



Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Bariatric procedure volume is down slightly but expected to remain flat for the next 12 months, though self-pay patients have declined, and doctors are holding their breath about what healthcare reform will mean for bariatric surgery. ♦ Laparoscopic bands are losing a little market share due to some disillusionment with the results and to the increased popularity of the gastric sleeve procedure. Johnson & Johnson's Realize is also taking share from Allergan's Lap-Band. ♦ All types of bariatric surgery resolve Type 2 diabetes in a large percentage of patients, and the benefit appears to precede weight loss, but the durability of the effect is still unknown. ♦ Bariatric surgeons are trying to make a case for bariatric surgery in all Type 2 diabetics, regardless of BMI – to offer the procedure to normal weight diabetics. So far, no insurance will cover this, but they are gathering data in an effort to get it covered. ♦ Interest in one-incision and endoscopic procedures is increasing, driven by patient demand, not superior clinical benefits.

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AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY (ASMBS)

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Last year the hot topic at ASMBS was the gastric sleeve procedure, and it is still gaining popularity mostly at the expense of laparoscopic gastric bands, but the key focus at this year's meeting was on centers of excellence, bariatric surgery to cure or prevent Type 2 diabetes and/or hypertension, and one-incision and no-incision (endoscopic) approaches.

The problem

Why do people gain weight and become obese? Randy Seeley, PharmD, of the University of Cincinnati pointed out that the average person consumes 912,500 calories a year. To gain one pound a year, a person only has to eat 4,050 extra calories a year, which is 11 calories a day (or one potato chip a day). Dr. Lee Kaplan of Massachusetts General Hospital said it has to do with a maladjustment in the body's energy "set point."

Seeley noted metabolic surgery alters ingestive, neuroendocrine, and metabolic function and leads to improvement, resolution, and/or prevention of a variety of metabolic disorders, including: obesity, hypertension, cardiovascular disease, lipid abnormalities, fatty liver disease, sleep apnea, inflammatory disease, neoplastic disorders, cognitive dysfunction, and more.

Why is gastric bypass surgery so effective? Dr. Kaplan said, "The old, classical model is that surgery works through mechanical mechanisms by restricting food intake and/or malabsorption. But we now know that surgery works through physiological methods: by altering the gastrointestinal signal to the brain (endocrine and neuronal signals)."

Procedure volume

Among the 20 bariatric surgeons questioned at ASMBS, procedure volume has dropped an average of 4% over the past year. Over the next 12 months, they predicted that procedure volume would remain flat, though many added a caveat that this depends on what happens with healthcare reform.

Procedures are currently almost evenly split between bypass and banding, with only 10% of procedures sleeve gastrectomy. Over the next year bypass procedures and banding are both expected to lose a little market share to sleeves.

Outlook for Bariatric Procedure Volume

Bariatric procedure	Now	In 1 Year
Gastric bypass	43%	40%
Laparoscopic bands	47%	45%
Sleeve gastrectomy	10%	15%

The surgeons most impacted by the recession have been those with a high percentage of self-pay patients, but even those with mostly or all insurance-paid patients are likely to feel the pinch in the near future as insurance companies make approvals more difficult or cut benefits.

Patient financing also has gotten harder. A source said, “These patients tend to be under-employed. It is a tough demographic. And the patients tend to have lower FICO scores. All financial institutions have tightened, and applicant credit has worsened.”

Jacqueline Sneve, vice president for strategic alliances at Surgical Review Corporation (SRC) – which does the Center of Excellence designations for ASMBS and keeps a database on bariatric surgeons – said, “As people lose their jobs, we expect less surgery, and we expect fewer self-pay patients. Someone who might have been willing to pay may not do it... Anecdotally, we are hearing that...it is a mixture... We expect that, because people are losing jobs, they will lose insurance. But we haven’t talked to anyone who has seen a dramatic effect yet (on procedure volume).”

Surgeon comments about the effect of the economy on their bariatric practice and about changes in types of procedures included:

- *Massachusetts*: “We’ve had growth despite the recession...In the people’s republic of Massachusetts...we don’t believe in cash pay for anything. Everything is insurance-driven. I have so few cash-pay patients that it is almost a rarity...and now that the state has guaranteed insurance for all...the (patient volume) numbers have been strong. We expected to have an effect from patients losing insurance as they are laid off, but I haven’t seen that. Our volume is flat to slightly up.”
- *Michigan*: “Only a handful of patients are cash-paying in our area. Most people have insurance or Medicare/Medicaid coverage...So, the economy hasn’t really affected me at all...but there are other policies and changes by insurance companies that have affected me. I really don’t know how the economy has affected my practice because there are too many other variables.”
- *Texas #1*: “The economy caused us to change things. Attendance at our seminars is down, but our city was not hit as hard as many others...We hope to apply to be a center of excellence by next year.”
- *Texas #2*: “We have been 100% bands, but we will start doing bypass and sleeves soon. I think we will remain mostly bands because people are not as scared of bands, and bands have had less bad press (than bypass).”

- *North Carolina*: “Our volume in June is double last month because of knowledge of insurance criteria. I expect our volume to continue to increase because this is a booming business. However, this month we did see some insurance go from a 10% copay to a 20% copay.”
- *Kentucky*: “We are up 20% this year because of some process changes we made and good insurance, but we expect the next 12 months to be flat.”
- *Ohio #1*: “Our volume is down about 10% from last year, and I expect it to go down another 10%. We mostly have insurance patients, so the economy hasn’t hurt us much.”
- *Ohio #2*: “My volume is down about 10% from last year. What happens over the next year depends on Congress and healthcare reform. Healthcare reform should be a positive, but it is such a daunting task that most doctors are extremely skeptical about what is being proposed. Most doctors recognize that a six-week Congressional discussion won’t result in the major overhaul the system needs.”
- *New York*: “Our volume is off about 20%. Healthcare reform will have an impact on what happens to our volume over the next year, and I don’t know if it (healthcare reform) will be a negative or a positive.”

Insurance

Insurance coverage of bariatric procedures had been improving until the recession hit. Now, insurance companies are getting more restrictive. SRC’s Sneve said, “Insurance was great until the economy tanked. I believe medical directors in many large, national insurance plans understand the value of bariatric surgery for specific populations. We’ve come a long way. It wasn’t that long ago that they didn’t want to discuss it at all. And they were discussing benefits. But now it stops at the financial piece. Their view is quarterly now...and the focus is on return on investment (ROI). When do they get the money back in terms of medical savings. And with bariatric surgery, the last study said 2-3.5 years...There seems to be a litmus test for this surgery but not for cardiology. ROI is really not applied to hip surgeries, back surgeries, knee surgeries, carotid surgeries, or transplants. So bariatric surgery as a surgery is viewed very differently than many other surgeries...They are not even doing quality of life year (QALY, quality-adjusted life year); it is just medical cost to medical savings – money saved on not paying for diabetic medications.”

While Medicare and most Medicaid pays for bariatric surgery, ~77% of all bariatric patients are covered by private insurance, not Medicare/Medicaid. Currently, no large health plan covers bariatric surgery in its *standard* benefit. Sneve said any patient who has coverage has it because the employer added a rider, paying extra to offer it as a benefit. She said insurance coverage is very regional, “For example, it is particularly hard for Floridians to get coverage for bariatric surgery...And the lack of coverage definitely prevents or hinders a patient’s ability to get the surgery...The Obesity Action Coalition can’t even get

a rider for it. They can't offer it to their employees because they can't get a rider. It is priced so high because they are in Florida, and they are a small company." A Texas doctor said, "All insurance companies cover bariatric surgery, but I can't offer it to my employees because it is so cost prohibitive... And some insurance companies are contracting to direct where patients go so they can send them to busy centers, which stalls the surgery." An Ohio doctor said, "Insurance companies are more and more making bariatric surgery an exclusion. Even trickier insurance companies say they will pay if the patient goes through a lot of hoops first. The trickiest ones approve the surgery, cover it, and then pay the hospital half to one-quarter of the cost of the surgery. And no insurance company covers the vitamin supplements, which can be a substantial cost for patients."

