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<th>Ref #</th>
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<th>Topic</th>
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<tr>
<td>1</td>
<td>1 / A</td>
<td>Diabetes</td>
<td>Rubino F, Nathan DM, Eckel RH, Schauer PR, Alberti KG, Zimmerman FZ, Del Prato S, L. J., Selkut SM, Herman WH, Amiel SA, Kaptan U, Terzic-Polder G, Cummings DE; Delegates of the 2nd Diabetes Surgery Summit. Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. Diabetes Care. 2016 Jun;39(6):861-77. PMID: 27222544</td>
<td>Tier 2 Source</td>
<td><a href="http://care.diabetesjournals.org/content/39/6/861">http://care.diabetesjournals.org/content/39/6/861</a></td>
<td>BACKGROUND: Despite growing evidence that bariatric/metabolic surgery powerfully improves type 2 diabetes (T2D), existing diabetes treatment algorithms do not include surgical options. AIM: The 2nd Diabetes Surgery Summit (DSS-II), an international consensus conference, was convened in collaboration with leading diabetes organizations to develop global guidelines to inform clinicians and policymakers about benefits and limitations of metabolic surgery for T2D. METHODS: A multidisciplinary group of 48 international clinicians/colleagues (75% nonsurgeons), including representatives of leading diabetes organizations, participated in DSS-II. After evidence appraisal (MEDLINE [1 January 2005-30 September 2015]), three rounds of Delphi-like questionnaires were used to measure consensus for 32 data-based conclusions. These drafts were presented at the combined DSS-II and 3rd World Congress on Interventional Therapies for Type 2 Diabetes (London, U.K., 28-30 September 2015), where they were open to public comment by other professionals and amended face-to-face by the Expert Committee. RESULTS: Given its role in metabolic regulation, the gastrointestinal tract constitutes a meaningful target to manage T2D. Numerous randomized clinical trials, albeit mostly short/midterm, demonstrate that metabolic surgery achieves excellent glycemic control and reduces cardiovascular risk factors. On the basis of such evidence, metabolic surgery should be recommended to treat T2D in patients with class II obesity (BMI ≥35 kg/m²) and in those with class III obesity (BMI ≥40 kg/m²) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. Surgery should also be considered for patients with T2D and BMI ≥30-35 kg/m² if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. These BMI thresholds should be reduced by 2.5 kg/m² for Asian patients. CONCLUSIONS: Although additional studies are needed to further demonstrate long-term benefits, there is sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among anti-diabetes interventions for people with T2D and obesity. To date, the DSS-II guidelines have been formally endorsed by 45 worldwide medical and scientific societies. Health care regulators should introduce appropriate reimbursement policies.</td>
<td>Evidence-based consensus guideline on the role of bariatric/metabolic surgery in the management of type 2 diabetes.</td>
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<td>2</td>
<td>1 / A</td>
<td>Diabetes</td>
<td>Cummings DE, Cohen P. Bariatric/Metabolic Surgery to Treat Type 2 Diabetes in Patients With a BMI &lt;35 kg/m². Diabetes Care. 2016 Jun;39(6):594-33. PMID: 27222550</td>
<td>Not Graded</td>
<td>Have contact your local library to obtain a copy of this citation.</td>
<td>OBJECTIVE: Global usage of bariatric surgery has been dictated for the past quarter century by National Institutes of Health recommendations restricting these operations to individuals with a BMI ≥35 kg/m². Strong evidence now demonstrates that bariatric procedures markedly improve or cause remission of type 2 diabetes mellitus (T2DM), in part through weight-independent mechanisms, and that baseline BMI does not predict surgical benefits on glycemic or cardiovascular outcomes. This impedes consideration of such operations as &quot;metabolic surgery,&quot; which is used expressly to treat T2DM, including among patients with a BMI &lt;35 kg/m² who constitute the majority of people with diabetes worldwide. Here, we review available evidence to inform that consideration. RESULTS: A meta-analysis of the 11 published randomized clinical trials (RCTs) directly comparing bariatric/metabolic surgery versus a variety of medical/lifestyle interventions for T2DM provides level 1A evidence that surgery is superior to T2DM remission, glycemic control, and HbA1c lowering. Importantly, this is equally true for patients whose baseline BMI is below or above 35 kg/m². Similar conclusions derive from meta-analyses of high-quality, nonrandomized, prospective comparisons. Meta-analysis of all pertinent published studies indicates that T2DM remission rates following bariatric/metabolic surgery are comparable above and below the 35 kg/m² BMI threshold. The safety, antidiabetes durability, and benefits on other cardiovascular risk factors from bariatric/metabolic surgery appear roughly comparable among patients with a BMI below or above 35 kg/m². Further studies are needed to extend long-term findings and measure &quot;hard&quot; macrovascular/microvascular outcomes and mortality in RCTs. CONCLUSIONS: Extant data, including level 1A evidence from numerous RCTs, support new guidelines from the 2nd Diabetes Surgery Summit that advocate for the Evidence-based consensus guideline on the role of bariatric/metabolic surgery in the management of type 2 diabetes.</td>
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Updated: November 3, 2016
Dr. Robert Bree Collaborative – Accountable Payment Models Workgroup
Adopted by the Bree Collaborative November 16, 2016

Tier-2 Source

http://circ.ahajournals.org/content/early/2013/11/05/circ.000057730.71477.ja

This well-regarded guideline provides a comprehensive review for the identification and management of obesity in adults. Includes clinical pathways and practice assessment tools.

Evidence-based society guideline.

- Applies to multiple components of Cycle 1.
- BMI >30 increases risk of CHD, Stroke, and CVD
- Elevated BMI increases risk of type 2 diabetes
- See-specific analyses indicates that elevated BMI is associated with increased risk of all-cause mortality


Tier-1 Source

http://www.nice.org.uk/guidance/cg189


Tier-1 Source


Suggests a lower BMI cutoff may be appropriate for estimation of risk of mortality in patients of asian descent.


Tier-1 Source

http://www.nice.org.uk/guidance/cg189

High quality resource

- This citation defines obesity on the basis of BMI, with or without waist circumference, for most patients. Modified ranges are proposed for Asian, African, and African-Caribbean populations. Waist circumference is also recommended as a measure for some groups.

Professional specialty standards.


Tier-2 Source

http://www.ahajournals.org/doi/abs/10.1161/HYP.0000000000000505

Professional specialty standards.

- This topic is in the process of being updated as of November 3, 2016


Tier-2 Source

http://care.diabetesjournals.org/content/38/Supplement_1/S1.full.pdf+html

High quality resource

- Table 1 provides criteria for the diagnosis of diabetes


Tier-1 Source

http://www.nhlbi.nih.gov/health/educational/bmr/BMIcalculator.htm

BMI calculator.

Suggests a lower BMI cutoff may be appropriate for estimation of risk of mortality in patients of asian descent.


Tier-1 Source


High quality resource

- National standard for screening for hypertension.
Screening for obstructive sleep apnea


DESCRIPTION: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on the diagnosis of obstructive sleep apnea in adults. METHODS: This guideline is based on published literature on this topic that was identified using MEDLINE (1966 through May 2013), the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews. Searches were limited to English-language publications. The clinical outcomes evaluated for this guideline included all-cause mortality, cardiovascular mortality, nonfatal cardiovascular disease, stroke, hypertension, type 2 diabetes, postsurgical outcomes, and quality of life. Sensitivities, specificities, and likelihood ratios were also assessed as outcomes of diagnostic tests. This guideline grades the evidence and recommendations by using ACP’s clinical practice guidelines grading system. RECOMMENDATION 1: ACP recommends a sleep study for patients with unexplained daytime sleepiness. (Grade: weak recommendation, low-quality evidence.) RECOMMENDATION 2: ACP recommends polysomnography for diagnostic testing in patients suspected of obstructive sleep apnea. ACP recommends portable sleep monitors in patients without serious comorbidities as an alternative to polysomnography when polysomnography is not available for diagnostic testing. (Grade: weak recommendation, moderate-quality evidence.)

Screening for obstructive sleep apnea


BACKGROUND: The patient population that is evaluated for bariatric surgery is characterized by a very high body mass index (BMI). Since obesity is the most important risk factor for obstructive sleep apnea (OSA), sleep disordered breathing is highly prevalent in this population. If undiagnosed before bariatric surgery, untreated OSA can lead to postoperative and perioperative complications. Debate exists whether all patients that are considered for bariatric surgery should undergo polysomnography (PSG) evaluation and screening for OSA as opposed to only those patients with clinical history or examination concerning sleep-disordered breathing. We examined the prevalence and severity of OSA in all patients that were considered for bariatric surgery. We hypothesized that, by utilizing preoperative questionnaires (regarding sleepiness and OSA respiratory symptoms) in combination with menopausal status and BMI data, we would be able to predict which subjects did not have sleep apnea without the use of polysomnography. In addition, we hypothesized that we would be able to predict which subjects had severe OSA (apnea-hypopnea index (AHI) > 30). METHODS: Three hundred forty-two consecutive subjects, evaluated for bariatric surgery from November 1, 2005 to January 31, 2007, underwent overnight polysomnography and completed questionnaires regarding sleepiness, menopausal status, and respiratory symptoms related to OSA. Apneas and hypopneas were classified as follows: mild apnea 1 ≤ AHI ≤ 5, moderate apnea 5 < AHI ≤ 15, and severe apnea AHI > 15. RESULTS: The overall sample prevalence of OSA was 77.2%. Of those, 30.7% had mild OSA, 19.2% had moderate OSA, and 27.2% had severe OSA. Among men, the prevalence of OSA was 10.6% and 7.5% among women. The mean AHI (events per hour) for men with OSA was 49.2 ± 13.5 and 26.3 ± 8.3 for women with OSA. Separate logistic regression models were developed for the following three outcomes: AHI ≥ 15 events per hour, AHI ≥ 15 events per hour, and AHI ≥ 30 events per hour. When predicting these three levels of OSA severity, the area under the curve (AUC) values were: 0.8, 0.7, and 0.8, respectively. The positive predictive value for the presence of sleep apnea (AHI ≥ 5) was 73% when using the most stringent possible cutoff for the prediction model. CONCLUSIONS: The prevalence of OSA in all patients considered for bariatric surgery was greater than 77%, irrespective of OSA symptoms, gender, menopausal status, age, or BMI. The prediction model that we developed for the presence of OSA (AHI ≥ 5 events per hour) has excellent discriminate ability (evidenced by an AUC value of 0.8). However, the negative predictive values for the presence of OSA were too low to be clinically useful due to the high prevalence of OSA in this high-risk group. We demonstrated that, by utilizing

Screening for obstructive sleep apnea


BACKGROUND: Obstructive sleep apnea (OSA) is associated with increased perioperative risk, but the incidence of postoperative complications and the severity of OSA associated with increased risk have not been established. We investigated the relationship between intermittent hypoxemia measured by home nocturnal oximetry with the occurrence of postoperative complications in patients with clinical signs of OSA identified during preoperative assessment for elective surgery. METHODS: This study was performed at a tertiary care hospital. Home nocturnal oximetry was performed on elective surgical patients with clinical features of OSA. The number of episodes per hour of oxygen desaturation (or oxygen desaturation index) of > or = 4% (ODI4%) was determined. Subjects with five or more desaturations per hour (ODI4% > 5) were compared to those with less than five desaturations per hour (ODI4% ≤ 5). Hospital records were reviewed to assess the incidence and type of postoperative complications. RESULTS: A total of 172 patients were included as part of this study. No significant differences were observed between groups in terms of age, body mass index, number of medical comorbidities, or smoking history. Patients with an ODI4% > 5 had a significantly higher rate of postoperative complications than those with ODI4% < 5 (15.8% vs 2.7%, respectively [p = 0.01], adjusted odds ratio, 7.2; 95% confidence interval, 2.3 to 5.3 [p = 0.002]). The complication rate also increased with increasing ODI severity [patients with an ODI4% of ≤ 15 events per hour, 13.8%; patients with an ODI4% of > 15 events per hour, 37.7%; p = 0.013]. Complications were respiratory (nine patients), cardiovascular (five patients), GI (one patient), and bleeding (two patients). The hospital length of stay was similar in both groups. CONCLUSION: An ODI4% > 5, determined by home nocturnal oximetry, in patients with clinical features of OSA is associated with an increased rate of postoperative complications.
Managing comorbidities; obstructive sleep apnea


STUDY OBJECTIVES: To evaluate safety and efficacy of phentermine 15 mg plus extended release topiramate 92 mg for treatment of moderate to severe obstructive sleep apnea (OSA) in obese adults. DESIGN: This phase 2, randomized, double-blind, placebo-controlled study included 2-week screening and 28-week treatment periods. Overnight polysomnography was performed at baseline, Week 8, and Week 28. SETTING: Single-center study conducted from August 2008 to September 2009. PARTICIPANTS: Forty-five subjects with moderate to severe OSA not receiving positive airway pressure (PAP) treatment with body mass index of 30-40 kg/m2. INTERVENTIONS: Subjects were randomized to receive placebo (n = 23) or phentermine 15 mg plus extended-release topiramate 92 mg (n = 22). Both groups received lifestyle modification counseling. MEASUREMENTS AND RESULTS: Primary endpoint, change in apnea-hypopnea index (AHI), significantly favored phentermine 15 mg plus extended-release topiramate 92 mg over placebo (-31.5 events/h, 95% CI: -41.0, -22.0) over placebo (-3.6 events/h, 95% CI: -25.0, -8.2) at Week 28 (P < 0.0001). At Week 28, there was a 30.2% (95% CI: 12.7, 7.6) 10.8 kg, 95% CI 13.5, 40% mean decrease in weight in the phentermine 15 mg plus extended-release topiramate 92 mg group compared with 4.9% (95% CI: -6.6, -2.0) 4.7 kg, 95% CI: -7.2, 2.2) in the placebo group (P = 0.0000) and a positive, significant (P = 0.000001) correlation between percent change in weight and change in AHI. Significant improvements in overnight oxygen saturation and reduction in blood pressure compared with placebo were observed. Phentermine 15 mg plus extended-release topiramate 92 mg was well tolerated with low adverse event rates. CONCLUSIONS: Phentermine 15 mg plus extended-release topiramate 92 mg indicated significant weight reductions and concomitant improvements in OSA and related symptoms vs placebo. This suggests weight loss mediated by phentermine 15 mg plus extended-release topiramate 92 mg may be useful in treatment of moderate to severe OSA in obese subjects unable or unwilling to comply with PAP treatment.

