POEMs

Patient-Oriented Evidence That Matters

Compression Reduces Recurrent Cellulitis in Patients with Chronic Leg Edema

Clinical Question

Does compression reduce the likelihood of recurrent cellulitis in people with chronic leg edema?

Bottom Line

Adding compression to patient education reduces the likelihood of recurrent cellulitis in patients with chronic leg edema. (Level of Evidence = 1b–)

Synopsis

The researchers screened 183 adults and ultimately identified 84 who met their inclusion criteria. The included patients had edema for at least three months and had experienced two or more episodes of cellulitis in the same leg during the previous two years. People who were unstable or receiving end-of-life care, who had a chronic wound requiring ongoing treatment, or who were already wearing compression garments were excluded. Patients were randomized to receive education only or education plus a compression garment. The garments were mostly knee-high compression stockings that included the foot but not necessarily the toes. The primary outcome was the number of episodes of recurrent cellulitis, diagnosed by a physician not otherwise involved with the study. It is not clear if the diagnosing physician was masked to the intervention. Groups were balanced at baseline: the mean age was 64 years, 49% were women, and 63% had edema for more than five years. Analysis was by intention to treat, and patients were no longer followed after an episode of cellulitis occurred. The trial was stopped early when an interim analysis revealed that episodes of cellulitis were much less common in the compression group (15% vs. 40%; $P = .002$; number needed to treat = 4). At that time, the median duration of follow-up was 209 days in the compression group and 77 days in the education-only group. Fewer patients in the compression group were hospitalized for cellulitis (3 vs. 6). A lymphedema quality-of-life score also improved in the intervention group, although broader quality-of-life scores did not improve.

Study design: Randomized controlled trial (nonblinded)

Funding source: Foundation

Allocation: Unconcealed

Setting: Inpatient (any location)

Reference: *Webb E, Neeman T, Bowden FJ, et al. Compression therapy to prevent recurrent cellulitis of the leg.* N Engl J Med. *2020;383(7):630-639.*

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Negative Colonoscopy Result Predicts No Colon Cancer for More Than 10 Years

Clinical Question

Can the 10-year interval for repeat colonoscopies be extended for patients with no findings?

Bottom Line

Following a high-quality colonoscopy (adequate bowel preparation, full visualization, and high rates of detection by the colonoscopist), patients at average risk with no neoplasm found on examination had the same rate of developing colorectal cancer or dying from it in the 10- to 17-year interval compared with the first five-year

interval and the five- to 10-year interval. (Level of Evidence = 1b)

Synopsis

The study, conducted in Poland, included 165,887 patients 50 to 66 years of age without a family history of colorectal cancer who had a negative result from a single screening colonoscopy. Although the patients had access to a subsequent colonoscopy after 10 years, more than 97% did not receive one, providing the opportunity to determine the natural history of colorectal cancer in this nationwide group. Outcomes were assessed through administrative records. For up to 17.4 years after an initial negative colonoscopy result, colorectal cancer incidence and related mortality were 72% and 81% lower than in the general population. Incidence of cancer was lower in patients with high-quality colonoscopy compared with low-quality colonoscopy. The rates of subsequent colorectal cancer and related mortality in patients receiving the high-quality colonoscopy were not different in the 10- to 17-year interval compared with the zero- to five-year and five- to 10-year intervals.

Study design: Cohort (prospective)

Funding source: Government

Setting: Population-based

Reference: *Pilonis ND, Bugajski M, Wieszczy P, et al. Long-term colorectal cancer incidence and mortality after a single negative screening colonoscopy.* Ann Intern Med. *2020;173(2):81-91.*

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Bariatric Surgery Associated with Decreased All-Cause Mortality and Lower Rates of Other Obesity-Related Events

Clinical Question

Is bariatric surgery associated with reductions in all-cause mortality or lower rates of obesity-related conditions?

Bottom Line

Based on population registry data, bariatric surgery is associated with lower all-cause mortality and a lower risk of developing many subsequent obesity-related conditions. Because the investigators excluded randomized trials, the patients' health habits and other unmeasured factors might account for the findings. (Level of Evidence = 2a–)

Synopsis

The authors searched PubMed, EMBASE, and the Web of Science for national or regional administrative database studies that evaluated mortality or incident obesity-related diseases for patients who have undergone any form of bariatric surgery. They defined obesity-related illnesses as type 2 diabetes mellitus, hypertension, obstructive sleep apnea, ischemic heart disease, cardiac failure, dyslipidemia, and venous thromboembolism. The authors excluded randomized trials but included studies that had a control group and a minimum of 18 months of follow-up. Two authors independently evaluated studies for inclusion. The authors did not describe searching for unpublished studies. They included 18 studies with 1,539,904 patients, in which 269,818 patients received some form of bariatric surgery: gastric bypass (n = 137,578, 51%), sleeve gastrectomy (n = 58,916, 22%), adjustable gastric band (n = 52,973, 20%), vertical banded gastroplasty (n = 6,397, 2%), biliopancreatic diversion (n = 1,002, 0.4%), or an alternative procedure or unspecified operation (n = 12,952, 5%). The median follow-up period was 59 months. The authors reported that the quality of the studies was high.

