

| Ref #  | Cycle # | Topic    | Citation   | Grade<br>(see Grade tab below) | Fulltext or Citation Link   | Abstract   | Comments by Reviewer   |
|--|---------|----------|--|--------------------------------|---|--|--|
| <b>Cycle 1: Disability due to obesity despite conservative therapy</b> |         |          |  |                                |   |  |  |
| 1  | I / A   | Diabetes | Rubino F, Nathan DM, Eckel RH, Schauer PR, Alberti KG, Zimmet PZ, Del Prato S, Ji L, Sadikot SM, Herman WH, Amiel SA, Kaplan LM, Taroncher-Oldenburg 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 | Tier 2 Source                  | <a href="http://care.diabetesjournals.org/content/39/6/861">http://care.diabetesjournals.org/content/39/6/861</a> | 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/scholars (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 III obesity (BMI ≥40 kg/m(2)) and in those with class II obesity (BMI 35.0-39.9 kg/m(2)) when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. Surgery should also be considered for patients with T2D and BMI 30.0-34.9 kg/m(2) if hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. These BMI thresholds should be reduced by 2.5 kg/m(2) 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 antidiabetes 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. | Evidence-based consensus guideline on the role of bariatric/metabolic surgery in the management of type 2 diabetes.<br>→ Includes a systematic review supporting the efficacy of surgery over medical/lifestyle interventions for glycemic control and weight loss in selected individuals with type 2 diabetes and we assigned an evidence grade of 1/A for this specific point. Does not include other hard endpoints (e.g. mortality, diabetic complications) or long-term outcomes. Direct comparison of risks vs benefits is unclear. |
| 2  | I / A   | Diabetes | Cummings DE, Cohen RV. Bariatric/Metabolic Surgery to Treat Type 2 Diabetes in Patients With a BMI <35 kg/m2. Diabetes Care. 2016 Jun;39(6):924-33. PMID: 27222550   | Not Graded                     | Please contact your local library to obtain a copy of this citation.  | 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/m(2). 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 impels consideration of such operations as "metabolic surgery," which is used expressly to treat T2DM, including among patients with a BMI <35 kg/m(2) 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 for T2DM remission, glycemic control, and HbA1c lowering. Importantly, this is equally true for patients whose baseline BMI is below or above 35 kg/m(2). 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/m(2) 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/m(2). Further studies are needed to extend long-term findings and measure "hard" 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  | Cites several different SR/meta-analyses. Narrative review; not graded.<br>→ Included in evidence table as supporting documentation.   |

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| 3  | I / A         | Assess risk of morbidity and mortality related to obesity | Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ, Jordan HS, Kendall KA, Lux LJ, Mentor-Marcel R, Morgan LC, Trisolini MG, Wnek J, Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Selke FW, Shen WK, Smith SC Jr, Tomaselli GF; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; Obesity Society. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014 Jun 24;129(25 Suppl 2):S102-38. | Tier-2 Source | <a href="http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.e">http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.e</a>   |  | Evidence-based society guideline.<br>→ Applies to multiple components of Cycle 1.<br>→ BMI >= 30 increases risk of CHD, Stroke, and CVD<br>→ Elevated BMI increases risk of type 2 diabetes<br>→ Sex-specific analysis indicates that elevated BMI is associated with increased risk of all-cause mortality              |
| 4  | I / A         | Diagnosis   | National Institute for Health and Care Excellence. Obesity: identification, assessment and management. Clinical guideline CG189. 27 Nov 2014.  | Tier-1 Source | <a href="http://www.nice.org.uk/guidance/cg189">http://www.nice.org.uk/guidance/cg189</a>   | This well-regarded guideline provides a comprehensive review for the identification and management of obesity in adults. Includes clinical pathways and practice assessment tools.   | High quality resource<br>→ 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.                          |
| 5  | I / A         | Diagnosis; Asian population                               | Wen CP, David Cheng TY, Tsai SP, Chan HT, Hsu HL, Hsu CC, Eriksen MP. Are Asians at greater mortality risks for being overweight than Caucasians? Redefining obesity for Asians. Public Health Nutr. 2009 Apr;12(4):497-506. PMID: 18547457  | 2/B           | Please contact your local library to obtain a copy of this citation.  | OBJECTIVES: To assess whether overweight Asians, assessed on the basis of WHO criteria, are at greater mortality risk than overweight Caucasians, and to determine whether alternative cut-off points (BMI = 23.0-24.9 kg/m2 for overweight and BMI >or= 25.0 kg/m2 for obesity) suggested by the WHO Western Pacific Regional Office are appropriate. DESIGN: The cohort was followed prospectively until the end of 2001. All-cause and CVD mortality risks of the overweight and obese group, relative to the reference group (BMI = 18.5-24.9 or 18.5-22.9 kg/m2), were assessed using Cox regression analysis, adjusting for age, smoking and gender. Excess deaths were estimated with a method proposed by the US Centers for Disease Control and Prevention. SETTING: National Health Interview Survey (NHIS 2001) and a middle-aged perspective cohort in Taiwan. SUBJECTS: Subjects comprised 36 386 civil servants and school teachers, aged 40 years and older, who underwent a medical examination during 1989-1992. RESULTS: In the WHO-defined overweight group, Asians showed a significant increase in all-cause mortality risk compared with Caucasians. Asians showed risks equivalent to Caucasians' at lower BMI (around 5 units). Every unit of BMI increase, at 25.0 kg/m2 or above, was associated with a 9 % increase in relative mortality risk from all causes. Applying a cut-off point of 25.0 kg/m2 for obesity would result a prevalence of 27.1 %, while the traditional WHO cut-off point of 30.0 kg/m2 yielded obesity prevalence of 4.1 %. Excess deaths due to obesity accounted for 8.6 % of all deaths and 21.1 % of CVD deaths, based on the alternative cut-offs. CONCLUSIONS: In this Asian population, significant mortality risks started at BMI >or= 25.0 kg/m2, rather than at BMI >or= 30.0 kg/m2. The study supports the use of BMI >or= 25.0 kg/m2 as a new cut-off point for obesity and BMI = 23.0-24.9 kg/m2 for overweight. The magnitude of obesity-attributable deaths has been hitherto under-appreciated among Asians. | Retrospective cohort study of Taiwanese patients. Author conclusion: " In this Asian population, significant mortality risks started at BMI >or= 25.0 kg/m2, rather than at BMI >or= 30.0 kg/m2. "<br>→ Suggests a lower BMI cutoff may be appropriate for estimation of risk of mortality in patients of asian descent. |
| 6  | I / A / 1     | BMI calculator  | Body Mass Index (BMI) calculator. National Institutes of Health.   | Tier-1 Source | <a href="http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm">http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm</a>   |  | BMI calculator.  |
| 7  | I / A / 2     | Definition of comorbidities                               | Washington State Health Care Authority. Health Technology Assessment. Health Technology Clinical Committee final evidence report: Bariatric surgery. 10 April 2015.  | Tier-1 Source | <a href="http://www.hca.wa.gov/hta/Documents/bariatric_final_rpt_040315.pdf">http://www.hca.wa.gov/hta/Documents/bariatric_final_rpt_040315.pdf</a>   |  | Respected source that relates weight loss following bariatric surgery to improvement in comorbidities.<br>→ Comorbidities improved by bariatric surgery include: hypertension, type 2 diabetes, sleep apnea, and hyperlipidemia.   |
| 8  | I / A / 2 / a | Screening for diabetes                                    | American Diabetes Association. (2) Classification and diagnosis of diabetes. Diabetes Care. 2015 Jan;38 Suppl:S8-S16. PMID: 25537714   | Tier-2 Source | <a href="http://care.diabetesjournals.org/content/38/Supplement_1/S8.full.pdf+html">http://care.diabetesjournals.org/content/38/Supplement_1/S8.full.pdf+html</a>   |  | Professional society standards.<br>→ Table 1 provides criteria for the diagnosis of diabetes   |
| 9  | I / A / 2 / b | Screening for hypertension                                | Final Recommendation Statement: High Blood Pressure in Adults: Screening. U.S. Preventive Services Task Force. November 2015.  | Tier-1 Source | <a href="http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening">http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening</a>                       |  | High quality resource<br>→ National standard for screening for hypertension.   |
| 10 | I / A / 2 / c | Screening for dyslipidemia                                | U.S. Preventive Services Task Force. Lipid disorders in adults (cholesterol, dyslipidemia): screening. Release date: June 2008.  | Tier-1 Source | <a href="http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-adults-cholesterol-dyslipidemia-screening">http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-adults-cholesterol-dyslipidemia-screening</a> |  | This topic is in the process of being updated as of November 3, 2016   |

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| 11 | I / A / 2 / d | Screening for obstructive sleep apnea | Qaseem A, Dallas P, Owens DK, Starkey M, Holty JE, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2014 Aug 5;161(3):210-20. PMID: 25089864 | Tier-2 Source | <a href="http://annals.org/article.aspx?articleid=1892620">http://annals.org/article.aspx?articleid=1892620</a>   | 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 by 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).   | Evidence-based professional society guideline.<br>→ Recommends an approach for testing of patients suspected of having obstructive sleep apnea.  |
| 12 | I / A / 2 / d | Screening for obstructive sleep apnea | Sareli AE, Cantor CR, Williams NN, Korus G, Raper SE, Pien G, Hurley S, Maislin G, Schwab RJ. Obstructive sleep apnea in patients undergoing bariatric surgery--a tertiary center experience. Obes Surg. 2011 Mar;21(3):316-27. PMID: 19669842  | 2/B           | <a href="http://link.springer.com/article/10.1007%2Fs11695-009-9928-1">http://link.springer.com/article/10.1007%2Fs11695-009-9928-1</a>                       | 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 perioperative and postoperative 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 5 ≤ AHI ≤ 15, moderate apnea 15 < AHI ≤ 30, and severe apnea AHI > 30. RESULTS: The overall sample prevalence of OSA was 77.2%. Of these, 30.7% had mild OSA; 19.3% had moderate OSA, and 27.2% had severe OSA. Among men, the prevalence of OSA was 93.6% and 73.5% among women. The mean AHI (events per hour) for men with OSA was 49.2 ± 35.5 and 26.3 ± 28.3 for women with OSA. Separate logistic regression models were developed for the following three outcomes: AHI ≥ 5 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, 0.72, and 0.8, respectively. The negative predictive value for the presence of sleep apnea (AHI ≥ 5) was 75% 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 discriminative ability (evidenced by an AUC value of 0.8). However, the negative prediction 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 | Cohort study indicating high prevalence of obstructive sleep apnea in patients considered for bariatric surgery. Single-center.<br>→ Suggests all patients should be tested for obstructive sleep apnea prior to bariatric surgery.  |
| 13 | I / A / 2 / d | Screening for obstructive sleep apnea | Hwang D, Shakir N, Limann B, Sison C, Kalra S, Shulman L, Souza Ade C, Greenberg H. Association of sleep-disordered breathing with postoperative complications. Chest. 2008 May;133(5):1128-34. PMID: 18339794  | 2/B           | <a href="http://journal.publications.chestnet.org/article.aspx?articleid=1085863">http://journal.publications.chestnet.org/article.aspx?articleid=1085863</a> | 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% > or = 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 investigated 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% > or = 5 had a significantly higher rate of postoperative complications than those with ODI4% < 5 (15.3% vs 2.7%, respectively [p < 0.01]; adjusted odds ratio, 7.2; 95% confidence interval, 1.5 to 33.3 [p = 0.012]). The complication rate also increased with increasing ODI severity (patients with an ODI4% of 5 to 15 events per hour, 13.8%; patients with an ODI4% of > or = 15 events per hour, 17.5%; p = 0.01) 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% > or = 5, determined by home nocturnal oximetry, in patients with clinical features of OSA is associated with an increased rate of postoperative complications.  | Cohort study including patients with clinical symptoms or signs suggesting risk of obstructive sleep apnea. Authors' 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."<br>→ Suggests that patients with nocturnal oxygen desaturation have a higher rate of complications associated with surgery. |

