SUMMER CME: ADULT OBESITY MANAGEMENT IN PRIMARY CARE

NORTHEAST FLORIDA MEDICINE

Published by the DCMS Foundation
Marking 164 Years of Local Organized Medicine

In partnership with the Medical Societies of Duval, Clay and Nassau Counties

VOLUME 68, Nº 2

SUMMER 2017

OBESITY

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- Inflammatory Bowel Disease & Pregnancy: Top Ten Questions (Part 1)
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Walking into the room, I see an alert, but worn, 81-year-old man. Through a review of his chart before our meeting, I learned he had a history of coronary artery disease and an ischemic cardiomyopathy. Over the last three months, he had four hospitalizations for acute decompensated heart failure. This admission was no different. He became short of breath at the rehab facility and was promptly sent to the emergency room. On arrival, he had ominous dyad of heart failure, “cold and wet.” His blood pressure was just shy of 80 systolic, a chest x-ray showed bilateral pleural effusions, and a creatinine 2 points higher than his baseline. He was now admitted for the 5th time.

Repeat echocardiogram showed a drop in his left ventricular function to less than 10% from 20 - 25%. He was started on dobutamine in an effort to help his breathing, blood pressure, and diuresis. Despite the man’s dire clinical circumstance, his overall cognition and spirit remained intact. After several days of dobutamine infusion, multiple attempts were made to stop the drug. With each attempt, his blood pressure promptly dropped and his breathing would get worse. After three attempts at weaning the dobutamine, it was quite clear his cardiac function was too weak to survive off the drug. He was now terminal.

As I began to talk to the patient, he was very optimistic that he would be able to return home. Despite nearly a week on dobutamine, my exam confirmed his low cardiac output and his now terminal state. Alone in his room, I began to discuss his situation. I initially danced around the subject, but finally came out and told him that he is dying. I explained that the IV dobutamine is keeping him alive and that all feasible medical options were exhausted. I immediately saw the stunned expression on his face. His smile disappeared. Not once in his multiple admissions for heart failure in the last three months did anyone tell him that he might be dying. Stunningly, end of life care and decisions were not discussed.

He asked that I leave the room and come back when his son and daughter were expected to visit.

Several hours later his children had gathered in the room. I entered to find his son, daughter, and hospitalist already discussing his condition and care. Both children immediately fired question after question about their father’s condition. They spoke directly and openly to me and the other physician, discussing “their” desire to make their father an Allow Natural Death, turn off his defibrillator, and get hospice involved. Both siblings asked about health care surrogate designation and even getting a power of attorney to have their father turn over all decisions to them. As these discussions continued their father sat quietly, staring blankly. Not once, did the discussion ask for his thoughts or opinion. I finally was able to steer the conversation to the patient. I physically moved to his bed and sat next to him. Placing my hand on his shoulder, I asked if he understood what was going on and if HE had any questions. He looked up, a tear in his eye, and wanted me to repeat the steps we would need to undertake to try to get home or to inpatient hospice. He then asked if he could just sit up on the side of the bed. Finally, his son leaned over to give his father a hand. As the patient sat at the edge of the bed, he reached out and held his daughter’s hand. Finally, at that moment everyone in the room began to talk with him and not about him.

As physicians, we have the honor and privilege of discussing the life and death of many of our patients. In the frantic nature of medical care, we need to take that extra time to become the patient’s advocate at the end of their lives. Speaking directly to patients - not about them - with family helps all involved take part in a very difficult decision making process. It is up to physicians to begin the discussion of end of life options months before that time arrives. Take time to sit down next to a patient’s bed, hold a hand and look directly into a patient’s eye when it is time to discuss end of life care. The digital era has removed humanism from medicine. At the most critical time in life, the impending death of our patients, physicians need to bring back the humanity of medicine. Speak to your patients, not about them. ✤
In the last year, there has been great uncertainty about the future of healthcare in our country. On a national level, we watch as politicians try and determine the best way to approach Health Care Reform. Unfortunately, the current proposal named the American Health Care Act (AHCA) could potentially leave millions uninsured and reverse many of the gains made under the Affordable Care Act. This includes getting rid of the ten essential requirements demanded of the health insurers, defunding Medicaid, removing protections of those with pre-existing conditions and removing the mandate that helped ensure there was a large enough insurance pool that is needed to support this effort to insure the masses. While some of those issues are controversial, there is great agreement that this new suggested legislation will be detrimental to the poorest, oldest and sickest individuals in our country. This is fundamentally in direct opposition to what would be in the best interest of our patients.

This is not just my opinion, but a shared sentiment throughout organized medicine. The American Medical Association, American Academy of Family Physicians, National Medical Association, American Academy of Pediatrics, the American College of Physicians, AARP, AHA, American Psychiatry Association, American Health Care Association, America’s Hospitals and Health Systems and the National Physicians Association are just a few of the leading organizations that have urged Congress to find a better, more comprehensive way to protect the citizens of our country. Many patient advocacy groups have also made statements in opposition to the AHCA in its current form. This includes over 50 organizations including the American Cancer Society, Cancer Action Network, American Heart Association, American Lung Association, Cystic Fibrosis Foundation, March of Dimes, National Organization for Rare Disorders, National MS Society and Women Heart: The National Coalition for Women with Heart Disease.

The Senators of our great Nation are now charged with the responsibility of turning this legislation into something that is in line with the mantra the medical community lives and dies by—“To first do no harm.” As a physician leader in this community, I know we cannot just sit with bated breath and wait to see what happens. We at the Duval County Medical Society decided to turn our eye to a place where we could potentially make a positive difference regardless of what happens nationally. We were reminded that there are issues in our own backyard that need our attention. In 2016, the Robert Wood Johnson Foundation County Health Rankings revealed that Duval County was ranked 48th in the state to 59th. How could this be? We had improved in our Clinical Care ranking from 11th to 10th. That meant we were taking care of patients in a very effective way. So why were we getting worse? Why are we failing? It’s because public health and community health is about more than making the correct diagnosis, writing a prescription or having a successful treatment. It’s about the Opioid epidemic that has gripped our community, infant mortality, gun violence and violent crimes, air and water pollution, infrastructure and socioeconomic and health disparities.

When I decided to become a doctor, I knew my responsibility to my community would be greater than what my medical training could offer, and I knew I would need the help of others to truly make a grand impact. This is the why the Future of Healthcare Conference was necessary and why it was so successful. The DCMS and DCMS Foundation invited all the stakeholders in our community to hear and commune with both local and national leaders that could help us understand the breadth of the problems affecting our community. But more importantly, it was a think tank to try and identify potential solutions to the concerns of our community.

The Conference was exactly what we hoped. It was enthusiastically attended by every health system, community groups, safety net groups like We Care Jacksonville and Volunteers in Medicine, local and state legislative officials, leaders in organized medicine including the AMA President-elect and citizens of Duval County who want to make a difference. Through this grand collaboration, we were able to identify food deserts as the area of public health that the DCMS will tackle over the next year.

The USDA defines food deserts as “parts of the country void of fresh fruit, vegetables, and other healthful whole foods, usually found in impoverished areas.” Grocery Chains do a demographic evaluation to determine if it is in their best business interest to place grocery stores in these areas. We want them to see that it is in the best interest of humanity for them to make these choices in Duval County.

At the DCMS, we have taken up the gauntlet to ensure that we work with city officials and the governing bodies to come up with a plan that will help to improve and eventually eliminate food deserts in our community. We are all in this together. Thanks to Richard A. Mullaney, Esq., Director, Public Policy Institute, Jacksonville University, we know the seven steps it will take to make this happen. Many who attended the Future of Healthcare conference told me they left feeling hopeful, invigorated and charged up to see this through.

If you missed this great event, I challenge you to contact us and let us know how you would like to assist in this effort to ensure all communities have access to nutritious and healthy foods. With everyone working together, we can direct the destiny of our community and we will be one step further on our Journey to be the number one healthiest county in Florida. ☀️

Interested in serving on our Future of Healthcare committee regarding food deserts? Please contact Tammy Chaney, DCMS Foundation Director, at tammy@dcmsonline.org or by phone at (904) 355-6561.
I really said I wasn’t going to do it this year.

When the most disappointing season of Jaguars football I can remember came to an end in December, followed by the hiring of Doug Marrone as the new head coach, I swore that I was never going to buy season tickets again.

It’s not the first time I’ve made this idle threat, but this time I meant it. I had been so excited for the 2016 season. The offense was going to be explosive and the defense was bolstered by new talent and free agent acquisitions. This was The Year of the Jaguars! Never mind the lack of depth on the offensive line, never mind the youth of the defense… the strengths will overcompensate!

3-13.

When Florida’s 2017 Legislative Session began in March, my level of enthusiasm was equally high. A number of very important issues for the physicians of Duval County seemed poised to break through and make it into law. Yes, there were also several issues that are troubling to physicians with a great deal of support, but with a strong offense and good defense, we should be able to overcome those issues.

The story of this 2017 Legislative Session was dominated by a power struggle in Tallahassee. Governor Rick Scott set forth a number of priorities. House Speaker Richard Corcoran and Senate President Joe Negron did the same. Unfortunately for physicians, those priorities were rarely aligned, leading to a session marred by political infighting. Governor Scott actually ran television commercials in local markets blasting Representatives in the House who opposed his support of Enterprise Florida.

As the days of the session drew to a close, less attention was paid to the bills being passed, and more on the inability of the House and Senate to agree on a budget. At the end, the session had to be extended by three days just to get a final budget deal approved. Lying in the wake: were a great number of bills we hoped would pass this session, as well as a great deal more we fought to keep from passing.

It’s not quite 3-13, but it feels like it.

The Jaguars brought in Tom Coughlin to be the Director of Football operations, a move that made many who have been long-time Jaguars fans excited about the future of the organization. They know he’s going to force the team to get out there and work for every yard. Big time free agent moves and another exciting NFL Draft have me once again thinking about the possibilities for this team in 2017…

…and yes, I did renew my season tickets.

The Legislature will pick up the pieces of this session very soon. The 2018 Legislative Session will start in January to accommodate the 2018 mid-term elections. That means that committee work on bills will begin as early as September. Many of our top priority bills were fully approved by the House or Senate, so there is a great foundation to work on building support. As we get closer to this time, hearing the voice of physicians will become even more important.

We’ve heard from Legislators that on issues such as making it illegal to mandate Maintenance of Certification in Florida, physicians are either apathetic or in support of MOC. We know that’s not true, so I will be asking for you to lend your voice to the discussion, so that we can show the power of organized medicine and truly stand out as the voice of medicine in Duval County…

…and yes, despite frustrations with 2017, I’ve got my ticket to the 2018 Legislative Session already purchased, and I’m ready to get to work, Tom Coughlin style!

Let’s take a closer look at some of the most prevalent issues from the 2017 Legislative Session.

What Passed

The Budget

This is the most important issue of any legislative session, and often the most contentious. That was most certainly the case this year, as the Legislature missed the deadline for submitting the budget, which forced the three-day extension. One of the major sticking points in the budget was a proposed cut to
hospital funding in Florida. In the final budget bill, there are $520 million in cuts from Florida hospitals.

Those cuts will impact safety net hospitals, such as UF Health Jacksonville, the hardest. The direct impact to the bottom line of UF Health Jacksonville will be more than $12 million.

There is some potential good news here. The Low Income Pool (LIP), a source of Federal income designed to assist safety net hospitals, may be available to help fill some or all of those cuts. The LIP funds were cut by the Obama administration as an effort to force Florida to expand Medicaid, which the Legislature opted not to do. President Trump and Governor Scott announced earlier this year that the LIP funds would once again be available to Florida this year. However, because of rules set in place under the previous administration, there are restrictions as to how those funds can be utilized. We will likely not know until the new rules from CMS on the issue are released, most likely in July.

**Permanent Medical Malpractice Cap Fund Extension**

This is one of those issues that you hope you won’t ever need to benefit from. When the legislation was passed in 2007 to put the cap on Med Mal, it was set to roll back after three years. That means that in 2010, 2013 and 2016, doctors had to go back to Tallahassee, hat in hand, to extend the cap. This year, a permanent extension to the cap was successfully passed, meaning that this should now be considered a permanent benefit for physicians.

**Pediatric Cardiac Advisory Council**

This bill requires AHCA to establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric open-heart surgery programs. It also establishes additional criteria that must be included in rules relating to adult cardiovascular services at hospitals seeking licensure for a Level One program.

**PRN Change**

This bill made some changes to the PRN program in Florida. Most notably, it provides that in certain circumstances, an impaired practitioner may be reported to a consultant rather than the Department of Health. It also revises the grounds for disciplinary action to include termination from the impaired partitioned program, under certain circumstances.

**Drug Price Transparency**

This bill will have AHCA collect data on the retail prices for 300 of the most commonly prescribed medicines in Florida. It will then need to compile and report that data on its website monthly.

**Everything Else**

**Medical Marijuana**

One of the most visible fights this legislative session was surrounding medical marijuana. When Florida voters approved Amendment 2 last fall, it required the state to take a closer look at the existing rules in place governing the distribution of medical marijuana in Florida. In order to respond to the overwhelming support of the Amendment, five different bills were introduced to help regulate the burgeoning industry.

Major differences in the bills surrounded the issue of how the drug can be ingested (oil, edible, smoke, etc.) and the number of distributors around the state. At the end of the session, the House and Senate could not reach an agreement and no bill was passed. This means that AHCA will be in charge independently of setting up the rules for the implementation of Amendment 2.

**Scope of Practice Expansion**

Like a bad penny, this issue continues to come up again and again. This year, three bills which would have dramatically changed the delivery of healthcare in Florida were defeated.

A House bill would have created a new classification of Advanced Independent Practicing Registered Nurse, which would have allowed Nurse Practitioners who received this certification to practice medicine independent of a physician protocol.

Another bill sought to give Optometrists the ability to perform most surgeries.

The final bill would have allowed for physicians licensed outside the state of Florida to receive permission to practice
telehealth on patients in Florida, without the oversight of the Florida Board of Medicine.

All three of these bills had tremendous support in the House, and were voted to the floor. We feel fortunate that we had strong support for physicians and patients in the Senate, and these bills did not get to the floor for a vote.

This is definitely an example of no action being a positive outcome, but these issues are already being discussed for the next legislative session, so any victory here is only temporary.

Hospital Regulations

Two different bills proposed this session would have dramatically changed the way that hospitals function in Florida. The first would have eliminated the current Certificate of Need (CON) process for approval of hospitals. It would replace it with a local entity which would oversee the process. That bill was often modified, ultimately removing hospices and other care facilities from the change. Towards the end of the session, it became a bargaining chip between the two legislative bodies and ultimately was not passed.

The second bill would have changed the formula which determines the need for Trauma Centers in Florida. Under the final version of the bill, Northeast Florida would have been found to require two Trauma Centers. This bill would have been devastating to UF Health Jacksonville, which relies on the Level One Trauma Center as a significant source of financial support. The death of the bill is a major blow to Orange Park Medical Center, which opened a Level Two Trauma Center in 2016. Earlier this year, a judge ruled that the center should not have been allowed to open. It is unclear what lies next for that center.

Payment Issues

Several priority issues for physicians in this session revolved around physician reimbursement or insurance coverage for their patients.

A fail first/prior authorization bill would have required insurers to provide the procedure to obtain protocol exceptions in writing and on their website. It would also put a timeline on processing exception requests.

Another bill would have prohibited insurance companies from retroactively denying claims under certain circumstances.

The final bill would have allowed physicians to enter into a Direct Primary Care agreement with patients, which would NOT be considered an insurance product. Patients would still be required to carry catastrophic coverage, however.

Each of these issues had tremendous support in one chamber, but got caught up in what we sometimes call a “Train Bill” where several issues are mashed together. Unfortunately, the final Train Bill was unable to get enough support to pass.

Insurance Changes

Several bills would have changed important insurance policies currently in place in Florida. One would have eliminated the PIP Motor Vehicle Insurance requirement. The other would have made dramatic shifts in the Workers Compensation system. Both were unsuccessful in this session, but we will almost certainly see them in 2018.

Maintenance of Certification

As I stated above, we worked to produce a law which would prohibit any agency from utilizing the Maintenance of Certification as a credentialing condition. There was some initial traction on this bill, but unfortunately, the voices in support of the MOC helped to defeat this measure. In my many talks with physicians around Northeast Florida, one recurring theme is frustration with the escalating cost of MOC, and the frequently irrelevant subject matter in those exams.

As my final plea (for this Legislative Session), I urge you to share with me your stories of frustration with the MOC process. If we do that and share your voices, in 2018 we will get this bill passed.

As always, you can reach me by phone at (904) 353-7536 or by email at bcampbell@dcmsonline.org.
Residents’ Corner: Naval Hospital Jacksonville

**A Look at Naval Hospital Jacksonville’s Family Medicine Residency**

By LT Kerry Sadler, MD and LCDR Karl Kuersteiner, MD

**About the Program**

Naval Hospital Jacksonville (NH Jacksonville), home to the Navy’s oldest and largest Family Medicine residency, trains full-scope family physicians to meet the medical needs of service members and their families around the world. In classes of thirteen, the Navy residents are exposed to a robust primary care clinical experience which is also enhanced by healthy engagement with a wide variety of sub-specialty hospital staff. To elevate the depth and diversity of clinical experiences, the residents rotate out to UF Health Jacksonville and Wolfson Children’s Hospital, gaining more experience in trauma, emergency medicine, critical care, and pediatrics. Opportunities for medical training in the operational environment are provided. The ultimate goal is to graduate clinicians capable of providing comprehensive care in settings from traditional hospitals and clinics, to the austere environment aboard ships and on the battlefield.

In addition to resident education, the Family Medicine residency supports over 40 medical students who rotate through NH Jacksonville every year. Annually, the program hosts the Science, Service, Medicine and Mentoring (S2M2) program which aims to encourage, nurture, and enhance high school students’ commitment to science and medicine through clinical experiences, lectures, and workshops.

**Patient Centered Care**

Naval Hospital Jacksonville has achieved the highest-level recognition from the National Committee for Quality Assurance for its patient-centered medical homes. In 2016, the Navy Surgeon General selected NH Jacksonville as the pilot study location for the Navy’s value-based care initiative. The cornerstone of this delivery model involves the establishment of integrated practice units (IPUs). In the IPU, patient care is administered by a multidisciplinary, co-located health care team that focuses on a patient’s specific clinical condition. The multidisciplinary team is comprised of both generalists and specialists in areas such as neurology, pain management, sports medicine, and orthopedics, and support services such as nutrition, wellness, behavioral health, pharmacy, radiology, and physical therapy, as well as a care navigator. NH Jacksonville is currently implementing four IPUs (with resident involvement) for diabetes, complicated obstetrics, low back pain, and osteoarthritis. The goal is improved patient outcomes, increased readiness, higher patient satisfaction, and improved value with optimal resource utilization. The new model improves the residents’ clinical knowledge for common yet complicated conditions, while simultaneously strengthening their ability to work in a complementary fashion with specialists to provide efficient, high-quality care.

NH Jacksonville was the first hospital on Florida’s First Coast to earn Baby Friendly Certification from the World Health Organization. The Baby Friendly Certification was reaffirmed in 2016. Additionally, every summer the Family Medicine Department runs a school physical rodeo, providing busy families an easy and convenient opportunity to complete annual visits and paperwork in a single morning for all school-aged family members. Resident physicians and staff volunteer their off-duty time to help ensure our pediatric population is ready for the school year.

**Operational Experiences**

Operational experiences represent a unique aspect of education and training at NH Jacksonville. This year, staff and corpsmen were involved with Continuing Promise 2017 (CP-17), a humanitarian mission which teamed up with host nation partners and local professionals to provide medical and dental care in Guatemala, Honduras, and Colombia. LCDR Robert Lennon, a family medicine physician and faculty member from NH Jacksonville, oversaw roughly 80 medical personnel as CP-17 Medical Site Officer in Charge.

All residents complete the military’s Combat Casualty Care Course (C4) which prepares medical officers to serve in echelon I and II health service support elements in an austere combat environment. C4 includes training in nuclear, biological, and chemical warfare.
Residents’ Corner: Naval Hospital Jacksonville

Residents run together to improve their physical fitness and relieve stress. LT Sajeewane Seales presents at the NH Jacksonville Research Symposium. Naval Hospital Jacksonville residents and staff at the 2017 USAFP conference in Seattle, Washington.

combat triage, casualty evacuation, combat health service support, and leadership. In addition, interns rotate to NH Jacksonville’s Naval Branch Health Clinic Jacksonville (which exclusively serves active duty) for a primer on military medicine. During that experience, LT Christopher “Woody” Parker embarked on a five-day underway aboard an amphibious transport ship, USS New York (LPD-21), where he had the opportunity to work side-by-side with the ship’s medical officer to care for sailors at sea.