Background: Studies have reported significant improvement of obstructive sleep apnea (OSA) in obese patients after bariatric surgery (BS). Weight loss following BS is rapid in the first few months, but it can take at least 1 year to reach the final result. The aim of this study is to measure the effect of BS on various clinical, respiratory, and sleep parameters of OSA at two postoperative intervals. METHODS: Prospectively, all patients being evaluated for BS underwent a polysomnography (PSG). Patients diagnosed with OSA preoperatively were invited to undergo a PSG at least 6 months postoperatively and if OSA persisted, again at least 12 months postoperatively. RESULTS: One hundred ten patients underwent a first postoperative PSG 7.7 months after surgery. The mean apnea-hypopnea index (AHI) significantly decreased from 39.5 to 15.6 (P = 0.00001). The AHI was reduced to below 10 and in 6 and 25.5% below 5. Fifty patients underwent a first PSG 7.1 months and a second PSG 16.9 months after surgery. The mean AHI decreased from 49.1 to 22.7 to 14.8 following BS. CONCLUSIONS: BS initiates dramatic improvement and even remission of clinical and sleep parameters during the first 7 months, which continues at a slower rate over the next 10 months. We recommend a follow-up PSG after surgery to check for residual and/or not necessary further treatment of obstructive sleep apnea.

Patients treated with Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, or biliopancreatic diversion (BPD) procedures. Authors concluded that BPD was the most successful procedure in improving or resolving OSA, with laparoscopic adjustable gastric banding being the least. In conclusion, bariatric surgery is a definitive treatment for obstructive sleep apnea, regardless of the specific type.

Cohort study of obese patients undergoing bariatric surgery with measures of sleep apnea before and after surgery. Patients self-selected for post-operative sleep apnea testing. Authors showed a significant reduction in sleep apnea at 7.1 and 16.9 months post-operatively. Of 171 patients with pre-operative tests, 110 were retested at 7.1 months and 50 were retested at 16.9 months.

Study of moderate quality supports the conclusion that bariatric surgery improves measures of sleep apnea.

Updated: November 3, 2016
Managing comorbidities: obstructive sleep apnea


CONTEXT: Obstructive sleep apnea (OSA) is strongly related to obesity. Weight loss is recommended as part of the overall management plan for obese patients diagnosed with OSA. OBJECTIVE: To determine whether surgically induced weight loss is more effective than conventional weight loss therapy in the management of OSA. DESIGN, SETTING, AND PATIENTS: A randomized controlled trial of 60 obese patients (body mass index $>35$ and $<40$) with recently diagnosed ($>6$ months) OSA and an apnea-hypopnea index (AHI) of 20 events/hour or more. These patients had been prescribed continuous positive airway pressure (CPAP) therapy to manage OSA and were identified via accredited community sleep clinics. The trial was conducted between September 2006 and March 2009 by university- and teaching hospital-based clinical researchers in Melbourne, Australia. Patients with obesity hypoventilation syndrome, previous bariatric surgery, contraindications to bariatric surgery, or significant cardiology, neurologic, vascular, gastrointestinal, or neoplastic disease were excluded. INTERVENTION: Patients were randomized to a conventional weight loss program that included regular consultations with a dietitian and physician, and the use of very low-calorie diets as necessary (n = 30) or to bariatric surgery (laparoscopic adjustable gastric banding; n = 30). MAIN OUTCOME MEASURES: The primary outcome was baseline to 2-year change in AHI on diagnostic polysomnography scored by staff blinded to randomization. Secondary outcomes were changes in weight, CPAP adherence, and functional status. RESULTS: Patients lost a mean of 5.1 kg (95% CI, 0.8 to 9.3 kg) in the conventional weight loss program compared with 27.4 kg (95% CI, 20.0 to 34.7 kg) in the bariatric surgery group (P < .001). The AHI decreased by 14.0 events/hour (95% CI, 3.3 to 24.6 events/hour) in the conventional weight loss group and by 25.5 events/hour (95% CI, 14.2 to 16.7 events/hour) in the bariatric surgery group. The between-group difference was -11.5 events/hour (95% CI, -28.3 to 5.3 events/hour; P = .18). CPAP adherence did not differ between the groups. The bariatric surgery group had greater improvement in the Short Form 36 physical component summary score (mean, 0.9 [95% CI, 0.5 to 1.8] vs 0.4). CONCLUSION: Among a group of obese patients with OSA, use of bariatric surgery compared with conventional weight loss therapy did not result in a statistically greater reduction in AHI despite major differences in weight loss. TRIAL REGISTRATION: anzctr.org Identifier: 1260000161828.

MAW and GERD


BACKGROUND: Overweight and obese persons are at increased risk for gastroesophageal reflux disease. An association between body-mass index (BMI)--the weight in kilograms divided by the square of the height in meters--and symptoms of gastroesophageal reflux disease in persons of normal weight has not been demonstrated. METHODS: In 2000, we used a supplemental questionnaire to determine the frequency, severity, and duration of symptoms of gastroesophageal reflux disease among randomly selected participants in the Nurses’ Health Study. After categorizing women according to BMI as measured in 1998, we used logistic-regression models to study the association between BMI and symptoms of gastroesophageal reflux disease. RESULTS: Of 10,545 women who completed the questionnaire (response rate, 86 percent), 2310 (22 percent) described their symptoms as moderate in severity. We observed a dose-dependent relationship between body-mass index (BMI)--the weight in kilograms divided by the square of the height in meters--and symptoms of gastroesophageal reflux disease in persons of normal weight has not been demonstrated. CONCLUSIONS: The association between BMI and symptoms of gastroesophageal reflux disease in persons of normal weight may cause or exacerbate symptoms of reflux.

Screening for non-alcoholic fatty liver disease


No abstract available


Screening for non-alcoholic fatty liver disease. Recommendations against screening for non-alcoholic fatty liver disease in obesity clinics “due to uncertainties surrounding diagnostic tests and treatment options, along with lack of knowledge related to the long-term benefits and cost-effectiveness of screening.”

Primary citation not available in this professional society guideline.

Non-alcoholic fatty liver disease

National Institute for Health and Care Excellence. Liver disease (non-alcoholic fatty liver disease (NAFLD)). Clinical guideline. July 2016

http://www.nice.org.uk/guidance/ngr17

No abstract available

High quality guideline

“Covers how to identify the adults, young people and children with non-alcoholic fatty liver disease (NAFLD) who have advanced liver fibrosis and are most at risk of further complications.”

Individual RCT with blinding for measures of sleep apnea. Intention to treat analysis with good follow-up. Unclear concealment. Small sample size with wide confidence intervals regarding effects on OSA outcomes.

At two years, weight loss improved measures of sleep apnea (apnea-hypopnea index) in patients treated for obesity surgery (12.7 kg weight loss) and non-surgery (5.1 kg weight loss), without statistically significant difference in AHI between groups. Supports surgical and non-surgical treatment of obesity to improve sleep apnea measures.

Updated: November 3, 2016
Non-alcoholic steatohepatitis (NASH) is a chronic progressive liver disease that is strongly associated with obesity. Currently, there is no approved therapy for NASH. Weight reduction is typically recommended, but efficacy data are lacking. We performed a randomized controlled trial to examine the effects of lifestyle intervention using a combination of diet, exercise, and behavior modification, with the goal of 7% to 10% weight reduction, on clinical parameters of NASH. The primary outcome measure was the change in NASH histological activity score (NAS) after 48 weeks of intervention. Thirty-one overweight or obese individuals (body mass index (BMI), 25.40 kg/m²) with biopsy-proven NASH were randomized in a 2:1 ratio to receive intensive lifestyle intervention (LSI) or structured education (control). After 48 weeks of intervention, participants assigned to the LS lost an average of 9.3% of their weight versus 2.3% in the control group (P = 0.003). A higher proportion of participants in the LS group had a reduction of NAS of at least 3 points or had posttreatment NAS of 2 or less as compared with the control group (72% versus 30%, P = 0.005). NAS improved significantly in the LS group (from 4.4 to 2.2) in comparison with the control group (from 4.9 to 5.1) (P = 0.007). Participants who achieved the study weight loss goal (≥7%), compared with those who lost less than 7%, had significant improvements in steatosis (-1.27 versus -0.41, P < 0.001), lobular inflammation (-0.82 versus -0.24, P = 0.03), ballooning injury (-1.27 versus -0.53, P < 0.001) and NAS (-3.45 versus -1.18, P < 0.001). CONCLUSION: Weight reduction achieved through lifestyle intervention leads to improvements in histology in NASH.

Motivational readiness for treatment in weight control programs: The TREatment MOtivation and REadiness (TRE-MORE) test. Journal of endocrinological investigation 2011 34:3 (e70-77)

The motivation degree before starting the treatment represents a pre-treatment predictor of successful weight management. The aim of this study is to develop and validate a new self-reported questionnaire of motivation and readiness to change before starting a lifestyle modification program (the TREatment MOtivation and REadiness test) (TRE-MORE) for overweight patients. TRE-MORE was evaluated in a consecutive series of 129 obese patients attending our Outpatient Clinic. Validation of the questionnaire was performed through test-retest reliability, internal consistency, psychopathological correlates, and concurrent validity. Subjects have been evaluated by means of a clinical interview, and different self-reported questionnaires, assessing the eating specific and general psychopathology, and quality of life. TRE-MORE total and subscales scores showed good test-retest reliability and internal consistency. We identified 10 items grouped in 3 areas (obstacles and desire to overcome, taking care of themselves, and sharing the problems, current lifestyle). TRE-MORE scores were significantly correlated with eating specific psychopathology and quality of life measures. Univariate and Receiver Operating Characteristic curve analysis showed that TRE-MORE total and subscales scores represent a good model for predicting a weight loss ≥5% of the initial weight after 6 months of treatment. TRE-MORE represents a validated and easy-to-use questionnaire assessing at the meantime the treatment motivation and readiness with good predictive capacity for weight loss.

Temperature control

BACKGROUND: Type 2 diabetes affects approximately 8 percent of adults in the United States. Some risk factors elevated plasma glucose concentrations in the fasting state and after an oral glucose load, overweight, and a sedentary lifestyle—are potentially reversible. We hypothesized that modifying these factors with a lifestyle intervention program or the administration of metformin would prevent or delay the development of diabetes. METHODS: We randomly assigned 3234 nondiabetic persons with elevated fasting and post-load plasma glucose concentrations to placebo, metformin (850 mg twice daily), or a lifestyle-modification program with the goals of at least a 7 percent weight loss and at least 150 minutes of physical activity per week. The mean age of the participants was 55 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 34.0; 68 percent were women, and 45 percent were members of minority groups. RESULTS: The average follow-up was 2.8 years. The incidence of diabetes was 21.0, 7.3, and 4.8 cases per 100 person-years in the placebo, metformin, and lifestyle groups, respectively. The lifestyle intervention reduced the incidence by 58 percent (95 percent confidence interval, 48 to 66 percent) and metformin by 31 percent (95 percent confidence interval, 17 to 43 percent), as compared with placebo; and among patients with type 2 diabetes, the lifestyle intervention had a significantly greater effect than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to receive in the lifestyle-intervention program and 13.9 would have to receive metformin. CONCLUSIONS: Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk. The lifestyle intervention was more effective than metformin.
24  Lifestyle interventions; Prevention of type-2 diabetes
2/B

We conducted a systematic review and meta-analysis of twenty-eight US-based studies applying the findings of the Diabetes Prevention Program, a clinical trial that tested the effects of a lifestyle intervention for people at high-risk for diabetes, in real-world settings. The average weight change at twelve months after the intervention was a loss of about 4% percent from participants’ baseline weight. Change in weight was similar regardless of whether the intervention was delivered by clinically trained professionals or lay educators. Additional analyses limited to seventeen studies with a nine-month or greater follow-up assessed showed similar weight change with any additional lifestyle session attended; weight loss increased by 0.25 percentage point. We conclude that costs associated with diabetes prevention can be lowered without sacrificing effectiveness, using non-medical personnel and motivating higher attendance at program sessions.

25  Lifestyle interventions
2/B

BACKGROUND: The Diabetes Prevention Program (DPP) found that an intensive lifestyle intervention can reduce the development of diabetes by more than half in adults with prediabetes, but there is little information about the feasibility of offering such an intervention in community settings. This study evaluated the delivery of a group-based DPP lifestyle intervention in partnership with the YMCA. METHODS: This pilot cluster-randomized trial was designed to compare group-based DPP lifestyle intervention delivery by the YMCA to brief counseling alone (control) in adults who attended a diabetes risk-screening event at one of two semi-urban YMCA facilities and who had a BMI>or=24 kg/m2, >or=2 diabetes risk factors, and a random capillary blood glucose of 110-139 mg/dL. Multivariate regression was used to compare between-group differences in changes in body weight, blood pressures, HbA1c, total cholesterol, and HDL-cholesterol after 6 and 12 months. RESULTS: Among 92 participants, controls were more often women (61% vs 50%) and of non-white race (32% vs 7%). Over 6 months, body weight decreased by 6.0% (95% CI=4.7, 7.3) in intervention participants and 2.0% (95% CI=0.6, 3.3) in controls; (p=0.01; difference between groups). Intervention participants also had greater changes in total cholesterol (-22 mg/dL vs +6 mg/dL; controls; p<0.001). These differences were sustained after 12 months, and adjustment for differences in race and gender did not alter these findings. With only two matched YMCA sites, it was not possible to adjust for potential clustering by site. CONCLUSIONS: The YMCA may be a promising channel for wide-scale dissemination of a low-cost approach to lifestyle diabetes prevention.

