

## Researchers examine effectiveness of blocking nerve to help with weight loss

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Among patients with morbid obesity, blocking the vagus nerve, which plays a role with appetite and metabolism, did not meet pre-specified efficacy objectives compared to a control group, although the intervention did result in greater weight loss, according to a study in the September 3 issue of *JAMA*.

Bariatric surgery can produce significant [weight loss](#) and improvement in health but is associated with several potential adverse effects. There is interest in the development of a device that could be as effective or nearly as effective as bariatric surgery but has fewer risks and is less invasive. One such possibility is blockade of the vagus nerve using electrodes implanted through minimally invasive laparoscopic surgery, according to background information in the article.

Sayed Ikramuddin, M.D., of the University of Minnesota, Minneapolis, and colleagues randomly assigned 239 participants who had a body mass index of 40 to 45 or 35 to 40 and 1 or more obesity-related condition to receive an implanted active vagal nerve block device (n = 162) or an implanted sham (inactive) device (n = 77). All participants received weight management education. The study was conducted at 10 sites in the United States and Australia between May and December 2011.

At 12 months in the intent-to-treat population, the average percentages of excess weight loss was 24.4 percent (9.2 percent of their initial body weight loss) in the vagal nerve block group and 15.9 percent (6.0 percent initial body weight loss) in the sham group, with an average difference

of 8.5 percentage points, which did not meet the primary efficacy objective of achieving superiority with a 10 percentage-point margin. Weight loss was statistically greater in the vagal nerve block group.

At 12 months, 52 percent of participants in the vagal nerve block group achieved at least 20 percent; and 38 percent, at least 25 percent of excess weight loss, which did not meet the primary efficacy objective performance goals of at least 55 percent of participants achieving a 20 percent excess weight loss and 45 percent achieving a 25 percent excess weight loss.

The device, procedure, or therapy-related serious adverse event rate in the vagal nerve block group was 3.7 percent, significantly lower than the 15 percent primary safety objective goal. The adverse events more frequent in the vagal nerve block group were heartburn, indigestion and abdominal pain attributed to therapy; all were reported as mild or moderate in severity.

"Additional studies are needed to compare effectiveness of vagal nerve block with other obesity treatments and to assess longterm durability of weight loss and safety," the authors conclude.

David E. Arterburn, M.D., M.P.H., of the Group Health Research Institute, Seattle, and David P. Fisher, M.D., of the Permanente Medical Group, Richmond, Calif., write in an accompanying editorial that several conclusions can be drawn from this study.

"First, vagal nerve blockade plus moderately intensive lifestyle counseling does not appear to be much more effective than an intensive lifestyle program. Second, based on comparisons with other studies, procedures for adjustable gastric banding, which reported a 50 percent excess weight loss; Roux-en-Y gastric bypass, a 68 percent excess weight loss; and vertical sleeve gastrectomy, a 65 percent [excess weight](#) loss, are

clearly more effective for initial weight loss than vagal nerve blockade. Third, the rate of serious adverse events with vagal nerve blockade (8.6 percent) is clinically important. Fourth, the long-term rates of weight regain and reoperation with vagal nerve blockade are currently unknown. Fifth, the report by Ikramuddin et al does not include a discussion of how vagal nerve blockade compares with other obesity treatments in terms of costs. Although vagal nerve blockade therapy is an innovative approach, it does not appear to be a sustained, effective treatment for severe obesity."

**More information:** [DOI: 10.1001/jama.2014.10540](https://doi.org/10.1001/jama.2014.10540)  
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