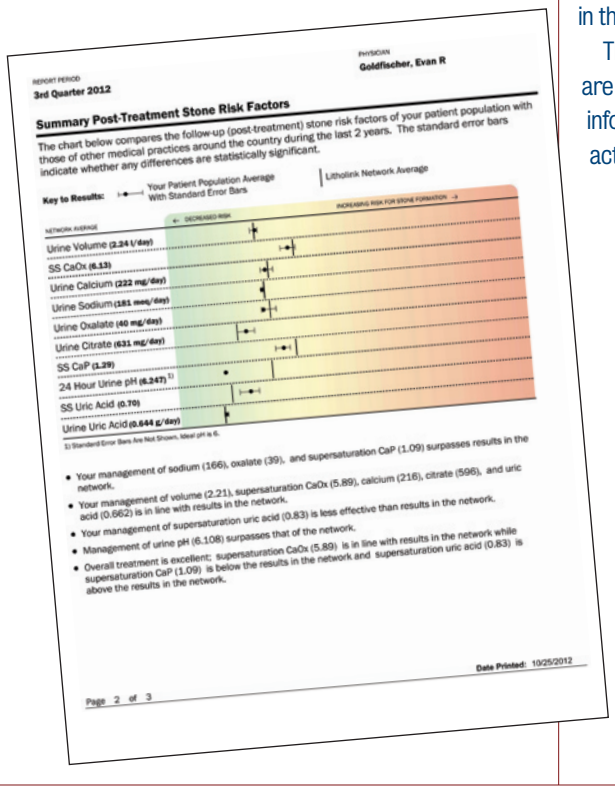
Litholink, a laboratory dedicated to measuring a patient's urine for risk factors for stone disease, has provided a solution to the physician's constant question: "Am I doing enough."

The Litholink process begins with a metabolic analysis done several weeks after the patient's bout with kidney stones. Using a special kit, the patient collects his or her urine for 24 to 48 hours and we send it on to Litholink. The company provides us an analysis of the factors—over thirty different measurements—putting the patient at high risk of stones. Using that information we are able to counsel our patients effectively.

LithoLink developed a structure that goes beyond metabolic analysis to also provide physicians with a way to measure outcomes of their treatment. Let's say Premier Medical Group does metabolic analyses on a thousand patients and then makes treatment recommendations to these patients based on the analyses. Six months into treatment, we send LithoLink another urine sample from the patients for follow-up analysis. Litholink compares the new analyses to the original and is able to determine how many patients have improved in the various categories.

The results of our practice, and of thousands of others around the country, are put into a central database. This allows Litholink to provide us with a comparison of our outcomes in relation to that of everyone else in the network. It's kind of a pulse. Doctors always wonder how they're doing as compared to their colleagues, and with the Litholink quarterly reports, you actually find out how you rank.

What is most important is gaining an idea of clinical areas that you can improve on as a physician in order to improve your patient's outcomes.



REPORT PERIOD
3rd Quarter 2012

PHYSICIAN
Goldfischer, Evan R

Summary Post-Treatment Stone Risk Factors

The chart below compares the follow-up (post-treatment) stone risk factors of your patient population with those of other medical practices around the country during the last 2 years. The standard error bars indicate whether any differences are statistically significant.

Key to Results: Your Patient Population Average With Standard Error Bars | Litholink Network Average

NETWORK AVERAGE ← DECREASED RISK — INCREASING RISK FOR STONE FORMATION →

Urine Volume (2.34 l/day)
SS CaOx (6.13)
Urine Calcium (222 mg/day)
Urine Sodium (181 meq/day)
Urine Oxalate (40 mg/day)
Urine Citrate (631 mg/day)
SS CaP (1.29)
24 Hour Urine pH (6.247) 1)
SS Uric Acid (0.70)
Urine Uric Acid (0.644 g/day)

1) Standard Error Bars Are Not Shown, Ideal pH is 6.

- Your management of sodium (166), oxalate (39), and supersaturation CaP (1.09) surpasses results in the network.
- Your management of volume (2.21), supersaturation CaOx (5.89), calcium (216), citrate (596), and uric acid (0.662) is in line with results in the network.
- Your management of supersaturation uric acid (0.83) is less effective than results in the network.
- Management of urine pH (6.108) surpasses that of the network.
- Overall treatment is excellent; supersaturation CaOx (5.89) is in line with results in the network while supersaturation CaP (1.09) is below the results in the network and supersaturation uric acid (0.83) is above the results in the network.

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A sample Litholink quarterly report providing physicians an overview of how well their patients are doing in reducing the risk of recurrent kidney stones.

Evan R. Goldfischer, MD, FACS

"Doctors are always wondering if they're doing enough for their patients. In regard to kidney stones, that means not only prescribing the right medicine and advising adoption of the proper diet to stave off recurrences, but also getting through to the patient about the importance of compliance.