Resident Research & Awards

The residency program received the 2017 Navy Outstanding Achievement in Scholarly Activity Award from the Uniformed Services Academy of Family Physicians, reflecting an outstanding commitment to research and scholarly activity. At this year’s annual conference in March, 19 residents were selected to present. Two NH Jacksonville residents distinguished themselves with individual awards. LT Paul Seales received first place for his work on non-pharmacologic cholesterol-lowering agents and LT Job Larson placed second overall for his work on novel longitudinal assessments of resident teaching. Also in March, LT Aaron Cantor gave a lecture on cutaneous angiosarcoma at the American Academy of Dermatology Annual Meeting in Orlando. In November, the program was represented during the World Organization of Family Doctors (WONCA) World Conference in Rio de Janeiro, Brazil, where LCDR Daniel Kuckel presented a Cognitive Behavioral Therapy workshop. In September, at the 2016 American Academy of Family Physicians Family Medicine Experience, LT Aaron Cantor presented his work studying the effects of fruit and vegetable prescriptions on several indicators of wellness, earning a second-place finish.

In May, LT Sajeewane Seales spearheaded the annual Navy Medicine East 2017 Regional Research Symposium at NH Jacksonville, which included lectures by several current and former Family Medicine program directors as well as a research competition. Also in May, LCDR Kuckel led the inaugural Chief Resident Leadership Forum, a joint effort to provide leadership training and share best practices for incoming Family Medicine resident leaders.

Each year the Jacksonville Business Journal selects Health Care Heroes who have improved the quality of healthcare, saved lives, made discoveries, and championed the next generation of healthcare providers. In 2016, Naval Hospital Jacksonville’s Family Medicine Residency Program Director CDR Kristian Sanchack was one of two command physicians to receive the honor.

Looking Ahead

As we look to the 2017-2018 academic year, we will miss our graduating residents and faculty who are preparing for operational and clinical assignments overseas (from Japan to Spain and Bahrain) and throughout the United States (from California to Virginia and South Carolina), but there is a sense of excitement regarding several upcoming academic enhancements. Naval Hospital Jacksonville’s program is designing a point-of-care ultrasound course with a focus on primary care and urgent care. Our population health curriculum is also undergoing a significant overhaul and we are re-emphasizing training in office-based procedures. Lastly, we are refocusing and refining our team’s clinical approach to more fully achieve the fourth element of the Quadruple Aim: military members’ readiness to deploy. We feel fortunate to serve our nation’s sailors, Marines, and their families as their physicians, and we owe a significant debt of gratitude to the community of Jacksonville, our academic partners, and the Duval County Medical Society for the warm hospitality.

Disclaimers

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government.

We are military service members. This work was prepared as part of our official duties. Title 17, USC, §105 provides that “Copyright protection under this title is not available for any work of the U.S. Government.” Title 17, USC, §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person’s official duties.
The Spectrum of Obesity Treatment: From Primary to Specialty Care

Over the past decade, obesity has increasingly been recognized as a significant disease in terms of patient health and health economics. According to the Centers for Disease Control and Prevention, over one-third of U.S. adults have obesity.1 Obesity increases all-cause mortality for those with a BMI ≥ 35 kg/m2.2 Patients with obesity are at increased risk for diabetes, hypertension, coronary artery disease, stroke, pulmonary disease, several types of cancer, fatty liver disease and arthritis.3 In 2010, total direct medical care costs for obesity were $315.8 billion.4 The personal and societal costs of obesity are staggering.

The treatment of obesity continues to evolve with the improved understanding of the underlying disease process. Recognition is growing that short-term interventions do not adequately address this chronic disease and associated comorbidities. The number of medications continues to increase and the addressed mechanisms broaden as more systems are understood to play a role in weight regulation. Endoscopic options are increasing in number to address the gap between those treated adequately with medications and those treated best with surgery. Surgery remains as the most effective treatment for clinically severe obesity, BMI ≥ 40 kg/m2 or ≥ 35 kg/m2 with comorbidities.

This Obesity issue of Northeast Florida Medicine includes articles from local healthcare professionals who are dedicated to fighting this serious and costly disease. Their articles cover a wide range of topics, from diagnosis to treatment and prevention.

Dr. Gretchen Ames is board-certified in clinical health psychology and is an assistant professor of psychology at the Mayo Clinic College of Medicine. She is also a consultant in the Department of Psychiatry and Psychology at Mayo Clinic Florida. Her article emphasizes the merits of understanding the complexity of a patient’s struggle with obesity with suggestions for clinicians on how address this matter with patients.

Dr. Craig Morgenthal is medical director for the Baptist Center for Bariatrics and section chief of the Division of General Surgery at Baptist Medical Center. His article touches on a variety of bariatric operations and the current outcomes with regard to postoperative metabolic improvements. The most common bariatric procedures (gastric bypass, sleeve gastrectomy, gastric banding and biliopancreatic diversion) are explained and updated trial outcomes are given. He also emphasizes increasing evidence that supports bariatric surgery not just for weight loss but as a metabolic intervention that can rapidly improve diabetes and other related co-morbidities.

Dr. Ghania Masri is an associate professor in the Department of Medicine at the University of Florida and is Medical Director of Ambulatory Services. Dr. Carmen Isache is a core faculty member of the Internal Medicine Residency and the Associate Program Director of the Infectious Disease Fellowship at the University of Florida in Jacksonville. Their CME article discusses the etiology of obesity and provides a plan for intervention in the primary care setting, including behavior modification and pharmacotherapy.

Drs. Enrique Elli and Levan Tsamalaidze review the history of robotics in surgery and the use of surgical robotics for bariatric surgery. They also examine the growing role of revisional bariatric surgery and the future of bariatric surgery as more experience is gained in this field. Dr. Elli is Co-director of the Bariatric Center and consultant within the Department of General Surgery at Mayo Clinic Florida. Dr. Tsamalaidze works in the Research Fellow Division of General Surgery at Mayo Clinic Florida.

Dr. Miguel Malespin is the Medical Director of Hepatology and Associate Program Director for the gastroenterology fellowship at University of Florida Health-Jacksonville. He joined with colleagues Drs. Andrea Fialho, Andre Fialho, Ahmad Alkhasawneh and Silvio W. de Melo, Jr. to focus on the rising incidence of chronic liver disease related to obesity. Non-alcoholic fatty liver disease (NAFLD) leading to non-alcoholic steatohepatitis (NASH) is rapidly becoming a leading cause for need for liver transplantation. Weight loss is the only effective therapy, and this team from UF Health Jacksonville discuss the medical and surgical therapies aimed at this goal.

Mrs. Lori Solem is an instructor in nutrition at the Mayo Clinic College of Medicine with significant experience in postsurgical bariatric nutrition care. Her article is a detailed discussion on early and late postoperative diet, as well as the nuances of fluid and protein intake after surgery. The importance of proper dietary habits, food intolerance, nausea, and micronutritional management is highlighted.

References:
Experiencing stress or burnout?

The DCMS Foundation is committed to providing a resource for members that is free and confidential. Our Physician Wellness Program provides three certified counselors who are experienced in coaching health care professionals. Call 904-631-1446 for help!

Online resources available: dcmsonline.org/Physician_Wellness
Your Patient’s Biologic Story
STARTS WITH THE FIRST STEP

“Today, I stop searching and start speaking to my doctor.”

**STELARA®**: The first and only interleukin-12 and interleukin-23 inhibitor approved for the treatment of adult patients with moderately to severely active Crohn’s disease.

---

**Indication**

STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have:

- failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
- failed or were intolerant to treatment with one or more TNF blockers.

---

**Important Safety Information**

**Infections**

STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In patients with psoriatic arthritis, serious infections included cholecystitis. In patients with Crohn’s disease, serious or other clinically significant infections included an abscess, gastroenteritis, ophthalmic herpes, pneumonia, and Leptospirosis monovitale.

Treatment with STELARA® should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of STELARA® in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with STELARA® and consider discontinuing STELARA® for serious or clinically significant infections until the infection resolves or is adequately treated.

---

**Theoretical Risk for Vulnerability to Particular Infections**

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria, *Salmonella*, and *Bacillus Calmette-Guérin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with STELARA® may be susceptible to these types of infections. Appropriate diagnostic testing should be considered, e.g., tissue culture, stool culture, as dictated by clinical circumstances.

Please see additional important Safety Information continued on next page.
For the treatment of adults with moderately to severely active Crohn’s disease who have failed or were intolerant to conventional therapy (but never failed treatment with a tumor necrosis factor [TNF] blocker) or have failed or were intolerant to treatment with one or more TNF blockers.

**START STRONG.**

**WITH A SINGLE IV INDUCTION DOSE**

- **Primary Endpoint:**
  - **Clinical Response (100-POCNT) at Week 6**
    - Placebo: 21%
    - STELARA: 34%
  - (P<0.001)

- **Secondary Endpoints:**
  - **70-Point Response at Week 3 and 6**
    - Placebo: 51%
    - STELARA: 65%
  - (P<0.001)

**Proportion of Patients (%)**

<table>
<thead>
<tr>
<th>Proportion of Patients (%)</th>
<th>Placebo (n=53/247)</th>
<th>STELARA® (n=84/249)</th>
<th>Placebo (n=60/209)</th>
<th>STELARA® (n=116/209)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>21%</td>
<td>34%</td>
<td>29%</td>
<td>56%</td>
</tr>
<tr>
<td>75%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0%</td>
<td></td>
<td></td>
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</tbody>
</table>

**Induction Study:**
- **Predominantly TNF blocker naïve**
  - (N=627)
  - Placebo: 32%
  - STELARA®: 39%

**Rapid Response as Early as Week 3**

*Weight-based induction dosage regimen: STELARA® 260 mg (weight 55 kg or less), STELARA® 390 mg (weight more than 55 kg to 65 kg), STELARA® 520 mg (weight more than 85 kg).*

*The TNF blocker failure IV induction study was a double-blind, placebo-controlled, randomized, phase 3 clinical trial in adult patients with moderately to severely active Crohn’s disease who were intolerant to or failed TNF blocker therapy (N=741). In both induction studies, patients were randomized to receive STELARA® weight-based dosage regimen, STELARA® 130 mg IV, or placebo. The 130 mg IV dose is not an approved induction dose. The primary endpoint for both studies was clinical response at Week 6, which was defined as reduction in CDAI score of >50 points or CDAI score of <150. Moderately to severely active Crohn’s disease was defined as CDAI score between ≥220 and ≤450.1,2

*The predominately TNF blocker naïve IV induction study was a double-blind, placebo-controlled, randomized, phase 3 clinical trial in adult patients with moderately to severely active Crohn’s disease (N=627). 65% of patients were TNF blocker naïve. Remaining population was patients previously exposed to, but who did not fail, treatment with TNF blockers. All patients in the study failed or were intolerant to conventional treatment (e.g., azathioprine, 6-mercaptopurine, methotrexate, or corticosteroids). In both induction studies, patients were randomized to receive STELARA® weight-based dosage regimen, STELARA® 130 mg IV, or placebo. The 130 mg IV dose is not an approved induction dose. The primary endpoint for both studies was clinical response at Week 6, which was defined as reduction in Crohn’s Disease Activity Index (CDAI) score of >100 points or CDAI score of <150. Moderately to severely active Crohn’s disease was defined as CDAI score between ≥220 and ≤450.1,2

*70-point response was defined as reduction in CDAI score ≥70 points.*

### Important Safety Information (cont’d)

**Pre-Treatment Evaluation of Tuberculosis (TB)**
Evaluate patients for TB prior to initiating treatment with STELARA®. Do not administer STELARA® to patients with active tuberculosis infection. Initiate treatment of latent TB before administering STELARA®. Close monitoring patients receiving STELARA® for signs and symptoms of active TB during and after treatment.

**Malignancies**
STELARA® is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received STELARA® in clinical studies. The safety of STELARA® has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving STELARA® who had risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving STELARA®, especially those >60 years or those with a history of FLUVA or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

**Hypersensitivity Reactions**
STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or excipients. Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with STELARA®. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STELARA®.

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS)**
One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed in clinical studies of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical studies of Crohn’s disease. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®. RPLS is a neurological disorder, which is not caused by an infection or dissection. RPLS can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes.
STAY THE COURSE.

A MAJORITY OF PATIENTS IN THE MAINTENANCE STUDY WERE IN CLINICAL REMISSION AT 52 WEEKS AFTER INDUCTION DOSE*

PRIMARY ENDPOINT: CLINICAL REMISSION

- STELARA® 90 mg subQ every 8 weeks
  - 53%
  - n=63/120
  - P<0.01

Placebo (induction responders)
- 36%
- n=47/131

OTHER ENDPOINT: CLINICAL REMISSION IN TNF BLOCKER—NAIVE POPULATION

- STELARA® 90 mg subQ every 8 weeks
  - 65%
  - n=34/52
  - (value is not statistically significant)

Placebo (induction responders)
- 49%
- n=50/103

MY FIRST STEP

"Believing I am more than my disease..."

*The maintenance study was a double-blind, placebo-controlled, randomized phase 3 study. Patients randomized in this study were those who had a clinical response to STELARA® at Week 6 during induction studies. The primary endpoint was clinical remission at Week 44 which was defined as CDAI score <150. Week 44 of the maintenance study or 52 weeks from initiation of the induction dose (8-week induction study + 44-week maintenance study—52 weeks).

*Maintenance dosing of STELARA® consists of a 90 mg subQ injection every 8 weeks after the induction dose.

*All patients randomized to placebo in the maintenance study had a single dose of STELARA® IV induction dose.

Important Safety Information (cont’d)

Immunizations
Prior to initiating therapy with STELARA®, patients should receive all age-appropriate immunizations recommended by current guidelines. Patients being treated with STELARA® should not receive live vaccines. BCG vaccines should not be given during treatment or within one year of initiating or discontinuing STELARA®. Exercise caution when administering live vaccines to household contacts of STELARA® patients, as shedding and subsequent transmission to STELARA® patients may occur. Non-live vaccinations received during a course of STELARA® may not elicit an immune response sufficient to prevent disease.

Please see additional Important Safety Information continued on next page.
Your Patient's Biologic Story
STARTS WITH THE FIRST STEP

For your adult patients with moderately to severely active Crohn's disease, visit www.ChooseSTELARAFirst.com

MY FIRST STEP
"I will find my way back to me."

Indication
STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have:
- failed or were intolerant to treatment with immunosuppressants or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or
- failed or were intolerant to treatment with one or more TNF blockers.

Important Safety Information (cont’d)

Concomitant Therapies
The safety of STELARA® in combination with other immunosuppressive agents or phototherapy was not evaluated in clinical studies of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models or malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA®. In Crohn's disease studies, concomitant use of 5-mercaptopurine, azathioprine, methotrexate and corticosteroids did not appear to influence the overall safety or efficacy of STELARA®.

Allelogen Immunotherapy
STELARA® may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

Most Common Adverse Reactions
The most common adverse reactions (≥3% and higher than that with placebo) in psoriasis clinical trials for STELARA® 45 mg, STELARA® 90 mg, or placebo were: nasopharyngitis (6%, 7%, 6%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. In psoriatic arthritis (PsA) studies, a higher incidence of arthralgia and nausea was observed in patients treated with STELARA® when compared with placebo (3% vs 1% for both). In Crohn's disease induction studies, common adverse reactions (≥2% or more of patients treated with STELARA® and higher than placebo) reported through Week 8 for STELARA® 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn's disease maintenance study, common adverse reactions (≥3% or more of patients treated with STELARA® and higher than placebo) reported through Week 44 were: nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%) and sinusitis (3% vs 2%).

Please see Brief Summary on adjacent pages. Please see full Prescribing Information and Medication Guide for STELARA® at STELARAHcp.com. Provide the Medication Guide to your patients and encourage discussion.

060385:160920

References
STELARA® (ustekinumab) Information. ADVERSE REACTIONS: The following serious adverse reactions are discussed elsewhere in the label: Infections [see Warnings and Precautions]; Malignancies [see Warnings and Precautions]; Hypersensitivity Reactions [see Warnings and Precautions]; Reversible Posterior Leuкоencephalopathy Syndrome [see Warnings and Precautions]; CINs (see Full Prescribing Information). Clinical trials were 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 practice. Pneumonia: The safety data reflect exposure to STELARA® in 3137 psoriasis subjects, including 2414 exposed for at least 6 months, 1855 exposed for at least one year, 1633 exposed for at least two years, 1569 exposed for at least three years, 1482 exposed for at least four years and 836 exposed for at least five years. Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% in at least one STELARA®-treated subject, by treatment group during the placebo-controlled period of PsA STUDY 1 and PsA STUDY 2 [see Clinical Studies (14) in Full Prescribing Information].

Table 1: Adverse reactions reported by ≥1% of subjects during Week 12 in PsA STUDY 1 and PsA STUDY 2

<table>
<thead>
<tr>
<th>STELARA® Placebo</th>
<th>45 mg</th>
<th>90 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects treated</td>
<td>505</td>
<td>504</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>51(10%)</td>
<td>56(11%)</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>36(7%)</td>
<td>36(7%)</td>
</tr>
<tr>
<td>Headache</td>
<td>23(4%)</td>
<td>33(6%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>14(3%)</td>
<td>18(3%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12(2%)</td>
<td>13(2%)</td>
</tr>
<tr>
<td>Rash</td>
<td>11(2%)</td>
<td>9(2%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>8(2%)</td>
<td>14(3%)</td>
</tr>
<tr>
<td>Pharyngitis/ear pain</td>
<td>7(1%)</td>
<td>9(2%)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>9(2%)</td>
<td>10(2%)</td>
</tr>
<tr>
<td>Injection site erythema</td>
<td>3(1%)</td>
<td>6(1%)</td>
</tr>
<tr>
<td>Otitis</td>
<td>4(1%)</td>
<td>4(1%)</td>
</tr>
<tr>
<td>Depression</td>
<td>3(1%)</td>
<td>9(2%)</td>
</tr>
</tbody>
</table>

Adverse reactions that occurred at rates less than 1% in the controlled period of PsA STUDIES 1 and 2 and in at least one STELARA®-treated subject, by treatment group during the placebo-controlled period of PsA STUDY 1 and PsA STUDY 2 [see Clinical Studies (14) in Full Prescribing Information].
Table 2: Common adverse reactions through Week 8 in Studies CD-1 and CD-2 occurring in ≥3% of STELARA®-treated patients and higher than placebo

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Placebo</th>
<th>STELARA® 6 mg/kg single intravenous induction dose</th>
<th>N=456</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vomiting</td>
<td>3.3%</td>
<td>4.7%</td>
<td></td>
</tr>
</tbody>
</table>

Other less common adverse reactions reported in patients in Studies CD-1 and CD-2 included diarrhea (1% vs 0%), pruritus (1% vs 0%), nausea (1% vs 0%), and headache (0% vs 3%).

Table 3: Common adverse reactions through Week 44 in Study CD-3 occurring in ≥3% of STELARA®-treated patients and higher than placebo

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Placebo</th>
<th>STELARA® 50 mg subcutaneous maintenance dose every 4 weeks</th>
<th>N=133</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nephritis</td>
<td>8%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Infection at site erythema</td>
<td>0%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>2%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>2%</td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Sinusitis</td>
<td>2%</td>
<td>3%</td>
<td></td>
</tr>
</tbody>
</table>

Infections: In patients with Crohn's disease, serious or other clinically significant infections included anaphylaxis, gastroenteritis, and pneumonia. In addition, listeriosis and ophthalmic herpes simplex virus infections occurred in one patient each. Two patients reported anaphylaxis one with 300 mg and one with a 600 mg intravenous dose of STELARA®. In both cases, the symptoms resolved within 1 hour. Immunogenicity: Approximately 5% of patients treated with STELARA® in psoriatic arthritis clinical studies developed antibodies to ustekinumab, which were generally low in titer. In Crohn's disease clinical studies, less than 3% of patients treated with STELARA® developed antibodies to ustekinumab. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was observed in Crohn's disease. The antibody response was not associated with clinical effects or laboratory tests. Infections: Anaphylaxis reactions have been observed in patients receiving subcutaneous and intravenous doses of STELARA®. Infections have been observed in patients receiving intravenous doses of STELARA® without evidence of injection site reactions. Infections have also been observed in patients receiving intravenous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving intravenous or subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®. Infections have been observed in patients receiving subcutaneous doses of STELARA®.
Talking to Patients about Obesity Diagnosis and Treatment: 
Going Beyond Eating Less and Exercising More

By Gretchen E. Ames, PhD, ABPP

Mayo Clinic Florida

Abstract: The prevalence of Class II (BMI ≥ 35-39.9) and III obesity (BMI ≥ 40) in the United States has increased dramatically in the past 30 years. Given this increase in prevalence and the severity of associated health problems, primary care visits are a critical time for patients to receive counseling about their obesity diagnosis and the associated risks to health and survival. Primary care providers (PCPs) have a variety of barriers to effective treatment for obesity including lack of knowledge regarding the etiology and maintenance of this disease. Moreover, PCPs may lack confidence in their skills to address a patient’s struggle with obesity, and when advice is provided, it is usually limited to recommendations for lifestyle change. It is important to increase awareness about the complexity of a patient’s struggle with obesity as a chronic disease rather than simply a personal problem of lack of willpower and self-discipline or poor lifestyle choices. PCPs should be aware of barriers to effective counseling and treatment and understand how they can address obesity in a brief office visit.

