

# Research Priorities in Bariatric Surgery

## *Misplaced Emphasis on Innovation?*

Mark A. Carlson, MD

Implementation of a new surgical procedure or surgically implanted device without an adequate understanding of the relevant pathophysiology may risk untoward patient outcomes. Such implementation seems to be occurring in the field of bariatric surgery. Consequently, it may be appropriate to reconsider the research priorities of bariatric surgery.

Currently, there are at least 4 highly effective surgical procedures for morbid obesity, including gastric bypass, biliopancreatic diversion, gastric banding, and sleeve gastrectomy.<sup>1,2</sup> Interestingly, these procedures also seem to be effective for obese type II diabetes,<sup>3,4</sup> and they even may have health benefits in diabetic patients without morbid obesity.<sup>5,6</sup> Despite decades of research, however, the mechanisms behind the effectiveness of these procedures are not well understood.<sup>7,8</sup> In fact, it almost seems that the more that is learned, the more that the scientific community's ignorance of gastrointestinal physiology becomes apparent.

Despite the existence of established weight loss operations, new procedure and device development in bariatrics seem to be booming: the US Patent and Trademark Office issued 12 "bariatric" patents in 2005, 164 in 2012, and approximately 100 through the first half of 2013 ([www.uspto.gov](http://www.uspto.gov)). As another indication of this development, 18% of the abstracts and posters (59 of 332 presentations) delivered at the 2012 American Society of Metabolic and Bariatric Surgery (ASMBS) described a novel procedure, modification of an existing procedure, or novel implantable device for bariatric surgery (per the 2012 ASMBS program guide, available at [www.asmb.org](http://www.asmb.org)). Furthermore, at a March 2013 symposium that included coverage of minimally invasive bariatric surgery, there were similar presentations of new procedures and devices, all looking to be the next big thing in the treatment of weight loss and diabetes.

Because efficacious bariatric procedures already exist, why is there this apparent rush to innovate new procedures? The reasons underlying this rush are speculative and may include recurrent themes such as a desire for personal recognition or financial gain on behalf of the investigators and industry. To be fair, the bariatric surgical expert might argue that procedure innovation is needed to provide a more varied selection of treatments, thereby increasing the appeal and utility of bariatric surgery. But would it not make more sense to determine why the existing procedures work? In terms of advancing the care of bariatric patients, it arguably would be more efficient (not to mention less risky to the patient) to delineate the mechanisms of existing bariatric procedures before new ones are pushed onto the public. With a better grasp of the relevant pathophysiology, the design or redesign of bariatric procedures and devices could proceed on a sounder footing.

Of note, it would be negligent not to mention the ongoing basic, preclinical, and clinical research studying the effects and mechanisms of bariatric procedures. This research also is being presented at society meetings and published in scientific journals. But it is unlikely that the underlying scientific questions will be solved within, say, the next 12 months.

So, there may be a misplaced research priority in bariatric surgery on procedure innovation and, perhaps, more emphasis should be placed on mechanistic research. In addition to this emphasis, it might be reasonable to elevate the priority of education in bariatric surgery. Enhancement of the education of patients, health care providers, hospital administrators, insurers, and regulatory agencies on the safety, clinical efficacy, and cost-effectiveness of the existing bariatric procedures could increase implementation while maintaining quality of these procedures. Such educational efforts would not involve any headline-grabbing research articles, but the patient and societal benefit of this education arguably would be greater than any other contemporary intervention in this field.

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Disclosure: The author declares no relevant funding sources and no conflicts of interest.

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ISSN: 0003-4932/13/00000-0001

DOI: 10.1097/SLA.0000000000000352



**FIGURE 1.** Reprinted with permission from *Surgery* 2013; 153:356.

Development of new treatments, procedures, or devices without an adequate understanding of the relevant physiology is a risky proposition. This strategy occasionally may produce a success, occasionally a spectacular failure, but the typical outcome is a middling result. The investigators then are left scrambling to find meaning in their work. The lack of understanding of the mechanisms underlying bariatric procedures recently was highlighted in a cartoon (Fig. 1) by

Walter Pories, a senior bariatric surgeon. In it, a surgeon is seen counseling a patient on what appears to be a bariatric operation (a gastric bypass). Yes, we have remarkably effective operations to treat obesity and diabetes and these operations have established risk profiles and track records. But our knowledge of how bariatric procedures actually work needs vast improvement. Pushing new procedures or devices into bariatric care before this happens may induce unnecessary risk in bariatric patients. Poor outcomes attributed to this risk could be disruptive to the field of bariatric surgery.