26  / 2 / 4
Manage comorbidities
Section 1.3.2: NICE CG 189(2014). Obesity: identification, assessment and management.
2/B

IMPORTANCE: Bariatric surgery is associated with sustained weight loss and improved physical health status for severely obese individuals. Mental health conditions may be common among patients seeking bariatric surgery, however the prevalence of these conditions and whether they are associated with postoperative outcomes remains unknown. OBJECTIVE: To determine the prevalence of mental health conditions among bariatric surgery candidates and recipients, to evaluate the association between preoperative mental health conditions and health outcomes following bariatric surgery, and to evaluate the association between surgery and the clinical course of mental health conditions. DATA SOURCES: We searched PubMed, MEDLINE on OVID, and PsycINFO for studies published between January 1988 and November 2015. Study quality was assessed using an adapted tool for risk of bias; quality of evidence was rated based on GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria. FINDINGS: We identified 58 publications meeting inclusion criteria: 59 reporting the prevalence of preoperative mental health conditions (61,363 patients) and 27 reporting associations between preoperative mental health conditions and postoperative outcomes (50,182 patients). Among patients seeking and undergoing bariatric surgery, the most common mental health conditions, based on random-effects estimates of prevalence, were depression (39% [95% CI, 34%-44%]), binge eating disorder (17% [95% CI, 12%-21%]), and obesity (87% [95% CI, 85%-89%]). There was conflicting evidence regarding the association between preoperative mental health conditions and postoperative weight loss. Neither depression nor binge eating disorder was consistently associated with differences in weight outcomes. Bariatric surgery was, however, consistently associated with postoperative decreases in the prevalence of depression (7 studies; 81-74% decrease) and the severity of depressive symptoms (6 studies; 40%-70% decrease). CONCLUSIONS AND RECOMMENDATIONS: Mental health conditions are common among bariatric surgery patients in particular, depression and binge eating disorder. There is inconsistent evidence regarding the association between preoperative mental health conditions and postoperative weight loss. Moderate-quality evidence supports an association between bariatric surgery and lower rates of depression postoperatively.

27  / 2 / 4 / d
Screen for mental health conditions
2/B

IMPORTANCE: Bariatric surgery is associated with sustained weight loss and improved physical health status for severely obese individuals. Mental health conditions may be common among patients seeking bariatric surgery, however the prevalence of these conditions and whether they are associated with postoperative outcomes remains unknown. OBJECTIVE: To determine the prevalence of mental health conditions among bariatric surgery candidates and recipients, to evaluate the association between preoperative mental health conditions and health outcomes following bariatric surgery, and to evaluate the association between surgery and the clinical course of mental health conditions. DATA SOURCES: We searched PubMed, MEDLINE on OVID, and PsycINFO for studies published between January 1988 and November 2015. Study quality was assessed using an adapted tool for risk of bias; quality of evidence was rated based on GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria. FINDINGS: We identified 58 publications meeting inclusion criteria: 59 reporting the prevalence of preoperative mental health conditions (61,363 patients) and 27 reporting associations between preoperative mental health conditions and postoperative outcomes (50,182 patients). Among patients seeking and undergoing bariatric surgery, the most common mental health conditions, based on random-effects estimates of prevalence, were depression (39% [95% CI, 34%-44%]), binge eating disorder (17% [95% CI, 12%-21%]), and obesity (87% [95% CI, 85%-89%]). There was conflicting evidence regarding the association between preoperative mental health conditions and postoperative weight loss. Neither depression nor binge eating disorder was consistently associated with differences in weight outcomes. Bariatric surgery was, however, consistently associated with postoperative decreases in the prevalence of depression (7 studies; 81-74% decrease) and the severity of depressive symptoms (6 studies; 40%-70% decrease). CONCLUSIONS AND RECOMMENDATIONS: Mental health conditions are common among bariatric surgery patients in particular, depression and binge eating disorder. There is inconsistent evidence regarding the association between preoperative mental health conditions and postoperative weight loss. Moderate-quality evidence supports an association between bariatric surgery and lower rates of depression postoperatively.

Updated: November 3, 2016
Dr. Robert Bree Collaborative – Accountable Payment Models Workgroup
Adopted by the Bree Collaborative November 16, 2016
OBJECTIVE: To evaluate the psychometric properties of a single-item depression screen against validated scoring algorithms for the Patient Health Questionnaire (PHQ) and the utility of those algorithms in screening for depression and suicidality in a Department of Veterans Affairs (VA) primary care setting. STUDY DESIGN: Recruitment phase of a randomized trial. METHODS: A total of 1,121 Portland VA patients with upcoming primary care clinic appointments were administered by telephone a single item assessing depressed mood over the past year and the PHQ. The PHQ-9 (9 items) encompasses DSM-IV criteria for major depression, the PHQ-8 (8 items) excludes the thoughts of death or suicide item, and the PHQ-2 (2 items) assesses depressed mood and anhedonia. Results: Of those responders, potential suicidality was assessed using 2 additional items assessing suicidal ideation. Patients receiving mental health specialty care were excluded. RESULTS: Using the PHQ-9 algorithm for major depression as the reference standard, the VA single item screen was specific (98%) but less sensitive (79%). A PHQ-2 score of 1 or 2 demonstrated similar specificity (95%) with high sensitivity (97%). For case finding, the PHQ-9 was similar to the PHQ-2. Approximately 20% of patients screened positive for moderate depression, 7% reported thoughts of death or suicide, and 1% reported thoughts of harming themselves, and 1% had specific plans. CONCLUSIONS: The PHQ-2 offers brevity and better psychometric properties for depression screening than the single-item screen. The PHQ-9 item assessing thoughts of death or suicide does not improve depression case finding; however, one third of patients endorsing this item reported recent active suicidal ideation.

Abstract: AIMS: The risk of early and late death in relation to smoking and ex-smoking were studied. METHODS AND RESULTS: A cohort of 1,711 Finnish men born between 1900 and 1919 were recruited in 1959 and followed up for 35 years. Information on smoking status was collected at each of six examinations made from 1959 to 1989 using a standardized questionnaire. Vital status at the end of 1994 was collected for every man. The effect of smoking on mortality was assessed using Cox proportional hazards model. Adjusted ratios for 35-year all-cause mortality were 1.62 (95% CI 1.40-1.88) in current smokers and 1.13 (CI 0.95-1.36) in former smokers compared with non-smokers. The hazards ratios for 35-year coronary heart disease mortality were 1.03 (CI 0.86-1.23) and 1.39 (CI 1.00-1.94), respectively. The risk for 10-year mortality was stronger than for 35-year mortality among both former and current smokers, given the same amount of cigarettes consumed. Men smoking persistently were most at risk, while those who persisted in quitting had no increased risk of death compared with non-smokers. CONCLUSION: Smoking increases the risk of premature death in middle-aged men and giving up smoking earlier in life can prevent smoking attributable premature death.

OBJECTIVE: To formulate clinical practice guidelines for the pharmacological management of obesity. PARTICIPANTS: An Endocrine Society-appointed Task Force of experts, a methodologist, and a medical writer. This guideline was co-sponsored by the European Society of Endocrinology and The Obesity Society. EVIDENCE: This evidence-based guideline was developed using the Grading of recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence. CONSENSUS PROCESS: One group meeting, several conference calls, and e-mail communications enabled consensus. Committees and members of the Endocrine Society, the European Society of Endocrinology, and The Obesity Society reviewed and commented on preliminary drafts of these guidelines. Two systematic reviews were conducted to summarize some of the supporting evidence. CONCLUSIONS: Weight loss is a pathway to health improvement for patients with obesity-associated risk factors and comorbidities. Medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone. Many medications commonly prescribed for diabetes, depression, and other chronic diseases have weight effects, either to promote weight gain or produce weight loss. Knowledgeable prescribing of medications, choosing whenever possible those that facilitate weight loss, can aid in the prevention and management of obesity and thus improve health.

The cohort is VA primary care patients who self-identified to participate in the study. Patients [were excluded if they] had received treatment from a mental health care clinician within the prior 6-month period or who had Alzheimer’s disease, cognitive problems, psychotic symptoms, or terminal illness documented in their medical records.  

Using the PHQ-9 as a reference standard, this study compared utility of shorter tests: a single question depression screen versus the PHQ-2. The PHQ-2 was superior, demonstrating similar sensitivity and specificity to the PHQ-9.  

Study with some limitations noted above, supports use of the PHQ-2 for screening for depression.
Drug treatment; orlistat

ShichIU e, TOSTad s, RIssIv e, TuBeso, f, BAKer e, Muddad s, MustadIp e, rissAn e. Effect of orlistat on weight regain and cardiovascular risk factors following a very-low-energy diet in abdominally obese patients: a 3-year randomized, placebo-controlled study. Diabetes Care. 2007 Jan;30(1):27-32. PMID: 17161328

http://care.diabetesjournals.org/content/30/1/27.full

OBJECTIVE: To investigate the efficacy of orlistat on the maintenance of weight loss over 3 years following a major weight loss induced by very-low-energy diet (VLED) in obese patients with metabolic risk factors such as dyslipidemia, impaired fasting glucose, and diet-induced type 2 diabetes. RESEARCH DESIGN AND METHODS: Initially, weight loss was induced by an 8-week VLED (600-800 kcal/day) in 383 patients with a mean BMI of 37.5 kg/m² (range 30.4-44.2). Those who lost > or = 10% of their body weight (39% of 383 patients) were then randomized to receive lifestyle counseling for 3 years together with either orlistat 120 mg t.i.d. or matching placebo capsules. Primary end points were the maintenance of > or = 5% weight loss after 3 years. Additionally, differences in the development of type 2 diabetes between orlistat and placebo were analyzed. RESULTS: The VLED induced a mean weight loss of 14.4 ± 2.0 kg among the subsequently randomized patients. The mean weight gain after 1 years was lower with orlistat than with placebo (4.6 ± 0.9 vs. 7.3 ± 7.1 kg; P = 0.02). The number of participants who achieved > or = 5% weight loss also favored orlistat (67% vs. 56%; P = 0.07). Waist circumference was significantly more reduced in the orlistat group (P = 0.05), but no other differences in the risk factors were observed between the two groups. The incidence of new cases of type 2 diabetes were significantly reduced in the orlistat group (8 cases out of 153 subjects) versus placebo (17 cases out of 156 subjects) (P = 0.04). CONCLUSIONS: The addition of orlistat to lifestyle intervention was associated with maintenance of an extra 2.4 kg weight loss after VLED for up to 3 years in obese subjects. The combination of orlistat and lifestyle intervention was associated with a reduced occurrence of type 2 diabetes.

Drug treatment; orlistat


BACKGROUND: We undertook a randomised controlled trial to assess the efficacy and tolerability of orlistat, a gastrointestinal lipase inhibitor, in promoting weight loss and preventing weight regain in obese patients over a 2-year period. METHODS: 743 patients (body mass index 28-47 kg/m²), recruited at 23 European centres, entered a 4-week, single-blind, placebo lead-in period on a slightly hypocaloric diet. 688 patients who completed the lead-in were assigned double-blind treatment with orlistat 120 mg (three times a day) or placebo for 1 year in conjunction with the hypocaloric diet. In a second 52-week double-blind period patients were reassigned orlistat or placebo with a weight maintenance (eucaloric) diet. FINDINGS: From the start of lead-in to the end of year 1, the orlistat group lost, on average, more bodyweight than the placebo group (10.2% [9.3 kg] vs 6.1% [4.1 kg]; LSM difference 3.9 kg [P = 0.001] from randomization to the end of year 1). During year 2, patients who continued with orlistat, regained, on average, half as much weight as those patients switched to placebo (P < 0.001). Patients switched from placebo to orlistat lost an additional 0.4 kg during year 2, compared with a mean regain of 2.5 kg in patients who continued on placebo (P < 0.001). Total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein ratio, and concentrations of glucose and insulin decreased more in the orlistat group than in the placebo group. Gastrointestinal adverse events were more common in the orlistat group. Other adverse symptoms occurred at a similar frequency during both treatments. INTERPRETATION: Orlistat taken with an appropriate diet promotes clinically significant weight loss and reduces weight regain in obese patients over a 2-year period. The use of orlistat beyond 2 years needs careful monitoring with respect to efficacy and adverse events.