Introduction

Obesity is a common problem in the U.S. population where 35 percent of men and 40.4 percent of women have a Body Mass Index (BMI; [kg/m²]) ≥ 30. Particularly alarming is the rapid rise in class II (BMI ≥ 35-39.9) and III obesity (BMI ≥ 40) in the past 30 years. This increase has resulted in a greater number of patients who have obesity-associated medical conditions like type 2 diabetes, metabolic syndrome, cancer, asthma, gallbladder disease, osteoarthritis, and chronic back pain. Given the high prevalence of obesity and severity of the associated health problems, primary care visits are a critical time for patients to receive counseling about their obesity diagnosis and the associated risks to health and survival. Moreover, engaging patients in a thoughtful conversation about the health risks of their obesity and a shared-decision about a treatment that goes beyond “eating less and exercising more” is imperative.

Unfortunately, primary care providers (PCPs) receive inadequate medical education and training in obesity management, nutrition, and exercise at every level of their training and are often poorly prepared to treat obese patients. A lack of education may lead to a host of devastating consequences such as poorer quality of care provided by physicians and reluctance by patients to seek care when there is a perception of weight bias from providers. Specifically a substantial body of research has consistently demonstrated that weight bias is highly prevalent in the medical settings where obese patients are often perceived as, lazy, lacking in self-control, and likely to be non-compliant with treatment. As BMI increases, physicians report less desire to help patients, spend less time in appointments, and perceive treating obese patients as a greater waste of time than treating patients with lower body weight. These biases may be related to the lack of understanding of a patient’s struggle with obesity as a chronic disease in a society where high calorie foods and physical inactivity are pervasive.

Provider barriers to effective treatment—knowledge

Many PCPs lack knowledge and understanding of obesity and oversimplify the etiology and maintenance of this disease. Obesity is a complex disease comprised of multiple disorders that affect energy intake, energy expenditure, and metabolic efficiency. The regulation of energy balance and body fat storage involves multiple pathways (e.g., metabolic, biochemical, central nervous system) and disruption in any one of these pathways may contribute to the development of obesity. The proposed environmental influences of modern society that are associated with development of obesity are alternations in the chemical composition of foods (e.g., highly processed and palatable, calorie dense), the rise of labor-saving devices resulting in the reduced need for daily physical activity, chronic stress contributing to increased abdominal fat storage, disruption in sleep and circadian rhythms, and increased use of obesity-promoting medications like steroids, insulin, and certain psychiatric medications. Furthermore, many providers have a poor understanding of metabolic adaptation to weight loss that occurs with restrictive
dieting and attenuates the long-term effectiveness of lifestyle change interventions\textsuperscript{9,13,14}. When patients with class II and III obesity have lost \( \geq 10 \) percent of their body weight and subsequently regained lost weight multiple times, lifestyle change recommendations—eat less and exercise more—alone are likely to be ineffective. With increased metabolic efficiency associated with restrictive dieting, maintenance of lost weight will require an indefinite reduction in calorie intake and a high level of physical activity that may be unsustainable for most obese patients in modern society\textsuperscript{15}. If providers fail to inquire adequately about previous weight loss attempts, they will likely continue offering lifestyle change recommendations that will be ineffective once a certain level of obesity has been reached and maintained for a period of time.

Therefore, it is imperative that PCPs better educate themselves about their patients’ struggle with obesity as a chronic medical condition in order to engage in thoughtful discussion and shared-decision making about when a biological intervention such as medication or bariatric surgery may be necessary. In spite of multiple dieting attempts, patients may continue to believe that lifestyle change will result in any amount of weight loss they desire. In the author’s clinical experience, patients sustain this belief even after years of repeating the same cycle of unsuccessful attempts at dieting. This cycle may include a diagnosis of obesity, a discussion about associated health problems with PCP, an attempt at weight loss through lifestyle change, 5-10 percent reduction in weight, and a plateau of weight loss as biological adaptation and an increase in caloric intake occur\textsuperscript{16}. When weight loss stops, patients attribute their lack of success to personal failure ultimately resulting in regain of more weight than was initially lost (Figure 1). When patients have made multiple attempts at weight reduction and have fallen short of their desired weight loss and improvement in health status, PCPs should consider offering treatments beyond lifestyle change particularly for patients with the highest levels of obesity.

Bariatric surgery is considered, unequivocally, the only treatment that reliably produces weight loss and improvements in health status that are well maintained over time for patients with clinically severe obesity\textsuperscript{17,18}. The weight loss operations most commonly performed in the United States are vertical sleeve gastrectomy (VSG) and Roux-en-Y gastric bypass (RYGB).\textsuperscript{19} Both VSG and RYGB are metabolic operations that change physiological signals between the brain and the gut resulting in the experience of reduced hunger, increased satiety, changes in food preference, and increased energy expenditure\textsuperscript{20-22}. Laparoscopic VSG removes approximately 75 percent of the stomach and results in approximately a 25 percent reduction in body weight in 12-months\textsuperscript{23,24}. Laparoscopic RYGB is a more complicated operation involving creation of a small gastric pouch and rerouting of the small intestine which is anastomosed to the gastric pouch resulting in approximately a 35 percent reduction in body weight in 12-months\textsuperscript{25}. Robot-assisted RYGB is becoming increasingly popular among surgeons as it may reduce length of time in the operating room and improve patient safety\textsuperscript{26,27}.

A recent qualitative study examining decision making regarding bariatric surgery found that PCPs, while they did discuss obesity with their patients, rarely offered a referral for bariatric surgery\textsuperscript{28}. The main factors influencing bariatric surgery referral were concerns about safety and efficacy, questions about long-term effectiveness, limited knowledge about bariatric surgery and limited familiarity with the most commonly performed operations in the U.S\textsuperscript{19}. Physicians in this study felt more comfortable treating obesity related comorbidities perceived to be the most serious, like diabetes, rather than addressing the obesity itself. Another recent study surveyed PCPs in Canada regarding knowledge and perception of bariatric surgery\textsuperscript{29}. The reasons for non-referral for greater than half of physicians surveyed included discomfort with education about risks and benefits of bariatric surgery,

![Figure 1. Cycle of dieting](image-url)
discomfort with explanation of bariatric operations to their patients, and discomfort with providing follow-up care after surgery. These results suggest that PCPs who have knowledge deficits should seek out additional training and/or continuing education, particularly regarding care of patients with BMI ≥ 35 who, after lack of success with multiple attempts at dieting, may need a biological intervention.

**Provider barriers to effective treatment—skills and confidence**

Along with knowledge deficits, PCPs often report lack of confidence in their skills to effectively address their patients’ struggle with obesity and when advice is provided, it is generally restricted to recommendations for lifestyle change. Obese patients frequently present with complex issues that cannot easily be addressed in brief primary care visits. Barriers that physicians perceive to be particularly challenging for their patients with class II and III obesity include emotion-based eating or food addiction, limited ability to engage in physical activity, patient excuses such as lack of time or desire to exercise, and previous unsuccessful attempts at weight loss. Specifically, providers may perceive that lack of success with weight loss undermines their patients’ confidence and, therefore, is a barrier to further attempts at lifestyle change. Rather than lack of confidence in their ability to induce weight loss, it may be that patients have little confidence that lifestyle change alone will be effective for them. In the author’s clinical experience, many patients with class II and III obesity do desire to lose weight and improve their health status. Many of them are already knowledgeable about the lifestyle changes necessary to induce weight loss and have attempted dieting multiple times in the past with many attempts resulting in large yet unsustainable weight losses. Consequently, patients may appear ambivalent about making another attempt at weight loss and providers may mistakenly interpret this as lack of motivation, desire, or readiness to make lifestyle changes. On the contrary, ambivalence—feeling two ways about making lifestyle change—is a normal part of the behavior change process as patients discover their own reasons and motivations for attempting weight loss (e.g., “My doctor told me I have diabetes now and that really scared me”). When patients voice ambivalence, both patients and providers may become frustrated with the lack of progress and success with weight loss. Hence, providers should go beyond simple recommendations of eating less and exercising more and consider a discussion of a biological intervention like medications or bariatric surgery (see prepared vignette at end of article). Many providers, however, feel uncomfortable discussing and making recommendations about the use of weight loss medications and are uncertain about when is the right time to recommend bariatric surgery.

Providers may also lack confidence in their ability to address barriers that patients bring up during an office visit. For example, if a provider mentions the option of bariatric surgery to a patient with class III obesity, the patient may dismiss it as a viable treatment option. Rejection of bariatric surgery has been associated with lack of understanding of the causes of one’s own obesity and the lack of understanding of the severity of one’s medical problems and the associated risk of premature death. Furthermore, patients lack knowledge about the safety and efficacy of bariatric surgery. Those with the highest level of obesity (BMI ≥ 40), and who are likely to derive the greatest benefit from bariatric surgery, may have the most misconceptions such as it is “too risky,” “doesn’t work,” or “I don’t need it. Many patients describe a culture of secrecy around bariatric surgery that includes a desire for secrecy and fear of negative judgment from friends and family members who believe that bariatric surgery is the “easy way out.” Therefore, it is imperative that providers understand that obesity is not simply a condition resulting from lack of personal responsibility, will power, and poor lifestyle choices. They must recognize when a referral for bariatric surgery may be indicated and address challenges like patients’ insistence on self-reliance (e.g., “I just need to give dieting one more try”) or shame (e.g., “people who have bariatric surgery lack willpower and self-discipline”). Nevertheless, any discussion about bariatric surgery requires shared-decision making and support of patient autonomy and choice as bariatric surgery is not an appropriate treatment for every patient suffering from class II or III obesity.

**Conclusion**

Obese patients are open to discussion about their weight during PCP visits and they desire advice from physicians about weight loss. Physician advice and/or referral to a weight loss program both have been shown to induce clinically meaningful reductions in weight and improvement in health status. Advice for patients with higher BMIs, however, should not be limited to recommendations about changes in diet or level of physical activity, particularly when patients are
highly knowledgeable and report frequent yet unsuccessful attempts at weight loss. Patients with class II obesity and medical co-morbidities or class III obesity should be offered the opportunity to learn more about bariatric surgery if they desire. Advice about obesity diagnosis and the associated health risks, especially for patients with higher BMIs who may be the most sensitive to weight bias, ought to be delivered in thoughtful manner while supporting patients’ autonomy and choice. Moreover, physicians should attend to their own potential personal biases about weight and be cognizant of the possibility of making premature assumptions about patients’ willingness, desire, or ability to adhere to treatment recommendations. The 2013 guidelines for Management of Overweight and Obesity in Adults are designed to assist PCPs in caring for their patients with obesity. Table 1 summarizes suggestions for addressing obesity in a brief office visit. The prepared vignette demonstrates a conversation about obesity and treatment between a patient and provider. The patient is a 50 year old female with a BMI of 37.9 and a five-year history of diabetes that is worsening with weight gain.

**Vignette When to Consider Bariatric Surgery**

Female; age 50 years; height 5’5”; 228 lbs.; BMI 37.9; diabetes, osteoarthritis; married; employed; no mental health history

Provider: I have the results of your A1C test from the labs we did last week. Your number has increased from 7.4 percent six months ago to 8.2 percent now. Is there anything that concerns you about the increase in your blood sugar in the past 6 months?

Patient: Honestly, I’m not surprised. I think I’ve gained some weight this year too, that’s upsetting.

Provider: Yes, your weight is up about 12 pounds from last year and your BMI is now 37.9.

Patient: Things have been very stressful for me at work. I got a promotion six months ago, but now I’m sitting behind a desk more and have more people to manage. I barely have time to eat during the day, and I’m exhausted when I get home from work.

Provider: A lot has changed for you in the past few months and now you have less time to focus on healthy eating and exercise. Is there anything that you think is going well right now with your eating or exercise routine?

**Table 1. Recommendations for a brief office visit.**

<table>
<thead>
<tr>
<th>What can be done in a brief office visit:</th>
<th>Recommended topics for discussion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure BMI and waist circumference</td>
<td>Level of risk by BMI category</td>
</tr>
<tr>
<td>Take brief weight history</td>
<td>Lowest adult weight to heaviest adult weight; precipitating events for weight gain</td>
</tr>
<tr>
<td>Take a brief history of attempts at dieting</td>
<td>Number of attempts; most weight lost; duration of maintenance of lost weight</td>
</tr>
<tr>
<td>Ask about readiness for change and what patient is already doing to manage weight</td>
<td>What is going well with eating and exercise right now?; Is there any room for improvement?; What is one step that you can take toward dietary change right now?</td>
</tr>
<tr>
<td>Identify high risk patients beyond BMI and waist circumference</td>
<td>Presence of metabolic syndrome; type 2 diabetes, sleep apnea; fatty liver disease; cardiovascular disease; functional impairment and limitations</td>
</tr>
<tr>
<td>Discuss that a 5-10% reduction in weight can result in clinical meaningful improvements in health status</td>
<td>Comprehensive lifestyle change program ( \geq 6 ) months in duration; commercial weight loss programs; weight loss maintenance program</td>
</tr>
<tr>
<td>Discuss referral to obesity medicine specialist or an MBSAQIP* designated surgery center</td>
<td>BMI ( \geq 35 ) with medical comorbidities or ( \geq 40 ); desire to lose weight to improve health and mobility; history of multiple unsuccessful attempts at dieting</td>
</tr>
<tr>
<td>Remain cognizant of potential weight bias</td>
<td>Obesity is not solely the result of poor lifestyle choices or lack of will power; be aware of biological and environmental contributors to development and maintenance of obesity</td>
</tr>
</tbody>
</table>

*Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program*
**Patient:** Well, I do try to bring my lunch to work every day. I may not get around to eating it, but at least I’m not going out for lunch every day.

**Provider:** Even though your life is busy, you still try to think ahead and plan what you are going to eat for the day.

**Patient:** Yes, it’s pretty much habit for me. I’ve dieted for years, and I know that I have to watch calories and try fit exercise in, but I just haven’t been able to do it lately.

**Provider:** You’ve been working on weight loss for years, what’s the most weight you’ve ever lost through a dieting effort?

**Patient:** Oh gosh, which time? Probably 40 pounds with Weight Watchers a few years back. I kept it off for a while but slowly started to regain. Now I’m heavier than ever.

**Provider:** You’ve attempted weight loss many times before but it’s been hard to maintain lost weight.

**Patient:** Yes, it doesn’t seem to matter what I do, I always regain. It’s very frustrating, so I haven’t wanted to work at it lately.

**Provider:** That’s a pretty common experience for people who have struggled with weight for a long time. But, I am concerned about your diabetes getting worse.

**Patient:** I am too. I don’t want to take insulin.

**Provider:** I see a lot of patients like you who are concerned about their health and have tried for years to lose weight. At this point, we could talk about starting insulin or talk about some other possible treatment options if that would be helpful to you.

**Patient:** Sure. Like I said, I really don’t want to start taking insulin.

**Provider:** For patients in your situation, I sometimes recommend considering bariatric surgery not only for weight loss but also for treatment of diabetes. For some patients, bariatric surgery can result in remission of diabetes.

**Patient:** I’ve actually thought about bariatric surgery before but wasn’t sure if it was right for me. One of my co-workers had it last year, and she looks great now.

**Provider:** If you want, I can make a referral for you to a bariatric surgery program where the providers can discuss with you in detail the operations, the health benefits, and help you decide if it’s the right treatment for you.

**Patient:** I think that would be good. It couldn’t hurt to learn more about it.

**Provider:** Ok, great. I will make the referral for you. Before you go to the appointment, it would be a good idea for you to call your insurance company to find out if bariatric surgery is a covered benefit on your plan. Does that sound ok?

**Patient:** Yes, thank you.

**References**


Current Trends in Metabolic and Bariatric Surgery

By Craig Morgenthal, MD, FACS

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Abstract: Obesity and morbid obesity, along with associated co-morbidities, are responsible for an increasing percentage of health care resources. It is important to understand the types of bariatric surgery most commonly used, as well as recent trials that support bariatric surgery as a metabolic intervention. Bariatric surgery along with medical treatment is superior to medical treatment alone for type 2 diabetes. Finally, it is necessary for physicians to understand the behaviors necessary for long term success.

Introduction

Obesity is a chronic disease with serious health consequences. The World Health Organization has listed obesity as a disease condition in its International Classification of Disease since 1979, and the American Medical Association officially recognized obesity as a disease in 2013. Essentially, every organ system is affected by morbid obesity with a resulting increase in morbidity, mortality, and cost of care. Bariatric surgery, often independent of the weight loss outcomes, shows significant improvement in metabolic disease.

The first systematic review and meta-analysis of co-morbidity outcomes following bariatric surgery was published in the Journal of the American Medical Association in 2004.1 Out of 22,094 patients who underwent bariatric surgery, diabetes had completely resolved in 76.8 percent of patients and resolved or improved in 86 percent. Hyperlipidemia improved in 70 percent, hypertension resolved in 61.7 percent and resolved or improved in 78.5 percent, and obstructive sleep apnea resolved in 85.7 percent. The American Society of Bariatric Surgery recognized the significance of the metabolic effects of these operations and changed its name to the American Society of Metabolic and Bariatric Surgery in 2006 in order to highlight the expanding and evolving view of surgery.

The 1991 National Institute of Health Consensus Statement stated that bariatric surgery is the most effective therapy for morbid obesity and can result in improvement or complete resolution of obesity related comorbidities. At that time, candidates for surgery included patients with a BMI of greater than 40 or greater than 35 with an obesity-related medical problem.2 These BMI levels are still used, even though the BMI cutoffs do not necessarily correlate with the onset of comorbidities and extensive data shows that patients with BMI 30 to 34.9 with a comorbid condition will benefit from bariatric surgery.3,4

Bariatric Surgery

The variety of bariatric operations offered to patients has increased over the years and continues to evolve. Currently, gastric bypass (GBP), sleeve gastrectomy (SG), gastric banding, and biliopancreatic diversion with duodenal switch (BPD/DS) are the most common procedures.

A gastric bypass is constructed by dividing the stomach to create a small gastric pouch, which is then anastomosed to a divided segment of small intestine, which is the Roux limb.

Figure 1. A gastric bypass is constructed by dividing the stomach to create a small gastric pouch, which is then anastomosed to a divided segment of small intestine, which is the Roux limb.
(Figure 1). The amount of food eaten is reduced as the pouch is approximately 30cc’s. Bypassing the stomach and a portion of the intestine results in controlled malabsorption of nutrients, and also changes food processing and hormone release due to food bypassing the pancreaticoduodenal axis. In gastric banding, a prosthetic band is used to make a small pouch at the top of the stomach, so that when properly adjusted, food must be eaten more slowly and satiety can be achieved with smaller portions.

**Figure 2.** A sleeve gastrectomy is completed by dividing and removing about 80 percent of the stomach, leaving a thin tube or “sleeve.”

A sleeve gastrectomy is completed by dividing and removing about 80 percent of the stomach, leaving a thin tube or “sleeve” (Figure 2). A bougie, or sizer, is used to make sure that the tube is not too large, which would result in poor restriction, or too tight, which could result in dysphagia, GERD, stricture, or maladaptive eating habits. With the sleeve, along with reducing caloric intake, there is an alteration in gastrointestinal hormone levels due to food emptying faster into the duodenum and also due to the reduction of ghrelin, an appetite stimulating hormone. The body’s main site of ghrelin production is in the gastric fundus and body, the majority of which is resected during SG.5,6

BPD/DS combines a sleeve gastrectomy with a Roux limb to the post pyloric duodenum and a short common channel for absorption of nutrients (Figure 3). This procedure combines restriction, hormonal changes, and more severe malabsorption with greater weight loss results but higher potential complication rates and long term nutrient malabsorption concerns.

As of 2014, 51.7 percent of bariatric operations performed in the United States were sleeve gastrectomy, followed by gastric bypass (26.8 percent), banding procedures (9.5 percent), BPDs (0.4 percent), and revisional bariatric operations (11.5 percent).7 By 2013, SG became the most commonly performed bariatric operation for multiple reasons. In recent years, there has been a significant drop in band procedures because, although some patients have good outcomes, there is inadequate long term weight loss and high removal rates.8,9,10 SG has become much more common because of excellent weight loss and reduction of comorbidities, along with a shorter operative time and reduced potential complications versus gastric bypass. The optimal choice of the type of bariatric procedure is dependent on individualized patient goals, risk assessment, and available expertise of the surgeons and institution.

**Trials**

A recent JAMA Surgery article looked at 10-year weight loss outcomes in 1787 patients who had GBP and compared this to a matched cohort who did not have surgery.11 Seventy-three

**Figure 3.** BPD/DS combines a sleeve gastrectomy with a Roux limb to the post pyloric duodenum and a short common channel for absorption of nutrients.
percent of the bypass patients were male, with a mean age of 52 years and mean BMI of 47.7. The non-surgical group had a similar patient composition and incidence of diabetes and other co-morbidities. Bypass patients lost 21 percent more of their baseline weight at 10 years than nonsurgical matches, with 72 percent losing more than 20 percent estimated weight loss and 40 percent having more than 30 percent estimated weight loss versus 11 percent and 4 percent, respectively of nonsurgical matches. The same study also looked at four-year weight change in the same GBP patients versus 379 patients who had a sleeve, and 246 who had lap band. Bypass patients lost 27.5 percent of baseline weight, sleeve lost 17.8 percent, and band lost 10.6 percent.

