

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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Competing interest: None

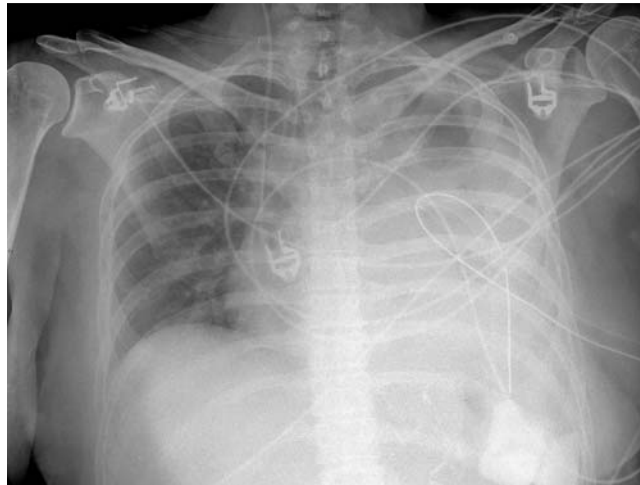


Fig. 1 Chest X-ray showing left lung empyema with a thoracic drain.



Fig. 2 Thoracic computed tomography (CT) scan showing empyema and mediastinitis with a surgical thoracic drain.



Fig. 3 Endoscopic image of the gastric pouch showing inadequate placement of fasteners around the gastrojejunostomy.

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