Endocrine Notes

Updates for physicians on practices, advances and research from the Cleveland Clinic Endocrinology & Metabolism Institute

Read about our new Diabetes Center on page 10
Dear Colleagues,

I am pleased to present the 2010 edition of Endocrine Notes, from Cleveland Clinic’s Endocrinology & Metabolism Institute.

As one of 26 Cleveland Clinic institutes grouping related specialties together to provide integrated, patient-centered care, our institute focuses on the endocrine system. Collaboration among specialists in endocrinology, endocrine surgery, bariatrics, bariatric surgery and cardiology allows us to transcend the traditional borders between disciplines and improve the care of our patients. Our entire staff remains committed to Cleveland Clinic’s core ideology: “Patients First.”

Within this institute, our Department of Endocrinology, Diabetes and Metabolism manages specialized centers of care for patients with diabetes, thyroid disorders and pituitary disorders. Our Department of Endocrine Surgery’s staff performs the highest number of surgical procedures in the region. Our Bariatric and Metabolic Institute is designated a Bariatric Surgery Center of Excellence by the American Society for Metabolic and Bariatric Surgery.

In the following pages, you will find highlights from this multidisciplinary team over the past year, including:

• A retrospective chart review comparing mortality among diabetic patients taking three different sulfonylureas
• A study confirming that adrenal mass growth is a statistically significant predictor of malignancy
• A study finding improved vitamin D absorption when the vitamin is taken with the largest meal
• A recommendation by our endocrinologists that GDH-PQQ glucose monitoring strips be banned
• The opening of a new, state-of-the-art Diabetes Center in October 2010
• The availability of robotic thyroidectomy and parathyroid surgery at Cleveland Clinic
• A case study involving allotransplantation of cryopreserved parathyroid tissue

I hope that you find this issue of Endocrine Notes useful for your practice. Your comments and questions are always welcome. Please feel free to contact me at 216.444.6568 or 800.223.2273, ext. 46568.

Sincerely,

James B. Young, MD
Chairman, Endocrinology & Metabolism Institute
Professor of Medicine and Executive Dean, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University
George and Linda Kaufman Chair
Physician Director, Institutional Relations and Development

To refer patients to Cleveland Clinic’s Endocrinology & Metabolism Institute, call 216.444.6568 or 800.223.2273, ext. 46568.
Glimepiride May Offer Slight Advantage for Diabetic Patients with CAD

For years, conflicting information about sulfonylureas has infiltrated the medical journals. More than 30 years ago, the University Group Diabetes Project published a paper warning that this class of oral antidiabetic drugs increased the risk of cardiovascular death. But these results seemed murky, creating more confusion than clarity. Other research groups published papers showing that sulfonylureas did not increase coronary artery disease (CAD). The conflicting information made it difficult for physicians to discern whether they could safely prescribe sulfonylureas.

In 2009, Robert Zimmerman, MD, Director of the Diabetes Center in Cleveland Clinic's Department of Endocrinology, Diabetes and Metabolism, published a paper in *Acta Diabetol* along with colleagues documenting a higher risk of mortality with sulfonylureas as compared with rosiglitazone, pioglitazone and metformin. Following this study, Dr. Zimmerman, endocrinology fellow Kevin Pantalone, DO, and colleagues wondered if one type of sulfonylurea was less likely to lead to mortality than another.

“Sulfonylureas have historically been analyzed as a medication class, which may be inappropriate given the differences in properties inherent to the individual sulfonylureas: hypoglycemic risk, sulfonylurea receptor selectivity and effects on myocardial ischemic preconditioning,” they write in their paper, published in the June 2010 issue of *Diabetes Care*.

Even though sulfonylureas are believed to have a higher mortality rate than other antidiabetic drugs, few studies have determined whether one sulfonylurea poses a higher risk than another. Drs. Zimmerman and Pantalone designed this study to document any differences in mortality rates for glyburide, glipizide and glimepiride.

They retrospectively reviewed the electronic medical records (EMRs) of 11,141 Cleveland Clinic patients, age 18 and older, who had type 2 diabetes with and without a history of coronary artery disease (CAD). None of the patients were on insulin or a noninsulin injectable at baseline. Of the total sample, 4,279 received glyburide, 4,325 received glipizide and 2,537 received glimepiride. They evaluated mortality based upon the EMR and Social Security Death Index.
“The advantage of doing a retrospective study using the EMR is the large number of patients that you can study,” says Dr. Zimmerman. “The disadvantage is that not everything is as perfect in the EMR as it would be if you were doing a prospective study; you don’t know about compliance.”

Of the different drugs, they suspected that glipizide might be less likely to cause mortality. “Other data showed that certain sulfonylureas bind to the heart more than others,” explains Dr. Zimmerman. Because glyburide and glimepiride bind to a sulfonylurea receptor in the heart as well as in the pancreas, they hypothesized that the drugs might potentiate damage, specifically in the setting of myocardial ischemia.

But study results indicate that prescribing glimepiride might be preferable for patients with a history of CAD because its impact on the heart is less than that of other sulfonylureas. “This is really a surprise because glipizide does not bind to the heart, and we thought it would be safer than glimepiride,” he says. “That is not what we found.”

Overall, the study showed no statistically significant difference in overall mortality risk among the individual sulfonylureas. However, it revealed a trend toward an increased risk of mortality with glyburide versus glimepiride (hazard ratio 1.36 [95% CI 0.96–1.91]) and with glipizide versus glimepiride (1.39 [95% CI 0.99–1.96]) in those with documented CAD. Of the 1,921 mortality events for the entire cohort, 322 involved patients with a prior history of CAD.

