

# Bariatric surgery versus non-surgical treatment for obesity: a systematic review and meta-analysis of randomised controlled trials

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## STUDY QUESTION

What are the summary effects of bariatric surgery compared with non-surgical treatment for obesity on body weight loss, comorbidities, adverse events, and quality of life?

## SUMMARY ANSWER

Bariatric surgery is more effective in inducing body weight loss and remission of type 2 diabetes and metabolic syndrome after a maximal follow-up of 2 years, no cardiovascular events or deaths were reported after bariatric surgery, and the most common adverse events after bariatric surgery were iron deficiency anaemia and reoperations.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Individual randomised controlled trials have shown that bariatric surgery is more effective than non-surgical treatment for obesity. This systematic review and meta-analysis is the most comprehensive evidence base comparing these treatment options.

## Selection criteria for studies

We searched Medline, Embase, and the Cochrane Library from their inception to June 2013. Eligible studies were randomised controlled trials (with  $\geq 6$  months of follow-up) that included individuals with a body mass index  $\geq 30$ , compared current bariatric surgery techniques (Roux-en-Y gastric bypass, adjustable gastric banding, sleeve gastrectomy,

and biliopancreatic diversion) with non-surgical treatment for obesity (diet, weight reducing medication, behavioural therapy, or any combination thereof), and reported on body weight, comorbidities, quality of life, or adverse events.

## Primary outcome(s)

Body weight loss; remission rates of type 2 diabetes, metabolic syndrome, or hypertension; and reduction in use of medications, adverse events, and quality of life.

## Main results and role of chance

The meta-analysis included 11 studies with 796 individuals. Individuals allocated to bariatric surgery lost more body weight (mean difference  $-26$  kg (95% confidence interval  $-31$  to  $-21$ )) compared with non-surgical treatment, had a higher remission rate of type 2 diabetes (relative risks 22.1 (3.2 to 154.3) in a complete case analysis and 5.3 (1.8 to 15.8) in a conservative analysis assuming diabetes remission in all non-surgically treated individuals with missing data), a higher remission rate of metabolic syndrome (relative risks 2.4 (1.6 to 3.6) in complete case analysis and 1.5 (0.9 to 2.3) in conservative analysis), and greater improvements in quality of life and reductions in the use of medication (no pooled data). Hypertension remission was not addressed by any of the studies. There were no cardiovascular events or death. The most common adverse events after bariatric surgery were iron deficiency anaemia (15% of individuals undergoing malabsorptive bariatric surgery) and reoperations (8%).

## Bias, confounding, and other reasons for caution

Summary measures of effect sizes are based on only 11 studies or fewer depending on outcome. Furthermore, the methodological quality of included studies suffered from unclear allocation concealment in five studies. The risk for attrition bias was high in four studies, and attrition was always higher in the non-surgical treatment group. All of the included studies were relatively small, conducted in centres of excellence for bariatric surgery, and limited to a maximum of two years' follow-up. The evidence beyond two years of follow-up, in particular on adverse events, cardiovascular diseases, and mortality remains unclear and calls for further research on the topic.

## Study funding/potential competing interests

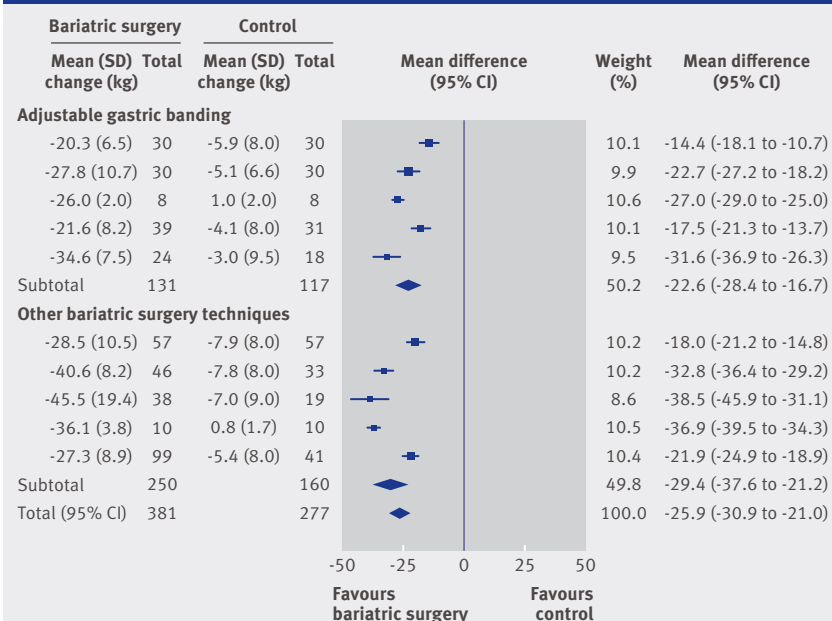
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## bmj.com