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## Reply to Letter: Comment on "Research Priorities in Bariatric Surgery: Misplaced Emphasis on Innovation?"

### Reply:

I read with interest the letter titled, "Research Priorities in Bariatric Surgery: Misplaced Emphasis on Innovation?"<sup>1</sup> In this letter, Dr Carlson has made a point for discussion regarding innovative bariatric research: Until we understand the relevant pathophysiology of obesity and the mechanisms for weight loss after conventional bariatric operations, new surgical procedures or medical devices for obesity research may lead to untoward patient outcomes. Consequently, it may be appropriate to reconsider the research priorities of bariatric surgery by delineating the mechanisms of the current bariatric procedures before new ones are pushed onto the public.

I wholeheartedly agree with Dr Carlson that we need a better understanding of the relevant pathophysiology of obesity and the mechanisms underlying bariatric surgery; however, I do not agree that bariatric research is misplaced, nor do I agree that innovative research will lead to untoward patient outcomes. We should ask ourselves, why do we need innovative research in bariatric surgery when we already have 4 highly effective bariatric operations for the treatment of morbid obesity, as stated by Dr Carlson? First, bariatric surgery is currently indicated only for the treatment of severe obesity, class II or higher. Second, although current bariatric operations are very effective and safe, these procedures are only being performed in a small fraction of patients who qualify for them. The reasons for the disparity include not only hurdles in obtaining

insurance coverage but also patients' reluctance to undergo a surgical intervention that carries the short- and long-term risks associated with bariatric surgery. Therefore, there is a huge therapeutic gap between conventional treatment options for obesity, such as diet, exercise, behavioral therapy, and bariatric surgery, particularly for individuals with class I obesity. Antiobesity drugs might be a good fit to fill this treatment gap, but they have been limited both by low efficacy and by certain drugs that have resulted in serious adverse side effects. Unlike Dr Carlson, I think it is important for us to continue research in this area to attempt to close the therapeutic gap of obesity treatment options.

It is also important to point out that severe obesity is a chronic disease that is associated with many obesity-related conditions. The Centers for Disease Control and Prevention estimated that the annual medical cost of obesity in the United States was \$147 billion in 2008, relating to the cost for management of obesity-related comorbidities such as diabetes, hypertension, sleep apnea, and coronary artery disease.<sup>2</sup> If left untreated, severe obesity and its associated comorbid conditions can even lead to premature death. So, watchful waiting without therapy for obesity can have its own untoward adverse effects on the individual. Therefore, research on new medical devices, more effective antiobesity drugs, and even safer surgical alternative procedures needs to continue in parallel with research into the mechanisms underlying bariatric surgery. We are still in our infancy in understanding the mechanisms underlying bariatric surgery; however, the past decade has spurred significant enthusiasm for this research. For example, in 2004, Rubino and Marescaux<sup>3</sup> reported the effect of duodenal-jejunal exclusion in a nonobese animal model of type 2 diabetes. This research leads to development of the duodenal sleeve liner, which

is currently under investigation as a nonsurgical option for treatment of diabetes. Research such as this is necessary to one day fill the large gap between conventional therapy and bariatric surgery for treating obesity. With that being said, all research needs to be done in an ethical manner after approval by one's institutional review board. For medical devices, research must conform to rules and regulation of the Food and Drug Administration. It is especially imperative for the patient to understand the risks versus benefits of the research and the option not to participate or, if willing, to give consent to participate.

In conclusion, research in innovative, minimally invasive approaches and antiobesity drugs for the treatment of obesity is very important, as obesity is an epidemic in this country and there is a large therapeutic gap in its management, particularly for individuals with class I obesity. These types of research can be done safely in the right setting. Limiting research in this arena can have its own untoward side effects for the individuals afflicted with this disease.

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