Why is there such a huge difference in reimbursement by Medicare and managed care? A North Carolina surgeon explained, "CMS (Centers for Medicare and Medicaid Services) is government-run. It pays less, but it covers bariatric surgery, though not in every state. Managed care has better coverage but doesn't understand the surgery completely. Dr. Scott Shikora of Tufts Medical Center, president of ASMBS, said, "Medicare reimburses hospitals well, but doctors very poorly, so many doctors limit Medicare patients or don't take them. And Medicare doesn't pre-approve patients, so the doctor doesn't know before he does the procedure if he is going to get paid...HMOs are unlikely to cost doctors money to take care of patients, but there is a lot of variability."

Insurance coverage of sleeves has been especially difficult, but the procedure will have a CPT code starting in January 2010, and experts predicted that this will help with coverage. Sneve said, "Most insurance companies (that cover bariatric surgery) cover bypass and the band. The sleeve is very debatable, and some cover it, and some don't. Some are not convinced the sleeve is standard of care. There is also a real preference by insurance companies for inpatient rather than outpatient procedures. They don't trust the outpatient setting. And Medicare doesn't pay for the outpatient setting." A Louisiana surgeon said, "It depends on whether universal healthcare includes this (bariatric surgery), or if it will be non-covered, and we will be discussing how to survive cash-pay only."

What is the insurance company attitude toward NOTES (natural orifice transluminal endoscopic surgery) procedures? Sneve said not many insurance companies limit NOTES, but, "if asked, minimally invasive is probably their preference, but I don't think there are many that restrict the choice."

Healthcare reform

Some surgeons were hesitant to make any predictions about the procedure volume outlook over the next 12 months because of the possibility of healthcare reform. And they just do not have a sense of whether healthcare reform will turn out to be a positive or a negative for bariatric surgery. Sneve said, "Bariatric surgery will either become part of healthcare reform and be a standard benefit, which could open the floodgates

(for procedures) for those who qualify. Or, it could be that healthcare reform doesn't include bariatric surgery, and at that point, the industry is really in trouble."

Cost-effectiveness

Dr. Matthew Hutter from Massachusetts General Hospital suggested it may be safety more than cost that will define the field of bariatric surgery going forward. He pointed out that bariatric surgery *is* cost-effective, using the usual threshold of \$50,000 per QALY saved. He said, "It is pretty convincing that this is a cost-effective procedure...A VA study found that the cost is offset within the first year. In another study, the cost is recouped in 3.5 years. More recent data on laparoscopic surgery found that all costs were recouped within 2 years...(The bottom line) is that bariatric surgery is cost saving in 1-5 years, and the cost-effectiveness is well below the \$50,000 QALY threshold."

But is that enough? Dr. Hutter said, "Payers and insurers still consider not covering bariatric surgery because of quality and safety. It isn't cost-effectiveness but quality and safety that are affecting insurance coverage...Thirty-day mortality was 1.9%-2.0%, but in more recent studies it was 0.9%...CMS had a non-coverage proposal in 2005...Thankfully, they reversed that, but only with an accreditation program. Why? Because of concerns for cost. The concern is the exponential risk in the short-term costs. Insurers are not faced with long-term costs, just the short-term expenses. People change insurance companies too frequently for them to recoup the costs."

Dr. Hutter pointed out that laparoscopic cholecystectomy almost went away because of bile duct injuries; there was almost a moratorium on it, and it took laparoscopic colectomy for cancer 8-12 years to overcome the trocar site recurrence safety signal, "We can show until we are blue in the face that these (bariatric) operations are cost-effective. We have to prove it with quality and safety...The cost-effective analysis of bariatric surgery is pretty compelling, but who cares? No one listens. We need to show: safety first, then quality, and then cost-effectiveness...This is a lesson we can learn from lap chole (laparoscopic cholecystectomy)."

Marketing

Currently, fewer than 5% of patients who qualify for bariatric surgery get it, an expert estimated. Surgeons and their administrative staff members at ASMBS were giving each other marketing advice. The key tip: build physician and patient referrals. Tarri Holt, program director for Clarion Bariatrics in Indianapolis, told surgeons, "Physician awareness is the key to increasing leads into the pipeline...Pound the pavement to primary care doctors."

The leading bariatric surgery device companies did not take an aggressive marketing approach at ASMBS. Rather, their focus was more low-key and aimed at helping doctors with practice management issues, support of the metabolic treatment advantages of bariatric surgery, etc.

Centers of Excellence

With CMS and many insurance companies only covering bariatric surgery performed at centers of excellence, more and more bariatric surgeons have earned this designation or are working on getting it. SRC's Sneve said, "At SCR, we support that bariatric surgery should only be done at centers of excellence because that is what we do. Humana, United-Healthcare, CIGNA, and soon Aetna all require a center of excellence. ASMBS and BSCO (Bariatric Surgery Centers of Excellence) require it as a part of their quality criteria.

Speakers at one ASMBS session described four different models for centers of excellence:

1. **Academic.** Dr. Shikora said that his hospital did one procedure a week before he got there in 1995, and now it does 10-14 a week, partly due to the growth of the field and to a combination of improving the public perception and acceptance, strategic use of the media, and outreach to other physicians for referrals. The challenge in an academic setting is bureaucracy and a cap on new hires.
2. **Hospital-employed physician.** Dr. Collin Brathwaite of Winthrop University Hospital in New York said the main way they obtain patients is word-of-mouth, but their volume has also grown significantly, driven by service, quality, and responsiveness to referring doctors. A key challenge for them has been access to operating room time.
3. **Rural model.** Dr. Wayne English of Marquette General Hospital in Michigan explained that even rural physicians can create a successful bariatric center of excellence.
4. **Metropolitan area model.** Dr. Robin Blackstone of Scottsdale AZ said her large volume private practice started bariatric surgery in 2001 with 2 surgeons under an exclusive contract with a local hospital. She said that she has been able to maintain volume despite the recession by identifying her center as a regional referral center and "getting people to realize (we) will take complicated patients."

A question for all these bariatric physicians, regardless of model, is what to do about patients who have bariatric surgery at another facility and then come to their facility/hospital with a problem. The consensus was that a center of excellence has an obligation to treat any of these patients who present. Dr. Shikora said ASMBS is likely to come out with an official position paper stating that it is the obligation of the bariatric physician to care for bariatric patients. Dr. Blackstone said, "We get calls from (outside the state), and we just decided that we were the referral center, so we would take them."

DIABETES AND BARIATRIC SURGERY

Bariatric surgery is becoming accepted, even standard, therapy for obese individuals with Type 2 diabetes. Dr. Philip Schauer of the Cleveland Clinic said, "We can now say bariatric surgery is standard of care for patients with Type 2 diabetes and severe obesity." However, there is an effort to prove that bariatric surgery is appropriate for people with normal body weight.

If bariatric surgery were shown to have a mortality benefit in patients with Type 2 diabetes and BMI 25-30, surgeons said that would be a big deal and would significantly increase the number of patients undergoing bariatric surgery – but only if insurance companies accept the data and reimburse the procedures.