Drug treatment; orlistat


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BACKGROUND: Lifestyle measures are considered the first line of therapy for treating overweight individuals, but many are unable to achieve a meaningful weight loss. OBJECTIVE: To determine the efficacy and safety of orlistat 60 mg, given three times daily, for weight loss in mildly overweight individuals. METHODS: A multicenter, 16-week, randomized, double-blind, placebo-controlled study was conducted in 191 overweight subjects at 20 US centers. The main outcome measure was change in weight from baseline to week 16; secondary measures included changes in body mass index, waist circumference, blood pressure, and fasting lipoprotein and glucose levels. RESULTS: Subjects in both groups lost weight over the treatment period. However, orlistat-treated subjects lost significantly more weight than placebo-treated subjects beyond 2 weeks of treatment. Weight loss was from baseline to week 16 was significantly greater in participants receiving orlistat versus those receiving placebo (0.05 vs. 0.01 kg; P = 0.01), intent-to-treat analysis. Orlistat-treated subjects who completed 16 weeks of treatment lost 4.8 ± 0.15% (mean ± SEM) of baseline weight compared with 3.1 ± 0.38% for the placebo group (P < 0.001). Orlistat-treated subjects, compared with those receiving placebo, also demonstrated a greater relative reduction in total (4.4% vs. 0.0%; P = 0.004) and low-density lipoprotein cholesterol (7.2% vs. 0.1%; P = 0.003) and both diastolic (-3.8% vs. 0.0%; P = 0.003) and systolic blood pressure (-4.7% vs. -0.8%; P = 0.01). Both groups showed a similar safety profile; gastrointestinal events were significantly more common in the orlistat-treated subjects. CONCLUSIONS: The use of orlistat 60 mg by mildly to moderately overweight individuals produced significant weight loss in conjunction with a reduced calorie diet and self-instructional materials. This amount of weight loss was associated with improvements in several weight-related risk factors. Orlistat 60 mg may be a useful adjunct to lifestyle measures and has the potential to contribute significantly to weight and risk factor improvement for overweight individuals.

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Dr. Robert Bree Collaborative – Accountable Payment Models Workgroup

Adopted by the Bree Collaborative November 16, 2016
Drug treatment; phentermine plus topiramate

SECTION 1.2.11: NICE CG189 (2014).

Asian populations have also been shown to have an elevated risk of type 2 diabetes, hypertension, dyslipidaemia, diabetes or prediabetes, or abdominal obesity to placebo, once-daily phentermine 7.5 mg plus topiramate 46 mg, or once-daily phentermine 15.0 mg plus topiramate 92 mg in a 1:1.2 ratio in 95 centers in the USA. Drugs were administered orally. Patients were randomly assigned by use of a computer-generated algorithm that was implemented through an interactive voice response system, and were stratified by sex and diabetic status. Investigators, patients, and study sponsors were masked to treatment. Primary endpoints were the percentage change in bodyweight and the proportion of patients achieving at least 5% weight loss. Analyses were by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00537857. FINDINGS: Of 2487 patients, 954 were assigned to placebo, 496 to phentermine 7.5 mg plus topiramate 46 mg and, 959 to phentermine 15.0 mg plus topiramate 92 mg 977, 488, and 983 patients, respectively, were analyzed. At 56 weeks, change in bodyweight was -1.4 kg (least-squares mean -1.2%, 95% CI -1.8 to -0.7), -8.1 kg (-7.8%, -8.5 to -7.1; p<0.001), and -10.2 kg (-8.8%, -10.4 to -8.3; p<0.001) in the patients assigned to phentermine, phentermine 7.5 mg plus topiramate 46 mg, and phentermine 15.0 mg plus topiramate 92 mg, respectively. P202 (24%) patients achieved at least 5% weight loss with placebo, 503 (62%; odds ratio 6.3, 95% CI 4.9 to 8.0; p<0.001) with phentermine 7.5 mg plus topiramate 46 mg and, 887 (70%; 90% CI 67.9 to 72.4; p<0.001) with phentermine 15.0 mg plus topiramate 92 mg; for ≥10% weight loss, the corresponding numbers were 73 (7%), 182 (37%; odds ratio 6.3, 95% CI 4.9 to 8.0; p<0.001), and 204 (21%; 95% CI 17.7 to 23.4; p<0.001) with phentermine 7.5 mg plus topiramate 46 mg, and phentermine 15.0 mg plus topiramate 92 mg, respectively. paraesthesia (11 [1%], 37 [7%], and 103 [10%], respectively), dizziness (31 [3%], 36 [7%], 99 [10%], respectively), and dry mouth (29 [4%], 75 [15%], and 173 [17%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), and dysgeusia (11 [1%], 37 [7%], and 103 [10%], respectively). The most common adverse events were dry mouth (29 [4%], 75 [15%], and 173 [17%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), nausea (47 [5%], 29 [6%], and 102 [10%], respectively), dizziness (31 [3%], 96 [20%], and 173 [17%], respectively), and dysgeusia (9 [1%], 37 [7%], and 103 [10%], respectively). 48 (4%) patients assigned to placebo, 10 (4%) to phentermine plus topiramate, 46·0 mg, and phentermine 15·0 mg plus topiramate 92·0 mg, respectively), paraesthesia (20 [2%], 7·6, 5·6 to 10·2; p<0·0001), and 467 (48%; 11·7, 8·9 to 15·4; p<0·0001). The most common adverse events were dry mouth (29 [4%], 75 [15%], and 173 [17%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), nausea (47 [5%], 29 [6%], and 102 [10%], respectively), dizziness (31 [3%], 96 [20%], and 173 [17%], respectively), and dysgeusia (9 [1%], 37 [7%], and 103 [10%], respectively). The most common adverse events were dry mouth (29 [4%], 75 [15%], and 173 [17%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), nausea (47 [5%], 29 [6%], and 102 [10%], respectively), dizziness (31 [3%], 96 [20%], and 173 [17%], respectively), and dysgeusia (9 [1%], 37 [7%], and 103 [10%], respectively). 48 (4%) patients assigned to placebo, 10 (4%) to phentermine plus topiramate, 46·0 mg, and phentermine 15·0 mg plus topiramate 92·0 mg, respectively), paraesthesia (11 [1%], 37 [7%], and 103 [10%], respectively). 38 (4%) patients assigned to placebo, 19 (4%) to phentermine 7·5 mg plus topiramate 46·0 mg, and phentermine 15·0 mg plus topiramate 92·0 mg, respectively), paraesthesia (11 [1%], 37 [7%], and 103 [10%], respectively). 38 (4%) patients assigned to placebo, 19 (4%) to phentermine 7·5 mg plus topiramate 46·0 mg, and phentermine 15·0 mg plus topiramate 92·0 mg, respectively)

![Image of a page from a document with text](image-url)
Asian population; Diabetes


http://care.diabetesjournals.org/content/35/8/751.full.pdf+html

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<td>Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGB), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body mass index of 35, at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. These procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006).</td>
<td>Medicare coverage standards</td>
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The purpose of this position statement is to provide an evidence-based review of the medical literature from 2011 to the present regarding insurance mandated preoperative weight loss, in contrast to physician, program, or patient-initiated weight loss (as previously described and differentiated in the 2011 statement), which purports to improve surgical or patient adherence to programmatic requirements. | Professional society statement supported by literature review. |

Authors' conclusion is that there is a lack of a compelling evidence base for the requirement of weight loss as a prerequisite for bariatric surgery. | 9 Authors' conclusion that there is a lack of a compelling evidence base for the requirement of weight loss as a prerequisite for bariatric surgery. |

Bariatric surgery comparison study from the Nurses' Health Study. Author conclusion: "For each 5-lb weight gain between age 18 and the year 1000, the risk of diabetes was increased by 84% (95% CI 1.26-4.4) for Asians, 44% (24-65) for Hispanics, 28% (9-49) for blacks, and 37% (25-48%) for whites." | Prospective cohort study from the Nurses' Health Study. Author conclusion: "For each 5-lb weight gain between age 18 and the year 1000, the risk of diabetes was increased by 84% (95% CI 1.26-4.4) for Asians, 44% (24-65) for Hispanics, 28% (9-49) for blacks, and 37% (25-48%) for whites." |
45 I / A / 1 Diabetes management


Abstract: HYPOTHESIS: Good preoperative glycemic control (hemoglobin A1c [HbA1c] levels <7%) is associated with decreased postoperative infections. DESIGN: Retrospective observational study using Veterans Affairs National Surgical Quality Improvement Program data from the Veterans Affairs Connecticut Healthcare System from January 1, 2000, through September 30, 2003. SETTING: Veterans Affairs Connecticut Healthcare System, a tertiary referral center and major university teaching site. PATIENTS: Six hundred forty-seven diabetic patients underwent major noncardiac surgery during the study period; 139 were excluded because the HbA1c levels were more than 180 days prior to surgery; 19 were excluded for other reasons; 490 diabetic patients were analyzed. The study patients were predominantly nonblack men with a median age of 71 years. MAIN OUTCOME MEASURES: Primary outcomes were infectious complications, including pneumonia, wound infection, urinary tract infection, or sepsis. Binary analysis was used first to determine the association of each independent variable (age, race, diabetic treatment, American Society of Anesthesiologists classification, Activities of Daily Living assessment, evidence vs emergent procedure, wound classification, operation length, and HbA1c [levels]) with outcome. Factors significant at P<.05 were used in a multivariable logistic regression model. RESULTS: In the multivariable model, age, gender, and insulin treatment (compared with non-insulin treatment) were associated with increased infectious complications with an adjusted odds ratio of 2.13 (95% confidence interval, 1.23-3.70) and a P value of .007. CONCLUSION: Good preoperative glycemic control (HbA1c levels <7%) is associated with a decrease in infectious complications across a variety of surgical procedures.

Retrospective observational study of VA patients undergoing major non-cardiac surgery.

9 Supports improved preoperative diabetes control to reduce postoperative infectious complications.

46 I / A / 1 Diabetes management


Tier 1 Source

High quality source

9 Outlines management recommendations for Type-2 diabetes.

47 I / A / 2 Nutritional status


BACKGROUND: Poor nutrition status is considered a risk factor for postoperative complications in the adult population. In elderly patients, who often have a poor nutrition status, this relationship has not been substantiated. Thus, the aim of this systematic review was to assess the merit of preoperative nutritional parameters used to predict postoperative outcome in elderly patients undergoing general surgery. METHODS: A systematic literature search of 10 consecutive years, 1998-2008, in PubMed, EMBASE, and Cochrane Databases was performed. Search terms used were nutrition status, preoperative, postoperative outcome, and surgery (hip or general). All studies selected were included in the methodology and graded. RESULTS: Of 463 articles found, 15 were included. They showed profound heterogeneity in the parameters used for preoperative nutrition status and postoperative outcome. The only significant preoperative predictors of postoperative outcome in elderly general surgery patients were serum albumin and >= 10% weight loss over previous 6 months. CONCLUSION: This systematic review revealed only 2 preoperative parameters to predict postoperative outcome in elderly general surgery patients: weight loss and serum albumin. Both are open to discussion in their use as a preoperative nutrition parameter. Nonetheless, serum albumin seems a reliable preoperative parameter to identify a patient at risk for nutrition deterioration and related complicated postoperative course.

9 Focus is pre-operative nutritional state as a risk factor for complications for patients 65 years of age or older.

9 Supports conclusion that reduced serum albumin and weight loss over previous six months predicts postoperative complication for elderly general surgery patients.

48 I / A / 3 Upper function; Cirrhosis


Abstract: Nonalcoholic steatohepatitis is becoming a common cause of liver cirrhosis and a significant number of patients undergoing bariatric surgery suffer with it. Themselves currently lack of consensus among surgeons regarding safety of bariatric surgery in patients with liver cirrhosis and the best bariatric procedure in these patients. This review investigates published English language scientific literature systematically in an attempt to answer these questions. Eleven studies that reported experience of bariatric surgery in cirrhotic obese patients were included in this review. This review shows an acceptably high overall risk of complications and perioperative mortality with bariatric surgery in cirrhotic patients. Surgeons must discuss the possibility of an unexpected intraoperative diagnosis of cirrhosis preoperatively with all bariatric surgery patients and agree on a course of action.

Systematic review of eleven uncontrolled retrospective studies of patients with cirrhosis undergoing bariatric surgery, mostly class A Child-Pugh score. Of 122 patients, 96.5% were class A Child-Pugh and the overall complication rate for all patients was 21.3%. This review includes findings of 10% mortality rate following laparoscopic diversion.

9 Small numbers of patients make interpretation of this data difficult.
### User Function; Cirrhosis


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**BACKGROUND & AIM:** This study aims to quantify the risk of cardiac surgery in patients with cirrhosis.

**METHODS:** Records of all adult patients undergoing cardiac surgery using cardiopulmonary bypass at the Cleveland Clinic (Cleveland, OH) from January 1992 to June 2002 were analyzed for any relationship of Child-Pugh class and/or score and MELD score with outcome measures of hepatic decompensation and death during the first 3 months after surgery. RESULTS: Forty-four patients underwent coronary artery bypass grafting (16 patients), valve surgery (15 patients), a combination of the 2 procedures (10 patients), or pericardiectomy (2 patients). Twelve patients (27%) developed hepatic decompensation, and 7 patients (16%) died. Proportions of hepatic decompensation were 3 of 31, 8 of 12, and 1 of 1 patients, and death, 1 of 31, 5 of 12, and 1 of 1 patients in Child-Pugh classes A, B, and C, respectively. The association of hepatic decompensation and mortality with Child-Pugh class, Child-Pugh score, and MELD score was significant (P < 0.005). Areas under the receiver operating characteristic curves for mortality were similar for Child-Pugh (0.84 +/- 0.09) and MELD scores (0.87 +/- 0.09). A cutoff Child-Pugh score >/=7 was found to have a sensitivity and specificity of 80% and 92% for mortality, with a negative predictive value of 97% (95% confidence interval [CI], 83-99) and positive predictive value of 67% (95% CI, 31-91), respectively. However, a similar cutoff value for MELD score could not be established. CONCLUSIONS: Child-Pugh score and/or class and MELD score are significantly associated with hepatic decompensation and mortality after cardiac surgery using cardiopulmonary bypass in patients with cirrhosis. Such surgery can be conducted safely in patients with a Child-Pugh score >/=7. Patients with a Child-Pugh score >/=11 have a significant risk for mortality.

