Serious complication following use of StomaphyX

Roux-en-Y gastric bypass (RYGB) is a popular surgical procedure to treat morbid obesity [1]. StomaphyX (endoGastric Solutions Inc., Redmond, Washington, USA) is designed for incisionless transoral endoscopic plication and revision of the gastric pouch (EPRGP) in case of pouch dilation with weight gain [2, 3]. Nonresorbable polypropylene fasteners create full-thickness plications of the pouch wall, reducing its volume. StomaphyX was cleared by the Food and Drug Administration (FDA) in April 2007 [4] and clinical results are becoming available, with only 3% early complications [5].

We present the case of a 38-year-old woman who underwent StomaphyX EPRGP in 2007, after RYGB in 2000. The procedure was carried out in a peripheral hospital by a surgeon and was not planned within the regulations governing ongoing clinical trials. After 3 days, the patient was referred to our hospital with fever and thoracic pain. Thoracic X-ray showed left lung empyema (Fig. 1). Antibiotics were started and she underwent two thoracic surgical procedures to drain the left hemithorax and to remove the pleural membranes (Fig. 2). Upper gastrointestinal endoscopy showed three StomaphyX fasteners through the distal oesophageal wall and a dilated gastric pouch with another three fasteners around the gastrojejunostomy (Fig. 3). Because of persistent empyema, a third draining thoracotomy was carried out 14 days later, which revealed adhesions at the distal esophagus. *Streptococcus viridans* and non-aureus *Staphylococcus* were cultured and antibiotics started. After a 28-day stay in the hospital, the patient was fit enough to be discharged. At present, 4 years after the complicated StomaphyX procedure, the patient is still under treatment for postoperative neuralgic pain of the left hemithorax. She was not covered by a clinical trial insurance. This case report illustrates the risk of serious complications of StomaphyX and the ethical implications of using new devices outside the control of regulated clinical trials.

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