PROCEEDINGS

of the

5th
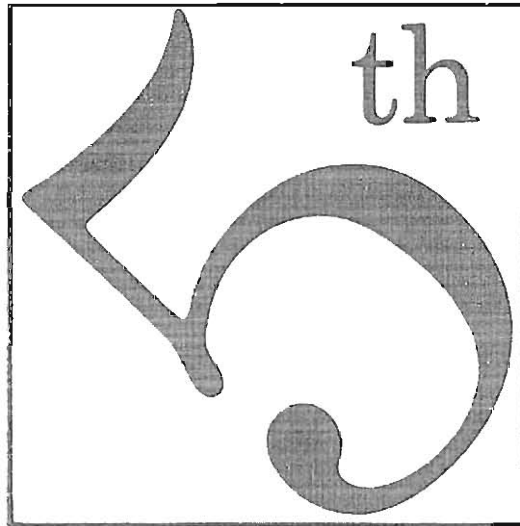
A · N · N · U · A · L

Bariatric
surgery
colloquium

PROCEEDINGS

OF THE 5TH ANNUAL

BARIATRIC SURGERY COLLOQUIUM

EDITED BY THOMAS J. BLOMMERS, PH.D.

Presented June 3-4, 1982

Iowa City, Iowa

Under the Auspices of

THE UNIVERSITY OF IOWA

Department of Surgery

Transcription by Patricia L. Piper

CONTRIBUTORS

John F. Alden, M.D.
Professor, Surgery
University of Minnesota
Medical School
Minneapolis, Minnesota

Thomas J. Blommers, Ph.D.
Clinical Research, Surgery
and Colloquium Coordinator
The University of Iowa
Iowa City, Iowa

Joseph A. Buckwalter, M.D.
Professor, Surgery
University of North Carolina
School of Medicine
Chapel Hill, North Carolina

Marilyn L. Bukoff, R.D., M.A.
Dietitian, Dietary Services
The University of Iowa
Iowa City, Iowa

Luigi M. DeLucia, M.D.
Private Practice, Surgery
10738 Riverside Drive
North Hollywood, California

C. Gregory Doherty
19 Gateview Court
San Francisco, California

Cornelius Doherty, M.D.
Private Practice, Surgery
490 Post Street
San Francisco, California

Gifford V. Eckhout, M.D.
Private Practice, Surgery
2045 Franklin, Suite 714
Denver, Colorado

Martin E. Felder, M.D.
Assistant Professor, Surgery
Brown University
Providence, Rhode Island

Cheri L. Florance, Ph.D.
Director, Communications
Disorders Institute
1450 Hawthorne Avenue
Columbus, Ohio

Kathye Gentry, M.S., PAC
Washington University
School of Medicine
4960 Audubon Avenue
St. Louis, Missouri

D. Michael Grace, M.D.
Associate Professor, General
Surgery, Western Ontario University
339 Windermer Road
London, Ontario, Canada

John D. Halverson, M.D.
Associate Professor, Surgery
Washington University School
of Medicine
4960 Audubon Avenue
St. Louis, Missouri

James P. Hayes, J.D.
Meardon, Sueppel, Downer and Hayes
122 South Linn Street
Iowa City, Iowa

Charles A. Herbst, M.D.
Associate Professor, Surgery
University of North Carolina
School of Medicine
Chapel Hill, North Carolina

Darwin K. Holian, M.D.
Private Practice, Surgery
5333 Hollister Avenue
Santa Barbara, California

L. Michael Howell, M.D.
Private Practice, Surgery
Fargo Clinic
737 Broadway, Box 2067
Fargo, North Dakota

Ben H. Knecht, M.D.
Clinical Instructor, Surgery
University of Washington
820 North Chelan Avenue
Wenatchee, Washington

John M. Kroyer, M.D.
Private Practice, Surgery
1741 Pacific Avenue
Long Beach, California

Henry L. Laws, M.D.
  Associate Professor, Surgery
  University of Alabama
  Birmingham, Alabama

Jeffrey W. Lewis, M.D.
  Assistant Professor, Surgery
  The University of Iowa
  Iowa City, Iowa

Richard I. MacArthur, M.D.
  Assistant Professor, Surgery
  University of Kansas
  Medical Center
  39th and Rainbow Boulevards
  Kansas City, Kansas

Edward W. Martin, M.D.
  Assistant Professor, Surgery
  Ohio State University
  College of Medicine
  410 West Tenth Avenue
  Columbus, Ohio

Edward E. Mason, M.D.
  Professor and Chairman,
  Division of General Surgery
  The University of Iowa
  Iowa City, Iowa

David K. Miller, M.D.
  Clinical Instructor, Surgery
  University of Utah
  School of Medicine
  Salt Lake City, Utah

Paul W. Moen, M.D.
  Private Practice, Surgery
  1504 Seventh Street
  Moline, Illinois

Cathy M. Mojzisik, R.N.
  Ohio State University
  School of Medicine
  410 West Tenth Avenue
  Columbus, Ohio

J. Patrick O'Leary, M.D.
  Professor, Surgery
  Vanderbilt University
  School of Medicine
  Chief, Surgical Service
  Veterans Administration
  Medical Center
  Nashville, Tennessee

Kenneth J. Printen, M.D.
  Professor, Surgery
  The University of Iowa
  Iowa City, Iowa

Sheldon M. Solochek, M.D.
  Private Practice, Surgery
  1218 West Kilbourn Avenue
  Milwaukee, Wisconsin

Jose C. Torres, M.D.
  Clinical Instructor, Surgery
  University of Louisville
  Louisville, Kentucky

TABLE OF CONTENTS

Page

WELCOME

Edward E. Mason, M.D.

This is the 100th year since Darwin's death and a number of us have used the word _evolution_ in talking about these operations for morbid obesity. This Colloquium is really an opportunity to look at the progress of that evolution.

We appreciate greatly that all of you have come, some from across the street, and others from long distances. In addition to those from the United States, surgeons from Australia, Canada, Denmark, Italy and Norway are also attending this meeting.

I want to call your attention to the arrangements that have been made by Ken Printen, Tom Blommers, Bob Davis and the people here at the Conference Center and the excellent job that they have done in planning and organizing this year's Colloquium.

BILIOPANCREATIC BYPASS

Darwin K. Holian, M.D.

I realize that I am probably the only surgeon doing the biliopancreatic bypass in the United States. My aim is to convince you, from clinical experience, about four things: 1) the procedure is well founded and physiological; 2) it is not too technically difficult; 3) it is almost without failure or side effects; and 4) patient acceptance is excellent.

My practice is located in a relatively small southern California city. Competition is fierce and one has to live with his patients. Encouraged by patient demand on the one hand and a new TA90 stapler on the other, I began gastric stapling procedures of varying types about four years ago. My results were so bad and patient acceptance so poor, that I was convinced there had to be a better way. At this same conference two years ago, I became intrigued with Dr. Scopinaro's thoughts and studies on what has been labeled the biliopancreatic bypass. I elected to do his Type 4 procedure because at that time it appeared to have the best results. The operation consists of a two-thirds gastrectomy done only to reduce acid secretion. I close the duodenum with a TA55® stapler. I put the TA90 stapler across the stomach and fold it in as everybody recommends with interrupted serosa-to-serosa sutures. Then I divide the small intestine in half and I suture the distal half of the intestine to the stomach. I suture the proximal end of the intestine to the terminal ileum 20 inches from the ileocecal valve. Scopinaro claims that, for the excessively obese, a 150-cm alimentary tract is successful in almost 100% of patients. I think a 50-cm common ileoconduit is very important. This creates a selective malabsorption syndrome allowing absorption of simple sugars, adequate protein, vitamins and bile salts, but does not allow digestion of fats or starchs. No diarrhea results. After the third postoperative week the patients are completely free of dietary restrictions. This makes them extremely happy.

Technically, the most difficult part of the procedure to perform is the retrocolic gastroileostomy. However, since the introduction of the curved disposable #25 EEA stapler, I have cut operating time by one hour and I am finally assured of a good anastomosis. I remove all vessels from the distal 5 cm of the greater curvature of the stomach using 2-0 Prolene sutures in that area and around the end of the small intestine. The EEA is introduced through an enterotomy about 4 inches from the cut end of the ileum. It is necessary to keep the gastroileostomy far enough away from the gastric closure so that the turned in stomach, particularly the corner, will not cover the stoma and cause obstruction. After firing the stapler, I leave it closed. At that point it becomes an internal retractor. I pull the anastomosis below the transverse mesocolon and suture the

edge of the rent in the mesocolon to the serosa of the stomach. Only then is the stapler opened and removed. The enterotomy is closed and the Roux-en-Y enteroenterostomy to the terminal ileum is completed.

The average six-month weight loss with no dietary restrictions is 45%. Average weight loss at one year in the first 11 patients is over 60%. Although oxylate excretions, as determined by Dr. Drenick, are high, neither Scopinaro nor I have seen renal stones or calcinosis in and our patients. We feel that this is because of the excellent hydration maintained by the patients. Some patients occasionally use cimetidine to relieve symptoms of hyperacidity. No ulcers have been demonstrated but since stomal ulcer pain radiates from the lower abdomen rather than epigastric area, it could easily be misdiagnosed. Any heartburn or discomfort of these patients is quickly controlled by cimetidine. Consequently, I assume they have untolerated acid. I did do five consecutive truncal vagotomies after reading the 1950 article by Storer and Dragstedt on the subject. However, postoperative gastric atony was a problem and two patients even today continue to have diarrhea. I have now abandoned the vagotomy in association with gastrectomy. I think a 50-cm common ileoconduit is very important.

I had one very interesting patient on whom I would like to report. The patient was a 37-year-old man with familial hyperlipidemia whose triglyceride and cholesterol levels ranged as high as 1200 mg/dl and 400 mg/dl respectively. His high and low density cholesterol levels were reversed from normal. Despite a coronary artery bypass of a 90% occluded left anterior descending artery, his angina remained severe. One year after arterial bypass, coronary angiography revealed extensive advances in small vessel disease and total occlusion of his right main coronary vessel. Repeat coronary artery bypass was not felt to be indicated. His cardiologist, who had heard about my work, proposed the Scopinaro bypass. The patient tolerated this procedure well. Three months later his palpebral and olecranal xanthomas, which had been like tumors, disappeared and his angina was subsiding. By the end of the first postoperative year, the patient had lost 96% of his excess weight, and he no longer had angina. His triglyceride levels were almost normal, his cholesterol was 165 mg/dl, and angiograms revealed that his coronary arteries were enlarging. Enlargement was so marked, as a matter of fact, that blood was seen flowing from the left anterior descending artery which had previously been 90% occluded. This almost unbelievable case is being published by his well-known cardiologist, Dr. John Vogel.

QUESTION: What do you consider to be markedly obese?

HOLIAN: I think 150% overweight.

QUESTION: How are you measuring 250 cm?

HOLIAN: I use an umbilical tape and I measure not as Dr. Scopinaro does along the mesenteric border, but along the antemesenteric border.

QUESTION: Is that 250 cm from the gastroenterostomy to the ileocecal valve?

HOLIAN: Correct.

QUESTION: How long does it take you?

HOLIAN: It used to take me between five and six hours but I have improved. Since I began using the EEA for the gastroileostomy, I can do almost everyone of them is less than four hours.

QUESTION: Do these patients have steatorrhea?

HOLIAN: Yes, they do have steatorrhea and for that reason the calcium binds to the fatty acids, releasing the oxylate for reabsorption. Therefore, the oxylate levels in their urinary excretion are high, but because their urinary volume is so good, there have been no kidney problems, nephrocalcinosis or stones during the seven years that Scopinaro and I have been following up these patients.

SCOPINARO: I want to thank Dr. Holian for trusting me and to congratulate him for his courage to be the first in the United States to start using the biliopancreatic operation. I only have three comments. First, I am happy you have enlarged the extent of your gastrectomies up to three-fourths. Second, I did recommend and am still recommending that cholecystectomy be performed routinely. If you don't do that, more than 80% of patients will develop gallstones. Third, as far as hyperoxyluria is concerned, I must say, Dr. Holian, you should have used healthy controls. Had you done that, you would have found about the same degree of hyperoxyluria in the healthy control patients kept on the same diet as in your patients. Our study on the urinary oxylate excretion was published more than one year ago in the International Journal of Obesity. Alan Hoffman in San Diego did the urinalyses and only one of 22 starved patients had hyperoxyluria to the same degree. When you and Drenick made me aware of that hyperoxyluria found in American biliopancreatic patients, I thought only the difference in dietary habits could explain that phenomenon. To demonstrate this I put seven normal weight, healthy patients on a high oxylate diet and sent the 24-hour urinary specimens to Hoffman and Drenick. They both had the same results. Regarding hyperoxyluria, there was no statistically significant difference between those patients on the high oxylate diet and those with biliopancreatic bypass.

We concluded that: 1) biliopancreatic bypass does result in excessive oxylate absorption; your patients probably had hyperoxyluria also before the operation and any normal subject taken and put on the same diet on the same oxylate intake would have more or less the same degree of hyperoxyluria; and 2) it is now evident that hyperoxyluria alone cannot account for the incidence of kidney stones after jejunoileal bypass, and therefore, there must be some other factor.

ROUX-EN-Y GASTRIC BYPASS
David K. Miller, M.D.

This presentation includes data from my series of 528 patients who underwent operative as treatment of morbid obesity at the LDA Hospital in Salt Lake City, Utah, between June 1979 and September 1981. These patients have all been followed up for at least six months. My entire series as of this date numbers 750 patients.

The patient profile is as follows:

Average age ....36 years
Average height ....64 inches
Average preoperative weight ......266 lb (2.2 x ideal)
Average hospital stay ....8.6 days
Average weight loss at 1 year ....99 lb (37% of initial weight or
                                          61% of excess weight)

The male to female ratio was 1:9. Eleven splenectomies (2%) were performed.

The procedure I use, Roux-en-Y gastric bypass, is done through a midline incision. It consists of constructing a 50 ml proximal gastric pouch by placing two applications of TA90® staples across the stomach while preserving the nerve of Latarjet and staying proximal to the first short gastric vessel. The stomach is divided between the staples. A Roux limb 50 cm in length is made 14 cm distal to the ligament of Treitz. The limb is brought up in front of the colon in nearly all cases except when the mesentery of the jejunum is too short. In those cases, it is passed through the transverse mesocolon. A hand-sutured, measured, 1.2-mm anastomosis is created between the greater curvature stapled edge and the jejunal limb.

Other procedures commonly performed simultaneously are umbilical herniorrhaphy and cholecystectomy. Approximately 28% of patients have required cholecystectomy either before, during or after gastric reduction operation.

Three patients had previous intestinal bypasses which were taken down at the time of gastric bypass. The operation can also be used in failed gastroplasty patients. The 99-lb average weight loss at two years represents a 37% average loss of total body weight or a 61% average loss of excessive body weight as per the Metropolitan Life Insurance tables.

Many other medical problems were improved by weight loss. One hundred sixty-five patients had a preoperative diagnosis of hypertension, 71 of whom required preoperative medications to control their blood pressure. At the time of this report only nine of these patients still required medication, and all were placed on a reduced dosage. Of the 62 patients no longer requiring blood pressure medication, the average blood pressure is now 123/77 mmHg.

Fifty-two patients had been classified as diabetics preoperatively; 18 required insulin or other medications for control. Only one patient continued to require medication postoperatively; and this patient's medication was reduced from 60 units twice a day to 10 units of insulin twice a day. Blood sugar levels in all these patients fell into the normal range after weight loss.

All patients who had symptomatic esophageal reflux preoperatively became asymptomatic by the third postoperative month. At the time of this presentation there were 17 pregnancies among postoperative patients. All deliveries to date have produced healthy infants. Five women who never were able to become pregnant or who had children but have been unable to get pregnant again during the past ten years, achieved pregnancy after weight loss.

Patients suffering from asthma, arthritis and Pickwickian syndrome also noticed improvement in their conditions. Many patients also felt more socially acceptable.

Injury to the spleen necessitated removal in 11 (2%) patients. Many of the complications arose from technical problems brought on by a lack of education regarding techniques and postoperative care. Six of the splenectomies were done in the first 40 patients. More recently, I have not had to perform a splenectomy in the last 300 cases.

Eleven patients developed leaks. Only one of these patients required reoperation to drain an infected hematoma. The other ten were successfully drained through CT-placed catheters. Leak continues to be the most dangerous enemy of this procedure. Proper awareness and prompt recognition of early symptoms and the use of the catheter have reduced the seriousness of this complication. These few patients required an additional seven to ten days of hospitalization. Three other patients developed subdiaphragmatic abscesses that drained spontaneously.

We have had no wound infections or eviscerations. We use prophylactic antibiotics and a closure consisting of running Prolene® placed in the fascia. In our early experience we used arterial lines but after several complications we discontinued this procedure. The Doppler® blood pressure cuffs have been very helpful.

Six of our patients developed marginal ulcers. I found that most of them were taking aspirin or anti-arthritic medicine. I now discourage the use of these medicines in all patients.

Only one patient has failed to lose an appropriate amount and maintain the loss. She lost 45 lb originally and then regained it.

Two patients died as a result of the operation. The first patient died of cardiac arrest after having developed septicemia. The second death occurred six

weeks after operation and was caused by pulmonary embolus. It happened the day the patient was to go home after a complicated course of infection, splenectomy, etc. She was not on heparin at the time, but we now routinely give all patients 4,000 units of subcutaneous heparin every eight hours and we have not had a single death from embolus since initiating this regimen. Two other patients had late small emboli from leg vein thromboses two and three weeks postoperatively. However, neither patient went on to develop serious pulmonary problems; one was treated with heparin and the other with coumadin.

Subsequent operations performed in these patients included the following:

Drainage of infected hematoma 1
Release of small bowel obstruction 2
Release of outlet obstruction 3
Panniculectomy 25
Cholecystectomy 14

All patients are studied preoperatively with oral cholecystograms and checked thoroughly during operation. The effect of the operation on gallstone formation is now being studied at some centers. These patients have an average serum preoperative cholesterol that borders on or exceeds the upper limits of normal; after operation, these levels fall to the lower limits of normal or below. This series shows a 3.7% incidence of subsequent gallbladder disease among those patients still at risk. This low incidence certainly would not justify prophylactic cholecystectomy.

In summary, I have presented 528 patients with a 50-cc proximal, divided, gastric bypass and a measured 1.2-cm Roux-en-Y anastomosis. They have had progressive and impressive weight losses with no tendency to regain weight. Diabetes, hypertension, infertility, arthritis, pulmonary insufficiency, social acceptance and self-worth are all improved or cured with a minimum of complications.

QUESTION: I am curious how you feel about the occasional marginal ulcers. Do you feel they are usually aspirin related?

MILLER: I have not had one in patients who have not been on aspirin. I put patients who have been taking aspirin on cimetidine and this corrects the problem. I discourage the use of any more aspirin.

QUESTION: Do you check for leaks routinely?

MILLER: I check for leaks only in patients who develop symptoms two or three days postoperatively. I have done routine gastrografin swallows two days after surgery in the past and found it to be a waste of time. I have likewise found that these patients postoperatively have normal laboratory values.

HORIZONTAL BANDED GASTROPLASTY

John M. Kroyer, M.D.

I begin my operative technique by freeing up the greater curvature of the stomach from about midposition all the way to the esophagus. Then, with a 34F dilator in the esophagus to identify the gastroesophageal junction, I make a window about 3 cm below, immediately adjacent to the lesser curvature. I use two rows of staples to divide the stomach.

Like most surgeons, I began using gastric bypass and then, after learning about the work of Cesar Gomez in late 1978, I switched to gastroplasty. I found that I had trouble with the Prolene stitch used to reinforce the outlet channel. After trying Marlex® mesh in dogs, I felt that from the histological standpoint it worked well, so I began to use it in my patients. I position it by placing a stitch posteriorly between the two ends of the staple line. Then I bring it to the anterior side and suture it to the front of the stomach. This is a banding of the outlet. Therefore, the procedure is called horizontal banded gastroplasty.

Because the stomach is mobilized along the greater curvature, it has a tendency to fall superiorly and posteriorly. When this happens the mesh may stick to something and the proximal pouch will fold over on itself, obstructing the outlet channel. This happened in two or three of my patients. Consequently, I added three sutures from the wall of the greater curvature of the stomach to the parietal peritoneum in order to fix the stomach in a more normal configuration. Since adopting this technique, the problem of obstruction has been minimal.

When one develops an operation that is a little different from the standard, we always have to prove at least two things: 1) that it is safe and 2) that it works. The development of this procedure was accompanied by the typical learning curve. There were 29 complications in the first 110 patients. I now have 300 patients, 200 of whom have a minimum follow-up time of at least one year. There has not been evidence of a leak or perforation or intraperitoneal abscess in any of these patients. There has been only one death in this series. It was not related to the type of the operation but rather to an episode of hypoxia. I believe that this series of patients proves that horizontal banded gastroplasty can be done safely.

When we operated on our earliest patients (a group of 79), we weren't thinking as strongly about the size of the pouch as we are now. Consequently, weight loss was not consistent.

The next group of 33 patients again served to demonstrate one problem of the big pouch. In 1979 when I first began doing these operations, it seemed to me that the patient weighing 120 lb and standing 5 feet 7 inches tall ought to have a different sized stomach than a patient who weighs 200 lb and is 4 feet 10 tall,

but I was wrong. The idea of making a slightly larger pouch in a lighter weight patient will not work. Instead of using volume and pressure as guides to pouch measurement, I try to make the vertical dimension of the pouch 3 cm and the horizontal dimension, 8 cm. These measurements give a 50-ml spheroid.

After the first 60 patients, I finally learned, as most everybody had already learned, that big pouches yield poor weight loss, so I started making only the 3-cm pouches. The weight loss pattern immediately improved. By 1980 I had standardized my method of measuring the pouch, and I began turning attention to the outlets. I concentrated on trying to make a 12-mm outlet by removing only five staples instead of six from the TA90, that is, two staples from the first row and three from the second. I found that this size opening would admit a 34F bougie. If the channel seemed a little large, I could easily add a stitch on the end of the staple line. This extra care in trying to assure a uniform channel size again produced more consistent weight loss.

I reviewed my first 133 patients and found that I had reoperated on a few because the mesh had come loose or had stretched in some places. Consequently, I changed the size of the mesh from a width of ¼ inch to ½ inch. I also put a tail on either end so that I could anchor the mesh better. The last change that I made in this series of 200 patients was to insist that they remain on liquids and soft foods for the first three postoperative weeks. The purpose of this was to allow time for fibrous tissue to develop around the mesh and in the area of the staple lines.