The reports we've gotten from Litholink over the last 15 years—comparing our results to those of academic centers as well as private practices across the country— have consistently put us in the top 2–5 percent.

That tells us that not only are our patients getting the information they need, they're actually following up on it."

IBS and a low-FODMAP diet

Arif M. Muslim, MD

A group of poorly digested carbohydrates (FODMAPs) could well be responsible for triggering the symptoms of irritable bowel syndrome. The poorly absorbed large molecules of these foods make their way to the colon, where the action of bacteria cause them to ferment, resulting in bouts of gas, bloating and bowel problems. A number of studies have shown that the majority of patients with IBS who try a low-FODMAP diet experience a significant lessening of symptoms.

Irritable bowel syndrome (IBS) is a chronic and often disabling condition manifested by abdominal pain, a change in bowel habits (diarrhea and constipation), abdominal distention and intestinal gas. IBS affects 10-20 percent of the U.S. population (more women than men) and accounts for about half of all visits to gastroenterologists.

IBS is not a disease in which structural or tissue abnormality occurs, but a functional disorder defined by its symptoms. The mechanisms causing them are not fully understood, but we know they include hyper-sensitivity to visceral sensation, altered motility (movement of food through the digestive tract), abnormal colonic fermentation and sugar malabsorption.

Most patients with IBS, however, report that their symptoms seem to be related to the foods they eat. In recent years, attention has been focused on diets that reduce the intake of poorly absorbed complex carbohydrates, called FODMAPs. The acronym stands for fermentable oligo-, di-, and mono-saccharides and polyols. Research studies have shown that a low-FODMAP diet helps the majority of patients with IBS.

FODMAP foods to avoid or limit

FRUIT
Apples, apricots, cherries, mango, pears, nectarines, peaches, pears, plums, prunes, watermelon and high concentrations of fructose from canned fruit, dried fruit or fruit juice

VEGETABLES
Artichokes, asparagus, avocado, beets, broccoli, brussel sprouts, cabbage, cauliflower, garlic (in large quantity), fennel, leeks, mushrooms, okra, onions, peas, radiccio, lettuce, scallions (white parts), shallots, sugar snap peas, snow peas

LEGUMES
Baked beans, chickpeas, lentils, kidney beans, soy beans

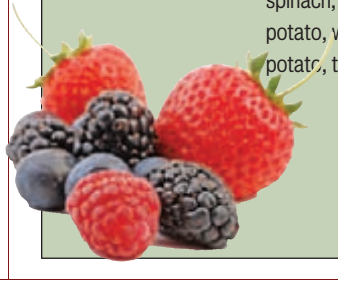
SWEETENERS
Honey, fructose, high fructose corn syrup, isomalt, maltitol, mannitol, sorbitol, xylitol

LACTOSE-CONTAINING FOODS
Custard, ice cream, margarine, milk (cow, goat, sheep), soft cheese (including cottage cheese and ricotta), yogurt

GRAINS
wheat or rye in large amounts, eg. bread, crackers, cookies, cous cous, pasta

Suitable foods for a Low-FODMAP diet

FRUIT
Banana, blueberry, grapefruit, grapes, honeydew melon, kiwi, lemon, lime, mandarin oranges, orange, raspberry, strawberry



VEGETABLES
Bell peppers, bok choy, carrots, celery, corn, eggplant, green beans, lettuce, parsnips, scallions (green parts only) spinach, sweet potato, white potato, tomato

STAPLES
Meats, fats, eggs

SWEETENERS
Artificial sweeteners that do not end in "ol," glucose, maple syrup, sugar (sucrose)

LACTOSE ALTERNATIVES
Butter, hard cheese, brie and camembert, lactose-free products, such as lactose-free ice cream and yogurt, gelato, rice milk & sorbet

GRAINS
Oats, gluten-free products & spelt products

FODMAPS have a cumulative effect on GI symptoms, so people with IBS may be able to tolerate small amounts of them and experience symptoms only when they've consumed enough to surpass their FODMAP threshold.

To keep to a low-FODMAP diet requires careful reading of the labels on prepared foods. Gluten-free products, though often low in FODMAPs, are not uniformly safe—many contain honey, pear juice, onions or garlic for flavoring.

Remember that ingredients are listed with the most predominant ones first. So, for example, if a FODMAP ingredient is listed last, the amount is likely to be quite small. Generally, try to avoid products in which multiple FODMAPs are present.

THE MEANINGS OF

Scrotal Pain

It's often said that pain is the body's early warning system. In the case of the male reproductive system, attending to pain may preserve fertility.

You don't have to be a martial arts expert to know that a blow to the scrotum tends to incapacitate a man, no matter how tough he might be. The testicles are actually organs suspended outside the body in the somewhat protective pouch of the scrotum. When they are subjected to blunt force trauma, most commonly from a sports injury or a blow, the resulting pain is deeper and more intense.