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| 14 | I / A / 2 / d | Manage comorbidities; obstructive sleep apnea   | Winslow DH, Bowden CH, DiDonato KP, McCullough PA. A randomized, double-blind, placebo-controlled study of an oral, extended-release formulation of phentermine/topiramate for the treatment of obstructive sleep apnea in obese adults. <i>Sleep</i> . 2012 Nov 1;35(11):1529-39. PMID: 23115402 | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3466800/pdf/aasm.35.11.1529.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3466800/pdf/aasm.35.11.1529.pdf</a> | 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/m(2). 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 (-31.5 events/h, 95% CI: -40.0, -22.9) over placebo (-16.6 events/h, 95% CI: -25.0, -8.2) at Week 28 (P =0.0084). At Week 28, there was a 10.2% (95% CI: -12.7, -7.6; 10.8 kg, 95% CI: -13.5, -8.0) mean decrease in weight in the phentermine 15 mg plus extended-release topiramate 92 mg group compared with 4.3% (95% CI: -6.6, -2.0; 4.7 kg, 95% CI: -7.2, -2.2) in the placebo group (P = 0.0006) and a positive, significant (P = 0.0003) 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 induced 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. | High quality, double-blinded RCT with intention to treat analysis and greater than 80% followup: n=45. Treatment with study drug showed significant improvement in OSA correlating with weight loss when compared to controls.<br>→ Well done study limited by small n. Shows improvement in OSA with weight loss induced by medical treatment.  |
| 15 | I / A / 2 / d | Managing comorbidities; obstructive sleep apnea | Ravesloot MJ, Hilgevoord AA, van Wagenveld BA, de Vries N. Assessment of the effect of bariatric surgery on obstructive sleep apnea at two postoperative intervals. <i>Obes Surg</i> . 2014 Jan;24(1):22-31. PMID: 23856989   | 3/C | <a href="http://link.springer.com/article/10.1007%2Fs11695-013-1023-y">http://link.springer.com/article/10.1007%2Fs11695-013-1023-y</a>                               | 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/h. In 58.2 %, the AHI was reduced to below 10 and in 25.5 % to 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 17.4/h 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 disease and if necessary reinitiation of continuous positive airway pressure, which may lead to higher treatment compliance.  | 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.<br>→ Study of moderate quality supports the conclusion that bariatric surgery improves measures of sleep apnea.  |
| 16 | I / A / 2 / d | Managing comorbidities; obstructive sleep apnea | Sarkhosh K, Switzer NJ, El-Hadi M, Birch DW, Shi X, Karmali S. The impact of bariatric surgery on obstructive sleep apnea: a systematic review. <i>Obes Surg</i> . 2013 Mar;23(3):414-23. PMID: 23299507  | 2/B | <a href="http://link.springer.com/article/10.1007%2Fs11695-012-0862-2">http://link.springer.com/article/10.1007%2Fs11695-012-0862-2</a>                               | There is a strong relationship between obesity and the development of obstructive sleep apnea (OSA). Respectively, bariatric surgery is often touted as the most effective option for treating obesity and its comorbidities, including OSA. Nevertheless, there remains paucity of data in the literature of the comparison of all the specific types of bariatric surgery themselves. In an effort to answer this question, a systematic review was performed, to determine, of the available bariatric procedures [Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, or biliopancreatic diversion (BPD)], which procedures were the most efficacious in the treatment of OSA. A total of 69 studies with 13,900 patients were included. All the procedures achieved profound effects on OSA, as over 75 % of patients saw at least an improvement in their sleep apnea. 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.   | Systematic review of randomized controlled trials (3), controlled trials (11) and case series (55), including 13,900 patients. Authors concluded that "75 % of patients saw at least an improvement in their sleep apnea." Papers included patients treated with Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, or biliopancreatic diversion (BPD) procedures. Authors concluded that BPD was most successful procedure for treating OSA in obese patients. No comparison to medical treatment.<br>→ Lower quality study suggests that bariatric surgery is effective in treating sleep apnea in obese patients. |

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| 17 | I / A / 2 / d     | Managing comorbidities; obstructive sleep apnea | Dixon JB, Schachter LM, O'Brien PE, Jones K, Grima M, Lambert G, Brown W, Bailey M, Naughton MT. Surgical vs conventional therapy for weight loss treatment of obstructive sleep apnea: a randomized controlled trial. JAMA. 2012 Sep 19;308(11):1142-9. PMID: 22990273  | 2/B           | <a href="http://jama.jamanetwork.com/article.aspx?articleid=1360864">http://jama.jamanetwork.com/article.aspx?articleid=1360864</a>                           | 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 <55) 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 cardiopulmonary, neurological, vascular, gastrointestinal, or neoplastic disease were excluded. INTERVENTIONS: 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 27.8 kg (95% CI, 20.9 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 36.7 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, 9.3 [95% CI, 0.5 to 18.0]; P = .04). CONCLUSION: Among a group of obese patients with OSA, the 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: 12605000161628. | 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.<br>→ At two years, weight loss improved measures of sleep apnea (apnea hypopnea index) in patients treated for obesity surgically (27.8 kg weight loss) and non-surgically (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. |
| 18 | I / A / 2 / e / i | BMI and GERD                                    | Jacobson BC, Somers SC, Fuchs CS, Kelly CP, Camargo CA Jr. Body-mass index and symptoms of gastroesophageal reflux in women. N Engl J Med. 2006 Jun 1;354(22):2340-8. PMID: 16738270   | 2/B           | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782772/pdf/nihms148868.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782772/pdf/nihms148868.pdf</a> | 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) reported having symptoms at least once a week, and 3419 (55 percent of those who had any symptoms) described their symptoms as moderate in severity. We observed a dose-dependent relationship between increasing BMI and frequent reflux symptoms (multivariate P for trend <0.001). As compared with women who had a BMI of 20.0 to 22.4, the multivariate odds ratios for frequent symptoms were 0.67 (95 percent confidence interval, 0.48 to 0.93) for a BMI of less than 20.0, 1.38 (95 percent confidence interval, 1.13 to 1.67) for a BMI of 22.5 to 24.9, 2.20 (95 percent confidence interval, 1.81 to 2.66) for a BMI of 25.0 to 27.4, 2.43 (95 percent confidence interval, 1.96 to 3.01) for a BMI of 27.5 to 29.9, 2.92 (95 percent confidence interval, 2.35 to 3.62) for a BMI of 30.0 to 34.9, and 2.93 (95 percent confidence interval, 2.24 to 3.85) for a BMI of 35.0 or more. Even in women with a normal baseline BMI, an increase in BMI of more than 3.5, as compared with no weight changes, was associated with an increased risk of frequent symptoms of reflux (odds ratio, 2.80; 95 percent confidence interval, 1.63 to 4.82). CONCLUSIONS: BMI is associated with symptoms of gastroesophageal reflux disease in both normal-weight and overweight women. Even moderate weight gain among persons of normal weight may cause or exacerbate symptoms of reflux.   | A supplemental survey distributed to the Nurses Health Study cohort was used to correlate symptoms of GERD with BMI. Authors controlled for age; cigarette smoking; activity; caloric intake; alcohol, coffee, and tea; intake in drinks; chocolate; post-menopausal hormone therapy; antihypertensive and asthma medication; and diabetes. The study identified a dose-dependent relationship between increasing BMI and frequent reflux symptoms.<br>→ Confirms correlation between BMI and symptoms of GERD.   |
| 19 | I / A / 2 / e / v | Screening for non-alcoholic fatty liver disease | Chalasani N, Younossi Z, Lavine JE, Diehl AM, Brunt EM, Cusi K, Charlton M, Sanyal AJ; American Gastroenterological Association; American Association for the Study of Liver Diseases; American College of Gastroenterology. The diagnosis and management of non-alcoholic fatty liver disease: practice guideline by the American Gastroenterological Association, American Association for the Study of Liver Diseases, and American College of Gastroenterology. Gastroenterology. 2012 Jun;142(7):1592-609. PMID: 22656328 | Tier-2 Source | <a href="http://www.sciencedirect.com/science/article/pii/S0016508512004945">http://www.sciencedirect.com/science/article/pii/S0016508512004945</a>           | No abstract available   | Recommends 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."<br>→ Primary citation not available in this professional society guideline.  |
| 20 | I / A / 2 / e / v | Non-alcoholic fatty liver disease               | National Institute for Health and Care Excellence. Liver disease (non-alcoholic fatty [NAFLD]). Clinical guideline. July 2016  | Tier-1 Source | <a href="https://www.nice.org.uk/guidance/ng49">https://www.nice.org.uk/guidance/ng49</a>   | No abstract available   | High quality guideline<br>→ "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. "  |

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| 21 | 1 / A / 2 / e / v | Non-alcoholic steatohepatitis | Promrat K, Kleiner DE, Niemeier HM, Jackvony E, Kearns M, Wands JR, Fava JL, Wing RR. Randomized controlled trial testing the effects of weight loss on nonalcoholic steatohepatitis. Hepatology. 2010 Jan;51(1):121-9. PMID: 19827166                                    | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799538/pdf/nihms-150161.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799538/pdf/nihms-150161.pdf</a>   | Nonalcoholic 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 a 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/m(2)) with biopsy-proven NASH were randomized in a 2:1 ratio to receive intensive lifestyle intervention (LS) or structured education (control). After 48 weeks of intervention, participants assigned to LS lost an average of 9.3% of their weight versus 0.2% 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 = 0.03). NAS improved significantly in the LS group (from 4.4 to 2.0) in comparison with the control group (from 4.9 to 3.5) (P = 0.05). Percent weight reduction correlated significantly with improvement in NAS (r = 0.497, P = 0.007). Participants who achieved the study weight loss goal (>or=7%), compared with those who lost less than 7%, had significant improvements in steatosis (-1.36 versus -0.41, P < 0.001), lobular inflammation (-0.82 versus -0.24, P = 0.03), ballooning injury (-1.27 versus -0.53, P = 0.03) and NAS (-3.45 versus -1.18, P < 0.001).CONCLUSION: Weight reduction achieved through lifestyle intervention leads to improvements in liver histology in NASH.     | Blinded, randomized controlled trial of patients with NASH, randomized to lifestyle versus education interventions. Lifestyle group lost 9.7% of body weight in 48 weeks, on average, and had improved hepatic histology, compared to the control group that had 0.2% reduction of body weight.<br>→ Supports the conclusion that weight loss is associated with improvement of hepatic histology in patients with NASH.   |
| 22 | 1 / B / 1         | Assess motivation             | Cresci B., Castellini G., Pala L., Ravaldi C., Faravelli C., Rotella C.M., Ricca V. 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) | 2/B | <a href="https://www.researchgate.net/publication/46220700_Motivational_readiness_for_treatment_in_weight_control_programs_The_TREatment_MOTivation_and_REadiness_TRE-MORE_test">https://www.researchgate.net/publication/46220700_Motivational_readiness_for_treatment_in_weight_control_programs_The_TREatment_MOTivation_and_REadiness_TRE-MORE_test</a> | The degree of motivation 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). TREMORE 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.  | Prospective cohort study of patients treated with diet, exercise, and lifestyle interventions. Study developed an index of motivation to predict success in achieving >=5% weight loss over 6 months. Authors noted a high rate of psychological comorbidities, which was not different with or without successful weight loss during the study period.<br>→ Test has utility in assessing motivation related to weight loss. Over 30% drop out rate.  |
| 23 | 1 / B / 3         | Temperature control           | Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, Nathan DM; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002 Feb 7;346(6):393-403.         | 1/A | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1370926/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1370926/</a>   | 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 51 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 11.0, 7.8, 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; the lifestyle intervention was significantly more effective than metformin. To prevent one case of diabetes during a period of three years, 6.9 persons would have to participate 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. | Randomized controlled trial of 3234 patients with elevated risk of diabetes and average BMI of 34. Study included blinding and intention to treat analysis, with good follow up, and adequate statistical power. The lifestyle group achieved greater average maximum weight loss of 5.6 kg versus placebo (0.1 kg). Lifestyle intervention consisted of "a 16-lesson curriculum covering diet, exercise, and behavior modification [was] designed to help the participants achieve these goals. The curriculum, taught by case managers on a one-to-one basis during the first 24 weeks after enrollment, was flexible, culturally sensitive, and individualized. Subsequent individual sessions (usually monthly) and group sessions with the case managers were designed to reinforce the behavioral changes."<br>→ Supports the effectiveness of lifestyle changes in preventing type 2 diabetes in high risk patients.. Weight loss persisted for three years and was greater than placebo group, with maximum weight loss occurring within one year. |

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| 24 |               | Lifestyle interventions; Prevention of type-2 diabetes | Ali MK, Echouffo-Tcheugui J, Williamson DF. How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? Health Aff (Millwood). 2012 Jan;31(1):67-75. PMID: 22232096 | 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 assessment showed similar weight change. With every additional lifestyle session attended, weight loss increased by 0.26 percentage point. We conclude that costs associated with diabetes prevention can be lowered without sacrificing effectiveness, using nonmedical personnel and motivating higher attendance at program sessions.   | Systematic review and meta-analysis with some variation in quality of clinical trials, demonstrating persistent weight loss with lifestyle interventions delivered by health care professionals, lay community members, or electronic media assisted formats. Weight loss of 4% measured at twelve months. Weight loss correlated with the number of core sessions offered by individual programs; attrition was unrelated to duration of the program.<br>→ Supports use of extended lifestyle intervention programs to achieve weightloss that do not require medical professionals.   |
| 25 |               | Lifestyle interventions                                | Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. 1. Am J Prev Med. 2008 Oct;35(4):357-63. PMID: 18779029                       | 2/B           | <a href="https://www.clinicalkey.com/service/content/pdf/watermarked/1-s2.0-S0749379708006041.pdf?locale=en_US">https://www.clinicalkey.com/service/content/pdf/watermarked/1-s2.0-S0749379708006041.pdf?locale=en_US</a> | 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 110-199 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 nonwhite race (29% vs 7%). After 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<0.001; 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.  | Non-randomized study of 92 patients at risk for diabetes with BMI >= 24. The study had imperfect matching of control subjects. For the self-selected experimental group, the "core curriculum involved 16 classroom-style meetings focused on building knowledge and skills for goal setting, self-monitoring, and problem-solving. Program sessions lasted 60–90 minutes, and the entire core curriculum was delivered over 16–20 weeks." The control group received brief education and orientation to YMCA resources. "The 46 participants allocated to the intervention arm attended an average of 57% (76% x 75%) of the maximum possible core curriculum sessions." Weight loss was greater in the experimental group and sustained over twelve months. Baseline BMI was 32.0 for the intervention patients and 30.8 for control patients. At 4-6 month follow up, the intervention patients had a mean weight loss of 5.7 kg versus control patients 1.8 kg.<br>→ A program administered through the YMCA offers a community-based intervention for achieving weight loss for patients at risk of developing diabetes. |
| 26 | I / B / 4     | Manage comorbidities                                   | Section 1.3.2: NICE CG 189 (2014). Obesity: identification, assessment and management.  | Tier-1 Source | <a href="http://www.nice.org.uk/guidance/cg189">http://www.nice.org.uk/guidance/cg189</a>   |   | High quality guideline<br>→ Presents information on identification, assessment, and management of obesity.  |
| 27 | I / B / 4 / d | Screen for mental health conditions                    | Dawes AJ, Maggard-Gibbons M, Maher AR, Booth MJ, Miake-Lye I, Beroes JM, Shekelle PG. Mental Health Conditions Among Patients Seeking and Undergoing Bariatric Surgery: A Meta-analysis. JAMA. 2016 Jan 12;315(2):150-63.       | 2/B           | <a href="http://jama.jamanetwork.com/article.aspx?articleid=2481004">http://jama.jamanetwork.com/article.aspx?articleid=2481004</a>   | 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 68 publications meeting inclusion criteria: 59 reporting the prevalence of preoperative mental health conditions (65,363 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 (19% [95% CI, 14%-25%]) and binge eating disorder (17% [95% CI, 13%-21%]). 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; 8%-74% decrease) and the severity of depressive symptoms (6 studies; 40%-70% decrease). CONCLUSIONS AND RELEVANCE: 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. | High-quality meta analysis indicating high prevalence of depression and binge-eating disorders among patients seeking or receiving bariatric surgery. No clear relationship between preoperative mental health conditions and weight loss following surgery. Moderate quality of evidence that depression improves following surgery.<br>→ Suggests value for screening for mental health conditions among patients seeking or receiving bariatric surgery.   |