Dr. Zimmerman hopes this paper adds clarity to the lengthy debate. Often, physicians must prescribe sulfonylureas although other therapies are preferred as first-line treatment or because patients are unable to tolerate alternative drugs. These results do not identify an increased mortality risk among the individual sulfonylureas, but they do suggest that glimepiride may be the preferred sulfonylurea for those with underlying CAD. This may help physicians make more informed decisions as they choose sulfonylureas.

For more information, please contact Dr. Zimmerman at 216.444.9428 or at zimerr@ccf.org.
Adrenal incidentalomas – named for the circumstantial nature in which they are discovered – are found in up to 5 percent of patients undergoing CT scans of the abdomen.

“This study is the first one attempting to determine a threshold growth that is a predictor of malignancy, in which 100 percent of the masses have surgical histopathology,” says Kevin M. Pantalone, DO, first author of the study and a fellow in the Department of Endocrinology, Diabetes and Metabolism.

The study of 132 patients (136 masses) revealed that malignancy was more likely when adrenal mass size increased by at least 0.8 cm.

“Our conclusion is based on concrete data. In all previously published studies combined that investigated adrenal mass growth as a predictor of malignancy, only 4.2 percent of cases were confirmed with surgical pathology,” Dr. Pantalone says. “You don’t really know unless you take it out and look at it.”

The study found that if absolute growth was 0.8 cm or more within three to 12 months, then sensitivity was 60 percent (i.e., 60 percent of malignant masses had a growth ≥ 0.8 cm) and specificity was 84.6 percent (i.e., 84.6 percent of benign masses had a growth < 0.8 cm).

Only one diagnostic gauge – the non-contrast Hounsfield unit (HU) – is 100 percent accurate in evaluating adrenal incidentalomas, says Dr. Pantalone. “It measures the density of the mass on noncontrast CT imaging. The lower the HU number, the higher the fat content.

“Dr. Hamrahian’s study, published in the November 2004 Journal of Clinical Endocrinology and Metabolism, was the first study using surgical pathology in 100 percent of cases to report that a non-contrast HU ≤ 10 had a specificity of 100 percent in ruling out adrenal malignancy,” says Dr. Pantalone.
If the noncontrast HU is ≤ 10 and the mass is not hormonally active, patients need only periodic monitoring for evidence of new excess hormone hypersecretion. “The optimal duration of follow-up is not known, but we typically follow patients annually for up to five years,” says Dr. Pantalone.

Diagnosis is more difficult when the noncontrast HU is > 10. In these cases, additional variables must be considered, such as mass size, mass growth and IV contrast percentage washout. However, none of the latter three variables has ever shown 100 percent sensitivity or specificity in confirming or excluding malignancy, he says.

Another of the study’s key findings was that growth rate and percentage growth rate are no more accurate than absolute growth in predicting malignancy.

Dr. Pantalone cautions against assuming that a non-growing mass is benign — or that a malignant mass will necessarily grow. “We had three malignant masses (metastases) that either didn’t grow or decreased slightly in size on follow-up imaging over four to 36 months,” says Dr. Pantalone. Similarly, benign masses exhibiting an absolute growth as high as 1.5 cm were observed over three to 12 months.

This study’s findings should be used in conjunction with other imaging and clinical characteristics when making a decision on surgical resection, he says. “Estimating malignancy with adrenal mass growth alone has its limitations, but when the noncontrast HU is > 10, it can be very important.”

For more information, please contact Dr. Pantalone at 216.445.0682 or at pantalk@ccf.org.
As medical breakthroughs go, two Cleveland Clinic physicians responsible for a recent finding on enhancing vitamin D efficacy see this one as a relative slam dunk.

“What we are trying to do is make life extraordinarily simple for people to follow,” says Dr. Angelo Licata, MD, PhD, in the Department of Endocrinology, Diabetes and Metabolism. Dr. Licata and colleague Guy B. Mulligan, MD, studied 17 patients who, despite taking seemingly sufficient doses of vitamin D, consistently failed to achieve an adequate serum level of 25-hydroxyvitamin D.

Their study showed that levels of vitamin D absorption were significantly increased – an average bump of 50 to 60 percent – when the vitamin was taken with the largest meal of the day. “That is remarkable consistency,” says Dr. Licata. “The simplicity of it led to some very significant results, which had a big impact for primary care. That’s what it’s all about. A simple thing created some big, big benefits.” So big that the study was published in the April 2010 Journal of Bone and Mineral Research.

Until now, participants in the study who had been routinely taking vitamin D had not had a rise in serum levels, says Dr. Licata. “That’s been the clinical observation and the complaint of generally every primary caregiver: Why isn’t the level changing?”

Most patients routinely take vitamins in the morning. The doctors found that subjects were taking their vitamin D with a glass of juice – or maybe just water. “That started to make the lights shine and the bells go off,” says Dr. Licata. “And we said, ‘Well, that might not be the right way to do it.’”

In those cases, a behavioral change was in order. “Most people like to get their medicines out of the way in the morning,” says Dr. Mulligan, “so we have to consciously change that behavior.”

Because vitamin D is fat-soluble, the doctors reasoned that absorption could potentially be improved if it was taken with a high-fat meal. “We see a different set of enzymes at work in those cases,” says Dr. Mulligan.
The study comprised 13 females and four males who were observed over a three-month period. Dr. Licata, who has worked extensively with patients with bone disease, had been recording vitamin D test results for several years when Dr. Mulligan helped spearhead the study last year.

In the study, patients maintained the vitamin D dosage they had been taking up to that point. Dr. Mulligan says the advice to patients was, “Whatever your dose is, let’s just change the way you’re taking it.”

In the spirit of simplicity, Dr. Licata said he and Dr. Mulligan purposely avoided using “sophisticated minutiae” as a tool in the study. “Expecting to calculate how much fat is in a meal is not where it’s at. A big meal is probably going to have a general mixture of fats, carbohydrates and protein. We just wanted a very simplistic primary care approach to deal with the problem. That’s all it was.”