### Opioids


This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grade of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for implementing guidelines for prescribing opioids for chronic pain (http://topics.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.htm) with additional tools to guide clinicians in implementing the recommendations.

### Smoking Cessation


This cohort study of forty-four adult patients with cirrhosis undergoing cardiac surgery were evaluated with Child-Pugh and MELD scores. A cutoff Child-Pugh score >/=7 was found to have a sensitivity and specificity of 80% and 92% for mortality, with a negative predictive value of 97% (95% confidence interval [CI], 83-99) and positive predictive value of 67% (95% CI, 31-91), respectively. However, a similar cutoff value for MELD score could not be established.

**Adopted by the Bree Collaborative November 16, 2016**

**Updated: November 3, 2016**

| CTA | High quality source | ± National guideline for prescribing opioids for chronic pain management |
| CTA | at four Swedish hospitals of smokers undergoing orthopedic or general surgery | Relative risk reduction for any postop complication was 49% and number needed to treat was 5. |
| CTA | 9 | Supports the conclusion that smoking cessation prior to surgery reduces postoperative complications if smoking discontinued as late as four weeks prior to surgery. |
52 / A / 6
Unhealthy alcohol use

BACKGROUND: Unhealthy alcohol use is prevalent but under-diagnosed in primary care settings. OBJECTIVE: To validate, in primary care, a single-item screening test for unhealthy alcohol use recommended by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). DESIGN: Cross-sectional study. PARTICIPANTS: Adult English speaking patients recruited from primary care waiting rooms. MEASUREMENTS: Participants were asked the single screening question, “How many times in the past year have you had 5 or more drinks in a day?”, where X is 5 for men and 4 for women, and a response of 1 or greater (corrected) is considered positive. Unhealthy alcohol use was defined as the presence of an alcohol use disorder, as determined by a standardized diagnostic interview, or risky consumption, as determined using a validated 30-day calendar method. MAIN RESULTS: Of 394 eligible primary care patients, 286 (73%) completed the interview. The single-question screen was 81.8% sensitive (95% confidence interval [CI] 75.5% to 88.5%) and 79.3% specific (95% CI 73.2% to 84.4%) for the detection of unhealthy alcohol use. It was slightly more sensitive (97.9%, 95% CI 77.2% to 95.2%) but was less specific (66.8%, 95% CI 60.2% to 72.3%) for the detection of a current alcohol use disorder. Text characteristics were similar to that of a commonly used three-item screen, and were affected very little by subject demographic characteristics. CONCLUSIONS: The single screening question recommended by the NAAA accurately identified unhealthy alcohol use in this sample of primary care patients. These findings support the use of this brief screen in primary care.

Cross-sectional study compared single-question screen of alcohol use with diagnostic interview or validated calendar method to identify unhealthy alcohol use.

Supports use of a single question screen to identify unhealthy alcohol use.

53 / A / 6
Unhealthy alcohol use

BACKGROUND AND AIMS: Alcohol consumption is a well-documented determinant of adverse perioperative outcome. We sought to determine the effect of active alcohol consumption following elective surgery. METHODS: We queried discharge records from the American College of Surgeons’ National Surgical Quality Improvement Program (NSQIP, 2005–2007) for all elective adult admissions. The 7,631 (15.5%) patients with documented alcohol use (active alcohol use of at least two drinks per day for 7 weeks of surgery) and 36,314 (84.5%) patients without alcohol use were used for logistic regression to determine the effect of alcohol use on length of stay. A multivariate analysis was performed with adjustments for demographic and comorbid factors. Primary outcome measures included length of stay (LOS), postoperative complications, and death. RESULTS: Alcohol use associated with elective surgery decreased over the course of the study (p < 0.0001). Alcohol use was an independent predictor of pneumonia (OR 1.98, 95% CI 1.84-2.13), sepsis (OR 1.19, 95% CI 1.03-1.37), superficial surgical site infection (SSI) (OR 1.15, 95% CI 1.02-1.31), wound disruption (OR 1.41, 95% CI 1.11-1.80), and prolonged LOS (OR 1.17, 95% CI 1.08-1.26). For SSI, these complications were independent risk factors for postoperative mortality. Active alcohol use was associated with earlier time to wound disruption (9 vs. 11 days; p < 0.01), longer median hospital stays (15 vs. 14 days; p < 0.0001), and longer LOS after operation (4 vs. 3 days; p < 0.0001). CONCLUSIONS: Active alcohol consumption is a significant determinant of adverse outcomes in elective surgery; patients who undergo elective surgery should be appropriately educated and counseled.

Retrospective cohort study from the database of the National Surgical Quality Improvement Program (2005–2007). Multivariate analysis was performed with adjustments for demographic and comorbid factors. Alcohol use was found to be an independent risk factor for pneumonia, sepsis, superficial surgical site infection, wound disruption, and prolonged length of hospital stay. Alcohol consumption was defined as at least two drinks per day within two weeks of surgery.

Supports the conclusion that pre-operative alcohol use is associated with post-operative complications.

54 / A / 7
Depression screening

BACKGROUND: Unhealthy alcohol use is prevalent but under-diagnosed in primary care settings. OBJECTIVE: To validate, in primary care, a single-item screening test for unhealthy alcohol use recommended by the National Institute on Alcohol Abuse and Alcoholism (NIAAA). DESIGN: Cross-sectional study. PARTICIPANTS: Adult English speaking patients recruited from primary care waiting rooms. MEASUREMENTS: Participants were asked the single screening question, “How many times in the past year have you had 5 or more drinks in a day?”, where X is 5 for men and 4 for women, and a response of 1 or greater (corrected) is considered positive. Unhealthy alcohol use was defined as the presence of an alcohol use disorder, as determined by a standardized diagnostic interview, or risky consumption, as determined using a validated 30-day calendar method. MAIN RESULTS: Of 394 eligible primary care patients, 286 (73%) completed the interview. The single-question screen was 81.8% sensitive (95% confidence interval [CI] 75.5% to 88.5%) and 79.3% specific (95% CI 73.2% to 84.4%) for the detection of unhealthy alcohol use. It was slightly more sensitive (97.9%, 95% CI 77.2% to 95.2%) but was less specific (66.8%, 95% CI 60.2% to 72.3%) for the detection of a current alcohol use disorder. Text characteristics were similar to that of a commonly used three-item screen, and were affected very little by subject demographic characteristics. CONCLUSIONS: The single screening question recommended by the NAAA accurately identified unhealthy alcohol use in this sample of primary care patients. These findings support the use of this brief screen in primary care.

Cross-sectional study compared single-question screen of alcohol use with diagnostic interview or validated calendar method to identify unhealthy alcohol use.

Supports use of a single question screen to identify unhealthy alcohol use.

Supports the conclusion that pre-operative alcohol use is associated with post-operative complications.

Supports use of a single question screen to identify unhealthy alcohol use.
Depression; Suicide outcomes


Purpose: Bariatric surgery is recognized as the treatment of choice for class II/III obesity (body mass index ≥40) and has been increasingly recommended for obese patients. Prior research has suggested an excess of deaths due to suicide following bariatric surgery, but few large long-term follow-up studies exist. We examined postbariatric surgery suicides by time since operation, sex, and suicide death rates as compared with US suicide rates. METHODS: Medical data following bariatric operations performed on Pennsylvania residents between January 1, 1995, and December 31, 2004 were obtained from the Pennsylvania Health Care Cost and Containment Council. Matching mortality data from suicides between September 1, 1995 and December 31, 2008 were obtained from the Division of Vital Records, Pennsylvania Department of Health. RESULTS: There were 31 suicides (16,683 operations), for an overall rate of 6.6/10,000; 12.1/10,000 among men and 3.2/10,000 among women. About 30% of suicides occurred within the first 2 years following surgery, with almost 70% occurring within 5 years. For every age category except the youngest, suicide rates were higher among men than women. Age- and sex-matched suicide rates in the US population (ages 15-64 years) were 2.4/10,000 (men) and 0.7/10,000 (women). CONCLUSIONS: Compared with age and sex-matched suicide rates in the US, there was a substantial excess of suicides among all patients who had bariatric surgery in Pennsylvania during a 10-year period. These data document the need to develop more comprehensive long-term surveillance and follow-up methods in order to evaluate factors associated with postbariatric surgery suicide.

Dementia screening


BACKGROUND: Dementia patients often present with confusing medical conditions and potentially face higher risk of complications during hospitalization. Because the general features of postoperative adverse outcomes among surgical patients with dementia are unknown, we conducted a nationwide, retrospective cohort study to characterize surgical complications among dementia patients compared with age- and sex-matched nondemented controls. METHODS: Reimbursement claims from the Taiwan National Health Insurance Research Database were studied. A total of 18,923 surgical patients were enrolled with preoperative diagnosis of dementia for 207,693 aged 60 years or older who received inpatient major surgeries between 2004 and 2007. Their preoperative comorbidities were adjusted and risks for major surgical complications were analyzed. RESULTS: Dementia patients who underwent surgery had a significantly higher overall postoperative complication rate, adjusted odds ratio (OR) 1.79 [95% confidence interval (CI) 1-2.1.86], with higher medical resource use, and in-hospital expenditures. Compared with controls, dementia patients had a higher incidence of certain postoperative complications that are less likely to be identified in their initial stage, such as acute renal failure, OR = 1.32 (1.10-1.47); pneumonia, OR = 1.38 (1.20-1.51); sepsisemia, OR = 1.81 (1.69-1.92); stroke, OR = 1.35 (1.35-1.31); and urinary tract infection, OR = 1.62 (1.5-1.74). CONCLUSIONS: These findings have specific implications for postoperative care of dementia patients regarding complications that are difficult to diagnose in their initial stages. Acute renal failure, pneumonia, sepsisemia, stroke, and urinary tract infection are the top priorities for prevention, early recognition, and intervention of postoperative complications among surgical patients with dementia. Further efforts are needed to determine specific protocols for health care teams serving this population.

Dementia screening


The Montreal Cognitive Assessment (MoCA) is a brief instrument developed for the screening of milder forms of cognitive impairment, having surpassed the well-known limitations of the Mini-Mental State Examination (MMSE). The aim of the present study was to validate the MoCA as a cognitive screening test for behavioral-variant frontotemporal dementia (bv-FTD) by examining its psychometric properties and diagnostic accuracy. Three matched subgroups of participants were considered: bv-FTD (n = 50); Alzheimer disease (n = 50); and a control group of healthy adults (n = 50). Compared with the MMSE, the MoCA demonstrated consistently superior psychometric properties and discriminant capacity, providing comprehensive information about the patients' cognitive profiles. The diagnostic accuracy of MoCA for bv-FTD was extremely high (area under the curve AUC (MoCA) = 0.934, 95% confidence interval (CI) = 0.866-0.974; AUC (MMSE) = 0.772, 95% CI = 0.677-0.870). With a cutoff below 17 points, the MoCA results for sensitivity, specificity, positive predictive value, negative predictive value, and classification accuracy were significantly superior to those of the MMSE. The MoCA is a sensitive and accurate instrument for screening the patients with bv-FTD and represents a more valid alternative to the MMSE.

Shared Decision-Making

Peterson D. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. Health Affairs, 2012, Sep: 31(9): 2006-10. PMID: 22949340

Decision aids are evidence-based sources of health information that can help patients make informed treatment decisions. However, little is known about how decision aids affect health care use when they are implemented outside of randomized controlled clinical trials. We conducted an observational study to examine the associations between introducing decision aids for hip and knee osteoarthritis and rates of joint replacement surgery and costs in a large health system in Washington State. Consistent with prior randomized trials, our introduction of decision aids was associated with 26 percent fewer hip replacement surgeries, 38 percent fewer knee replacements, and 12-21 percent lower costs over six months. These findings support the concept that patient decision aids for some health conditions, for which treatment decisions are highly sensitive to both patients' and physicians' preferences, may reduce rates of elective surgery and lower costs.

Ten-year retrospective cohort study controlled for age and sex, comparing suicide rate between patients with or without bariatric surgery. Data sources were the Pennsylvania Health Care Cost and Containment Council and the Division of Vital Records, Pennsylvania State Department of Health.

Suicide rate following bariatric surgery was higher among men than women, and both substantially higher than the general population.

BACKGROUND: Despite the increasing use of Roux-en-Y gastric bypass (RYGBP) in the treatment of morbid obesity, data about postoperative nutritional deficiencies and their treatment remain scarce. OBJECTIVE: The aim of this study was to evaluate the efficacy of a standard multivitamin preparation in the prevention and treatment of nutritional deficiencies in obese patients after RYGBP. DESIGN: This was a retrospective study of 2 yr of follow-up of obese patients after RYGBP surgery. Between the first and the sixth postoperative months, a standardized multivitamin preparation was prescribed for all patients. Specific requirements for additional substitutional treatments were systematically assessed by a biologic workup at 3, 6, 9, 12, 18, and 24 mo. RESULTS: A total of 137 morbidly obese patients (110 women and 27 men) were included. The mean (+/- SD) age at the time of surgery was 39.9 +/- 10.9, and the body mass index (in kg/m(2)) was 46.7 +/- 6.5. Three months after RYGBP, 34% of these patients required at least one specific supplement in addition to the multivitamin preparation. At 6 and 24 mo, this proportion increased to 59% and 88%, respectively. Two years after RYGBP, a mean amount of 2.9 +/- 1.4 specific supplements had been prescribed for each patient, including vitamin B-12, iron, calcium + vitamin D, and folic acid. At that time, the mean-monthly cost of the substitutional treatment was $54.83. CONCLUSION: Nutritional deficiencies are very common after RYGBP and occur despite supplementation with the standard multivitamin preparation. Therefore, careful postoperative follow-up is indicated to detect and treat those deficiencies.