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| 28 | I / B / 4 / d | Depression screening; PHQ-2 | Corson K, Gerrity MS, Dobscha SK. Screening for depression and suicidality in a VA primary care setting: 2 items are better than 1 item. Am J Manag Care. 2004 Nov;10(11 Pt 2):839-45. PMID: 15609737  | 2/B           | <a href="http://www.ajmc.com/publications/issue/2004/2004-11-vol10-n11Pt2/Nov04-1949p839-845/">http://www.ajmc.com/publications/issue/2004/2004-11-vol10-n11Pt2/Nov04-1949p839-845/</a> | 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 these 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 1211 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. Patients whose responses suggested potential suicidality were administered 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 (88%) but less sensitive (78%). A PHQ-2 score of > or =3 demonstrated similar specificity (91%) with high sensitivity (97%). For case finding, the PHQ-8 was similar to the PHQ-9. Approximately 20% of patients screened positive for moderate depression, 7% reported thoughts of death or suicide, 2% 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. | The cohort is VA primary care patients who self-selected 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. |
| 29 | I / B / 4 / e | Diabetes management         | NICE 2008 Guidance - Recommendation 76. National Institute for Health and Care Excellence (NICE). Type 2 Diabetes: national clinical guideline for management in primary and secondary care (update). CG66. 2008; updated July 2014.   | Tier 1 Source | <a href="http://www.nice.org.uk/guidance/cg87/resources/cg66-type-2-diabetes-full-guideline2">http://www.nice.org.uk/guidance/cg87/resources/cg66-type-2-diabetes-full-guideline2</a>   |  | High quality source<br>→ Outlines management recommendations for Type-2 diabetes.   |
| 30 | I / B / 4 / k | Smoking cessation           | Quao Q, Tervahauta M, Nissinen A, Tuomilehto J. Mortality from all causes and from coronary heart disease related to smoking and changes in smoking during a 35-year follow-up of middle-aged Finnish men. Eur Heart J, 2000 Oct; 21(19): 1621-6. PMID: 10988015   | 2 / B         | <a href="http://eurheartj.oxfordjournals.org/content/ehj/21/19/1621.full.pdf">http://eurheartj.oxfordjournals.org/content/ehj/21/19/1621.full.pdf</a>                                   | Abstract: AIMS: The risk of early and late death in relation to smoking and ex-smoking were studied. METHODS AND RESULTS: A cohort of 1711 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 0.93-1.36) in former smokers compared with non-smokers. The hazards ratios for 35-year coronary heart disease mortality were 1.63 (CI 1.24-2.13) 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.   | Prospective cohort study of Finnish males with good follow-up over 35 years. Uncontrolled for all variables except smoking. Increased risk of death due to coronary artery disease for patients who continued to smoke. Men who persisted in quitting smoking reduced risk to level of non-smokers. → Supports discontinuation of smoking as a means for reducing death due to coronary disease.  |
| 31 | I / C / 1     | Drug treatment              | Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342-62. doi: 10.1210/jc.2014-3415. Epub 2015 Jan 15. PMID: 25590212 | Tier-2 Source | <a href="http://press.endocrine.org/doi/pdf/10.1210/jc.2014-3415">http://press.endocrine.org/doi/pdf/10.1210/jc.2014-3415</a>   | 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 with favorable weight profiles, can aid in the prevention and management of obesity and thus improve health.  | Professional society guideline.<br>→ Outlines use of medications in the management of obesity.  |

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| 32 | I / C / 1 | Drug treatment; orlistat | Richelsen B, Tonstad S, Rössner S, Toubro S, Niskanen L, Madsbad S, Mustajoki P, Rissanen A. 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. <i>Diabetes Care</i> . 2007 Jan;30(1):27-32. PMID: 17192328 | 2/B | <a href="http://care.diabetesjournals.org/content/30/1/27.long">http://care.diabetesjournals.org/content/30/1/27.long</a>                           | 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-treated 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/m <sup>2</sup> (range 30.0-45.2). Those who lost > or = 5% of their body weight (309 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 3 years was lower with orlistat than with placebo (4.6 +/- 8.6 vs. 7.0 +/- 7.1 kg; P < 0.02). The number of participants who achieved > or =5% weight loss also favored orlistat (67 vs. 56%; P = 0.037). 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 incidences 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 = 0.041). 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.   | Blinded, randomized controlled trial of 309 obese patients with >= 5% weight loss following 8 week very-low energy diet, then randomized into lifestyle plus orlistat versus lifestyle plus placebo. Drop out rate was 33.3% for the orlistat group and 37.2% for the placebo group during 3 year follow-up period. The lifestyle plus orlistat group maintained 2.4 kg more weight loss at end of 3 years.<br>→ Suggest the addition of orlistat to lifestyle management improves long-term weight loss maintenance. |
| 33 | I / C / 1 | Drug treatment; orlistat | Sjöström L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HP, Krempf M. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. European Multicentre Orlistat Study Group. <i>Lancet</i> . 1998 Jul 18;352(9123):167-72. PMID: 9683204                                 | 2/B | <a href="http://www.sciencedirect.com/science/article/pii/S0140673697115094">http://www.sciencedirect.com/science/article/pii/S0140673697115094</a> | 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/m <sup>2</sup> ), recruited at 15 European centres, entered a 4-week, single-blind, placebo lead-in period on a slightly hypocaloric diet (600 kcal/day deficit). 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% [10.3 kg] vs 6.1% [6.1 kg]; LSM difference 3.9 kg [p<0.001] from randomisation 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 0.9 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 (LDL) cholesterol, LDL/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.   | Double-blind, randomized controlled trial of overweight and obese patients with intention to treat analysis and borderline 80% follow-up (through year 1; lower at year 2 due to withdrawals). Orlistat plus diet produced more weight loss than placebo plus diet over a two year period.<br>→ Indicates orlistat plus diet is more effective for weight loss than diet alone.   |
| 34 | I / C / 1 | Drug treatment; orlistat | Anderson JW, Schwartz SM, Hauptman J, Boldrin M, Rossi M, Bansal V, Hale CA. Low-dose orlistat effects on body weight of mildly to moderately overweight individuals: a 16 week, double-blind, placebo-controlled trial. <i>Ann Pharmacother</i> . 2006 Oct;40(10):1717-23.   | 2/B | Please contact your local library to obtain a copy of this citation.  | 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 3 times daily, for weight loss in mildly to moderately overweight individuals. METHODS: A multicenter, 16 week, randomized, double-blind, placebo-controlled study was conducted in 391 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 from baseline to week 16 was significantly greater in participants receiving orlistat versus those receiving placebo (3.05 vs 1.90 kg; p < 0.001, intent-to-treat analysis). Orlistat-treated subjects who completed 16 weeks of treatment lost 4.8 +/- 0.35% (mean +/- SE) 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 -0.6%; p = 0.005) and both diastolic (-3.9% vs -0.5%; p = 0.001) and systolic blood pressure (-4.7% vs -1.8%; p = 0.004). 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. | 16 week, double-blind, randomized, placebo-controlled trial of orlistat versus placebo on weight loss and metabolic measures in mild to moderate overweight individuals. Lifestyle interventions not standardized in experimental or control groups. 25% dropout rate.<br>→ Suggest benefit of orlistat in mild to moderately overweight individuals  |

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| 35 | I / C / 1     | Drug treatment; phentermine plus topiramate         | Gadde KM, Allison DB, Ryan DH, Peterson CA, Troupin B, Schwiers ML, Day WW. Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial. Lancet. 2011 Apr 16;377(9774):1341-52. PMID: 21481449 | 2/B           | <a href="http://search.proquest.com/docview/862551699/fulltextPDF/54333C1DC13848AAPQ/1?accountid=42115">http://search.proquest.com/docview/862551699/fulltextPDF/54333C1DC13848AAPQ/1?accountid=42115</a> | BACKGROUND: Obesity is associated with a reduction in life expectancy and an increase in mortality from cardiovascular diseases, cancer, and other causes. We therefore assessed the efficacy and safety of two doses of phentermine plus topiramate controlled-release combination as an adjunct to diet and lifestyle modification for weight loss and metabolic risk reduction in individuals who were overweight and obese, with two or more risk factors. METHODS: In this 56-week phase 3 trial, we randomly assigned overweight or obese adults (aged 18-70 years), with a body-mass index of 27-45 kg/m(2) and two or more comorbidities (hypertension, dyslipidaemia, diabetes or prediabetes, or abdominal obesity) to placebo, once-daily phentermine 7.5 mg plus topiramate 46.0 mg, or once-daily phentermine 15.0 mg plus topiramate 92.0 mg in a 2:1:2 ratio in 93 centres 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. Analysis was by intention to treat. This study is registered with Clinical Trials.gov, number NCT00553787. FINDINGS: Of 2487 patients, 994 were assigned to placebo, 498 to phentermine 7.5 mg plus topiramate 46.0 mg, and 995 to phentermine 15.0 mg plus topiramate 92.0 mg; 979, 488, and 981 patients, respectively, were analysed. 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<0.0001), and -10.2 kg (-9.8%, -10.4 to -9.3; p<0.0001) in the patients assigned to placebo, phentermine 7.5 mg plus topiramate 46.0 mg, and phentermine 15.0 mg plus topiramate 92.0 mg, respectively. 204 (21%) patients achieved at least 5% weight loss with placebo, 303 (62%; odds ratio 6.3, 95% CI 4.9 to 8.0; p<0.0001) with phentermine 7.5 mg plus topiramate 46.0 mg, and 687 (70%; 9.0, 7.3 to 11.1; p<0.0001) with phentermine 15.0 mg plus topiramate 92.0 mg; for ≥10% weight loss, the corresponding numbers were 72 (7%), 182 (37%; 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 (24 [2%], 67 [13%], and 207 [21%] in the groups assigned to placebo, phentermine 7.5 mg plus topiramate 46.0 mg, and phentermine 15.0 mg plus topiramate 92.0 mg, respectively), paraesthesia (20 [2%], 68 [14%], and 204 [21%], respectively), constipation (59 [6%], 75 [15%], and 173 [17%], respectively), insomnia (47 [5%], 29 [6%], and 102 [10%], respectively), dizziness (31 [3%], 36 [7%], 99 [10%], respectively), and dysgeusia (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 17 (2%) to phentermine 15.0 mg plus topiramate 92.0 mg were discontinued because of adverse events. | Double-blind, randomized controlled trial with adequate statistical power with less than 80% included in end point analysis. Cohort included overweight and obese patients with at least two co-morbidities. Patients treated with phentermine plus topiramate had greater weight loss than those treated with placebo plus instructions to follow a self-directed reduced-calorie diet and lifestyle management program. Selected measures associated with co-morbidities improved with drug therapy; higher drug doses resulted in greater improvement in weight and other outcomes.<br>→ Suggests that in patients instructed in self-directed life-style and diet, treatment with phentermine plus topiramate is more effective for weight loss than placebo.  |
| 36 | I / C / 4 / b | Review of treatment options; Shared decision making | Section 1.2.11: NICE CG189 (2014).   | Tier-1 Source | <a href="http://www.nice.org.uk/guidance/cg189">http://www.nice.org.uk/guidance/cg189</a>   | Guide to discussion of treatment options based on BMI, waist circumference, and comorbidities.  | High quality guideline<br>→ Defines four treatment tracks to discuss with patients, based on BMI, waist circumference, and comorbidities.  |
| 37 |               | Indications for surgery; Asian population           | Kasama K, Mui W, Lee WJ, Lakdawala M, Naitoh T, Seki Y, Sasaki A, Wakabayashi G, Sasaki I, Kawamura I, Kow L, Frydenberg H, Chen A, Narwaria M, Chowbey P. IFSO-APC consensus statements 2011. Obes Surg. 2012 May;22(5):677-84. PMID: 22367008  | 3/C           | <a href="http://link.springer.com/article/10.1007%2Fs11695-012-0610-7">http://link.springer.com/article/10.1007%2Fs11695-012-0610-7</a>   | Associations of BMI with body composition and health outcomes may differ between Asian and European populations. Asian populations have also been shown to have an elevated risk of type 2 diabetes, hypertension, and hyperlipidemia at a relatively low level of BMI. New surgical indication for Asian patients should be discussed by the expert of this field. Forty-four bariatric experts in Asia-Pacific and other regions were chosen to have a voting privilege for IFSO-APC Consensus at the 2nd IFSO-APC Congress. A computerized audience-response voting system was used to analyze the agreement with the sentence of the consensus. Of all delegates, 95% agreed with the necessity of the establishment of IFSO-APC consensus statements, and 98% agreed with the necessity of a new indication for Asian patients. IFSO-APC Consensus statements 2011. Bariatric surgery should be considered for the treatment of obesity for acceptable Asian candidates with BMI ≥ 35 with or without co-morbidities. Bariatric/GI metabolic surgery should be considered for the treatment of T2DM or metabolic syndrome for patients who are inadequately controlled by lifestyle alternations and medical treatment for acceptable Asian candidates with BMI ≥ 30. The surgical approach may be considered as a non-primary alternative to treat inadequately controlled T2DM, or metabolic syndrome, for suitable Asian candidates with BMI ≥ 27.5. Other eight sentences are agreed with by majority of the voting delegates to form IFSO-APC consensus statements. This will help to make safe and wholesome the progress of bariatric and metabolic surgery in Asia.  | Consensus statement regarding surgical treatment of obesity in Asians:<br>(1) Bariatric surgery should be considered for the treatment of obesity for acceptable Asian candidates with BMI≥35 with or without co-morbidities;<br>(2) Bariatric/GI metabolic surgery should be considered for the treatment of T2DM or metabolic syndrome for patients who are inadequately controlled by lifestyle alternations and medical treatment for acceptable Asian candidates with BMI≥30;<br>(3) The surgical approach may be considered as a nonprimary alternative to treat inadequately controlled T2DM, or metabolic syndrome, for suitable Asian candidates with BMI≥27.5.<br>→ Suggests that indications for bariatric surgery may be different for patients of Asian descent. This recommendation differs from the Health Technology Assessment Program's limitations of coverage. |

