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## **PREFACE**

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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## **EXECUTIVE SUMMARY**

## INTRODUCTION

Obesity rates in the US have risen to near epidemic levels. While caloric restriction, exercise, and behavioral modification remain mainstays for the treatment of overweight individuals (BMI 25 to <30), these strategies have not produced sustainable long-term weight loss in the severely obese (BMI≥40). Bariatric surgery has become increasingly popular for the treatment of severe obesity, and has been linked to sustainable weight loss.

A variety of surgical procedures have been used to induce weight loss for severely obese patients. They result in weight loss via different mechanisms: mechanically restricting the size of the stomach, bypassing a portion of the intestines, or by a combination of these mechanisms. Additionally, there is evidence that these procedures generate alterations in gastric and neuropeptides that play a role in weight loss and early satiety.

Currently, the most common procedures performed are done laparoscopically, and they include gastric banding (adjustable gastric band), gastric bypass (Roux-en-Y gastric bypass (RYGB)) and gastric sleeve. The biliopancreatic diversion and vertical banded gastroplasty (VBG) are performed infrequently and are primarily done by select surgeons and centers (specifics of these procedures will not described in detail).

Gastric banding achieves weight loss by creating gastric restriction. The uppermost portion of the stomach is encircled by a band to create a gastric pouch with a capacity of 15 to 30 cc. The band consists of an inflatable doughnut-shaped balloon whose diameter can be adjusted by adding or removing saline via a reservoir port beneath the skin. The bands are adjustable allowing the size of the gastric outlet to be modified, depending on the rate of a patient's weight loss.

Gastric bypass achieves weight loss through a combination of gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch results in feelings of satiety following even small meals. This small pouch is connected to the lower segment of the small intestine, bypassing the proximal small intestine. Thus, absorptive function is reduced. Possibly also aiding weight loss is the production of unpleasant gastrointestinal symptoms following ingestion of particular foods: symptoms include abdominal pain, cramping, and diarrhea.

Gastric sleeve is a more recently adopted procedure where the stomach is stapled into a tube. This procedure has been gaining interest as it relatively simple to perform and offers a lower post-operative complication rate. It appears to have successful weight loss results and improvements in comorbidities, but longer term results, beyond 5 years, are not yet known.

However, not all patients receive equal benefit from bariatric surgery. Psychosocial factors are commonly cited as important predictors of post-operative outcomes. Many bariatric practices formally screen for mental health conditions during the pre-operative assessment in order to select patients they believe have with the highest likelihood of success; others, including the Veterans Health Administration, do not require formal psychosocial evaluation.

Given the increased interest in surgical weight loss and the desire to select patients who will benefit the most from this intervention, the 3 key questions for this review are as follows:

Key Question 1. What is the prevalence of mental health conditions among bariatric surgery candidates?

Key Question 2. What is the association between pre-operative mental health conditions and bariatric outcomes, including weight loss, quality of life, adherence to behavioral guidelines, risk of suicide, prevalence of mental health conditions, and peri-operative complications?

Key Question 3. Is there evidence to support any pre-operative intervention for patients with mental health disorders to improve post-operative bariatric outcomes, including weight loss?

## **METHODS**

#### **Data Sources and Searches**

We searched PubMed, MEDLINE on OVID, and PsycINFO using a broad set of search terms including "bariatric" or "obesity" or the names of the various surgical procedures and then terms for mental health conditions, maladaptive eating, binge eating, and other eating disorders. Because a member of our team had participated in an earlier systematic review on the related topic of pre-operative predictors of weight loss following bariatric surgery and our review of that project's search strategy and methods for identifying relevant articles gave us confidence their results were relevant to our needs, we used their search and results to cover the period from 1988 through 2010, and therefore ran our searches from October 2009 through August 2014. We then supplemented these 2 searches with a "related articles" search in PubMed between January 1990 and August 2014 to identify literature related to a key article by Malik and colleagues, as well as a targeted search in the psychological literature database PsycINFO for articles related to bariatric surgery and mental health conditions published between January 2009 and August 2014. Additional studies were recommended for inclusion by technical expert panel members and peer reviewers.