We have talked about weight loss goals ranging from 50% to 100% of excess weight; I even heard of one modest series with 20% of initial weight as a goal. It seems that no matter what the patients weigh initially, in a given period of time and with the same operation, they all lose about the same amount in terms of percent of excess weight. There is, however, some degree of variation for which we must try to find an explanation. Printen and Mason told us a long time ago that people over 50 years old generally don't do as well because they are less vigorous. Perhaps when we are talking about results we should think more in terms of energy output rather than caloric intake.

By taking into consideration these and other differences among patients it is possible to develop an equation that will roughly predict how much a given patient will be likely to lose. After determining this amount, the patient can then set his or her weight loss goal. Seventy-five percent of my patients will reach their goal. Nevertheless, I have not been completely satisfied, and recently I have adopted Mason's idea of creating a window with the EEA® stapler so that the Marlex mesh reinforcement can be placed outside of the stomach and sutured only to itself.

QUESTION: Why did you start using Dr. Mason's EEA technique?

KROYER: My weight loss failure rate was running in the neighborhood of 18%. I felt that was too high.

QUESTION: Do you turn any patients down because they are "sweetoholics" and constantly consume large amounts of sugars?

KROYER: No, I don't. From the approximate 800 patients in which I have performed some kind of bariatric surgery, I have learned very little in regard to how to predict ahead of time who will be a good candidate. I do not want to set myself up as judge. I have consistently been proved wrong when I've tried to prejudge a patient.

QUESTION: Do you use a double application of the stapler? Have you noticed any disruption of the staples?

KROYER: I thought everybody had solved that problem a couple of years ago by adopting double staple lines, and I haven't seen any disruptions for a long time. But, again, in this battle against the patients tremendous drive to eat, it seemed to me the weakest point in the operation was the staple line. When we doubled it, there were less disruptions. Then we had a channel that became weaker and the channels began to stretch. Now we are reinforcing the channels and they are not often dilating. Some of the pouches were stretching, so we have reacted by making smaller pouches to make stretching more difficult. And, sure enough, in the last eight months I have seen three or four more staple line disruptions. Apparently the staple line is again the weakest point. It may be that, by making the EEA type of connection and isolating the space between the staple lines, one can expect the mucosa of this space to disintegrate and be replaced by collagen fibers. That may give us a stronger staple line, stronger than two lines would be and the scar would be as wide as the separation of both lines.

GASTROPLASTY WITH MESH REINFORCEMENT

D. Michael Grace, M.D.

In gastroplasty the size of the stoma has always been of concern. There was worry a few years ago about strictures being caused by wrapping of the greater curvature or any stoma with Marlex mesh or other mesh materials. For the last three years I have been using such a procedure. In the first 50 patients there were no problems whatsoever, but more recently some problems have been cropping up. I still feel it is a reasonably good procedure which I am continuing to do and with which I am satisfied. Dr. Kroyer's technique of suturing down the greater curvature of the stomach may well improve my results.

My work was carried out at the Western Ontario University Hospital. We have residents but I do the operations myself because I think consistency is important for results. Our maximal referral distance is about 120 miles. This allows for monthly follow-up visits which I also do myself with our dietitian. Postoperatively, I choose patients who are more than 100 lb above ideal weight, usually between 20 and 50 years old. The preoperative investigation is minimal although we do a number of research investigations for which we hope to gather data over the next several years. We do not accept patients who smoke.

I perform the operation through an upper midline incision. There is minimal mobilization of the fundus and no division of vessels on the lesser curvature. I use a red rubber catheter to guide the the TA90 into position across the stomach. After positioning the stapler I place a double application of staples. The horizontal pouch is small (< 100 ml) but unmeasured. I use a 6 x 2-cm strip of either Marlex, polypropylene or Prolene mesh to wrap the greater curvature stoma. This material is quite inert although I can verify that after a few days it adheres to the stomach. I pass a 2-0 Prolene suture through the mesh and the back of the stomach at the end of the staple line. The suture passes completely through the stomach and is tied down on top of the mesh on the anterior side. The Prolene suture penetrates the mesh 5 mm from each end; therefore, the circumference of the stoma is in fact 5 cm. This gives an internal diameter of approximately 1.2 cm.

My first nine patients had only one staple line. I stopped using the single staple line because of an experience with a patient who had a prophylactic gastroplasty after kidney stones obliged takedown of a small bowel bypass. As Dr. Mason has pointed out, such patients tend to eat too much, and they don't heal as well. This particular patient overate, disrupted his single staple line and gained weight. Subsequently, I began using the double application of the stapler and have had no further staple line disruptions.

My group of patients with two staple lines averaged 295 lb preoperatively. At 18 months, weight loss is about 33% of body weight. Unfortunately the number of patients with long-term follow-up is small. There is a suggestion that some patients may begin to regain with time. This may be partially due to the fact that I am not making the pouches quite as small as some, and I may have to pay more attention to that. Overall the weight loss has been quite acceptable. No patient with two staple lines has lost less than 15% of initial weight, and, in fact, all but one has lost more than 20% of body weight at one year.

In regard to complications my key concern is obstruction. When obstruction occurred it seemed to be caused by a kink or rotation. That's why Dr. Kroyer's suggestion of fixing or sewing down the stomach may be a very useful one to me.

There were no early obstructions in the first 50 patients. Since then there have been four, surprisingly, all but one in men. One of our radiologists used a Grunsey catheter to dilate a strictured gastrogastrostomy in the only female patient who had an obstruction; since then she has done well. The three men who developed early obstruction all had other problems. One had cirrhosis and esophageal varices at endoscopy although we did not recognize portal hypertension at operation. He developed obstruction at three weeks. A second man had a duodenal ulcer and in retrospect I might have been wiser to have performed vagotomy and pyloroplasty rather than gastroplasty. The third man had very extensive keloid formation and may have had a healing abnormality. None of these obstructions was complete. All these patients had 4 to 5-mm stomas and were getting fluids down but vomited excessively. Some colleagues have urged me not to reoperate too early on these people, but rather to support them with jejunostomy or gastrostomy and wait it out. Nevertheless, dilatation of the Marlex mesh is difficult.

The two late obstructions were again incomplete. The stomata would take a pediatric gastroscope and barium would empty, but the patients continued to vomit. These obstructions developed more than a year postoperatively. In one patient the staple line had lifted vertically and the opening was sitting quite high on the gastric fundus. Fluid was pooled in the lower pocket along the lesser curvature. It was a question of pooling in a large pouch which was dragging on the stoma rather than organic obstruction. Both patients had gastrogastrostomies. If I were to revise them today, I might prefer to do a Roux-en-Y.

There have been no deaths in over 130 patients. Only one patient developed a leak. The patient had left lower lobe pneumonia and postoperative fever. I suspected a leak and ordered roentgenographic studies. Although these studies proved negative, I still chose to reoperate. At operation we could not find a hole but the patient clearly had a leak. The area was drained. I felt the Marlex

mesh might act as a foreign body and took it out. The patient did well with no fistula development, although late weight loss has been unsatisfactory without the Marlex reinforcement.

One woman had a postoperative liver abscess. She came back a month after operation with high fever. A CT scan confirmed the diagnosis. She had no leak or other intra-abdominal problem. We operated to drain the abscess, and she did well after losing 80 lb in a year.

A 31-year-old, 310-lb man had weak ischemic changes in both legs. His angiography showed a common iliac embolus in one leg and a popliteal embolus in the other. There were no apparent pulmonary emboli. He had a thrombectomy and ended up losing just the tip of his little toe. There is still some question as to what happened. He was on subcutaneous heparin, he had no left heart source for his emobli, either from left atrium or valve, and no evidence of infarct. He perhaps had a paradoxical embolism. After embolectomy he went on to lose 110 lb by the end of the first postoperative year. He is also able to walk with no claudication or other problem.

In conclusion, I am going to keep doing what I am doing although I am here to learn. I might add that one of my pet projects is to emphasize the importance of exercise and emphasize the example that we must set to our patients.

QUESTION: How many staples do you remove from the cartridge? Do you use a bougie for the channel?

GRACE: Like Dr. Kroyer, I remove three staples from the longer row and two from the shorter row, five staples in all. I have not used a bougie. I use the length of the Marlex mesh to calibrate the size. This seems to be pretty consistent although the amount of stomach bunched underneath may effect the stomal size.

QUESTION: Do you use an NG tube in the distal pouch?

GRACE: Yes. We cut extra holes in the tube so that holes lie above and below the staple line. In fact, it is put through the opening before I wrap it with Marlex mesh.

EVOLUTION OF GASTRIC PARTITIONING

Edward W. Martin, M.D.

I am going to summarize the Ohio State experience to date and suggest where we are going. We started performing our horizontal, mid-stapleline outlet gastroplasties using the TA55 stapling apparatus. It was the easiest instrument to use, and it had the advantage of forcing us to make a small pouch. But our data from patients in whom we used this technique show that with time, the patients will all be eating again and will regain their weight. Consequently, we no longer recommend the use of the TA55.

We thought that at least a partial explanation for the failure of the TA55 apparatus was due to bunching of the stomach leading to a larger stoma. We began using the TA90 and the data were only slightly improved, 10% to 20% weight loss. The patients were all disrupting their staple lines. We then went back to the laboratory. We studied the strength of the staple line and how long it was necessary to wait postoperatively before we could start feeding the patient. We thought that if we kept patients on liquids for eight weeks before introducing solid food, we would have a better chance of not seeing disruptions of the staple line. Indeed, we eliminated our early disruptions but we knew from our data that there were patients failing at two to four weeks postoperatively and also patients failing around five months. The problem of late staple line disruption still had to be solved.

We then turned to the double row, TA90 stapling apparatus. With this technique and a liquid diet for eight weeks, our patients are achieving about 20% weight loss. Hearing how well others were doing, we decided to look back and analyze our data at six months, 12 months, 18 months and 24 months. We had 206 patients that we could evaluate with pretty good data retrieval. Weight loss at six months averaged about 20% of body weight. This loss was maintained but did not improve at 12 months. In fact, some patients had regained weight. Nevertheless, the approximate 20% weight loss has been maintained out to 24 months. Our weight loss curve is typical. The average patient loses for the first 12 months, and then reaches a plateau. Some patients will regain a little after that point, although very few of them who don't disrupt early, regain all of their weight.

We had to reoperate on 15% of our patients. I actually went through a period in this project during which I thought this was like diverticulitis requiring staged operations. The first operation would produce 60 to 100-lb weight loss which would leave most patients somewhere around 180 to 190 lb, still fat and chubby and not happy. A second operation would get them down below 150 lb.

We have had a consistent 16% morbidity. We have about one death in every 100 patients. We have lost track of 8.3% of our patients.

I am concerned about how we evaluate success. I think we should use the criterion of whether or not the patient's health hazard owing to obesity has been significantly reduced. We ought to analyze our data a little better and see how many are still at high risk of dying at an early age. Seventy percent of our patients have reduced to a weight that will probably not cause untimely death and they have been able to stay there. Nevertheless, we have not seen very many beauties who made it down to 120 or 130 lb.

In many of our patients the stomas have enlarged. Some surgeons, like Dr. Chiari at Ohio State, want to figure out a mechanical way to prevent stomal dilatation. I prefer to work closely on a monthly basis with these patients and not to try to mechanically solve the problem. I simply do not allow the patients to eat. I attempt to select better patients who will try hard to stay on total liquids until reaching goal weight. Preoperatively, I make them establish a weight at which they will be satisfied. I believe this is helpful psychologically. I have had one patient who only lost 12.7% of her weight by 12 months. But in general, most of these patients have done well and are now seeking for body contouring. Therefore I conclude that taking solid food away from the patients will be very successful.

In spite of my relative success with these patients, I wanted to determine whether there are any better procedures and if there are, why this is so. Consequently, we stopped doing our procedure for a while, and we tried to gather all the data at Ohio State to see where we have been and where we perhaps might go.

As a result we have now established a very strict protocol for our patients. Part of this protocol involves work in the clinical research center where we are looking at all of the gut hormones. We also continue to do the routine laboratory work.

Our patients continue to have gastric partitioning with a stoma in the middle of the staple line. They are then placed on liquids only until they reach goal weight.

I feel it is absolutely necessary not to allow my obese patients to eat. Once you let them eat, they are going to out-eat the procedure. An enforced liquid diet is just another barrier. I think every single barrier you can put in front of these patients is going to lead to a little more success. And, frankly, I have had so little success, I have got to keep on trying.

Postoperatively all patients will undergo endoscopy to allow examination of the stoma. All will have upper GI films at six months and 12 months. I think all

patients should be seen every month for the first year, and at least every other month during the second year unless they have reached goal weight. Once they attain goal weight follow-up visits can be spaced farther apart.

I know that the ultimate goal is to make all of these patients thin, but I just don't believe I can do that at this time. Perhaps we will find a better method of patient selection and matching to whatever procedure will work for the individual patient. We need a definite commitment from the physician, the patient and from everybody associated with the project.

QUESTION: Since satiety does not last long on a full liquid diet it seems that the patients might be getting too many calories. Don't you think that a full liquid diet is a mistake?

MARTIN: Studies in rats have shown that the rat will eat dry food excessively; but if the food is moistened and mushy, the animal won't touch it. When we say liquids, we really mean pureed foods, food that in itself is anorexic. Again it is just another barrier. The patient can't eat without a blender. But you are right. They can beat the operation. They can beat anything we do to them. I think that has been said before.

QUESTION: Have you tried some of the protein-sparing liquids?

MARTIN: We have tried to stay to a diet balanced for proteins, fats and carbohydrates.

QUESTION: Have you run into any psychological problems with your patients being on a liquid diet?

MARTIN: All of them have problems.

QUESTION: What do you do about it?

MARTIN: I sit and listen to them. That is why I do so few patients. One a week is enough.

QUESTION: Do you have follow-up information on those patients who did reach goal weight? Do they stay at goal weight or do some eventually begin to regain their weight?

MARTIN: We have had very few patients that have made it to goal weight. But the ones that do, develop a very different body image. In general, those that reach goal weight, don't gain their weight back.

QUESTION: Anyone can lose weight on liquids but when you take them off they gain the weight back. If your gastric partitioning doesn't work in the first place, why should it work a year later when the liquid diet is discontinued? Obviously they can't spend the rest of their lives on a liquid diet. You say that you know gastric bypass works better. Why don't you just do gastric bypass and do research on that?

MARTIN: If the patients wait a year before eating solids they give their stomas plenty of time to heal and form scarring. When they go from liquids to solids, they will vomit. The gastric partitioning will work for about six months. But if the patient wants to beat it, he will. In regard to the second question, I would prefer to find a procedure that does not bypass the duodenum. I would like to try to figure out a way to keep the GI tract in continuity.

GASTROGASTROSTOMY

Richard I. MacArthur, M.D.

Our series at the University of Kansas includes 154 patients. We have actually done 174 gastrogastrostomies but 12 were done in conjunction with a small bowel bypass takedown and eight were done as a revision of a previous gastric operation for morbid obesity. Therefore, they have been excluded from the study.

Our patient selection process is standard and similar to that of most other surgeons. Patients must be twice ideal weight according to the weight table of the Metropolitan Life Insurance Company. We also do preoperative psychological evaluations.

Our preoperative evaluation is fairly simple. We discuss with the patient the history of their obesity, then talk about their diet. We have a dietitian see all of the patients preoperatively and on every follow-up visit. We discuss the family history and find out if they have any medical problems that need to be evaluated. If they do have a significant problem such as congestive heart failure or pulmonary insufficiency, it is managed prior to surgery. We do not spend a lot of time testing these patients preoperatively. We do a routine blood screen, an EKG and a chest x-ray. In the early 1970s when we had just begun our series we routinely admitted patients for extensive preoperative studies. We found that this was a waste of money which produced no significant results.

The psychological evaluation that we use consists of the Minnesota Multiphasic Personality Inventory and the Simple Institute of Living test. Our psychologist has now given this test to about 400 patients and she is getting pretty good at telling us on whom not to operate. She can't tell us with certainty who will do well with the operation, but she does feel she can tell us which patients will to do badly.

Preoperatively we have all of the patients take a Betadine® or pHisoHex® shower. We give them prophylactic antibiotics. We have stopped routinely heparinizing patients. We found no benefit from such a practice. All patients receive a Betadine prep preoperatively.

Eighty percent of our 154 patients are women. The average age is 35 years. The average weight is about 218% of ideal for the men and 213% for the women. The length of stay averages eight days.

We mobilize the fundus of the stomach and place the TA90 across it. We always try to preserve the upper vessel on the lesser curvature side. We apply the stapler twice so that we have four parallel rows of staples, creating about a 60-ml pouch. Using the cautery we create a 1-cm opening in the proximal and distal pouches and then hand sew a two-layer silk gastrogastrostomy. The nasogastric tube is passed into the distal pouch during suturing of the

gastrogastrostomy in order to avoid sewing the outlet shut by accident. Average blood loss is not very great and only five patients have received blood transfusions.

The operation lasts about two hours. The residents do about 80% of the procedures although the attending surgeons are always in the room. Eighty-one percent of the patients are extubated by the time they leave the recovery room. Only a few patients are intubated overnight. We keep almost all the patients in the intensive care unit (ICU) the first night. We do this primarily because of a nursing shortage on the other patient care units. I feel a lot more comfortable knowing that these rather large patients remain overnight in the ICU where they can get the initial good pulmonary care that they need.

Interestingly about 25% to 30% of patients undergo some additional operation. The most common thing we have done is cholecystectomy. Another interesting fact is that we have managed to save at least four injured spleens by using Avitene® and local pressure. I believe this is a real step forward.

We have had one death in the series a 47-year-old woman weighing 300 lb who had a history of pulmonary hypertension and congestive heart failure. The cardiologists thought that the operation would benefit her. Unfortunately she developed pulmonary sepsis and acute renal failure, and died postoperatively.

Our overall complication rate is about 17% and includes the usual pulmonary infections and so on. Our wound infection rate is 2%. Only about ten patients (6.5%) have stayed in the hospital an increased amount of time. Two of those were patients with leaks. Interestingly, both had gone home and then came back, one at two weeks and the other at three weeks, with symptoms of leak and abscesses. Both patients were treated with simple drainage and they recovered without further complications.

Our late complications include eight staple-line disruptions. We have had to take down the operation in three patients because they couldn't tolerate it. The psychologist had recommended that all three of these patients be turned down. I did them anyway, and learned my lesson.

The weight loss at three months averaged 14.5% of the original weight; at six months, about 20%; and at 12 months, 28.4%. I believe follow-up visits are very important for these patients. I try to see them once a month for the first six months, every two months to the end of the first year and then at least every three months to the end of the second year. I don't think that any of us have a miracle solution to the problem from which these patients suffer. It is critically important to have a team effort with these patients. We have the dietitian see the patients routinely. We have the psychologist available to work with the patients who have additional problems. We try to encourage everybody to

increase their level of exercise after they have had the operation. It takes a lot of support from everybody, family, friends and their physician, to get a satisfactory result.

QUESTION: To what do you attribute the disruption of the staples?

MacARTHUR: Of the eight patients who have disrupted, five had double rows and three of had single rows of staples. Statistically, there is a higher chance that the single row or application will disrupt. We prefer the double row and we think it is better.

QUESTION: You reported one postoperative bleeder. Could you explain?

MacARTHUR: That was in a patient who had a clip come off in the splenic hilum. It had to be repaired at a second operation.

QUESTION: You reported 28% weight loss at the end of one year. What are your results at two and three years? Is there any sign that the gastrogastrostomy is widening?

MacARTHUR: In the patients that I can tell you about at two years, we have not seen a significant change. We have a relatively small number at two years so I haven't reported that. In the patients that I have followed up for two years, the weight loss has been constant.

QUESTION: You mentioned gastritis, what do you think the cause of it was?

MacARTHUR: I am not sure. We only had the one patient who had a very severe case of gastritis. The gastritis developed just distal to the staple line and the patient had significant bleeding. We resected that part of the stomach and created a divided-stomach gastrogastrostomy. Since then the patient has had no problems. I have no idea why this occurred. We tried to manage it with Tagamet® and antacids but it was just unmanageable.

QUESTION: You stopped doing the upper GI in your series because you felt it was not productive. Aren't afraid of missing a diagnosis of a gastric cancer?

MacARTHUR: You can do upper GIs in 100,000 of these patients and you will never find a gastric cancer. None of the people who have done upper GI workups on these patients have every found anything significant. These are young, healthy, obese patients in whom the upper GI series is just not cost effective.

QUESTION: Do you have problems with stenosis after gastrogastrostomy?

MacARTHUR: We have had two patients that developed stenosis that required revision. We have in both instances tried to dilate the stenosis using the endoscope. We have now moved our anastomoses from the lateral to the medial edge of the stomach thinking that this should make it easier to dilate a stenotic stricture.

QUESTION: Why did you have to take down the operation in two patients?

MacARTHUR: The patients presented with repeated hospitalizations, vomiting and an enormous number of somatic complaints. Eventually they in essence demanded that the operation be taken down.

QUESTION: Did the staple line failures occur early or late?

MacARTHUR: The average time was about eight or nine months after operation.

COMPARISON OF GASTRIC BYPASS AND VERTICAL BANDED GASTROPLASTY

Edward E. Mason, Ph.D., M.D.

The Roux-en-Y gastric bypass seems to be about the best operation that we have, but it is complicated and it certainly changes the anatomy and physiology. It would be nice if we could find some way to solve the problem of overweight without making such a radical change. For this reason we keep coming back to various forms of gastroplasty. The removal of three staples from the cartridge has been a very attractive procedure because of its simplicity but everyone has had problems with this. One basic requisite of the stoma is that it not be in line with the staples. Stapling in continuity made gastric bypass simpler, but in gastroplasty if the stoma is in the staple line, it tends to unzip.

In 1979 it became apparent that the Gomez-type gastroplasty with its reinforcement of the stoma would eventually fail because the Prolene suture cuts through and gets lost in the lumen. This was true of any reinforcement material that penetrates the stomach. I began searching for ways of reinforcing the stoma without putting the reinforcement material through the wall of the stomach. This led first to a divided stomach, horizontal gastroplasty, and then to stapled, horizontal gastroplasty with a window near the greater curvature stoma through which to place the reinforcing band. I banded with different materials and had difficulty with infection which I attributed to inevitable contamination of the field. A lot of dissection was necessary and the greater curvature and fundic portion of the stomach is somewhat thin-walled and stretchable. I simply had too much difficulty on the greater curvature. I decided, therefore, to move the stoma to the lesser curvature.