The primary function of Vitamin D – known as the “sunshine vitamin” for its ability to be made through exposure to the sun – is to build and maintain healthy bones and teeth. It is especially important for children, whose bone and tooth formation may suffer if they do not get adequate supplies. Foods commonly high in vitamin D include milk, eggs, fish and pure cod liver oil.

For more information, contact Dr. Licata at 216.444.6248 or at licataa@ccf.org.
As glucose testing strips and meters have become more accurate and plentiful, hospitals have used the technology to test glucose levels with speed and ease. Such quick results enable healthcare professionals to adjust insulin levels as needed, making diabetes management responsive to the individual. Lab tests provide the most accurate results, but monitors generally offer fast and reliable data.

“But in this case, something had gone terribly wrong,” says Laurence (Ned) Kennedy, MD, Chairman of Cleveland Clinic’s Department of Endocrinology, Diabetes and Metabolism. Monitoring results are only as good as the equipment used, and it was soon discovered that the testing strips had failed.

This anecdote describes one of the cases sent to the U.S. Food and Drug Administration (FDA) as an example of what can happen in certain situations when a strip that is not specific for glucose is used, says Dr. Kennedy. GDH-PQQ strips have caused erroneous measurements resulted in the deaths of 13 people since 1997. Half of those deaths occurred in 2008, after the FDA launched its campaign to warn hospitals of the problems with GDH-PQQ.

The April 2010 issue of Diabetes Care featured a study about GDH-PQQ. The editors asked Dr. Kennedy to write an editorial highlighting potential problems doctors could face with blood glucose monitors and strips in the clinical setting.

“Any time you’re measuring anything in the blood, you want to make sure that your method is as specific as possible for the substance you’re measuring,” he says. “Lab measurements for blood glucose are usually done with a very specific enzyme.” Lab tests measure hexokinase to determine glucose levels. Many consider this to be the pinnacle of glucose measure-
ment. In contrast, various testing strips focus on different enzymes to measure glucose levels. Strips detect glucose oxidase, glucose dehydrogenase nicotinamide adenine dinucleotide (GHD-NAD), GDH flavin adenine dinucleotide (GDH-FAD) and GDH pyrroloquinolinequinone (GDH-PQQ).

In theory, all of these strips test an appropriate enzyme and provide accurate glucose measurements. But “GDH-PQQ will actually register other sugars apart from glucose,” says Dr. Kennedy. This leads to incorrect measurements and skews results. “So if someone with a normal glucose level has a high level of maltose, it will register as glucose,” he says.

In studies, GDH-PQQ strips garnered glucose results that were five to 13 times higher than what lab tests showed. It became clear that results from GDH-PQQ strips were wrong in patients receiving certain medications or undergoing dialysis. The FDA recommended that facilities using GDH-PQQ should never use them on patients receiving:

- extrarenal (icodextrin) peritoneal dialysis solution
- immunoglobulins such as octagam, gammunine N, Rho(D) Immune Globulin Intravenous (Human) (WinRho® SDF Liquid), Vaccinia Immune Globulin Intravenous (Human) and HepaGamB®
- abatacept (Orencia®)
- Adept® Adhesion Reduction Solution (4 percent icodextrin)
- BEXXAR™ radioimmunotherapy agent
- any product containing or metabolizing into maltose, galactose or xylose

In the editorial, Dr. Kennedy and Leann Olansky, MD, an endocrinologist colleague in the department, explore the accuracy of all glucose meters and strips. They note that there are no universal guidelines; most organizations adhere to the International Organizations for Standardization rules, which dictate that accuracy should be within 15 mg/dL for glucose levels less than 75 mg/dL and within 20 percent for levels greater than 75 mg/dL 95 percent of the time.

“Common experience tells us that the majority of patients using meters for self-monitoring of blood glucose are unaware of the magnitude of the potential inaccuracy of results, and we suspect that many healthcare providers also tend to ascribe greater accuracy than is warranted to portable glucose meter results,” they write in the editorial.

Dr. Kennedy urges the FDA to ban the use of GDH-PQQ strips because inaccurate glucose levels can cause physicians to order treatments that can lead to permanent harm or even death for their patients.

“You could probably say that in more than 999 out of 1,000 instances there is absolutely nothing wrong with these strips. The number of instances in which they might be expected to give rise to problems is very, very small,” he says.

Most hospitals still using GDH-PQQ do so because they were part of an approved protocol the institutions adopted when deciding how to monitor glucose levels with glucose meters. While some might be reluctant to change the procedures, an FDA mandate would require such adjustments.

Says Dr. Kennedy: “If there are strips that are not subject to error, why should anyone use these other ones?”

For more information, please contact Dr. Kennedy at 216.445.8645 or at kenne41@ccf.org.
Cleveland Clinic Establishes New Diabetes Center

A new, freestanding Diabetes Center has been created within Cleveland Clinic’s Endocrinology & Metabolism Institute. Run by endocrinologists, the state-of-the-art facility hopes to encourage patients to receive specialty care early – getting them on the right track with their diabetes care before returning them to their primary care physicians.

“This new center brings all of the Cleveland Clinic specialists who are recognized for their expertise in diagnosing and treating diabetes together to help people with diabetes live longer and healthier lives,” says Robert Zimmerman, MD, endocrinologist and Director of the new center.

Encouraging Early Specialty Care and Education

Central to the Diabetes Center’s mission is early education and effective disease management. One goal is to encourage patients to seek help from endocrinologists much sooner in their care than is currently the standard.

