Newer techniques in bariatric surgery for morbid obesity: laparoscopic adjustable gastric banding, biliopancreatic diversion, and long-limb gastric bypass

BlueCross BlueShield Association

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Citation

Authors' objectives
A previous TEC Assessment completed in 2003 (Vol. 18, No. 10) concluded that less-invasive procedures and alternatives to gastric bypass did not meet the TEC criteria. The purpose of this Assessment is to update the literature on laparoscopic adjustable gastric banding, biliopancreatic diversion, and long-limb gastric bypass to determine whether the current evidence base allows more definitive conclusions to be drawn on the efficacy of weight loss and the rates of adverse events for these newer procedures.

Authors' conclusions
1. The technology must have final approval from the appropriate governmental regulatory bodies.

The interventions under consideration are surgical procedures and are not subject to U.S. Food and Drug Administration (FDA) regulations. However, certain devices that may be used as part of the procedure may be subject to FDA approval. The Lap-Band system received Premarket Application (PMA) approval by the FDA in June 2001 for use in morbidly obese patients. No other devices are currently FDA approved for use in bariatric surgery.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

Laparoscopic Adjustable Gastric Banding. The evidence is not sufficient to form conclusions on the benefit/risk ratio of LAGB compared to gastric bypass. While a number of new studies have been reviewed since 2003 that add to the evidence base, there remain deficiencies in the literature, particularly for determining the rates of long-term adverse events.

The available comparative trials reinforce the conclusion of the 2003 Assessment that LAGB results in less weight loss at 1 year compared to GBY. This difference may lessen by years 2 to 3, but appears to remain substantial. The data from the large number of single-arm series are sufficient to confirm that short-term complications are low with LAGB. Mortality from the procedure is rare, and other postoperative complications occur at low rates, lower than those for open or laparoscopic gastric bypass.

The rates of long-term complications cannot be reliably determined from the available data. For LAGB, the frequency of long-term complications is higher than short-term complications, but there is a wide range of reported values and a great deal of uncertainty concerning the summary values reported in this Assessment. This uncertainty derives from the lack of systematic surveillance and reporting of long-term adverse events, and from the incomplete follow-up that is seen in most of these trials. As a result, it is not possible to determine the overall benefit/risk ratio for LAGB from the available data. Long-term prospective trials that have adequate follow-up and report systematically on complications for at least 35 years are needed to remediate these important deficiencies in the current evidence base.
Biliopancreatic Diversion. The evidence is not sufficient to support conclusions on the benefit/risk ratio for BPD compared with gastric bypass. While there have been numerous studies of BPD published since the 2003 Assessment, there remains a lack of high-quality comparative trials. The available evidence, derived from 1 comparative trial and 7 single-arm series, suggests that weight loss outcomes at 1 year are in the same range as for gastric bypass. These data are not sufficient to distinguish small differences in weight loss between the 2 procedures, but the data do not support the hypothesis that BPD results in greater weight loss than GBY.

Complication rates are poorly reported in these trials. The data suggest that mortality is low (approximately 1%) and in the same range as for GBY. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data suggests that long-term nutritional and vitamin deficiencies occur at a high rate following BPD. The rates of nutritional deficiencies and the consequences of these deficiencies require further investigation.

Long-limb Gastric Bypass. The evidence on LL-GBY is not sufficient to form conclusions on the efficacy or safety of LL-GBY compared to standard GBY. A total of 6 comparative trials of LL-GBY vs. standard GBY and 1 single-arm study of LL-GBY were reviewed for this Assessment. The majority of the comparisons of weight loss in these studies, including the strongest evidence contained in 2 RCTs, report that weight loss at 1 year does not differ between the two groups. Thus, this evidence does not support the hypothesis that weight loss is better with LL-GBY. The evidence on the super-obese population is weak, and not sufficient to conclude whether the LL-GBY is superior for this group of patients. The evidence on adverse events of this procedure is not sufficient to form conclusions on the comparative rates of adverse events between the two procedures.

3. The technology must improve the net health outcome.

For the procedures reviewed (LAGB, BPD, LL-GBY), there is insufficient evidence to conclude whether these procedures improve the net health outcome since the evidence is not sufficient to permit conclusions on their overall benefit/risk ratio.

4. The technology must be as beneficial as any established alternatives.

For the procedures reviewed (LAGB, BPD, LL-GBY), there is insufficient evidence to conclude whether these procedures improve the net health outcome since the evidence is not sufficient to permit conclusions on their overall benefit/risk ratio compared with open gastric bypass.

5. The improvement must be attainable outside the investigational settings.

For the procedures reviewed (i.e., laparoscopic adjustable gastric banding, biliopancreatic diversion, long-limb gastric bypass), improvement in health outcomes has not been demonstrated in the investigational setting.

Based on the above, laparoscopic adjustable gastric banding, biliopancreatic diversion, and long-limb gastric bypass do not meet the TEC criteria.

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