As previously mentioned, SG has become the most common bariatric operation in the United States. While, in general, reported weight loss outcomes have been greater with gastric bypass, these results may come with more potential complications, as GBP is a technically more complex operation than the sleeve. The American College of Surgeons-Bariatric Surgery Center Network of 109 hospitals prospectively collected data on 28,616 patients. GBP resulted in higher one year reoperation and intervention rates than the sleeve. The same study also looked at four-year weight change in the same GBP patients versus 379 patients who had a sleeve, and 246 who had lap band. Bypass patients lost 27.5 percent of baseline weight, sleeve lost 17.8 percent, and band lost 10.6 percent.

The three-year outcomes of a randomized trial (STAMPEDE: Surgical Treatment and Medications Potentially Eradicating Diabetes Efficiently) of 150 obese patients with uncontrolled type 2 diabetes was published in NEJM in 2014. Patients received intensive medical therapy alone or in combination with gastric bypass or sleeve gastrectomy, with the primary end point HbA1c ≤ 6. Age at baseline was 48, 68 percent were women, mean BMI was 36, and mean HbA1c was 9.3. At three years, bypass patients had 24.5 percent mean reduction in weight from baseline and 38 percent of patients had achieved HbA1c ≤ 6, while sleeve patients had a 21.1 mean weight reduction and 24 percent achieved the primary endpoint. Five percent of patients in the intensive medical treatment group reached the endpoint, and weight loss was 4.2 percent. A secondary endpoint was how many patients achieved HbA1c ≤ 7 and were medication free versus how many still required medications. Of medically treated patients, none achieved HbA1c ≤ 7 without medications and 40 percent achieved this with medication. Of the gastric bypass patients, 65 percent achieved this goal with medications, and 58 percent did not require medication. Four patients in the surgical arm underwent reoperation, but there were no deaths, life-threatening complications, or major late complications.

The five-year outcomes of the STAMPEDE trial were published in February 2017, with 90 percent of 149 living patients completing follow-up. Only 5 percent (2 of 38 patients) of medically treated patients met the primary end point of HbA1c ≤ 6, while 29 percent GBP (14 of 49), and 23 percent SG (11 of 47) achieved this target. Body weight changes from baseline were also superior in the surgical groups with 23 percent in GBP; 19 percent SG, and 5 percent in the intensive medical treatment alone group.

Diabetes and Surgery

Numerous randomized trials have shown bariatric surgery achieves superior glycemic control and reduction of cardiovascular risk factors in obese patients with type 2 diabetes (T2DM) versus medical and lifestyle intervention. The gastrointestinal tract has an important role in glucose regulation, and therefore GI interventions are meaningful targets for the management of T2DM. NIH criteria from 1991, while outdated, are still used but body weight-centric criteria do not include measures of metabolic disease severity. The 2nd Diabetes Surgery Summit, an international consensus conference representing 45 leading professional medical and surgical societies (including the American Diabetes Association, American Association of Clinical Endocrinologists, Endocrine Society, The Obesity Society, the American College of Surgeons, American Society of Metabolic and Bariatric Surgery among others) met in September 2015 to develop guidelines to inform clinicians and policymakers about the benefits and limitations of metabolic surgery for T2DM.

Participants reviewed multiple randomized controlled trials that consistently showed the benefits of metabolic surgery in terms of weight loss and glycemic control versus intensive medical treatments. Their analysis of the trials showed a median HbA1c reduction of 0.5 percent for medical treatment alone versus 2.0
percent for surgical intervention with medical treatment. However, duration of follow-up in these trials were mostly 1 to 2 years, with few 3 to 5 years. Over time there is some erosion of diabetes control and the term “cure” is inappropriate, with “remission” being preferred. Thirty-five to fifty percent of patients achieving remission will eventually relapse. Nonetheless, participants noted that even temporary improvement of control should be viewed as an important achievement in the overall lifelong, comprehensive diabetes treatment plan and the prevention of microvascular complications and cardiovascular disease.

After reviewing all available evidence, the consensus recommendations of the conference were that metabolic surgery should be a recommended option to treat T2DM in appropriate surgical candidates with class III obesity (BMI ≥ 40) and in those with class II obesity (BMI 35 to 39.9) where hyperglycemia is inadequately controlled by lifestyle and optimal medical treatment. Surgery should also be considered for patients with T2DM and BMI 30 to 34.9 if hyperglycemia is inadequately controlled despite optimal treatment. BMI thresholds should be reduced by 2.5 for Asian patients. Asian T2DM patients have increased visceral adiposity at normal or mildly increased weight and have islet cell dysfunction earlier in the course of their diabetes.17

Achieving Successful Long Term Outcomes

There is no cure for morbid obesity, but bariatric surgery is the most effective intervention available to patients. Keeping weight off long term is the key to preventing relapse of co-morbidities and providers must be diligent to educate and encourage patients to develop healthy habits and prevent weight regain. In order to optimize outcomes, physicians must address any psychological issues that may exist prior to or after surgery, encourage a sustainable nutrition plan, ensure participation in a bariatric program, and promote an active lifestyle.

Patients with depression, binge-eating, “loss of control” eating, and grazing have worse postoperative weight loss and a higher incidence of weight regain.18,19 Mood stabilization prior to surgery, as well as counseling and participation in support groups prior to and after surgery, can help address these issues and improve weight loss outcomes.

Starting before and continuing after surgery it is recommended to encourage a high protein, low carb, low (non-fried, non-greasy) fat diet to be eaten in three small meals. After any type of bariatric surgery the dietary recommendations are similar, and food should be chewed thoroughly and eaten slowly. The goal is to maintain variety in the diet, while at the same time getting at least 60 to 80 grams of protein daily. Promoting protein over carbs will allow increased loss of fat mass, while maintaining muscle mass, which will raise metabolic rate and allow more successful weight loss.20 Fat loss is also maximized by engaging in moderate intensity exercise for 30 to 60 minutes a day. Cardiorespiratory type exercise is the main intervention to allow weight loss and maintenance; however, strength and resistance training increases lean body mass and energy expenditure. Attendance at physician office visits and support groups, both online and in person, will help with patient motivation and long term adherence to weight loss goals.

Conclusion

Over the past 15 years, bariatric procedures have made improvements in safety with reduction in morbidity and mortality, reoperations, and long term complications. These improvements have coincided with the extensive penetrance of minimally invasive surgical techniques, as well as the adoption of dedicated centers of excellence with increased experience using a team management approach.

For morbidly obese patients who are unsuccessful in achieving weight loss with lifestyle modification or medical treatment, bariatric surgery can be a life changing event and may also be life-saving. Patients must be ready to use their new tools correctly and make good choices with eating small portions of a healthy diet, exercising regularly, and staying focused for the long term by attending support groups and following with their bariatric program.
References


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**Review of Adult Obesity Management in Primary Care**

**Background:**
The Duval County Medical Society (DCMS) is proud to provide its members with free continuing medical education (CME) opportunities in subject areas mandated and suggested by the State of Florida Board of Medicine to obtain and retain medical licensure. The DCMS would like to thank the St. Vincent's Healthcare Committee on CME for reviewing and accrediting this activity in compliance with the Accreditation Council on Continuing Medical Education (ACCME).

This issue of *Northeast Florida Medicine* includes an article, "Review of Adult Obesity Management in Primary Care" authored by Carmen L. Isache, MD and Ghania Masri, MD, which has been approved for 1 AMA PRA Category 1 credit.™ For a full description of CME requirements for Florida physicians, please visit www.dcmsonline.org.

**Faculty/Credentials:**
Carmen L. Isache, MD and Ghania Masri, MD, Department of Internal Medicine, University of Florida College of Medicine, Jacksonville, FL

**Objectives:**
1. Define obesity and prevalence in the United States.
2. Understand the role of lifestyle and behavioral changes in preventing and treating obesity.
3. Review the role of pharmacologic agents and bariatric surgery in treating obesity.

**Date of release: June 15, 2017**

**Date Credit Expires: June 15, 2019**

**Estimated Completion Time: 1 hour**

**How to Earn this CME Credit:**
1. Read the "Review of Adult Obesity Management in Primary Care” article.
2. Complete the posttest. Scan and email your test to Kristy Williford at kristy@dcmsonline.org or mail it to 1301 Riverplace Blvd., Suite 1638, Jacksonville, FL 32207.
3. You can also go to www.dcmsonline.org/NEFMCE to read the article and take the CME test online.
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**Faculty Disclosure:**
Carmen L. Isache, MD and Ghania Masri, MD report no significant relations to disclose, financial or otherwise with any commercial supporter or product manufacturer associated with this activity.

**Disclosure of Conflicts of Interest:**
St. Vincent’s Healthcare (SVHC) requires speakers, faculty, CME Committee and other individuals who are in a position to control the content of this educations activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly evaluated by SVHC for fair balance, scientific objectivity of studies mentioned in the presentation and educational materials used as basis for content, and appropriateness of patient care recommendations.
Review of Adult Obesity Management in Primary Care

By Carmen L. Isache, MD and Ghaania Masri, MD

Dept. of Internal Medicine, University of Florida College of Medicine, Jacksonville, FL

Abstract: Obesity is common, serious and costly. As per Centers for Disease Control and Prevention (CDC) data, more than one-third of U.S. adults (34.9 percent or 78.6 million) are obese.¹ Obesity is a multifactorial condition, in which excess body fat may put a person at risk of increased mortality and morbidity.² It imposes a great psychological, medical and economic burden on our nation and the entire world. Obesity represents a complex disorder, involving appetite regulation and energy metabolism, that needs to be appropriately screened for and managed, starting from the primary care physician’s office. Management of adult obesity includes behavioral therapy and lifestyle intervention, pharmacological adjunctive weight loss medication and bariatric surgery. Each weight loss plan is made based on individual, patient-related factors. However, in order for any plan to be successful, the patient needs to be placed in the center of the decision-making process.

Introduction

Obesity is a multifactorial condition, in which excess body fat may put a person at risk of increased mortality and morbidity.² The CDC defines overweight and obesity as a weight that is higher than what is considered to be a healthy weight for a given height.¹ Body Mass Index, or BMI, is used as a screening tool for overweight or obesity. Overweight is defined as a BMI of 25 kg/m² to 29.9 kg/m² and obesity as a BMI of ≥30 kg/m². An increase in obesity rates has led to worsening health outcomes and an explosion of health care costs. Being overweight or obese significantly increases a patient’s risk of developing more than twenty other different diseases and health conditions, including type 2 diabetes, hypertension, metabolic syndrome, cardiovascular disease, specific cancers and osteoarthritis.³

It is estimated that obesity accounts for 9.1 percent of annual health care spending in the United States (U.S.), costing our nation up to $147 billion dollars in 2008.⁴ Obesity imposes a great psychological, medical and economic burden; therefore, efforts to reduce its incidence need to become a priority. There is no single or simple solution to the obesity epidemic. It’s a complex problem and there has to be a multifaceted approach. Policy makers, state and local organizations, business, community and school leaders, healthcare professionals and individuals must work together to create an environment that supports a healthy lifestyle. Primary care providers should screen all their patients for obesity and determine who is in need of further counseling and management.

Prevalence in United States of America

According to data gathered by the CDC between 2011 and 2014, more than one-third of U.S. adults are obese.¹ The prevalence of obesity was reported to be slightly higher in women compared to men (38.3 percent versus 34.3 percent) and was also shown to be more prevalent among certain ethnic groups such as non-Hispanic blacks who have the highest age-adjusted rates of obesity (48.1 percent), followed by Hispanics (42.5 percent), non-Hispanic whites (34.5 percent), and non-Hispanic Asians (11.7 percent). Obesity is higher among middle aged adults, age 40-59 years (40.2 percent) and older adults, age 60 and over (37.0 percent) than among younger adults.⁵

As far as relation between obesity and socioeconomic status, the CDC reports that among men, obesity prevalence is generally similar at all income levels. However, higher income women were less likely to be obese when compared to lower income women. Also, those with college degrees were less likely to be obese when compared with less educated women. There was no significant trend between obesity and education among men.⁶

Etiology and pathophysiology

Obesity, defined as having a body-mass index (BMI) greater than 30 kg/m², was finally recognized by the American Medical Association as a chronic disease in 2013. (Table 1)

Since obesity is associated with multiple other comorbidities, primary care physicians have an enormous responsibility to screen adults for obesity and offer patients effective counseling and guidance.

There is increasing evidence to suggest that obesity is not just a simple problem of will power or self-control but a complex disorder...
involving appetite regulation and energy metabolism, associated with various comorbid conditions.\textsuperscript{2,3,7} Although the etiology of obesity has not been firmly established, genetic, metabolic, biochemical, cultural and psychosocial factors contribute to obesity. Some individuals may become overweight or obese partly because they have a genetic or biologic predisposition to gain weight; however, in most cases, the increasing prevalence of overweight and obese individuals reflects changes in society and behaviors over the past 20 to 30 years. Lifestyle patterns are influenced by an overabundance of energy-dense food choices and decreased opportunities and motivation for physical activity.\textsuperscript{7}

According to the U.S. Surgeon General, approximately 25 percent of American adults are completely sedentary, and more than 60 percent are not regularly active at the recommended level of 30 minutes per day.\textsuperscript{8} An estimated 300,000 preventable deaths occur each year in the U.S. because of unhealthy diet and physical inactivity,\textsuperscript{9} which are known contributors to obesity.

In 2000, the World Health Organization (WHO) published a technical report in which researchers addressed the increased risk for other medical conditions in patients with obesity. The chronic, life-threatening health problems associated with obesity fall into the following categories: cardiovascular problems, conditions associated with insulin resistance, certain types of cancers (e.g. hormonally related and large bowel cancers) and gallbladder disease. The risks of developing these medical conditions were categorized based on severity: greatly increased risk (relative risk > 3) for non-insulin dependent diabetes mellitus, gallbladder disease, dyslipidemia and sleep apnea, moderately increased risk (relative risk of 2-3) for coronary artery disease, osteoarthritis of knees, gout and hypertension, slightly increased risk (relative risk of 1-2) for cancer (breast cancer in postmenopausal women, endometrial cancer, colon cancer), reproductive hormone abnormalities, impaired fertility, polycystic ovary syndrome, low back pain and fetal defects associated with maternal obesity.\textsuperscript{10}

### Screening for obesity

The United States Preventive Service Task Force and the National Institute of Health recommend screening all adults for obesity by calculating BMI and measuring waist circumference. Men with a waist circumference of more than 40 inches and women with a waist circumference of more than 35 inches are at increased risk for metabolic syndrome, diabetes, dyslipidemia and hypertension.\textsuperscript{12}

Patients diagnosed with obesity should be assessed prudently for other health risk factors with complete history, physical exam and laboratory tests. The primary care physician needs to share the obesity diagnosis with their patient and also discuss the other potential health risks associated with diagnosis.

### Management of obesity

In 2013, the American College of Cardiology, American Heart Association Task Force on Practice Guidelines and The Obesity Society updated the guidelines for management of overweight and obese adults in order to help primary care physicians better manage this category of patients.\textsuperscript{13} The main goal is to decrease obesity-related cardiovascular disease by identifying patients who are obese or overweight and offering those patients comprehensive counseling regarding lifestyle intervention, alone or in conjunction with pharmacological weight loss therapy. This enormous task starts with assessing the patient's readiness to make the needed changes in order to achieve their weight loss goal and also to identify any possible barriers to success.

The American Association of Clinical Endocrinologists and the American College of Endocrinology have also published clinical practice guidelines for medical care of patients with obesity.\textsuperscript{14} In these guidelines, one of the issues addressed is prevention. Prevention is categorized as primary, secondary and tertiary. Primary prevention is defined as preventing the development of overweight and obesity. This can be done by educating the public and promoting healthy eating and regular exercise. Secondary prevention is defined as preventing future weight gain and the development of weight-related complications in overweight and obese patients. This is done by educating the public and promoting healthy eating and regular exercise. Secondary prevention is defined as preventing future weight gain and the development of weight-related complications in overweight and obese patients. This is done by educating the public and promoting healthy eating and regular exercise. Secondary prevention is defined as preventing future weight gain and the development of weight-related complications in overweight and obese patients. This is done by educating the public and promoting healthy eating and regular exercise.

#### Table 1. Weight classification by BMI

<table>
<thead>
<tr>
<th>BMI (kg/m(^2))</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5-24.9</td>
<td>Ideal</td>
</tr>
<tr>
<td>25-29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>30-34.9</td>
<td>Obesity (Class I)</td>
</tr>
<tr>
<td>35-39.9</td>
<td>Obesity (Class II)</td>
</tr>
<tr>
<td>≥40</td>
<td>Morbid obesity (Class III)</td>
</tr>
</tbody>
</table>

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**Behavioral therapy and lifestyle intervention**

There is no doubt that counseling patients on lifestyle changes represents a major challenge and a time-consuming activity that most primary care physicians have difficulties with, especially due to the lack of reimbursement and resources.

There is evidence to support behavioral changes being effective in helping obese and overweight patients lose weight resulting in a decreased risk of obesity-associated comorbidities such as diabetes mellitus and cardiovascular disease. The Diabetes Prevention Program Outcomes Study was one of the landmark trials, conducted over 15 years, which showed that intense lifestyle changes surpass the use of Metformin, an oral hypoglycemic agent, in preventing type 2 diabetes mellitus in overweight patients (27 percent versus 18 percent reduction in diabetes incidence, respectively). It is essential to educate primary care providers on counseling strategies for weight loss. Assessing a patient's history of weight gain or loss, dietary habits, physical activity and sleep history are very important. A primary care physician should discuss with their patient realistic goals of weight loss and emphasize that 10 percent of body weight loss has a positive effect on their overall health and mortality. The patient and their physician should together develop a weight loss program to include a diet compatible with the patient's taste that can be maintained for at least one year. The patient needs to understand that the main core of weight loss is to keep a negative calorie-energy balance. Multiple studies confirmed there is no difference in weight loss rate between different diet plans. The best diet is the one to which the patient will adhere the most. The key factor is to achieve an average of 500 calories deficit per day in order to achieve a four-pound weight loss in a month.

Physicians should empower their patients by making them an essential part of a patient-centered decision-making process on a weight loss program. The patient needs to be encouraged to feel in control with the plan, to self-monitor their weight, to keep a food dairy and to participate in a type of physical activity that fits their lifestyle.

Weight regain following weight loss remains a major challenge. The maximum weight loss usually occurs in the first six months, and then weight may plateau by the end of the following six months. This may discourage patients to continue with their lifestyle changes, therefore the primary care physician needs to encourage them to continue adhering to the long-term weight loss program, including regular exercise and weekly weight self-monitoring. Behavioral intervention has a higher chance of success when attempted through a multidisciplinary approach. Dieticians, nurses, educators, physical activity trainers and clinical psychologists play an important role, in addition to the primary care provider, in helping the patient adhere to the weight loss plan.

In 2011, the Centers for Medicare and Medicaid Services approved payment for an intensive behavioral therapy program provided by primary care physicians. This program offers patients 14 visits face-to-face with their primary care physician, once a week for the first two months, then every other week for the following four months. Patients who lose 3 kg in the first six months can be qualified for another 6-12 months of service. Each visit should last for at least 15 minutes with average reimbursement of $26.00. Unfortunately, due to this low compensation, less than one percent of Medicare beneficiaries have received this benefit.

**Pharmacological adjunctive weight loss medication**

In the past few years, the U.S. Food and Drug Administration (FDA) has approved several new long-term medications to be used in conjunction with behavioral therapy for weight loss. These medications are indicated for patients with a BMI above 30 or for patients with BMI above 27 with comorbidities. They are designed to help patients adhere to low calorie diets and maintain weight loss. Primary care physicians should discuss with their patients the risks and potential side effects of these medications and help the patient determine if the benefits outweigh the risks.

**Phentermine** has been on the market for a long time. It is a sympathomimetic weight loss drug approved for up to 12 weeks of use. The greater appetite suppression effect and weight loss usually occur in the first four weeks. Phentermine is a stimulant and common side effects include tachycardia, increase in blood pressure, feeling jittery and insomnia. This drug should be avoided in the elderly or patients with coronary artery disease.