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| 38                                  |           | Asian population; Diabetes  | Shai I, Jiang R, Manson JE, Stampfer MJ, Willett WC, Colditz GA, Hu FB. Ethnicity, obesity, and risk of type 2 diabetes in women: a 20-year follow-up study. Diabetes Care. 2006 Jul;29(7):1585-90. PMID: 16801583  | 2/B                   | <a href="http://care.diabetesjournals.org/content/29/7/1585.full.pdf+html">http://care.diabetesjournals.org/content/29/7/1585.full.pdf+html</a>   | OBJECTIVE: To examine ethnic differences in risk of type 2 diabetes, taking dietary and lifestyle risk factors into account. RESEARCH DESIGN AND METHODS: A prospective (1980-2000) cohort (from The Nurses' Health Study) including 78,419 apparently healthy women (75,584 whites, 801 Asians, 613 Hispanics, and 1,421 blacks) was studied. Detailed dietary and lifestyle information for each participant was repeatedly collected every 4 years. Compared with whites, the age-adjusted relative risks (RRs) were 1.43 (95% CI 1.08-1.90) for Asians, 1.76 (1.32-2.34) for Hispanics, and 2.18 (1.82-2.61) for blacks. After adjustment for BMI, the RRs changed to 2.26 (1.70-2.99) for Asians, 1.86 (1.40-2.47) for Hispanics, and 1.34 (1.12-1.61) for blacks. For each 5-unit increment in BMI, the multivariate RR of diabetes was 2.36 (1.83-3.04) for Asians, 2.21 (1.75-2.79) for Hispanics, 1.96 (1.93-2.00) for whites, and 1.55 (1.36-1.77) for blacks (P for interaction <0.001). For each 5-kg weight gain between age 18 and the year 1980, the risk of diabetes was increased by 84% (95% CI 58-114) for Asians, 44% (26-63) for Hispanics, 38% (28-49) for blacks, and 37% (35-38%) for whites. A healthy diet high in cereal fiber and polyunsaturated fat and low in trans fat and glycemic load was more strongly associated with a lower risk of diabetes among minorities (RR 0.54 [95% CI 0.39-0.73]) than among whites (0.77 [0.72-0.84]). CONCLUSIONS: The risk of diabetes is significantly higher among Asians, Hispanics, and blacks than among whites before and after taking into account differences in BMI. Weight gain is particularly detrimental for Asians. Our data suggest that the inverse association of a healthy diet with diabetes is stronger for minorities than for whites. | Prospective cohort study from the Nurses' Health Study. Author conclusion: "For each 5-kg weight gain between age 18 and the year 1980, the risk of diabetes was increased by 84% (95% CI 58-114) for Asians, 44% (26-63) for Hispanics, 38% (28-49) for blacks, and 37% (35-38%) for whites."<br>→ Study supports the conclusion that Asian patients are particularly susceptible to diabetes with weight gain.  |  |
| 39                                  |           | Outcomes of surgical versus non-surgical treatment for obesity          | Sjöström L, Narbro K, Sjöström CD, Karason K, Larsson B, Wedel H, Lystig T, Sullivan M, Bouchard C, Carlsson B, Bengtsson C, Dahlgren S, Gummesson A, Jacobson P, Karlsson J, Lindroos AK, Lönnroth H, Näslund I, Olbers T, Stenlöf K, Torgerson J, Agren G, Carlsson LM; Swedish Obese Subjects Study. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med. 2007 Aug 23;357(8):741-52. | 2/B                   | <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMoa066254">http://www.nejm.org/doi/pdf/10.1056/NEJMoa066254</a>   | BACKGROUND: Obesity is associated with increased mortality. Weight loss improves cardiovascular risk factors, but no prospective interventional studies have reported whether weight loss decreases overall mortality. In fact, many observational studies suggest that weight reduction is associated with increased mortality. METHODS: The prospective, controlled Swedish Obese Subjects study involved 4047 obese subjects. Of these subjects, 2010 underwent bariatric surgery (surgery group) and 2037 received conventional treatment (matched control group). We report on overall mortality during an average of 10.9 years of follow-up. At the time of the analysis (November 1, 2005), vital status was known for all but three subjects (follow-up rate, 99.9%). RESULTS: The average weight change in control subjects was less than +/-2% during the period of up to 15 years during which weights were recorded. Maximum weight losses in the surgical subgroups were observed after 1 to 2 years: gastric bypass, 32%; vertical-banded gastroplasty, 25%; and banding, 20%. After 10 years, the weight losses from baseline were stabilized at 25%, 16%, and 14%, respectively. There were 129 deaths in the control group and 101 deaths in the surgery group. The unadjusted overall hazard ratio was 0.76 in the surgery group (P=0.04), as compared with the control group, and the hazard ratio adjusted for sex, age, and risk factors was 0.71 (P=0.01). The most common causes of death were myocardial infarction (control group, 25 subjects; surgery group, 13 subjects) and cancer (control group, 47; surgery group, 29). CONCLUSIONS: Bariatric surgery for severe obesity is associated with long-term weight loss and decreased overall mortality.   | Matched cohort of Swedish patients selecting surgical or non-surgical treatment of obesity. Inclusion BMI was 34 for men and 38 for women. Follow-up: In the surgery group, participation rates of subjects at follow-up examination at 2, 10, and 15 years were 94%, 84%, and 66%, respectively. Corresponding examination rates among subjects in the control group were 83%, 75%, and 87%. Deaths were greater in the non-surgical control group at 10.9 years. Weight loss in controls was +/- 2% at 15 years. Weight loss in the surgical group was 14-25% at 10 years, depending on procedure.<br>→ Demonstrates that patients undergoing bariatric surgery compared to patients undergoing non-surgical therapy, have lower death rate and increased weight loss at ten years. |  |
| 40                                  | I / D / 2 | CMS standards for bariatric surgery                                     | CMS. Medicare. National coverage determination (NCD) for bariatric surgery for treatment of morbid obesity (100.1). Publication Number 100-3, Manual Section Number 100.1. Effective date 2/12/2009.  | National CMS standard | <a href="https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&amp;bc=AgAAgAAAAAAA&amp;nclver=3">https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&amp;bc=AgAAgAAAAAAA&amp;nclver=3</a> | Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have 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).  | Medicare coverage standards<br>→ Coverage requires unsuccessful results with unspecified medical treatment of unspecified duration. Coverage is dependent upon facilities being certified.  |  |
| 41                                  | I / D / 2 | Appropriateness standards; prerequisite of weight loss prior to surgery | Kim JJ, Rogers AM, Ballem N, Schirmer B; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. ASBMS updated position statement on insurance mandated preoperative weight loss requirements. Surg Obes Relat Dis. 2016 Jun;12(5):955-9. PMID: 27523728  | Tier-2 Source         | Please contact your local library to obtain a copy of this citation.  | "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 risk or assess patient adherence to programmatic requirements."  | Professional society statement supported by literature review.<br>→ 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.   |  |
| <b>Cycle 2: Fitness for Surgery</b> |           |   |   |                       |   |  |   |  |
| 42                                  | II        | Indications for bariatric surgery                                       | Washington State Health Care Authority. Health Technology Assessment. Health Technology Clinical Committee draft findings and decision: Bariatric surgery. 10 July 2015.  | Tier-1 Source         | <a href="http://hca.wa.gov/assets/program/bariatric_final_findings_decision_071015[1].pdf">http://hca.wa.gov/assets/program/bariatric_final_findings_decision_071015[1].pdf</a>   |  | High quality source<br>→ Recommendations of HTAP for insurance coverage for overweight and obesity.   |  |
| 43                                  | II        | Indications for bariatric surgery                                       | Washington State Health Care Authority. Health Technology Assessment. Health Technology Clinical Committee final evidence report: Bariatric surgery. 10 April 2015.   | Tier-1 Source         | <a href="http://hca.wa.gov/assets/program/bariatric_final_rpt_040315[1].pdf">http://hca.wa.gov/assets/program/bariatric_final_rpt_040315[1].pdf</a>   |  | High quality source<br>→ Medical evidence report supporting the above citation  |  |
| 44                                  | II        | Indications for bariatric surgery                                       | Regence. Medical Policy Manual: policy number 58: Bariatric surgery. [effective date] 1 June 2016.  | Tier-1 Source         | <a href="http://blue.regence.com/trgmedpol/surgery/sur58.pdf">http://blue.regence.com/trgmedpol/surgery/sur58.pdf</a>   |  | High quality source<br>→ Medical policy coverage determination from health plan   |  |

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| 45 | II / A / 1 | Diabetes management       | Dronge AS, Perkal MF, Kancir S, Concato J, Aslan M, Rosenthal RA. Long-term glycemic control and postoperative infectious complications. Arch Surg. 2006 Apr; 141(4): 375-80; discussion 380. PMID: 16618895  | 2/B           | <a href="http://archsurg.jamanetwork.com/article.aspx?articleid=398289">http://archsurg.jamanetwork.com/article.aspx?articleid=398289</a>   | Abstract: HYPOTHESIS: Good preoperative glycemic control (hemoglobin A(1c) [HbA(1c)] 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 HbA(1c) 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. Bivariate 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, elective vs emergent procedure, wound classification, operation length, and HbA(1c) levels) with outcome. Factors significant at P<.05 were used in a multivariable logistic regression model. RESULTS: In the multivariable model, age, American Society of Anesthesiologists class, operation length, wound class, and HbA(1c) levels were significantly associated with postoperative infections. Emergency/urgent cases and dependence in Activities of Daily Living were significant in bivariate analysis but failed to reach statistical significance in the multivariable model. An HbA(1c) level of less than 7% was significantly associated with decreased 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 (HbA(1c) 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.<br>→ Supports improved preoperative diabetes control to reduce postoperative infectious complications.   |
| 46 | II / A / 1 | Diabetes management       | NICE 2008 Guidance - Recommendation 76. National Institute for Health and Care Excellence (NICE). Type 2 Diabetes: national clinical guideline for management in primary and secondary care (update). CG66. 2008; updated July 2014.  | Tier 1 Source | <a href="http://www.nice.org.uk/guidance/cg87/resources/cg66-type-2-diabetes-full-guideline2">http://www.nice.org.uk/guidance/cg87/resources/cg66-type-2-diabetes-full-guideline2</a> |   | High quality source<br>→ Outlines management recommendations for Type-2 diabetes.   |
| 47 | II / A / 2 | Nutritional status        | van Stijn MF, Korkic-Halilovic I, Bakker MS, van der Ploeg T, van Leeuwen PA, Houjijk AP. Preoperative nutrition status and postoperative outcome in elderly general surgery patients: a systematic review. JPEN: Journal of Parenteral & Enteral Nutrition, 2013 Jan; 37(1): 37-43. PMID: 22549764 | 2/B           | <a href="http://pen.sagepub.com/content/37/1/37.full.pdf+html">http://pen.sagepub.com/content/37/1/37.full.pdf+html</a>   | 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 nutrition 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 assessment, postoperative outcome, and surgery (hip or general), including their synonyms and MeSH terms. Limits used in the search were human studies, published in English, and age (65 years or older). Articles were screened using inclusion and exclusion criteria. All selected articles were checked on 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 in the previous 6 months. CONCLUSIONS: 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.  | Focus is pre-operative nutritional state as a risk factor for complications for patients 65 years of age or older.<br>→ Supports conclusion that reduced serum albumin and weight loss over previous six months predicts postoperative complications for elderly general surgery patients.  |
| 48 | II / A / 3 | Liver function; Cirrhosis | Jan A, Narwaria M, Mahawar KK. A Systematic Review of Bariatric Surgery in Patients with Liver Cirrhosis. Obes Surg. 2015 Aug;25(8):1518-26. PMID: 25982807   | 2/B           | <a href="http://link.springer.com/article/10.1007%2Fs11695-015-1727-2">http://link.springer.com/article/10.1007%2Fs11695-015-1727-2</a>   | Nonalcoholic steatohepatitis is becoming a common cause of liver cirrhosis and a significant number of patients undergoing bariatric surgery suffer with it. There is 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 higher 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 20% mortality rate following biliopancreatic diversion.<br>→ Small numbers of patients make interpretation of this data difficult. |