“Patients with diabetes tend not to be referred to endocrinologists until late in their disease. My aim is for us to see more newly diagnosed patients with diabetes, for a limited time, to make sure they are on the right track with their care and then return them to their primary care doctors,” says Laurence (Ned) Kennedy, MD, Chairman of the Department of Endocrinology, Diabetes and Metabolism in the Endocrinology & Metabolism Institute.

Various studies, he says, show that emphasizing good control of blood sugar is most effective in newly diagnosed patients. “If you wait until the patient has had diabetes for 10 to 15 years, then putting emphasis on excessively tight blood sugar control could possibly do more harm than good,” he notes. “We need to turn people’s thinking around and get diabetes patients specialty care sooner.”

Through the center, patients learn how to live a healthier lifestyle, to monitor glucose regularly, to adjust insulin and diet as needed, to check their feet and legs for wounds and sores, to have annual vision screenings and to be aware of signs that may indicate the beginning of a complication or diabetes-related problem.

“Research indicates that this type of patient-involved disease management is the most successful for long-term disease control,” Dr. Zimmerman notes.

At Cleveland Clinic, patients who received diabetes education through the Department of Endocrinology, Diabetes and Metabolism were evaluated for improvement in HbA1c at three and six months following their education session and compared with those who were referred for education but did not attend (see chart at right). The results reinforce the emphasis the new center places on early diabetes education.

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“We need to turn people’s thinking around and get diabetes patients specialty care sooner.”

– Laurence (Ned) Kennedy, MD

A study by Cleveland Clinic endocrinologists found average improvement for the education group at six months was an approximate 1.2 HbA1c percentage point decrease from baseline. Most of the education participants received one education session. The majority of these patients either had no diabetes medication changes or had their doses decreased during this period. Some were even taken off their diabetes medications completely because of improved blood glucose control. Susan Iannica, RN, a diabetes educator who was involved in the study, noted that nearly all of the patients reported a high level of satisfaction.
Expanding Care into the Community

The Diabetes Center is expanding its endocrine presence at sites throughout the Cleveland Clinic system.

“Patients need convenient access to high-quality care and education from specialists, nurses and other trusted providers with broad experience in diabetes care,” explains Dr. Zimmerman.

Many patients, both those at risk for diabetes or currently receiving care for the condition, will benefit from the center’s educationally focused care model as well as from the research in diabetes care and prevention that takes place in the Diabetes Center itself.

Finding Answers, Advancing Care

Research is the foundation for advancing the understanding of diabetes. At the Diabetes Center, endocrinologists work to rapidly translate clinical research into advanced patient care.

Recent research has focused on the risks of developing coronary artery disease or congestive heart failure and overall mortality in patients taking various antidiabetic agents; the effects of various types of bariatric surgery on type 2 diabetes; and participation in numerous multicenter drug trials.

Educating Healthcare Professionals

The new center will serve as a hub for diabetes education for providers, both within the Cleveland Clinic system and nationally, Dr. Zimmerman says.

One well-established educational event is Diabetes Day, a yearly program for physicians and other healthcare professionals involved in diabetes care. Cleveland Clinic and Joslin Diabetes Center in Boston also host an annual Diabetes and the Heart national summit. Locally, many diabetes training courses are organized for nurses throughout Northeast Ohio.

For more information about the Cleveland Clinic Diabetes Center or to make a referral, please call 216.444.6568.
DIABETES CENTER VITAL STATS

Established in Fall 2010, Cleveland Clinic’s new Diabetes Center is a 9,000-square-foot, freestanding facility that features:

- A multidisciplinary team, including endocrinologists, diabetes educators, dietitians, nurse practitioners and a podiatrist
- Easy access to renowned Cleveland Clinic specialists often involved in diabetes care, such as cardiologists, ophthalmologists, nephrologists and dermatologists – as well as close collaboration with primary care physicians
- State-of-the-art technology, such as iPro™ 72-hour glucose monitoring, continuous glucose monitoring, insulin pumps and fundus photography
- Individual and group diabetes education classes

DIABETES CENTER EXPERTISE

Cleveland Clinic’s Endocrinology Program is continually ranked among the Top 10 nationwide in U.S. News & World Report’s annual survey of the best hospitals — the top ranking in Ohio. The Endocrinology & Metabolism Institute’s Diabetes Center combines this leadership with that of Cleveland Clinic’s nationally ranked programs in cardiovascular disease, kidney disease and other specialties closely linked to diabetes care.
Robotic Thyroidectomy

Now Available at Cleveland Clinic

Patients now have another minimally invasive surgical option for thyroid removal at Cleveland Clinic: a robotic thyroidectomy that avoids a scar on the neck.

Endocrine surgeons in the Cleveland Clinic’s Thyroid Center began offering the robotic procedure in July 2009, making Cleveland Clinic among a handful of centers in the nation currently offering this new approach.

“Robotic thyroidectomy is a good option for patients who have thyroid nodules requiring thyroid surgery and do not want an incision in their neck,” explains Eren Berber, MD, Director of Robotic Endocrine Surgery at Cleveland Clinic’s Thyroid Center.

Robotic thyroidectomy is conducted through one port involving a 5- to 6-mm incision axilliary incision. The surgical instruments (attached to the robotic arms), and one camera are placed through these ports. The surgeon, operating the robot from a computer console, detaches the thyroid by dividing the blood vessels and removes the dissected thyroid gland.

Dr. Berber says that the surgical outcomes and precision of robotic thyroidectomy are similar to those of open surgery and other minimally invasive approaches. Initial studies have shown a decreased incidence of hypocalcemia in patients who had robotic thyroidectomy versus those patients who had open thyroid surgery.

The robotic thyroidectomy technology currently works best for patients who:
- Are not overweight
- Have a smaller thyroid gland (no larger than 4 cm)
- Have smaller nodules (no larger than 2.5 cm)

The technology is not a good option for patients who have thyroiditis or Graves’ disease. Cleveland Clinic endocrine surgeons perform about 500 thyroid surgeries a year.