## **Study Selection**

For Key Question 1, studies with data about prevalence were included based on the population being studied and the sample size. Studies were included if they met one of the following criteria: (1) data were from a study with random or consecutive sampling and a sample size of at least 200 subjects; (2) data were from a clinical trial; (3) study reported data on United States Veterans; or (4) if not meeting any of the criteria 1-3, then if data were reported for over 500 patients or for multiple sites. Included studies had to measure specific mental health conditions or eating disorders using a formal method (such as a validated instrument or the Structured Clinical Interview). Studies had to report actual prevalence data. In addition, we required preoperative classifications of mental health conditions and eating disorders to be made preoperatively; in other words, we excluded studies that asked patients to recall their historical preoperative health status. For Key Question 2, we used the same criteria to restrict the studies to those of better quality or greater generalizability. Each study had to report post-operative assessment of one of our outcomes of interest. For Key Question 3, the assessed intervention had to occur pre-operatively, while the outcomes had to be post-operative, and the target of the intervention related to eating disorders, mental health comorbidities, or quality of life.

## **Data Abstraction and Quality Assessment**

Data were extracted by 2 independent reviewers, and discrepancies were reconciled by the entire study team.

For Key Question 1 and Key Question 2, articles about prevalence and association were assessed for the representativeness to some larger population of the included participants.

For Key Question 3, articles addressing pre-operative interventions were assessed for quality using a modified Cochrane Risk of Bias tool. This tool provides a framework for systematically assessing the degree of bias for comparative studies. Systematic biases can either over- or underestimate the effect size. Studies are rated on 6 types of bias: selection, performance, detection, attrition, reporting, and other. We applied this tool to the 5 intervention studies. Of note, this tool is not specific to randomized clinical trials. Only 2 of the criteria concern blinding and allocation. The additional criteria cover bias related to outcomes and other confounders (risk predictors) and are appropriate to assess for intervention studies, regardless of study design.

## **Data Synthesis and Analysis**

The data synthesis is narrative. For Key Question 1 we calculated the weighted median for prevalence estimates, and compared these between subjects of studies based on study design and sample. Studies for Key Questions 2 and 3 were summarized narratively.

## **RESULTS**

#### **Results of Literature Search**

From our systematic database searches, we identified 1,275 citations. We combined these with 79 references identified in an article by Livhits and colleagues and 9 references identified by a panel of experts. After dual title, abstract, and full article review, 66 references were included, with 54 addressing Key Question 1, 24 addressing Key Question 2, and 5 addressing Key Question 3.

## **Summary of Results for Key Question 1**

We identified 54 studies meeting criteria for quality and informative estimation of prevalence. Five of these studies were about VA samples. The assessed populations, not counting the VA samples (that were predominantly male), were relatively similar. In most studies, 67 to 85% of subjects were female, their mean age was mid-40 years of age, and the mean body mass index (BMI) was 45 to 50 kg/m2.

The weighted median prevalence of each disorder across all studies was:

Table 1. Mental Health Conditions in Bariatric Surgery Candidates and Patients

<b>Mental Health Conditions</b>	Weighted Median
Anxiety	15%
Depression	25%
Any mood disorder	27%
Eating Disorders	16%
Personality Disorders	1%
Post-Traumatic Stress Disorder	1%
Psychosis	1%
Substance abuse disorders*	7%
Suicidal ideation/suicidality	11%

<sup>\*</sup> Substance abuse disorders refers to alcohol and drug abuse or those merely described as substance abuse. Tobacco use was not included.

Some mental health conditions varied in their prevalence estimate. This variability is unexplained, but is probably related to how the diagnosis was made, sample sizes, and real differences between populations.