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| 49 | II / A / 3 | Liver function; Cirrhosis | Suman A, Barnes DS, Zein NN, Levinthal GN, Connor JT, Carey WD. Predicting outcome after cardiac surgery in patients with cirrhosis: a comparison of Child-Pugh and MELD scores. Clin Gastroenterol Hepatol. 2004 Aug;2(8):719-23. PMID: 15290666        | 2/B           | Please contact your local library to obtain a copy of this citation.  | BACKGROUND & AIMS: This study aims to quantify the risk of cardiac surgery in patients with cirrhosis. METHODS: Records of all adult patients with cirrhosis 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 Model for End-Stage Liver Disease (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 (16 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 86% 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 >=8 have a significant risk for mortality. | Retrospective 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 86% 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."<br>→ Elevated Child-Pugh Score is associated post-operative mortality in patients with cirrhosis undergoing cardiac surgery.<br>Child-Pugh Score includes total bilirubin, serum albumin, PT INR, ascites, and hepatic encephalopathy. |
| 50 | II / A / 4 | Opioids                   | Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain - United States 2016. 18 March 2016.  | Tier-1 Source | <a href="http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm">http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm</a>   | 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 Grading 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 prescribing opioids for chronic pain ( <a href="http://stacks.cdc.gov/view/cdc/38025">http://stacks.cdc.gov/view/cdc/38025</a> ) as well as a website ( <a href="http://www.cdc.gov/drugoverdose/prescribingresources.html">http://www.cdc.gov/drugoverdose/prescribingresources.html</a> ) with additional tools to guide clinicians in implementing the recommendations.   | High quality source<br>→ National guideline for prescribing opioids for chronic pain management.   |
| 51 | II / A / 5 | Smoking Cessation         | Lindström D, Sadr Azodi O, Wladis A, Tønnesen H, Linder S, Näsell H, Ponzer S, Adami J. Effects of a perioperative smoking cessation intervention on postoperative complications: a randomized trial. Ann Surg. 2008 Nov; 248(5): 739-45. PMID: 18948800 | 1/A           | <a href="http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000658-200811000-00008&amp;LSLINK=80&amp;D=ovft">http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000658-200811000-00008&amp;LSLINK=80&amp;D=ovft</a> | OBJECTIVE: To determine whether an intervention with smoking cessation starting 4 weeks before general and orthopedic surgery would reduce the frequency of postoperative complications. SUMMARY BACKGROUND DATA: Complications are a major concern after elective surgery and smokers have an increased risk. There is insufficient evidence concerning how the duration of preoperative smoking intervention affects postoperative complications. METHODS: A randomized controlled trial, conducted between February 2004 and December 2006 at 4 university-affiliated hospitals in the Stockholm region, Sweden. The outcome assessment was blinded. The follow-up period for the primary outcome was 30 days. Eligibility criteria were active daily smokers, aged 18 to 79 years. Of the 238 patients assessed, 76 refused participating, and 117 men and women undergoing surgery for primary hernia repair, laparoscopic cholecystectomy, or a hip or knee prosthesis were enrolled. INTERVENTION: Smoking cessation therapy with individual counseling and nicotine substitution started 4 weeks before surgery and continued 4 weeks postoperatively. The control group received standard care. The main outcome measure was frequency of any postoperative complication. RESULTS: An intention-to-treat analysis showed that the overall complication rate in the control group was 41%, and in the intervention group, it was 21% (P = 0.03). Relative risk reduction for the primary outcome of any postoperative complication was 49% and number needed to treat was 5 (95% CI, 3-40). An analysis per protocol showed that abstainers had fewer complications (15%) than those who continued to smoke or only reduced smoking (35%), although this difference was not statistically significant. CONCLUSION: Perioperative smoking cessation seems to be an effective tool to reduce postoperative complications even if it is introduced as late as 4 weeks before surgery.                         | RCT 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.<br>→ Supports the conclusion that smoking cessation prior to surgery reduces postoperative complications if smoking discontinued as late as four weeks prior to surgery.  |

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| 52 | II / A / 6 | Unhealthy alcohol use | Smith PC, Schmidt SM, Allensworth-Davies D, Saitz R. Primary care validation of a single-question alcohol screening test. J Gen Intern Med. 2009 Jul; 24(7):783-8. PMID: 19247718  | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2695521/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2695521/</a>   | 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 X 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) 72.5% to 88.5%) and 79.3% specific (95% CI 73.1% to 84.4%) for the detection of unhealthy alcohol use. It was slightly more sensitive (87.9%, 95% CI 72.7% to 95.2%) but was less specific (66.8%, 95% CI 60.8% to 72.3%) for the detection of a current alcohol use disorder. Test 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 NIAAA 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.<br>→ Supports use of a single question screen to identify unhealthy alcohol use.  |
| 53 | II / A / 6 | Unhealthy alcohol use | Nath B, Li Y, Carroll JE, Szabo G, Tseng JF, Shah SA. Alcohol exposure as a risk factor for adverse outcomes in elective surgery. J Gastrointest Surg. 2010 Nov;14(11):1732-41. PMID: 20839071   | 2/B | <a href="http://download.springer.com/static/pdf/605/art%253A10.1007%252Fs11605-010-1350-4.pdf?auth66=1425423256_257e5eba9ffa60b6f861a68902b79c4c&amp;ext=.pdf">http://download.springer.com/static/pdf/605/art%253A10.1007%252Fs11605-010-1350-4.pdf?auth66=1425423256_257e5eba9ffa60b6f861a68902b79c4c&amp;ext=.pdf</a> | 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 (2.5%) patients with documented alcohol use (active alcohol use of at least two drinks per day within 2 weeks of surgery; ETOH use) underwent elective surgery; 301,994 (97.5%) patients denied ETOH use. Multivariate analysis was performed with adjustments for demographic and comorbid factors. Primary outcome measures included length of stay (LOS), postoperative complications, and death. RESULTS: ETOH use associated with elective surgery decreased over the course of the study (p < 0.0001). ETOH 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). Except for SSI, these complications were independent risk factors for postoperative mortality. ETOH use was associated with earlier time to wound disruption (9 vs. 11 days; p = 0.04), longer median hospital stays (5 vs. 3 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 with ETOH use who are scheduled to 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 use was defined as at least two drinks per day within two weeks of surgery.<br>→ Supports the conclusion that pre-operative alcohol use is associated with post-operative complications. |
| 54 | II / A / 7 | Depression screening  | Luppino FS, de Wit LM, Bouvy PF, Stijnen T, Cuijpers P, Penninx BW, Zitman FG. Overweight, obesity, and depression: a systematic review and meta-analysis of longitudinal studies. Arch Gen Psychiatry. 2010 Mar;67(3):220-9. PMID: 20194822 | 1/A | <a href="http://archpsyc.amanetwork.com/article.aspx?articleid=210608">http://archpsyc.amanetwork.com/article.aspx?articleid=210608</a>   | CONTEXT: Association between obesity and depression has repeatedly been established. For treatment and prevention purposes, it is important to acquire more insight into their longitudinal interaction. OBJECTIVE: To conduct a systematic review and meta-analysis on the longitudinal relationship between depression, overweight, and obesity and to identify possible influencing factors. DATA SOURCES: Studies were found using PubMed, PsycINFO, and EMBASE databases and selected on several criteria. STUDY SELECTION: Studies examining the longitudinal bidirectional relation between depression and overweight (body mass index 25-29.99) or obesity (body mass index > or =30) were selected. DATA EXTRACTION: Unadjusted and adjusted odds ratios (ORs) were extracted or provided by the authors. DATA SYNTHESIS: Overall, unadjusted ORs were calculated and subgroup analyses were performed for the 15 included studies (N = 58 745) to estimate the effect of possible moderators (sex, age, depression severity). Obesity at baseline increased the risk of onset of depression at follow-up (unadjusted OR, 1.55; 95% confidence interval [CI], 1.22-1.98; P < .001). This association was more pronounced among Americans than among Europeans (P = .05) and for depressive disorder than for depressive symptoms (P = .05). Overweight increased the risk of onset of depression at follow-up (unadjusted OR, 1.27; 95% CI, 1.07-1.51; P < .01). This association was statistically significant among adults (aged 20-59 years and > or =60 years) but not among younger persons (aged <20 years). Baseline depression (symptoms and disorder) was not predictive of overweight over time. However, depression increased the odds for developing obesity (OR, 1.58; 95% CI, 1.33-1.87; P < .001). Subgroup analyses did not reveal specific moderators of the association. CONCLUSIONS: This meta-analysis confirms a reciprocal link between depression and obesity. Obesity was found to increase the risk of depression, most pronounced among Americans and for clinically diagnosed depression. In addition, depression was found to be predictive of developing obesity. | Meta-analysis of fifteen studies including nearly 59,000 patients that demonstrated reciprocal relationship between depression and obesity.<br>→ Overweight increased risk of depression by 27% and depression increased the risk of obesity by 58% in this study.   |

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| 55 | II / A / 7 | Depression; Suicide risk | Tindle HA, Omalu B, Courcoulas A, Marcus M, Hammers J, Kuller LH. Risk of suicide after long-term follow-up from bariatric surgery. Am J Med. 2010 Nov;123(11):1036-42. PMID: 20843498                       | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4296730/pdf/nihms223580.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4296730/pdf/nihms223580.pdf</a> | PURPOSE: Bariatric surgery is recognized as the treatment of choice for class III obesity (body mass index $\geq 40$ ) 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, age, 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, 1996 and December 28, 2006 were obtained from the Division of Vital Records, Pennsylvania State Department of Health. RESULTS: There were 31 suicides (16,683 operations), for an overall rate of 6.6/10,000; 13.7 per 10,000 among men and 5.2 per 10,000 among women. About 30% of suicides occurred within the first 2 years following surgery, with almost 70% occurring within 3 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 35-64 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 a need to develop more comprehensive longer-term surveillance and follow-up methods in order to evaluate factors associated with postbariatric surgery suicide.   | 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.<br>→ Suicide rate following bariatric surgery was higher among men than women, and both substantially higher than the general population. |
| 56 | II / A / 8 | Dementia screening       | Hu CJ, Liao CC, Chang CC, Wu CH, Chen TI. Postoperative adverse outcomes in surgical patients with dementia: a retrospective cohort study. World Journal of Surgery, 2012 Sep; 36(9): 2051-8. PMID: 22535212 | 2/B | <a href="http://link.springer.com/article/10.1007/s00268-012-1609-x">http://link.springer.com/article/10.1007/s00268-012-1609-x</a>                           | BACKGROUND: Dementia patients often present with coexisting 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 sex- and age-matched nondementia 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 persons 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] 1.72-1.86), with higher medical resources 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 (1.19-1.47); pneumonia, OR = 2.18 (2.06-2.31); septicemia, OR = 1.8 (1.69-1.92); stroke, OR = 1.51 (1.43-1.6); 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, septicemia, 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. | Retrospective cohort study of the Taiwan National Health Insurance Research Database.<br>→ Suggests that for patients undergoing surgical procedures, those with dementia have a higher rate of postoperative complications.   |
| 57 | II / A / 8 | Dementia screening       | Freitas S, Simões MR, Alves L, Duro D, Santana I. Montreal Cognitive Assessment (MoCA): validation study for frontotemporal dementia. J Geriatr Psychiatry Neurol. 2012 Sep; 25(3): 146-54. PMID: 22859702   | 2/B | Please contact your local library to obtain a copy of this citation.  | 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-.974; AUC [MMSE] = 0.772, 95% CI = 0.677-0.850). 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 better option than the MMSE.   | Validates use of MoCA as an instrument for screening for cognitive impairment.<br>→ Limitation: study cohort is patients undergoing hip surgery for displaced femoral neck fracture.   |
| 58 | II / B / 1 | Shared Decision Making   | Arterburn 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): 2094-104. PMID: 22949460                          | 2/B | <a href="http://content.healthaffairs.org/content/31/9/2094.full.pdf+html">http://content.healthaffairs.org/content/31/9/2094.full.pdf+html</a>               | 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.  | Cohort is patients considering joint replacement surgery.<br>→ Supports use of shared decision-making to avoid surgery that the patient with otherwise not choose.   |