Tretbar presented a similar operation as a fundic exclusion but didn't feel any need to reinforce the outlet. I have not seen data about weight loss that would indicate that this kind of pouch will work without some kind of reinforcement of the outlet. My solution was to create a vertical pouch with a window near the lesser curvature through which to pass the banding material. I call this vertical banded gastroplasty.

Each variation in procedure produces a characteristic weight loss pattern. The 1971 gastroplasty is the worst operation in our series. The best ones are the gastric bypasses, either loop or Roux-en-Y. The other procedures fall in between. When we compared vertical banded gastroplasty with gastric bypass we saw essentially the same weight loss at six months. I feel this operation proves that it is not necessary to bypass stomach or duodenum. If a small measured pouch and a secure partition are guaranteed, and if the outlet is the correct size, the long-term weight loss will be satisfactory.

An additional factor in determining the success of an operation is the rate of revision. We have used an actuarial type of analysis to compute the survivorship of the operation. We found we were reoperating on 15% per year of patients who had horizontal, banded, greater curvature gastroplasty. The Marlex banding material was cutting into the stomach and causing obstruction. It is interesting that whatever the revision rate is for the first few years, it seems to continue. If you have a bad operation, it stays bad. If you have a good operation, it stays good. Therefore, it is a good idea to calculate revision rates per year and examine them carefully. They indicated even within the first six months and certainly within the first year, whether the operation is good or bad. That is why we dropped gastroplasty in 1971. We could see by the end of the year that it was not a satisfactory procedure.

Although at this point we have no long-term information on vertical banded gastroplasty, of the first 83 patients done over 18 months, not one has had revision. If an operation can produce weight loss equal to gastric bypass without revisions, it must be considered seriously.

In reviewing our mortality rate with these different procedures used over the past 17 years, I am shocked at how high it was initially, (as much as 6%) while treating a condition that many refused to consider as a disease. The 1971 gastroplasty, however, did not carry a high mortality. Much was done to reduce mortality for gastric bypass patients. Fortunately, the low mortality of the 1971 gastroplasty remained the rule for the more modern variations of the procedure. With vertical banded gastroplasty, only one patient has died, the cause was pulmonary embolus. This patient was unusual in that he had a history of pulmonary embolus and a previous intestinal bypass taken down. We have not had any patients die of problems with the vertical banded operation per se. Consequently, I believe the procedure can be quite safe.

Vertical banded gastroplasty is a very simple procedure. One of the problems it avoids is the difficult positioning of the nasogastric tube. In a horizontal pouch the tube must bend and may rest in a position pressing against the wall of the stomach. This can cause erosion of the stomach wall. The problem of acute dilatation of the excluded stomach resulting from inadequate decompression is also avoided.

Regardless of the type of procedure, it is important to measure the pouch. Many surgeons claim their pouches are 50 ml, but they don't say at what pressure they measure them. Often these are merely estimates. One cannot look at the anterior wall of that pouch and know how big it is. The posterior wall may balloon out greatly. With actual measurement of volume and pressure it is easy to end up with pouches that are the correct size.

The advantage of vertical banded gastroplasty is the separation of the stoma from the partition. Another advantage is the careful calibration of the stoma by accurately mesauring the circumference of the Marlex band. Stomal trauma is also avoided except for a small area around the window where there are some staples. Nothing is sewn into the wall of the stomach. The stoma is the correct size to begin with and remains the correct size and as a result of that early obstruction rarely occurs.

QUESTION: What distance do you place the anvil from the Ewald tube?

MASON: The anvil is put next to the Ewald tube but not so snugly that it pulls the stomach tightly around the tube. Ideally at the conclusion of the procedure the collar of Marlex will be filled. It should neither appear pleated like an accordion nor be too loose. The anvil is placed in the lesser sac up against the posterior wall adjacent to the indwelling 32F Ewald tube.

QUESTION: Is the chance of pouch stretching decreased by having a lesser curvature vertical configuration? The stomach wall seems to be thicker. Do you find that true? Have you investigated this?

MASON: Dr. Kridelbaugh told me he has been using barium thickened with bran to measure volume at six months. In the ten patients studied so far he has seen little change in the volume. I believe there is less stretching, at least in part, because the outlet is not obstructed. Nature designed the fundus to stretch; it may be a mistake to use the fundus for the pouch. Of course, we did use fundic pouches over the years because they are an analog of gastric resection. With gastric resection surgeons always positioned the stoma on the greater curvature. We merely followed suit. But Tretbar showed us that you could use the vertical pouch.

QUESTION: Have you used a radiolabel or radiomarker on the Marlex? How many people have ended up stretching that channel by one year?

MASON: We don't use a marker although is a good idea. As yet we have not seen stretching. It isn't possible with the Marlex.

QUESTION: Can you add a Nissen procedure to vertical banded gastroplasty in patients with gastroesophageal reflux?

MASON: I have added a Nissen on two occasions, but I am not sure that it is needed. The procedure is similar to a Collis gastroplasty, and may be an antireflux procedure itself.

COMPARISON OF GASTRIC BYPASS AND GASTROGASTROSTOMY

L. Michael Howell, M.D.

An obesity operation is a great help in weight loss, but the patient must also have a strong motivation to lose. The operation is elective, therefore, adequate preparation is always possible. A simple test to see if the patient can hold his/her breath for greater than 30 seconds is a good indication as to adequate pulmonary function. The patients must stop smoking for a minimum of three weeks prior to operation. My insistence on adequate pulmonary function is a significant factor in having no operative deaths in over 800 operations. With good preparation, patients infrequently need to be in the intensive care unit postoperatively. Thus, their hospital bill is, I think, reasonable. The usual hospital bill this last year has averaged $2,600.

In the preoperative evaluation, an oxygen consumption test is done to correlate the patient's resting caloric metabolism with their history. In other words, a high oxygen consumption does correlate well with a patient's ability to lose weight faster than patients with a low oxygen consumption rate. This helps explain why men lose weight much faster than women.

My technique is described in Surg Gynecol Obstet Feb 1982, pp 225-256. With both operations, I take the upper one-half of the greater curvature vessels including the short gastrics, up to the fat pad adjacent to the esophagus using mainly the LDS[®] instrument. This allows excellent mobility to staple high and also to swing the upper pouch caudally so that the mesocolon can be stitched to the anastomosis, thus preventing afferent limb obstruction. A double firing of the TA90 is placed to give a 35 to 50 ml pouch. Then a retrocolic loop gastrojejunostomy is performed.

With the gastric bypass the stomach opening is placed posteriorly, transversely, and near, but not on, the greater curvature. The 11 to 14-mm, handsewn anastomosis consists of running 3-0 Vicryl[®] for the inner layer and interrupted 3-0 silk for the outer layer. In addition, 1-0 Prolene is very loosely stitched around the completed anastomosis and tied over a 16 Hegar dilator to prevent long-term dilation of the stoma.

The mescolon is fixed to the anastomosis with interrupted sutures. The end of the nasogastric (NG) tube is placed into the afferent limb through the anastomosis. The upper gastric area is drained with a number 19, round, Jackson-Pratt drain for five to six days postoperatively. Venadyne[®] boots or very low dose subcutaneous heparin are used to ward off embolus.

With the gastroplasty-like procedure, a gastrogastrostomy is placed in the middle of the anterior stomach adjacent to the double stapled row. The

anastomotic technique is the same with both the gastrogastrostmoy and gastric bypass procedures.

This year I began using circumferential 1-0 Prolene with the gastric bypass operation because I have had late failures (four and five years postoperatively) owing to excess stretching of the anastomoses. Without the Prolene, the anastomosis commonly stretches to 20 to 30 mm in diameter and, in most patients, this does not allow weight regain because of dumping syndrome. However, in a few patients, the jejunum adapts and these people have regained most of the weight lost. If the stoma does not stretch beyond 20 mm in diameter, the severe weight regain will not occur.

We have known for at least three years that with the gastrogastrostomy the anastomosis must be fixed in a rigid fashion so it can never expand beyond 14 mm in diameter, thus, the circumferential Prolene suture has been used in all these gastrogastrostomy cases. However, it has not been used in any of these gastric bypass patients.

Because of the normally good preoperative preparation, postoperative care is generally not complicated. The NG tube is usually removed on the second or third day after operation. We give the patients water on the fourth postoperative day, clear liquids on the fifth, and a special 600 calorie diet on the sixth postoperative day. We discharge the patients on the seventh or eighth day. For the first three to four weeks the diet is intentionally kept to soft foods. The gastric bypass patients are routinely placed on vitamins with iron, and we check serum iron levels at half year intervals for the first years.

Analysis of data from the first 350 gastric bypass (GB) and 150 gastrogastrostomy (GP) patients was carried out. An analysis of postoperative complications was performed using the chi-square test procedures and Yate's correction. The incidence of postoperative complications between operations was deemed significant if the p value was less than 0.05.

The postoperative complications are listed on Table 1 and the significant differences are indicated by an asterisk. Iron deficiency was very common, particularly in menstruating women. Most of the time, this is resolved with oral iron preparations, usually ferrous gluconate. One patient required a hysterectomy because she could not tolerate her slightly increased menstrual flow. All but two of the stomal ulcers healed with medication; the two that did not were converted to a gastrogastrostomy with good results. Afferent loop obstruction has not been a problem since we have been able to successfully suture the anastomosis to the mesocolon. The sickest patients I have had were those with intra-abdominal abscesses, and they all required reoperation and a prolonged postoperative course in the intensive care unit.

Table 1: Postop Complications

	Gastric Bypass	Gastrogastrostomy
Number of cases	350	150
Wound infection	3%	2%
Intra-abdominal abscess	2%	0.6%
Leaks or death	0	0
Pulmonary emboli	0.5%	0.6%
Afferent loop obstruction	0.8%	0
Pneumonia or atelectasis	2%	1%
Stomal ulcers	3.4%	1.3%
Staple failure	2%	3%
Iron deficiency*	40%	5%
Mild B12 deficiency*	3%	0
Reactive hypoglycemia	1.1%	0
Stomal obstruction*	0.5%	4.6%
Symptomatic bile reflux	3%	0
Mild temporary hair loss*	70%	35%
Ventral hernia	5%	3%
Revision rate*	3%	20%

*Statistically significant

I believe in excellent operative exposure, gentle handling of the epigastric pouch, never pulling on it, and never clamping it. I don't place any traction on it or on the esophagus. As a result, I have not had any leaks, perforations, or operative deaths (in over 800 cases to date). However, one 53-year-old woman had a cardiac arrest and died six weeks after discharge.

Divorce is relatively common among my patients. Alcoholism has also been a late problem for many male patients.

We had to remove seven spleens in the first 500 cases. There were four cases of significant superficial phlebitis, three cases of intraperitoneal hemorrhage, five cases of small bowel obstruction, and nine cases of staple failure.

Mild B12 deficiency is usually handled with injection of Cobalamed® at regular intervals. Stomal obstruction has been a problem with gastrogastrostomy patients because we have purposely made the anastomoses in the range of 8 to 12 mm in diameter, rather than 11 to 14 mm as with the gastric bypass patients. Mild temporary hair loss is more common with gastric bypass. This reflects the fact that the patients lose more weight at a significantly faster rate than the gastrogastrostomy patients (Table 2). This leads to some mild temporary protein malnutrition. The revision rate is much higher among gastrogastrostomy patients, mainly because there have been substantially more patients unhappy with their

Table 2: Weight loss

	Gastric Bypass	Gastrogastrostomy
Number of cases	350	150
Average preoperative weight	280 lb	270 lb
Average preoperative height	5'4"	5'4"
Weight loss in lb (% of preoperative weight loss)		
One year postoperative	98 (35%)*	67 (25%)*
Two years postoperative	104 (37%)*	65 (24%)*
Three years postoperative	102 (36%)*	63 (23%)*
Four years postoperative	95 (34%)	
Five years postoperative	92 (33%)	
Six years postoperative	90 (32%)	
Seven years postoperative	90 (32%)	

*Statistically significant

results, particularly when they compare themselves with someone they know who had a gastric bypass.

I believe the gastric bypass results in greater weight loss than the gastrogastrostomy for the following reasons:

1. Dumping syndrome with notable intolerance to rich foods, sweets and dairy products.

2. Less absorptive area.

3. Food in the distal stomach seems to stimulate the appetite and in the jejunum it seems to suppress it.

I question the long-term effectiveness of the gastrogastrostomy. We all have seen patients with esophageal strictures as small as 7 or 8 mm in diameter and yet, many of these patients are still obese.

The operation is half the battle against morbid obesity and close attention to improving long-term habits is vital. In that regard, a patient support group has been very helpful both in the preoperative preparation and the postoperative management and long-term efforts at improving health habits.

The gastric bypass provides significantly more weight loss, higher patient satisfaction, and fewer revisions than gastrogastrostomy. In my experience, the operative risk is the same with both procedures. Although there are a few more long-term complications with gastric bypass, I believe it is the preferred operation.

COMPARISON OF GASTRIC BYPASS AND LESSER CURVATURE GASTROPLASTY
Jose C. Torres, M.D.

Over the last three years Dr. Auk and I have performed about 450 lesser curvature Roux-en-Y gastric bypasses and 100 gastroplasties with gastrogastrostomy also at the lesser curvature. However, this report is based on 250 gastric bypass patients with a minimum follow-up time of nine months and 50 gastroplasty patients with a minimum follow-up time of one year.

Our criteria for operation are essentially the same as those of most other surgeons. We do stress strong motivation and understanding of the operation, and we refer patients to our gastric bypass club or clinic to learn more about the procedure. We want them to be completely decided and prepared to return for follow-up visits indefinitely.

We used two applications of the TA55 with 4.8-mm staples to make the partition and the TA30® to close the gastrostomy and jejunostomy. We reinforce the staple line with 4-0 Surgilon®. We use the Ilus21® or the EEA21 for the gastrogastrostomy in gastroplasty and the gastrojejunostomy in gastric bypass.

For the last six months we have been performing gastric bypasses exclusively. We partition the stomach from the umbilicus to the lesser curvature bypassing 97%. We divide the jejunum about 20 inches from the ligament of Treitz. We pass the distal segment retrocolically and anastomose it to the lesser curvature using the EEA or Ilus21. Lately we have been placing a reinforcing 2-0 Ethibond® suture. Previously we used Prolene but this gave some problems with ulceration and migration. We measure the size of the stoma at about 10 mm in diameter. The jejunostomy is closed with the TA30. The proximal jejunum is anastomosed to the distal jejunum about 40 inches from the gastric anastomosis with the EEA21 or Ilus21.

We also use the TA55 to partition our gastroplasties, leaving about 1½ to 2 inches on the lesser curvature space to introduce the Ilus instrument. We reinforce the 10-mm diameter outlet with 2-0 Ethibond. In both gastric bypass and gastroplasty the pouch volumes vary from 25 to 35 ml.

We reserve the use of gastroplasty for our patients who are lighter in weight initially. Many of these patients are borderline weighing between 100 and 130 lb above ideal. The average admission weight was 277 lb for the gastric bypass group and 228 lb for the gastroplasty group.

Preoperatively we noticed the expected occurrence of concomitant diseases. For example, 36% of patients had cholelithiasis. Nine patients had had other operations for obesity including one intestinal bypass.

During the initial operation we performed concomitant procedures in 29% of the gastric bypass patients and 38% of the gastroplasty patients. Our average

operating time in the gastric bypass group was one hour 48 minutes and in the gastroplasty group, one hour 18 minutes.

Postoperative hospitalization lasted an average of 4.6 days for the gastric bypass group and 4.2 days for the gastroplasty group. The total complication rate was 22% for the gastric bypass patients and 26% for the gastroplasty patients. Approximately 4% of patients had an early complication. Two patients had anastomotic leaks, one early, the other late. There were two mortalities in the gastric bypass group, and none in the gastroplasty group. Six patients in the bypass group developed postoperative bleeding, three of whom required a second operation. In the gastroplasty group four developed postoperative bleeding and underwent reoperation.

Six patients had wound infections in the gastric bypass group. There were none in the other group. We had to convert the gastroplasty to gastric bypass in one patient who had bile esophagitis, and in another five patients owing to failure to achieve adequate weight loss.

In the gastric bypass group weight loss averaged 81 lb (66% of excess) at six months. By 18 months the bypass patients were down to only 26% above ideal weight. In comparison the gastroplasty group took 12 months to lose more than 51% of excess, and at 18 months, they were still about 32% over ideal weight. The gastric bypass produced better weight loss both in average kilograms and in percent of excess weight lost. We set a loss of 50% of excess weight by the end of the first postoperative year as our goal. Using this criterion 1.6% of patients in the gastric bypass group failed as compared with 18% of patients in the gastroplasty group.

In conclusion lesser curvature Roux-en-Y gastric bypass has less complications than lesser curvature gastroplasty. In addition, gastric bypass provided weight loss that was far superior to gastroplasty in our hands.

CLASSIC GASTRIC BYPASS, SHOULD WE CHANGE?
Ben H. Knecht, M.D.

Since December, 1973, I have been performing the classic gastric bypass as described by Mason. At this gathering in 1979, Dr. Mason and Dr. Gomez recommended I continue with the classic bypass until something better was developed. Lately, I have been asking myself whether I should still continue doing this procedure. Are there other procedures with long-term follow-up studies demonstrating low morbidity and mortality and persistent loss of greater than 25% of initial weight. To answer these questions, I reviewed my group of 171 patients in addition to other published reports.

Prior to 1976, I operated on 26 patients in whom I did not completely mobilized the fundus. Thus, they had a larger pouch. This group's average preoperative weight was 289 lb with an ideal weight of 125 lb. In 1976, I began taking down the fundus completely and abolishing the angle of His which resulted in a smaller, less expandable pouch. As expected, weight loss was more rapid, greater and more persistent over the past five years. The 145 patients operated on since 1976 had an average preoperative weight of 295 lb and an ideal weight of 196 lb.

I feel obesity surgery is a failure if 25% of the initial weight cannot be lost and maintained over time. In the 26 patients done before 1976, a little less than half failed to lose or maintain a loss of 25% of their initial weight. Only 11 of 145 patients operated since 1976 have failed. None of the nine patients followed up for at least six years has failed to lose or maintain a loss of at least 25% of their initial weight. I have not measured the pouch size other than with a ruler and have been duly admonished by Dr. Mason. They are approximately the size of the thumb, and I use a handsewn anastomosis 10 to 12 mm in diameter. ·

I only operate on patients who are at least twice their ideal weight. I do not accept patients over the age of 50 years. A number of immediate and interesting long-term complications have resulted. Based on Pellier and Hermrick's major complication categories I have had two major surgical complications, an acute pancreatitis and a small subphrenic abscess after splenectomy. Two other subphrenic abscesses occurred as a result of the only two gastric leaks that I have witnessed. A learning curve is obvious. I have had only one operative death which occurred in 1976 in one of the two patients with gastric leaks. Three late deaths have occurred owing to problems not related to the operation. Stomal and pouch complications may occur anytime after surgery. Five patients with stomal obstructions required reoperation. Two patients developed duodenal ulcers about two years after operation. The diagnosis was confirmed by passing a pediatric endoscope through the anastomosis and up the

afferent limb. Some patients needed to be readmitted to help them adjust to eating less than 30 ml at a meal.

This cost in morbidity and mortality is offset buy a 39% initial weight loss at one year. My 28 earliest patients maintained a mean weight loss of 116 lb (40% of initial weight).

It is difficult to compare reports of patients published by other surgeons. Until recently there had been four popular stomach procedures performed to control obesity. Several papers allow separation of the presented patients according to the type of procedure. Freeman compared 15 Alden-type gastric bypasses with 63 Gomez-type gastroplasties and noted that each procedure had its pros and cons. Lechner did a randomized prospective study comparing 50 modified Gomez gastroplasties and 50 Alden-type procedures. MacLean's group from Montreal published an interesting paper that noted the evolution of their gastroplasty approach comprising 33 Gomez-types and 53 Ohio-types. Most of the series have only one year of follow-up observation.

The goals of these surgeons' papers were also mixed. Some, like Dr. Hermrick and his group from Kansas City, and Dr. Buckwalter, concentrated on complications. Many dealt more with weight loss and their operative technique.

Although a statistical analysis of this mix of papers is not valid, I do want to show trends or at least note the numbers that are curved when groups are pooled together. Again using Pellier and Hermrick's major complication categories, each surgeon's results were added together. There were 1,403 Mason-type procedures, and 278 Ohio procedurs. The Mason-type procedure carried a surgical complication rate from a low of 10% to a high 37% among patients reported by Griffin. Mason, with 800 patients, had a 25% complication rate while Hermrick had a 17% rate with his 400 patients. The major surgical complication rate is smaller with the Gomez and Ohio gastroplasties. More cutting and sewing seems to be lead to more surgical problems.

Early deaths have occurred in all of the groups. The Mason and Alden procedures, which tend to have more surgical complications, have more deaths. The low death rate with the Gomez and Ohio groups are very enviable. I am not sure that the death rate difference can be explained as simply relating to the more difficult techniques, of the Alden and Mason. For example, the Mason procedures were started when pre- and postoperative care of the massively obese patient was just being worked out. All of our patients have profitted from the cautions and instructions of these early surgical ventures.

Stomal and pouch complications have remained a surprisingly consistent problem with each surgeon, no matter which basic type of operation is utilized. The simplicity of the Ohio and Gomez procedures initially suggested a

complication-free approach to surgical weight loss. Dr. Alden is the only surgeon reporting complications from a sizable series who has not had a gastric leak. Metabolic complications and late deaths are reported by surgeons who follow up their patients more than two years. Unfortunately, most published reports present follow-up data of less than two years' duration.

Dr. MacLean of Montreal suggests that 25% of initial weight should be lost before the patient should be considered successful. The National Institutes of Health Concensus Symposium wasn't clear on this issue. Neveretheless, all but the Ohio procedure meet this criterion. In comparing the procedures for percent initial weight lost and major surgical complications, the operations done by Alden and Gomez, at least at one year, seem to be at best. Freeman, who compared 15 Alden bypasses and 63 modified Gomez gastroplasties, concluded that the Alden-type gastric bypass, although a tough operation, produced better results. Lechner found better weight loss with his 50 Alden gastric bypasses when compared to 50 Gomez gastroplasties. The complications were very similar.