In obese patients undergoing laparoscopic sleeve gastrectomy (LSG) procedures revealed that 51% of these patients required at least one specific supplement in addition to the multivitamin preparation. At 6 and 24 mo, this proportion increased to 59% and 88%, respectively. Two years after RYGBP, a mean amount of 2.9 +/- 1.4 specific supplements had been prescribed for each patient, including vitamin B-12, iron, calcium + vitamin D, and folic acid. At that time, the mean-monthly cost of the substitutional treatment was $54.83. CONCLUSION: Nutritional deficiencies are very common after RYGBP and occur despite supplementation with the standard multivitamin preparation. Therefore, careful postoperative follow-up is indicated to detect and treat those deficiencies.

Roux-en-Y gastric bypass (RYGBP) procedure revealed micronutrient deficiencies following surgery despite standardized multivitamin therapy. Study suggests vitamin deficiencies are common after RYGBP despite standardized multivitamin therapy.

Advance directives specifying limitations in care were associated with lower adjusted probabilities of in-hospital death in high- and medium-spending regions (9.8%; 95% CI, 6.2%-13.4% in high-spending regions; 5.9%; 95% CI, 1.0%-10.8% in medium-spending regions). Advance directions were associated with higher adjusted probabilities of hospice use in high- and medium-spending regions (17%; 95% CI, 11%-23% in high-spending regions; 11%; 95% CI, 6%-16% in medium-spending regions), but not in low-spending regions. CONCLUSION: Advance directives specifying limitations in end-of-life care were associated with significantly lower levels of Medicare spending, lower likelihood of in-hospital death, and higher use of hospice care in regions characterized by higher levels of end-of-life spending.

Prospective uncontrolled cohort study of Medicare patients correlating use of advance directives to lower spending, in hospital death, and use of hospice care in geographic regions characterized by higher levels of end of life spending. The study supports the use of advance directives to reduce the use of inappropriate and costly end-of-life care.

Updated: November 3, 2016
Dr. Robert Bree Collaborative – Accountable Payment Models Workgroup
Adopted by the Bree Collaborative November 16, 2016
62 End-of-Life Care


The End-of-Life Care workgroup met from January 2014 to November 2014 to develop the following five focus areas corresponding to how an individual would ideally experience advance care planning for the end of life. These focus areas work to empower patients to voice their wishes and make sure that the care that all Washingtonians receive at the end of life is the care they and their families want. The focus areas are supported by multi-stakeholder recommendations. These include: "1. Increase awareness of advance care planning, advance directives, and POLST in Washington State...2. Increase the number of people who participate in advance care planning in the clinical and community settings...3. Increase the number of people who record their wishes and goals for end-of-life care using documents that accurately represent their values; are easily understandable by all readers including family members, friends, and health care providers; and can be acted upon in the health care setting...4. Increase the accessibility of completed advance directives and POLST for health systems and providers...5. Increase the likelihood that a patient’s end-of-life care choices are honored...."
Cycle 3: Surgical Repair


Programmatic standard

66
II/1/D

Surgical volume


CONTEXT: Delirium is a common and serious complication in elderly patients. Evidence suggests that delirium is associated with long-term poor outcome but delirium often occurs in individuals with more severe underlying disease. OBJECTIVE: To assess the association between delirium in elderly patients and long-term poor outcome, defined as mortality, institutionalization, or dementia, while controlling for important confounders.

DATA SOURCES: A systematic search of studies published between January 2001 and April 2020 was conducted using the databases of MEDLINE, EMBASE, PsycINFO, and CINAHL. STUDY SELECTION: Observational studies of elderly patients with delirium as a study variable and data on mortality, institutionalization, or dementia after a minimum follow-up of 3 months, and published in the English or Dutch language. Titles, abstracts, and articles were reviewed independently by 2 of the authors. Of 2391 references in the original search, 51 relevant articles were identified. DATA EXTRATION: Information on study design, characteristics of the study population, and outcome were extracted. Quality of studies was assessed based on elements of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies. DATA SYNTHESIS: The primary analyses included only high-quality studies with statistical control for age, sex, comorbid illness or illness severity, and baseline dementia. Pooled-effect estimates were calculated with random-effects models. The primary analysis with adjusted hazard ratios (HRs) showed that delirium is associated with an increased risk of death compared with controls after an average follow-up of 22.7 months (7 studies; 271,714 patients [38.0%] with delirium, 618,243 controls [27.5%]; HR, 1.95 [95% confidence interval, 1.91-1.98]; I², 44.0%). Moreover, patients who had experienced delirium were also at increased risk of institutionalization (7 studies; average follow-up, 14.6 months; 176,327 patients [31.4%] with delirium and 219,252 controls [20.7%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I², 0%). Delirium also increased the risk of dementia (8 studies; average follow-up, 4.1 years; 135,866 patients [38.2%] with delirium and 352,185 controls [20.1%]; OR, 2.52 [95% CI, 1.89-3.34]; I², 52.4%). The sensitivity, trim-and-fill, and secondary analyses with unadjusted high-quality risk estimates stratified according to the study characteristics confirmed the robustness of these results.

CONCLUSION: This meta-analysis provides evidence that delirium in elderly patients is associated with poor outcome independent of important confounders, such as age, sex, comorbid illness or illness severity, and baseline dementia. JAMA 2020; 324(4): 441-51.

Objective: To systematically examine the association between annual hospital and surgeon case volume and patient outcomes in bariatric surgery. BACKGROUND: Bariatric surgery remains a technically demanding field with significant risk for mortality and morbidity. To mitigate this risk, minimum annual hospital and surgeon case volume requirements are being set and certain hospitals are being designated as "Bariatric Surgery Centers of Excellence". METHODS: A comprehensive systematic review on volume-outcome association in bariatric surgery was conducted by searching MEDLINE, Cochrane Database of Systematic Reviews, and Evidence Based Medicine Reviews databases. Abstracts of identified articles were reviewed and pertinent full-text versions were retrieved. Manual search of bibliographies was performed and relevant studies were retrieved. Methodological quality assessment and data extraction were completed in a systematic fashion. Pooling of results was not feasible due to the heterogeneity of the studies. A qualitative summary of results is presented. RESULTS: From a total of 2928 unique citations, 24 studies involving a total of 458,032 patients. Author findings: A positive association between annual surgeon volume and patient outcomes was reported in 11 of 13 studies. A positive association between annual hospital volume and patient outcomes was reported in 14 of 17 studies.

CONCLUSION: There is strong evidence of improved patient outcomes in the hands of high-volume surgeons and high-volume centers. This study supports the concept of "Bariatric Surgery Center of Excellence" accreditation; however, future research into the quality of care characteristics of successful bariatric programs is recommended. Understanding the characteristics of high-volume surgeons, which lead to improved patient outcomes, also requires further investigation.
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III / A / 1

Hospital volume - Surgeon volume


BACKGROUND: The relationship between volume and outcomes in bariatric surgery is well-established in the open surgery era and in the absence of national accreditation. The recent Metabolic Bariatric Surgery Accreditation and Quality Improvement Program proposed an annual threshold volume of 50 stapling cases. This study aimed to examine the effect of hospital and surgeon volume on clinical outcome following bariatric surgery in this laparoscopic era.

METHODS: The Nationwide Inpatient Sample was used for analysis of the outcomes experienced by morbidly obese patients who underwent an elective laparoscopic stapling bariatric surgical procedure between 2006 and 2010. In this analysis, low-volume centers (LVC < 50 stapling cases/year) were compared with high-volume centers (HVC ≥ 50 stapling cases/year). Multivariate analysis was performed to examine risk-adjusted serious morbidity and volume at each hospital during a 2-year period (2003 to 2005). We then ascertained the proportion of hospital level variation explained by each measure using hierarchical modeling techniques. Finally, we compared the ability of each measure to predict future performance, as assessed with risk-adjusted morbidity rate in the next 2 years (2005 to 2006). RESULTS: Risk-adjusted morbidity explained 83% of future hospital-level variation in morbidity compared with only 21% for hospital volume. When comparing the "best" with the "worst" hospital quarters, risk-adjusted morbidity predicted a more than fourfold difference in future performance (1.7% versus 12.2%; odds ratio [OR]: 4.5; 95% CI, 3.3 to 5.5). Hospital volume predicted only a twofold difference (2.5% versus 4.5%; OR: 1.9; 95% CI, 1.5 to 2.4) from the best to the worst quartile. CONCLUSIONS: Risk-adjusted morbidity is much better than hospital volume at predicting future performance with bariatric surgery. Rather than focusing on volume, accreditation and centers of excellence programs should focus more on directly measuring outcomes.

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III / B

Hospital volume


BACKGROUND: Payers and professional organizations are expanding accreditation and "centers of excellence" programs in bariatric surgery. Rather than directly measuring outcomes, most programs rely on procedure volume. We sought to determine whether risk-adjusted outcomes or hospital volume were better at predicting future hospital morbidity with bariatric surgery. STUDY DESIGN: We identified all patients who underwent gastric bypass in the New York State Inpatient database (n = 52,381 patients, n = 105 hospitals). Morbidity was ascertained using a previously validated combination of diagnostic and procedure codes. We first calculated the risk-adjusted morbidity and volume at each hospital during a 2-year period (2003 to 2005). We then ascertained the proportion of hospital level variation explained by each measure using hierarchical modeling techniques. Finally, we compared the ability of each measure to predict future performance, as assessed with risk-adjusted morbidity rate in the next 2 years (2005 to 2006). RESULTS: Risk-adjusted morbidity explained 83% of future hospital-level variation in morbidity compared with only 21% for hospital volume. When comparing the "best" with the "worst" hospital quarters, risk-adjusted morbidity predicted a more than fourfold difference in future performance (1.7% versus 12.2%; odds ratio [OR]: 4.5; 95% CI, 3.3 to 5.5). Hospital volume predicted only a twofold difference (2.5% versus 4.5%; OR: 1.9; 95% CI, 1.5 to 2.4) from the best to the worst quartile. CONCLUSIONS: Risk-adjusted morbidity is much better than hospital volume at predicting future performance with bariatric surgery. Rather than focusing on volume, accreditation and centers of excellence programs should focus more on directly measuring outcomes.

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III / A

Facility volume


BACKGROUND: The dramatic rise in the prevalence of obesity worldwide has led to the rapid growth of bariatric surgery. The aim of this pooled analysis is to evaluate the relationship between institutional and surgeon volume and outcomes following bariatric surgery. Medical, Ethical, trial registers, conference proceedings and reference lists were searched for trials comparing clinical outcome following bariatric surgery at high and low volume hospitals and by high and low volume surgeons. Outcomes analysed were mortality, morbidity and length of hospital stay. Fifteen publications were included in this analysis. In total, 288,732 bariatric procedures were included in the institutional volume analysis, and 32,500 bariatric operations were included in the surgeon volume analysis. Mortality was reduced following surgery at high volume institutions (HR 0.74; 95% CI 0.68 to 0.80; p < 0.001). Similarly, morbidity was reduced in high-volume institutions (7.94% versus 8.85%; pooled odds ratio 0.35; p < 0.001) and with high volume surgeons (HR 0.47; 95% CI 0.43 to 0.51). There were insufficient data for conclusive statistical analysis of length of hospital stay. This pooled analysis does suggest a benefit in the centralisation of bariatric surgery to high volume institutions and surgeons with respect to mortality and morbidity. Future high-powered studies with adjustment for procedural and patient case mix are required to further define the volume-outcome relationship in bariatric surgery.

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III / A

Facility volume


BACKGROUND: Payers and professional organizations are expanding accreditation and "centers of excellence" programs in bariatric surgery. Rather than focusing on volume, accreditation and centers of excellence programs should focus more on directly measuring outcomes. Retrospective cohort study of New York state patients undergoing bariatric surgery during a two-year period; study included 32,381 patients at 105 hospitals. Risk-adjusted morbidity was superior to hospital volume in predicting hospital-based patient outcomes. Systematic review of 15 retrospective studies including 289,732 procedures. This is a retrospective cohort study evaluating morbidity and mortality of laparoscopic stapling procedures relative to facility volume. It supports the conclusion that accredited, high volume centers have improved outcomes.
Facility accreditation  Nguyen NT, Nguyen B, Nguyen VQ, Ziogas A, Hohmann S, Stamos MJ. 

See your local Library for a copy of this citation.

BACKGROUND: In an effort to improve the quality of care in bariatric surgery, 2 accreditation programs based on volume have been initiated. The aim of this study was to analyze the perioperative outcomes of bariatric surgery performed at accredited vs nonaccredited centers. STUDY DESIGN: Patient-level data obtained from the University HealthSystem Consortium for patients who underwent bariatric surgery for the treatment of morbid obesity between 2007 and 2009 were reviewed. Perioperative outcomes were analyzed according to accreditation status. The primary outcome was in-hospital mortality. Secondary outcomes included length of stay, 30-day readmission, overall complications, and cost. Comparisons of length of stay and cost were performed at the-hospital level data. RESULUTS: Of the 0,288 bariatric operations performed during the study period, 89.2% of cases were performed at 71 accredited centers; 10.8% of cases were performed at 43 nonaccredited centers. The rate of in-hospital mortality was significantly lower in accredited centers (0.05% vs 0.21%). Compared with nonaccredited centers, bariatric surgery performed at accredited centers was also associated with shorter length of stay (mean difference 0.3 days; 95% CI 0.10 to 0.46) and lower cost (mean difference, $1,788; 95% CI, $2,865 to $3,952). Post-hoc analyses based on procedural type and severity of illness suggested possible associations between center accreditation and improved in-hospital mortality in patients who underwent gastric bypass and patients with higher severity of illness; similarly, patients requiring prolonged ICU or hospital stay (≥7 days) had significantly lower in-hospital mortality within accredited centers. CONCLUSIONS: Within the context of academic centers, accreditation status was associated with lower in-hospital mortality. The lower mortality rate associated with accredited centers may be attributed to their ability to recognize and rescue complications.