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| 59 | II / C / 4 | Nutritional supplements                       | Damms-Machado A, Friedrich A, Kramer KM, Stingel K, Meile T, Küper MA, Königsrainer A, Bischoff SC. Pre- and postoperative nutritional deficiencies in obese patients undergoing laparoscopic sleeve gastrectomy. <i>Obes Surg.</i> 2012 Jun;22(6):881-9. PMID: 22403000 | 2/B | <a href="http://link.springer.com/article/10.1007%2Fs11695-012-0609-0">http://link.springer.com/article/10.1007%2Fs11695-012-0609-0</a> | BACKGROUND: Laparoscopic sleeve gastrectomy (LSG) has been identified as an innovative surgical approach for the treatment of obesity and is increasingly applied worldwide. However, data on outcome of LSG regarding nutrient deficiencies, protein status, and body composition are scarce. METHODS: Obese subjects (54; f:m = 4:1) scheduled for LSG were included in this study. Micronutrient analysis, protein status assessment, and bioimpedance measures were performed before and 1, 3, 6, and 12 months after LSG. RESULTS: In 51% of the subjects, at least one micronutrient deficiency was found prior to surgery. Baseline concentrations were below normal for 25-OH vitamin D (27%), iron (29%), vitamin B6 (11%), vitamin B12 (9%), folate (6%), and potassium (7%). Frequencies of deficiencies for vitamin B12, folate, iron, and vitamin B6 tended to increase following LSG within the first year after intervention. Also, parameters of protein status (albumin, transferrin, cholinesterase, and total protein) decreased. After surgery, bioimpedance measures indicated a reduction of total body fat, but also of body cell mass. CONCLUSIONS: Preoperative micronutrient deficiencies were common in morbid obese individuals scheduled for LSG. LSG had a modest effect on micronutrient status by further reducing iron, vitamin B12, vitamin B6, and folate within the first year after intervention. Our data suggest that especially obese patients with preoperative deficits require control and supplementation of micronutrients and protein in the postoperative period.   | Observational study following 54 obese patients, not otherwise characterized, undergoing laparoscopic sleeve gastrectomy (LSG) procedures revealed that 51% had a micronutrient deficiency prior to surgery and surgery aggravated these deficiencies.<br>→ Suggests micronutrient deficiency is common in patients before and after LSG.                 |
| 60 | II / C / 4 | Nutritional supplements                       | Gasteyger C, Suter M, Gaillard RC, Giusti V. Nutritional deficiencies after Roux-en-Y gastric bypass for morbid obesity often cannot be prevented by standard multivitamin supplementation. <i>Am J Clin Nutr.</i> 2008 May;87(5):1128-33. PMID: 18469230                | 2/B | <a href="http://ajcn.nutrition.org/content/87/5/1128.long">http://ajcn.nutrition.org/content/87/5/1128.long</a>                         | 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 y 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 substitutive 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 +/- 10.0 y, 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 98%, 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 substitutive treatment was \$34.83. 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.  | Retrospective cohort study of obese patients undergoing Roux-en-Y gastric bypass (RYGBP) procedure revealed micronutrient deficiencies following surgery despite standardized multivitamin therapy.<br>→ Study suggests vitamin deficiencies are common after RYGBP despite standardized multivitamin therapy.  |
| 61 | II / B / 3 | Advance Directives; Durable Power of Attorney | Nicholas LH, Langa KM, Iwashyna TJ. Regional variation in the association between advance directives and end-of-life Medicare expenditures. <i>JAMA.</i> 2011 Oct 5; 306(13): 1447-53. PMID: 21972306  | 2/B | <a href="http://jama.jamanetwork.com/article.aspx?articleid=1104465">http://jama.jamanetwork.com/article.aspx?articleid=1104465</a>     | CONTEXT: It is unclear if advance directives (living wills) are associated with end-of-life expenditures and treatments. OBJECTIVE: To examine regional variation in the associations between treatment-limiting advance directive use, end-of-life Medicare expenditures, and use of palliative and intensive treatments. DESIGN, SETTING, AND PATIENTS: Prospectively collected survey data from the Health and Retirement Study for 3302 Medicare beneficiaries who died between 1998 and 2007 linked to Medicare claims and the National Death Index. Multivariable regression models examined associations between advance directives, end-of-life Medicare expenditures, and treatments by level of Medicare spending in the decedent's hospital referral region. MAIN OUTCOME MEASURES: Medicare expenditures, life-sustaining treatments, hospice care, and in-hospital death over the last 6 months of life. RESULTS: Advance directives specifying limits in care were associated with lower spending in hospital referral regions with high average levels of end-of-life expenditures (-\$5585 per decedent; 95% CI, -\$10,903 to -\$267), but there was no difference in spending in hospital referral regions with low or medium levels of end-of-life expenditures. Directives were associated with lower adjusted probabilities of in-hospital death in high- and medium-spending regions (-9.8%; 95% CI, -16% to -3% in high-spending regions; -5.3%; 95% CI, -10% to -0.4% in medium-spending regions). Advance directives were associated with higher adjusted probabilities of hospice use in high- and medium-spending regions (17%; 95% CI, 11% to 23% in high-spending regions, 11%; 95% CI, 6% to 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 advanced directives to lower spending, in hospital death, and use of hospice care in geographic regions characterized by higher levels of end of life spending.<br>→ Supports the use of advance directives to reduce the use of inappropriate and costly end-of-life care. |

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| 62 | II / B / 3     | End-of-Life Care                             | Bree Collaborative. End-of-life care and recommendations. Nov 2014.  | VM Tier-3 Source | <a href="http://www.breecollaborative.org/wp-content/uploads/EOL-Care-Final-Report.pdf">http://www.breecollaborative.org/wp-content/uploads/EOL-Care-Final-Report.pdf</a> | 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 that 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 OLST 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...."  | Consensus standard from Washington state multistakeholder group.<br>→ Robert Bree Collaborative standard for end-of-life care.   |
| 63 | II / C / 1 / a | Fitness for Surgery; Cardiopulmonary Fitness | Fleisher LA, et.al.; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; American Society of Echocardiography; American Society of Nuclear Cardiology; Heart Rhythm Society; Society of Cardiovascular Anesthesiologists; Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; Society for Vascular Surgery. ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery: a report... Circulation. 2007 Oct 23; 116(17): e418-99. PMID: 17901357 | VM Tier-2 Source | <a href="http://circ.ahajournals.org/content/116/17/e418.full">http://circ.ahajournals.org/content/116/17/e418.full</a>   | Presents guideline for cardiovascular evaluation for patients that will have non cardiac surgery.   | Society guideline.<br>→ Guide to preoperative evaluation for non-cardiac surgery.  |
| 64 | II / C / 1 / a | Fitness for Surgery; Cardiopulmonary Fitness | Poirier P, Alpert MA, Fleisher LA, Thompson PD, Sugerman HJ, Burke LE, Marceau P, Franklin BA; American Heart Association Obesity Committee of Council on Nutrition, Physical Activity and Metabolism, Council on Cardiopulmonary Perioperative and Critical Care, Council on Cardiovascular Surgery and Anesthesia, Council on Cardiovas. Cardiovascular evaluation and management of severely obese patients undergoing surgery: a science advisory from the American Heart Association. Circulation. 2009 Jul 7;120(1):86-95. PMID: 19528335                                  | VM Tier-3 Source | <a href="http://circ.ahajournals.org/content/120/1/86.full.pdf+html">http://circ.ahajournals.org/content/120/1/86.full.pdf+html</a>                                       | Obesity is associated with comorbidities that may lead to disability and death. During the past 20 years, the number of individuals with a body mass index >30, 40, and 50 kg/m(2), respectively, has doubled, quadrupled, and quintupled in the United States. The risk of developing comorbid conditions rises with increasing body mass index. Possible cardiac symptoms such as exertional dyspnea and lower-extremity edema occur commonly and are nonspecific in obesity. The physical examination and electrocardiogram often underestimate cardiac dysfunction in obese patients. The risk of an adverse perioperative cardiac event in obese patients is related to the nature and severity of their underlying heart disease, associated comorbidities, and the type of surgery. Severe obesity has not been associated with increased mortality in patients undergoing cardiac surgery but has been associated with an increased length of hospital stay and with a greater likelihood of renal failure and prolonged assisted ventilation. Comorbidities that influence the preoperative cardiac risk assessment of severely obese patients include the presence of atherosclerotic cardiovascular disease, heart failure, systemic hypertension, pulmonary hypertension related to sleep apnea and hypoventilation, cardiac arrhythmias (primarily atrial fibrillation), and deep vein thrombosis. When preoperatively evaluating risk for surgery, the clinician should consider age, gender, cardiorespiratory fitness, electrolyte disorders, and heart failure as independent predictors for surgical morbidity and mortality. An obesity surgery mortality score for gastric bypass has also been proposed. Given the high prevalence of severely obese patients, this scientific advisory was developed to provide cardiologists, surgeons, anesthesiologists, and other healthcare professionals with recommendations for the preoperative cardiovascular evaluation, intraoperative and perioperative management, and postoperative cardiovascular care of this increasingly prevalent patient population. | Opinion-based advisory from the American Heart Association.<br>→ Advises on preoperative cardiovascular evaluation in patients with obesity.   |
| 65 | II / C / 1 / c | Nasal culture for Staphylococcus aureus      | Bode LGM. Et.al. Preventing surgical-site infections in nasal carriers of Staphylococcus aureus. New England Journal of Medicine, 2010 Jan 7; 362(1): 9-17. PMID: 20054045   | 1/B              | <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMoa0808939">http://www.nejm.org/doi/pdf/10.1056/NEJMoa0808939</a>   | BACKGROUND: Nasal carriers of Staphylococcus aureus are at increased risk for health care-associated infections with this organism. Decolonization of nasal and extranasal sites on hospital admission may reduce this risk. METHODS: In a randomized, double-blind, placebo-controlled, multicenter trial, we assessed whether rapid identification of S. aureus nasal carriers by means of a real-time polymerase-chain-reaction (PCR) assay, followed by treatment with mupirocin nasal ointment and chlorhexidine soap, reduces the risk of hospital-associated S. aureus infection. RESULTS: From October 2005 through June 2007, a total of 6771 patients were screened on admission. A total of 1270 nasal swabs from 1251 patients were positive for S. aureus. We enrolled 917 of these patients in the intention-to-treat analysis, of whom 808 (88.1%) underwent a surgical procedure. All the S. aureus strains identified on PCR assay were susceptible to methicillin and mupirocin. The rate of S. aureus infection was 3.4% (17 of 504 patients) in the mupirocin-chlorhexidine group, as compared with 7.7% (32 of 413 patients) in the placebo group (relative risk of infection, 0.42; 95% confidence interval [CI], 0.23 to 0.75). The effect of mupirocin-chlorhexidine treatment was most pronounced for deep surgical-site infections (relative risk, 0.21; 95% CI, 0.07 to 0.62). There was no significant difference in all-cause in-hospital mortality between the two groups. The time to the onset of nosocomial infection was shorter in the placebo group than in the mupirocin-chlorhexidine group (P=0.005). CONCLUSIONS: The number of surgical-site S. aureus infections acquired in the hospital can be reduced by rapid screening and decolonizing of nasal carriers of S. aureus on admission. (Current Controlled Trials number, ISRCTN56186788.  | Cohort included a variety of surgical procedures, as well as patients hospitalized for medical issues.<br>→ Supports treatment of nasal carriers of Staphylococcus aureus to reduce incidence of surgical site infections. |

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| 66 | II / C / 1 / d | Delirium | Witlox J, Eurelings LS, de Jonghe JF, Kalisvaart KJ, Eikelenboom P, van Gool WA. Delirium in elderly patients and the risk of postdischarge mortality, institutionalization, and dementia: a meta-analysis. JAMA. 2010 Jul 28; 304(4): 443-51. PMID: 20664045 | 1/A | <a href="http://jama.jamanetwork.com/data/Journals/JAMA/4522/jrv05005_443_451.pdf">http://jama.jamanetwork.com/data/Journals/JAMA/4522/jrv05005_443_451.pdf</a> | 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 1981 and April 2010 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 2939 references in the original search, 51 relevant articles were identified. DATA EXTRACTION: 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, 616/2243 controls [27.5%]; HR, 1.95 [95% confidence interval {CI}, 1.51-2.52]; I(2), 44.0%). Moreover, patients who had experienced delirium were also at increased risk of institutionalization (7 studies; average follow-up, 14.6 months; 176/527 patients [33.4%] with delirium and 219/2052 controls [10.7%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I(2), 0%) and dementia (2 studies; average follow-up, 4.1 years; 35/56 patients [62.5%] with delirium and 15/185 controls [8.1%]; OR, 12.52 [95% CI, 1.86-84.21]; I(2), 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.+137:144 | Cohort is elderly patients treated in hospital or acute care setting for medical or surgical conditions.<br>→ Supports the conclusion that delirium is associated with poor outcomes. |
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**Cycle 3: Surgical Repair**

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| 67 | III / A / 1 | Programmatic standards | American College of Surgeons. Standards manual: resources for optimal care of the metabolic and bariatric surgery patient 2016. Effective October 2016.    | Tier-2 Source | <a href="https://www.facs.org/~media/files/quality%20programs/bariatric/mbsqip%20standardsmanual.ashx">https://www.facs.org/~media/files/quality%20programs/bariatric/mbsqip%20standardsmanual.ashx</a>   |   | Professional society guideline<br>→ Programmatic standard for bariatric surgery from the American College of Surgeons.  |
| 68 | III / A / 2 | Surgeon volume         | Zevin B, Aggarwal R, Grantcharov TP. Volume-outcome association in bariatric surgery: a systematic review. Ann Surg. 2012 Jul;256(1):60-71. PMID: 22584692 | 2/B           | <a href="http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000658-201207000-00010&amp;LSLINK=80&amp;D=ovft">http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000658-201207000-00010&amp;LSLINK=80&amp;D=ovft</a> | 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 morbidity and mortality. 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." The effects of these interventions on patient outcomes remain unclear. 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 were selected for review. Two studies were prospective cohorts (level of evidence [LOE] 1), 3 were retrospective cohorts (LOE 3), 2 were retrospective case controls (LOE 3), and 17 were retrospective case series (LOE 4). The overall methodological quality of the reviewed studies was fair. 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. CONCLUSIONS: 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. | Systematic review of 24 prospective and retrospective studies involving 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.<br>→ Supports the relationship between higher volume surgeons and higher volume hospitals with better outcomes for bariatric surgery. |