I return to my original question. Should I change from the obesity operation I am currently using? Unfortunately the Alden and Gomez procedures, which stand out for obtaining greater weight loss with little morbidity and mortality, have only one year of follow-up time. How many of the Gomez stomas hold their small size and what is the best way to design the stoma? How long will the double application of staples hold in the new Alden procedures and in the new gastroplasties? Until these long-term questions are answered I believe it is appropriate for me to continue with the classic Mason gastric bypass, which, in my hands, has produced a lasting loss of 40% of initial weight.

DISCUSSION OF VARIATIONS OF TECHNIQUE AND TECHNICAL PROBLEMS

John F. Alden, M.D., Cornelius Doherty, M.D., Henry L. Laws, M.D., and Jeffrey W. Lewis, M.D.

LEWIS: What type of criteria or methods can a surgeon use to evaluate these different operative procedures?

LAWS: I believe we should do as Kr. Knecht has done; that is, establish minimum criteria for a satisfactory operation. High on the list of priorities, of ocurse, is the achievement of adequate long-term weight loss. This should be done with a mortality rate of less than 1% and a low rate of morbidity. Do we have any operation that achieves that at this point?

LEWIS: Dr. Alden, you have been one of the leaders in gastric bypass and continue to show us the way in making this operation safer and technically more feasible. In spite of all the recent talk of gastroplasty, I think you have continued to perform gastric bypass. What thoughts do you have now? Do you think this is an operation that is still valid or do you anticipate it being supplanted by gastroplasty?

ALDEN: At this stage I find myself somewhat troubled because we are so quick to adopt new procedures that don't measure up to our old standard, the gastric bypass. Perhaps it is not proper for us to experiment as much as we do with patients, to try procedures that are untried in the laboratory. I think there are too many of us going in too many directions. I think the operations have to have three elements. They have to be safe, they have to be reversible and they have to be reliable as far as their results are concerned.

DOHERTY: I would like offer some of the experience that I have had in using Dr. Mason's vertical banded gastroplasty. I had never taken care of a morbidly obese patient or seen one taken care of until about 18 months ago. Consequently, I came into this business without bias. I prepared myself as best I could. Here are the important technical things that I would like to share with you.

We start out by having a foot plate at the end of the operating table. I like to carry out this procedure with the head of the table elevated and I believe it is necessary to use external venous compression devices to prevent pooling and hypotension during operation. I also believe that these devices are helpful in preventing predisposition to thrombophlebitis and possible pulmonary emboli.

I have used the different retractor systems available and I have found that the Gomez gastroplasty retractor has been the best in my hands. We use a low level ether screen which allows us to communicate with the anesthesiologist throughout the procedure.

When the Gomez retractor is in place, a sheet drape is wrapped around the bottom transverse bar. The end of the sheet drape is then clamped to the draping

on a neurosurgery instrument table. This allows us to change the level of the operating table without jeopardizing our sterile field. Tilting the head up is helpful for safe exposure of the distal esophagus and the area of the angle of His.

Proper placement of the TA90 is the most difficult step to learn in the operation. The only way this can be learned is by experience. All steps of the operation are done with direct vision and good exposure. This dictum must never be compromised. In using the attachments of the Gomez gastroplasty retractor we have found that the Mayo blades, rather than the subcostal blades, give us more room within the abdomen to manipulate the vertical placement of the TA90 Auto-Suture device.

We initially used the liver retractor attachment that comes with the Gomez gastroplasty set, but this retractor has the disadvantage of being able to lacerate the liver. We had this happen twice without any consequence, but it is disconcerting so we asked the Pilling Company to design a different liver retractor, which is 5½ inches wide and 7½ inches deep (catalog #60312). This liver retractor offers a tremendous exposure.

We now use a silicone tube to isolate the distal esophagus. We also use the silicone tube to occlude the outlet channel when we measure the pouch volume under pressure.

We measure down the lesser curvature of the stomach with a length of tube proximally placed at the esophagus to a distal distance of approximately 10 cm. We pick a place on the lesser curvature where the vascularity will permit entry without a hematoma. We use a disposable EEA.

A point to know is that if you take a sheet of Marlex mesh and pull it transversely, it doesn't stretch. However, if the Marlex mesh is cut longitudinally it will stretch, and even more so after autoclaving. It is very difficult to mark the measured Marlex mesh with most pens that are sterile and available in the operating room. However, a Devon Foamarker® works well.

In the third patient in my series an obstruction of the outlet occurred. The Marlex mesh attached under the liver and there was contracture of the scar with tenting up and then obstruction of the outlet. This complication is prevented by covering the Marlex mesh with omentum. However, I was unprepared for a problem that may accompany covering the Marlex mesh with omentum. Should a leak occur in the outlet channel under the covering omentum, it will be clinically occult. A tension cyst forms and continues to enlarge until it reaches a critical size. It then ruptures and the toxins and bacteria explosively contaminate the peritoneal cavity and are immediately absorbed into the brain stem. This happened to one of my patients, who suddenly developed a temperature of 105°F and became disoriented,

hypotensive, apneic, and, in spite of immediate resuscitation, developed cardiac arrest, failed to respond to resuscitation and expired in approximately 20 minutes.

Because of this experience I am unwilling to do this procedure without putting a suture line behind the staples. I now use a 2-0 Dexon® suture placed about 4 mm behind the staples of the window in a running locking circumferential suture line. I have carried this out on approximately 45 patients without any difficulty or obstruction.

Fibrocytes migrate into the interstices of the Marlex mesh ring that bands the outlet. The mesh itself is covered with a pseudoseroma. It does not invade the gastric wall. The mesh is snug around the stomach channel, but not too tight, and is sewn to itself at precisely marked lines.

Reversal of the vertical banded gastroplasty can be accomplished by making small gastrotomy wounds on each side of the staple line above the mesh collar. The forks of the GIA® are placed in these openings and the partition is divided. The previous staple line falls to the back and the area where the forks entered the gastrotomy wounds is closed transversely. The mesh stays in place.

There has been much speculation and prediction that the pouches will enlarge over a period of time. I studied x-ray views of one patient whose pouch was 8-cm long and 4.5-cm wide at the time of operation. It now measures 16 x 9 cm. It should be understood that there is a slight radiation magnification.

I know that some people here are looking at this field and thinking about making a commitment to provide this service to their patients. It is a difficult decision. A pledge that I made to my patients and myself is that I was going to do it right.

I decided that: 1) It is important to learn from really good people and believe their teaching. I have had the great privilege of sharing Dr. Mason's experience. 2) You must listen to your patients. 3) You have to have really good anesthesia. Dr. Hugh Vincent has done almost all of my cases. 4) We have maintained a very close, compatible, competent operative team. This can get you through all of the stresses and difficulties that accompany vertical banded gastroplasty.

LEWIS: Turning to another topic, I wonder how the panel feels about the biliopancreatic bypass? None of us have had very much experience with this but perhaps we have some thoughts on it.

LAWS: You can't argue with the numbers. I am astounded that there are no renal stones. It looks like a more complicated operation in that it includes gastrectomy and cholecystectomy. The results as indicated by both experts are

spectacular, but I think it may be a compliment to their expertise that their mortality is not greater considering how extensive this operation is.

ALDEN: I think there may be a particular place for this operation among young morbidly obese patients with hypercholesterolemia. There are several solutions for hypercholesterolemia, and in such a patient, this may be an excellent one. I would think that it would take a longer time in the operating room and that the possibility of complications, at least in the hands of the average surgeon, would be greater than the other operations that we have discussed. It is good that people are not taking it up until some studies and confirmation of the original thoughts have been made.

LEWIS: I agree. I think that the results at this point look very good but I don't think it is the operation with which patients should begin.

QUESTION: Would you please describe the gastric bypass as you now perform it?

ALDEN: The gastric bypass I do now is somewhat different from what I first described. A significant number of patients with the loop gastroenterostomy have bile regurgitation, particularly at night. If you question them about it, they admit to being rather miserable. Consequently, I began converting patients with loops to Roux-en-Ys and decided that maybe the Roux-en-Y was the best operation. Currently, I do a Roux-en-Y gastric bypass. I haven't seen evidence I can accept to show that the use of two cartridges of staples across the stomach is better than one so I still use a single cartridge of staples. I no longer take down the greater curvature of the stomach at all. I make a tunnel in the lesser omentum and place a catheter behind the stomach and out through an avascular space lateral to the esophagus. I make my anastomoses by hand and I always use a Witzel gastrostomy to protect the distal pouch. I am still afraid of distal pouch blowouts.

LEWIS: Dr. Doherty, could you elaborate again how you place the Dexon suture around the EEA stapling ring and how many do you place?

DOHERTY: I place one running, locking stitch of 2-0 Dexon circumferentially and probably about 3 mm behind the staple line. Actually in using the EEA, about 25% or 30% of the time you have to put in interrupted sutures anyway because then will be bleeding between the staples.

LEWIS: We have not been doing this. Fortunately, we have not suffered any perforations to scare us into it. Dr. Doherty, are you using 70 cm of pressure to measure the pouch now and why?

DOHERTY: I don't have a good Ewald tube so we had a catheter designed for us by National Catheter. It is too short in many patients for us to measure to 70 cm of water pressure. At least we measure pressure at 50 cc but often it is much higher depending on the length of the tube. The difference in volume seems to be about

another 6 or 8 ml between 50 and 70 cc of pressure but you don't get much stretching past 70 cc.

LEWIS: What are the indications for operation?

LAWS: They vary with from surgeon to surgeon. We do not psychologically evaluate the patients. We try to avoid operating on patients who we think are hysterics and have a lot of convergence symptoms, people that seem hostile and have bitterness toward other surgeons and physicians. We will operate on people with limited intellect and we have operated on a couple of schizophrenics who have done all right. We try not to operate on people who do not have a realistic attitude about the end result. These people have to understand that they probably are not going to lose more than 35% of their body weight. It is the uncommon person who loses a lot more than that. In regard to medical contraindications, we do not operate on patients with ischemic heart disease or aortic stenosis. If a patient has reflux esophagitis, we do a Roux-en-Y gastric bypass. If a person has a history of ulcerative disease but no active ulcer, we do a gastroplasty and not a gastric bypass.

The technique we generally we use includes a vertical staple line, and a single application of the stapler. We use the Gomez retractor and place the patient in a 37-degree head up position. We oversewn the staple line with a running 2-0 suture. We pass a 32F, 10.7-mm dilator and then place a silastic ring around the outlet. We don't routinely use a tape around the esophagus. When we place the ring we think it very important to limit the number of stitches especially at the junction. We place two sutures to hold the ring. These are kept clear of the dilator so that a good 0.5 mm of gastric wall lies between the suture and the dilator. The one change that I have from my written description is that we shorten the TA90 stapling cartridge on the butt end of the instrument by taking out three or four staples and then, after the recommendation of Dr. Charles Brogue, we cut that staple cartridge off with a pair of wire cutters. This avoids curshing the mucosa. Since the ring does not react as would Marlex, we oversew it with a row of Lembert sutures.

Dr. Norman Halpern and I now have about 145 primary operations. Our patients who have gastric bypass had concomitant reflux esophagitis. We think that about 20% of patients have excessive vomiting. We have had two questionable pulmonary emboli. We have had two wound dehiscences. We have had one stenosis of the outlet that required reoperation. The outlets can usually be dilated either by endoscopy or with a Maloney dilator. We have had at least nine ring erosions in 121 patients, which we consider a very serious problem. We picked these people up because they failed to lose weight.

We think that the operation that we are doing, ring gastroplasty, is as good as gastric bypass. We now have about 70 patients with the same results, all but one has lost more than 20% of preoperative weight. The average loss is 36% of preoperative weight. This includes data from the five patients who had ring erosion. If a ring does erode it can be removed, but this is not necessary because it does not have to be because it generally does not bother the patient.

LEWIS: When did the staple line and stomal failures occur?

LAWS: We think they actually occur quite early but we don't pick them up until later. We try to perform endoscopy in all patients at about a year after operation. Unfortunately this is a rather expensive undertaking and I have difficulty justifying it for all of my patients.

LEWIS: I am glad to hear you mention some of the costs of follow-up care. At The University of Iowa, the cost for endoscopy is almost $600. It is indeed an expensive procedure. The patients also have many hospital costs of which we are often unaware.

ALDEN: All the male patients should be questioned about whether or not they have the symptoms of apnea with sleep. This occurs more frequently than we think. The patient himself will often not know; it is the wife who will sit next to him and say, "Oh, he does that. Sometimes I think he dies in the night." An inadvertent operation in a patient with sleep apnea can cause tragedy. Such patients used to be monitored, prepared and observed carefully. Sleep apnea is not a contraindication but it is a warning sign.

If our operations are good, there should be few contraindications to it. I believe the idea of putting blame on the patient for the operation that fails is something that we ought to get away from. If a person has a hernia and he is a hard worker, we will still repair the hernia and we expect that it will fail occasionally. If the patient is a big eater and he continues to eat big in spite of the fact that we have done an operation, we say that the operation was very good but the patient failed. These things are not necessarily true.

The major reason I would not operate on a patient would be that I felt I could not get along with him very well. I know it is going to be a long association between the two of us. We must also operate on patients who have greatest need and adhere to our height weight requirements. I have no other specific contraindications. I look forward to patients who have medical complications such as diabetes, hypertension, and orthopaedic difficulties, but I am cautious of the person with ischemic heart disease.

LEWIS: Dr. Doherty, is peptic ulcer disease a contraindication to gastroplasty?

DOHERTY: I haven't operated on any patient with active peptic ulcer disease. I have operated on a few who had a past history of it but were asymptomatic. I

don't think it is a contraindication but I am very careful in selecting patients from the beginning. I think you can probably have a little more freedom in offering this operation to people with a history of peptic ulcer disease than you had with the previous operations.

LEWIS: Dr. Laws, do you make any changes in the operative procedure if the patient has had a duodenal ulcer in the past?

LAWS: No. If they have had a duodenal ulcer in the past and it is an intractable duodenal ulcer, that would be a different thing. On the other hand, if they have a history of duodenal ulcer disease and no active ulcer, we would offer them a gastroplasty.

ALDEN: If the person has a severe recurrent ulcer and some of the major concomitant complications, a gastric resection with a very small pouch would seem the operation of choice.

DOHERTY?: For a patient who has a longstanding history of intermittent, but uncertain ulcerive disease, a truncal vagotomy should be done at the time of gastric bypass. A pyloroplasty must be avoided in these patients, otherwise reflux into the bypassed segment of stomach may cause hemorrhagic gastritis. Truncal vagotomy in a gastric bypass patient does not require pyloroplasty or pyloromyotomy.

LEWIS: Dr. Alden, what do you think of gastric reduction procedures for patients who have symptomatic reflux?

ALDEN: I think they are wonderful. A Roux-en-Y gastric bypass cures the reflux, the weight increases and the patient is happier than any of your other patients. But it must be a Roux-en-Y; it can't be a loop gastrostomy. There is no need for Nissen fundoplication. Just diverting the gastric contents from the cardia and from the lower part of the esophagus with a long Roux-en-Y limb is sufficient to relieve both problems.

LEWIS: What particular procedure should be done when a Roux-en-Y fails to provide adequate weight loss.

ALDEN: That is the hardest question I have had. I think the first thing is to order an upper GI series. Most of the time you will find disruption in the staple line. In that case, the stomach should be restapled. If the pouch is large, it should be made smaller. I haven't come to the point of banding the anastomosis. I considered it and may be close to doing so in some of the patients that have had inadequate weight loss. But at the moment, I am not sure whether it is appropriate to do so.

LEWIS: I have seen a small number of these patients who have had problems losing weight. In such cases I make the pouch and anastomosis smaller. So far I have had fairly good results with that alone.

OBESITY SURGERY IN THE OLDER AGE PATIENT

Martin E. Felder, M.D.

Lost owing to transmission breakdown.

A COMPUTER INFORMATION SYSTEM FOR VERTICAL BANDED GASTROPLASTY

C. Gregory Doherty

We recognized at the inception of our vertical banded gastroplasty program that a computer would be necessary to keep track of the large volume of operative and follow-up data and to accurately assess the performance of the procedure. Owing to the somewhat unique aspects of data management for this procedure, and the need for flexibility in the tasks the computer was to perform, we decided to purchase a computer with sufficient storage capacity and processing capability, and then to develop new programs specifically tailored to our unit to monitor the vertical banded gastroplasty.

The lack of an adequate hospital computing system and the need to keep costs at a minimum led us to choose a microcomputer that could meet our current and future processing needs. The computer contains two microprocessors: the first is an 8-bit processor that allows us to access the large library of prewritten programs for 8-bit computers, and the second is a 16-bit processor that has more processing power and added capabilities. The computer has over 100,000 characters of internal memory, and 20 million characters of hard disk storage. The system also includes a video terminal for communication with the computer, a printer to generate reports, and a plotter to create graphs of follow-up data. Currently, our computer is a powerful single-user workstation, but the equipment may be inexpensively expanded to allow for multiterminal processing.

A prewritten software package that could meet our exact needs was not available, so the programs were custom developed using the CP/M® microcomputer operating system and the Pascal programming language. The initial system design called for programs to handle only follow-up and operative information, but sidelines have included billing for the physician, filling out insurance forms, maintenance of a patient directory, and provisions for form letters and mailing labels for follow-up contact with patients.

The primary functions of the system are to add new patients and follow-up data and to change information on existing patients, to update billing information and to generate reports and graphs. When a patient is first added to the data base we record personal information such as name and address, operative information including date of surgery, initial height and weight, pouch pressure and volume, and preoperative blood pressure. At this time we can also record insurance and billing information if it is available. After a patient has been added to the file, follow-up information may also be added. Each time a patient comes in for an office visit, weight and blood pressure, and the date of the visit are all recorded. Typically, follow-up data is collected often during the first two postoperative months, then the frequency decreases. There is room in each

patient's record for up to 30 follow-up visits. From this record of follow-up weights and blood pressures we can print reports that summarize each patient's performance, and the performance of the procedure overall. The most useful report lists all patients on file with their initial weights, their most current follow-up weight, the amount of weight lost, and the number of days since operation. From this list the physician can easily spot those patients who are not losing weight at the expected rate or those who are gaining weight. The complete report lists all follow-up weights for each patient, and for each entry it also computes the weight lost, the percent of initial weight lost, the percent of excess weight lost, and the percent of ideal weight. These weight loss indicators buffer the raw weight data and remove some of the weight dependent discrepancies. Other reports include mailing lists and labels, billing statements, and an accounts receivable summary.

The data plotting facility generates various graphs for either each patient or a specific group of patients. The quantities plotted versus time include weight, weight lost, percent initial weight, percent initial weight lost, percent excess weight, and percent of excess weight lost. Various output parameters may be specified including axis scaling and the amount of time past since operation for which the graph is to be run. The graphs serve as a useful, quick summary of each patient's success with the procedure.

The statistical package groups patients by various criteria and then prints means and standard deviations for various quantities such as age, height, weight, weight lost, initial weight, etc. for each group of patients. The patients can be grouped by sex, age, time since operation, initial weight, and weight lost. This allows the physician to isolate problems in certain subgroups, and to observe trends in rate of weight loss between different groups of patients, for instance, those with different initial weights.

The final function of our system is a program that considers all follow-up data for each patient and operative input from the physician and then generates an audit of the vertical banded gastroplasty procedure as per the format indicated by Dr. E. E. Mason in Surgical Treatment of Obesity. This includes a summary of failure to lose weight, operative complications, and the mortality of the procedure.

Though our current volume of follow-up and operative data is relatively small and inconclusive as to the success of the vertical banded gastroplasty over the long term, our computer system is a tool that gives us the ability to closely watch and assess each patient's performance, and the performance of the procedure overall. As such, our vertical banded gastroplasty computer system is an integral part of our preoperative and postoperative program.

LEWIS: How long would it take to learn to program this computer or to use it the way you have described?

DOHERTY: If you have a package program, then it does not take long to learn. But, if you have to go through the process of writing your own programs, it can require a great deal of time.

QUESTION: How much would I expect to pay a programmer to create a tailored program for an Apple II® computer?

DOHERTY: It depends on what you want the system to do and what your volume of data will be. This is especially true for an Apple II since it is a small system. If you have a large volume of data, the programmer is going to have to go through a lot of internal tricks to maintain and quickly access the stored information. There is a lot of prewritten software available that would allow one to manipulate numbers, but if you want something as extensive as our system, you are probably in for an investment in equipment of $14,000 to $16,000. Program development would probably cost an additional $3,000 for the full system.

QUESTION: Where can one find prewritten software? Where do you start?

DOHERTY: It depends on your approach. If you have access to a large computer, then you are going to take an entirely different approach from what we took. We did not have computer facilities so we had to get something that was both affordable and would also work for us on a smaller scale. If you have large system facilities available for the computer, then the manufacturer can tell you about doing statistical operations. Microcomputers present difficulties in that you have to deal essentially with a retail store and a retail environment. Sometimes you don't get your questions answered or you don't know exactly what to ask. The key elements that any good system should incorporate are data storage and management and the capability to perform statistical analyses. There are statistical as well as data base management packages and data base managers available for microcomputers but the key is to have them be interphasable, to be able to run statistical programs on data generated by the data base manager.

RADIOGRAPHIC STUDIES IN GASTRIC REDUCTION PROCEDURES

Luigi M. DeLucia, M.D.

Very little has been said or written about radiographic, endoscopic or isotopic studies after gastric reduction procedures. Such studies are important in assessing the efficacy of our procedures. I used three types of radiographic agents, Gastrografin, liquid barium and solid barium (an equal parts mixture of barium and bread).

The Gastrografin studies are most valuable in the early postoperative stage whenever we suspect blowout or leak. The classical blowout is accompanied by the well-known clinical manifestations of tachypnea, tachycardia and left shoulder pain. Temperature and/or white count elevations are less diagnostic and often result from atelectasis. If Gastrografin studies were used more frequently we would perhaps find a greater evidence of small leaks. One such patient underwent vertical gastroplasty by transection. On the seventh postoperative day a lateral x-ray view revealed no extravasation. The patient was doing fine and was completely asymptomatic, however, she developed a white count elevation that I could not explain. On the eleventh postoperative day a repeat of the Gastrografin study revealed an anteriorly located gas bubble. This was confirmed by the AP view. Leaks such as this usually respond quickly to antibiotics and prolong the hospitalization by only about three or four days.