**Orlistat** is a lipase inhibitor which decreases absorption of approximately one third of the dietary fat. This drug was approved in 1999 as a prescription drug, dosed 120 mg three times a day, with meals. In 2007, the FDA approved Orlistat at 60 mg three times a day, as a nonprescription drug. The four-year XENDOS double-blinded prospective study randomized 3,305 Swedish patients to placebo versus Orlistat, both in conjunction with lifestyle changes. At the end of the study, the Orlistat group had significant lower incidence of type 2 diabetes mellitus (18.8 percent vs 28.8 percent) and a significantly higher number of patients had a loss of 10 percent of body weight (26 percent vs 16 percent).
Lorcaserin is a selective serotonin 5-HT2C receptor agonist which stimulates receptors in the appetite nervous center, promoting satiety. The BLOOM trial demonstrated the safety of lorcaserin use and an average loss of 8 percent of body weight at one year. Patients on lorcaserin were also noted to have an improvement in blood pressure control and a decrease in their hemoglobin A1c, low-density lipoproteins (LDL) and triglycerides levels. Weight loss at 12 weeks is usually predictive of weight loss at 52 weeks. Patients are expected to lose more than 5 percent of their body weight by 12 weeks of lorcaserin use. As far as side effect profile, lorcaserin was shown to cause no increase in incidence of valvulopathy, a finding that supports the hypothesis that valvulopathy is not associated with activation of the 5-HT2C receptors, as opposed to prior weight-loss drugs such as fenfluramine which activated the 5-HT2B receptor in cardiac valvular interstitial cells, thought to cause serotonin-associated valvulopathy.22

The Phentermine-topiramate controlled-release tablet combines phentermine, a sympathomimetic amine that decreases appetite, with topiramate which increases gamma-aminobutyric acid activity in the brain and induces prolonged satiety. Primary care physicians should monitor patients closely for weight loss and possible side effects, with a goal of more than 3 percent of body weight loss in the first 12 weeks and more than 5 percent of body weight loss at 24 weeks. The SEQUEL trial, a placebo-controlled, double-blind study that included 676 overweight and obese patients with more than two weight-related comorbidities, demonstrated drug safety at 108 weeks of use with average weight loss significantly greater compared to placebo, at two years. Other secondary benefits included improvement of lipid profile and hemoglobin A1c.23

The Naltrexone-bupropion sustained-release tablet is a fixed combination of two active ingredients with a unique action on the hypothalamus, leading to decreased appetite, ability to control food preference and increased metabolism. The COR-II phase III trial was a double-blind, placebo-controlled study that included 1,496 overweight or obese participants, randomized 2:1 to receive combined naltrexone plus bupropion or placebo for up to 56 weeks. This clinical trial determined the safety of this drug at 56 weeks and also showed that the participants who received naltrexone-bupropion achieved more than 5 percent of body weight loss at 28 weeks and at 56 weeks, in significantly higher numbers compared to the placebo group. Along with the weight loss, this medication also had positive effects on cardiovascular risk factors by improving lipid profile and hemoglobin A1c.24 This medication is contraindicated however in patients with seizure disorder, uncontrolled hypertension and opiate dependence.

Liraglutide is one of the latest drugs approved by the FDA for treating obesity. This drug has been on the market prior, for treatment of diabetes. Liraglutide is a glucagon-like-peptide-1 (GLP-1) analogue that has been shown to contribute to weight loss by regulating appetite and caloric intake. A randomized double-blind trial conducted in obese patients who did not have type 2 diabetes mellitus concluded that patients treated with liraglutide, as an adjunct to diet and exercise, lost approximately 8 percent of their body weight at 56 weeks.25

Bariatric Surgery

Bariatric surgery is indicated for patients with a BMI greater than 40 or greater than 35 with comorbidities, who are motivated to lose weight and did not respond to behavioral therapy with or without adjunctive pharmacological treatment.26 Bariatric surgery has a long term sustained weight loss benefit. Even though it may carry upfront risks, it has a positive effect on comorbidities, quality of life and it has been shown to decrease mortality up to five years after procedure.27

Conclusion

Primary care physicians have a tremendous responsibility for screening, preventing and treating patients with obesity. Diet, exercise, and behavioral modification continue to be the cornerstone of obesity management. Pharmacotherapy is an adjunctive tool to lifestyle changes and it may help adherence to behavioral modification and improve weight loss maintenance. There is no one-size-fits-all solution. However, placing the patient in the center of the decision-making process will result in the greatest chance of leading to a successful weight loss plan. Establishing a medical home care model and improving reimbursement for coordination of care by the primary care physicians may also aid significantly in prevention and management of obesity.
References


Review of Adult Obesity Management in Primary Care

CME Questions & Answers (circle one answer)/Free to DCMS Members/$55.00 charge non-members*

(Return by June 15, 2019 BY MAIL: 1301 Riverplace Blvd. Suite 1638, Jacksonville, FL 32207 or ONLINE: www.dcmsonline.org/NEFMCME)

1. As per data gathered by the Centers for Disease Control, how many U.S. adults are currently obese?
   a. 5 percent of the adult U.S. population
   b. One third of the adult U.S. population
   c. Half of the adult U.S. population
   d. 70 percent of the adult U.S. population

2. The Centers for Disease Control defines obesity as a BMI equal or greater than:
   a. 20 kg/m²
   b. 25 kg/m²
   c. 30 kg/m²
   d. 40 kg/m²

3. Being overweight or obese significantly increases a patient’s risk of developing which of the following conditions?
   a. Diabetes mellitus type 2
   b. Hypertension
   c. Cardiovascular disease
   d. All of the above

4. Obesity has been found to have a higher prevalence in which of the following ethnic groups?
   a. African-Americans
   b. Caucasians
   c. Hispanics
   d. Asians

5. How many preventable deaths are estimated to occur each year in the United States due to unhealthy diet and physical inactivity?
   a. None
   b. 1 million
   c. 1000
   d. 300,000

6. What waist circumference was shown to be associated with increased risk for metabolic syndrome, diabetes mellitus, dyslipidemia and hypertension?
   a. Equal or greater than 35 inches in women and equal or greater than 40 inches in men.
   b. Greater than 50 inches in women and greater than 30 inches in men.
   c. Under 30 inches in women and greater than 40 inches in men.
   d. Under 35 inches in women and under 40 inches in men.

7. During a weight loss program, when does the maximum weight loss usually occur?
   a. In the first two years
   b. In the first month
   c. It remains constant throughout the weight loss program
   d. Usually occurs in the first six months and may plateau by the end of the following six months

8. Which drug recently approved by the FDA for treating obesity has been on the market prior, for treatment of diabetes?
   a. Orlistat
   b. Liaglutide
   c. Phentermine
   d. Lorcaserin

9. When is bariatric surgery indicated for treatment of obesity?
   a. In patients with a BMI equal or greater than 40 kg/m² or 35 kg/m² plus obesity-associated comorbidities
   b. In patients with a BMI equal or greater than 25 kg/m² who develop hypertension
   c. In men with waist circumference greater than 30 inches
   d. In men with diabetes mellitus and BMI greater than 25 kg/m²

10. The cornerstone of obesity management is:
    a. Bariatric surgery
    b. Pharmacological therapy
    c. Diet, exercise and behavioral modification
    d. None of the above

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(Please evaluate this article. Circle one number using this scale: 1= Strongly Agree to 5= Strongly Disagree)

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The articles were appropriate to my practice: 1 2 3 4 5
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Obesity

Robotics and the Future of Bariatric Surgery

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Abstract: Obesity is an increasing epidemic worldwide. Bariatric surgery has been proven to be a safe and effective treatment of the disease of obesity. The number of bariatric procedures increased significantly in the past few years, approaching 250,000 cases per year in the United States alone. Conventional laparoscopy has been established as the gold standard for Roux-en-Y gastric bypass (RYGB) surgery. However, a large proportion of these procedures can be complex and challenging. In spite of the success achieved with bariatric surgery, problems remain including gastric leakage, sepsis, bleeding, intensive care stays, long hospitalizations, and reoperations. In order to overcome the technical disadvantages of laparoscopic surgery, including lack of three-dimensional (3D) imaging and loss of some freedom of motion, robotic surgical systems were introduced in 1997. One of the more recent advances in bariatric surgery is the da Vinci robotic surgical system (Intuitive Surgical, Sunnyvale, CA).

Introduction

Minimally invasive techniques have revolutionized the field of bariatric surgery. Since its introduction in the late 1980s, laparoscopic surgery has expanded in operations performed and reduced complications and length of stay comparing with open approach. However, some limitations of laparoscopic surgery are still encountered. Ergonomics in laparoscopy are a limiting factor for bariatric surgeons. Abdominal wall torquing affects the surgeon’s joints and fatigue. After many years of practicing, injuries, joint and muscle fatigue are commonly seen in surgeons. Furthermore, laparoscopic equipment has no articulation and, in obese patients, fine or precise movements can be very challenging for the surgeon. Laparoscopic surgery loses the hand-eye target coordination, which is very important in open surgery. The lack of this coordination puts a significant toll on surgeons and assistant ergonomics as well. In order to overcome the technical disadvantages of laparoscopic surgery, including lack of three-dimensional (3D) imaging and loss of some freedom of motion, robotic surgical systems were introduced in 1997. Compared with traditional laparoscopy, robotic surgical systems are considered to achieve better postoperative quality, while diminishing limitations of laparoscopic surgery and providing an excellent interface for the surgeon. The use of robotic techniques in these revisional procedures may reduce the length of stay, leaks rate and reoperations, benefitting this unfortunate group of patients.

Digging into the past, the term “robot” was first used in Capek’s 1920 play Rossum’s Universal Robots and is derived from the Czechoslovakian word “robata,” meaning “forced labor.” Robotic surgery became available in the United States in the early 2000s after obtaining FDA clearance. While it was widely accepted and adopted by surgeons in the field of urology and gynecology, the application for general surgical procedures took much longer. Nonetheless, the number of complex robotic cases in general surgery has considerably increased in the last five years.

The Intuitive da Vinci surgical robot went through many upgrades and improvements since the launch of the first commercial device in the early 2000s. Today, the latest device is the da Vinci Xi. While it still has the essential robotic features, it can now be used for multi-quadrant operations without the need for re-docking.

The da Vinci surgical robot consists in three different parts (Figure 1): patient cart, surgeon console, and control tower. The

Figure 1

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operating surgeon sits at the console, while the bedside surgeon helps with positioning the cart, exchanging instruments and assisting with the procedure. At present time, robotic surgery has become routine for many hospitals with experienced and well-trained teams comprised of nurses and technicians dedicated to robotic surgery.

The first reports in robotic surgery for general surgery were scarce with only a few case series. Today, large series in multiple intra-abdominal complex procedures are published and several trials are forthcoming.\textsuperscript{1,3,11} The application of robotic interventions in bariatric surgery increased in the last few years.\textsuperscript{2,12,13,14} Advantages of robotic operations in weight loss surgery, also common to other surgical procedures, include high definition magnification of the surgical field, superior binocular three-dimensional visualization of the anatomy, full range of motion with articulated instruments, tremor filtration and motion scaling, and comfortable ergonomics for the surgeon. Thus, the use of the robotic system may improve a surgeon's skills during dissection, resulting in better clinical outcomes in certain cases.\textsuperscript{15} Robotic surgery plays an important role in overcoming some of the challenges of laparoscopic surgery in this specific patient population.

Robotic surgery has provided surgeons the advantage of three-dimensional vision and increased dexterity and precision by downsizing a surgeon's movements, enabling a fine tissue dissection and filtering out physiological tremor. It overcomes the restraint of torque on ports from thick abdominal wall, and minimizes port site trauma by remote center technology. There is no doubt that these are challenging cases where robotic surgery may play a role in decreasing complications and conversions to open surgery.

The main limitation with robotic surgery is the perceived higher cost and set-up time compared with laparoscopy. However, with increased experience, it is seen that set-up times are reduced, and costs may also come down as material prices reduce.\textsuperscript{1}

The Evolution of Robotic Bariatric Surgery

The number of bariatric procedures increased significantly in the past few years, approaching 250,000 cases per year in the United States alone.\textsuperscript{2} Since the first laparoscopic Roux-en-Y gastric bypass (LRYGB) was reported in 1994, laparoscopic bariatric surgery (LBS) has become widely used for the treatment of morbid obesity because of shorter hospital stay, faster convalescence, and lower postoperative complication rates compared with open bariatric procedure.\textsuperscript{5}

As a result, conventional laparoscopy has been established as the gold standard for Roux-en-Y gastric bypass (RYGB) surgery. However, a large proportion of these procedures can be complex and challenging. In spite of the success achieved with bariatric surgery, problems remain including gastric leakage, sepsis, bleeding, intensive care stays, long hospitalizations, and reoperations.\textsuperscript{3} These problems have led bariatric surgeons to seek other options to continue the process of lowering complications and improving outcomes.\textsuperscript{1} Consequently, because morbidity from this kind of surgery is still relevant, advanced technologies might further improve the outcomes of minimally invasive bariatric surgery.\textsuperscript{16}

The use of robotics in bariatric surgery has been evolving and the number of procedures has been growing over the last decade. Robotic surgery systems combine the advantages of minimally invasive surgery with the easier performance of open surgery, allowing surgeons to potentially decrease postoperative complications.\textsuperscript{1}

A Review of the Role of Robotics in Bariatric Surgery

One of the most apparent benefits of robotic technology is when an extensive amount of suturing is involved (such as hand sewn anastomoses during gastric bypass). Certain series published have noted a lower leak rate with robotic-assisted laparoscopic roux-en-y gastric bypass.\textsuperscript{2,3} A recent review of more than 1,500 patients demonstrated a significant reduction in anastomotic strictures with robotic gastric bypass.\textsuperscript{2} Some studies have demonstrated shorter hospital length of stay with robotic gastric bypass;\textsuperscript{2} however, this is not uniformly reported. The robotic platform has been shown to allow for a low rate of complications during the learning curve.\textsuperscript{12} The learning curve of laparoscopic gastric bypass is around 100 cases where for robotic is around 50 cases or less.\textsuperscript{14}

There is little data published on the role of robotics in biliopancreatic diversion and duodenal switch. This is likely reflective of the overall small number of these operations that are performed yearly. One of the main advantages of using robotic techniques is the construction of the duodeno-ileal anastomosis (proximal alimentary limb anastomosis) and the dissection of the second portion of the duodenum. This anastomosis requires complex suturing and is especially prone to leaks. Complex suturing technique is the main advantage of the robotic technology and thus more suitable for creating duodeno-ileal anastomosis than laparoscopy. The added dexterity offered by the robot may decrease the incidence of leaks.\textsuperscript{13}
An advantage of the robotic approach for gastric bypass and biliopancreatic diversion is that the learning curve may be significantly less than the traditional laparoscopic approach. Some have reported the number of cases to be less than 20 for gastric bypass.\textsuperscript{14} Cost is a topic of intense discussion surrounding the utility of robotics in surgery centers. As with any technology, costs are likely to decrease with advancing technology and increased vendor competition. Other factors to be considered while evaluating cost include the decreased learning curve as well as learning curve-related complications. According to several studies decreased rate of complications actually creates a cost advantage with robotic gastric bypass.\textsuperscript{14,17}

Revisional Bariatric Surgery

With the continued increase in the number of primary bariatric procedures, it is not surprising that the number and complexity of revisional cases continues to increase.\textsuperscript{8} Reasons for pursuing revisional surgery include converting an older, failed procedure, such as vertical banded gastroplasty or gastric bands, treating a complication of a previous weight loss surgery, and/or adding a component of malabsorption (as in conversions to gastric bypass or biliopancreatic diversion). There is limited and controversial literature on the role of robotics in revisional weight loss surgery. Some authors report that robotic-assisted revisional weight loss surgery is associated with a significantly lower rate of complications.\textsuperscript{14,18} In other studies, conversion rates to an open procedure with revisional bariatric surgery is approximately 10.4 percent.

Future of Bariatric Surgery

Since initially described, there has been a steady increase in the number of surgeons using robotics to perform weight loss surgical procedures.\textsuperscript{15} Despite the increase in its use, the literature surrounding this topic is still relatively limited. This paucity in the literature offers a host of opportunities for development, research, and innovation. The current, as well as future, proposed robotic platforms offer potential in the advancement of decreased incision, single incision, and incision-less (endoscopic and natural orifice) surgery. The continued integration of radiologic imaging and other adjuncts for augmented visualization makes feasible creation of a real time operative map. These technology advances may be useful especially in complex revisional cases, as well as in other complex gastrointestinal and oncological surgeries. The robotic platform provides superior visualization, increased degrees of movement, technological promise, and ergonomic advantages, and with future innovations and research, surgeons are likely to see even more widespread adoption of this tool in bariatric surgical procedures. Despite the advantages purported by industry and surgeons who have adopted robotics into their practice, use of a robotic platform is still relatively small in elective weight loss surgery. It is crucial that physicians objectively evaluate the data and evaluate it with large comparative trials.

New technologies are being developed in the treatment of obesity, not all of them surgical. Trans-oral therapies (intragastric balloon, endoscopic sleeve) are becoming more popular, but still long term data is needed to evaluate efficacy. Newer techniques with less side effects, complications and shorter hospital stays are needed to satisfy the increased demand for these procedures. As technology evolves and becomes more affordable, access to these newer techniques will be available to more patients.

Conclusion

In conclusion, while robotic surgery enhances surgeon abilities and allows for a more precise dissection and tissue manipulation, more evidence is needed to define the role of robotic surgery in bariatrics. Nevertheless, an increasing number of surgeons are adopting this technology to overcome the difficulties of conventional laparoscopic surgery.
References


**Current Concepts on Non-Alcoholic Fatty Liver Disease and Obesity Epidemic**

By Andrea Fialho, MD,1 Andre Fialho, MD,1 Ahmad Alkhasawneh, MD,2 Silvio W. de Melo, Jr., MD,1 and Miguel Malespin, MD1

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**Abstract:** Non-alcoholic fatty liver disease (NAFLD) is one of the most common causes of chronic liver disease in the United States. It affects approximately 30 million people and prevalence of NAFLD is increasing as a result of the current obesity epidemic. Despite the introduction of promising noninvasive diagnostic tests, histologic confirmation with liver biopsy remains the standard of care. NAFLD carries a significant disease burden and an increased risk of hepatic and non-hepatic mortality. Weight loss remains the mainstay of therapy as there is currently no other accepted standard of care.

**Introduction**

Non-alcoholic fatty liver disease (NAFLD) is a common cause of chronic liver disease in the Western world and its prevalence is increasing in parallel with the obesity epidemic. The current reported prevalence in the United States in approximately 30 million persons and currently it is the second leading indication for liver transplantation after hepatitis C.1,2,3 Despite the increased disease burden, management through weight loss remains the standard of care. NAFLD is defined as the presence of hepatic steatosis occurring in the absence of alcohol abuse. Histologically, it requires the presence of fat deposition in more than five percent of hepatocytes.5 It is important to rule out significant alcohol consumption (more than 20g/day in women and 30g/day in men), as alcoholic liver disease can be indistinguishable from NAFL and NASH histologically.

**Definition**

NAFLD encompasses a spectrum of liver disease including non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH).4 NAFLD is defined as the presence of hepatic steatosis occurring in the absence of alcohol abuse. Histologically, it requires the presence of fat deposition in more than five percent of hepatocytes.5 It is important to rule out significant alcohol consumption (more than 20g/day in women and 30g/day in men), as alcoholic liver disease can be indistinguishable from NAFL and NASH histologically.

**Prevalence**

The prevalence of NAFLD in the U.S. population using ultrasonography for diagnosis is approximately 10 percent, which represents approximately 30 million affected persons.6 This number dwarfs the estimated 4-6 million persons presumed to be affected with chronic hepatitis C.7 Men seem to be at higher risk for NAFLD compared to women.6 There is also a difference in prevalence within ethnic groups. NAFLD is more common in Hispanic-Americans (24-58.3 percent) and White-Americans (18-44 percent) with African-Americans (13-34 percent) having the lowest reported risk.6,8 In addition, Hispanic-Americans seem to develop the disease at a younger age and tend to progress to more severe disease.9,10

In patients with morbid obesity, the prevalence of NAFL and NASH can be as high as 91 percent and 35 percent respectively.11 NAFLD has been shown to occur in 69-74 percent of diabetic individuals.8,12

**Risk factors**

NAFLD is strongly associated with metabolic syndrome which includes the presence of central obesity, dyslipidemia, hypertension, and insulin-resistance.13

Insulin resistance plays a critical role in the development of hepatic steatosis and its progression to NASH by promoting the accumulation of triglycerides in the liver and inducing lipogenesis within adipose tissue, thus leading to a higher concentration of free fatty acids to the liver.14,15 In fact, type 2 diabetes is associated with worse histologic features of NAFLD including NASH and progression to fibrosis.16,17
There has also been an increased interest in the role that genetics play in the pathogenesis of NAFLD. Current evidence suggests that polymorphisms in the gene PNPLA3 could account for development and progression of NAFLD even in the absence of metabolic syndrome.\textsuperscript{18}

Diagnosing NAFLD requires a review of the reversible factors in the medical history and medications. Less common causes of NAFLD include medications such as methotrexate, amiodarone, tamoxifen, familial hyperlipidemic conditions, hypothyroidism, polycystic ovarian syndrome, and hypopituitarism.\textsuperscript{19,20}

**Patho-Physiology**

The pathophysiology of NASH is not completely understood. Many experts believe in the “multiple hit” hypothesis, in which insulin resistance plays a pivotal role. The first “hit” is the accumulation of triglyceride in the liver. Insulin resistance leads to an increased hepatic delivery of free fatty acids, which are stored in the form of triglycerides and generate oxidative stress.\textsuperscript{21} The hepatocytes become susceptible to further damage from oxidative stress and pro-inflammatory cytokines which are thought to provide the second “hit.”\textsuperscript{22} This leads to a vicious cycle of inflammation and apoptosis of hepatocytes, with deposition of extracellular collagen which can lead to fibrosis. More recently a third “hit” has been proposed, which is an abnormal proliferation of hepatocyte progenitor cells in response to increased oxidative stress. Hepatocyte progenitor cells in turn have been associated with increased collagen deposition and fibrosis.\textsuperscript{23}

**Prognosis**

NAFL and NASH are often considered a spectrum of disease. NAFL is more benign and has been shown to progress to NASH in 44 percent of the cases after 8 years, while NASH progresses to fibrosis in 20-37 percent of the cases.\textsuperscript{24,25}

Patients with NAFLD have an increased 10-year cardiovascular risk\textsuperscript{26} and cardiovascular disease remains the most common cause of death in patients with NAFLD.