Dr. Francisco Rubino of New York Presbyterian/Weill Cornell Medical College said that bariatric surgery should be called *metabolic surgery* instead when it is performed to control metabolic disease as opposed to body weight per se. He also argued that excess weight loss (EWL) should not be the only, nor even the primary, outcome of metabolic surgery, "Many patients don't achieve 50% EWL reduction, but they do achieve improvement in comorbidities (e.g., diabetes)...It is not a mechanical but a physiological mechanism. Energy intake is not the only target...I think we need to totally revise our criteria for surgery and put risk in there (not just weight). We should be offering a (surgery) option to more patients... My suggestion is that patients with BMI >30 and diabetes should be offered a reasonable period of intensive medical therapy. When they fail, there is no reason to insist on a strategy that will continue to leave the patient at risk of developing serious complications, spending a lot of money for medication, and potential complications. They should be offered *diabetes remission by surgical operation*."

He suggested that many common beliefs about bariatric (or metabolic) surgery are not really scientific facts, including:

- *Excess weight "causes" diabetes.* Epidemiologically there is a strong association between increased body mass index (BMI) and the risk of developing diabetes, but he said it is a "stretch" to consider this a cause-effect relationship, "I submit this is not (true)...that this is only a correlation, not a cause-effect relationship. If there were cause-effect, every obese patient should be diabetic, and we should not see diabetic non-obese patients."
- *There is no evidence that weight loss cures diabetes.* Alternatively, he suggested that diet, exercise, and surgery cause weight loss which improves diabetes.

Dr. Rubino said the number of hormones produced by the GI tract is huge, "If you just operate on the stomach vs. the small bowel, you change hormones differently...So, it is possible that, at least when we do operations that involve the duodenum, we may be doing something special." According to Dr.

Rubino, if weight loss per se improved diabetes, then the following should be true – but aren't:

- Diabetes improvement should follow weight loss.
- Weight loss from different types of interventions should result in similar improvement in diabetes, independent of the type of intervention. There is no evidence for that, he said, explaining, "Equivalent weight loss with diet and surgery do not produce the same improvement in diabetes ... A study comparing weight loss with diet and surgery found much better diabetes improvement with (gastric) bypass."

"It could be that with bypass operations we are doing something with the physiology which eventually results in weight loss and diabetes improvement," Dr. Rubino said, adding, "We thought weight loss led to improvement in diabetes, but we may be wrong."

Impact on cardiovascular risk

A prospective study in Asians found that Roux-en-Y bypass in Type 2 diabetics with BMI <35 (22-35) significantly reduced the risk of a stroke or a fatal cardiac event.

Impact of Roux-en-Y on Cardiovascular Risk of Type 2 Diabetics

Measurement	Baseline	9 months	p-value
Fasting blood glucose	233	89	---
HbA1c	10.1	6.1	---
Discontinuation of medication	---	80% at 1 month 100% at 3 months	---
Hypertension resolved	---	67%	---
Dyslipidemia resolved	---	100%	---
10-year predicted cardiovascular disease (CVD) risk for:			
Fatal or non-fatal cardiac event	14.9%	4.7%	0.001
Fatal cardiac event	9.8%	2.5%	0.004
Stroke	3.7%	2.5%	0.03

Durability of the impact on diabetes

Data on the durability of the resolution of Type 2 diabetes following gastric bypass has been limited, but Dr. Silas Chikinguwo of Virginia Commonwealth University presented data at ASMBS from a 172-patient study with five-year follow-up. His study found that 89% of patients who had Roux-en-Y surgery had early resolution of their diabetes, but

Long-Term Diabetes Control with Gastric Bypass

Measurement	Result	Change in BMI	Mean EWL
Complete resolution of Type 2 diabetes	89.0%	Down 18.9	70.0
No resolution of Type 2 diabetes	11.0%	N/A	58.2
Recurrence of Type 2 diabetes in patients with initial resolution	43.1%	Down 11.1	Nadir 66.0 decreased to 48.9
Durable resolution of Type 2 diabetes	56.9%	N/A	Nadir 73.0 decreased to 57.8

it recurred in 43.1%. He said, "Recurrence was associated with weight gain (regain of lost weight), but it is not clear which occurred first – the diabetes or the weight gain." Diabetes resolution was higher in females than males (90.3% vs. 82.1%, $p < 0.05$), but it was more durable in females, and it was more durable in younger patients than older patients."

Discussing these findings, another expert commented, "(In our patients) with a BMI of 30-35, we had some (diabetes) recurrences but without any weight regain yet...It was before the first year. The patients simply restarted eating normally, so it seems from our data that the relapse is secondary more to recovery of eating habits, eating capacity, than weight gain."

Data from a 5-year study of the effect of laparoscopic banding on Type 2 diabetes were presented by Samuel Sultan of New York University. Sultan and colleagues looked at 87 morbidly obese patients from 2002 to 2004 who had a band, and they found a substantial (80%) improvement/resolution of the diabetes, and sustained improvement in diabetes, with a significant reduction in HbA1c, and these results were sustained over time. He also reported that there was no statistically significant relationship between how long a patient had had diabetes and successful remission with banding, though shorter the duration of diabetes had numerically higher rates of remission.

5-Year Diabetes Control with Lap-Band

Measurement	Result	
Change in BMI	Down 10.7	
EWL	47.3%	
Effect on diabetes		
	Remission	
	Improved	
Diabetes medication	53.5%	22.5%
Glucose	39.1%	21.9%
HbA1c <6	37.5%	37.5%

Non-obese patients

ASMBS surgeons are trying to make a case for treating all Type 2 diabetes with bariatric surgery. They are not suggesting that the surgery is appropriate only for obese people or only for normal weight people with refractory diabetes. Rather, they are suggesting that bariatric surgery is appropriate for almost anyone with Type 2 diabetes as a "cure" for that disease, and this includes normal weight people with diabetes who are well controlled with oral medications. ASMBS president Dr. Shikora said, "The evidence suggests the best resolution (of Type 2 diabetes) is early diagnosis. If a patient is on insulin, the likelihood of benefit is less...You could equate this (bariatric surgery for normal weight diabetics) with preventive medicine. Why not take care of diabetes early where there is the highest likelihood of cure. It is possible it (bariatric surgery) is a cure for many patients – and a benefit even if the diabetes returns...If there is a mortality benefit, it would increase use – if the healthcare system could handle the increase in volume. But a lot of insurance companies have demonstrated an unwillingness to increase volume – so they avoid and delay."

Dr. Shashank Shah of India presented a study showing that Roux-en-Y gastric bypass is effective and safe in Type 2 diabetics with BMI >22 but <35 kg/m². He conducted a prospective study in 15 Type 2 diabetics (80% on insulin, 20% on oral agents) with a mean BMI of 28 and HbA1c of 11. At 1 month post-procedure, 80% were off anti-diabetic medications. At 3 months, all were off anti-diabetic medications. At 9 months, all were still off anti-diabetic medications with a mean HbA1c of 5.9. He concluded, "Bottom line, we had remission in all subjects, most by one month. The effect persisted at 6 and 9 months. Maximum weight loss was 20%...This study appears to confirm the proposition to use the gastric bypass operation to control Type 2 diabetes in individuals with a BMI <35 kg/m². Of course, we need to look at longer safety and efficacy and a larger study."

An expert discussing these findings said, "Endocrinologists routinely criticized us whenever we suggested surgery for diabetics with a BMI <35, saying there are no data. This paper is starting to address that...Clearly, there is a pattern of success here. I think you do need larger and longer studies."