“The robotic approach is also available for selected patients with parathyroid disease,” says Dr. Berber.

For more information, contact Eren Berber, MD, at 216.444.0555 or berbere@ccf.org.
Allotransplantation of Cryopreserved Parathyroid Tissue for Severe Hypocalcemia in a Renal Transplant Patient

In patients with end stage renal disease (ESRD), calcium, vitamin D and parathyroid disorders frequently occur due to secondary or tertiary hyperparathyroidism. A subtotal parathyroidectomy is typically an effective treatment, paired with an autotransplant of a small amount of residual parathyroid tissue, if needed. However, in 1 to 2 percent of patients, severe hypocalcemia can develop after surgery from the insufficient remaining parathyroid tissue.

At Cleveland Clinic, surgeons recently performed a successful allotransplantation of cryopreserved parathyroid tissue to reverse hypocalcemia in an immuno-suppressed kidney transplant recipient.

“While it is rare, there are instances in which a patient will have his or her parathyroids removed, or a remaining part that was thought to be working well dies off, leaving the patient with none,” says Mira Milas, MD, Director of the Cleveland Clinic Thyroid Center. “Allotransplantation is an option for select patients who do not have a ‘safety net’ — their own stored parathyroid tissue.”

Dr. Milas’s team included Stuart M. Flechner, MD, of Cleveland Clinic’s Glickman Urological & Kidney Institute and the Cleveland Clinic Transplant Center; Erin Berber, MD, of the Endocrinology & Metabolism Institute; Medhat Askar, MD, PhD, of the Transplant Center; Brian Stephany, MD, of the Urological & Kidney Institute and the Transplant Center; and Ashok Agarwal, PhD, Director of the Clinical Andrology Laboratory in the Urological & Kidney Institute.
The patient in this case was a 36-year-old man with ESRD from chronic glomerulonephritis who had received a renal transplant in November 2003. The graft was removed in March 2006. He waited for a DD kidney but had a high PRA of 75 percent to class I HLA. In April 2009, he underwent a 3½ gland parathyroidectomy and autotransplant of residual parathyroid tissue due to severe hyperparathyroidism at another hospital while on hemodialysis. In May 2009, he received a zero MM DD kidney transplant.

"Our patient originally had nearly all of his parathyroids removed and a very small amount transplanted back into adjacent muscle. While he continued to be on dialysis, his calcium could be regulated easily during dialysis. The patient did not have any of his own parathyroid tissue in cryostorage," Dr. Milas explains. “He came into the fortunate circumstances that he could get another healthy, functioning kidney and didn't need to be on dialysis.

"However, this unmasked a relative insufficiency of his parathyroid autotransplant to help support the calcium balance that a healthy kidney would need."

After being discharged doing well from his successful kidney transplant, the patient returned with cramping and stiffness in his muscles to the point that he could not walk. His calcium levels had dropped to life-threatening range: as low as 2 mg/dL, she says. The patient failed to improve while on maximal medical therapy.

Following permission from Cleveland Clinic's Innovative Practice Committee, a repository of stored parathyroid tissue at Cleveland Clinic was subsequently screened for a suitable donor. The patient then underwent our first parathyroid allotransplant in July 2009.

Within two weeks of the first parathyroid cell allograft, the symptoms of left knee pain, leg weakness and numbness resolved, and the patient began walking with a cane for support. By one month post-transplant, the patient could walk normally, absent any support.

Serum total and ionized calcium levels remained in the range of 5 to 8 mg/dL and 0.7 to 1.0 mmol/L, respectively, for several months (figure 1). During this time, the patient was receiving 500 mg calcium carbonate hourly while awake. Serum PTH levels quickly increased from baseline, and stayed in the 10 to 15 pg/mL range for several months (figure 2). The patient was given daily oral calcitriol 0.5 µg following his kidney transplant, and had normal vitamin D levels throughout the follow-up period.

Although the patient felt well, he could not be weaned off oral calcium, and by three months the PTH had fallen to 10 pg/mL. Therefore, in October 2009, a repeat parathyroid allograft (from the same donor) was placed just below the first. His PTH levels in the ipsilateral arm rose to the 10- to 15-pg/mL range for two months, then increased further to 25 pg/mL during the third month.
This was accompanied by a rise in serum calcium to more than 8 mg/dL and ionized fraction more than 1 mmol/L (figure 1). There was no antibody detected to any of the parathyroid donor HLA phenotypes at any time.

While application of this type of procedure may be rare, Dr. Milas says there is a select population of patients who may be helped by allotransplantation of cryopreserved parathyroid tissue. It was advantageous that this first patient was already immunosuppressed because of his kidney transplant.

“This procedure, while uncommon, has greatly helped this gentleman,” she concludes. “A year later, the patient has maintained normal calcium and parathyroid hormone balance without supplemental medications.”

She adds that the allotransplant was only made possible because of Cleveland Clinic’s many resources, including a multidisciplinary team that involved the patient’s kidney transplant surgeon, nephrologist and endocrine surgeons, and the Andrology Lab.

The parathyroid cryopreservation resource is also available to physicians and surgeons in the greater Cleveland area. Additional information about this can be obtained from Lab Director Dr. Agarwal at 216.444.8182.

For more information, contact Mira Milas, MD, at 216.444.4985 or at milasm@ccf.org.
This one-day course will highlight recent advances in the management of thyroid disorders and thyroid cancer.

The year 2010 witnessed the publication of new guidelines in the treatment of thyroid nodules, differentiated thyroid cancer and medullary thyroid cancer. More so than ever before, innovations of new surgical technologies, thyroid cancer diagnostic tests, and new therapies for thyroid cancer are influencing patient care options. This course is designed to address the key concepts of these advancements during lectures, panel discussions, and operative technique videos.