It is important to highlight that patients with NAFL have a favorable clinical course as compared to NASH. While the presence of hepatic steatosis can be ascertained by NASH requires a liver biopsy. Thus, several studies have been conducted to identify clinical models of prediction of NASH without the need for liver biopsy.

**Diagnosis**

**Invasive tests**

The gold standard for the diagnosis of NAFLD is a liver biopsy.\textsuperscript{27} Liver biopsy can be performed by using a percutaneous or transjugular approach. Complications associated with percutaneous liver biopsy can occur in 5.6 percent of the cases, the most common of which are bleeding and pain.\textsuperscript{28} The transjugular liver biopsy approach has a risk of 7.6 percent, with complications including abdominal pain and subcapsular bleeding.\textsuperscript{29} Typical histopathologic findings in NAFL include hepatocyte steatosis while lobular inflammation and hepatocyte ballooning will also exist in NASH (Figures 1 and 2).

**Non-invasive tests**

There are no specific serologic tests that are performed in patients suspected of having NAFLD though it is important to rule out other causes of chronic liver disease including hepatic viral diseases, hereditary hemochromatosis, and autoimmune liver diseases.

Abdominal imaging is often used to diagnose hepatic steatosis. Abdominal ultrasound has a sensitivity of 66 percent and a specificity of 93 percent for fatty liver diagnosis, while computed tomography has a sensitivity of 72 percent and a specificity of
Obesity 91 percent. The most accurate test to quantify fat in the liver is magnetic resonance spectroscopy. This imaging modality measures the proportion of proton density that is attributable to fat in the liver and has a sensitivity of 80-91 percent and specificity of 80-87 percent for diagnosis of hepatic steatosis.

Predictive models have been developed to diagnose NASH using a combination of clinical and laboratory data. These models, such as the HAIR score (hypertension, aspartate aminotransferase, insulin resistance) and the NASH predictive index, still need to be validated for their use in clinical practice. A ferritin of more than 1.5 times upper limit of normal has been shown to correlate with NASH and liver fibrosis.

Of the predictive models of fibrosis in NAFLD, one of the most validated scores is the NAFLD fibrosis score, which can be a useful tool to diagnose fibrosis in patients with hepatic steatosis. Another useful score to predict fibrosis is the NASH-fibroSURE. The later uses a mathematical formula that includes serologic markers to calculate the degree of fibrosis with a sensitivity of 92 percent and a specificity of 71 percent.

Several imaging modalities are now available to estimate the degree of hepatic fibrosis in NAFLD. Vibration controlled transient elastography, also known as FibroScan® (EchoSens, Paris, France), is a quick and easy way to estimate liver stiffness and fibrosis at the clinic using shear waves. Another option for estimation of liver fibrosis is the acoustic radiation force impulse, which consists of a regular ultrasound probe with integrated capacity to measure the displacement of tissue caused by acoustic force. A promising non-invasive method to estimate fibrosis is the magnetic resonance elastography, which uses MRI to measure the tissue displacement caused by shear forces.

**Treatment**

Several drugs are under investigation for treatment of NASH. To date, no single drug can be recommended according to the American Association for the Study of Liver Disease. The cornerstone of treatment for NASH is weight loss through diet and exercise. In morbidly obese patients who fail to achieve weight loss, bariatric surgery should be considered after diet and exercise have failed.

**Non-pharmacologic**

Life style modification is essential in the treatment of fatty liver. Studies have shown that a diet low in carbohydrate, as well as the Mediterranean diet, can lead to improvement in hepatic steatosis compared to other diets. Aerobic exercise 30-45 minutes three times a week has shown to improve hepatic steatosis even in the absence of weight loss and should always be recommended.

Weight loss has been shown to improve NASH histology and promote fibrosis regression in NAFLD. In patients with 5 percent total body weight loss, NASH resolution occurred in 58 percent and inflammation improved in 82 percent. When patients lost 10 percent of their body weight, NASH resolved in 90 percent and inflammation improved in 100 percent. Thus, the target reduction should be 10 percent of total body weight.

**Surgical treatment**

There are three main surgical options for weight reduction that have been shown to impact NASH histology. Roux-en-Y gastric bypass (RYGB) surgery has the best treatment outcomes in NASH histology compared to adjustable gastric band (AGB) and sleeve gastrectomy (SG). Approximately 90 percent of the patients with NASH treated with RYGB have improvement in inflammation and 70 percent have improvement in fibrosis. The AGB and SG are associated with less improvement in steatosis, inflammation and fibrosis.

**Pharmacologic Treatment with Established Data**

Vitamin E is an antioxidant substance that has been shown to improve the inflammation associated with NASH. However, in non-diabetic patients with NASH, vitamin E did not improve liver fibrosis despite improving inflammation. Unfortunately, long-standing use of vitamin E has been associated with an increased prostate cancer risk in men. In addition, a meta-analysis showed an increase in all-cause mortality. Currently, vitamin E can only be recommended in non-diabetic patients with NASH.

Studies have shown that pioglitazone, a thiazolidinedione that improves insulin sensitivity, is associated with an improvement in inflammation in NASH. Few studies have shown improvement in fibrosis in these patients. Major side effects include weight gain secondary to fluid retention and worsening heart failure. Studies have shown that pioglitazone, a thiazolidinedione that improves insulin sensitivity, is associated with an improvement in inflammation in NASH. Few studies have shown improvement in fibrosis in these patients. Major side effects include weight gain secondary to fluid retention and worsening heart failure. Currently, vitamin E can only be recommended in non-diabetic patients with NASH.

**Pharmacologic treatment with data under investigation**

The role of the farnesoid X nuclear receptor ligand obeticholic acid in NASH patients with diabetes was evaluated in the FLINT trial. This randomized controlled trial showed that obeticholic acid improved hepatic inflammation in diabetic patients with NASH. The main side effect of the drug was pruritus and increased levels of low-density lipoprotein levels. The safety of this drug in NASH patients needs to be further investigated given the high rates of cardiovascular disease in this population.
The HMG-CoA reductase inhibitors have been studied in patients with NASH with conflicting results. There have been conflicting findings in terms of improvement in inflammation and progression to fibrosis. Further, large randomized-control trials are needed to confirm the benefit of statins on liver inflammation and progression to fibrosis. Thus, to date statins cannot be routinely recommended as treatment for patients with NASH.

There has been a long-standing association with statins and hepatotoxicity, although episodes of acute liver failure remain rare. The effect of statins on liver function tests is dose dependent. When statins cause elevations in liver transaminases, it is usually less than three times the upper limit of normal and most often resolves even without dose adjustment.

It is important to emphasize the safety of statin use in patients with NAFLD, particularly if indicated from a cardiovascular and hyperlipidemia standpoint. In fact, the use of statins has been associated with improved cardiovascular outcomes in patients with NAFLD. Atorvastatin has been associated with liver function tests elevation in only 0.7 percent of the patients, of which 0.3 percent required treatment discontinuation. The use of statins has been shown to be safe in patients with chronic liver disease and compensated cirrhosis, but is contraindicated in patients with decompensated cirrhosis.

Recent studies have shown that caffeinated coffee consumption may improve fibrosis in patients with NASH, although it does not seem to prevent or reverse the inflammation associated with NASH. The beneficial effects of coffee on NAFLD are thought to be due to its antioxidant proprieties. The exact quantity of coffee needed to improve fibrosis is not established. The average intake of caffeinated coffee in one study was 206.4 mg/day.

Several other drugs are currently being investigated for possible role in the treatment of NASH. These include simtuzumab, cenicriviroc and GFT505 as shown in Table 1.

**Table 1.**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mechanism of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obeticholic acid</td>
<td>Farsenoid receptor agonist</td>
</tr>
<tr>
<td>Simtuzumab</td>
<td>Anti-lysyl aminopeptidase-like 2 monoclonal antibody</td>
</tr>
<tr>
<td>Cenicriviroc</td>
<td>CCR2/CCR5 antagonist</td>
</tr>
<tr>
<td>GS-9450</td>
<td>Caspase inhibitor</td>
</tr>
</tbody>
</table>

Liver transplantation for NASH

Cirrhosis due to NASH is currently the second most common indication for liver transplantation in the U.S. and it is estimated that by 2030, it will become the leading indication for liver transplantation.

Liver transplantation in patients with NASH can be challenging. Although the overall survival at 1 and 5 years remains the same in comparison to other indications, NASH is associated with longer operative time and post-operative hospital stay. In addition, metabolic syndrome, insulin resistance and hypertension after liver transplant can occur in 44 percent, 41 percent and 51 percent of the individuals independent of the indication for liver transplantation. This may be at least in part due to the immunosuppressive medications used after liver transplantation, specifically tacrolimus and corticosteroids, which can promote the development of insulin resistance and hypertension. Patients with NASH are also at increased risk of cardiovascular complications after liver transplantation compared with other indications and remain the most common cause of death in patients with NASH after liver transplant.

Overall the 5-year survival after liver transplantation for NASH is 90 percent. Recurrence of disease can occur in 30 percent and progression to fibrosis tends to occur in 18 percent of the transplanted patients. Fibrosis tends to occur more often in patients on corticosteroids and in those who develop diabetes after transplant.

Conclusion

NAFLD is a disease with increasing prevalence that affects approximately 30 million Americans and is estimated to become the most common cause of liver transplantation by 2030.

Despite its great impact in public health, lifestyle modification and weight loss continue to be the only recommended treatment for NAFLD. This is difficult to achieve and maintain, leading often to cirrhosis. There are currently no well-accepted pharmacological therapeutic options for NAFLD. Vitamin E and pioglitazone have been the most studies drugs but their use remains controversial. There has been increasing interest in the development of drugs for NASH with promising results. Several drugs are currently under investigation, including obeticholic acid, simtuzumab, and cenicriviroc. These emerging treatment options will hopefully alter the progression to cirrhosis.
References


**Bariatric Surgery: Bariatric Perioperative Nutrition Care**

By Lori Solem, MA, RDN, LD/N

**Mayo Clinic Florida**

**Abstract:** The health benefits of bariatric surgery are evident through improvement in weight-related comorbidities, weight reduction, and reported improvement in some aspects of life.1,2 This transformation begins with nutrition assessment and education preoperatively and requires continued lifestyle examination to prevent obesity relapse.3,4

Pre- and post-operative nutrition care plays a pivotal role in the success of patients who have undergone bariatric surgery. The role of nutrition care and quality of nutrition education carries tremendous potential for the patient considering bariatric surgery.5 Nutrition education provided by a registered dietitian is central to the success of this patient population— in avoidance of postoperative complications, improved tolerance of the postoperative diet, and in preventing postoperative weight regain.3

However, long-term success and weight regain depends on patient compliance with the postoperative nutrition regimen and adherence to lifestyle changes.6 Bariatric surgery results in physical, sociocultural, and psychological lifestyle changes that have the potential to influence adherence to nutrition and activity recommendations.7

**Introduction:**

Nutrition care is a fundamental component of the bariatric surgery process. Nutrition assessment and dietary management in bariatric surgery have been correlated with success.8,9 A complete nutrition assessment should be conducted preoperatively to identify a patient’s nutritional and educational needs. This is essential to determine any pre-existing nutritional deficiencies, develop appropriate dietary interventions, and create a plan for a postoperative diet that will enhance a patient’s likelihood of success after surgery.10

Management of the postoperative diet begins preoperatively with a thorough assessment of nutrient status, a strong educational program, and follow-up to reinforce important principals associated with long-term maintenance of weight loss.1,11 Not only should the practitioner review the standard assessment components (i.e., medical comorbidities, weight history, laboratory values, and nutritional intake), it is also important to evaluate other issues that could affect nutrient status, including readiness for change, realistic goal setting, general nutrition knowledge, as well as behavioral, cultural, psychosocial, and economic issues.7,12

The role of nutrition education and medical nutrition therapy in bariatric surgery will continue to grow as tools to enhance surgical outcome and long-term weight loss maintenance are explored further and identified. Table 1 outlines various factors to assess during weight management intake interviews.3

| Table 1. Factors to assess during weight management intake interviews |
|----------------|-----------------|----------------|----------------|
| **A. Anthropometrics** | **Weight** | **Body Mass Index** | **Waist Circumference** |
| **B. Medical** | Identify potential causes: endocrine, neurological; medications; genetics (age of onset, family history). | Identify obesity-associated disorders (current complications and risk of future complications): metabolic, anatomic, degenerative, and/or neoplastic complications. |
| **C. Psychological** | Identify psychological etiology: psychotropic medications, depression, post-traumatic stress disorder, addictive behaviors. | Eating disorders: binge eating, bulimia |
| **D. Nutritional** | Evaluate obesity severity and extent of physical disability. | Assess risk for potential barriers to treatments: psychiatric history-suicidal ideation, untreated psychological disorders. |

**Early Postoperative Diet**

The diet after bariatric surgery is based upon a staged approach with emphasis on nutritional needs at each stage of healing and weight loss. Additionally, consideration is given to the texture and volume of food that patients can tolerate.11 A large variation in food tolerances is seen, and patients who have undergone bariatric surgery benefit from well-planned dietary advancement, both to ensure proper healing of the surgery and to develop lifelong healthy eating habits.11,12

The early diet stages begin with liquids for up to two weeks after the operation.14 Early hydration and consumption of protein to meet metabolic demands are essential, even in these early postoperative days. Following a liquid diet can also help to avoid irritation to the surgical sites.
Once the patient is able to comfortably advance the texture of their diet to soft solid foods, these are introduced into the diet, with a continued emphasis on protein sources. Gradually, as the gastrointestinal tract heals, patients are able to tolerate more solid textures of foods. Throughout all of the diet stages, it is key to reinforce the importance of adequate fluid intake to prevent dehydration.11 (Table 2)

**Long-term Postoperative Diet**

By six months to a year after surgery, the majority of patients are able to tolerate most foods, and tend to eat three small meals per day, with or without the inclusion of planned snacks. Most patients require some reassurance of the ability of the pouch to tolerate a wide variety of foods with time.12

The early postoperative diet stages are based upon meeting essential nutrient needs and maintaining adequate hydration. However, as weight stabilizes, patients are encouraged to obtain the bulk of their energy needs from dietary sources.11 The macronutrient requirements of patients who have undergone a sleeve gastrectomy (SG) or a Roux-en-Y-gastric-bypass (RYGB) do not differ from those of the general population, although exact needs should be individually assessed.5,13

### Fluid Intake and Hydration

It is recommended that postoperative bariatric surgery patients consume at least 64 ounces of fluids daily.13 If a patient loses fluids due to vomiting, diarrhea, etc. additional fluids are warranted. Patients are encouraged to avoid fruit juices, sugar-sweetened beverages, and carbonated beverages postoperatively.15,16

Recommended fluids include nonfat milk, water, sugar-free/caffeine-free/non-carbonated beverages. For patients consuming caffeinated beverages, it is recommended to limit intake to 2-3 cups of caffeinated beverages daily. Patients are encouraged to sip liquids slowly between meals.12,17 In the early diet stages, patients are instructed to sip 8 ounces over 30 to 60 minutes and stop drinking 30 minutes before next meal.

Patients should also be educated on the warning signs of dehydration (concentrated urine, lightheadedness, constipation, dry mouth, nausea, thirst). They should also be educated that dehydration can increase their risk for kidney stones and low blood pressure, as well as constipation.

### Food Aversions/Intolerances

Food intolerances are observed less frequently post-SG versus RYGB; however, postoperative food intolerances and/or food aversions vary widely amongst patients.3,16 For any reported food intolerances it is important to check for the following: chewing food thoroughly, eating slowly, not drinking with meals or too close to meals. Some patients will need to progress the texture of their diet more gradually following bariatric surgery.

### Nausea/Vomiting

Nausea and/or vomiting can usually be attributed to a patient not chewing food well enough before swallowing, eating too rapidly or too much volume at a meal, drinking fluids with meals or drinking too close to meal times, or moving through the diet progression too rapidly.3 A patient with persistent nausea, vomiting, and abdominal pain could have a blockage or stricture of the stoma. For patients complaining of diarrhea, it is important to assess the fat content of the diet to identify potential for complications leading to limited tolerance of foods.15 Diarrhea could also be an indication of lactose intolerance postoperatively.

### Protein Intake

The standard recommendation for protein intake following RYGB and SG surgery is a minimum 60 grams daily. With duodenal switch surgery, 70-80 grams daily is recommended. Protein intake should be divided and ingested throughout the day. Total protein intake can be calculated using the formula: weight (kg) x (1.2 if BMI > 40 or 0.5 if BMI < 40).

<table>
<thead>
<tr>
<th>Diet Type</th>
<th>Description of Foods</th>
<th>Number of Meals</th>
<th>Length of Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Bariatric</td>
<td>Diluted fruit juice, regular Gatorade™ or regular Powerade™</td>
<td>Sips throughout the day</td>
<td>1 week</td>
</tr>
<tr>
<td>Clear Liquids</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pureed</td>
<td>Foods consisting of a smooth paste or thick liquid with no distinct pieces. Foods and liquids must be low in fat and sugar.</td>
<td>3 to 6 meals per day*</td>
<td>3 to 4 weeks</td>
</tr>
<tr>
<td>Mechanical-soft</td>
<td>Foods consisting of very small, tender, moist, easily-chewed pieces. Meat must be ground, fish flaked and other foods must be chopped and mashed. Foods and liquids must be low in fat and sugar.</td>
<td>3 to 5 meals per day*</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Soft</td>
<td>Foods consisting of very small, tender, moist, easily-chewed pieces. Foods must be chopped or diced. Foods and liquids must be low in fat and sugar.</td>
<td>3 to 4 meals per day*</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Regular</td>
<td>Foods of any consistence may be tried carefully. Continue to choose foods and liquids low in fat and sugar.</td>
<td>3 meals per day*</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

*Surgeon and/or dietitian may provide further direction about the number of meals per day patient may have.
surgery protein malabsorption is more of a concern and a higher protein intake is needed, the target being 80 grams daily in these patients. Nutritionally compromised patients may require 80 to 100 grams of protein daily (patients with revisional surgeries, wound complications, etc.). Due to the restricted pouch size, potential intolerances to foods such as meat and dairy, it is not uncommon for protein intake to be inadequate. Patients will often require suggestions on alternative protein sources. In many cases, protein supplements may be warranted. Patients are encouraged to choose supplements that are generally low in sugar and high in protein. Prealbumin levels are routinely ordered at 6 months and 12 months after bariatric surgery to monitor adequacy of protein intakes.3,5

The recommendations for vitamin and mineral supplementation following a RYGB or sleeve gastrectomy procedure are provided in Table 3.12,18

Patient Education

Educating patients on healthy eating for bariatric surgery eating has two perspectives: what to eat and how to eat. Eating patterns are of equal importance as a patient’s food choices in the bariatric surgery patient.3,10,20 Nutrition education provided to bariatric surgery patients must cover both of these aspects of a patient’s long term eating behaviors to ensure the highest likelihood of weight management success.

The dietitian’s role on the bariatric team is to help the patient understand how their eating habits might differ after surgery and to ease them through the adjustment by providing a source of accountability for the patient as well as being a primary support system to help then navigate through the postoperative diet progression of liquids, to soft solids foods, and eventually back to a maintenance diet.