Analysis: A NICE example? Variation in provision of bariatric surgery in England (*BMJ* 2013;346:f2453)

Editorial: Is surgery a magic bullet against diabetes? (*BMJ* 2012;345:e4552)

## Mean change in body weight (kg) after bariatric surgery versus non-surgical treatment (control) for obesity, with subgroup analysis for adjustable gastric banding versus other bariatric surgery techniques



# Efficacy of anti-inflammatory or antibiotic treatment in patients with non-complicated acute bronchitis and discoloured sputum: randomised placebo controlled trial

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## bmj.com

Research: Improving antibiotic prescribing in acute respiratory tract infections (*BMJ* 2013;347:f4403)

Practice: Investigation of "non-responding" presumed lower respiratory tract infection in primary care (*BMJ* 2011;343:d5840)

## STUDY QUESTION

How efficacious are oral anti-inflammatory drugs and antibiotics compared with placebo at resolving cough in patients with uncomplicated acute bronchitis and discoloured sputum?

## SUMMARY ANSWER

The number of days with cough did not differ significantly between patients treated with ibuprofen, amoxicillin-clavulanic acid, or placebo.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Recently, bronchitis has been considered more an inflammatory than infectious process, yet the efficacy of non-steroidal anti-inflammatory drugs (NSAIDs) in patients with acute bronchitis has not been assessed in randomised clinical trials. The use of NSAIDs or antibiotics in patients with uncomplicated acute bronchitis and discoloured sputum was not superior to placebo in reducing the number of days with cough.

## Design

Parallel group, single blinded, placebo controlled randomised clinical trial. Patients were randomised to one of three treatment arms: ibuprofen 600 mg three times daily (n=136), amoxicillin-clavulanic acid 500 mg/125 mg three times daily (n=137), or placebo three times daily (n=143) for 10 days. We used a block randomisation method with treatment and placebo blocks issued with a drug number and assigned to consecutive patients in sequential order. Patients were masked to treatment allocation.

## Participants and setting

Eligible participants were adults aged 18 to 70 without associated respiratory comorbidity or immunosuppression. They had to present symptoms associated with respiratory tract infection of less than one week's duration, with cough as the predominant symptom and discoloured sputum and at least one other criterion of lower respiratory tract infection such as dyspnoea, wheezing, chest discomfort, or chest pain. Twenty five general practitioners from nine primary care centres in Catalonia recruited the participants.

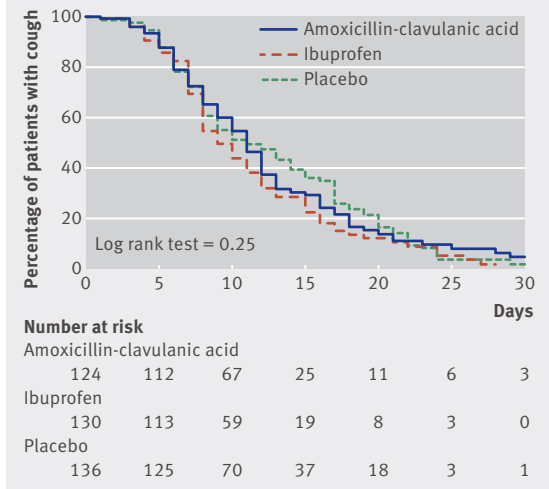
## Primary outcome

Number of days with frequent cough in the intention to treat population—that is, the number of days from the randomisation visit until the last day the patient scored  $\geq 1$  on both the daytime and the night time cough items in a symptom diary.