Two months after treatment some extravasation was still visible, but it was not causing problems. Nine months later the lateral film of a barium bread study revealed the fundic pouch and no leak could be distinguished.

An x-ray view of the stomach after bariatric surgery can be quiet confusing to the radiologist who is not familiar with these procedures. The best medium to outline the stomach after bariatric operations is the classical liquid barium. A vertical gastroplasty with transection, banding and lesser curvature outlet should form an hourglass appearance.

I use solid barium studies not only to evaluate the efficacy of the operation, but also to evaluate the behavioral modification of the patient. I usually run this study for four hours, but when necessary, I extend it to six or even seven hours. These studies are done on an outpatient basis. Transit time varies somewhat from patient to patient. However, the typical patient passes about one-third of the barium-soaked bread in the first 90 minutes. By two hours after ingestion the amount of transit usually increases to about 50%. Some barium may remain in the stomach even eight hours after ingestion. Weight loss in such a patient will be excellent. Many of my patients reach ideal weight.

I have tried to determine which of the postingestion films are most predictive of outcome. I believe the one-hour transit film is probably the best.

Any patient who has a 90% transit by one hour after ingestion will probably fail to lose and maintain adequate weight loss. The majority of my patients lost more than 60% of excess weight by 22 months after operation. The average amount of food transit of successful patients is 45% by one hour (range 4% to 87%). I had six failures in 46 patients which yields a failure rate of 13%.

My definition of failure is arbitrary: excess weight loss $\leq$ 56% at two years. I can roughly predict the outcome at approximately two years after operation. The patient who has less than 89% transit at the end of one hour has about one chance in ten of failing. Weight loss among the patients who failed ranged from 23% to 56% and averaged 39% of excess weight. The failure rate for patients who have more than a 90% transit by one hour is 62%, and I predict this figure will increase with time.

I have used severeal different procedures including both single and double rows of staples and without reinforcement. When using a single row of staples without reinforcement, my failure rate was 100%. The failure rate for patients with the transgastric suture reinforcement dropped to 36%.

If a patient does not lose weight adequately after a gastric reduction procedure it should be considered a surgical failure until proven otherwise. The solidity of both partition and outlet appears to be more critical in my experience than the size of the fundic pouch, and the only partition which appears to be immune to the problem of dehiscence is that resulting from the transection of the two gastric walls with closure by the standard method of inversion and suture approximation.

EFFECTS ON INSULIN-DEPENDENT DIABETICS

Charles A. Herbst, M.D.

In July, 1979, at an International Diabetes Workshop in Washington, D.C. sponsored by the National Diabetes Data Group and the NIH, the classification of diabetes was redefined into two types. Type I is insulin dependent, ketosis prone diabetes mellitus. This was formerly known as "juvenile diabetes," but it can occur at any age. It is characterized by abrupt onset, insulinopenia, and dependence on injected insulin to sustain life. Such patients are prone to ketosis. Type II consists of noninsulin-depedent patients who are not prone to ketosis. These patients usually present with minimal or no symptoms. Most, but not all, are over 40 years of age at onset. Type II patients may require insulin for correction of fasting hyperglycemia, but are not dependent on insulin for prevention of ketosis.

Although not well understood, there appears to be a correlation between obesity and Type II diabetes mellitus. Both are characterized by insulin resistance. Sixty to 90% of all Type II diabetics are obese patients in Western societies. Weight loss usually improves glucose control and lowers insulin requirements in these patients. Type II diabetes is one of many indications for gastric bariatric surgery in morbidly obese patients.

This report compares insulin requirements in 23 morbidly obese, Type II diabetics before and after surgically induced weight loss. Six of these patients were studied in greater detail for changes in fasting glucose, hemoglobin A_{1c}, glucose tolerance, and glucose resistance, to better understand the mechanisms of diabetic amelioration following successful gastric bariatric surgery.

Twenty-three insulin-treated, morbidly obese, diabetic patients underwent gastric operations to induce weight loss at North Carolina Memorial Hospital over a three year period between 1978 and 1981. All were at least 100 lb over ideal weight, and all were classified as Type II or noninsulin dependent, nonketosis prone diabetics. Nevertheless, they all requied insulin for correction of persistent hyperglycemia. One patient was a man, the rest were women. Ages ranged from 25 to 53 years (mean 41). Thirteen patients had Roux-en-Y gastric bypasses, one had greater curvature gastroplasty, and nine had gastrogastrostomies.

The average insulin requirement preoperatively was 74 units per day (±25) with a range of 10 to 230 units (Figure 1). By the sixth postoperative week insulin requirements had decreased to 7.8 units per day (±5.5) (p<0.001). Fourteen patients had been able to discontinue insulin by six weeks, many even before discharge. The remaining patients had decreased requirements by 72% (100

units to 28 units). These improve-
ments have been maintained over
long-term follow-up periods ranging
from six to 39 months (mean 20.2
months).

All patients had weight reduc-
tion as a consequence of surgery
(preoperative mean weight 115.5 kg,
mean weight at six weeks, 101.3 kg;
mean weight at six to 39 months,
92.9 kg). One patient gained
weight after a year because of a
stretched stoma. She still weighs
less than her preoperative weight
102 kg versus 129 kg) and has not
required reinstitution of insulin.

These data confirm significant
reduction in insulin requirements
in Type II morbidly obese diabetics
with surgically induced weight
loss. What is the physiology
behind this amelioration? Drs.
Hughes and Gwynne of our Division
of Endocrinology randomly selected
and admitted six of these patients

Fig 1: Insulin requirements in morbidly
obese diabetic patients

to our Clinical Research Unit for preoperative and postoperative studies and
infusion tests. Informed consent was obtained as approved by the Committee on
Protection of Human Subjects. Patients were placed on a standard, balanced,
weight-maintaining diet for five days (40% carbohydrates, 40% fats, 20% protein
based on 30 Kcal per kg of ideal body weight) following which fasting blood
glucose, hemoglobin A_{1C}, and insulin levels were measured (Tables 1 and 2). An
IV glucose tolerance test (Table 3) was performed to determine the glucose
disappearance constant (k_g). Steady state plasma glucose and glucose clearance
were determined as measures of total insulin resistance using an infusion of
glucose, insulin, epinephrin, and propranolol after the method of Shen, et al.

Details of these six patients are outlined in Table 4. The mean preoperative
weight was 117.5 kg. Postoperative studies were obtained from five to 12 months
when it appeared that weight was beginning to stabilize. The mean postoperative
weight was 85.8 kg. All patients were able to discontinue insulin; two require
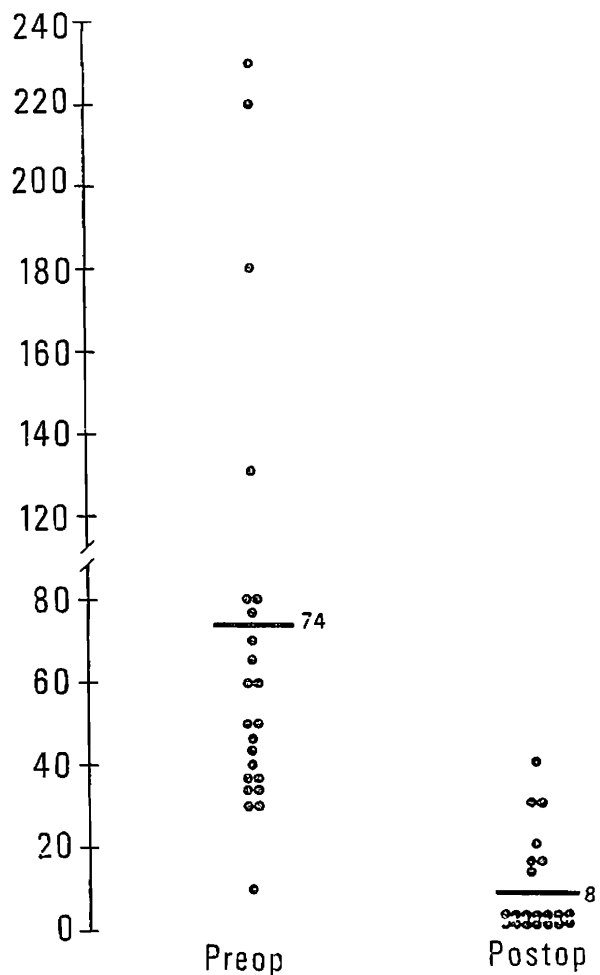
Table 1: Fasting blood glucose*

Patients	Preoperative	Postoperative
FC	288	134
BD	342	131
FL	324	264
RM	350	104
SP	276	124
TS	346	236
Mean	321±26	166±54
		(p<0.001)

*Average of 3 determinations in mg/dl

Table 2: Hgb A_{1C}

Patients	Preoperative	Postoperative
FC	20.7	7.9
BD	7.8	4.3
FL	11.7	20.8
RM	13.5	8.1
SP	14.9	7.6
TS	12.4	8.8
Mean	11.8±2.0	7.9±1.7
		(p<0.05)

Table 3: IV glucose tolerance disappearance (k_g)*

Patients	Preoperative	Postoperative
FC	0.209	0.525
BD	0.238	0.354
FL	0.149	0.214
TS	0.109	0.447
Mean	.176±.058	.385±.134
		(p<.05)

*Percent/min; normal > 1.2%/min

Table 4:

| | Age | Duration (yrs) | | Preoperative | | Postoperative | |
		Obesity	Diabetes	Insulin	Wt (kg)	Insulin	Wt (kg)
FC	41	40	10	70	122	0	90.5
BD	40	23	13	50	116	0	67.2
FL	41	40	9	220	115	Orinase	84.4
RN*	42	30	3	50	128	0	100.9
SP*	35	15	7	90	109	0	85.5
TS*	41	30	15	180	115	Orinase	86.0

*Hypertension

oral hypoglycemics to control elevated fasting sugars. Note that one patient, BD, had significant weight loss approaching ideal weight.

Average fasting blood glucoses (3 determinations) dropped from a preoperative level at 321 (±26) mg/dl to 166 (±54) mg/dl ($p<0.001$). Caloric restriction studies on other obese Type II diabetics have shown that this decrease in fasting blood sugar occurs prior to significant weight loss. Thus, it is apparent that a decrease in caloric intake rather than weight change has the greatest affect on fasting blood sugar.

Measurement of hemoglobin A_{1C} levels verify that this affect is sustained. Nonenzymatic glycosylation of human hemoglobin takes place at a specific site on the protein depending upon the concentration of blood sugar and is accumulative throughout the life of the RBC. Normallly, about 5% of hemoglobin is covalently linked to glucose, resulting in the formation of a distinct minor component designated as hemoglobin A_{1C}. There is a two- to threefold increase in this glycoprotein in patients with diabetes mellitus. Thus, hemoglobin A_{1C} in these six patients dropped from a preoperative level of 11.8$\pm$2.0 to 7.9$\pm$1.7 postoperatively (Table 2). This was a significant decrease. Normal hemoglobin A_{1C} levels range from 4.7 to 10 in our laboratory.

IV glucose tolerance was performed by infusing 25 gm of glucose over five minutes and obtaining venous samples from the contralateral arm at five, 15, 30, 45, 60, 90, 180, and 240 minutes after infusion. The glucose disappearance constant (k_g) was determined by dividing 69.3 by the halflife ($T_{\frac{1}{2}}$) of glucose disappearance which, in turn, is determined graphically from the plot of log of glucose concentration versus time. The lower limit of normal for k_g is 1.2% per minute.

Infusion studies were obtained in only four patients postoperatively. IV glucose tolerance tests confirmed that all four patients had improvement of the

glucose disappearance constant, but in none did the k_g become normal. Mean k_g improved significantly from .176 to .385 after operation (p<0.05).

We determined total insulin resistance using a modification of the method of Shen, et al. Glucose at 6 mg/min/kg of lean body mass, epinephrin at 6 mcg/min, propranolol at 0.08 mg/min, and regular pork insulin at 80 mU/min were infused intravenously. Epinephrin and propranolol prevent endogenous insulin release and, together with infused glucose, they inhibit hepatic glucose production. The insulin infusion allows achievement of a similar steady state plasma insulin level in all subjects (diabetics and normal). Steady state insulin levels are achieved after 120 minutes (Figure 2). Thus, plasma glucose concentration observed during the steady state period is a measure of an individual's insulin resistance at the cellular level. Figure 3 is adpated from Ginsberg, Journal of Clinical Investigation, March, 1975, and shows steady state plasma glucose levels of diabetics around two times higher than normal controls. These nonobese patients were not on insulin. Normal steady state plasma glucose is between 110 and 140 mg/dl.
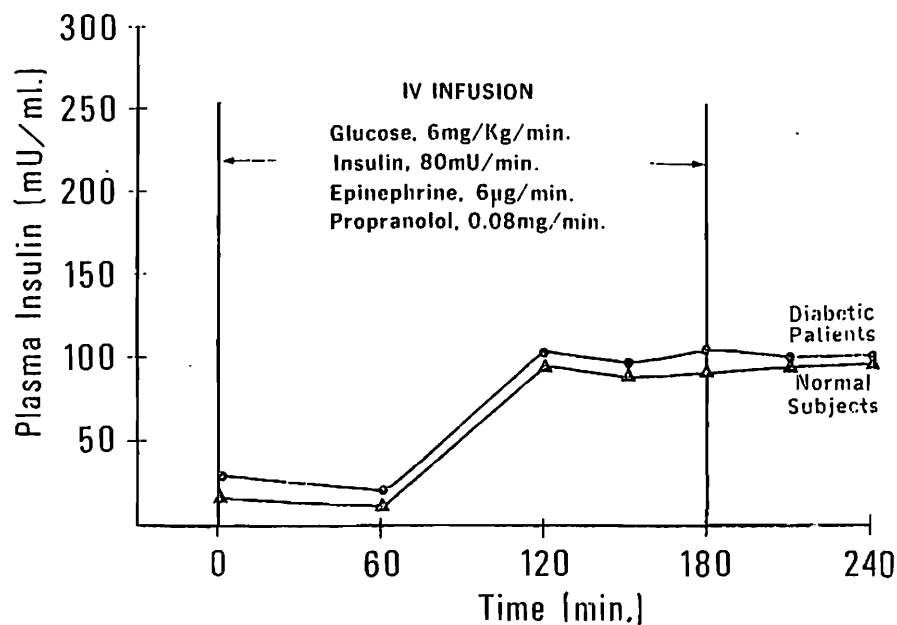
Fig 2. Steady state plasma glucose infusion test

By 180 minutes of infusion, steady state plasma insulin levels were reached and comparable in all patients. The simultaneous steady state plasma glucose levels were determined and showed a measurable drop postoperatively from 362 mg/dl to 246 mg/dl (Table 5). Although this was an improvement in all patients (BD dropped below normal levels) the changes were not significant due to the small sample size.

Another way of expressing this is with plasma glucose clearance rather than steady state plasma glucose since urinary losses of glucose may cause steady state
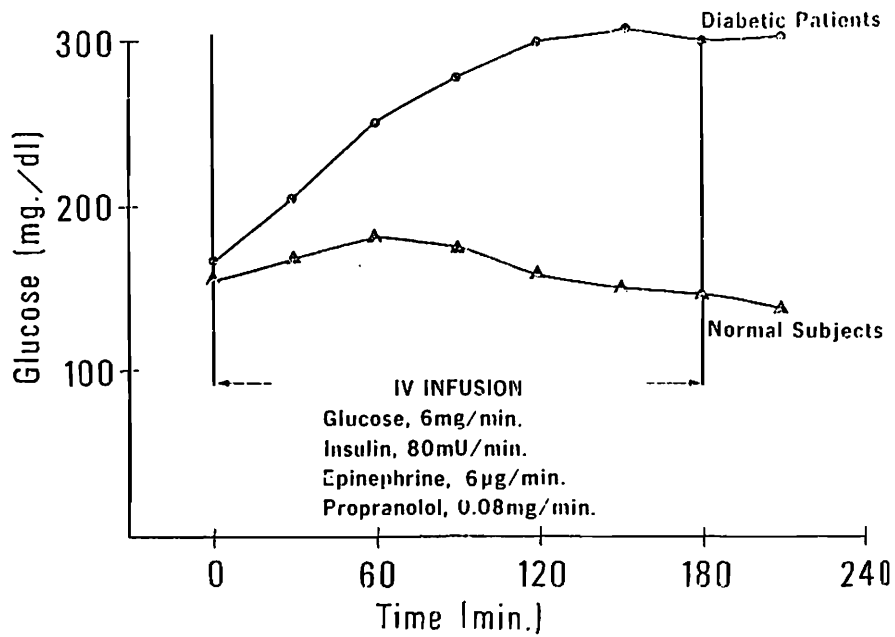
Fig 3. Steady state plasma glucose infusion test

Table 5: Standard infusion studies: Steady state plasma glucose (mg/dl)*

Patients	Preoperative	Postoperative
FC	352	235
BD	272	62
FL	409	364
TS	418	323
Mean	362	246

*Normal SSPG 110-140 mg/dl

plasma glucose to underestimate insulin resistance. The urinary losses are subtracted from the glucose infusion rate when the stady state plasma glucose is reached (expressed in ml/min of plasma cleared of glucose).

Glucose clearance showed an increase from 76.9 ml/min preoperatively to 228 ml/min postoperatively (Table 6). This change was larger than the changes in steady state plasma glucose and indicates greater insulin resistance than that documented by steady state plasma glucose since it corrects for urinary glucose losses. Again, the differences were not significant because of the small number of patients.

We conclude that morbidly obese patients with Type II diabetes mellitus requiring insulin for control of hyperglycemia can markedly decrease and often

Table 6:   Standard infusion studies: Clearance cc/min

Patients	Preoperative	Postoperative
FC	99.5	160.5
BD	113.8	582.0
FL	31.1	63.7
TS	63.3	107.0
Mean	76.9	228.0

eliminate their insulin requirements after gastric bariatric surgery (Figure 4). Fasting blood sugars are reduced by decreasing oral intake. This in turn reduces insulin requirements. Long-term control is maintained as indicated by lowered hemoglobin A_{1C} levels. After weight loss, glucose tolerance was improved and insulin resistance reduced even though they did not return to normal levels in any of our patients. We speculate that this may be related to the amount of weight loss.
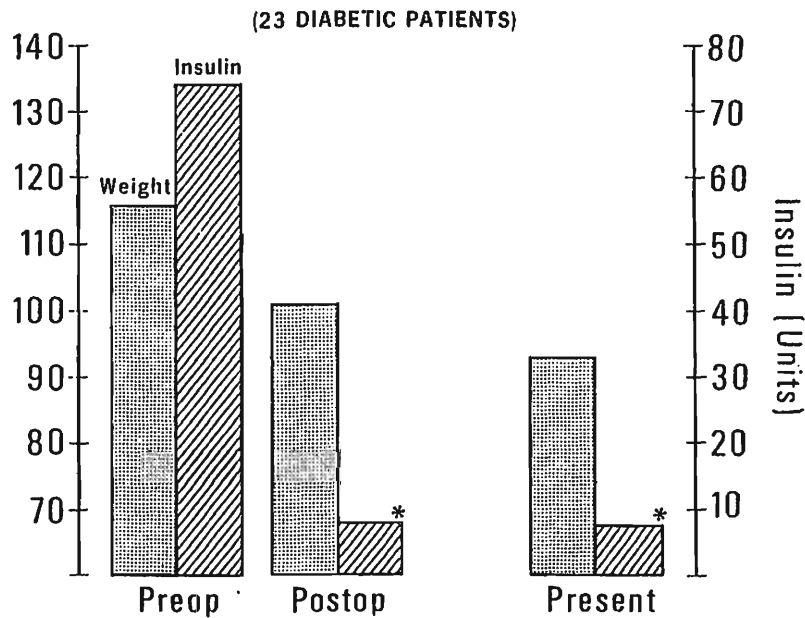

Fig 4.   Insulin requirements following bariatric surgery

These imrpovements do not appear related to the type of gastric operation performed, but rather to the success of the operation itself in limiting oral intake and producing weight loss. Thus, diabetes mellitus in morbidly obese patients is a good indication for gastric bariatric surgery.

MASON: Since a gastroenterostomy allows glucose to go directly into the small bowel and be rapidly absorbed thus stimulating insulin, and since the digestive hormones such as gastrin released in the duodenum when food passes through also stimulate the secretion of insulin, I am surprised that you conclude that the type of operation does not have an effect on these various measurements of glucose metabolism.

HERBST: We performed IV rather than oral glucose tolerance tests. There might well be a difference, for example, in the gastric bypass with a Roux-en-Y for orally ingested food. In theory, one of the benefits of that operation is the dumping syndrome. It would be necessary to perform oral glucose tolerance tests to determine the effect of gastroenterostomies.

QUESTION: Would you do this operation on somebody less than 100 lb overweight?

HERBST: Our statistics show that we can often get the patient off insulin after weight loss. This makes it easier for the internist to control the patient. So, yes, we would.

QUESTION: Where do you draw the line?

HERBST: I think that is a matter of judgment and depends upon the patient, how much insulin they require and how difficult they are to control.

O'LEARY: When you use regular insulin in vitro you can actually measure the amount of insulin bound to cells. Have you done any direct insulin binding studies?

HERBST: No we have not done that. We did measure free insulin levels which were elevated in all patients, but we did not measure antibody bound insulin. Free insulin levels remained elevated in the postoperative period. Although they did drop somewhat, they were still over the normal values.

O'LEARY: If you modify the amount of glucose in the diet, you can change insulin binding in patients. The high insulin resistance, which can be demonstrated in most of these patients, can be ameliorated simply by changing the composition of the carbohydrates and fat in their intake. This is our observation, at least, in a very small number of patients.

PRINTEN: Your data are about the type II diabetics, most of the type I patients that we see are skinny and very sick. Do you have any experience with type I diabetics?

HERBST: No, we have not had any experience with them.

QUESTION: Have you avoided them?

HERBST: We have not made a specific effort to avoid them. However, I would be reluctant to operate on such a patient. Most of those patients are not obese, but are the skinny, juvenile type who obviously don't need an obesity operation.

BLEEDING FROM THE BYPASSED POUCH

John F. Alden, M.D.