Keynote Speaker

Rebecca Bahn, MD
Professor of Endocrinology, Mayo Clinic Rochester, MN
will present
Pathogenesis of Graves’ Ophthalmopathy: Implications for Novel Therapies

Location

Cleveland Clinic Administrative Campus
3050 Science Park Drive, Beachwood, OH 4412

Registration begins at: 6:30 a.m. | Course: 6:55 a.m. – 5:45 p.m.
Breakfast and lunch will be provided.
Registration fees are $150 for external physicians, registration fee of $75 for Cleveland clinic physicians.
Parking is conveniently located right outside of facility and is free to course participants.
This activity has been approved for AMA PRA Category 1 Credit™.
## Current Clinical Trials

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<td>ACROSTUDY - A Multicenter, Post-Marketing Surveillance Study of Somavert Therapy in Patients with Acromegaly in the USA and Europe</td>
<td>Amir Hamrahian, MD</td>
<td>Melanie Williams 216.444.5410</td>
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<td>Pelvic Floor Disorders in Bariatric Surgery Patients</td>
<td>Stacy Brethauer, MD</td>
<td>Sharon O'Keefe 216.445.8461</td>
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<td>A Prospective Randomized, Controlled Trial Comparing Advanced Practice Medical Management vs. Advanced Practice Medical Management Plus Bariatric Surgery in The Treatment of Type 2 Diabetes Mellitus</td>
<td>Philip Shauer, MD</td>
<td>Chytaine Hall 216.445.3983</td>
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<td>Prospective Randomized Comparison of Bilateral vs. Focal Neck Exploration for Sporadic Hyperparathyroidism</td>
<td>Allan Siperstein, MD</td>
<td>Linda Heil 216.444.2262</td>
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### Staff Directory
Endocrinology & Metabolism Institute

#### Institute Leadership

- **James Young, MD**  
  Institute Chairman  
  Endocrinology & Metabolism Institute  
  216.444.2333

- **Allan Siperstein, MD**  
  Chairman, Department of Endocrine Surgery  
  216.444.5664

- **Laurence (Ned) Kennedy, MD**  
  Chairman, Department of Endocrinology, Diabetes and Metabolism  
  216.445.8645

- **Philip Schauer, MD**  
  Chairman, Bariatric and Metabolic Institute  
  216.444.4794

#### Department of Endocrinology, Diabetes and Metabolism

- **Sanjit Bindra, MD**  
  Specialty Interest(s): General endocrinology, diabetes  
  Location(s): Lakewood Hospital Professional Building  
  Office: 216.529.5300  |  Fax: 216.529.5301  
  Appointments: 216.529.5300

- **Kevin Borst, DO**  
  Specialty Interest(s): Endocrine disorders in pregnancy, general endocrinology, diabetes  
  Location(s): Lakewood Hospital Professional Building  
  Office: 216.529.5300  |  Fax: 216.529.5301  
  Appointments: 216.529.5300

- **Krupa Doshi, MD**  
  Specialty Interest(s): General endocrinology, diabetes, parathyroid and calcium disorders, hirsutism, thyroid disorders, adrenal disorders, osteoporosis  
  Location(s): Main campus  
  Office: 216.445.0741  |  Fax: 216.445.1656  
  Appointments: 216.445.6568

- **Amir Hamrahian, MD**  
  Specialty Interest(s): Pituitary and adrenal disorders  
  Location(s): Main campus  
  Office: 216.445.8538  |  Fax: 216.445.1656  
  Appointments: 216.444.6568

- **Betul Hatipoglu, MD**  
  Specialty Interest(s): Diabetes, thyroid disorders, pituitary disorders, adrenal disorders, alternative medicine  
  Location(s): Main campus  
  Office: 216.445.6709  |  Fax: 216.445.1656  
  Appointments: 216.444.6568

- **Suman Jana, MD**  
  Specialty Interest(s): General endocrinology, diabetes, thyroid disease, thyroid cancer  
  Location(s): Main campus; Medina  
  Office: 216.444.0567  |  Fax: 216.445.1656  
  Appointments: Main campus: 216.444.6568; Medina: 330.721.5700

- **Sangeeta Kashyap, MD**  
  Specialty Interest(s): Endocrinology, diabetes, metabolism, insulin resistance and cardiovascular risk prevention, obesity, metabolic syndrome and diseases, hyperlipidemia  
  Location(s): Main campus  
  Office: 216.445.2679  |  Fax: 216.445.1656  
  Appointments: 216.444.6568

- **Laurence (Ned) Kennedy, MD**  
  Department Chair  
  Specialty Interest(s): General endocrinology, diabetes, pituitary disorders, hyperthyroidism, hypothyroidism, thyroiditis  
  Location(s): Main campus; Ashtabula County Medical Center; Cleveland Clinic Florida, Weston  
  Office: 216.445.8645  |  Fax: 216.445.1656  
  Appointments: Main Campus, 216.444.6568; Ashtabula, 440.997.6969; Florida, 954.659.6038
Leila Khan, MD  
Specialty Interest(s): General endocrinology, diabetes, calcium/bone disorders  
Location(s): Main campus; Willoughby Hills Family Health Center  
Appointments: Main campus: 216.444.6568; Willoughby Hills: 440.943.2500

M. Cecilia Lansang, MD, MPH  
Specialty Interest(s): General endocrinology, diabetes  
Location(s): Main campus  
Office: 216.445.5246 | Fax: 216.445.1656  
Appointments: 216.444.6568

Melissa Li-Ng, MD  
Specialty Interest(s): General endocrinology, diabetes  
Location(s): Main campus; Solon Family Health Center  
Office: 216.444.0539 | Fax: 216.445.1656  
Appointments: Main campus, 216.444.6568; Solon, 440.519.6800