Studies of Veterans, however, reported the highest prevalence of all mental health diagnoses except eating disorders, and in some cases these differences were quite marked. For example, the median prevalence of post-traumatic stress disorder (PTSD) in Veteran samples was 24% compared to 1% overall. Additional sources of variation were likely attributable to the method used to make the diagnosis, geographic variations in the populations themselves, and chance (in particular, the Veteran samples were small relative to the other studies, with sample sizes of 25-102 subjects).

## **Summary of Results of Key Question 2**

We identified 24 studies reporting data on the association between pre-operative mental health diagnoses and post-operative outcomes. Three articles specifically addressed outcomes among Veteran populations. The most consistent evidence suggests lower rates of depression, fewer symptoms of depression, and decreased usage of anti-depressant therapies after bariatric surgery. The majority of studies found no association between the presence of any Axis I disorder—including depression—and weight outcomes.

Depression improved following bariatric surgery in all 8 studies measuring changes in mental health outcomes. The evidence for an association between bariatric surgery and rates of alcohol abuse was mixed, and appeared to depend on the type of surgery being performed. Two studies found increased rates of alcohol consumption, alcohol abuse, and treatment for alcohol dependence after bariatric surgery, but only for patients undergoing RYGB as opposed to LAGB.

Two studies specifically reported on suicide, one finding increased rates compared to an age- and sex-matched US population and another suggesting increased rates compared to non-surgical, severely obese controls.

All 5 studies measuring quality of life showed improvements following bariatric surgery. In studies using a scale with multiple domains, there was improvement across all components with larger and more sustainable changes being seen in physical status than in mental status. There was no clear evidence on post-operative changes in PTSD or bipolar disorder. Minimal evidence exists regarding changes in cognitive function, and results appear to vary by domain.

There is insufficient evidence to determine the relationship between pre-operative mental health conditions and post-operative weight loss outcomes.

## **Summary of Results of Key Question 3**

We identified no studies assessing the effect of a pre-operative intervention targeted at mental health conditions or eating disorders that assessed post-operative outcomes. We did identify 5 studies of interventions aimed at improving pre-operative conditions or behaviors in bariatric surgery candidates that measured changes in pre-operative status. None provided significant evidence that such interventions may improve pre-operative mental health conditions or eating disorders or pre-operative weight loss.

## DISCUSSION

## **Key Findings and Quality of Evidence**

# Key Question 1

Summary of Findings

Bariatric surgery candidates and those receiving surgery have depression, anxiety, and certain eating disorders (*eg*, binge eating) at rates equal to or exceeding 15%. Other mental health disorders, such as psychoses, are less frequent. Published prevalence estimates vary, particularly for depression and binge eating disorder. The few assessments done in Veteran populations found higher proportions of comorbidities than are present in other populations, particularly PTSD.

## Quality of Evidence

We judged the quality of evidence as moderate for the overall conclusion that mental health conditions and eating disorders are common in bariatric patients. The exact estimates we judge as low, due to the inconsistency noted, particularly for depression and eating disorders. All estimates for Veterans are judged low due to the small number of patients assessed (at most about 300 patients).

## Key Question 2

## Summary of Findings

There are conflicting data regarding the impact of mental health conditions on post-operative outcomes, including weight loss, mental health symptoms, quality of life, and suicide. The most consistent evidence suggests lower rates of depression, fewer symptoms of depression, and decreased usage of anti-depressant therapies after bariatric surgery. A causal role of bariatric surgery cannot be established with the existing studies. Aside from depression, only quality of life demonstrated consistent improvement across multiple studies, although the use of different scales and timelines complicates the evaluation. There is insufficient evidence to determine the relationship between preoperative mental health conditions and post-operative weight loss outcomes.

## *Quality of Evidence*

The quality of evidence is moderate that bariatric surgery is associated with lower rates and fewer symptoms of depression, compared to pre-operative status. The quality of evidence is low regarding the association between bariatric surgery and quality of life improvements following surgery. All other associations between mental health conditions and outcomes following bariatric surgery are judged very low-quality evidence.

