Emerging Technology List

ENDOSCOPIC SUTURING SYSTEM

| Technology: | Endoscopic suturing system (endoluminal gastroplication) for gastroesophageal reflux. |
| Manufacturer: | C. R. Bard, Inc., Billerica, MA, U.S. |
| Purpose: | Treatment of gastroesophageal reflux disease (GERD). |
| Current Regulatory Status: | The Bard® EndoCinch™ Suturing System received licensing approval from Health Canada in 2001. A few centres in Ontario are already using the EndoCinch system and several other Canadian centers will be using it in the near future (Gordon Blair, Bard Canada, Mississauga (ON): personal communication, 2001 Dec 14). Marketing approval for EndoCinch was granted by the U.S. Food and Drug Administration (FDA) in March 2000.¹ |
| Description: | Gastroesophageal reflux disease, commonly known as severe heartburn, is a widespread, chronic condition, with considerable variation in severity.² The EndoCinch™ system has recently been used to treat this condition. EndoCinch is a flexible endoscope with a suturing device at one end. The endoscope is inserted down the patient’s throat and sutures are placed near the lower esophageal sphincter. The sutures are tied together to create a pleat, which acts to prevent reflux from the stomach to the esophagus. The procedure is performed on an outpatient basis and general anesthesia is usually not required. |
| Cost: | The manufacturer estimates the cost per procedure, in the U.S. with the EndoCinch system is approximately US $3,000.³ |
| Evidence of Efficacy and Safety: | A prospective, multi-centre, uncontrolled study on 64 patients suffering from GERD showed improvement in heartburn severity and frequency as well as regurgitation at six months follow-up (p > 0.0001 for each).² The number of patients using proton pump inhibitors (PPIs) or multiple medications daily decreased by 75%. While 61% of patients (39/64) reported moderate to severe regurgitation at baseline, this decreased to 8% (4/51) in the patients available for six months follow-up. Eleven of the 64 patients required a repeat procedure to correct “suboptimal results” with the original suturing procedure. Adverse effects included hypoxia (n = 4), sore throat (n = 20), chest pain (n = 10), abdominal pain (n = 9), vomiting (n = 9), mucosal tear (n = 2), gastric bleeding (n = 2) and suture perforation (n = 1). Most adverse effects were procedural rather than device related, (none of the physicians in the trial had previously performed this procedure on humans). According to the manufacturer’s web site, 102 GERD patients treated with EndoCinch in the U.K. showed an improvement in symptoms and a reduction in the use of proton pump inhibitor drugs. Complications included minor hematemesis (vomiting of blood because of internal bleeding) in two patients and transient difficulty in swallowing in three patients. Longer-term follow-up suggested that most patients with good improvement maintained that improvement after two to four years.⁵ Full details of the study do not appear to have been published. |

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A study of 30 patients who underwent this procedure found a reduction of approximately 66% in the use of anti-secretory medication in the patients who were successfully treated. Heartburn resolved completely in 20/30 patients, resolved partially in 4/30 and was unimproved in 6/30. If the results of this procedure are maintained, long term cost savings in medications might offset the cost of the procedure within several years.\(^6\)

Other technologies used to treat GERD include over-the-counter medications, lifestyle changes (diet, cessation of smoking, etc.), \(\text{H}_2\) receptor antagonists, PPIs, and surgery (open or laparoscopic fundoplication). Another new treatment for GERD, the Stretta procedure, is considered in a separate CCOHTA Emerging Technology List no.12.\(^7\) One study, of 20 patients, found the EndoCinch and Stretta procedures to be basically equivalent in outcomes in short-term follow-up.\(^8\)

Endoscopic suturing may be a promising alternative for the treatment of persons with severe GERD. The potential benefits are a reduced use of medications and an avoidance of major surgery. Appropriate patient selection is important.\(^9\) Patients may require re-treatment after several years or as a result of procedural difficulties with the initial suturing. A recent editorial makes several cautionary observations concerning this technology.\(^10\) The author points out that the patients in the U.S. clinical trial appear to have had less severe GERD. Obese patients, those with large hiatus hernia, and patients with swallowing difficulties were excluded from the trial. Further studies are needed to establish the long-term effectiveness of this technology, and to determine the costs, safety and patient preferences for the EndoCinch treatment in comparison with other therapies.

References:


This summary was prepared by David Hailey, PhD and Leigh-Ann Topfer, MLS.

This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada. ISSN 1499-108X (online only)