Vinni Makin, MD  
Specialty Interest(s): General endocrinology, diabetes, hirsutism, acne, thyroid disorders  
Location(s): Main campus; Solon Family Health Center  
Office: Main campus, 216.444.0539; Solon, 440.519.6800 | Fax: Main campus, 216.445.1656; Solon, 440.519.6908  
Appointments: Main campus, 216.444.6568; Solon, 440.519.6800

Adi Mehta, MD  
Specialty Interest(s): Diabetes mellitus, thyroid disorders, gynecologic endocrinology, endocrine complications of pregnancy, menopause, lipid disorders, general and adolescent endocrinology  
Location(s): Main campus; Beachwood Family Health Center  
Office: 216.445.5312 | Fax: 216.445.7261  
Appointments: Main campus, 216.444.6568; Beachwood, 216.839.3000

Guy Mulligan, MD  
Specialty Interest(s): General endocrinology, diabetes  
Location(s): Main campus; Twinsburg Medical Office; South Pointe/Charles Miner Medical Building  
Office: 330.888.4000 | Fax: 330.963.4561  
Appointments: Main Campus, 216.444.6568; Twinsburg, 330.888.4000; South Pointe, 216.295.1010

Christian Nasr, MD  
Co-director, Thyroid Center  
Specialty Interest(s): Thyroid nodules, thyroid cancers, flushing syndromes  
Location(s): Main campus  
Office: 216.445.1788 | Fax: 216.445.1656  
Appointments: 216.444.6568

Leann Olansky, MD  
Specialty Interest(s): Diabetes and diabetes complications, gestational diabetes, general endocrinology  
Location(s): Main campus; Huron Hospital  
Office: 216.444.2642 | Fax: 216.445.1656  
Appointments: Main campus: 216.444.6568; Huron Hospital: 216.761.6500

Richard Shewbridge, MD  
Specialty Interest(s): Endocrinology, diabetes, thyroid disorders, hyperlipidemia, osteoporosis  
Location(s): Medina  
Office: 330.725.3713 | Fax: 330.725.2141  
Appointments: 330.725.3713

Mario Skugor, MD  
Co-director, Thyroid Center  
Associate Director, Endocrinology Fellowship Program  
Specialty Interest(s): Osteoporosis and calcium metabolism, obesity and diabetes, multiple endocrine neoplasia syndromes, thyroid disorders, thyroid cancer  
Location(s): Main campus  
Office: 216.445.0739 | Fax: 216.445.1656  
Appointments: 216.444.6568

Mariam Stevens, MD  
Specialty Interest(s): Diabetes, gestational diabetes, goiter, Graves' disease, Hashimoto's disease, hirsutism, hyperthyroidism, hypoglycemia, hypothyroidism, polycystic ovary syndrome, thyroid disease, thyroid nodule  
Location(s): Independence Family Health Center  
Office: 216.986.4000 | Fax: 216.986.4995  
Appointments: 216.986.4000

Robert Zimmerman, MD  
Director, Cleveland Clinic Diabetes Center  
Vice Chairman, Department of Endocrinology, Diabetes and Metabolism  
Program Director, Endocrinology Training Program  
Specialty Interest(s): Diabetes, thyroid disorders, growth hormone in adults  
Location(s): Main campus  
Office: 216.444.9428 | Fax: 216.445.1656  
Appointments: 216.444.6568

Department of Endocrine Surgery  
Eren Berber, MD  
Director, Robotic Endocrine Surgery  
Specialty Interest(s): Endocrine surgery (thyroid and parathyroid), laparoscopic solid-organ surgery, advanced laparoscopic surgery, laparoscopic radiofrequency ablation of liver tumors, pancreatic neuroendocrine tumors, robotic thyroid and parathyroid surgery, laparoscopic and robotic adrenalectomy and liver surgery  
Location(s): Main campus  
Office: 216.445.0555 | Fax: 216.636.0662  
Appointments: 216.444.6568
Kresimira (Mira) Milas, MD  
**Director, Thyroid Center**  
Specialty Interest(s): Endocrine surgery (thyroid and parathyroid), thyroid cancer, multiple endocrine neoplasia syndromes, hereditary thyroid disorders  
Location(s): Main campus  
Office: 216.444.4985  |  Fax: 216.636.0662  
Appointments: 216.444.6568

Jamie Mitchell, MD  
Specialty Interest(s): Endocrine surgery (thyroid, parathyroid and adrenal), laparoscopic solid organ surgery, advanced laparoscopic surgery, laparoscopic radiofrequency ablation of liver tumors  
Location(s): Main campus; Independence Family Health Center; Solon Family Health Center  
Office: 216.445.9713  |  Fax: 216.636.0662  
Appointments: Main campus, 216.444.6568; Independence, 216.986.4000; Solon, 440.519.6800

Joyce J. Shin, MD  
Specialty Interest(s): Endocrine surgery (thyroid and parathyroid), advanced laparoscopic surgery, laparoscopic adrenalectomy, neuroendocrine tumors, thyroid/parathyroid ultrasound, intra-abdominal ultrasound, laparoscopic radiofrequency thermal ablation of liver tumors  
Location(s): Main campus  
Office: 216.636.9365  |  Fax: 216.636.0662  
Appointments: 216.444.6568