## Key Question 3

## Summary of Findings

There were no studies that assessed the impact of a pre-operative intervention on mental health disorders to post-operative outcomes following bariatric surgery, such as surgical weight loss including prevalence of the mental health disorders. Five low-quality studies reported pre-operative improvements in targeted mental health behaviors, as well as pre-operative physician-supervised weight loss before surgery and substance abuse, for bariatric surgery candidates.

## Quality of Evidence

There is no evidence specific to Key Question 3 and only low-quality evidence that interventions to change pre-operative psychosocial factors have clinically important effects on pre-operative status.

## **Applicability**

There are striking differences in the gender of patients assessed in VA compared to non-VA populations, as 70% to 80% of non-VA patients are female while 70% to 80% of VA patients are male. From the limited VA studies that have been done, the prevalence of mental health conditions and eating disorders is higher than in non-VA populations. Therefore, generalizing results from the non-VA population to the VA population needs to be done with caution.

## **Research Gaps/Future Research**

In order to generate VA-relevant data, a more broadly-based data collection effort is needed among Veterans seeking bariatric surgery. This should include a sufficient number of sites to be representative of diversity in the VA, and use the same standardized instruments for classifying disorders. A protocol for follow-up of such patients could help answer questions about the association between pre-operative mental health conditions and post-operative outcomes. To assess the effectiveness of pre-operative interventions, randomized clinical trials are necessary.

#### **Conclusions**

Mental health conditions and eating disorders are common in bariatric surgery candidates and patients, in particular depression, anxiety, and binge eating disorders. There is inconsistent evidence about the effect of mental health conditions and eating disorders on subsequent post-operative outcomes, with the exception of improvement in depression and possibly quality of life. There are no studies assessing the effect of pre-operative interventions aimed at mental health conditions or eating disorders. There is insufficient evidence to recommend for or against routine specialized pre-operative mental health screening in bariatric surgery candidates in addition to the existing general evaluation by the surgical and/or medical bariatric team.

# **Abbreviations Table**

AUDIT	Alcohol Use Disorders Identification Test
BDI	Beck Depression Inventory
BED	Binge Eating Disorder
BES	Binge Eating Syndrome
BMI	Body Mass Index
BPD	Biliary Pancreatic Diversion
CBT	Cognitive Behavioral Therapy
CI	Confidence Interval
DSM-IV	Diagnostic and Statistical Manual, 4th Edition
EBI	Eating Behavior Inventory
EDE	Eating Disorders Examination
EDO	Eating Disorders in Obesity questionnaire
ESP	Evidence-based Synthesis Program
GIQLI	Gastrointestinal Quality of Life Instrument
HADS	Hospital Anxiety and Depression Scale
HAM-D	Hamilton Depression Rating Scale
HR	Hazard Ratio
HRQOL	Health-Related Quality of Life
HVE	High-Volume Exercise
ICD-9	International Classification of Diseases, 9th edition
IWQOL	Impact of Weight on Quality of Life
LABS	Longitudinal Assessment of Bariatric Surgery
LAGB	Laparoscopic Adjustable Gastric Band
LASA	Linear Analog Scale Assessment
MCS	Mental Component Score
MMPI-2	Minnesota Multiphasic Personality Inventory-2
OCD	Obsessive Compulsive Disorder
PCS	Physical Component Score
PHQ-9	Patient Health Questionnaire-9
PTSD	Post-Traumatic Stress Disorder
QEWP-R	Questionnaire of Eating and Weight Patterns, Revised
Q-LES-Q	Quality of Life Enjoyment and Satisfaction Questionnaire
QOL	Quality of Life
RCT	Randomized Controlled Trial
RYGB	Roux-en-Y gastric bypass
SCID	Structured Clinical Interview for DSM
SF-36	Short Form-36
SOS	Swedish Obese Subjects
VBG	Vertical Banded Gastroplasty
Y-BOCS	Yale-Brown Obsessive Compulsive Scale