## Main results and the role of chance

The median number of days with frequent cough was slightly lower among patients assigned to ibuprofen (9 days, 95% confidence interval 8 to 10 days) than those receiving amox-

## Kaplan-Meier survival analysis of days with frequent cough, from baseline visit until patient scored $\geq 1$ for both daytime and night time cough



icillin-clavulanic acid (11 days, 10 to 12 days) or placebo (11 days, 8 to 14 days). However, no statistically significant differences were observed between the three study groups (log rank test=0.251). Neither amoxicillin-clavulanic acid nor ibuprofen increased the likelihood of cough resolution compared with placebo (hazard ratio 1.03, 95% confidence interval 0.78 to 1.35 and 1.23, 0.93 to 1.61, respectively).

## Harms

Adverse events were observed in 27 patients, more commonly in the antibiotic arm (12%) than the ibuprofen or placebo arms (5% and 3%, respectively;  $P < 0.01$ ).

## Bias, confounding, and other reasons for caution

This was a single blinded clinical trial. The tablets used for the three types of treatment were, however, similar in size and colour. They were placed in numbered black pill containers of identical appearance prepared by an independent pharmacist and were sealed before being given to the investigators. Therefore it was unlikely that the investigators would be intentionally biased.

## Generalisability to other populations

These results are valid only for patients with uncomplicated acute bronchitis.

## Study funding/potential competing interests

This study was supported by a grant from the Instituto de Salud Carlos III (Spanish Ministry of Health) (EC07/90333).

Trial registration number ISRCTN07852892.

# Including post-discharge mortality in calculation of hospital standardised mortality ratios: retrospective analysis of hospital episode statistics

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EDITORIAL by Nicoll and colleagues

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## STUDY QUESTION

To assess whether including mortality (shortly) after discharge affects the standardised mortality ratios of individual hospitals and the overall variation between hospitals in such ratios.

## SUMMARY ANSWER

Selecting mortality timeframes that include the post-discharge period changes the standardised mortality ratios of individual hospitals and affects judgments about performance.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Hospitals with a low in-hospital standardised mortality ratio are regarded as having a high degree of quality of care. In-hospital standardised mortality ratio and early post-discharge mortality were inversely associated, suggesting that low in-hospital mortality may reflect high post-discharge mortality instead of the assumed high quality of care.

## Participants and setting

We examined 1 228 815 patient discharges from 60 hospitals in the Netherlands in the period 2008-10.

## Design

We did a retrospective analysis of routinely collected hospital data. We calculated standardised mortality ratios by comparing observed deaths with deaths predicted by a case mix adjustment method. These data were linked to the Dutch population register by Statistics Netherlands to allow inclusion of deaths after discharge.

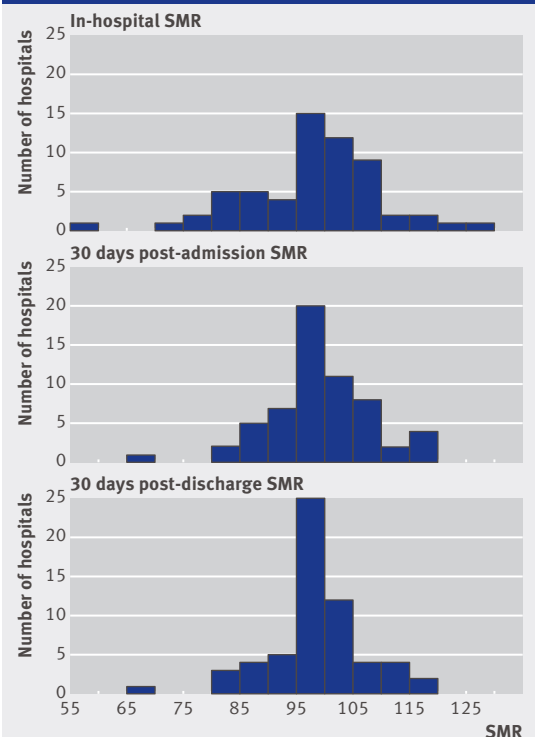
## Primary outcome(s)

The standardised mortality ratios were calculated using three different timeframes for observed mortality: from admission to discharge (in-hospital ratio), from admission to 30 days after admission (30 days post-admission ratio), and from admission to 30 days after discharge (30 days post-discharge ratio).