Asked if there will be relapses of the diabetes if the patients are followed longer, Dr. Shah said, "Most of these subjects have now completed nearly two years, and they are still stable in most parameters except borderline increase in lipids in some patients."

Asked if patients with lower BMI (e.g., 22) had better diabetes resolution than patients with a higher BMI (e.g., 35), Dr. Shah said that subgroup analysis will be done at the end of three years.

Identification of responders

Dr. Richard Perugini of the University of Massachusetts reported that a relatively simple test, the glucose disposition index (DI) – which is the product of insulin sensitivity (IS) x beta cell sensitivity – could be used to predict which severely obese patients would not have resolution of their Type 2 diabetes with laparoscopic gastric bypass. He used this formula to study 242 bypass patients, 21% of whom had Type 2 diabetes, and he found the probability of remission of the diabetes at one year post-surgery increased as the DI increased. Age was not predictive. He said, "The median time to remission (of diabetes) was 15 days if the DI was >29 and 230 days if the DI was <29. The median time to remission was 16 days if the patient was not on insulin and 360 days if the patient was on insulin...Patients who are diabetic and basically at DI ≤24 have a lower chance of being cured, and those with a DI 24-100 have a greater chance of resolution of diabetes...We are studying non-diabetic patients with good glucose disposition to see if they will be bothered by hypoglycemia."

What is the best surgery for Type 2 diabetics?

All of the bariatric surgeries are effective in treating Type 2 diabetes, but surgeons debated which approach is best – band, sleeve, or bypass. A speaker said, "Both bypass and banding lead to weight loss, and that clearly leads to control of diabetes, but the intestinal manipulations have physiologic effects that lead to immediate control of diabetes that is completely independent of weight loss."

Meta-Analysis of 19 Studies of 4,070 Diabetic Bariatric Patients

Measurement	Band	Sleeve	Bypass	Duodenal switch/BPD
EWL	46.2%	55.5%	59.7%	63.6%
Diabetes resolved	46.7%	79.7%	80.3%	95.1%
Diabetes resolved <2 years	55.0%	81.4%	81.6%	94.0%
Diabetes resolved ≥2 years	58.3%	77.5%	N/A	N/A

What happens when patients regain weight? Dr. Schauer said, "Our observation is the level of diabetes is less than before the surgery...but there is something about those individuals who do regain weight after the operation. The operation is not as physiologically effective on them as in other people, and the diabetes may not be as physiologically effective in those patients either."

The electronic audience responses at two sessions gave some insights into how surgeons, not just speakers, were looking at this issue:

1. Is there strong evidence to suggest the diabetes resolution associated with bariatric surgery is **not** directly related to weight loss either in morbidly obese or non-morbidly obese subjects? 75% said yes.
2. For a 45-year-old man with a BMI of 29, with a 9-year history of Type 2 diabetes, an HbA1c of 8.9%, and dyslipidemia, who is taking Lantus 55U (insulin) at bedtime and two oral agents, the best surgical option is: 92% said a duodenal switch.
3. 78% said the factors that predict remission for Type 2 diabetes after bariatric surgery include the amount of weight loss, duration of diabetes prior to surgery, and the type of surgery – but not gender.
4. For a diabetic patient with GERD (gastroesophageal reflux disease), a BMI of 45, and no hiatal hernia, 94% believe the best operation for treatment of the GERD is laparoscopic gastric bypass, not band or sleeve.
5. For a male patient with a history of hypertension and sleep apnea who has a BMI of 40 and a hiatal hernia, 91% believe the best operations would be a laparoscopic hiatal hernia repair with mesh and gastric bypass.

Dr. Ricardo Cohen of Brazil argued, “Bariatric (metabolic) surgery may provide a multifactorial approach, improving all components of the metabolic syndrome and not directly linked to greater weight loss. BMI should not be used as a cut-off criteria for a surgical indication.” Dr. Cohen, who had a research grant from Covidien, presented his 27-patient study of Roux-en-Y gastric bypass in Type 2 diabetes patients with BMI 30-35. He called the results “impressive,” saying 78% had resolution/improvement in their diabetes, and all insulin users, including non-responders, came off insulin, and 32% of patients are off all medications. He reported no correlation between BMI and HbA1c level at 12 months, “In this population, at 12 months there is no relationship between weight loss and diabetes resolution.”

Dr. Cohen also reported interim results from another protocol: a 24-month study in patients with a mean baseline BMI of 28.4, HbA1c of 8.6, and an average 14.5-year history of Type 2 diabetes, with 32.5% using insulin. At 10 months, EWL was only 6.4%, but 65% no longer used any diabetes medications, blood pressure was in good control, and triglycerides and LDL were down.

Asked which operation is best for patients with a BMI <30, Dr. Cohen said, “That is a tough question...I’m excited with the (early) results (for bariatric surgery). Maybe I’m biased as an investigator...but we have patients with HbA1c <6 and without medications. It is short follow-up, but it is exciting.” Dr. Schauer added, “The lower the BMI, the more you go into the black box of uncertainty...As you get to lower BMI, especially those with severe diabetes, we really don’t know the effect of a small amount of weight loss (BMI 27 to 23). It may have a neutral effect. I think the closer to normal body weight, we need more data.”

Dr. Bruce Wolf of Oregon Health Sciences University said the National Institutes of Health (NIH) has convened a panel to rewrite the guidelines on obesity, including surgery, “We hope that will be a meaningful update.” Dr. Wolf predicted that the demand of bariatric surgery in the future will outstrip current capacity.

HYPERTENSION AND BARIATRIC SURGERY

In addition to resolving or improving Type 2 diabetes, bariatric surgery can bring good improvement or resolution of hypertension. In one study of 1,377 bypass patients with 4-year follow-up, a speaker said hypertension resolved in 54.5% and resolved or improved in 74.5%. A meta-analysis found hypertension resolved with gastric bypass surgery in 43.2% of patients and resolved/improved in 70.8%. In a third study, hypertension resolved in two-thirds of patients after bypass. The speaker said, “I think we have pretty strong data that Roux-en-Y reduced the hypertension risk...Most attention has been focused on (metabolic) surgery for diabetes...Hypertension may respond early following bariatric surgery, and this response may precede significant weight loss.”

In one study, it appeared that the blood pressure drop took ~1 month to reach maximum lowering and then remained fairly constant out to 12 months. In another study, the blood pressure drop occurred mostly in the first week and then stabilized.

BARIATRIC SURGERY AND GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD)

GERD is associated with obesity. While proton pump inhibitors (PPIs) are an extremely effective way of stopping acid secretion in the stomach, if they don’t work, anti-reflux surgery may be appropriate for patients with BMI <35 or for patients with BMI 35-40 after they lose some weight because anti-reflux surgery fails with BMI >35.

Experts said:

- **Eosinophilic esophagitis (EoE) is rapidly and exponentially on the rise.** It presents much like GERD, but it is not the same thing. Patients may respond to PPIs, but Dr. Sayeed Ikramuddin of the University of Minnesota warned, “You need to carefully think about what to offer these patients.”
- **There are less data on GERD and sleeves,** and what data there are appear conflicting – some indicating sleeve has a better result, and some saying the band has a better result. A speaker said, “Can the sleeve exacerbate GERD? It probably can...and we need to think about that as we go smaller and smaller with our sleeves.”
- Weight loss in the super-obese **improves most comorbidities** with the duodenal switch but not necessarily GERD.
- **Gastric bypass is the most effective bariatric procedure** for GERD.
- Bypass also probably is the **best option for Barrett’s esophagus**, though continued surveillance of those patients is necessary.