Eleven studies found a decreased association between surgery and all-cause mortality (odds ratio [OR] = 0.62; 95% CI, 0.55 to 0.69) with heterogeneity but no evidence for publication bias. Six studies found a decreased association between surgery and the subsequent development of type 2 diabetes (OR = 0.39; 95% CI, 0.18 to 0.83), but with statistical heterogeneity and no evidence for publication bias. Five studies found a lower risk of incident hypertension after surgery (OR = 0.36; 95% CI, 0.32 to 0.40) with no evidence for heterogeneity or publication bias. One study reported incident sleep apnea, which occurred in 1.1% of patients undergoing surgery compared with 2% of control patients. Five studies reported that incident ischemic heart disease was lower after surgery (OR = 0.46; 95% CI, 0.29 to 0.73), but with statistical heterogeneity and no evidence for publication bias. Two studies found no association between surgery and incident heart failure. One study reported venous thromboembolism, which occurred in 1.7% of patients undergoing surgery compared with 4.4%

of control patients (hazard ratio = 0.60; 95% CI, 0.43 to 0.84). Because this analysis excluded randomized trials, it is possible that the magnitude of the lower risks of bad outcomes associated with bariatric surgery is inflated.

Study design: Meta-analysis (other)

Funding source: Government

Setting: Various (meta-analysis)

Reference: *Wiggins T, Guidozzi N, Welbourn R, et al. Association of bariatric surgery with all-cause mortality and incidence of obesity-related disease at a population level: a systematic review and meta-analysis.* PLoS Med. *2020;17(7):e1003206.*

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Fewer Subsequent Strokes with Ticagrelor Plus Aspirin than with Aspirin Alone

Clinical Question

Is ticagrelor (Brilinta) plus aspirin superior to aspirin alone for decreasing the risk of subsequent stroke or death in patients with acute ischemic stroke?

Bottom Line

For patients with mild to moderate acute nonembolic ischemic stroke, treatment with ticagrelor plus aspirin for 30 days resulted in fewer subsequent strokes but similar overall disability and an increase in severe bleeding compared with aspirin alone (number needed to treat to prevent one event of the composite outcome of stroke or death = 92; number needed to harm to cause one episode of severe bleeding = 263). (Level of Evidence = 1b)

Synopsis

Although a previous study of ticagrelor did not show a benefit over aspirin in patients with acute ischemic stroke, the effect of ticagrelor plus aspirin is not known. Using concealed allocation, the investigators randomized patients with mild to moderate acute nonembolic ischemic strokes (National Institutes of Health Stroke Scale score less than 5) or high-risk transient ischemic attacks to receive ticagrelor plus aspirin (n = 5,523) or matching placebo plus aspirin (n = 5,493). Patients receiving thrombolysis or thrombectomy and those who had intracranial bleeding were excluded. Ticagrelor (or matching placebo) was given at a loading dose of 180 mg, followed by a maintenance dosage of 90 mg twice daily for 30 days. Aspirin was given at a loading dose of 300 mg to 325 mg, followed by a dosage of 75 mg to 100 mg daily. The two groups were balanced at baseline: mean age was 65 years, 39% were women, and 91% presented with ischemic stroke. The primary outcome, a composite of subsequent stroke or death at 30 days, occurred less often in the ticagrelor plus aspirin group than in the aspirin-only group (5.5% vs. 6.6%; hazard ratio [HR] = 0.83; 95% CI, 0.71 to 0.96; P = .02). The secondary outcome of subsequent strokes was decreased from 6.3% to 5.0% in the ticagrelor plus aspirin group (HR = 0.79; 95% CI, 0.68 to 0.93; P = .004). Disability at the end of the treatment period did not differ significantly between the two groups. Severe bleeding was rare but more common in the ticagrelor plus aspirin group (0.5% vs. 0.1%; HR = 3.99; 95% CI, 1.74 to 9.14; P = .001). In the ticagrelor plus aspirin group, 2.8% of patients discontinued treatment because of bleeding (vs. 0.6% in the aspirin-only group).

Study design: Randomized controlled trial (double-blinded)

Funding source: Industry

Allocation: Concealed

Setting: Inpatient (any location) with outpatient follow-up

Reference: *Johnston SC, Amarenco P, Denison H, et al.; THALES Investigators. Ticagrelor and aspirin or aspirin alone in acute ischemic stroke or TIA.* N Engl J Med. *2020;383(3):207-217.*

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