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| 69 | III / A / 1 | Hospital volume;<br>Surgeon volume | Markar SR, Penna M, Karthikesalingam A, Hashemi M. The impact of hospital and surgeon volume on clinical outcome following bariatric surgery. <i>Obes Surg</i> . 2012 Jul;22(7):1126-34. PMID: 22527591                                   | 2/B | <a href="http://link.springer.com/article/10.1007%2Fs11695-012-0639-7">http://link.springer.com/article/10.1007%2Fs11695-012-0639-7</a> | 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, Embase, trial registries, 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, 289,732 bariatric procedures were included in the institutional volume analysis, and 32,920 bariatric operations were included in the surgeon volume analysis. Mortality was reduced following surgery at high volume institutions (0.24 vs. 2.18 %; pooled odds ratio = 0.26; P = 0.004) and by high volume surgeons (0.41 vs. 2.77 %; pooled odds ratio = 0.21; P < 0.001). Similarly, morbidity was reduced in high volume institutions (7.84 vs. 8.85 %; pooled odds ratio = 0.52; P < 0.001) and with high volume surgeons (6.92 vs. 7.29 %; pooled odds ratio = 0.47; P < 0.001). 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.   | Systematic review of 15 retrospective studies including 289,732 procedures.<br>→ Suggests inverse relationship between morbidity and mortality with hospital and surgeon volumes for bariatric procedures.  |
| 70 | III / A     | Hospital volume                    | Dimick JB, Osborne NH, Nicholas L, Birkmeyer JD. Identifying high-quality bariatric surgery centers: hospital volume or risk-adjusted outcomes? <i>J Am Coll Surg</i> . 2009 Dec;209(6):702-6. PMID: 19959037                             | 2/B | <a href="http://www.clinicalkey.com">http://www.clinicalkey.com</a>   | 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 = 32,381 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 2004). 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, 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 quartiles, risk-adjusted morbidity predicted a more than fourfold difference in future performance (1.7% versus 7.2%; odds ratio [OR]: 4.5; 95% CI, 3.5 to 5.9). 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 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.  | Retrospective cohort study of New York state patients undergoing bariatric 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 outcome.<br>→ Suggests including data beyond only hospital volume for predicting outcomes. |
| 71 | III / A     | Facility volume                    | Jafari MD, Jafari F, Young MT, Smith BR, Phalen MJ, Nguyen NT. Volume and outcome relationship in bariatric surgery in the laparoscopic era. <i>Surg Endosc</i> . 2013 Dec;27(12):4539-46. doi: 10.1007/s00464-013-3112-3. PMID: 23943121 | 2/B | See your local Library for a copy of this citation  | BACKGROUND: The relationship between volume and outcomes in bariatric surgery is well established in the literature. However, the analyses were performed primarily 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 volume and accreditation on surgical outcomes for 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 in-hospital mortality between the LVCs and HVCs. Additionally, within the HVC group, risk-adjusted outcomes of accredited versus nonaccredited centers were examined. RESULTS: Between 2006 and 2010, 277,760 laparoscopic stapling bariatric procedures were performed, with 85% of the cases managed at HVCs. The mean number of laparoscopic stapling cases managed per year was 17 ± 14 at LVCs and 144 ± 117 at HVCs. The in-hospital mortality was higher at LVCs (0.17%) than at HVCs (0.07%). Multivariate analysis showed that laparoscopic stapling procedures performed at LVCs had higher rates of mortality than those performed at HVCs [odds ratio (OR) 2.5; 95% confidence interval (CI) 1.3-4.8; p < 0.01] as well as higher rates of serious morbidity (OR 1.2; 95% CI 1.1-1.4; p < 0.01). The in-hospital mortality rate at nonaccredited HVCs was 0.22% compared with 0.06% at accredited HVCs. Multivariate analysis showed that nonaccredited centers had higher rates of mortality than accredited centers (OR 3.6; 95% CI 1.5-8.3; p < 0.01) but lower rates of serious morbidity (OR 0.8; 95% CI 0.7-0.9; p < 0.01). CONCLUSION: In this era of laparoscopy, hospitals managing more than 50 laparoscopic stapling cases per year have improved outcomes. However, nonaccredited HVCs have outcomes similar to those of LVCs. Therefore, the impact of accreditation on outcomes may be greater than that of volume. | This is a retrospective cohort study evaluating morbidity and mortality of laparoscopic stapling procedures related to facility volume.<br>→ Supports the conclusion that accredited, high volume centers have improved outcomes  |

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| 72 | III / A     | Facility accreditation          | Nguyen NT, Nguyen B, Nguyen VQ, Ziogas A, Hohmann S, Stamos MJ. Outcomes of bariatric surgery performed at accredited vs nonaccredited centers. J Am Coll Surg. 2012 Oct;215(4):467-74. doi: 0.1016/j.jamcollsurg.2012.05.032. PMID: 22727608                  | 2/B | 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. RESULTS: Of the 35,284 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 (0.06% 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 0.16 to 0.44) and lower cost (mean difference, \$3,758; 95% CI, \$2,965 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.  | This is a retrospective cohort study evaluating mortality, length of stay, and cost at high-volume centers accredited either by the ASMBS or ACS versus nonaccredited center performing bariatric surgery.<br>→ 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. |
| 73 | III / A / 3 | Hospital volume; Surgeon volume | Birkmeyer NJ, Dimick JB, Share D, Hawasli A, English WJ, Genaw J, Finks JF, Carlin AM, Birkmeyer JD; Michigan Bariatric Surgery Collaborative. Hospital complication rates with bariatric surgery in Michigan. JAMA. 2010 Jul 28;304(4):435-42. PMID: 20664044 | 1/A | <a href="http://jama.jamanetwork.com/article.aspx?articleid=186297">http://jama.jamanetwork.com/article.aspx?articleid=186297</a> | 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 MEASURE: 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, 0.001%-0.13%) 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) to 3.5% (95% CI, 2.4-5.0) (risk difference, 1.9; 95% CI, 0.08-3.7) 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, 2.2-3.2; and > or = 300 cases, 2.3%; 95% CI, 2.0%-2.6%; P = .003) and surgeon level (< 100 cases, 3.8%; 95% CI, 3.2%-4.5%; 100-249 cases, 2.4%; 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, 2.5%-3.1%; non-COE, 2.0%; 95% CI, 1.5%-2.4%; P = .41). 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. | Prospective registry-based, state-wide study assessing complication rates of bariatric procedures, hospital volume, surgeon volume, and designation as a center of excellence.<br>→ 30-day complication rate correlated with hospital and surgeon volume, but not with COE status.   |

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| 74 | III / A / 3 | Surgeon specialization | Sahni NR, Dalton M, Cutler DM, Birkmeyer JD, Chandra A. Surgeon specialization and operative mortality in United States: retrospective analysis. <i>BMJ</i> . 2016 Jul 21;354:i3571. doi: 10.1136/bmj.i3571. PMID: 27444190   | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4957587/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4957587/</a>   | <p>OBJECTIVE: To measure the association between a surgeon's degree of specialization in a specific procedure and patient mortality.</p> <p>DESIGN: Retrospective analysis of Medicare data.</p> <p>SETTING: US patients aged 66 or older enrolled in traditional fee for service Medicare.</p> <p>PARTICIPANTS: 25 152 US surgeons who performed one of eight procedures (carotid endarterectomy, coronary artery bypass grafting, valve replacement, abdominal aortic aneurysm repair, lung resection, cystectomy, pancreatic resection, or esophagectomy) on 695 987 patients in 2008-13.</p> <p>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).</p> <p>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 28%, 95% confidence interval 0% to 48%); coronary artery bypass grafting (15%, 4% to 25%); valve replacement (46%, 37% to 53%); abdominal aortic aneurysm repair (42%, 29% to 53%); lung resection (28%, 5% to 46%); and cystectomy (41%, 8% to 63%). In five procedures (carotid endarterectomy, 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.</p> <p>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.</p> | <p>High quality retrospective cohort study addressing the issue of surgeon volume and degree of specialization controlling for comorbidities and using 30 day operative mortality as an outcome. Does not include patients undergoing bariatric surgery.</p> <p>→ Supports the conclusion that surgical specialization reduces operative mortality and may be more important than surgical volume for some procedures. Note: bariatric surgery was not among the procedures evaluated.</p> |
| 75 | III / A / 3 | Hospital accreditation | Azagury D, Morton JM. Bariatric Surgery Outcomes in US Accredited vs Non-Accredited Centers: A Systematic Review. <i>J Am Coll Surg</i> . 2016 Jul 13. pii: S1072-7515(16)30267-8. PMID: 27423398   | 2/B | Please contact your local library to obtain a copy of this citation.  | <p>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 accreditation on surgical outcomes.</p> <p>STUDY DESIGN: The PRISMA (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 biliopancreatic diversion or 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.</p> <p>RESULTS: Thirteen studies were published in a very short time frame and covered &gt;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, morbidity was reduced in 8 of 11 studies, although more discreetly, with odds ratios ranging from 1.09 to 1.39.</p> <p>CONCLUSIONS: This study found that the preponderance of medical evidence supports accreditation for bariatric surgery.</p>   | <p>Systematic review of retrospective cohort studies with multiple potential confounders.</p> <p>→ Supports the conclusion that surgery performed in accredited centers has lower morbidity and mortality.</p>   |
| 76 | III / B / 1 | Opioids                | Washington State Agency Medical Directors' Group (AMDG). Interagency guideline prescribing opioids for pain. 3rd edition. June 2015.  |     | <a href="http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf">http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf</a>   |   | <p>State standard for use of opioids.</p> <p>→ "... focus [includes] opioid use in acute, subacute, and perioperative pain phases and in special populations; includes sections on tapering and opioid use disorder."</p>  |
| 77 | III / B / 1 | Pain management        | Elia N, Lysakowski C, Tramèr MR. Does multimodal analgesia with acetaminophen, nonsteroidal antiinflammatory drugs, or selective cyclooxygenase-2 inhibitors and patient-controlled analgesia morphine offer advantages over morphine alone? Meta-analyses of randomized trials. <i>Anesthesiology</i> . 2005 Dec;103(6):1296-304. PMID: 16306743 | 2/B | <a href="http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000542-200512000-00025&amp;LSLINK=80&amp;D=ovft">http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;AN=0000542-200512000-00025&amp;LSLINK=80&amp;D=ovft</a> | <p>The authors analyzed data from 52 randomized placebo-controlled trials (4,893 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, 15-117 mg); it was significantly decreased with all regimens by 15-55%. There was evidence of a reduction in pain intensity at 24 h (1 cm on the 0- to 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, 37) 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.</p>   | <p>Studies included "patients [undergoing] major orthopedic (13 trials), abdominal (12), gynecologic (16), spine (9), or thoracic (2) procedures. Anesthetic techniques included general anesthesia in 43 trials and spinal or epidural in 5, and were not specified in 4." Acetaminophen, NSAIDs, and /or COX-2 inhibitors all reduce morphine need after surgery.</p> <p>→ Supports use of multimodal analgesia to reduce opiate need.</p>   |