## Main results and the role of chance

We classified hospitals into “worse than expected,” “conforms to expected,” and “better than expected” on the basis of the three standardised mortality ratios. Compared with in-hospital standardised mortality ratio, 20 (33%) hospitals were categorised differently with the 30 days post-admission ratio and 13 (22%) with the 30 days post-discharge ratio. The overall variation in standardised mortality ratios was smaller with the 30 days post-admission or 30 days post-discharge ratios than with the in-hospital

## Distributions of hospitals according to in-hospital standardised mortality ratio (SMR), 30 days post-admission SMR, and 30 days post-discharge SMR



ratio. Furthermore, in-hospital standardised mortality ratio and mortality shortly after discharge were inversely associated (Pearson correlation coefficient  $-0.37$ ;  $P=0.004$ ), suggesting discharge bias. Low in-hospital mortality at least partly reflects a high post-discharge mortality and not only a high degree of quality of care.

## Bias, confounding, and other reasons for caution

Because the administrative data used for this study were pseudonymised, approximately 10% of the discharges could not be linked.

## Generalisability to other populations

If hospital mortality is used as a performance measure, guarding against bias and reducing the potential for “gaming” is essential. Our study suggests that standardised mortality ratios including post-discharge mortality are less vulnerable to discharge bias than are in-hospital standardised mortality ratios and are therefore preferable.

## Study funding/potential competing interests

The study was commissioned by the Dutch Ministry of Health, Welfare and Sport.

# Risk of moderate to advanced kidney disease in patients with psoriasis: population based cohort study

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Practice: Assessment and management of psoriasis: summary of NICE guidance (*BMJ* 2012;345:e6712)

## STUDY QUESTION

Is psoriasis a risk factor for chronic kidney disease?

## SUMMARY ANSWER

Moderate to severe psoriasis is associated with chronic kidney disease, independent of traditional risk factors.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Psoriasis is associated with systemic conditions including diabetes and cardiovascular disease, but its association with renal disease is unclear. Our results suggest that psoriasis affecting 3% or more of body surface area is a risk factor for chronic kidney disease. Patients with moderate to severe psoriasis should undergo screening for renal insufficiency, and nephrotoxic drugs should be used with caution in this at risk population.

## Participants and setting

The study was conducted with a medical records database from the United Kingdom (The Health Improvement Network (THIN)). We conducted a cohort study of patients aged 18-90 with psoriasis, matched to unexposed patients on age, practice, and time of visit, to identify the incidence of chronic kidney disease and a nested cross sectional study of patients aged 25-64 with psoriasis with

measurements of disease involvement (% affected body surface area) and matched to controls on age and practice.

## Design, size, and duration

The cohort study included 143 883 patients with psoriasis (136 529 with mild psoriasis and 7354 with severe psoriasis defined by use of treatments consistent with severe disease) and 689 702 unaffected patients. Data were collected from 2003 to 2010. The main outcome measure was incident stage 3-5 chronic kidney disease. In the nested study of 8731 patients with psoriasis and 87 310 controls, categorizations of disease extent were obtained from a survey of patients' physicians and prevalence of chronic kidney disease was assessed.

## Main results and the role of chance

After adjustment for risk factors for chronic kidney disease, the hazard ratios (95% confidence intervals) for incident chronic kidney disease were 1.05 (1.02 to 1.07), 0.99 (0.97 to 1.02), and 1.93 (1.79 to 2.08) in the overall, mild, and severe psoriasis groups, respectively. Age modified the risk in the severe psoriasis group. The risk of dialysis dependent renal disease was also increased in those with severe psoriasis (adjusted hazard ratio 4.15, 1.70 to 10.11). In the nested analysis, the adjusted odds ratios for chronic kidney disease were 0.89 (0.72 to 1.10), 1.36 (1.06 to 1.74), and 1.58 (1.07 to 2.34) in the mild, moderate, and severe psoriasis groups, respectively. Our findings were robust to multiple sensitivity analyses.

## Bias, confounding, and other reasons for caution

We accounted for confounders such as diabetes, hypertension, and use of nephrotoxic drugs. Misclassification bias could be possible when treatments are used as a proxy measure of severity of psoriasis, but direct measurements of affected body surface area corroborated our findings. Ascertainment bias is possible; though we found similar results when we adjusted for screening frequency and examined dialysis dependent renal disease.

## Generalisability to other populations

As the data source is broadly representative of the UK population, our findings are likely generalizable to other populations.

## Study funding/potential competing interests

This study was supported by grants from the National Institutes of Health. MRD and JMG have received research grants and funding from various bodies and pharmaceutical companies (see bmj.com for full details). JMG chairs the data and safety monitoring boards for Celgene and Merck.

Relative risk and prevalence odds ratio of chronic kidney disease in patients with psoriasis