When gastric bypass was introduced for the treatment of morbid obesity, surgeons were concerned about the ulcerogenic potential of this procedure because of its anatomic similarity to antral exclusion. As we all know, antral exclusion provokes ulceration. Fortunately, the incidence of marginal ulcers has been low, about 1.4%. There has, however, been no attempt to document the incidence of peptic ulceration in the bypassed stomach or duodenum. Consequently, we have reviewed our combined experience with over 3,000 gastric bypasses in order to determine the frequency and severity of proven acid peptic disease in the bypassed stomach.

Retrospective study revealed eight patients (0.3%) who bled from the bypassed stomach. The most common presenting symptoms were melena and hematemasis. Bleeding was both acute and chronic. Four patients required repeated hospitalizations. Five patients underwent emergency laparotomy to control massive hemorrhage. Duodenal ulcer, hemorrhagic gastritis and gastric ulcers were the lesions encountered. Bleeding episodes occurred as early as three months and as long as three years after gastric bypass. It was not related to the type of gastroenterostomy used. All four of the chronically bleeding patients were treated with cimetidine without success. All patients had experienced excellent but not excessive weight loss prior to their episode of bleeding.

While bleeding from the bypassed stomach is much less common than marginal ulcer, it must be considered in the diagnostic workup of a patient with evidence of GI bleeding following gastric bypass. The symptoms and presentation of both complications are identical. Endoscopy can effectively distinguish between the two conditions. The marginal ulcer can be seen in virtually all cases. In patients who have acute bleeding from the distal pouch, endoscopy will discover blood in either the afferent loop or far down in the Roux-en-Y limb if this type of anastomosis has been used. Upper GI examination with contrast medium was of no help in establishing the diagnosis in this group of patients even though several underwent multiple examinations.

Unlike most patients with marginal ulcer, our patients with bleeding from the distal pouch did not respond to medical management. Resection of the bypassed pouch with either Billroth I or Billroth II reconstruction was curative in all cases. There has been no recurrence of bleeding in any of the patients.

The cause of peptic ulceration in these patients remains obscure. However, since all had satisfactory weight loss without other major symptoms, we feel that each patient had a technically sound operation. In a review of marginal ulcers after gastric bypass, it was found that the majority of ulcers occurred in

patients with enlarged proximal pouches. Nevertheless, several patients with small pouches also developed stomal ulcers. The proposed etiologic factor in these patients was an abnormal vagal response to ingested food. The hypothesis seems corroborated by the fact that all the ulcers healed after vagotomy without the need to further reduce the pouch size.

Patients with bleeding from the distal pouch may represent a different problem. They could have either hypersecretion from vagal stimulation or an abnormally active vagal response from the ingestion of food.

In summary, eight of 3,000 patients with gastric bypass developed bleeding from acid peptic disease in the bypassed segment of the stomach. Bleeding was both acute and chronic. It did not respond to medical management and required operative treatment. Endoscopy differentiated between stomal ulcers and distal pouch bleeding. Resection of the distal pouch was curative in all cases.

HALVERSON: In the old days, with larger pouches and larger anastomoses reported for gastric bypasses, indeed the incidence of peptic ulceration was reported all the way from 1% to 6% in one series. Your results seem consistent with that experience in terms of upper GI bleeding and ulceration after these operations. Do you think that the modification of the operations as initiated by you (stapling, smaller pouches and smaller stomata) has influenced both the amount of acid secreted from the upper pouch and the amount of bile refluxing back through that small stoma.

ALDEN: A large pouch will leave a large area to secrete acid. I don't think stomal size is as important. A large pouch almost ensures that there will be an increased incidence of ulcers in the patients who have had bypasses.

QUESTION: Have you had any experience with diagnostic or therapeutic radiology or angiography for this problem? Do you think it might play a role?

ALDEN: Do you mean radioisotopes?

QUESTION: I was thinking about embolization?

ALDEN: No, I have no experience whatsoever and I think it probably won't be of very much value. I think you really have only two options. Angiography will pinpoint the bleeding, but you already know that in advance because you are familiar with the situation, you have endoscopy and you see the problem. Embolization would probably only provide a temporary solution. Distal gastric resection in these patients is not difficult and seems preferable.

QUESTION: Why don't you do a vagotomy instead of resection?

ALDEN: I don't think you have the same security with vagotomy as with resection. I suspect that it might be valuable in some patients but not in others. I feel much more secure with distal gastrectomy. The stomach is wasted anyway.

QUESTION: I notice that you have not had anybody perforate from the duodenum or distal stomach, why wouldn't that happen?

ALDEN: It does happen.

QUESTION: Are you missing some patients who have duodenal ulcer because they have intractable pain and do any of these ulcers perforate?

ALDEN: I have one person with a perforated ulcer. I would not have diagnosed it except that the patient had gallstones and I thought she had an acute gallbladder. Her gallbladder did contain stones, but she also had a perforated ulcer which was causing the pain. I do think we miss some ulcers. I believe enough in cimetidine to occasionally use it in lieu of an x-ray. If the pain goes away, and it usually does, I assume it was caused by distal gastritis. Many of these resected stomachs will develop a frank hemorrhagic gastritis after operation.

QUESTION: Do you think there is any relationship between distal gastritis and ingestion of salicylates?

ALDEN: I don't know. In view of the fact that intravenous salicylates will cause the same problem I would say that it is possible. People have the idea that salicylates are a topical problem, that they erode the stomach. This is not true. They destroy the mucosal barrier, and they don't have to be ingested orally.

QUESTION: When you do a Billroth I or Billroth II resection, do you take down the original gastroenterostomy?

ALDEN: If the pouch was too large, then I take down the gastroenterostomy. I prefer the Billroth I operation under most circumstances. With Billroth I, I can use the old stoma and anastomose it to the duodenum.

HALVERSON?: Many of our patients are troubled with arthralgia or arthritis. Internists often treat these conditions with Indocin®, Butazoladin®, and other noxious drugs which have a deletereous effect on the gastric mucosa. We have seen two or three patients with this problem. One woman literally scorched her upper gastric pouch mucosa and developed an obstruction. A normal dose of such medications taken into a stomach reduced in size by 90% becomes a tenfold dose. I can't explain why some patients are more susceptible than others, but I have noticed this problem in my practice and when talking with others.

ALDEN: I have seen such problems with other medications as well. It is definitely something about which to be concerned.

GALLBLADDER DISEASE

Sheldon M. Solochek, M.D.

The incidence of gallbladder disease in the general population is anywhere from 5% to 20% (autopsy specimens). Dr. Rim in Milwaukee studied 73,000 TOPS members, all women. He found that the incidence of gallbladder disease in those who were double their ideal weight was 29%. My own statistics are even higher than that.

Our series consists of 540 patients, 510 with loop gastric bypasses and 30 with Gomez gastroplasties, 20 of whom have now been converted to bypasses. The average age is 34.1 years (range 14 to 63). The initial weights ranged from 160% to 431% of ideal weight with a mean of 220%. The male:female ratio was 1:10.

The first group of patients underwent operation between January, 1975, and October, 1980. After returning from the international meeting on obesity in Genoa in the late fall of 1980, I started getting more radical in my approach to gallbladder disease. There were 270 patients in both groups. The incidence of gallbladder disease in the first group (A) was 45.9% (Figure 1). Twenty percent of these patients had had a prior cholecystectomy. This compares favorably with Dr. Madura's study on the patients undergoing jejunoileal bypasses at Indiana.
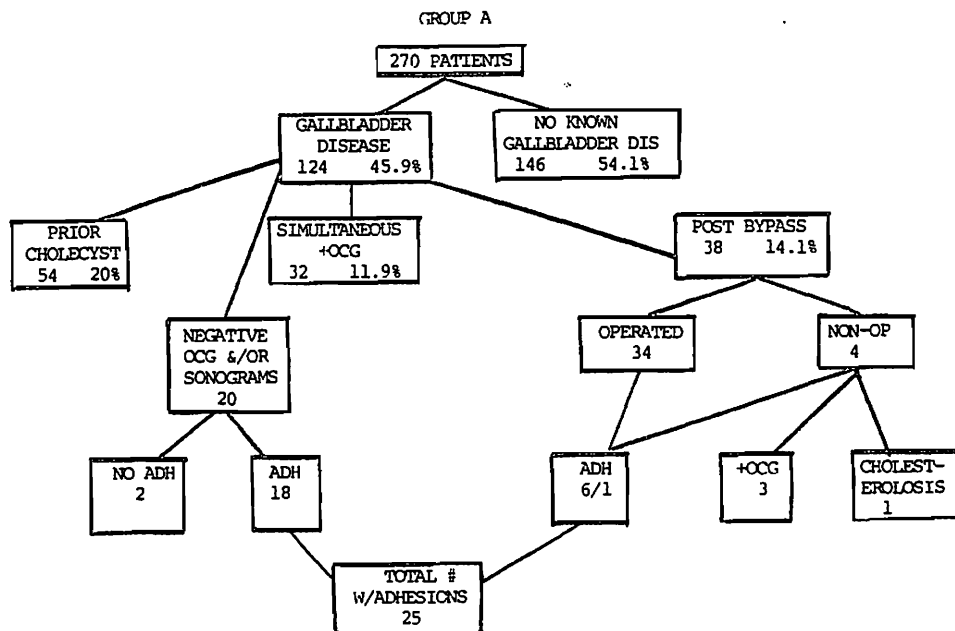

Fig 1. Group A

Data for patients operated on after October 1980 (Group B) can be found in Figure 2. In this group gallbladders were removed if they had adhesions that appeared inflammatory. These were usually adhesions of the mesocolon or omentum. Gallbladders were also removed if they appeared abnormally discolored, if

cholesterolosis could be seen through the wall of the gallbladder or if, under transillumination with a fiberoptic source, cholesterol polyps or debris in the gallbladder could be discovered. The incidence of simultaneous cholecystectomy rises to 50% in Group B. The need for preoperative cholecystectomy remained similar in Group A, 21.1% vs 20%.
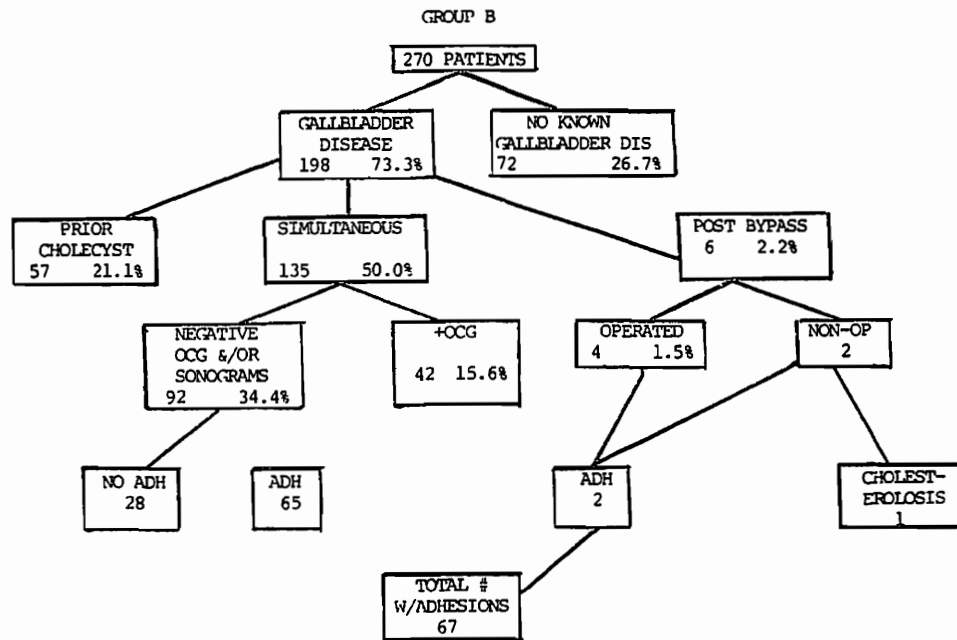
GROUP B

270 PATIENTS

GALLBLADDER DISEASE
198   73.3%

NO KNOWN GALLBLADDER DIS
72   26.7%

PRIOR CHOLECYST
57   21.1%

SIMULTANEOUS
135   50.0%

POST BYPASS
6   2.2%

NEGATIVE OCG &/OR SONOGRAMS
92   34.4%

+OCG
42   15.6%

OPERATED
4   1.5%

NON-OP
2

NO ADH
28

ADH
65

ADH
2

CHOLEST-EROLOSIS
1

TOTAL # W/ADHESIONS
67

Fig 2. Group B

Of patients in Group B who had simultaneous cholecystectmies, 93 had negative OCGs and sonograms and 15% had positive x-ray evidence of gallbladder disease. Twenty-eight patients had no adhesions. Most of these had cholesterolosis. Sixty-five had adhesions.

In the combined series of 540 patients, the total incidence of gallbladder disease is 59% (Figure 3). The incidence is higher in the older aged patients (Figure 4).

Dr. Rim, in his study of TOPS patients, found that as weight and age increase, the incidence of gallbladder disease increases. Patients who are over 55 years old and weigh 200% of ideal weight have an 42%-incidence of gallbladder disease.

Dr. Diehl studied the incidence of gallbladder disease according to race and found that Mexican-Americans have a high percentage; the American Indians have an even higher percentage. Blacks, on the other hand, have a relatively low percentage of gallbladder disease when compared with Caucasians. In my series Caucasians have a 50% incidence and Blacks have 28% incidence. The Hispanics in
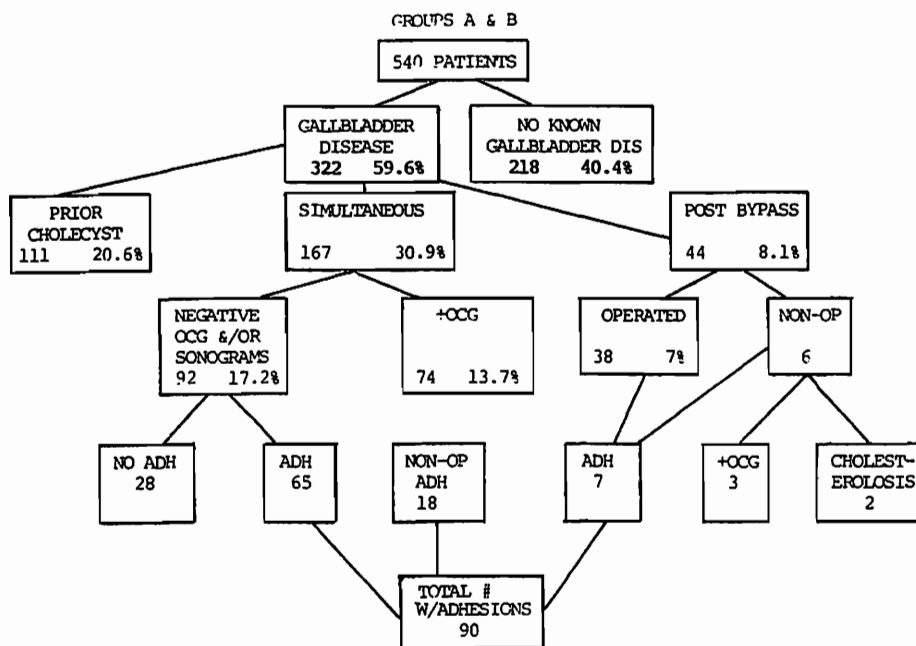
GROUPS A & B

Fig 3. Groups A and B

Gallbladder Disease in the Morbidly Obese
Incidence by Age
540 Patients
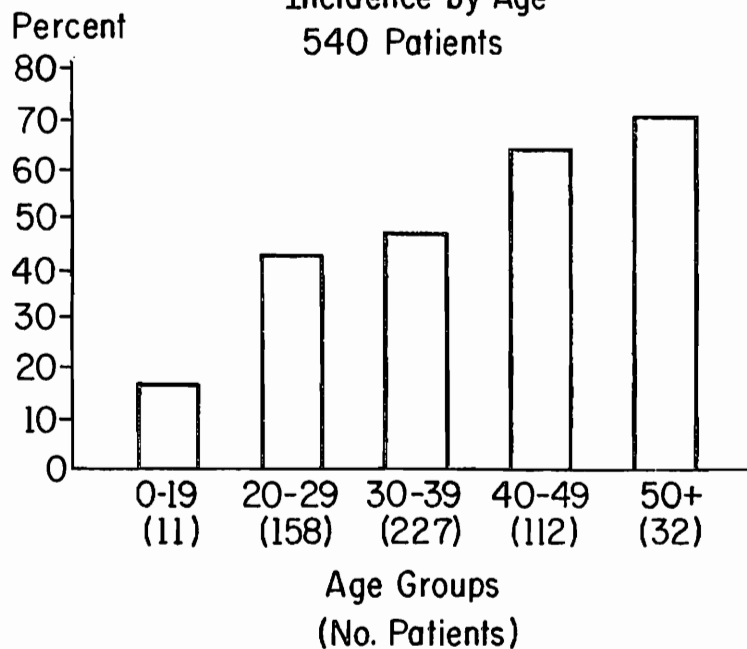
Fig 4. Incidence of gallbladder disease by age in morbidly obese patients

my series had a 38.5% incidence and the American Indians had a 100% incidence. I must point out that I had very few Hispanics and Indians.

The pathologic diagnoses for gallbladders that did not have calculi were cholesterolosis, inflammatory infiltrates, fibrosis, Rokitansky-Aschoff sinuses, granulomas, and lymphoid nodules. About 65 to 70 patients had cholesterolosis

with no stones. All gallbladders that were removed were diseased, even if they didn't contain stones. They may have been minimally diseased, but there definitely was something wrong.

Cholesterol polyps look very much like cholesterol stones. They have a little mulberry appearance but they are actually polypoid structures coming off the mucosa of the gallbladder and they are comprised of foam cells filled with cholesterol. Some of these eventually outgrow their circulation and drop off creating a nidus for gallstone formation.

Ninety-six percent of those patients who required cholecystectomy at some time after gastric bypass were reoperated on within the first two post bypass years (Table 1). This is the period of most rapid weight loss and I think that this is the main reason why people develop gallstones. Dr. Scopinaro mentioned that 80% in his series had gallstones. Dr. Madura found a 43% incidence of gallstones among patients he studied, not including the postoperative gallbladder disease, and 33% of his patients had lithogenic bile. Such patients are susceptible to gallstone formation. I believe that weight loss, and not the procedure, is the main contributing factor to cholelithiasis in morbidly obese patients. The incidence of gallbladder disease among people over 50 years of age is over 70% and they haven't had a bypass at that time. The obesity plus the many diets and fasts contribute to their incidence of gallbladder disease.

Table 1: Timing of postoperative cholecystectomy

Less than 12 months	17	(46.8%)
12-24 months	18	(49.4%)
Over 24 months	3	(3.8%)

Patient who are diabetic, according to Dr. Madura, have a 14% higher incidence in gallbladder disease. Therefore, diabetic patients should be treated even more aggressively.

I had a 15% postoperative incidence of gallbladder disease in my Group A series. When corrected for sex, race and age, the incidence is actually over 20% and increasing. In summary, I think we have to be more aggressive in removing gallbladders. If there is any indication that a gallbladder is abnormal it should be removed.

HALVERSON: In patients with jejunoileal bypass it is quite clear that bile salt absorption is impaired and the ratio of glysine conjugates of the bile acids has changed, hence by inference, changing the zeta potential on the Mi cells and

altering absorption. This, in turn, changes the siability coefficient of the bile and results in gallstones. That is a very different situation from what you are describing here. In fact, about five or six years ago Dr. Mabee published an article in Surgery showing that when people gained weight they increased the chance of supersaturating the bile with cholesterol. Can you reconcile his information with what you are observing in your patients? What is going on in these patients?

SOLOCHEK: These obese patients are supersaturated with cholesterol, but, as they rapidly lose weight in the immediate postoperative period, they mobilize the cholesterol out of the adipose cells. Cholesterol secretion into bile increases, upsetting the delicate balance. This can lead to a tremendous amount of gallstones in a very short period of time.

QUESTION: Did you ever find a stone at operation that was not seen on films?

SOLOCHEK: Yes. We had one incidence where we actually found a stone that was not visible on oral cholecystogram or ultrasound studies. We have also seen cholesterol polyps which look like stones through the wall of the gallbladder.

QUESTION: How do you transilluminate the gallbladder?

SOLOCHEK: We use a light source from a laparoscopy setup and put it underneath the gallbladder with the light turned down. This lights up the entire gallbladder. The cholesterolosis actually reflects the light producing small characteristic streaks in the wall of the gallbladder. Of course, any filling defects or debris in the gallbladder also show up.

COMMENTS: In Australia, we also have a high incidence of gallstone disease after gastric bypass in our series of 100 patients. Of a group of 52 patients who had normal gallbladders by x-ray study and no palpable stones at the time of operation, ten developed gallstones between six and 12 months after operation. Many of these patients do not develop stones postoperatively. We have looked at various data to see if we can discern which of the patients are going to get gallstones postoperatively. Most of them are women. There is very little difference in age, obesity index or the amount of weight loss. There does not seem to be any sort of clinical differences between those who do and those who do not develop postoperative stones. At operation we could find no cholesterol crystals present in gallbladder bile either in patients who ultimately went on to develop stones or in those who did not. Most of these patients have supersaturated bile. We incubated ultracentrifuged bile to see if there was any difference in these two groups of patients. The patients who actually developed stones also developed crystals within days. This was not the case for patients who did not develop stones. The main difference between these two groups is the rapid nucleation among patients who develop stones. However, the growth rate is

the same in both groups. Consequently it seems that there is something apart from supersaturation in the bile that determines which of these patients will develop gallstones in the postoperative period. We treated our patients with chenodeoxycholic acid because new stone formation can sometimes be reversed. Once the patient has lost weight the stones may dissolve. We have had two patients who had spontaneous disappearance of postoperative stones that has been visible on x-ray films. Four other patients dissolved stones while being treated with chenodeoxycholic acid. Although chenodeoxycholic acid treatment is plagued by recurrence in the ordinary gallstone patient it may be an effective treatment for this complication after gastric operations for obesity.

O'LEARY: How do you know that the stones dissolved because of the chenodeoxycholic acid and didn't just spontaneously disappear as happened in 20% of your series?

RESPONSE: First we document that the patient has stones. Then we give the patient time to see if the stones will spontaneously dissolve. If this doesn't happen we begin treatment with chenodeoxycholic acid.

