TITLE: Linx Reflux Management System for the Treatment of Gastroesophageal Reflux Disease: Clinical Effectiveness

DATE: 23 September 2016

RESEARCH QUESTION

What is the clinical effectiveness of the Linx Reflux Management System for the treatment of gastroesophageal reflux disease?

KEY FINDINGS

One systematic review and eight non-randomized studies were identified regarding the clinical effectiveness of the Linx Reflux Management System for the treatment of gastroesophageal reflux disease.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI Institute, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and September 12, 2016. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

SELECTION CRITERIA

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.
Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Adult patients with GERD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Linx Reflux Management System (magnetic sphincter augmentation)</td>
</tr>
<tr>
<td>Comparator</td>
<td>Standard Care; Drug treatment; No active treatment</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Clinical effectiveness in treating, managing, improving GERD symptoms; Impact on reflux; Long term outcomes; Device malfunction; Patient safety</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies</td>
</tr>
</tbody>
</table>

GERD = gastroesophageal reflux disease.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

One systematic review and eight non-randomized studies were identified regarding the clinical effectiveness of the Linx Reflux Management System for the treatment of gastroesophageal reflux disease. No relevant health technology assessments, meta-analyses, or randomized controlled trials were identified.

Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

One systematic review examined five prospective case series and one prospective registry of patients who received a magnetic sphincter augmentation device (MSAD) for the control of gastroesophageal reflux disease (GERD). The authors determined that patients who received the device experienced an improvement in GERD health-related quality of life (HRQL) scores but the difference was not significant when compared with patients who underwent laparoscopic fundoplication (LF). Dysphagia, excessive bloating, reoperation rate, and hospital readmission were all less in the MSAD group. The authors concluded that there was not currently sufficient existing evidence to support the safety and effectiveness of the Linx device.

Eight non-randomized studies were identified. Three studies compared the effectiveness of Linx versus LF. When compared with laparoscopic Toupet fundoplication, GERD HRQL scores, proton pump inhibitor (PPI) use, gas-related symptoms, and dysphagia were similar between groups. No adverse events were reported in the abstract. When compared with laparoscopic Nissen fundoplication, GERD HRQL, PPI use, and dysphagia were similar between groups at one year follow-up. More patients in the LF group had severe gas and bloating and were unable to belch or vomit. A second study comparing laparoscopic Nissen fundoplication and Linx found that both treatments were effective in the short term. Severe dysphagia was significantly more common in the Linx group. Bloating, flatulence, and diarrhea were less common in the Linx group.
Five studies\textsuperscript{3,6,9} examined patients who received Linx for GERD but did not have a comparator group. The length of patient follow-up ranged from two weeks\textsuperscript{3} to four years.\textsuperscript{8} Linx was used in patients who experienced GERD following laparoscopic sleeve gastrectomy.\textsuperscript{3} Two to four weeks after the procedure, patients reported a significant improvement in reflux symptoms, regurgitation, epigastric pain, sensation of fullness, dysphagia, and cough symptoms.\textsuperscript{3} At four weeks follow-up, the authors of one study observed that heartburn, bloating, respiratory complaints, and sleep disturbance were all significantly reduced from baseline.\textsuperscript{7} A reduction of PPI use of more than 50% was achieved in more than 80% of patients.\textsuperscript{7} In a study of Linx for GERD\textsuperscript{6} with a median follow-up time of five months, 76.9% of patients no longer required PPIs and the most commonly reported side effect was dysphagia. At two years follow up,\textsuperscript{8} GERD HRQL scores were significantly improved. Eighty-six percent of patients reported that they no longer required PPIs to manage their GERD.\textsuperscript{9} In one study with a four year follow-up,\textsuperscript{8} all patients reported an improvement in GERD HRQL measures and 80% (20 of 25 patients) continued to report no need for PPIs. No long-term adverse events were reported.\textsuperscript{8}
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies


PREPARED BY:
Canadian Agency for Drugs and Technologies in Health
Tel: 1-866-898-8439
www.cadth.ca
APPENDIX – FURTHER INFORMATION:

Clinical Practice Guidelines and Guidance Documents – Methodology Not Specified


Linx Not Specified in Document


Non-Randomized Studies – Linx Not Specified in Abstract


**Review Articles**


Additional References


