

## TitleLaparoscopic Adjustable Gastric BandingAgencyASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures -<br/>Surgical<br/>PO Box 553, Stepney SA 5069 Australia; Tel: +61 8 8363 7513 Fax: +61 8 8362 2077;<br/>http://www.surgeons.org/asernip-s/ReferenceASERNIP-S Report number 9

The aim of the report is to systematically review the literature on assessing the safety and efficacy of laparoscopic adjustable gastric banding in treating obesity.

## Methods

*Search Strategy* – Two search strategies were devised to retrieve literature from the MEDLINE, Current Contents, Embase, and Cochrane Library databases up until February 2000.

*Study Selection* – Inclusion of papers was based on a predetermined protocol that specified suitable studies by type of participants, comparators, outcomes, and type of study. English language papers were selected. Acceptable study designs included randomized controlled trials, controlled clinical trials, case series, or case reports.

*Data Collection and Analysis* – Thirty-seven papers met the inclusion criteria. They were tabulated and critically appraised in terms of methodology and design, outcomes, and the possible influence of bias, confounding, and chance.

## Results

There was little high-level evidence available and few comparative studies.

*Safety*: Mortality rates were below 1 in 1000, which is less than the rates quoted in many reviews of other surgical procedures for treating obesity. Likewise, morbidity rates did not appear to exceed those quoted for other procedures.

*Efficacy*: Most operations appear to be completed in under 2 hours. Most studies reported rates of conversion to open procedures of under 4%. Patients appear to be discharged earlier than those undergoing vertical banded gastroplasty, and also appear to become more mobile and independent after surgery, although initially positive responses to the surgery tend to diminish with time. The laparoscopic adjustable gastric band appears capable of producing substantial weight loss up to 4 years, although longer-term data has not been published. The consistency of weight loss across the patient population is also unclear due to poor reporting of variance in most studies.

## Safety and Efficacy Classification

The ASERNIP-S review group recommended a classification of 2: "The safety and/or efficacy of the procedure cannot be determined at present due to an evidence base of incomplete and/or poor quality. It is recommended that further research be conducted to establish safety and/or efficacy." (the classification list is available at *www.racs.edu.au/open/asernip-s/asernipsreviewprocess.htm*) Specifically, a register of adjustable bands and a record of serious complications should be established, possibly with anonymous reporting. Manufacturers of the adjustable bands should be encouraged to participate.

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