Hospital complication rates with bariatric surgery in Michigan. JAMA. 2010 Jul 28;304(4):435-42. PMID: 2064044


CONTEXT: Despite the growing popularity of bariatric surgery, there remain concerns about perioperative safety and variation in outcomes across hospitals. OBJECTIVE: To assess complication rates of different bariatric procedures and variability in rates of serious complications across hospitals and according to procedure volume and center of excellence (COE) status. DESIGN, SETTING, AND PATIENTS: Involving 25 hospitals and 62 surgeons statewide, the Michigan Bariatric Surgery Collaborative (MBSC) administers an externally audited, prospective clinical registry. We evaluated short-term morbidity in 15,275 Michigan patients undergoing 1 of 3 common bariatric procedures between 2006 and 2009. We used multilevel regression models to assess variation in risk-adjusted complication rates across hospitals and the effects of procedure volume and COE designation (by the American College of Surgeons or American Society for Metabolic and Bariatric Surgery) status. MAIN OUTCOME MEASURES: Complications occurring within 30 days of surgery. RESULTS: Overall, 7.3% of patients experienced perioperative complications, most of which were wound problems and other minor complications. Serious complications were most common after gastric bypass (3.6%; 95% confidence interval [CI], 3.2%-4.0%), followed by sleeve gastrectomy (2.2%; 95% CI, 1.2%-3.2%), and laparoscopic adjustable gastric band (0.9%; 95% CI, 0.6%-1.1%) procedures (P < .001). Mortality occurred in 0.04% (95% CI, 0.003%-0.12%) of laparoscopic adjustable gastric band, 0 sleeve gastrectomy, and 0.14% (95% CI, 0.08%-0.25%) of the gastric bypass patients. After adjustment for patient characteristics and procedure mix, rates of serious complications varied from 1.6% (95% CI, 1.3-2.0%) in 3% (95% CI, 2.4-4.0%) to 3.5% (95% CI, 2.4-5.5%) (risk difference, 1.9; 95% CI, -0.8-3.7) across hospitals. Average annual procedure volume was inversely associated with rates of serious complications at both the hospital level (< 150 cases, 4.1%; 95% CI, 3.0%-5.1%; 150-299 cases, 2.7%; 95% CI, 2.2-3.3%; > or = 300 cases, 2.3%; 95% CI, 1.9%-2.6%; P = .001) and surgeon level (< 100 cases, 3.8%; 95% CI, 3.2%-4.5%; 100-249 cases, 3.4%; 95% CI, 2.1%-2.8%; > or = 250 cases, 1.9%; 95% CI, 1.4%-2.3%; P = .001). Adjusted rates of serious complications were similar in COE and non-COE hospitals (COE, 2.7%; 95% CI, 2.3%-3.1%; non-COE, 2.0%; 95% CI, 1.5%-2.4%; P = .45). CONCLUSIONS: The frequency of serious complications among patients undergoing bariatric surgery in Michigan was relatively low. Rates of serious complications are inversely associated with hospital and surgeon procedure volume, but unrelated to COE accreditation by professional organizations.

This is a retrospective cohort study evaluating mortality, length of stay, and cost at high-volume centers accredited either by the AMSBS or ACS versus nonaccredited center performing bariatric surgery.

Data supports the statement that surgery performed at accredited centers has shorter length of stay and lower cost as well as reduced in-hospital mortality.

Prospective registry-based, state-wide study assessing complication rates of bariatric procedures, hospital volume, surgeon volume, and designation as a center of excellence.

30-day complication rate correlated with hospital volume and surgeon volume, but not with COE status.

OBJECTIVE: To measure the association between a surgeon's degree of specialization in a specific procedure and patient mortality.

DESIGN: Retrospective analysis of Medicare data.

SETTING: US patients aged 66 or older enrolled in traditional fee-for-service Medicare.


MAIN OUTCOME MEASURE: Relative risk reduction in risk-adjusted and volume-adjusted 30 day operative mortality between surgeons in the bottom quarter and top quarter of surgeon specialization (defined as the number of times the surgeon performed the specific procedure divided by his/her total operative volume across all procedures).

RESULTS: For all four cardiovascular procedures and two out of four cancer resections, a surgeon's degree of specialization was a significant predictor of operative mortality independent of the number of times he or she performed that procedure: carotid endarterectomy (relative risk reduction between bottom and top quarter of surgeons 26%, 95% confidence interval 0%-46%); coronary artery bypass grafting (25%, 4% to 25%); valve replacement (46%, 17% to 53%); abdominal aortic aneurysm repair (45%, 25% to 53%); lung resection (28%, 5% to 46%); and cystectomy (41%, 8% to 61%). In five procedures (cardiovascular surgery, valve replacement, lung resection, cystectomy, and esophagectomy), the relative risk reduction from surgeon specialization was greater than that from surgeon volume for that specific procedure. Furthermore, surgeon specialization accounted for 9% (coronary artery bypass grafting) to 100% (cystectomy) of the relative risk reduction otherwise attributable to volume in that specific procedure.

CONCLUSION: For several common procedures, surgeon specialization was an important predictor of operative mortality independent of volume in that specific procedure. When selecting a surgeon, patients, referring physicians, and administrators assigning operative workload may want to consider a surgeon's procedure specific volume as well as the degree to which a surgeon specializes in that procedure.


BACKGROUND: Accreditation for bariatric surgery has been scrutinized recently for its impact on surgical outcomes. This study aimed to systematically examine the medical literature to examine the impact of bariatric surgery accreditation on surgical outcomes.

STUDY DESIGN: The PROSMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and checklist were used. The MEDLINE database was searched for the following terms (2000 through September 2014): gastric bypass or bariatric surgery or sleeve gastrectomy or vertical banded gastroplasty or laparoscopic duodenal switch or adjustable gastric band or weight loss surgery and accreditation or center of excellence or credentialing or national coverage decision or CMS or Medicare. Only studies in English and articles comparing accredited with non-accredited centers were included. Quality was assessed using the Newcastle-Ottawa scale for evaluation of all studies.

RESULTS: Thirteen studies were published in a very short time frame and covered >1.5 million patients. Ten of the 13 studies identified a substantial benefit of Center of Excellence accreditation for risk-adjusted outcomes. Six of the 8 studies reported a considerable reduction in mortality in patients operated on in Centers of Excellence, with odds ratios ranging from 2.26 to 3.57 for non-accredited centers. 2 studies showed no significant difference. Similarly, mortality was reduced in 8 of 11 studies, although more discreetly, with odds ratios ranging from 1.28 to 1.39. CONCLUSIONS: This study found that the preponderance of medical evidence supports accreditation for bariatric surgery.


The authors analyzed data from 52 randomized placebo-controlled trials (8,693 adults) testing acetaminophen, nonsteroidal antiinflammatory drugs, or selective cyclooxygenase-2 inhibitors given in conjunction with morphine after surgery. The median of the average 24-h morphine consumption in controls was 49 mg (range, 15-157 mg); it was significantly decreased with all regimens by 15-33%. There was evidence of a reduction in pain intensity at 24 h (1 cm on the 0-10 cm visual analog scale) only with nonsteroidal antiinflammatory drugs. Nonsteroidal antiinflammatory drugs also significantly reduced the incidence of nausea/vomiting from 28.8% to 22.0% (number needed to treat, 15) and of sedation from 15.4% to 12.7% (number needed to treat, 27) but increased the risk of severe bleeding from 0% to 1.7% (number needed to harm, 59). Selective cyclooxygenase-2 inhibitors increased the risk of renal failure in cardiac patients from 0% to 1.4% (number needed to harm, 73). A decrease in morphine consumption is not a good indicator of the usefulness of a supplemental analgesic. There is evidence that the combination of nonsteroidal antiinflammatory drugs with patient-controlled analgesia morphine offers some advantages over morphine alone.
BACKGROUND: Surgical site infections (SSIs) are wound infections that occur after invasive (surgical) procedures. Preventive bathing or showering with an antiseptic skin wash product is a well-accepted procedure for reducing skin bacteria (microflora). It is less clear whether reducing skin microflora leads to a lower incidence of surgical site infection. OBJECTIVES: To review the evidence for preoperative bathing or showering with antiseptics for preventing hospital-acquired (nosocomial) surgical site infections. SEARCH METHODS: For this update we searched the Cochrane Wounds Group Specialised Register (searched 18 December 2014); the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 14 2014); Medline (1950 to December Week 4 2014); Embase (In Process & Other Non-Indexed Citations December 18, 2014); Ovid EMASE (2012 to 2014 Week 51), EBSCO CINAHL (2012 to December 18 2014) and reference lists of articles. SELECTION CRITERIA: Randomised controlled trials comparing any antiseptic preparation used for preoperative full-body bathing or showering with an antiseptic skin wash product for reducing surgical site infections are eligible for inclusion. DATA COLLECTION AND ANALYSIS: Two review authors independently assessed studies for inclusion, risk of bias and extracted data. Study authors were contacted for additional information. MAIN RESULTS: We did not identify any new trials for inclusion in this fifth update. Seven trials involving a total of 10,157 surgical patients were included. Four of the included trials had three comparison groups. The antiseptic used in all trials was 4% chlorhexidine gluconate (Hibitane/Rohox). Three trials involving 7771 patients compared chlorhexidine with a placebo. Bathing with chlorhexidine compared with placebo did not result in a statistically significant reduction in SSIs; the relative risk of SSI (RR) was 0.91 (95% confidence interval (CI) 0.80 to 1.04). When only trials of high quality were included in this comparison, the RR of SSI was 0.95 (95% confidence interval (CI) 0.82 to 1.04). Three trials of 1443 participants compared bar soap with chlorhexidine, when combined there was no difference in the risk of SSIs (RR 1.02, 95% CI 0.97 to 1.08). Three trials of 1092 patients compared bathing with chlorhexidine with no washing, one large study found a statistically significant difference in favour of bathing with chlorhexidine (RR 0.36, 95% CI 0.27 to 0.49). The smaller studies found no difference between patients who washed with chlorhexidine and those who did not wash preoperatively. AUTHORS’ CONCLUSIONS: This review provides no clear evidence of benefit for preoperative bathing or bathing with chlorhexidine over other wash products, to reduce surgical site infection. Efforts to reduce the incidence of nosocomial surgical site infection should focus on interventions where effect has been demonstrated.
### Perioperative antibiotics

**Antifibrinolytic use for minimizing perioperative allogeneic blood transfusion.**


**BACKGROUND:** Concerns regarding the safety of transfused blood have led to the development of a range of interventions to minimize blood loss during major surgery. Antifibrinolytic drugs are widely used, particularly in cardiac surgery, and previous reviews have found them to be effective in reducing blood loss, the need for transfusion, and the need for re-operation due to continued or recurrent bleeding. In the last few years questions have been raised regarding the comparative performance of the drugs. The safety of the most popular agent, aprotinin, has been challenged, and it was withdrawn from world markets in May 2008 because of concern that it increased the risk of cardiovascular complications and death.

**OBJECTIVES:** To assess the comparative effects of the antifibrinolytic drugs aprotinin, tranexamic acid (TXA), and epsilon aminocaproic acid (EACA) on blood loss during surgery, the need for red blood cell (RBC) transfusion, and adverse events, particularly vascular occlusion, renal dysfunction, and death.

**SEARCH STRATEGY:** We searched the Cochrane Injuries Group’s Specialised Register (July 2010), Cochrane Central Register of Controlled Trials (The Cochrane Library 2010, Issue 3), MEDLINE (Ovid SP) (1950 to July 2010), EMBASE (Ovid SP) (1980 to July 2010). References in identified trials and review articles were checked and trial authors were contacted to identify any additional studies. The searches were last updated in July 2010. SELECTION CRITERIA: Randomised controlled trials (RCTs) of antifibrinolytic drugs in adults scheduled for non-urgent surgery. Eligible trials compared antifibrinolytic drugs with placebo (or no treatment), or with each other.

**DATA COLLECTION AND ANALYSIS:** Two authors independently assessed trial quality and extracted data. This version of the review includes a sensitivity analysis excluding trials authored by Prof. Joachim Boldt. MAIN RESULTS: This review summarises data from 252 RCTs that recruited over 25,000 participants. Data from the head-to-head trials suggest an advantage of aprotinin over the lysine analogues TXA and EACA in terms of reducing perioperative blood loss, but the differences were small. Compared to control, aprotinin reduced the probability of requiring RBC transfusion by a relative risk (RR) 0.66 (95% confidence interval [CI] 0.60 to 0.72). The RR for RBC transfusion with TXA was 0.61 (95% CI 0.51 to 0.71) and was 0.61 (95% CI 0.57 to 0.69) with EACA. When the pooled estimates from the head-to-head trials of the two lysine analogues were combined and compared to aprotinin alone, aprotinin appeared more effective in reducing the need for RBC transfusion (RR 0.35, 95% CI 0.26 to 0.46). Aprotinin reduced the need for re-operation due to bleeding by a relative risk (RR) 0.46, 95% CI 0.34 to 0.62. This translates into an absolute risk reduction of 2% and a number-needed-to-treat (NNT) of 50 (95% CI 33 to 100). A similar trend was seen with EACA (RR 0.32, 95% CI 0.11 to 0.99) but not TXA (RR 0.80, 95% CI 0.55 to 1.17). The blood transfusion absolute risk reduction of 2% and a number needed to treat of 50 for TXA and 33 for EACA. A similar trend was seen with EACA (RR 0.32, 95% CI 0.11 to 0.99) but not TXA (RR 0.80, 95% CI 0.55 to 1.17). The blood transfusion absolute risk reduction of 2% and a number needed to treat of 50 for TXA and 33 for EACA.