LAPAROSCOPIC GASTRIC BANDING (LGB)

Allergan’s Lap-Band is losing market share for three reasons:

1. **The increasing popularity of sleeve gastrectomy.** Sleeves are taking share from both bypass and bands. On average the loss is relatively small (down 2%), but in individual practices that are starting to do sleeve procedures, the loss is a little more substantial (down 6%).
2. **Competition from Johnson & Johnson’s Realize band.** Most doctors have started using both Lap-Band and Realize or plan to start Realize soon. The two key reasons for the interest in Realize are: (a) Patient demand for Realize, and (b) The Realize website, which got very high praise from doctors. On average surgeons estimated that their current use is 82% Lap-Band and 18% Realize, but two-thirds said that their use of Realize would increase over the next year.

3. A decrease in self-pay patients due to the recession.

More band patients tend to be self-pay than bypass or sleeve patients, and many doctors said the recession has seriously reduced the number of self-pay patients.

Comments included:

- *Kentucky*: “We are about 40% Lap-Band, 60% Realize now, but we will be 35% Lap-Band and 65% Realize next year. It’s a combination of physician preference, J&J marketing, and consumer demand. Patients come in and ask for Realize.”
- *Georgia*: “We’ve only done a few Realize bands, and those were patient-driven. Patients are not coming in and asking for Realize, and our surgeons prefer Lap-Band.”
- *Tennessee*: “We have been all Lap-Band, but we will start doing Realize soon to be complete. I don’t think either is worth a damn. I wouldn’t put a band in a family member.”
- *Ohio*: “We started doing bands 2-3 years ago because 9 of 10 patient calls were for it. Now we are 40% bands, but that is likely to decrease to 30% over the next year as we do more bypass, but the sleeve looks attractive, and we may start that...We were 100% Lap-Band until recently, but my partner did seven Realize, and I got trained on Realize. We’ll use both for a while and compare them. They are pretty similar. Right now the main advantage to Realize is company support...Ethicon doesn’t care which you do – the band or bypass – because they sell both bands and staplers, while Allergan just pushes bands. Allergan’s (co-marketing) deal with Covidien may change that perception, though.”
- *New York*: “Our band use is likely to go down from 40% this year to 35% next year because when a lot of patients who initially chose the band hear about the sleeve, they choose the sleeve, though the two procedures compare favorably...We are not doing Realize yet, but we will start at some point and will offer it to patients in case they have a preference.”

Dr. Jenny Choi of Columbia University reported on a study of banding in 63 patients with low BMI (30-35). She concluded, “Moderately obese patients below the current guidelines for bariatric surgery have similar weight loss and associated benefits. Laparoscopic gastric banding is a safe and effective treatment for patients with BMI 30-35 kg/m².”

Banding in Patients with BMI 30-35

Measurement	Low BMI n=63	Band patients meeting NIH criteria for surgery n=475
Baseline BMI	36.7	46.7 *
EWL at 6 months	33.3%	Nss
EWL at 12 months	39.1%	Nss
EWL at 18 months	37.3%	<0.05
EWL at 24 months	44.5%	Nss

* Comorbidities included hypertension, diabetes, hyperlipidemia, GERD, stress incontinence, and obstructive sleep apnea.

SLEEVE GASTRECTOMY

This was the hot topic last year at ASMBS, and usage is still growing. How much it grows over the next year will depend on insurance coverage improving.

Dr. George Eid of Pittsburgh said, “A lot of surgeons and centers in the U.S. and worldwide started offering sleeve gastrectomy as a primary procedure. Our society (ASMBS) in 2007 looked at this issue, trying to come out with a position statement. They looked at published literature from 2003-2007 and had 15 studies with follow-up 6 months to 3 years, with EWL 33%-83%...but what was interesting was the variety of techniques used, especially the sizing of the bougie (32-60 Fr). They concluded sleeve gastrectomy may be an option for certain carefully selected patients...but encouraged us to prospectively collect data.”

Dr. Eid presented the first long-term data on sleeve gastrectomy: ≥3-year data on 39 of 77 consecutive patients. He said the results indicate that the procedure is safe, effective, and durable for at least five years in morbidly obese patients, “I think our data support the use of sleeve gastrectomy as a definitive bariatric operation as a primary procedure...I think we would all agree there is still some learning curve with the sleeve...but we are really encouraged by the results.”

Long-Term Follow-up of Sleeve Gastrectomy

Measurement	Sleeve
Mortality	0
Early complications	5% *
Late complications	15% **
EWL	
36-47 months	58%
48-59 months	46%
≥60 months	42%
58 months	46%
Effect on comorbidities	
Improvement in Type 2 diabetes	40%
Remission of Type 2 diabetes	26%
Improvement in hypertension	40%
Remission of hypertension	31%

* 1 pulmonary embolism, 3 dysphagia

** new onset GERD that responded to a PPI

Sleeve gastrectomy is also being used as a revision for failed bands. Dr. Raul Rosenthal of the Cleveland Clinic Florida said, “Sleeves will take more from bypass than bands...Bypasses seem to do much better on weight loss...but patient preference is the No. 1 reason (for doing sleeves)...Patients come and ask for the sleeve. I think bypass is better for a failed restrictive procedure, but if a band slips, and you can’t replace it, it wouldn’t be a bad idea to replace it with another restrictive procedure.”

Dr. Rosenthal said revisions have increased dramatically, “But that makes sense because the more (procedures) we do, the

more revisions there will be.” He said European surgeons who put in a lot of bands are now taking them out, “They recommend taking them (the bands) out, and 2-3 months later doing the revisions...They wait 2-3 months to do a resection.”

But (sleeve) revisions surgery has a price. Dr. Rosenthal said that price is complications. He cited a complication rate of 1.4% with a primary sleeve procedure, but 12.5% converting a band to a sleeve.

LAPAROSCOPIC BANDS VS. ROUX-EN-Y BYPASS VS. SLEEVE GASTRECTOMY

In a debate, Dr. Paul O'Brien of Australia argued that, in his country, where both the band and the sleeve are reimbursed equally, the band is preferred because of safety, proven efficacy, proven durability, and adjustability and reversibility, “The worry with the sleeve is that at 5-8 years it will fail because we have seen that in the history of bariatric surgery from way back (with other procedures/devices)...We only have five-year data on the sleeve, so possibly we have an operation with a very limited lifespan.”

Dr. O'Brien's Comparison of Band and Sleeve

Measurement	Band	Sleeve
Safety	Yes	No
Efficacy	Yes	Yes
Durable	Yes	Probably no
Low revision rate	No	Not known
Feasible	Yes	Yes
Adjustable	Yes	No
Reversible	Yes	No
Good evidence base	Yes	No

A poster by researchers at Youngstown State University reported on a comparison of weight loss with gastric bypass and laparoscopic bands which found that patients lost ~25% more weight with Roux-en-Y than a band at both 12 and 18 months. Another study, this time a retrospective review of 413 bariatric patients, looked at the effect of the two procedures on dyslipidemia.

Bypass vs. Band

Measurement	Bypass	Band
Weight loss study		
Number of patients	88	49
EWL at 1 month	21.8%	17.7%
EWL at 3 months	37.2%	25.5%
EWL at 6 months	51.6%	35.5%
EWL at 12 months	64.2%	39.2%
EWL at 18 months	66.7%	42.2%
Dyslipidemia study		
Total cholesterol at 12 and 18 months	Significantly more decrease with bypass	
LDL at 12 and 18 months	Significantly more decrease with bypass	
HDL	Increased	No change

Which is better for adolescents – bands or sleeves?