Conclusion

Eating habits, micronutrient deficiencies, and nutritional management of patients undergoing bariatric surgery should be monitored consistently throughout their pre and postoperative course. Deficiencies of micronutrients following bariatric surgery can arise from several factors including preoperative deficiency, reduced dietary intake following bariatric surgery, malabsorption, as well as inadequate supplementation.3,19

Learning how to choose healthy foods, avoid skipping meals, and prepare meals and snacks on a daily basis are part of the new skill set patients must learn. Many patients will need continued reminders that the surgery has changed their body but not their environment. Frequent education, social support, and individual counseling with a registered dietitian are essential for bariatric surgery patients.1,2,5

References

Table 3. Supplementation after Roux-en-Y gastric bypass and gastric sleeve procedures

<table>
<thead>
<tr>
<th>Supplement</th>
<th>Dosage*</th>
<th>Representative preparations</th>
<th>Monitoring †</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multivitamin with minerals and iron, one or two per day, each chewable tablet (or liquid equivalent) minimally containing</strong>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>500 mcg (1600 units)</td>
<td>Multivitamins with minerals (including iron): Representative trade names (US) include: Centrum® (NOT Centrum Silver®) as mineral content is too low, Centrum Performance®, One-A-Day Maximum®, Complete Multivitamin for Adults</td>
<td>Thiamine (optional) Erythrocyte transketolase activity (optional)</td>
<td>Thiamine deficiency has been associated with intractable vomiting following bariatric surgery and Wernicke encephalopathy has been reported. See text.</td>
</tr>
<tr>
<td>Vitamin B1 (thiamine)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin E</td>
<td>10 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin K</td>
<td>Male: 120 mcg; Female: 90 mcg</td>
<td></td>
<td>Prothrombin Time/INR (optional as a measure of vitamin K status)</td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td>10 mg elemental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Folic acid</td>
<td>400 mcg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biotin</td>
<td>30 mcg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selenium</td>
<td>55 mcg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zinc</td>
<td>Male: 11 mg; Female: 8 mg</td>
<td></td>
<td></td>
<td>Sinc deficiency may be associated with chronic diarrhea</td>
</tr>
<tr>
<td>Copper</td>
<td>2 mg</td>
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<tr>
<td><strong>Calcium and vitamin D</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Calcium citrate</td>
<td>1200 to 1500 mg (elemental calcium) per day preferably in two equally divided doses</td>
<td>Tablets, capsules: 180, 200, 250 mg Effervescent tablet: 500 mg Oral suspension: 760 mg per 5 ml</td>
<td>25-Hydroxyvitamin D</td>
<td>Calcium citrate preparations may be better absorbed than calcium carbonate under conditions of reduced gastric acidity but require consumption of more tablets. Do not take within two hours of iron supplement.</td>
</tr>
<tr>
<td>Vitamin D3 (cholecaliferol)</td>
<td>800 units per day</td>
<td>Tablets, capsules: 400, 1000, 2000 units Chewable tablet: 400 units Oral drops: 400 units per drop</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Iron and ascorbic acid</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Ferrous fumarate</td>
<td>40 to 65 mg (elemental iron) per day for premenopausal women 18 to 27 mg (elemental iron) per day for others May be included in multivitamin</td>
<td>Combination (eg, Vitron-C®) ferrous fumarate (65 mg elemental) with ascorbic acid (125 mg); ferrous sulfate oral liquid: 44 or 60 mg elemental per 5 mL; ascorbic acid liquid: 100 mg/mL.</td>
<td>Iron studies, ferretin. CBC</td>
<td>Iron supplementation is based on monitoring. Iron is contained in the multivitamin-mineral tablet and additional supplementation is not recommended unless the patient has documented iron deficiency. If additional supplementation indicated, 100 to 150 mg ascorbic acid enhances iron absorption under conditions of reduced gastric acidity. Do not take within two hours of calcium supplement.</td>
</tr>
<tr>
<td>Ferrous gluconate</td>
<td></td>
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<td></td>
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<tr>
<td>Ferrous sulfate</td>
<td></td>
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<tr>
<td><strong>Vitamin B12 (cyanocobalamin)</strong></td>
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</tr>
<tr>
<td>Oral tablet</td>
<td>500 to 1000 mcg per day</td>
<td>Tablet: 250, 500, 1000 mg</td>
<td>CBC, Vitamin B12 (methylmalonic acid, homocysteine optional)</td>
<td>B12 deficiency is a frequent complication within one year of RYGB surgery in absence of adequate supplementation</td>
</tr>
<tr>
<td>Sublingual or buccal tablet</td>
<td>500 to 1000 mcg per day</td>
<td>Sublingual tablet or lozenge 500 mcg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sublingual spray</td>
<td>400 mcg per day</td>
<td>200 mcg per spray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intranasal spray</td>
<td>500 mcg once per week</td>
<td>500 mcg per 0.1 mL intranasal spray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intramuscular injection</td>
<td>1000 mcg IM once per month or 3000 mcg IM once every six months</td>
<td>1000 mcg/mL injection</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients with deficiency state will need treatment beyond these recommendations.

*IM: intramuscularly; TIBC: total iron binding capacity; RYGB: Roux-en-Y gastric bypass; PTH: parathyroid hormone; CEC: complete blood count; RBC: red blood cell.
* Maintenance dosage for adult, oral administration, unless specified otherwise.
† Routine lab monitoring at baseline and every three to six months during first year, then annually thereafter. See text for additional information.
‡ Multivitamin should provide US Food and Drug Administration daily recommended intake for other vitamins and minerals. Iron containing multivitamin preparations that do not contain calcium may be preferred. Calcium should be administered as a separate preparation at least two hours before or after multivitamin with iron supplements to increase absorption.

Adapted from:
For adult patients with moderately to severely active UC or CD

Entyvio®
vedolizumab

FASTEST GROWING BIOLOGIC ACROSS UC & CD

*Based on an analysis of all products available in SHA database comparing patient counts from Jan-Dec 2015 to Jan-Dec 2016.

INDICATIONS
Adult Ulcerative Colitis (UC)
ENTRYVIO (vedolizumab) is indicated in adult patients with moderately to severely active UC who have had an inadequate response to, or were intolerant to, a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids for inducing and maintaining clinical response, inducing and maintaining clinical remission, improving endoscopic appearance of the mucosa, and achieving corticosteroid-free remission.

Adult Crohn's Disease (CD)
ENTRYVIO (vedolizumab) is indicated in adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids for achieving clinical response, achieving clinical remission, and achieving corticosteroid-free remission.

IMPORTANT SAFETY INFORMATION
• ENTRYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTRYVIO or any of its excipients.
• Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTRYVIO immediately and initiate appropriate treatment.
• Patients treated with ENTRYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTRYVIO, including abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTRYVIO is
• Provides remission at 52 weeks for patients with moderately to severely active ulcerative colitis (UC) or Crohn’s disease (CD)2
  - Studied in patients who have failed conventional therapies or a biologic
  - Individual results may vary

• Clinical trials evaluated safety in more than 3300 adults on Entyvio2
  - Including more than 800 patients who received Entyvio for more than 2 years

• A distinct mechanism of action that specifically blocks lymphocyte migration, a key contributor to inflammation in the gut2

• Entyvio specifically binds to α4β7 integrin, blocking its interaction with MAdCAM-1, which is mainly expressed on gut endothelial cells2

• 300-mg dose for adult patients2

IMPORTANT SAFETY INFORMATION (continued)
not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.

• Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist: if confirmed, discontinue ENTYVIO dosing permanently.

• There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.

• Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines.

Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.

• Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please see brief summary of Prescribing Information on adjacent pages.


To learn more, visit EntyvioHCP.com
brief summary of full prescribing information

ENTYVO (vedolizumab) for injection, for intravenous use

Indications and Usage
Adult Ulcerative Colitis (UC)
ENTYVO (vedolizumab) is indicated for:
- inducing and maintaining clinical response,
- inducing and maintaining remission,
- improving the endoscopic appearance of the mucosa, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Adult Crohn’s Disease (CD)
ENTYVO (vedolizumab) is indicated for:
- achieving clinical response,
- achieving clinical remission, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Contraindications
ENTYVO is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVO or any of its excipients (such as dyes, bronchospasm, urticaria, flushing, rash and increased heart rate) [see warnings and precautions and adverse reactions].

Warnings and Precautions
Infusion-Related Reactions and Hypersensitivity Reactions
In UC Trials I and II and CD Trials I and III, hypersensitivity reactions occurred including a case of anaphylaxis (one out of 1434 patients [0.07%]) [see adverse reactions]. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. The majority were mild to moderate in severity as assessed by the investigator. Experience with other biologic medications suggests that hypersensitivity reactions and anaphylaxis to ENTYVO may vary in their time of onset from during infusion or immediately post-infusion to occurring up to several hours post-infusion.

If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVO immediately and initiate appropriate treatment (e.g., epinephrine and antihistamines).

Infections
Patients treated with ENTYVO are at increased risk for developing infections [see adverse reactions]. The most commonly reported infections in clinical trials occurring at a rate greater on ENTYVO than placebo involved the upper respiratory and nasal mucosa (e.g., nasopharyngitis, upper respiratory tract infection). Serious infections have also been reported in patients treated with ENTYVO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis and cytomegaloviral colitis.

ENTYVO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding treatment in patients who develop a severe infection while on treatment with ENTYVO. Exercise caution when considering the use of ENTYVO in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice. For progressive multifocal leukoencephalopathy (PML) [see Warnings and Precautions].

Progressive Multifocal Leukoencephalopathy
Another integrin receptor antagonist has been associated with progressive multifocal leukoencephalopathy (PML), a rare and often fatal opportunistic infection of the central nervous system (CNS). PML is caused by the John Cunningham (JC) virus and typically only occurs in patients who are immunocompromised.

In ENTYVO clinical trials, patients were actively monitored for PML with frequent and regular screenings, and evaluations of any new, unexplained neurological symptoms, as necessary. While zero cases of PML were identified among patients with at least 24 months of exposure, a risk of PML cannot be ruled out. No claims of comparative safety to other integrin receptor antagonists can be made based on this data.

Monitor patients on ENTYVO for any new onset, or worsening, of neurological signs and symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbances of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. The progression of deficits usually leads to death or severe disability over weeks or months. If PML is suspected, withhold dosing with ENTYVO and refer to a neurologist; if confirmed, discontinue dosing permanently.

Liver injury
There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVO. In general, the combination of transaminase elevations and elevated bilirubin without evidence of obstruction is generally recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. ENTYVO should be discontinued in patients with jaundice or other evidence of significant liver injury [see Adverse Reactions].

Live and Oral Vaccines
Prior to initiating treatment with ENTYVO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVO may receive non-live vaccines (e.g., influenza vaccine injection) and may receive live vaccines if the benefits outweigh the risks. There is no data on the secondary transmission of infection by live vaccines in patients receiving ENTYVO [see Adverse Reactions].

Adverse reactions
The following topics are also discussed in detail in the Warnings and Precautions section:
- Infusion-Related Reactions and Hypersensitivity Reactions [see Warnings and Precautions]
- Infections [see Warnings and Precautions]
- Progressive Multifocal Leukoencephalopathy [see Warnings and Precautions]
- Liver Injury [see Warnings and Precautions]

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 practice.

The data described below reflect exposure to ENTYVO in 3,326 patients and healthy volunteers in clinical trials, including 1,385 exposed for greater than one year, and 835 exposed for greater than two years.

The safety data described in Table 1 are derived from four controlled Phase 3 trials (UC Trials I and II, and CD Trials I and III); data from patients receiving open-label ENTYVO treatment at Weeks 0 and 2 (prior to entry into UC Trial II and CD Trial III) and from Weeks 6 to 52 (non-responders at Week 6 of UC Trial I and CD Trial I) are included.

In these trials, 1,434 patients received ENTYVO 300 mg for up to 52 weeks, and 297 patients received placebo for up to 52 weeks. Of these, 769 patients had ulcerative colitis and 962 patients had Crohn’s disease. Patients were exposed for a mean duration of 259 days (UC Trials I and II) and 247 days (CD Trials I and III).

Adverse reactions were reported in 52% of patients treated with ENTYVO and 45% of patients treated with placebo (UC Trials I and II: 49% with ENTYVO and 37% with placebo; CD Trials I and III: 55% with ENTYVO and 47% with placebo). Serious adverse reactions were reported in 7% of patients treated with ENTYVO compared to 4% of patients treated with placebo (UC Trials I and II: 8% with ENTYVO and 7% with placebo; CD Trials I and III: 12% with ENTYVO and 9%, with placebo).

The most common adverse reactions (reported by ≥3% of patients treated with ENTYVO in the UC Trials I and II and CD Trials I and III combined group and ≥1% higher than in combined placebo group) were nasopharyngitis, headache, arachnoiditis, nasalia, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain and pain in extremities (Table 1).
### Table 1. Adverse Reactions in ≥3% of ENTYVIO-treated Patients and ≥1% Higher than in Placebo (UC Trials I and II and CD Trials I and III*)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ENTYVIO† (N=1434)</th>
<th>Placebo‡ (N=297)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>13%</td>
<td>7%</td>
</tr>
<tr>
<td>Headache</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12%</td>
<td>10%</td>
</tr>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>8%</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>7%</td>
<td>6%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>6%</td>
<td>3%</td>
</tr>
<tr>
<td>Cough</td>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Influenza</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Back pain</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Rash</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Pain in extremities</td>
<td>3%</td>
<td>1%</td>
</tr>
</tbody>
</table>

*Data from patients receiving open-label ENTYVIO treatment at Weeks 0 and 2 (prior to entry into UC Trial II and CD Trial III) and from Weeks 6 to 52 (non-responders at Week 6 of UC Trial I and CD Trial I) are included.

†Patients who received ENTYVIO for up to 52 weeks.

‡Patients who received placebo for up to 52 weeks.

In controlled- and open-label long-term extension trials in adults treated with ENTYVIO, serious infections have been reported, including anal abscesses (some fatal), tuberculosis, salmonella sepsis, listeria meningitis, giardiasis and cytomegaloviral colitis.

In UC Trials I and II and CD Trials I and III, sepsis, including bacterial sepsis and septic shock, was reported in four of 1434 (0.3%) patients treated with ENTYVIO and in two of 297 patients treated with placebo (0.7%). During these trials, two Crohn’s disease patients treated with ENTYVIO and one died due to reported sepsis or septic shock; both of these patients had significant comorbidities and a complicated hospital course that contributed to the deaths. In an open label long-term extension trial, additional cases of sepsis (some fatal), including bacterial sepsis and septic shock, were reported. The rate of Serious Infections in patients with ulcerative colitis or Crohn’s disease receiving ENTYVIO was two per 1000 patient-years.

In clinical trials, all patients were screened for tuberculosis. One case of latent, pulmonary tuberculosis was diagnosed during the controlled trials with ENTYVIO. Additional cases of pulmonary tuberculosis were diagnosed during the open-label trial. All of these observed cases occurred outside the United States, and none of the patients had extrapulmonary manifestations.

**Liver Injury**

There have been reports of elevations of transaminases and/or bilirubin in patients receiving ENTYVIO [see Warnings and Precautions]. In UC Trials I and II and CD Trials I and III, three patients reported serious adverse reactions of hepatitis, manifested as elevated transaminases with or without elevated bilirubin and symptoms consistent with hepatitis (e.g., malaise, nausea, vomiting, abdominal pain, anorexia). These adverse reactions occurred following two to five ENTYVIO doses; however, based on case report information, it is unclear if the reactions indicated drug-induced hepatitis or the natural etiology. All patients recovered following discontinuation of therapy with some requiring corticosteroid treatment. In controlled trials, the incidence of ALT and AST elevations ≥3 x ULN was <2% in patients treated with ENTYVIO and in patients treated with placebo. In the open-label trial, one additional case of serious hepatitis was observed.

**Malignancies**

In UC Trials I and II and CD Trials I and III, malignancies (excluding dysplasia and basal cell carcinoma) were reported in six of 1434 (0.4%) patients treated with ENTYVIO, including colon cancer (n=2), transitional cell carcinoma (n=1), breast cancer (n=1), carcinoid tumor of the appendix (n=1) and squamous cell carcinoma (n=1). Malignancy was reported in one of 297 (0.3%) patients treated with placebo (squamous cell carcinoma).

Malignancies (excluding dysplasia and basal cell carcinoma) observed during the ongoing open-label long-term extension trial included B-cell lymphoma, breast cancer, colon cancer, malignant hepato neoplasm, malignant lung neoplasm, malignant melanoma, lung cancer of primary neuroendocrine carcinoma, renal cancer and squamous cell carcinoma. Overall, the number of malignancies in the clinical trials was small; however, long-term exposure was limited.

**Live and Oral Vaccines**

There are no data on the secondary transmission of infection by live vaccines in patients receiving ENTYVIO.

In a placebo-controlled study of healthy volunteers, 61 subjects were given a single ENTYVIO 750 mg dose (2.5 times the recommended dose), and 62 subjects received placebo followed by intramuscular vaccination with Hepatis B surface antigen and oral cholera vaccine. After intramuscular vaccination with three doses of recombinant Hepatitis B surface antigen, those treated with ENTYVIO did not have lower rates of protective immunity to Hepatitis B virus. However, those exposed to ENTYVIO did have lower seroconversion rates and anti-cholera titers relative to placebo after receiving the two doses of a killed, oral cholera vaccine. The impact on other oral vaccines and on nasal vaccines in patients is unknown.

**Immunogenicity**

As with all therapeutic proteins, there is potential for immunogenicity. In UC Trials I and II and CD Trials I and III, in patients who received ENTYVIO, the frequency of antibodies detected in patients was 13% at 24 weeks after the last dose of study drug (greater than five half-lives after last dose). During treatment, 56 of 1434 (4%) of patients treated with ENTYVIO had detectable anti-vedolizumab antibody at any time during the 52 weeks of continuous treatment. Nine of 56 patients were persistently positive (at two or more study visits) for anti-vedolizumab antibody and 33 of 56 patients developed neutralizing antibodies to vedolizumab. Among eight of these nine subjects who were persistently positive anti-vedolizumab antibody and available vedolizumab concentration data, six had undetectable and two had reduced vedolizumab concentrations. None of the nine subjects with persistently positive anti-vedolizumab antibody achieved clinical remission at Weeks 6 or 52 in the controlled trials.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody positivity) in an assay may be influenced...
by several factors, including sample handling, timing of sample collection, concomitant medications, presence of vedolizumab, and underlying disease. For these reasons, comparison of the incidence of antibodies to ENTYvio with the incidence of antibodies to other products may be misleading.

**DRUG INTERACTIONS**

**Natalizumab**
Because of the potential for increased risk of PML and other infections, avoid the concomitant use of ENTYvio with natalizumab.

**TNF Blockers**
Because of the potential for increased risk of infections, avoid the concomitant use of ENTYvio with TNF blockers.

**Live Vaccines**
Live vaccines may be administered concurrently with ENTYvio only if the benefits outweigh the risks [see Warnings and Precautions].

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

**Pregnancy Exposure Registry**
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ENTYvio during pregnancy. Information about the registry can be obtained by calling 1-877-TAKEDA (1-877-825-3327).

**Pregnancy Category B**

**Risk Summary**
There are no studies with ENTYvio in pregnant women. No fetal harm was observed in animal reproduction studies with intravenous administration of vedolizumab to rabbits and monkeys at dose levels 20 times the recommended human dosage. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the benefits to the mother outweigh the risk to the unborn child.

**Clinical Considerations**
Any adverse pregnancy effect from ENTYvio would likely be greater during the second and third trimesters of pregnancy. Monoclonal antibodies are transported across the placenta in a linear fashion as pregnancy progresses, with the largest amount transferred during the third trimester.

**Animal Data**
A reproduction study has been performed in pregnant rabbits at single intravenous doses up to 100 mg/kg administered on gestation Day 7 (about 20 times the recommended human dosage) and has revealed no evidence of impaired fertility or harm to the fetus due to vedolizumab. A pre- and post-natal development study in monkeys showed no evidence of any adverse effect on pre- and post-natal development at intravenous doses up to 100 mg/kg (about 20 times the recommended human dosage).

**Nursing Mothers**
It is unknown whether vedolizumab is present in human milk. Vedolizumab was detected in the milk of lactating monkeys. Exercise caution when administering vedolizumab to a nursing woman.

**Pediatric Use**
Safety and effectiveness of ENTYvio in pediatric patients have not been established.

**Geriatric Use**
Clinical trials of ENTYvio did not include sufficient numbers of subjects aged 65 and over (46 Crohn's and ulcerative colitis patients aged 65 and over were treated with ENTYvio during controlled Phase 3 trials) to determine whether they respond differently from younger subjects. However, no overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Distributed by:
Takeda Pharmaceuticals America, Inc.
Deerfield, IL 60015

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Issued: May 2014

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VM8245 R1_Brf   L-BZV-0514-7
Physicians are taught that patients present with a chief complaint. However, we know that is not always the case. Sometimes they present searching for information. They are often concerned about what that they don’t know. They present not with a list of complaints but a list of questions. As physicians, we are often forced to utter admissions such as “Well, that really is not my field” or “You will need to ask the specialist regarding that issue.” Over the course of my career specializing in the treatment Inflammatory Bowel Disease (IBD), whether it be Crohn’s disease or ulcerative colitis, there seems to be a pattern to the concerns and questions. Perhaps these will be familiar to you.

Question 1: What exactly is IBD and how did I get it?

Well, this certainly gets to the heart of the matter. Inflammatory bowel diseases are a group of heterogeneous disorders that result in chronic intestinal inflammation affecting the digestive tract. It exists within the spectrum of Immune Mediated Inflammatory Disorders. These disorders include psoriasis, rheumatoid arthritis, as well as Crohn’s Disease and ulcerative colitis. These illnesses all seem to share a common pathway of overproduction of protein mediators of inflammation yet with variable expressions. The etiology of IBD is still being unraveled; however, it is currently thought to arise as a result of a dysregulated immune response in genetically susceptible individuals to environmental triggers.