**CONCLUSION:** The ERAS protocol in the setting of bariatric surgery shortened hospital stay and was cost-effective. There was no increase in perioperative morbidity. REGISTRATION NUMBER: NCT01303809

**Authors’ conclusions:** "Aprotinin, although effective in reducing bleeding, had a higher rate of death than tranexamic acid and amicaproic acid, which appeared free of serious side-effects." **Study evaluates benefits and risks of different drugs to reduce surgical blood loss.**

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**National standard**

**CMS specifications for measures to prevent infection and venous thromboembolism.** "1" and "3" in this station relate to perioperative antibiotic use.

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### Glycemic Control

**Perioperative antibiotics; Enhanced Recovery After Surgery (ERAS)**


**BACKGROUND:** Optimized perioperative care within an enhanced recovery after surgery (ERAS) protocol is designed to reduce morbidity after surgery, resulting in a shorter hospital stay. The present study evaluated this approach in the context of sleeve gastrectomy for patients with morbid obesity.

**METHODS:** Patients were allocated to perioperative care according to a bariatric ERAS protocol or a control group that received standard care. These groups were also compared with a historical group of patients who underwent laparoscopic sleeve gastrectomy at the same institution between 2006 and 2012, selected using matched propensity scores.

**The primary outcome was median length of hospital stay. Secondary outcomes included readmission rates, postoperative morbidity, postoperative fatigue and mean cost per patient. RESULTS:** Of 116 patients included in the analysis, 78 were allocated to the ERAS (40) or control (38) group and there were 38 in the historical group. There were no differences in baseline characteristics between groups. Median hospital stay was significantly shorter in the ERAS group (1 day) than in the control (2 days, P < 0.001) and historical (3 days, P < 0.001) groups. It was also shorter in the control group than in the historical group (P = 0.010). There was no difference in readmission rates, postoperative complications or postoperative fatigue. The mean cost per patient was significantly higher in the historical group than in the ERAS (P = 0.010) and control (P = 0.018) groups. **CONCLUSION:** The ERAS protocol in the setting of bariatric surgery shortened hospital stay and was cost-effective. There was no increase in perioperative morbidity. REGISTRATION NUMBER: NCT01303809 (http://www.clinicaltrials.gov).
Goal-directed hemodynamic therapy


BACKGROUND: Complications from major surgery are undesirable, common, and potentially avoidable. The long-term consequences of short-term surgical complications have recently been recognized to have a profound influence on longevity and quality of life in survivors. In the past 30 years, there have been a number of studies conducted attempting to reduce surgical mortality and morbidity by deliberately and preemptively manipulating peroperative hemodynamics. Early studies had a high control-group mortality rate and were criticized for this as being unrepresentative of current practice and raised opposition to its implementation as routine care. We performed this review to update this body of literature and to examine the effect of changes in current practice and quality of care to see whether the conclusions from previous quantitative analyses of this field remain valid. METHODS: Randomized clinical trials evaluating the use of preemptive hemodynamic intervention to improve surgical outcome were identified using multiple methods. Electronic databases (MEDLINE, EMBASE, and the Cochrane Controlled Clinical Trials register) were screened for potential trials, reference lists of identified trials were examined, and additional sources were sought from experts and industry-representatives. Identified studies that fulfilled the entry criteria were examined in full and subjected to quantitative analysis, subgroup analysis, and sensitivity analysis where possible. RESULTS: There were 29 studies identified, 25 of which reported surgical complications. In total, the 29 trials involved 4805 patients with an overall mortality of 7.6%. The use of preemptive hemodynamic intervention significantly reduced mortality (pooled odds ratio [95% confidence interval] of 0.48 [0.33-0.78]; P < 0.0002) and surgical complications (odds ratio 0.43 [0.34-0.53]; P < 0.0001). Subgroup analysis showed significant reductions in mortality for studies using a pulmonary artery catheter, supranormal resuscitation targets, studies using cardiac index or oxygen delivery as goals, and the use of fluids and inotropes as opposed to fluids alone. By contrast, there was a significant reduction in mortality for each of the 4 subgroups analyzed. CONCLUSION: The use of a preemptive strategy of hemodynamic monitoring and coupled therapy reduces surgical mortality and morbidity.

Patients with limited cardiac reserve are less likely to survive and develop more complications following major surgery. By augmenting oxygen delivery index (DO2I) with a combination of intravenous fluids and inotropes (goal directed therapy (GDT)), postoperative mortality and morbidity of high-risk patients may be reduced. However, although most studies suggest that GDT may improve outcome in high-risk surgical patients, it is still not widely practiced. We set out to test the hypothesis that GDT results in greatest benefit in terms of mortality and morbidity in patients with the highest risk of mortality and have undertaken a systematic review of the current literature to see if this is correct. We performed a systematic search of Medline, Embase and CENTRAL databases for randomized controlled trials (RCTs) and reviews of GDT in surgical patients. To minimize heterogeneity we excluded studies involving cardiac, trauma, and paediatric surgery. Extremely high risk, high risk and intermediate risks of mortality were defined as >20%, 5 to 20% and <5% mortality rates in the control arm of the trials, respectively. Meta analyses were performed and Forest plots drawn using RevMan software. Data are presented as odd ratios (OR); 95% confidence intervals (CI), and P-values. A total of 32 RCTs including 2,808 patients were reviewed. All studies reported mortality. Five studies (including 300 patients) were excluded from assessment of complication rates as the number of patients with complications was not reported. The mortality benefit of GDT was confined to the extremely high-risk group (OR = 0.16; 95% CI 0.09 to 0.29; P = 0.0001). Complication rates were reduced in all subgroups (OR = 0.45; 95% CI 0.34 to 0.60; P = 0.00001). The morbidity benefit was greatest amongst patients in the extremely high-risk subgroup (OR = 0.27; 95% CI 0.15 to 0.51; P = 0.001), followed by the intermediate risk subgroup (OR = 0.43; 95% CI 0.27 to 0.67; P = 0.0002), and the high-risk subgroup (OR = 0.56; 95% CI 0.36 to 0.88; P = 0.02). Despite heterogeneity in trial quality and design, we found GDT to be beneficial in all high-risk patients undergoing major surgery. The mortality benefit of GDT was confined to the subgroup of patients at extremely high risk of death. The reduction of complication rates was seen across all subgroups of GDT patients.

Goal-directed hemodynamic therapy


BACKGROUND: Complications from major surgery are undesirable, common, and potentially avoidable. The long-term consequences of short-term surgical complications have recently been recognized to have a profound influence on longevity and quality of life in survivors. In the past 30 years, there have been a number of studies conducted attempting to reduce surgical mortality and morbidity by deliberately and preemptively manipulating peroperative hemodynamics. Early studies had a high control-group mortality rate and were criticized for this as being unrepresentative of current practice and raised opposition to its implementation as routine care. We performed this review to update this body of literature and to examine the effect of changes in current practice and quality of care to see whether the conclusions from previous quantitative analyses of this field remain valid. METHODS: Randomized clinical trials evaluating the use of preemptive hemodynamic intervention to improve surgical outcome were identified using multiple methods. Electronic databases (MEDLINE, EMBASE, and the Cochrane Controlled Clinical Trials register) were screened for potential trials, reference lists of identified trials were examined, and additional sources were sought from experts and industry-representatives. Identified studies that fulfilled the entry criteria were examined in full and subjected to quantitative analysis, subgroup analysis, and sensitivity analysis where possible. RESULTS: There were 29 studies identified, 25 of which reported surgical complications. In total, the 29 trials involved 4805 patients with an overall mortality of 7.6%. The use of preemptive hemodynamic intervention significantly reduced mortality (pooled odds ratio [95% confidence interval] of 0.48 [0.33-0.78]; P < 0.0002) and surgical complications (odds ratio 0.43 [0.34-0.53]; P < 0.0001). Subgroup analysis showed significant reductions in mortality for studies using a pulmonary artery catheter, supranormal resuscitation targets, studies using cardiac index or oxygen delivery as goals, and the use of fluids and inotropes as opposed to fluids alone. By contrast, there was a significant reduction in mortality for each of the 4 subgroups analyzed. CONCLUSION: The use of a preemptive strategy of hemodynamic monitoring and coupled therapy reduces surgical mortality and morbidity.
Perioperative Discharge Process

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The current understanding of prophylaxis of pulmonary complications in bariatric surgery is weak. Purpose: The aim of this study was to observe how changes in perioperative and postoperative treatments affect the incidence of pulmonary complications in bariatric patients. Materials: This is a retrospective clinical study of 400 consecutive bariatric patients. The patients, who either underwent a sleeve gastrectomy or a Roux-en-Y gastric bypass, were divided consecutively into four subgroups with different approaches to perioperative treatment. Methods: The first group (patients 0-100) was recovered in the intensive care unit with minimal mobilization (ICU). They had a urinary catheter and a drain. The second group (patients 101-200) was similar to the first group, but the patients used a continuous positive airway pressure (CPAP) device intermittently (ICU-CPAP). The third group (patients 201-300) was recovered on a normal ward without a urinary catheter or a drain and used a CPAP device (ward-slow). The fourth group (patients 301-400) walked to the operating theater and was mobilized in the recovery room during the first 2 h after the operation (ward-fast). CPAP was also used. Primary endpoints were pulmonary complications, pneumonia, and infection, non-urea descriptus (NURD). Results: The number of pulmonary complications among the groups was significantly different. A longer operation time increased the risk for infection (p < 0.001 95% CI from 2.02 to 6.59%). Conclusions: Operation time increases the risk for pulmonary complications. Changes in perioperative care toward the ERAS protocol may have a positive effect on the number of pulmonary complications.


Discharge Process


BACKGROUND: Emergency department visits and rehospitalization are common after hospital discharge. OBJECTIVE: To test the effects of an intervention designed to minimize hospital utilization after discharge. Design: Randomized trial using block randomization of 6 and 8. Randomly arranged index cards were placed in opaque envelopes labeled consecutively with study numbers, and participants were assigned a study group by revealing the index card. SETTING: General medical service at an urban, academic, safety-net hospital. PATIENTS: 749 English-speaking hospitalized adults (mean age, 50 years). INTERVENTION: A nurse discharge advocate worked with patients during their hospital stay to arrange follow-up appointments, confirm medication reconciliation, and conduct patient education with an individualized instruction booklet that was sent to their primary care provider. A clinical pharmacist called patients 2 to 4 days after discharge to reinforce the discharge plan and review medications. Participants and providers were not blinded to treatment assignment. MEASUREMENTS: Primary outcomes were emergency department visits and hospitalizations within 30 days of discharge. Secondary outcomes were self-reported preparedness for discharge and frequency of primary care providers’ follow-up within 30 days of discharge. Research staff doing follow-up were blinded to study group assignment. RESULTS: Participants in the intervention group (n = 370) had a lower rate of hospital utilization than those receiving usual care (n = 368) (0.314 vs. 0.451 visit per person per month; incidence rate ratio, 0.695 [95% CI, 0.515 to 0.937]; p = 0.009). The intervention was most effective among participants with hospital utilization in the 6 months before index admission (P < 0.05). Adverse events were not assessed; these data were collected but are still being analyzed. LIMITATIONS: This was a single-center study in which not all potentially eligible patients could be enrolled, and outcome assessment sometimes relied on participant report. CONCLUSION: A package of discharge services reduced hospital utilization within 30 days of discharge. FUNDING: Agency for Healthcare Research and Quality and National Heart, Lung, and Blood Institute, National Institutes of Health.

Discharge Process


OBJECTIVE: To test the effects of an intervention designed to minimize hospital utilization after discharge. BACKGROUND: Emergency department visits and rehospitalization are common after hospital discharge. The current understanding of prophylaxis of pulmonary complications in bariatric surgery is weak. PURPOSE: The aim of this study was to observe how changes in perioperative and postoperative treatments affect the incidence of pulmonary complications in bariatric patients. MATERIALS: This is a retrospective clinical study of 400 consecutive bariatric patients. The patients, who either underwent a sleeve gastrectomy or a Roux-en-Y gastric bypass, were divided consecutively into four subgroups with different approaches to perioperative treatment. METHODS: The first group (patients 0-100) was recovered in the intensive care unit with minimal mobilization (ICU). They had a urinary catheter and a drain. The second group (patients 101-200) was similar to the first group, but the patients used a continuous positive airway pressure (CPAP) device intermittently (ICU-CPAP). The third group (patients 201-300) was recovered on a normal ward without a urinary catheter or a drain and used a CPAP device (ward-slow). The fourth group (patients 301-400) walked to the operating theater and was mobilized in the recovery room during the first 2 h after the operation (ward-fast). CPAP was also used. Primary endpoints were pulmonary complications, pneumonia, and infection, non-urea descriptus (NURD). RESULTS: The number of pulmonary complications among the groups was significantly different. A longer operation time increased the risk for infection (p < 0.001 95% CI from 2.02 to 6.59%). Conclusions: Operation time increases the risk for pulmonary complications. Changes in perioperative care toward the ERAS protocol may have a positive effect on the number of pulmonary complications.

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Dr. Robert Bree Collaborative – Accountable Payment Models Workgroup
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