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| 78 | III / B / 2 / b | Urinary catheter < 48 hours | Technical specifications for ACE Demonstration Quality Monitoring Program. Measures 1-4: Surgical Care Improvement Project measures. CMS, [revised] 2011.                                    | National standard | <a href="http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/ACEQualityMeasures.pdf">http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/ACEQualityMeasures.pdf</a> | Introduction: The CMS Surgical Care Improvement Project (SCIP) measures are a subset of National Quality Hospital Measures created through the joint efforts of the Centers for Medicare & Medicaid and the Joint Commission (Specifications Manual for National Hospital Quality Measures Version 2.5 effective for discharges 10-01-2008 through 03-31-2009). The SCIP measures have been endorsed by the National Quality Forum, and are used by Hospital Compare, the Premier demonstration, and RHQDAPU. Corresponding measures are used by PQRI at the individual physician level. The NQF endorsed measures are calculated across a defined list of major surgical procedures and separately for the MS-DRG ACE demonstration surgical procedure groups of CABG, Cardiac Valves, and Hip and Knee Replacement.   | National standard<br>→ CMS specifications to prevent infection and venous thromboembolism for surgical patients.   |
| 79 | III / B / 2 / b | Urinary catheter < 48 hours | The Joint Commission. Surgical Care Improvement Project (SCIP). Specifications manual for national hospital inpatient quality measures v4.3b. (2014)   | National standard | <a href="http://www.jointcommission.org/surgical_care_improvement_project/">http://www.jointcommission.org/surgical_care_improvement_project/</a>   |   | SCIP-Inf-9 standard. Recommends removal of urinary catheter on post-operative day 1 or post-operative day 2.<br>→ The Joint Commission standard for postoperative removal of urinary catheter.   |
| 80 | III / B / 2 / c | Hair removal                | The Joint Commission. Surgical Care Improvement Project (SCIP). Specifications manual for national hospital inpatient quality measures v4.3b. (2014)   | National standard | <a href="http://www.jointcommission.org/surgical_care_improvement_project/">http://www.jointcommission.org/surgical_care_improvement_project/</a>   |   | SCIP-Inf-6 standard. Specifies avoidance of shaving to prep surgical site.<br>→ The Joint Commission standard for pre-operative hair removal.  |
| 81 | III / B / 2 / d | Skin preparation            | Bode LGM. Et.al. Preventing surgical-site infections in nasal carriers of Staphylococcus aureus. New England Journal of Medicine, 2010 Jan 7; 362(1): 9-17. PMID: 20054045                   | 1 / B             | <a href="http://www.nejm.org/doi/pdf/10.1056/NEJMoa0808939">http://www.nejm.org/doi/pdf/10.1056/NEJMoa0808939</a>   | BACKGROUND: Nasal carriers of Staphylococcus aureus are at increased risk for health care-associated infections with this organism. Decolonization of nasal and extranasal sites on hospital admission may reduce this risk. METHODS: In a randomized, double-blind, placebo-controlled, multicenter trial, we assessed whether rapid identification of S. aureus nasal carriers by means of a real-time polymerase-chain-reaction (PCR) assay, followed by treatment with mupirocin nasal ointment and chlorhexidine soap, reduces the risk of hospital-associated S. aureus infection. RESULTS: From October 2005 through June 2007, a total of 6771 patients were screened on admission. A total of 1270 nasal swabs from 1251 patients were positive for S. aureus. We enrolled 917 of these patients in the intention-to-treat analysis, of whom 808 (88.1%) underwent a surgical procedure. All the S. aureus strains identified on PCR assay were susceptible to methicillin and mupirocin. The rate of S. aureus infection was 3.4% (17 of 504 patients) in the mupirocin-chlorhexidine group, as compared with 7.7% (32 of 413 patients) in the placebo group (relative risk of infection, 0.42; 95% confidence interval [CI], 0.23 to 0.75). The effect of mupirocin-chlorhexidine treatment was most pronounced for deep surgical-site infections (relative risk, 0.21; 95% CI, 0.07 to 0.62). There was no significant difference in all-cause in-hospital mortality between the two groups. The time to the onset of nosocomial infection was shorter in the placebo group than in the mupirocin-chlorhexidine group (P=0.005). CONCLUSIONS: The number of surgical-site S. aureus infections acquired in the hospital can be reduced by rapid screening and decolonizing of nasal carriers of S. aureus on admission. (Current Controlled Trials number, ISRCTN56186788.  | Cohort includes a high proportion of patients undergoing surgery, including cardiothoracic surgery.<br>→ Supports treatment of patients with Staphylococcus aureus diagnosed by nasal swab PCR assay to reduce incidence of surgical site infections.  |
| 82 | III / B / 2 / d | Skin preparation            | Webster J, Osborne S. Preoperative bathing or showering with skin antiseptics to prevent surgical site infection. Cochrane Database of Systematic Reviews 2015, Issue 2. Art. No.: CD004985. | Tier-1 Source     | <a href="http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004985.pub5/abstract">http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004985.pub5/abstract</a>   | BACKGROUND: Surgical site infections (SSIs) are wound infections that occur after invasive (surgical) procedures. Preoperative 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 fifth update we searched the Cochrane Wounds Group Specialised Register (searched 18 December 2014); the Cochrane Central Register of Controlled Trials (The Cochrane Library 2014 Issue 11); Ovid MEDLINE (2012 to December Week 4 2014), Ovid MEDLINE (In-Process & Other Non-Indexed Citations December 18, 2014); Ovid EMBASE (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 non-antiseptic preparations in people undergoing surgery. DATA COLLECTION AND ANALYSIS: Two review authors independently assessed studies for selection, 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 participants were included. Four of the included trials had three comparison groups. The antiseptic used in all trials was 4% chlorhexidine gluconate (Hibiscrub/Riohex). Three trials involving 7791 participants 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%CI 0.82 to 1.10). 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 0.57 to 1.84). Three trials of 1192 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 0.17 to 0.79). 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 showering 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. | Cochrane meta-analysis of including seven trials involving a total of 10,157 surgical participants. Authors' conclusion: "This review provides no clear evidence of benefit for preoperative showering or bathing with chlorhexidine over other wash products, to reduce surgical site infection."<br>→ Does not support the conclusion that chlorhexidine is superior to other wash products for preoperative skin preparation. |

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| 83   | III / B / 2    | Perioperative antibiotics; anticoagulation | Technical specifications for ACE Demonstration Quality Monitoring Program. Measures 1-4: Surgical Care Improvement Project measures. CMS, [revised] 2011.  | Tier-1 Evidence   | <a href="http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/ACEQualityMeasures.pdf">http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/ACEQualityMeasures.pdf</a>               | Introduction: The CMS Surgical Care Improvement Project (SCIP) measures are a subset of National Quality Hospital Measures created through the joint efforts of the Centers for Medicare & Medicaid and the Joint Commission (Specifications Manual for National Hospital Quality Measures Version 2.5 effective for discharges 10-01-2008 through 03-31-2009). The SCIP measures have been endorsed by the National Quality Forum, and are used by Hospital Compare, the Premier demonstration, and RHQDAPU. Corresponding measures are used by PQRI at the individual physician level. The NQF endorsed measures are calculated across a defined list of major surgical procedures and separately for the MS-DRG ACE demonstration surgical procedure groups of CABG, Cardiac Valves, and Hip and Knee Replacement.   | National standard<br>→ CMS specifications for measures to prevent infection and venous thromboembolism. Measures "1" and "3" in this citation relate to perioperative antibiotic use.   |
| 84   | III / B / 3    | Tranexamic acid                            | Henry DA, Carless PA, Moxey AJ, O'Connell D, Stokes BJ, Fergusson DA, Ker K. Anti-fibrinolytic use for minimising perioperative allogeneic blood transfusion. Cochrane Database Syst Rev. 2011 Mar 16;(3):CD001886.                                      | Tier-1 Source     | <a href="http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001886.pub4/abstract">http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001886.pub4/abstract</a>   | BACKGROUND: Concerns regarding the safety of transfused blood have led to the development of a range of interventions to minimise blood loss during major surgery. Anti-fibrinolytic 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 concerns that it increased the risk of cardiovascular complications and death. OBJECTIVES: To assess the comparative effects of the anti-fibrinolytic 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 anti-fibrinolytic drugs in adults scheduled for non-urgent surgery. Eligible trials compared anti-fibrinolytic 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 34% (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 0.53 to 0.70) and was 0.81 (95% CI 0.67 to 0.99) 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 0.90; 95% CI 0.81 to 0.99). Aprotinin reduced the need for re-operation due to bleeding by a relative 54% (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 | Cochrane meta-analysis for study cohorts of adults undergoing non-emergent surgery. Authors' conclusions: "Aprotinin, although effective in reducing bleeding, had a higher rate of death than tranexamic acid and aminocaproic acid, which appeared free of serious side-effects."<br>→ Study evaluates benefits and risks of different drugs to reduce surgical blood loss. |
| 85   | III / B / 5    | Glycemic Control                           | The Joint Commission. Surgical Care Improvement Project (SCIP). Specifications manual for national hospital inpatient quality measures v4.3b. (2014)   | National standard | <a href="http://www.jointcommission.org/surgical-care-improvement-project/">http://www.jointcommission.org/surgical-care-improvement-project/</a>   |   | National standard.<br>→ The Joint Commission standard for perioperative glycemic control.   |
| 86   | III / B / 6    | Temperature control                        | The Joint Commission. Surgical Care Improvement Project (SCIP). Specifications manual for national hospital inpatient quality measures v4.3b. (2014)   | National standard | <a href="http://www.jointcommission.org/surgical-care-improvement-project/">http://www.jointcommission.org/surgical-care-improvement-project/</a>   |   | National standard.<br>→ The Joint Commission standard for perioperative temperature control.  |
| <b>Cycle 4: Post-operative Care and Return to Function</b> |                |  |  |                   |   |   |   |
| 87   | IV / A / 1 / a | Enhanced Recovery After Surgery (ERAS)     | Lemanu DP, Singh PP, Berridge K, Burr M, Birch C, Babor R, MacCormick AD, Arroll B, Hill AG. Randomized clinical trial of enhanced recovery versus standard care after laparoscopic sleeve gastrectomy. Br J Surg. 2013 Mar;100(4):482-9. PMID: 23339040 | 2/B               | <a href="http://onlinelibrary.wiley.com/doi/10.1002/bjs.9026/abstract;jsessionid=6F18BBB7719B7A475F760E5CC31319EC.f02t03">http://onlinelibrary.wiley.com/doi/10.1002/bjs.9026/abstract;jsessionid=6F18BBB7719B7A475F760E5CC31319EC.f02t03</a> | 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 2010, 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 ( <a href="http://www.clinicaltrials.gov">http://www.clinicaltrials.gov</a> ).  | Randomized blinded study of patients undergoing laparoscopic sleeve gastrectomy with or without ERAS protocol post-operatively.<br>→ Suggests that ERAS post-operative protocol reduces hospital length of stay and costs for patients undergoing this type of bariatric surgery. Relatively small study.   |

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| 88 | IV / A / 4 | Goal-directed hemodynamic therapy | Hamilton MA, Cecconi M, Rhodes A. A systematic review and meta-analysis on the use of preemptive hemodynamic intervention to improve postoperative outcomes in moderate and high-risk surgical patients. <i>Anesth Analg</i> . 2011 Jun;112(6):1392-402. PMID: 20966436   | 2/B | <a href="http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;D=&amp;AN=00000539-201106000-00027&amp;PDF=y">http://ovidsp.ovid.com/ovidweb.cgi?T=JS&amp;CSC=Y&amp;NEWS=N&amp;PAGE=fulltext&amp;D=&amp;AN=00000539-201106000-00027&amp;PDF=y</a> | 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 perioperative 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 quantifiable analysis, subgroup analysis, and sensitivity analysis where possible. RESULTS: There were 29 studies identified, 23 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 morbidity 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. | Meta-analysis of 23 randomized controlled trials of variable quality. Undisclosed surgical interventions for patients with moderate to high risk of complication.<br>→ Suggests that goal-directed hemodynamic interventions reduce mortality and complications in patients at risk for post-surgical complications. |
| 89 | IV / A / 4 | Goal-directed hemodynamic therapy | Cecconi M, Corredor C, Arulkumaran N, Abuella G, Ball J, Grounds RM, Hamilton M, Rhodes A. Clinical review: Goal-directed therapy-what is the evidence in surgical patients? The effect on different risk groups. <i>Crit Care</i> . 2013 Mar 5;17(2):209. PMID: 23672779 | 2/B | <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3679445/pdf/cc11823.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3679445/pdf/cc11823.pdf</a>   | 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 arms 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 = 0.20, 95% CI 0.09 to 0.41; 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 < 0.0001), 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 0.89; P = 0.01). 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.            | Meta-analysis of 32 randomized controlled trials of variable quality that included patients at intermediate risk of mortality following surgery.<br>→ Suggests patients with intermediate risk of mortality following surgery may benefit from goal directed therapy peri-operatively. Harms not discussed.          |

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| 90 | IV / A / 1 | Perioperative Continuous Positive Airway Pressure (CPAP) | Javanainen MH, Scheinin T, Mustonen H, Leivonen M. Do Changes in Perioperative and Postoperative Treatment Protocol Influence the Frequency of Pulmonary Complications? A Retrospective Analysis of Four Different Bariatric Groups. <i>Obes Surg.</i> 2016 May 24. [Epub ahead of print] PMID: 27220851            | 2/B | Please contact your local library to obtain a copy of this citation.  | 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-ultra descriptus (NUD). RESULTS: The number of pulmonary complications among the groups was significantly different. A long 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.  | Retrospective study of 400 patients undergoing bariatric surgery: first 100 patients recovered in the ICU, the fourth group of 100 was recovered with early ambulation, blow bottle and CPAP. Pulmonary complications were lower in the fourth group compared to the first group. OR time was substantially longer in the first group than the fourth group, but the authors suggest the time could be influenced by learning curve for the surgical procedure.<br>→ Difficult to separate the effect of shortened operating time versus post-operative CPAP + blow bottle interventions on pulmonary complications. Difficult to draw conclusions regarding the value of post-operative CPAP based on the provided data. |
| 91 | IV / B     | Discharge Process  | Wagner C, Zabari M. Reducing readmissions: care transitions toolkit. Washington State Hospital Association, 2013  | 3/C | <a href="https://www.wsha.org/images/activEdit/1.18.13_FINAL_CT_Toolkit_Web.pdf">https://www.wsha.org/images/activEdit/1.18.13_FINAL_CT_Toolkit_Web.pdf</a> | "Washington State Care Transitions" is a state-wide initiative to foster safe, timely, effective, and coordinated care as patients move between settings. The six strategies are as follows: consistent plan of care with primary care provider and home health care (if applicable) upon arrival and discharge from the hospital; coordinated follow up call or visit at discharge; timely visit to primary care provider; reconciliation of medications soon after transition; patient education coordinated between settings; and support through increased care management for high-risk patients.   | Consensus-based Washington State standard<br>→ Outlines standards for hospital discharge  |
| 92 | IV / B     | Discharge Process  | Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, Forsythe SR, O'Donnell JK, Paasche-Orlow MK, Manasseh C, Martin S, Culpepper L. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. <i>Ann Intern Med.</i> 2009 Feb 3; 150(3): 178-87. PMID: 19189907 | 2/B | <a href="http://annals.org/article.aspx?articleid=744252">http://annals.org/article.aspx?articleid=744252</a>   | 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, 49.9 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 = 0.014). Adverse events were not assessed; these data were collected but are still being analyzed. LIMITATION: 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. | Single-center, prospective cohort study with selection bias based on resource constraints. Control group not defined. Study cohort of general medicine patients with a mean age of 50 years old in experimental group.<br>→ Supports the value of a nurse/pharmacist systematic approach to discharge process to reduce aggregate hospital readmissions. "Implementing this discharge intervention required about 1.5 hours of nursing time and 30 minutes of pharmacist time per participant."   |