Allan Siperstein, MD  
**Department Chair**  
Specialty Interest(s): Endocrine surgery (thyroid and parathyroid), advanced laparoscopic surgery, laparoscopic adrenalectomy, pancreatic endocrine tumors, gastroparesis, bariatric surgery  
Location(s): Main campus  
Office: 216.444.5664  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Bipan Chand, MD  
Specialty Interest(s): Advanced laparoscopy and endoscopy, endoscopy in the obese patient, gastric surgery focusing on reflux disease, hiatal hernia, bariatric operations and gastric cancer, biliary and spleen surgery, natural orifice transluminal endoscopic surgery (NOTES), endoluminal surgery  
Location(s): Main campus  
Office: 216.444.6668  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Karen Cooper, DO  
Specialty Interest(s): Bariatric medicine, family medicine, kinesiology and nutrition sciences, exercise instruction  
Location(s): Main campus  
Office: 216.445.1114  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Matthew Kroh, MD  
Specialty Interest(s): Advanced laparoscopic surgery, bariatric surgery, gastrointestinal surgery, endoscopy, single-incision laparoscopic surgery  
Location(s): Main campus  
Office: 216.445.9966  |  Fax: 216.444.2153  
Appointments: 216.445.2224

Tomasz Rogula, MD, PhD  
Specialty Interest(s): Advanced laparoscopic surgery, bariatric surgery, gastrointestinal surgery, endoscopy, single-incision laparoscopic surgery  
Location(s): Main campus; Strongsville Family Health and Surgery Center  
Office: 216.445.0255  |  Fax: 216.445.1586  
Appointments: Main campus: 216.445.2224; Strongsville: 440.878.2500

Philip Schauer, MD  
**Department Chair**  
Specialty Interest(s): Bariatric surgery, laparoscopic surgery, gastrointestinal surgery, colon surgery, weight management, hemia surgery, biliary surgery, surgery for GERD  
Location(s): Main campus  
Office: 216.444.4794  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Angelo Licata, MD  
Specialty Interest(s): Metabolic bone and skeletal problems, calcium disorders, renal stones, osteoporosis  
Location(s): Main campus  
Phone: 216.444.6248  |  Appointments: 216.444.6564

S. Sethu Reddy, MD  
Specialty Interest(s): Diabetes mellitus, lipid disorders, thyroid, adrenal and pituitary disorders, obesity, osteoporosis, general endocrinology  
Location(s): Main campus  
Office: 216.444.1866  |  Fax: 216.445.7261  
Appointments: 216.444.6568

**Bariatric and Metabolic Institute**

Stacy Brethauer, MD  
Specialty Interest(s): Bariatric surgery, laparoscopic surgery, gastrointestinal surgery, hemia repair, endoscopy, surgery for GERD, hiatal hemia, solid-organ endoluminal surgery, single-incision laparoscopic surgery  
Location(s): Main campus  
Office: 216.444.9244  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Karen Cooper, DO  
Specialty Interest(s): Bariatric medicine, family medicine, kinesiology and nutrition sciences, exercise instruction  
Location(s): Main campus  
Office: 216.445.1114  |  Fax: 216.445.1586  
Appointments: 216.445.2224

Matthew Kroh, MD  
Specialty Interest(s): Advanced laparoscopic surgery, bariatric surgery, gastrointestinal surgery, endoscopy, single-incision laparoscopic surgery  
Location(s): Main campus  
Office: 216.445.9966  |  Fax: 216.444.2153  
Appointments: 216.445.2224

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Specialty Interest(s): Advanced laparoscopic surgery, bariatric surgery, gastrointestinal surgery, endoscopy, single-incision laparoscopic surgery  
Location(s): Main campus; Strongsville Family Health and Surgery Center  
Office: 216.445.0255  |  Fax: 216.445.1586  
Appointments: Main campus: 216.445.2224; Strongsville: 440.878.2500

Philip Schauer, MD  
**Department Chair**  
Specialty Interest(s): Bariatric surgery, laparoscopic surgery, gastrointestinal surgery, colon surgery, weight management, hemia surgery, biliary surgery, surgery for GERD  
Location(s): Main campus  
Office: 216.444.4794  |  Fax: 216.445.1586  
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Location(s): Main campus  
Office: 216.444.1866  |  Fax: 216.445.7261  
Appointments: 216.444.6568

**Consultant Staff**

Derrick Cetin, DO  
Specialty Interest(s): Bariatric medicine, medical weight management, nutrition sciences, obesity management, preoperative evaluation, diabetes care  
Location(s): Main Campus  
Office: 216.445.4255  |  Fax: 216.636.1588  
Appointments: 216.445.2224

Bipan Chand, MD  
Specialty Interest(s): Advanced laparoscopy and endoscopy, endoscopy in the obese patient, gastric surgery focusing on reflux disease, hiatal hernia, bariatric operations and gastric cancer, biliary and spleen surgery, natural orifice transluminal endoscopic surgery (NOTES), endoluminal surgery  
Location(s): Main campus  
Office: 216.444.6668  |  Fax: 216.445.1586  
Appointments: 216.445.2224

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Specialty Interest(s): Bariatric medicine, family medicine, kinesiology and nutrition sciences, exercise instruction  
Location(s): Main campus  
Office: 216.445.1114  |  Fax: 216.445.1586  
Appointments: 216.445.2224

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Specialty Interest(s): Advanced laparoscopic surgery, bariatric surgery, gastrointestinal surgery, endoscopy, single-incision laparoscopic surgery  
Location(s): Main campus  
Office: 216.445.9966  |  Fax: 216.444.2153  
Appointments: 216.445.2224

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Location(s): Main campus; Strongsville Family Health and Surgery Center  
Office: 216.445.0255  |  Fax: 216.445.1586  
Appointments: Main campus: 216.445.2224; Strongsville: 440.878.2500

Philip Schauer, MD  
**Department Chair**  
Specialty Interest(s): Bariatric surgery, laparoscopic surgery, gastrointestinal surgery, colon surgery, weight management, hemia surgery, biliary surgery, surgery for GERD  
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Office: 216.444.1866  |  Fax: 216.445.7261  
Appointments: 216.444.6568
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