Surprisingly, the fattest children in the world are boys in China, which a speaker pointed out tracks with the arrival of McDonald's in that country. For a child, a BMI of 34.7 is equivalent to having chemotherapy for cancer.

Dr. George Fielding of New York University and Dr. Camilio Boza of Santiago, Chile, debated which procedure is best for adolescents. Dr. Fielding argued that the Lap-Band is very effective for teenagers and that U.S. teens will comply with band adjustments. He said that his key message to children is, “I'm giving them a tool, and all I ask is that they use it. And don't drink regular Coke ever again.”

Dr. Boza said his center started all three procedures – bypass, band, and sleeve. They've now done ~200 bands, and last year did more sleeves than bypasses, and the trend is to more sleeves, “At the beginning, we were very, very excited (about bands). It was an easy technique and less complicated than gastric bypass, so we thought it would be a good choice...but we started to see that when you started to adjust them...more and more, the patients are very happy with the weight loss but start having problems with fluid...At the end, we started to see many (band) patients with good weight loss but very poor quality of life – a number of patients with very bad quality of life, even after achieving weight loss goals. The (band) adjustment necessary to have the weight loss is not associated with a good quality of life...However, in the other 50% of (band) patients, the results are very good. And you do have patients where you achieve the perfect adjustment. The problem is the other 50%, and that is what we couldn't figure out, and that is why we abandoned it (the band)...We have a period of 3-4 months to try to save the band...but now we are more eager to take them out because we haven't seen good results.”

Dr. Boza presented initial results from 536 bariatric surgery patients:

- 88.5% EWL after 2 years with the sleeve, which is more than with the band.
- BMI “really drops down.”
- Operative time was shorter than laparoscopic bypass (70.2 minutes vs. 80.5 minutes).

Dr. Boza's Comparison of Band and Sleeve

Measurement	Band n=199	Sleeve n=552
Operating time	57.1 minutes	76.8 minutes
Late complications	29.1%	3.0%
Slippage	12 patients	0
Food intolerance	13 patients	0
Port dysfunction	8 patients	0
EWL	58%	Significantly more at 6, 12, and 24 months
Dyslipidemia resolved	20.5%	84.8%
Insulin use resolved	42.8%	93.1%
Hypertension resolved	21.7%	62.5%

- Hospital length of stay was shorter with the sleeve (2.8 days).
- Quality of life was “much better” with the sleeve than bands.
- Weight loss was greatest with the sleeve.

Two doctors in the audience argued that the band is better than the sleeve, in particular because of leaks with the sleeve. Dr. Boza admitted another study found a leak rate of 18% with revisions and 1.4% as the primary operation.

Which is better for the super-obese – band or sleeve?

Dr. Emma Patterson, an Allergan consultant from Portland OR, and Dr. Paul Cirangle of San Francisco debated this topic. Dr. Patterson argued in favor of the band, citing a 7% leakage rate with the sleeve, saying, “Conversely, the band is very safe and can be done as an outpatient...Banding is safer than the sleeve, banding has a longer proven track record, and banding is usually fine as one-stage (procedure)...I think we should be careful of doing something to follow trends.”

Dr. Cirangle said, “Perhaps you need not the ‘best operation’ but the ‘most advantageous’ operation...We have done almost 1,500 sleeves...The sleeve is a wiser approach because:

- These are individuals who clearly will have a compliance issue (with the band). I’m worried they will not come in for monthly adjustments and comply with dietary requirements.
- Options for revision are fewer (with the band).
- There are more pronounced physiologic effects with the sleeve.
- There is a higher incidence of complications with the band, and the presence of a prosthesis adds additional risk.
- The band is more technically difficult.”

However, Dr. Cirangle admitted insurance currently is a problem for the sleeve and for revisions to the band, “No third party program in California covers revisions, and that is something that has to be considered...Few pay for (the sleeve). Most of the patients we have now for the sleeve are self-pay... You can have a band, but you can’t switch from the band to another procedure...Medicare won’t cover the sleeve...and with Medicare there is no pre-approval process. You don’t know if you are going to get paid or not...so we haven’t done the sleeve with any Medicare patients.”

Dr. Fielding added, “We also found that switching from the band to the sleeve, patients don’t do as well...We have had a lot of problems with that because patients have learned how to maladaptively eat.”

Dr. Michel Gagner of Miami commented, “In some cases it is very difficult to put the band where you don’t even see the G

(gastroesophageal) junction. How do you put a band in someone with a big liver, and you can’t see the G junction?” Dr. Patterson responded, “We are always able to do it...A couple of times we backed out and had them lose more weight, and then did the (band).”

A Mayo Clinic doctor asked, “We have had a lot of luck with a very low calorie protein diet...We can get 50-100 pounds of weight loss pre-op and then can proceed with bypass. But I like doing these operations for reduction in comorbidity. We look at reduction in weight as success/fairly, but improvement in comorbidity (is very important). Are there significant differences, and if not should we pick the safer operation?” Dr. Patterson responded, “Most patients have an insurance requirement to lose a little weight – 5% – first...I agree we should focus on comorbidities, and I don’t think there is a difference (in that) in the two operations.”

ONE-INCISION PROCEDURES

Patients are increasingly asking for this type of procedure for cosmetic reasons, and doctors are complying, even though they generally believe it is more difficult. There are several names for this one-incision type of bariatric surgery, though most often it is referred to as SILS:

- **SILS** (single-incision laparoscopic surgery) – Covidien “owns” that name, and it sells the SILS port, a single, flexible port fitted through a small incision in the umbilicus that can accommodate ≤ 3 laparoscopic instruments for easy specimen removal and greater stability, support, and maneuverability for hand instruments. However, doctors use the term SILS to refer to any one-incision bariatric surgery.
- **SPA** (single port access) – which is “owned” by Drexel University.
- **LESS** (laparo-endoscopic single-site) – which is trademarked by Olympus.
- **SSL** (single-site laparoscopy) – which is Johnson & Johnson’s name for its one-incision procedure.
- **SLIT** (single laparoscopic incision transabdominal) – Dr. Ninh Nguyen of the University of California, Irvine, said, “It is a much smaller jump from a laparoscopic sleeve to SLIT than from an open procedure to laparoscopy. Patients love it (SLIT), but there is no real clinical difference...SLIT sleeve gastrectomy is feasible...(But) sleeve gastrectomy is now getting accepted...If we are derailed by leaks through SLIT, that could be a problem.”
- **R-PORT** – which is “owned” by Olympus. Dr. Daniel Scott of the University of Texas Southwestern Medical Center said, “I think this will be prime time for cholecystectomy, but I’m not sure about it for obesity.”

Surgeon comments about one-incision surgery included:

- *North Carolina*: “We did our first SILS procedure, and patients **love** it. It’s good, and it works.”
- *Louisiana*: “I’m not interested in SILS, though it is a hot topic.”
- *Tennessee*: “SILS, ROSE (restorative obesity surgery, endoscopic), and NOTES are not ready for prime time, and I’m a prime time guy.”
- *New York*: “I’m not doing SILS yet. It is hard to say if the technology will really get there and at the right cost, but it is not there yet.”

The limitations to single-site bariatric surgery include head space constraints on the port, instrument conflicts, range of motion, visualization, need for additional ports (e.g., liver retractor). Umbilical access can be extremely difficult in some obese patients because the reach can be >24 cm, and the angles can be very challenging. On this, doctors generally agreed: cosmesis is good. Dr. Scott cited some remaining questions about one-incision procedures:

- **Are the results equivalent to other surgery?**
- **Is there less pain?** Dr. Scott predicted this would be a subtle difference.
- **Is the incisional hernia rate increased?** Dr. Scott said this is something he worries about.