Question 2: How common is IBD?

The major forms of these disorders, ulcerative colitis (UC) and Crohn’s disease (CD), manifest both distinct and overlapping clinical and pathological characteristics. In North America, incidence rates range from 2.2 to 14.3 per 100,000 person-years for UC and 3.1 to 14.6 per 100,000 person-years for CD. As many as 200,000 Canadians, 1.4 million persons in the U.S. and 2.2 million Europeans suffer from these diseases.

Question 3: How likely is it that my child will get this illness?

Of course, the data regarding risk is available. However, the real subject is fear. Fear that the child will need to deal with this unrelenting foe for a lifetime. It is quite true that there is a genetic predilection to developing IBD.

Here are some numbers:

First-degree relatives of patients with IBD have approximately a 3 to 20-fold greater likelihood of developing the disease than the general population. Another way to look at it would as follows: there are between 5.2 and 22.5 percent of first degree relatives of an affected IBD patient who also had IBD.3,4

The siblings of patients with CD have an estimated relative risk of developing CD up to 35 times the background population risk and 4 for UC.6,7 Offspring where both parents have CD have even greater risk with approximately 36 percent likely to develop the disease. Ashkenazi Jews also have an increased risk of IBD.5,7 However, most significantly, twin studies have indicated that heritability is high in CD with concordance rates in monozygotic twins of 27–50 percent compared with 2–4 percent in dzyzgotic twins.8,9,10

Consistent with epidemiological predictions, over 70 IBD-associated genetic associations were identified in candidate gene, linkage, and genome-wide association studies (GWAS).11,12,13 More recent meta-analysis of CD and UC genome-wide association scans, followed by validation of significant findings using genotyping of independent case-control cohorts, identified further associations, increasing the number of IBD-associated risk loci to 201.13,14,15

These numbers will certainly make the head spin of anyone, let alone an epidemiologist. Perhaps the answer is as follows:

Assuming a patient will live to age 70, the lifetime risk of developing IBD for first degree relatives of a UC patient is between 1.6 and 5.2 percent and for CD it is between 4.8 and 7.8 percent.2

The art of medicine is not to merely relay this information. It is also to relay it in context. I try to assuage the understandable trepidation by adding how their child is more likely to have their good looks than their illness.
Question 4: Should I stop my medications?

Tough question. It depends upon the medication. Asacol HD coating has been associated with congenital abnormalities at very high doses in animal studies. However, mesalamine, balsalazide, olsalazine and sulfasalazine have not. If the patient is on Asacol HD, I recommend changing to another medication. Why roll the dice when alternatives are available? If you use sulfasalazine, don't forget to add daily folic acid.

Methotrexate (MTX) is contraindicated during conception and pregnancy. It is associated with congenital limb and craniofacial abnormalities. MTX is used to treat many rheumatologic and dermatologic conditions. However, its risk in pregnancy is a major concern. In essence, if a patient is fertile, MTX should be on the back burner for IMID patients.

The use of immunosuppressive agents such as azathioprine and 6-mercaptopurine have been commonplace in IBD for decades. There has always been some trepidation regarding the use of these agents in pregnancy. However, the late Dr. Dan Present of Mt Sinai hospital in NYC, who along with Dr Burton Korelitz were the fathers of immunotherapy in IBD, had an entire wall of patient photos who gave birth to healthy babies on azathioprine. These physicians were right. The latest studies confirm the safety and importance of these agents in patients who are in remission on steady state therapy.

There is a plethora of biologic agents that work by blocking the activity of tumor necrosis factor. These medications have revolutionized not merely our treatment but our approach to even thinking about IBD. Over 1,500 pregnancies have been reviewed in patients on one of these agents with benign findings regarding adverse events. Another study revealed there is no negative effect upon pregnancy outcomes nor congenital abnormalities, preterm delivery, and low birth weight.

However, it is not so simple. Certolizumab pegol is the only anti-TNF biologic that does not cross the placenta. It also has the lowest therapeutic gain when it comes to drug efficacy. However, the biologics that are dramatically more effective come with a caveat. There is significant transfer across the placental barrier in the later third of pregnancy. Yet, although there is exposure of the fetus to the agent, a large recent study revealed that this exposure did not affect infant growth rate, immune system development or rate of infections. Moreover, stopping the biologic agent prematurely may lead to antibody formation upon resumption of the medication months later. These antibodies may lead to intolerance of the drug or diminished drug efficacy.

In essence, if the patient is on an anti-TNF agent the drug should be continued. If the timing of the drug can be scheduled and manipulated so that the last dose prior to delivery is at the juncture between second and third trimester and resumed just after delivery, that would be optimum. This would limit exposure of the fetus to the biologic, yet decrease the likelihood of forming these nepharious antibodies.

Question 5: Can I breast feed while on my IBD meds?

To answer your patient, yes, you may! Aminosalicylates enter breast milk but have been shown to be safe. Moreover, thiopurines such as 6-mercaptopurine and azathioprine have negligible breast milk concentrations. These trace concentrations peak within four hours of taking the medication. The patient may want to breast feed after this four-hour window has passed to minimize exposure. Anti-tnf alpha agents are in negligible concentrations in breast milk.

What’s Next?

The next five questions will be addressed in the Autumn Northeast Florida Medicine journal. However, the true issue is the chasm between gastroenterologists and our colleagues in obstetrics and internal medicine/family practice. It is my fervent hope that this article will begin to fill in that crevasse. Hopefully, these pages will allow us to get on the same page by learning from each other. ♦
References:


The inaugural Duval County Medical Society (DCMS) & DCMS Foundation Future of Healthcare Conference wrapped up on May 23 but, as Conference Chair Dr. Sunil Joshi pointed out, this is not the end; it’s just the beginning.

The conference spanned two days and covered many important topics including food deserts, obesity, cardiovascular disease, mental health, infant mortality, and healthcare disparities. Guest speakers included member and non-member physicians, elected officials, and even a former professional athlete. The conference was hosted at University of North Florida’s University Center with more than 200 Jacksonville medical professionals and community members in attendance.

To conclude the Conference, Dr. Joshi announced that next steps will focus on dealing with the area’s food deserts. A committee is already in the process of being formed to develop public policy to improve the issue.

“I want people who come [to the conference] -who love it and love the people here- to understand that they can make a difference,” Dr. Joshi said. “It’s not somebody else’s problem. It’s our problem.”

The DCMS has a long-standing tradition with the American Medical Association (AMA) which includes an annual visit to Duval County by the AMA President-elect. This year, the DCMS combined this important and educational visit with the Future of Healthcare Conference. AMA President-elect David J. Barbe opened the conference with a keynote address concerning national issues such as healthcare reform, Medicaid funding, and the AMA’s opposition to the recently-passed American Health Care Act of 2017.

Additionally, Barbe praised the Future of Healthcare Conference, saying that he “has not attending anything like it” and commended DCMS leaders for bringing together the entire community to improve healthcare.

The goal of the conference was not to just identify problems, but to bring together a variety of perspectives to develop solutions, and ultimately improve public health both locally and nationally. After all, there was a single common idea that every guest speaker seemed to emphasize: making a difference on the local level is vital to working towards grand-scale changes.

Jacksonville Mayor Lenny Curry kicked off day two of the conference by sharing information on his Journey to One mission, a citywide campaign to improve health and ultimately become the healthiest county in the state. Through Journey to One, Curry hopes to promote and improve a variety of health factors in Jacksonville including nutrition, exercise, walkability, disease prevention and weight management.

The goal to become the number one healthiest county stems from the Robert Wood Johnson Foundation’s County Health Rankings. Kitty Jerome, the Director of Coaching and Outreach for the Action Center at County Health Rankings & Roadmaps, reminded attendees that Duval County is currently ranked 55th in health outcomes out of Florida’s 67 counties. This is especially concerning given that Jacksonville is home to some of the nation’s most renowned healthcare facilities, a sentiment that Jacksonville City Council President Lori Boyer also shared in her talk. However, Jacksonville’s size allows there to be a significant divide between its residents in terms of health.

“If the south side of Jacksonville was the entire city, in terms of quality of life, Jacksonville would be one of the most
desirable places to live in this country,” Dr. Joshi said. “But we need to take care of those parts of Jacksonville that have not been taken care of.”

The consensus to focus on food deserts addresses this issue, since food deserts are characteristically located in low-income areas where the overall health of residents is lower than average.

Florida Deputy Secretary for Health Dr. Kelli Wells delved even further into the food desert crisis, pointing out Jacksonville’s Health Zone 1 (considered the urban core) as not just a food desert, but a “food swamp”- meaning that fast food with very little nutritional value makes up the majority of available food in the area. In Jacksonville, food deserts are mostly found near the 295 beltway, according to speaker Luke Layow, President and CEO of Feeding Northeast Florida. The organization works to establish food security across eight counties in Northeast Florida including Duval. Layow, whose talk focused primarily on food deserts, addressed “food insecurity,” or the uncertainty associated with having limited access to food. He explained the rate of food insecurity in Duval County is at 20 percent, which is five percent above the state average. However, it doesn’t have to be that way.

“Hunger is not a supply issue,” he said. “It’s a logistics issue.”

Layow noted that Feeding Northeast Florida helps those in need have access to fresh and nutritious food that would otherwise be thrown out by grocers. Food pantries typically would not take perishable food, due to a lack of coolers or freezers to store them. However, the organization has created satellite food distribution centers across Northeast Florida that are equipped with coolers and freezers to handle perishable food donations. 57 percent of those served by the organization are families working full or part time, and nearly 30 percent are children, according to Layow.

In fact, several speakers noted the detrimental effect of food deserts on children and families. Dr. Wells identified links between areas with high infant mortality rates and areas in or around food deserts, calling infant mortality rates “a key measure of population health.” Faye Johnson, CEO of Northeast Florida’s Healthy Start Coalition, examined the way infant mortality is affected by healthcare disparities in low-income pregnant women. In addition to health, economic and social factors, babies of low-income mothers are often impacted by “toxic stress” during pregnancy.

Johnson, in her presentation, defined toxic stress as “stress caused by extreme poverty, neglect, abuse, exposure to violence, or severe depression” which hinders a developing brain. In worst case scenarios, the child will suffer long-term mental and physical health disadvantages that only perpetuate the cycle of health disparities throughout generations. However, the Northeast Florida Healthy Start Coalition’s Magnolia Project aims to reduce these disparities by providing screenings, pre- and postnatal care, and education to low-income women in Health Zone 1. In addition, initiatives like Yoga in the Street have been shown to improve mood and reduce blood pressure in women who participate, helping to combat toxic stress.

Many speakers also shed light on mental health as a whole. Audrey Moran, Senior Vice President for Social Responsibility
and Community Advocacy at Baptist Health, explained how Duval County’s severe shortage of psychiatric resources has made it difficult for mentally ill individuals to be treated.

She also shared her own son’s success story of overcoming depression through treatment at Wolfson Children’s Hospital. He gave her permission to share his story because he insisted that mental illness isn’t talked about enough. Moran’s son is now a senior psychology major at the University of North Florida, and aims to become a child psychologist.

Kitty Jerome also discussed mental health, which is one of the factors that weighs into the annual county health rankings. She noted stigma towards mental illness in the general public also discourages people to seek treatment.

“One thing is raising the issue and talking about it,” Jerome said. “Being sure that families know that they can open up conversations with kids about mental healthcare.”

Finally, obesity may have been the most heavily discussed topic throughout the conference. According to the County Health Rankings, 31 percent of adults in Duval County have a body mass index of 30 or more. The state average is 26 percent. The DCMS and City of Jacksonville are working to improve this statistic through 904 Mission One Million presented by 904THIN, a weight loss movement co-chaired by Mayor Curry and Dr. Joshi. The initiative was represented at the conference with a table providing guests an opportunity to sign up for the challenge and declare their personal goals. Since its launch in 2016, 904 Mission One Million participants have lost more than 75,000 pounds.

CEO Susan Neely of the American Beverage Association promoted the organization’s Balance Calories Initiative, which focuses on reducing calories within popular beverage companies, including PepsiCo., Coca Cola, and Dr. Pepper Snapple Group. The goal is to reduce beverage calories from sugar consumed per person by 20 percent by the year 2025. Neely called the Balance Calories Initiative the “single largest voluntary effort to reduce childhood obesity,” providing nearly 18,000 jobs and garnering $116.7M in charitable donations.

Many community organizations play a role in improving community health and combatting obesity. Dr. Matt Longjohn, Vice President and National Health Officer of YMCA of the USA, explained that the YMCA has influenced over 15,000 changes nationwide to increase healthy eating and physical activity in early childhood and afterschool programs. Currently, 58 percent of YMCAs are located in areas where household income is below the national average, and their diabetes prevention program has been covered by Medicaid for beneficiaries with prediabetes, making their resources more inclusive to those who otherwise may struggle to access them.

Luckily, in addition to voluntary and community efforts like the Balance Calories Initiative and the YMCA’s diabetes prevention program, state government plans are underway to address the issues discussed throughout the conference. Florida Surgeon General Dr. Celeste Philip listed healthy weight, public safety, maternal and child health, and behavioral health as just a few of the current priorities of the State Health Improvement Plan (SHIP) for the period of 2017-2021. Now, the goal is to strategize on a local level.
“The government can’t do everything,” Dr. Joshi said. “The people have to start doing some things, and then the government will follow suit. I know it’s a naive, ‘I think everything’s gonna work’ attitude, but you’ve got to have that attitude to make things happen.”

Dr. Jeffrey Mechanick, President of the American College of Endocrinology, also insisted on a “community to government” approach. He cited his perspective as being inspired by a healthcare committee in Yakama, Washington that centered itself around functions, activity, structure, charity and dialogue, and encouraged people to participate through schools, workplaces, and places of worship.

Additionally, 2017 Duval County Medical Society President Dr. Tra’Chella Johnson-Foy said events like the Future of Healthcare Conference are another effective way to take action, as it gives stakeholders information to share with others in their fields.

“We want it to not stop here,” she said. “We want to be able to truly move beyond what’s going on in this room today and actually make some things happen, so that there can be some true outcomes from what we’re doing.”

Fortunately, in this day and age, communicating between stakeholders, providers, and healthcare representatives is easier than ever. Florida Senator Aaron P. Bean explained in depth how technology such as telehealth has aided the delivery process of information among both professionals and the general public.

In addition to the many engaging guest speakers, an exhibition hall showcased 20 locally and nationally-run organizations throughout the event. From Colonial Life, to Baptist Health, and We Care Jacksonville, the exhibition hall included a mix of for-profit and not-profit sponsors.

The DCMS also hosted a poster competition on opening night giving local residents and fellows an opportunity to showcase their research. Dr. Julio Perez-Downes of UF Health came in first place with his study on patient mortality with severely elevated NT-proBNP levels.

Director of the Public Policy Institute at Jacksonville University Rick Mullaney was the final speaker, and outlined the “pathway forward” with a seven-point public policy plan encouraging guests to take initiative with the problems discussed throughout the conference. He pointed out the diagnosing a problem is an early step, but to make a difference attendees will also have to develop a strategy, formalize a public policy and work to get it adopted.

According to Florida Medical Association President Dr. David Becker, these kinds of conferences are the first step to taking that initiative.

“To bring all these entities together to intercommunicate so that we can figure out how best to approach the problems, I think is the starting point of getting it going,” Dr. Becker said.

There are already suggestions on the table such as offering incentives to companies for bringing fresh food options to Health Zone 1. Dr. Joshi, in his concluding speech, offered the possibility of using already existing, city-provided infrastructure to create markets where there are currently food deserts. Additionally, he mentioned that this could benefit both economic development and public safety if the companies providing the food were to hire from zip codes with high rates of unemployed residents.

Overall, the 2017 Future of Healthcare Conference not only brought many great minds together, but paved the way for public policy and change in Duval County.

“An educated society tends to be a healthier society,” said Dr. Johnson Foy. “Once you are really, truly educating people on what those issues are, and are able to think about solutions, it creates an opportunity for the whole society to be healthier.”

The second annual Future of Healthcare Conference will be held May 21-22, 2018.
Is there anything better than hearing your child speak enthusiastically? Max called from Gainesville the other day. As a second-year medical student, he will soon be given a license. It is a license to break down barriers. He will soon be allowed to ask the most intimate questions and probe the most private places. His license will allow him to insert himself into bizarre family dynamics. James Bond had a license to kill. Max will be given a license to save. It will be quite a life. So, when he breathlessly told me about his first I.V., I loved it. With that simple insertion of a venous catheter into the knuckle of an O.R. patient came an epiphany. He has permission to do seemingly unimaginable things to fulfill The Oath of Maimonides: to save a life is akin to saving the Universe. Pretty cool license if you ask me. No wonder he was so exuberant. The breaking of the skin for that first I.V. is just the beginning, but what a beginning it is. I may not remember everything that I have done in medicine, but I do remember that first flash of blood.

I was a second-year student at the Sackler School of Medicine in Tel Aviv, Israel. There was a metal rack of test tubes set up at the nurse’s station.

“Take one,” came the command. And so, I did. I took the random tube and matched the name to the room on the board. And off I went. I entered the room of a man who I thought was dead. Gaunt and pale. Shallow breaths. Sunken eyes. I checked the name band that dangled loosely from his thin wrist. He didn’t utter a sound. I wrapped the blue rubber hose as tightly as I could around his upper arm. I poked and prodded and stuck him. He never flinched. He never moaned. I never found his vein. I checked for a pulse. He was alive but this was most assuredly not living. Nevertheless, a lab was ordered. Blood was needed. I had the test tube in my pocket but I could not find a vein. I started to sweat like Nixon. Forehead. Upper lip. Arm pits. The sweat started to drip out of my latex gloves. I gave up. I stood up and apologized to the man who said nothing. I left the room. Now what do I do? I could not draw blood. I was a medical student, and this is how we graded each other and ourselves. How many chest tubes did you put in today? How many I.V.’s did you nail? How many people did you intubate? Medical students don’t rate themselves by cognitive accomplishments. Rather, we rated ourselves based upon the number of definable tasks that were completed. After years of being graded and tested on seemingly meaningless subjects and tasks, who knew that being a doctor has very little to do with asymptotes and vectors and cooling points? Who knew that parameters to enter medicine would in no way correlate with what a doctor really does? So, when confronted with the enormous task of perhaps obtaining a license to save, we took solace in being able to perform chores: like drawing blood. And yet, here I was. The empty test tube in my pocket felt like a grenade about to explode and ruin my whole career. I looked down the hallway. No one saw me as I ran down the back staircase. I was on the ground floor in a garden. I was about to toss the empty test tube into the garbage can. I would tell no one. When the lab was not available later that day I would say that it must have gotten lost. Maybe it was the transporter. Maybe it was the lab tech. Maybe it was anyone other than me. My hand was in the garbage can when I felt someone pull it out. I was all alone in the garden, but I felt someone grab my hand. I was in Israel, the Land of My Forefathers, and I felt them all. I apologized to them and ran back up the stairs. I was not going to be that kind of guy. I was not going to embarrass my heritage. Not here and not now. I ran up the stairs, and I found the chief of the department chatting with colleagues at the nurse’s station.

I took the test tube out of my pocket and with a strong hand and an outstretched arm, I put it right in front of his face and declared “Dr. Dolev, my name is Mark Fleisher, and I was unable to draw blood on this man.”

He gently replied that it was no big deal and to please take another test tube for another patient.

I wasn’t sure that he understood the enormity of this moment.

“Dr. Dolev,” I repeated, “I am Mark Fleisher, and I just wanted you to know that I was unable to accomplish this important task. You need to know without equivocation or obfuscation that I tried to draw blood on this man and was unable to do so. I am here to let you know that I failed at accomplishing my job.”

A grin turned in to a smile as Dr. Dolev put his hand on my shoulder. “I know who you are. Just put the tube back in the rack and try to draw blood on someone else.”

With that, I did. I could not believe that I was so close to taking the wrong path. I was repulsed that I had the capacity to be that kind of guy: duplicitous, deceitful and cunning. Thank goodness I felt that hand. We are given these choices all day long. What kind of person do we want to be? What kind of person will we be? That moment has stayed with me almost 30 years. I still remember when I received my diploma from Dr. Dolev. Who knew that he had been the Surgeon General of the State of Israel? Who knew that he was in charge of the medical team during the raid on Entebbe to free hundreds of hostages? All I knew was that he was my teacher and mentor, one of many hands that I feel every day. When he gave me my diploma two years later, he introduced me as “Dr. Mark Fleisher, who takes even drawing a test tube of blood VERY seriously.” And with that he gave me my diploma with a strong hand, an outstretched arm and a giant smile.

So, Max put in his first I.V. in some guy’s knuckle. Max was able to accomplish this task when his father could not. It is one of many ways in which my two sons have already surpassed me. There’s nothing better than that.

Want to contribute to the Creative Corner? Email your submission to kristy@dcmsonline.org

Creative Corner articles do not necessarily reflect the views of the Duval County Medical Society or DCMS Foundation.
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