The initial rush of pain occurs as the testicle swells. Then, the pressure caused by the swelling impinges on the surrounding nerves, spreading the pain to the lower abdomen, which is why such an injury is often accompanied by nausea.

"In most cases, depending on the severity of the blow, the pain starts relaxing considerably within an hour or less," says Dr. Walter Parker of Premier's Urology Division. "If there is a great deal of persistent pain, bruising and swelling, that suggests a higher grade injury. A severe trauma can fracture the tunica vaginalis, the membrane covering the testicle, and that needs to be medically attended to," he says.

The most severe form scrotal pain is a result of ***testicular torsion***. Each testicle is suspended in the scrotum by a spermatic cord that contains blood vessels, nerves and the ducts carrying sperm from the testicle. If the testicle twists about on the cord (torsion), blood supply to the testicle can be cut off and, without prompt medical care, lead to losing the testicle.

"Testicular torsion is most common in teenagers, but it can come at any age," says Dr. Parker. "I've seen it in infants and in 70-year-old men." The condition is relatively rare, affecting about 1 in 4,000 males under the age of 25 annually. Torsion can follow strenuous activity, such as heavy lifting, or trauma, but it often occurs for no apparent reason and the pain of it may begin abruptly during sleep. The abrupt and excruciating pain of testicular torsion should be considered an urgent message to seek emergency care.

Progressively painful, the onset of acute ***epididymitis***—which often develops over a 24-hour period—serves as a warning of infection of the epidiymis, a coiled tube that collects sperm from the testicle. "In younger patients, say under 35, epididymitis tends to be the result of an STD, such as gonorrhea or chlamydia," says Dr. Parker. "In older patients, it is more likely to be connected to urinary tract infection, which is sometimes related to BPH or bacterial prostatitis." The pain of epididymitis typically starts at the back of one testicle and then spreads to involve the whole scrotum, accompanied by swelling, tenderness, redness, and warm skin.

The condition is successfully managed with antibiotics, either broad-spectrum or targeted to the particular bacterium involved.

The sudden pain of ***orchitis***, an inf ammation of one or both testicles, ranges from mild to severe. The condition is usually associated with the virus that causes mumps and more than one-third of post-puberty males who contract mumps will develop it. Orchitis may also have a bacterial origin, or spread from existing epididymitis, in which case it's called epididymo-orchitis.

Bacterial orchitis is treated with antibiotics plus rest, ice packs and analgesics for pain control. Treatment for viral orchitis is palliative while the body's immune system fights off the virus over the course of 3-10 days.

Walter Parker, MD

"Most men are very good about reporting scrotal pain but, surprisingly, you do see the occasional patient who is reluctant and, unfortunately, seeks care too late. In at least 50 percent of the cases where I've done surgical exploration for testicular torsion, I've had to remove the testicle because it was too late. Yet, if you can get the blood flowing again in time, in under 6-12 hours, the results tend to be very good.

It's often quite obvious when a patient has torsion. The pain is very intense and men with the condition just cannot get comfortable; they feel nauseous and can't bear to be touched. On the other hand, patients with epididymitis, which is also a painful condition, can usually sit there calmly without pain unless they move around.

Testicular torsion is a real vascular emergency. I advise men who experience the abrupt onset of very intense scrotal pain, especially in the absence of trauma, to get to an emergency room quickly to have their situation evaluated."

PREMIER *medical group*
1 Columbia Street
Poughkeepsie, New York 12601
www.premiermedicalhv.com

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Faces of Premier

Good healthcare requires teamwork. We're proud of the dedicated team that makes up Premier Medical Group. Their loyalty contributes to the comfort and security of our patients.

Penny Napolitano

Director of Finance

The growth of Premier Medical Group and the growth of its patient base have made it smart to have an internal financial director. Running a business is difficult these days, especially when it has to do with the health care industry. There have been many changes and a lot of new regulations, not only for Premier as a medical provider, but also for Premier as a business. There's a great deal more reporting of data required these days, and things have gotten more complex on the state and federal level.

Under the direction of Penny Napolitano, all of our medical billing is done internally, not through some third party billing company. She makes sure the patients get the level of satisfaction they need in regards to questions about a statement or an Explanation of Benefits (EOB) they might receive from an insurance company. Penny deals directly with our billing supervisor regarding issues with insurance companies or patients.

She is also personally involved with all the vendors we deal with—from Central Hudson to the pharmaceutical firms that supply our medications— and her efficiency and responsiveness go a long way towards making doing business with Premier a pleasant prospect. Keeping the business side on the same level as the medical side is really important to us: Premier provides premier medical care and we try to provide premier attention to our vendors and our patients.

The majority of Napolitano's time is spent on the daily financial responsibilities of Premier, things like monitoring costs and analyzing productivity and revenue. She makes sure the numbers make sense.