Asked how the additional \$800 cost of SILS can be justified, a speaker said, “You don’t necessarily need the expensive, articulated equipment. Many of us are using disposable trocars.” A doctor in the audience said, “I think the technology is getting ahead of us...I think the insurance companies will worry if it costs more and if there is any increase in the complication risk.” Another expert responded, “There is no increase in complications with SILS, but the number (of patients so far) is small. The session moderator noted, “There are anecdotal reports of complications with SILS.” A New England doctor added, “I’ve done about two dozen SILS gallbladders...so I think there really is something to this beyond a gimmick.”

Dr. Dana Portenier of Duke, a SILS surgeon, described why he chose to do this procedure, “What everyone predicted over the past few years was NOTES...That has been an extremely exciting thought process for surgeons...However, we’ve all been disappointed that this hasn’t come to fruition. It really hasn’t evolved for technical reasons. SILS isn’t something extremely attractive to surgeons, and it wasn’t attractive to me. I was asked if I wanted to get trained, and I said, ‘Why? I can take a gallbladder out through a couple of little holes. Why do I want to struggle and fight to do it through one small incision?’ It took some of our trainees finding out their competition was doing it and asking why we weren’t. So, I started to look into it, and I found patients do care about it. I may not care about it, but patients do...You, as a surgeon, may not be interested (in SILS), but someone in town may,

and then before you know it, patients may be going to another surgeon. Everyone has to pay attention to SILS, or you will get left behind.”

The advantage to SILS is, quite simply, cosmesis. Dr. Portenier said, “It will be extremely difficult to prove a significant scientific benefit to SILS over standard laparoscopic surgery...but we can hypothesize/theorize that there is less pain, less narcotic use, less wound complications, and potentially a shorter hospital stay.”

Who will get a single-incision procedure? Dr. Portenier predicted: females, pear shapes, low to mid-range BMI, and patients with no previous abdominal surgery. He said, “There are two bariatric procedures it fits nicely for: The Lap-Band is technically the easiest SILS procedure. The port requires a larger incision already. So, I think for Lap-Band surgery it really makes sense. Sleeve gastrectomy is a similar sort of thing. It typically requires a larger incision already, too...I’m doing SILS gastric bypass, but I don’t think that it makes a lot of sense. It has taken a procedure that takes 1-1.25 hour and probably doubles the time. But with the adoption of new technologies, this will be an evolving phase. And it will be very realistic that people will do gastric bypass (with SILS) in selected patients in the future. I don’t know that I would recommend it today.”

In order to do single-site incision procedures, surgeons need specialized instruments. Among those they are using are:

- **Covidien’s EndoStitch**
- **EndoGastric Solutions’ StomaphyX** – which reportedly is done primarily in patients who already had a bypass and who are gaining weight (which is 15%-20% of Roux-en-Y bypass patients). Dr. Scott said, “Several devices have come and gone. What differentiates this is it showed in animal studies that it could get full thickness bites of the stomach wall vs. other devices that only got the inner layer. There is hope the StomaphyX Plus device will have more long-term durable results...Durability is the question...It may work best in those just beginning to regain weight...This is not covered by insurance, and it is \$10,000 at my institution to have this done, so the patient has to think very carefully about whether to do this or not.” A multicenter randomized trial is underway vs. sham in post-gastric bypass patients.

NO-INCISION (ENDOSCOPIC) PROCEDURES

Dr. Thompson said durability remains the unanswered question to less invasive endoscopic approaches.

Restorative Obesity Surgery, Endoscopic (ROSE)

SILS and ROSE were the two new procedures that bariatric surgeons were showing the most interest in. ROSE reduces the size of a patient’s stomach pouch and stoma to the original post-gastric bypass proportions – eliminating the stretch – to

help the patient back into normal weight loss, without the problems of gastric bypass. ROSE is based on USGI Medical's Incisionless Operating Platform. A Georgia surgeon said, "ROSE procedures are exciting. We are doing that now." A Kentucky doctor said, "We have one surgeon doing SILS, and another starting ROSE. Insurance doesn't cover ROSE, but we are looking at it as a primary procedure."

NOTES (Natural Orifice Transluminal Endoscopic Surgery)

Dr. Schauer said a paradigm shift is occurring in bariatric surgery – endoscopic approaches or NOTES. NOTES was a big topic at Digestive Disease Week in May 2009, but it wasn't as prominent at ASMBS.

While NOTES is generating a lot of interest and talk, not everyone is convinced. A New York doctor said, "NOTES started with laparoscopy, and now they want to push the envelope, but I'd rather have a hole in my abdominal wall than a hole in my stomach (from a perforation or a surgery that broke open), and that is a concern. I'm not sure of the wisdom of NOTES."

Among the NOTES procedures discussed at ASMBS were:

➤ **Bard's EndoCinch for endoscopic gastroplasty.** The TRIM trial is ongoing to prove the value of this endoluminal suturing device. Dr. Schauer said, "The preliminary results appear somewhat promising on body weight and glucose homeostasis."

➤ **Satiety's transoral gastroplasty (TOGA)** – a 45 Fr restrictor, delivered alongside an endoscope, with stapled "pleats" at the distal end of the sleeve to restrict outflow. Enrollment was completed in May 2009 in a 275-patient, prospective, randomized, multicenter, sham-controlled, pivotal FDA study. Dr. Leena Khaitan of University Hospitals in Cleveland OH said the company is working on a new generation device that "will be a little more user friendly."

Dr. Khaitan said the early observations from the trial are: "At early follow-up, sham and controls are doing well. At three months, several controls think they had the procedure, feel restriction. Once they are beyond six months, I think we will see a diversion between the two groups...There is a lot less pain. Some sham patients had as much pain as treatment patients. Patients have been very satisfied with the procedure...The advantage is this is less invasive; there is no incision."

Asked if there have been any esophageal tears, Dr. Khaitan said, "Not in our personal eyepiece, but there was one in the U.S. trial to date, and that patient was recognized right away and taken urgently to surgery, underwent repair, left the hospital in 4-5 days, and is doing well...I think we will see staple line gaps...and it will be up to the company to find solutions to that...but that is theoretical...It is the late results that will separate the wheat from the chaff."

Dr. Schauer said the early results have been published, and enrollment in a pivotal study is nearly completed. He said this rivals other accepted procedures, with EWL 50%-60%.

Dr. Chris Thompson of Brigham & Women's Hospital said a 62-patient study in Brussels and Mexico City with the original device found 24% EWL at 6 months, but partial staple line breakdown in 13 of 21 patients. With the second-generation device, EWL was 43% at 1 year.

➤ **Satiety's Endoscopic stapling with Satiety's TOGA,** a stapling device inserted inside the stomach to create plications to reduce gastric volume.

MISCELLANEOUS

Implants

➤ **Allergan's BioEnterics' IntraGastric Balloon (BIB)** – an alternative to surgery in massively obese individuals. A trial in 2,515 patients found the device was placed successfully in all but 0.08% of patients, and complications were only 2.5%, but there were 5 gastric perforations, and two of these patients died. Nausea is also a problem (~40%). There are U.S. trials ongoing.

➤ **BaroSense's BaroSense** – an implantable device to cause restriction inside the stomach. It is completely reversible, potentially an outpatient procedure, and entirely endoscopic.

