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Best evidence topic

Is the LINX reflux management system an effective treatment for gastro-oesophageal reflux disease?

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ABSTRACT

A best evidence topic in surgery was written according to a structured protocol. The question addressed whether LINX™ Reflux management system is an efficacious treatment for patients with symptoms of gastro-oesophageal reflux disease (GORD) not controlled by proton pump inhibitors (PPI). Forty-eight LINX-related papers were identified using the reported search, of which three represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group, study type, relevant outcomes and results of these papers are tabulated. All three studies were prospective case studies. They demonstrated that LINX is an efficacious treatment for GORD patients with good short and medium term outcomes and an acceptable safety profile. Further studies are required to determine its long term outcomes and its relative efficacy as compared to other established treatments.

1. Introduction

The LINX® Reflux Management System (Torax Medical, Inc., Shoreview, MN, USA) is a newly-licensed surgical treatment for GORD. It is a magnetic device that aims to augment the lower oesophageal sphincter without altering hiatal anatomy [1]. The Best Bets approach is a validated, concise and systematic method of collecting and appraising evidence to answer clinically relevant questions for which evidence is scarce, and has been fully described in a previous publication by the International Journal of Surgery (IJS) [2]. Briefly, it is a mini-review, constructed around a clinical scenario, involving a systematic search and standardised assessment of tabulated outcome measures, concluding with a discussion and clinical bottom line. In order to review the evidence base for the efficacy of LINX in GORD, a best evidence topic was constructed according to the recognised protocol.

2. Clinical scenario

You are in upper gastrointestinal surgery outpatients reviewing a 31 year old female with severe reflux symptoms despite high-dose PPI treatment. She has had no previous upper abdominal surgery, and her investigations have revealed uncomplicated GORD without hiatus hernia. She asks you whether LINX would be a suitable option for her.

3. Three part question

In patients with GORD, does LINX give good symptomatic relief?

4. Search strategy

A standardised literature search was performed on the Medline database (Medline 1948 to April 2014 using OVID interface). The search terms were as follows: (((LINX) OR MSA) OR sphincter device) AND (((reflux) OR GERD) OR GORD). The search was limited to English papers to include case series, randomized and non-randomized clinical trials, comparative studies and systematic reviews. In addition, reference lists of selected papers were searched. The search was current as of 25th April 2014.

5. Search outcome

Two hundred and thirty nine abstracts were identified using the reported search, which were appraised independently by two authors. Of these, only 44 were related to the LINX reflux management system. Thirty six papers were irrelevant, two were reviews. Of the remaining six papers, three provided longer follow up data

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Table 1
Three papers reporting most recent data from case series of LINX patients.

Author, date and country	Study type and level of evidence[a]	Patient group	Outcomes	Key results	Comments
Bonavina L, Saino G, Bona D, Sironi A, Lazzari V; Dec 2013; Italy [5]	Prospective case series, level II-3	100 consecutive LINX patients from single centre Length of follow up: Median 3 years (range 368d to 6 years)	Oesophageal pH: Quality of life: PPI use: Adverse outcomes:	Median % time pH < 4: 8% reduced to 3.2% ($p < 0.001$) Normalisation of oesophageal acid exposure or ≥50% reduction: 80% of patients Median GERD-HRQL[b] score: 16 on PPIs and 24 off PPIs at baseline, improved to 2 ($p < 0.001$) ≥50% reduction (improvement) in score: 93% of patients % of patients: 100% at baseline, reduced to 15% 3 removals 1) 378 days post implant for persistent odynophagia; Dor fundoplication performed immediately after removal 2) 771 days post implant for continued GORD symptoms; Toupet fundoplication immediately after removal 3) 406 days post implant for persistent dysphagia unresponsive to oesophageal dilation; immediate reconstruction of angle of His with Lortat-Jacob antireflux procedure 2 oesophageal dilations post implant 1) 5 days after, for dysphagia and odynophagia 2) 335 days after, for dysphagia 4 mild chest pain/odynophagia that improved within four months 3 had increased belching that did not require treatment	This is a large single-centre study, which reports good outcomes at a median of three years. Thirty of these patients are also included in Lipham's analysis [6]. Removals of LINX in this cohort occurred a considerable time after insertion (up to 771 days), so there is a possibility that there will be additional future removals in this cohort with longer follow up.
Lipham JC, DeMeester TR, Ganz RA, Bonavina L, Saino G, Dunn DH, Fockens P, Bemelman W. Mar 2012, USA. [6]	Prospective case series, level II-3	44 patients from four study centres in US and Europe Length of follow up: Median 3.7 years (range 119-1827d)	Oesophageal pH: ≥50% reduction (improvement) in score: 100% of patients PPI use: Adverse effects:	Mean % time pH < 4: 11.9% reduced to 3.8% at three years Normalisation of oesophageal acid exposure: 80% achieving normalization; $p < 0.001$ Mean GERD-HRQL[b] score: 25.7 at baseline, improved to 3.3 reduction in pH. % of patients: 100% at baseline, reduced to 20% Dysphagia in 43%, all resolved by 3 months 3 removals 1) At 226 days for dysphagia; Nissen fundoplication at later date 2) At 468 days, for MRI evaluation of unrelated neurological symptoms 3) At 1302 days for continued GORD symptoms; Nissen fundoplication	This study includes patients from a four study centres, which is encouraging for the generalisability of its good results. It has the smallest sample size of the three studies. Again, removals occurred late (up to 1302 days post insertion), which may herald a future high incidence of late removal of LINX.

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