COMMENT: I certainly agree with Dr. Solochek that cholesterolosis should be removed. I have been disturbed by the incidence of cholelithiasis in the postoperative period. Consequently, for the last three years I have been routinely taking a large bore needle and a large syringe and aspirating all gallbladders. I send the bile to the pathologist and ask him to tell me whether it is lithogenic or not. The pathologist looks for cholesterol crystals, microliths or calcium bilirubinate. Calcium bilirubinate is an amorphous debris. However, if patients do have a lot of calcium bilirubinate the bile will have a brownish discoloration. The microliths and cholesterol crystals are undisputably lithogenic. The calcium bilirubinate is less diagnostic, however, if it is strongly present I routinely remove the gallbladder. By aspirating the bile out of the gallbladder, one can commonly feel stones that would not have been felt otherwise.

IMPROVEMENT IN OXYGEN CONSUMPTION

Donald Zavala, M.D.

Morbidly obese patients belong to a rather select group of entrapped, desparate people who live a miserable existence. They are often unable to work. They are prone to a variety of conditions including hypertension, stroke, coronary heart disease, degenerative joint disease, diabetes mellitus, liver disease, gallstones, renal stones, stasis ulcers, hernias, certain types of carcinoma, psychological problems, especially low self-esteem and even premature death. The list goes on and on.

Many of these people do not eat because they are hungry. They simply overindulge because food is available. Their eating continues as long as they have the time and the energy to eat. One of our patients even claimed to eat during her sleep.

The most common cause of overweight in the United States is simply overeating, that is food in excess of energy requirements of the individual. In recent decades an incalculable amount of time, money and effort have been spent to devise solutions to the problem of the overweight. It has been estimated that anywhere from ten to 50 million Americans suffer from this affliction. The National Health and Nutrition Survey made almost ten years ago found that 5% of men and 7% of women between the ages of about 20 and 74 years were severely obese.

The population of Iowa is no exception. We have an abundant supply of food and have been called the bread basket of the nation. Obesity here is a very serious problem. Indeed, over the past 15 years the surgeons at The University of Iowa have performed bariatric operations on over 1,000 patients.

We use the body mass index (weight in kilograms divided by height in meters squared) to estimate obesity. We judge the patient to be obese when the index reaches 25. An index of 30 will produce an increased mortality. Morbidly obese patients have indices of 45 and above. The mean index for obese patients treated at The University of Iowa is 54.

The likelihood of an individual maintaining a 40 lb weight loss for five years approximates that of surviving cancer of the stomach for five years after the diagnosis is made. Obviously, the chances are not good that these patients are going to maintain a 40 lb weight loss in spite of the vast armamentarium of diets, exercise and behavioral and pharmacologic approaches.

The success of any metabolic study is dependent on two major factors: 1) the expertise of the technician and 2) the quality of equipment. For data analysis we use the 4052 Tectromics computer. The data are displayed on a CRT screen and hard copy can be generated in only a few moments. Input and output regarding five major devices pass through this computer via a multichannel analog digital

converter. These five devices are: a high temperature, silicone fuel cell, oxygen analyzer made in Sunnyville, California; a CO_2 analyzer from Helsinki, Finland; a pneumotachometer that measures the frequency of breathing and the minute ventilation; a cardiotachometer to measure heart rate; and finally a Hewlett-Packard oxyimeter to measure O_2 saturation on patients during exercise without the need for an arterial line.

Air passes to and from the patient through a two-way Hons-Rudolph valve into a mixing chamber where O_2 and CO_2 are analyzed. This is done 100 times per second by the computer. There is tapoff to check the in tidal O_2 and CO_2.

We utilize a 12-line ECG monitor during exercise to keep track of the cardiovascular status of the patient. This is important in these patients.

We obtain a resting blood gas before exercise and an arterial blood gas in the final stage of exercise if the patient is exercising on a bicycle. We cannot do this if the patient is on a treadmill but the oxyimeter is proven to be so accurate that we rarely need to draw blood gases during exercise.

For obese patients we seldom use a bicycle. It is difficult for them to sit on it. We transferred them to a treadmill set at two miles per hour at 0 elevation. Although this is about the speed of a slow turtle, it is enough to require great effort on the part of the patient. Some patients, even at this extremely low work level, actually exceeded their anaerobic threshold.

The maximum levels were predicted for all of our patients so that we would know what the end points were. From the standpoint of safety, this was extremely important.

We used a special chair for the patients during basal metabolic study. If you do the study with the patient in the recumbent position, the VO_2 oxygen consumption will increase at least 15% because the diaphragm moves up producing high results. We also use a wide blood pressure cuff.

One man had a minute ventilation of almost 93 l/min. The normal is about 20 l/min. This means a fantastic amount of air is going through the patient's lungs. Furthermore, this patient's VO_2 rose to 3.5 l/min (normal = 2.2 l/min). For a normal person that would be equivalent to running the 25 mile marathon, although the patient was only walking at two miles per hour. This patient is obviously paying a fantastic price for his obesity. He crossed his anaerobic threshold and desaturated. His oxyimeter reading dropped from 94% to 76%. After walking three minutes at two miles an hour we drew blood gases and found that his PO_2 dropped from 73 to 44 torr. This patient was a hypoventilator who had problems sleeping at night and would frequently fall asleep during the day.

After weight loss, all of these factors improved. His minute ventilation dropped from 93 to 56 l/min; his VO_2 dropped to about 2.5 l/min. His PO_2 rose

and his O_2 went from 75 to 82. Resting PCO_2 dropped from a preoperative level of 37 to 33 after weight loss and exercise.

We tested 13 patients six months after operation. Their average age and weight at operation were 33 years and 345 lb respectively. The largest patient weighed over 500 lb, and was 67 inches tall. There were nine females and four males. At the end of six months, the weight loss averaged 90 lb. The average heart rate, at rest, dropped from 82 to 64 beats/min. The VO_2 and PCO_2 dropped with weight loss as well as the respiratory quotient, 0.72 to 0.69.

We predicted that the frequency of breathing would fall, but it actually rose. The frequency of breathing times tidal volume gives the minute ventilation rate. These patients consume a tremendous amount of oxygen. We divided the patients according to sex and found that the women increased the frequency of breathing but the men did not. We believe the reason for this may involve an increase in hormonal activity in women after weight loss. This, of course, requires further study before we can draw definitive conclusions.

HALVERSON: Have you made any attempt to subdivide your patients according to the presence or absence of hypoventilation syndrome, left ventricular dyskinesia and pulmonary hypertension? Also, what are your postoperative care recommendations?

ZAVALA: Since we only have 13 patients, we have not made these subdivisions yet. In regard to postoperative care, it is necessary to get these patients up and moving. Nonetheless, they may cross their anaerobic threshold. If there is some concern about this preoperatively, it would perhaps be best to delay operation and place patients in the hospital on a very strict diet. Exercise at a low level should also be initiated. The most accurate measures of the patient's respiratory status are the blood gas levels. If blood gases are abnormal operation should be delayed while the patient loses weight on a hospital supervised diet.

QUESTION: Should oxygen therapy be used postoperatively?

ZAVALA: Oxygen therapy should be used with great caution. Exercise is probably better.

DISCUSSION OF BARIATRIC SURGERY'S OVERALL EFFECT ON PATIENTS

John D. Halverson, M.D., Paul W. Moen, M.D., J. Patrick O'Leary, M.D., and Kenneth J. Printen, M.D.

O'LEARY: I would like to discuss for a moment our experience with bariatric surgery in patients over the age of 50 years. We have performed initial operations in 33 such patients and have done five revisions. Two of the revisions were performed to correct a dilated pouch and the remaining three were done to correct biliary gastritis.

Most of these patients' ages fell in the 50 to 55-year range, but we did have four patients who were 57 and one each age 59, 60 and 64 years. Two patients were 100 lb over ideal weight, 13 were 101 to 125 lb over ideal, seven were 126 to 150 lb over ideal and three were more than 151 lb over ideal weight. Six had heart disease, 27 were hypertensive, eight were diabetics and 22 had musculoskeletal disorders consisting of either low back pain or aches and pains in the hips, knees, thighs, ankles and legs. We performed 21 concomitant cholecystectomies. Nine had had a previous cholecystectomy. We removed the gallbladder after bypass from the remaining three patients. We removed the spleen from four patients, in three this was due to inadvertent bleeding. The other patient had a splenic aneurysm. I have done nine liver needle biopsies, seven omentectomies, one appendectomy and four umbilical or ventral hernial repairs. Our operating time for most of the patients was under 2½ hours. However, the operation did take longer in the revision patients and in some who also had other comcomitant procedures.

These patients stay longer in the hospital after operation. They do not respond quite as readily as the younger age group.

In regard to weight loss, I think that our patients have done very well. We hear criticisms that the older age group does not lose as well, but at least two of our patients have lost over 100% of their excess weight and the majority have lost 60% or more.

The early complications included one death, a couple of pleural effusions and one patient who required mechanical ventilation for 48 hours. There was also one wound infection. One patient developed phlebitis after discharge. Other late complications include two ventral hernias and the esophagitis and dilated pouches that necessitated the five previously mentioned revisions.

Including patients over age 50, we have now operated on a total of 428 patients. We perform a standard loop gastric bypass with a 50-ml pouch and a 1-cm anastomosis. In the last 260 patients we have used double TA90 staple lines and gastrostomies in the distal pouches.

We sent questionnaires to 300 of these patients, 204 of which were completed and returned to us. These patients felt that the main reasons for having the operation were poor self image and medical complications of obesity. The complications mentioned most often were hypertension, diabetes and musculoskeletal problems. Operation was a last resort for 62 patients who claimed they tried everything else. Included in this group are several patients who said they had reached the point of suicide. Other reasons that caused patients to seek operative treatment included limited physical activity, insomnia and inability to conceive. Many of these people were finding it increasingly difficult to do their job or to find jobs in the first place.

When we asked how bypass had changed their lives, 196 patients reported a better self image after operation. The medical complications either improved or disappeared in 103 patients. The great majority of the patients who were taking antihypertensive drugs no longer need these medications, and we have only one diabetic in this series who still requires insulin. Most patients claim they are able to do things with their families that they have never done before. They felt they had better career opportunities and better sexual relations. Four women were able to conceive who could not before, and have a child and three clamied they were more relaxed and could now sleep better.

One hundred and five patients believed their marriage improved after operation. Only four felt it was worse. Twenty-six of the patients were single and therefore did not answer regarding this point. Overall, the majority of patients were extremely pleased, would recommend the operation to others, and would have it again if necessary.

In spite of this success, there is one message that I would like you to tell all your bypass patients and that is: Don't wail on the scale if you cheat when you eat.

QUESTION: Do you think the double staple lines cut down on the chance of dehiscence?

O'LEARY: Most people agree that a double row of staples make dehiscence less likely. However, at this point there is still no concrete evidence from animal studies regarding the double staple line. Furthermore, certain care must be taken in placing the second application of staples. It is dangerous to put those rows too far apart. Our data from animals indicates that a too wide placement causes ischemia in the area between. We have had one death that was probably related to ischemia occurring between double rows of staples that were 1 cm apart. We certainly had deaths in our animal laboratory.

PRINTEN: We have done similar work in the animal laboratory. We found that all the stomachs in the experimental animals would necrosis when the staple lines were

placed 1 cm apart. We also found that it if we place them on top of each other they are less likely to cause leaks, at least in the experimental animals.

QUESTION: Should a double application of staples be mandatory?

HALVERSON: Alden still uses only one row and so do I. I feel strongly that we need to select the patients carefully and avoid the ones who will unduly strain their operations.

QUESTION: Are the instrument companies developing a stapler that will leave four rows of staples in a single firing?

MOEN: Yes, but as yet there are many technical difficulties that have yet to be overcome.

QUESTION: What type of screening should be used for children?

MOEN: They should all be worked up by pediatricians preoperatively. Endocrinological causes of obesity should be ruled out.

QUESTION: What do you do for children with Prader-Willi syndrome?

PRINTEN: These children have the disease that beats the operation. The disease process inclines them to eat all day long; they will eat anything including bandages and even IV tubing. Obviously, the goals in treating children with Prader-Willi syndrome should be different. It is unrealistic to expect a permanent and marked weight loss. However, the oepration does keep them checked so that they don't continue to gain. If you operate while the patient is young enough, it is possible to retard weight gain so that height and weight catch up with each other on the normal growth curve.

IMPROVING SELECTION CRITERIA

Marilyn L. Bukoff, R.D., M.A.

I feel there is a need for objective criteria to aid in selection of candidates for gastric reduction surgery. At the present time, most surgeons select patients based on subjective feelings. Although that is the fastest and easiest thing to do, I believe that some failed operations may be related to poor patient selection.

In an attempt to find objective criteria that will differentiate good from poor candidates, I have been gathering some information on gastric reduction patients. The type of data being collected includes patient education, income, occupation, the occupation of the spouse and the environmental and condition of the patient's family during childhood.

A review of the literature produced only three articles that address selection of candidates for gastric reduction surgery. These studies used psychological testing to try to find some objective criteria for patient selection. Tools used to study patients in these three reports included psychiatric diagnoses based on DSN3 criteria, the Minnesota Multiphasic Personality Inventory (MMPI), a problem index and a brief intelligence test. Self-report rating scales and demographic data forms were also used. None of the studies produced conclusive selection criteria. Indeed, if anything, they added to the controversy as to whether gastric reduction patients do have psychological problems and how severe these may be.

I am doing two different studies. The first is a retrospective study of patients who underwent Roux-en-Y gastric bypass sometime between 1976 and 1978. There were 29 patients in this group. The mean pouch volume was about 52 ml and the mean stomal size was 12.7 mm. Two of these 29 patients died and five were lost to follow-up. The remaining 22 patients were contacted either by phone or were mailed a questionnaire. Twenty were women and two were men. When contacted, most of the patients were between their fourth and sixth postoperative years. The variables that I studied were educational level, income and occupation at time of operation and spouse occupation if the person was married.

The second study is prospective and was begun in September 1981. At this time the study is still incomplete. However, the variables being studied are similar.

The mean income, which is combined if both husband and wife are working, is $12,600 for both studies. The majority of patients are married and most are employed. Statistical analysis comparing different socioeconomic factors failed to show a significant correlation with weight loss. Nor was there any significant relationship between demographic factors and weight loss. I divided the patients

into three groups according to the number of years of education (0 to 12 years, 13 to 16 years and over 16 years). I obtained the mean scores of these different levels and compared them with each of ten subscales of the family environmental scale. Two tailed, two sample t tests again failed to reveal any significant differences between groups.

I did find a correlation between higher income groups and family cohesiveness, although this does not correlate with weight loss. Some studies have suggested that families that are not coherent are predisposed to eating disorders. Another study by Muse on alcoholics and their treatment suggests that alcoholics whose families scored high in cohesion have a better treatment outcome. It is hoped that this will carry over to obese patients.

In conclusion, at this point it is not possible to distinguish demographic variables that will accurately predict patient outcome after gastric reduction operations. However, that does not mean that predictive variables do not exist. Further prospective study with larger groups of patients is necessary and should be undertaken at a number of centers.

MEASUREMENT OF IMPACT ON LIFE

Cheri L. Florance, Ph.D.

Our overall goal for the morbidly obese patient is to facilitate weight loss and improve health. We also would like to improve the patient's mental well-being, interpersonal relationships, private self-concept and ability to function on the job. To formulate a program for the morbidly obese patients we used a similar program that we had developed over the past ten years to treat stutterers. The stuttering patient often leads a lonely isolated existence because of the inability to communicate. As these patients were able to learn to speak, they faced massive changes in their lives. Our program for stutterers was one of the first effective treatment regimens for this disorder. In fact, the program was reviewed by the President's Mental Health Commission and determined to be a major breakthrough in the treatment of mental illness. This resulted in patients coming to our center from all over the world, and consequently gave us the opportunity to study a large number of patients with a wide age range from various cultures. As our program continued to develop, we found that some of these patients were readily complying with treatment and making enormous changes in all aspects of their lives while others were rebelling against treatment, engaging in self-defeating behaviors and attempting to do things that would slow down their progress thus inevitably leading to failure. We became obsessed with trying to understand why patients would try to sabotage their own successful outcomes. We began to study the problem systematically but failed to identify factors that would characterize the compliant or noncompliant patient.

Clinically we began to feel that the problem went beyond our special population of stutterers. It seemed to be based in some phenomenon of human nature. Therefore, we started replicating our work on morbidly obese and stroke patients. We found that these patients, in addition to their specific medical problem, i.e., speech, obesity, or stroke, presented with many different problems that often required differential treatment. Therefore, we theorized that if we tailored treatment to the individual patient's unique needs, our chances of helping the patient might improve.

After five years of steady work we believe that the most important factor in predicting outcome relates to the patient's defense mechanisms and abilty to cope. Stutterers and morbidly obese patients often blame everything that happens to them on their weight or their speech. Their affliction becomes an excuse for their lack of success in their job or their lack of positive social relationships. Consequently a mechanism which contributes to a healthy ego or sense of well-being has not yet evolved. When we treat such patients and remove the excess weight or improve their speech, we take away this singular excuse and leave them with no

subconscious way of coping with emotional stress. For this reason we began our program by trying to strengthen the patient's ability to solve problems, integrate information into daily routine, and to control daily life and behavior.

To further study this we assigned patients to groups according to outcome. We consider the surgical outcome, compliance to the postoperative regime, weight loss and impact on the patient's basic life system. We feel that if there is no change in the patient's life system, relapse may be forthcoming.

To define success we looked at several variables other than just weight loss. We asked the medical staff how they felt about the patient's outcome and whether they felt it was a success. We also studied the patient's own self-perceptions regarding improvements in life style and self-concept. We developed a questionnaire to survey these subjective opinions which was administered to 82 patients during postoperative checkups. Seventy-five percent of the patients had reached at least the sixth postoperative month and some were as much as two years after operation. Seventy-five percent had lost a minimum of 50 lb with many having lost well over 100 lb.

We found that 77% of patients felt they had improved their physical health and well-being. Ninety percent of patients felt they had achieved improved eating habits and no longer considered their lives to be controlled by eating. In regard to the activities of daily living, including personal and vocational achievements, 83% of patient noted an improvement. Sixty-two percent also felt that interpersonal relationships were better, and only 10% felt they were worse. We found the same basic patterns among our stuttering population. However, in interpersonal relationships if one person changes, the other may need to change concomitantly. If this does not occur, the intensity of the relationship may lessen or cease completely. In terms of private self-concept, 81% of patients felt they were better and more in control of their lives.

To check for bias we compared the staff evaluation of the patients with the patient's own evaluation. We found an 86% rate of agreement.

In summary, we have found that in addition to changes in physical appearance, patients are experiencing dramatic changes in their sense of well-being and personality development.

WEBER (Astoria): I would like to describe the experience that I had in initiating a program of bariatric surgery in a small community hospital. Our hospital has 75 beds. I decided to use vertical banded gastroplasty, however, I was faced with a problem. Although the nurses and dietitian were interested, the psychiatric and psychological backup was lacking, both in terms of experience and interest. In further thinking about the patients it also occurred to me that not all morbidly obese patients are the same in terms of psychological makeup. While they all need

close, long-term follow-up study, clearly some need more support and closer supervision. It occurred to me that any program should have the capabilities for tailoring the pre- and postoperative care to the individual needs of the patient, especially with regard to behavior modification. It is easy to be fooled by some patients. We sense that some will do well and others, not so well, but personality disorders can often be unpredictable. My solution to that was to ask Dr. Florance to see if she could screen my patients using the experience that she had with the large series at Ohio State. With Dr. Florance's help, we devised a testing method in order to place the patients into categories preoperatively. These consisted of high risk patients, low risk patients, and those who fell in between. In this way we determined in advance which patients would require more vigorous follow-up care. Thus we were able to set up a series of tailor-made behavioral modification modalities to help improve the risks for these patients. For my community, using a small facility where other backup was otherwise not available, this has proved to be a very rewarding experience.

PREADMISSION PATIENT EDUCATION

Cathy M. Mojzisik, R.N.

Preadmission education should provide the patient with information that will serve as a basis from which a decision can be reached regarding whether or not to undergo a gastric reduction operation. As a provider of this information, I became interested in analyzing the effectiveness of my teaching and in trying to understand what the patients do and do not learn.

Three questions guided my research. The first was, what do the patients know before they come to the clinic, and what was the source of their information? The second question was, what do patients actually learn about the operation? The third question was what do patients not learn?

To answer these questions, I asked 29 patients who entered our obesity clinic to fill out a pretest before attending the educational group session. It consisted of multiple choice and true/false questions regarding the operative techniques, pre- and postoperative care, and definitions of what is truly meant by exercise. There were also questions about the risks and complications of the operation.

Upon completion of the pretest, the patients gathered as a group to participate in my educational session. During this session I discussed preoperative care, what we expected from the patient prior to coming to the clinic in terms of behavior modification, the hospitalization, preoperative tests, postoperative care and exercises. I went to great lengths to describe the operation, our follow-up program and the risks. Visual aids were helpful in communicating this information.

Approximately one month after the initial clinic visit the patients were admitted into the hospital and the test was readministered. The results showed that patients knew in advance about the operation. They were able to describe a simple statement regarding the principles of operation. They knew that they would be placed on some form of liquid diet postoperatively and they were even able to tell me that blenderized foods were considered to be liquid. They knew that they would be responsible for counting calories and would be on a low calorie diet. They also knew that they would be expected to exercise and change their life style, and that this operation offered no guarantees.

From my educational session they learned the size of the staples. While this may seem inconsequential to the surgeon, it is something about which the patient has no concept. Three of ten people were able to tell me that the staples are smaller than an office staple. This helps the patients to realize that the staple line dividing the pouch is fragile and thin, and that they need to be very careful about what and how much they eat. The patients also learned that we still

consider our procedure to be experimental. They know that our technique is one of many.

In regard to complications the patients learned that staple line disruption can and does occur and that it is not caused by falling down stairs or changing a tire, but rather by overeating. They understood problems of basic food intolerances. Nine of ten patients could list three categories of foods that may cause problems. They knew that common intolerances included beef, chicken and bread.

While patients demonstrated a basic understanding of some late postoperative complications such as staple line disruption and food intolerances, they did not learn as well about other potentially more serious complications. In fact, only 60% of patients have recognized that there may be complications after bariatric operations. I spent a great deal of time communicating the dangers of perforation to them, but there was no difference between the pre- and post-test scores regarding this complication. Dehydration is another complication about which the patients clearly are not assimilating information in spite of the fact that I stress this possibility and its treatment during the preoperative educational session. Indeed, three of ten people came into the clinic not identifying that they could die as a result of an operative complication.