➤ **GI Dynamics' EndoBarrier** – an entirely endoscopic, retrievable sleeve in which a soft tube barrier system is placed endoscopically and positioned in the duodenal bulb to block food from contacting the mucosa. It is 2 feet long and made of an impermeable fluoropolymer. Corinne Vigilante, a nurse practitioner from Burlington MA, said that 7 of 21 patients in whom the device was implanted had it explanted. Those with the device lost 7-29 pounds, and all patients reported increased satiety with less caloric intake. She said, "In our experience, the device appears effective and safe. The company has gone back and continues to modify the device. It is a minimally invasive option for pre-surgical weight loss. It allows patients to begin making behavioral/nutrition changes while facilitating weight loss."

Dr. Thompson said this has been studied in Chile, with a shorter sleeve that doesn't bypass the stomach, with ~22% EWL at 12 weeks. He said, "This might have a role. There was a good effect on Type 2 diabetes."

The question, Dr. Schauer said, is durability and the potential long-term concern with respect to dislodgment or long-term side effects.

➤ **ValenTx's implanted sleeve** – In a single-center, first-in-man study in 12 patients in Mexico, the device was well tolerated with no nausea or vomiting, and the device was safely removed at the end of the study. However, 3 devices were removed ahead of schedule due to pain. Dr. Thompson

said, “The goal is to leave the cuff in after taking the sleeve out...and the sleeve can be replaced as needed. EWL was ~40% at 12 weeks. Early results are very good.”

Other procedures

Vertical gastric plication – either anterior plication or greater curve plication. The work on this is very preliminary, but Dr. Schauer said some work has been done at the Cleveland Clinic, “We are beginning to see some encouraging results. It is quite early, but, nevertheless, if this does show durability, it is a procedure that might eliminate some of the concerns with the sleeve – leaking, etc. – because there is no cutting of the stomach at all.”

Robotics

➤ A few surgeons have an **Intuitive Surgical’s Da Vinci** robot at their hospital, but none was using it for bariatric surgery. Surgeons at Hamot Medical Center in Erie PA had a poster on complications with and without using a Da Vinci for Roux-en-Y surgery.

Roux-en-Y With and Without the Da Vinci Robot

Measurement	Da Vinci n=114	No Da Vinci n=179
Duration	222 minutes	179 minutes
Leaks	2.2	0
Bleeding	0	0
Stenosis	4.3%	7.2%
Marginal ulcers	3.5%	5.6%

➤ **EndoRobotics** is developing a fully insertable, micro-robotic imaging and surgical device platform for minimally invasive surgery. There was no news about this at ASMBS. It is a vision system for laparoscopes based on intellectual property from Columbia University inventors. The high resolution, high definition digital camera, combined with robotic effectors, will provide a fully-integrated lighting platform with full pan, tilt, zoom, and surgical instrument tracking functionality. The platform is stereoscopic and can be delivered in either a 2-D or 3-D format. The company expects to launch its first product, VisionTrackerOne, in the U.S. in 1Q11. It will offer robotic “*point-and-shoot*” digital camera technology.

➤ **EnteroMedics’ VBLOC (vagal nerve block)**. Most of the bariatric surgeons questioned about VBLOC were at least vaguely aware of it, but none knew very much about it, and it was generating no excitement at the meeting. A New York doctor said, “It’s experimental. It could take root for a short period of time, but will it stand the test of time? Cost is not an issue if it is effective.” A Texas doctor said, “It will face issues with Medicare and insurance companies.” A New England doctor said, “There isn’t enough magnitude of benefit. There is only about 10% weight loss.”

A speaker said the ongoing, 294-patient, double-blind, 15-center, 60-month VBLOC study will be unblinded after all patients have had the implant for one year, which he expected would be later this year. All patients get a device, with two-thirds of them turned on the first year, and the others turned off. After one year, all are turned on. He said, “At this point, we have reactivated many patients...There are two leads, and throughout the day, the leads check for impedance, so patients do have some sensation for the first year.”

An open-label study of 10 obese females looked at diet effects with VBLOC and found that right after initiation there was an 80% improvement in quickness of fullness and that was sustained at about 50% over time. Hunger between meals decreased 60% at initiation and that was maintained at ~40%. The type of caloric intake stayed about the same – 37% fat, 41% carbohydrates – but total intake fell significantly.

In another open-label trial (12-18 months) with a second-generation device (VBLOC-RF2), 38 patients in 3 countries have been implanted.

Open-Label VBLOC Results

Time period	Result	
Efficacy: EWL		
1 month	9.1%	
3 months	15.0%	
6 months	21.4%	
9 months	27.4%	
12 months	29.1%	
Safety		
Deaths	0	
Unanticipated complications	0	
EKG abnormalities	0	
Effect on comorbidities		
Hypertension	SBP	DBP
1 month	-12.9	-10.7
3 months	-11.1	-5.7
6 months	-10.0	-5.7
Type 2 diabetes: HbA1c change		
1 month	-1.4%	
3 months	-1.3%	

Asked what happens with the device long-term, a speaker said, “My understanding is this will stay in...When you turn it off, it doesn’t do anything. We do have patients who don’t wear it, but the device is still in place...but there is no damage or erosion through the vagus nerve...The body does encapsulate the electrodes kind of like around the (gastric) band, and there don’t appear to be any complications.”

Two posters were presented on two small experiences with VBLOC, looking at the effect on comorbidities:

- A 6-patient, 5-center, 6-month study on the effect on Type 2 diabetes.

- A 26-patient, 4-site, 6-month study on the effect on hypertension.

VBLOC Effect on Comorbidities

Measurement	1 month	3 months	6 months
Diabetes study			
EWL	9%	11%	12%
HbA1c	-1.4%	-1.3%	-1.7%
Decrease in baseline medications	1 patient		
Hypertension study			
EWL	-10%	-17%	-21%
SBP (baseline 136)	-14	-11	-13
DBP (baseline 87)	-11	-6	-6

Instrumentation

Surgeons tend to prefer one type of instrumentation for doing bypass – generally either Johnson & Johnson/Ethicon or Covidien. The choice is often how they were trained, but sometimes it is dictated by hospital contracting. No surgeons questioned at ASMBS had recently changed instrument suppliers, and one expected a shift over the next year. A North Carolina source said, “We use Ethicon instruments because that’s what our hospital contract is.” A Texas source said, “We use both Ethicon and Covidien instruments. That hasn’t changed, and I don’t expect a change.” A Louisiana surgeon said, “We’ve used Covidien for three years. Service has been good, and there has been no change in our sales rep.” Another doctor said, “We use Ethicon instruments. The choice is based on surgeon preference, and that is based on your training. One is probably not better than the other.”

Covidien did have one particularly interesting new product – the Duet TRS Reload, an endoscopic stapler pre-loaded with a synthetic absorbable polymer tissue reinforcement material. Covidien sales reps said it should reduce leaks, especially with sleeve procedures. Other companies make reinforcement strips for stapling, but this is built into the stapler. Covidien customers generally thought this would be very useful, but none of the J&J users planned to switch to get it. A Texas doctor said, “Duet is a big deal. It saves time.” A Colorado doctor said, “A lot of surgeons swear by tissue reinforcement. I’m not one of those, but even if I were, I wouldn’t change instrument companies for that feature.”

Our Resolution campaign

At ASMBS, Covidien announced the launch of the Our Resolution movement, a collaborative effort between healthcare experts, non-profit organizations, health agencies, patients, and spokespersons who share the goal of resolving Type 2 diabetes. The movement is focused around the discovery that gastric bypass surgery resolves diabetes in ~77% of morbidly obese patients. The campaign aims to educate healthcare providers and patients about the impact of Type 2 diabetes and the potential of bariatric surgery as a treatment option. The campaign is supported by the National Association of Bariatric Nurses and the Obesity Action Coalition. ♦