I have speculated with Dr. O'Leary about why patients retain some piece of information but not another. He calls it selective deafness. I believe that people hear what they want to hear. They retain the kind of information that is interesting and visual such as staple size. This is something they can share with their family and friends, and that is readily recognizable. But when it comes to talking about death or perforation or some of the other more dangerous complications, I believe the patients wish to deny these possibilities, not only to themselves but also to their friends.

As a result of this study I now stress even more the dangerous complications and the risk of death. I try to set the tone very early and to let the patient know that this a drastic procedure, and I use even more visual aids. I feel that such methods should be incorporated into all preoperative teaching programs.

PREOPERATIVE AND POSTOPERATIVE PSYCHIATRIC STUDY

Kathye Gentry, M.S., PAC

We studied a group of psychiatrically and psychologically stable patients selected for surgical treatment of obesity in order to determine the psychological changes resulting from the operation as well as the psychological traits that might be used preoperatively to optimize the selection of patients most likely to comply with the postoperative dietary requirements. Postoperative dietary compliance has been shown to be important to the success of operative treatment. If high caloric intake continues postoperatively, the patient is likely to fail to lose and maintain weight loss.

All patients in our study underwent thorough medical and psychiatric screening and careful dietary counseling. Frequent postoperative contact also was carried out. We followed standard selection criteria in choosing patients (Table 1). Psychological stability in our study was defined as the acceptance of the need for extreme caloric restriction postoperatively, acceptance of responsibility for maintaining long-term weight loss, and a realistic attitude toward the impact of weight loss on the patient's life. Failure to meet any of these criteria resulted in exclusion from operation. Psychiatric evaluation was conducted by a resident psychiatrist using the Renard Research Interview which was based on diagnostic criteria developed by Finer et al. In addition to the preoperative evaluation, patients were also interviewed during the period of hospitalization. Patients were eliminated if during these sessions it was felt that they maintained an unrealistic attitude about either the operation or the effect it would have upon their lives. One-half of all patients who were admitted to the hospital for final preoperative evaluation were rejected, in most cases, for psychological reasons.

Table 1: Criteria for selection

1. Weight of more than 100% over ideal.
2. Documented medically supervised attempts at weight loss.
3. Exogenous obesity.
4. General good health.
5. Lack of active diagnosable psychiatric disease or psychological instability.

Thirty-three patients selected for operation were given five psychometric tests (Table 2). The clinical analysis questionnaire provides a multidimensional psychological profile of the subject. The index of self-esteem is a short-form, self-report scale. The optimism-pessimism test measures optimistic and pessimistic traits as they pertain to interpersonal relationships, the ability to perform tasks and perceptions of the future.

Table 2: Psychometric tests

---

1.   Clinical analysis questionnaire.
2.   Index of self-esteem.
3.   Optimism/pessimism scale.
4.   Eating questionnaire I.
5.   Eating questionnaire II.

Two eating behavior questionnaires were developed to assess obesity. The first questionnaire consisted of a series of open-ended questions covering the reasons for obesity, the motivation for weight loss and past attempts at weight loss. The second questionnaire was an indepth structured interview that included evaluation of attitudes about food and self-image as an obese person. It also included the dietary history, the patterns of hunger and food intake, assessment of activity, and patient satisfaction with various aspects of living.

All but one of the patients were women, and the mean age was 32 years. Seventy-six percent of patients were white; 24% were black; the rest belonged to other races. The mean preoperative weight was 225% of ideal. All patients underwent a stapled, loop gastric bypass.

The five psychometric tests were readministered in the second postoperative year. The weight loss ranged from 20% to 93% of excess weight. The most rapid rate of weight loss occurred during the first six postoperative months. By the end of the 24th postoperative month, 83% of patients had lost more than 50% of excess weight. Postoperative employment also improved.

Nonetheless, noncompliance occurred in four basic areas. There was evidence of noncompliance of one or more types in 36% of patients. It should be noted that this rate compares favorably to the rate of noncompliance in the general medical patient population as a whole, and, therefore, we feel the patients have a reasonable rate of compliant behavior for this study. There was a history of primary effective disorder or depression in four patients and a history of alcoholism in two. Three other patients had a history of either hysteria, mild mental retardation or anxiety neurosis. There was no current active psychiatric disease. These diagnoses were based on the rigid research criteria previously mentioned. Postoperatively no active or newly diagnosed psychiatric disease developed in any of the patients.

Preoperatively the clinical analysis questionnaire revealed a profile that was not different from the standard population. There was a slightly higher incidence of depressive traits. None of the traits, however, correlated with the percent of excess weight lost postoperatively. Preoperative evaluation demonstrated low self-esteem in all patients. This low self-esteem continued

postoperatively despite marked weight loss in most patients. In spite of this low self-esteem, patients did have higher levels of optimism. However, these high levels of optimism again did not correlate with the percent of excess weight lost.

All patients had tried multiple weight loss regimens preoperatively. Most had never maintained a weight loss for more than three months. When asked to rate themselves regarding psychological weaknesses, patients consistently rated themselves low (Table 3). These feelings did not change significantly after operation. The absence or presence of psychological strengths did not correlate with weight loss. Even when motivated, patients reported little or no ability to adhere to diets. They blamed feelings of nervousness and discouragement and the boring quality of dietary foods as the major reasons for failing to adhere to diets. Many patients identified concerns of their parents or their marriage partners as the major external motivators for their dieting. On the other hand, nervousness, boredom and the sight of food itself were reported as the internal triggering mechanisms for overeating (Table 4). Postoperatively, a larger percent of excess body weight was lost by the patients who gave overeating as the reason for obesity (p < 0.05).

Table 3: Psychological weaknesses: Number of patients with abnormal traits preoperatively and postoperatively

Trait	Preoperative (N)	Postoperative (N)
Nervousness	7	11
No self-confidence	19	19
Shy, self-conscious	19	18
Overconcern with others opinions	19	16
Difficulty expressing feelings	19	16
Need for personal perfection	33	33

Sixty-four percent of the patients stated their motivation for weight loss was a desire for better health. The remainder were motivated by vanity or peer pressure. The group motivated by concern for health lost less weight (p < 0.05) than those who were motivated by either vanity or peer pressure.

Body image as reported by the patients was uniformly poor but improved postoperatively (Table 5). Food was used as a reward or a measure of parental affection during childhood. As adults eating patterns continued to be related to emotional stress. Those patients who ate in response to pleasant feelings or a sense of accomplishment lost more weight postoperatively (p < 0.0005) suggesting the institution of new reward systems that were not based on food.

Table 4: Motivating factors.

Reason for Obesity	N	Motivation for Weight Loss	N	Motivation for Eating	N	Motivation for Surgery	N
Overeating*	19	Be healthier*	12	Boredom	6	Lose some wt	13
Liking to eat	3	Look better	9	Sight of food	5	Be thin	6
Heredity	3	Able to work	4	Nervousness	3	Enforce diet	6
Wrong foods	2	Please kids	2	Cooking	2	Decrease hunger	3
Other	6	Other	3	Parties/ holidays	2	New start in life	3
				Being alone	2	Other	2
				Need for more Other	3		

*$p < 0.05$

Table 5: Body image as measured by patient perception of weight and satisfaction with mirror image

	Preoperative (N)	Postoperative (N)
Perception of weight		
Very overweight	33	19
Slightly overweight	0	10
About average weight	0	4
Satisfaction with body		
Very dissatisfied	24	8
Moderately dissatisfied	8	12
Neutral	1	8
Satisfied	0	5

Some preoperative patterns were more resistant to change. Eating brought on by a feeling of nervousness, boredom, anxiety or depression continued although less food was consumed. Overall, 60% of patients reported a decreasing interest in food. All patients had reported binging preoperatively. Postoperatively, 92% reported cessation of this practice. Patients generally felt that they had a good social life preoperatively but 80% reported increased social activity after operation. All patients anticipated even more activity as weight loss continued.

A review of the psychological literature revealed that even in the mild to moderately obese population, there is a high rate of failure to maintain weight loss. Nonsurgical treatment of morbid obesity is unlikely to be permanently successful. After gastric reduction, 90% of patients can be shown to lose at

least 50% of excess weight. Patients in this report followed up for more than two postoperative years have maintained their weight loss without serious complications or adverse life-style changes.

Although there was no measurable improvement in self-esteem, patients did report an increase in self-confidence that was accompanied by an almost universal expression of satisfaction with life postoperatively that persisted well beyond the initial weight loss period. The fact that these feelings of well-being persist may indicate that the psychological components contributing to the morbid obesity in the patients have indeed undergone change. Moreover, the dramatic changes in eating behavior may indicate that relief from hunger is the factor that allows maintenance of weight loss. The psychologically benign postoperative course and the persistence of weight loss after the initial rapid weight loss phase suggest that the operation does not induce emotional decompensation. Since dietary compliance postoperatively is crucial, it is felt that only psychiatrically and psychologically stable patients should undergo gastric reduction. The development of further psychometric tests to facilitate the selection of the ideal surgical population will depend upon the recognition of the factors required for the initiation and maintenance of behavioral changes that are necessary for an optimal result.

DISCUSSION OF MALPRACTICE AND BARIATRIC SURGERY

James P. Hayes, J.D., Edward E. Mason, Ph.D., M.D., and J. Patrick O'Leary, M.D.

O'LEARY: It seems appropriate that we approach a problem that has been in the closet of medicine for a number of years and has only recently become paramount in many of our practices. In the past, we always did what we felt was the best for patients, and now we find ourselves in a position of being held accountable for this in court. Although it is not completely inappropriate that this should happen, it has been a rude awakening for many of us. To better understand the problems that exist, we have asked James P. Hayes, who received his degree in law from The University of Iowa and practices in Iowa City, to open the discussion and to give us the legal aspects of the problem.

HAYES: I stand before you with some temerity. Dr. O'Leary did not mention that I am a plaintiff's lawyer in medical negligence cases. Nonetheless the words that I have to say I hope will be of some benefit in an overall perspective from the viewpoint of the plaintiff's lawyer and from your viewpoint as physicians. Medical negligence and the lawsuits and settlements which surround litigation of such cases from probably the single most emotion-laden area of the law. I represented a young fellow a few years ago who was totally blinded by medical malpractice. He was awarded the largest verdict issuing from medical negligence in the State of Iowa. Nevertheless, he told me many times after the award that he would never counsel anyone to file a medical malpractice suit because it is so emotionally disruptive.

In malpractice cases we must never lose sight of basic premises. We get caught up with clients who see a bad result and figure that they have a medical malpractice case. They see negligence, and even when there are no damages, they contemplate a medical malpractice suit. They read the papers and see all of these cases that are filed in huge amounts and this perhaps engenders some greed.

There are four basics elements that must be present in order to justify a malpractice suite. The physician must have a clear duty to the patient. There must be dereliction of duty on the part of the physician; there must be damages to the patient/client; and the damages must be caused by dereliction of the duty.

Many clients come into my office having one of these four basic elements, but not the other three. It becomes a sorting out process that requires a great effort on the part of the attorney. A doctor should not be sued and brought into public ridicule or public discredit unnecessarily. At the same time, when the patient/client has been terribly injured his/her rights must be protected.

Informed consent is probably the hottest issue in medical negligence cases. Miscommunication and misunderstanding are the major problems with any medical complaint that reaches the attorney's office. Only about 20 of every 100

complaints that come to my office turn out to be viable negligence cases. Nevertheless, it falls upon the lawyer to sit down and explain to the client why he/she does not have a case. Unfortunately, by the time legal advice is sought there has been such a wedge driven between the patient and the physician that little hope remains of ever getting them back together.

I have learned over the years that the best way to avoid litigation is to keep good records. When the patient comes for the first interview with an attorney it is an emotional time because the patient is upset about his/her injury. In making the determination about the viability of a case I rely more upon the record than what the patient tells me. I also have the records informally reviewed by an expert in the particular area of question. I avoid professional testifiers and look for a practicing physician who can give me more than just an opinion as to whether or not my client may have a case.

I take no marginal cases because, in my experience, marginal cases cannot be won. In order for a physician to be legally negligent he/she must fail to deliver to the patient the expected standard of treatment, care and attention that similar physicians under like circumstances would deliver. I have found over the years that in order to win a malpractice case, the patient/client must be able to prove gross negligence.

Unfortunately, there are too many lawyers who file law suits based on the client's perception of what happened and not on careful examination of the records. But it is also true that there are instances of malpractice. Initially, most judges and juries are prejudiced in favor of the physician. When a case goes to trial, it makes a difference whether or not the damage has resulted from an elective operation. Juries, in particular, seem to use a different set of standards when judging operations that are cosmetic. They are much more likely to find in favor of the patient if the procedure was mandatory.

One of the legal premises that probably gets more cases dismissed than anything is the statute of limitations. The statute of limitations in most states is generally two years from the time the injury occurred or two years from the time the injury was discovered, or, in the case of minors, one year after the person becomes an adult.

O'LEARY: Had I addressed the problem of medical malpractice ten years ago to a group of medical students or the medical community, there would have been no one in the audience. Today there has been a complete turnabout primarily instigated by the large number of suits and skyrocketing malpractice insurance premiums. To protect ourselves, aside from practicing the best possible medicine of which we are capable, we have to assume an adversary relationship with the patient's chart. In most cases it is the chart which turns the litigation against the physician.

We must constantly fight and strive to preserve adequate documentation of what we are doing. We are a litigation prone society. If the expected result is not forthcoming we are quick to seek legal recourse.

In Tennessee, we have witnessed a spiraling escalation in the number of malpractice cases. There were 280 cases in 1978; 904 cases in 1979; and by 1980 there were 1,262 cases. It cost the physicians in the State of Tennessee $875,000 for malpractice insurance in 1974. By 1980, it cost $16,000,000.

The majority of malpractice cases are brought because of one of four reasons: 1) lack of informed consent; 2) improper candidacy of the patient; 3) fraudulent concealment in the presentation of the disease state from with the patient; and 4) breach of contract. Those are the four most common allegations in the State of Tennessee. This brings up the question as to what we can do as a medical community to improve the situation.

MASON: If a surgeon feels that the patient is having some difficulty he/she would be well advised to start documenting the fact that the available information has been collected and analyzed and some conclusion has been drawn. An explanation that conclusion was reached and treatment plans to correct problems must also be documented. If that information is in the chart, it will be a great help to the attorney who reviews the case to decide whether he/she thinks litigation is justified, and it will be a great help to the physician who has to be defended.

Maintaining standards of medical care is crucial to the practice of good medicine. In bariatric surgery one of the problems, more than in other kinds of surgery, is that the standard is in a state of flux. This must be explained to the attorney and to the court. We need to remember that it is the surgeon who is most informed during the court proceedings owing to his/her extensive training, practice and familiarity with the care of these patients. One should not allow an attorney to ask a series of yes or no questions. The answers are rarely that simple. During questioning the surgeon must explain his/her answers, draw pictures and do whatever necessary to get points across. All of us have a certain feeling of being in foreign territory when we get into the court room or into a hearing. But if we are prepared to communicate, document and explain, our job will be easier.

Another point which I think we ought to remember is that we need to be tolerant of different viewpoints. The physician is trained in the scientific method and seeks truth through that method. The legal method is also a search for truth, but it goes about it in a somewhat different way. We would like to be friends of the court if we have to be involved as expert witnesses; we would like to feel that we could go to the court and answer their questions and explain all these things about which we are asked. We are not hired by the plaintiff, we are

not hired by the defense. We are just there to do our duty. We have a duty to provide the truth as we see it.

The best way to avoid litigation is to provide an uncomplicated course for the patient. We need to have a living, cured, relieved and informed patient. We need to care for the patient and document our care with excellent records. We need to be informed ourselves and to know the state of the art which is time bound and constantly changing. We must always be professional and pleasant. We need to avoid unnecessary activities especially if they may be injurious. We must not abandon, neglect or abuse the patient and we must never be antagonistic, arrogant, aggressive, hot-headed, or hostile. None of these things will guarantee the avoidance of litigation, but they will help to keep it to only the most meritorious cases.

QUESTION: Would a video tape for the family and the patient be of any value in terms of education about the procedure?

HAYES: It would be of great value, both for the patient and for informing the attorney for the plaintiff should there be a suit. It would also be informative for representatives of insurance companies. Nevertheless, video tapes probably won't be admissable into court because the aren't viewed under oath. They will refresh recollection and remind the patient and family about what was explained.

QUESTION: How extensive should a consent form be?

HAYES: I know that long consent forms often are a nuisance. However, they are absolutely essential. Nothing is less useful in my viewpoint than a statement in the record that all risks were explained to the patient and the patient understands it.   That doesn't mean anything to me nor does it mean anything to the court or the jury. I believe the consent form must be as specific as possible regarding the major risks. If nothing else, this at least shows an intention on the part of the surgeon to inform the patient.

QUESTION: How do the courts view the fact that there are several variations of bariatric surgery and that a surgeon may choose to do one operation today and another operation tomorrow?

HAYES: If there is not a set standard, then it becomes a judgment call on the part of the surgeon. Whenever it is a question of judgment and not a violation of a standard of care, there is no negligence.

QUESTION: Is it legal to tape a conversation between the patinet, the doctor and the family?

HAYES: Yes, as long as the necessary consent forms are signed.

QUESTION: Why isn't an oral consent just as valid as a written one?

HAYES: The oral consent sometimes is forgotten. It doesn't take much longer to make a note of it.

QUESTION: When can one bring a recorded tape of an interview between the doctor and the patient into court?

HAYES: If it is possible to prove the authenticity of the tape, if it has been witnessed, then it probably could be used.

O'LEARY: Often an informal comment made by a physician in a social setting is taken to be authoritative. Can such comments be brought into court?

HAYES: Sometimes they are brought into court. On other occasions they may be the primary motivating factor for the patient to seek litigation. Even gestures sometimes are enough to cause trouble. Such things should be avoided.

QUESTION: Under what circumstances is a counter-suit by the physician against the patient justifiable?

HAYES: In general it would not be a viable alternative. The courts almost routinely turn these cases down.

QUESTION: What precaution should be taken when using an experimental procedure such as biliopancreatic bypass?

O'LEARY: The best protection is informed consent and documentation, that the patient understands this operation is in the process of development.

HAYES: I agree. A patient can consent intelligently to an experimental operation if he/she has adequate understanding of all the facts. In such cases there should be page after page of explanation in the signed consent form so that there cannot be any misunderstanding.

QUESTION: What should a surgeon do when he/she undertakes a new procedure for the first time? Should the patient know this?

HAYES: Again, adequate informed consent is the key to avoiding litigation.

SUMMATION AND ADJOURNMENT

Edward E. Mason, Ph.D., M.D.

Bariatric surgery is an evolutionary process. Changes have occurred and continue to occur, sometimes too rapidly. Last year a few more gastroplasties than gastric bypasses were being performed. This year that majority has increased to the point that now three gastroplasty-type procedures are being performed for every gastric bypass. There is tremendous pressure on the medical profession to do something for these patients. At the same time we want to make these operations as simple as possible. This has resulted in the performance of many procedures that have not yet withstood the test of time. Surgeons seem to flock . towards those procedures that appear to be the simplest.

A lot of bariatric surgeons seem bent on individually repeating the evolutionary process that bariatric surgery as a discipline has already gone through. This is not only an unnecessary waste of time, it is a potentially dangerous mistake. We should strive to learn from the experience of others. Experience has established guidelines and criteria that should be met. One example can be found in the fashioning of the outlet. The outlet must be the correct size initially. It cannot be made too small in the hope that it will eventually end up the right size. The objective of gastric operations is not to obstruct the channel but to make it large enough to allow adequate nutrition without overconsumption. The surgeon must not begin with the premise that obstruction is a necessary part of the procedure.

The experience that I have had over 17 years with these operations has taught me that if the operation is bad initially, it will stay bad. Such a procedure will eventually require operative correction in all patients. In regard to outlets, they not only must be the correct size initially, but they must be reinforced in some way to keep them from stretching over the long term. We have learned that reinforcement that penetrates the wall of the stomach will erode and ultimately fail. Therfore, the reinforcing material must be external. To achieve this the stoma cannot be placed in the staple line.

The suggestion of using Marlex to reinforce the stoma will undoubtedly tempt some people to apply this material where it should not be applied. I think it is a mistake to put Marlex over an anastomosis. Experiments have shown that an anastomosis needs to have living tissue around it in order to promote proper healing. If used to cover an anastomosis, Marlex may cause infection and obstruction. However, it can be used safely in procedures like vertical banded gastroplasty because in such cases it is not covering a large area of healing stomach.

The use of a silastic band for reinforcement is also potentially dangerous and needs careful study. Silastic, unlike Marlex mesh, is solid material. Connective tissue cannot grow through it to make it an additional layer in the wall of the stomach. It is a foreign material that will perhaps never be completely safe. A bursa will form around it that could lead to complications. I believe such methods of reinforcmeent should only be used in institutions where close and long-term follow-up studies can be undertaken.

There has been concern about revising failed operations. The technique to be used, of course, depends on the type of operation being revised. Careful measurement of pouch volume and outlet size are essential and all criteria for a satisfactory gastric reduction operation should be met just as if the revision were the initial procedure. Revisions carry more potential risks than initial procedures.

A little prevention is worth a lot when compared with the tremendous effort that revision entails. For this reason I have pursued vertical banded gastroplasty which I think will prove to be an optimum procedure that satisfies the criteria of a good operation initially.

It may be that some patients just cannot be helped. However, we must admit that there are also many failed operations. I am surprised by the attitude of some surgeons who feel that if the patient fails with the first operation, he/she is incorrigible and undeserving of a revision. Our premise is that these patients are incorrigible from before the initial operation or they would not need it in the first place. They can't be treated in any other way so we do an operation. If the surgeon has that attitude toward the patient to begin with, I cannot understand how, if for some reason the patient ceases to lose and begins gaining weight, the surgeon can then decide that this patient has not been compliant and doesn't deserve a revision. Indeed, this is the nature of the problem. None of the morbidly obese patients are compliant. This leads to the problem of patient selection. I don't believe that we should rely on preoperative measures of potential patient compliance in selecting candidates for operation.

There is no limit to the amount of thinking and work that remains to be done in the field of bariatric surgery. However, I believe that truly new ideas should be tested with great care and preparation. It would be far better to watch someone who has experience and then follow their technique scruptulously for a while without changing it. Changes should only be instigated after careful research and planning.