A post-market study of the Endo GIA* Reinforced Reload with Tri-Staple* Technology

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The primary objective of this prospective, two-arm, multicenter, post-market study is to evaluate safety through the incidence of reported device-related adverse events (AEs) through 30 days following use of the Endo GIA* Reinforced Reload with Tri-…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON42234

Source
ToetsingOnline

Brief title
Reinforced Reload Study

Condition

- Gastrointestinal therapeutic procedures

Synonym
sleeve gastrectomy or gastric bypass

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Sponsor funding: COVIDIEN

Intervention

Keyword: Device, Endo GIA, Observational, Tri-Staple

Outcome measures

Primary outcome

The primary endpoint is the incidence of reported device-related adverse events

(AEs) at 30 days.

Secondary outcome

Secondary outcome measures assessed will include

> the Staple line assessment:

- Intraoperative assessments: Incidence of staple line bleeding (measured as

* 50 cc)

- Incidence of leakage (as measured by air leak test, or standard of care,

as applicable)

- Post-operative assessments:

* Duration of leakage (in days) for thoracic procedures

* Incidence of leakage for abdominal procedures

* Incidence of post-operative infection

* Additional intervention(s) to treat staple-line failure

> Incidence of repeat hospital admissions for procedural-related complications

Study description

Background summary

Staple-line failure can be a severe complication following both thoracic and abdominal surgical procedures, leading to the development of a variety of

staple line reinforcement techniques.
Postoperative air leak is the most common complication after lung resection, with a reported incidence between 4% and 58% (1-5) and up to 90% in patients with concomitant chronic obstructive pulmonary disease (COPD) and fused fissure (6). Complications of air leak include longer need for chest tube with associated pain, reduced mobility, longer hospital stay, and an increased risk for further complications (2).
In gastrointestinal surgery, the intraluminal pressures that staple lines are exposed to are not as severe as those in thoracic surgery unless there is a distal obstruction or severe ileus. For this reason, leaks are not as common in gastrointestinal resection as in thoracic resection. However, when leaks are present, the associated complications can be severe. Leak rates following laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) have been reported between 1% and 3% (7-11) with leak-associated mortality reported at 0.1% (7).
Postoperative leak is also a serious complication in pancreatic and hepatic resection. Pancreatic stump leak rates have been reported at 21% in a meta-analysis of 483 stapled pancreatic resections across 10 studies (12). Additionally, a 10-year series investigating peri-operative outcomes following pancreatic head resections reported a leakage rate of 25% to 26% (13). Bile leakage following liver resection has been reported at 2.6% to 33%, with significant postoperative morbidity and leak-related mortality at up to 39% (14, 15). Increasing complexity of liver surgery has been associated with an increased rate of bile leakage (15).Techniques to minimize leaks include running sutures/oversewing or stapling; fibrin or synthetic glue; or buttress reinforcement with biological (e.g., bovine pericardial or collagen strips) or synthetic materials (e.g., expanded polytetrafluoroethylene sleeves [ePTFE]) (16-20).
Different reinforcement techniques may provide varying degrees of efficacy (21). In addition, sutured reinforcement increases the total operative time (22) and can be very challenging when done laparoscopically. In a meta-analysis of 9991 LSG cases, leak rates were 2.1% when a buttress material was used compared to 3.2% when buttress was not used. Among buttress material options, leak rates were 2.0% when using bioabsorbable buttress materials (SeamGuard and Duet TRS) compared to 3.4% when using nonabsorbable buttress material (Peri-Strips Dry). Another meta-analysis of 88 studies (8920 patients) found that buttressing with an absorbable polymer membrane (SeamGuard) resulted in a significantly lower leak rate (1.1%), compared to oversewing with sutures (2.0%), no reinforcement (2.6%), and nonabsorbable bovine pericardial strips (3.3%) (23). In pancreatic resection, leak rates were 24% using bare metal staples and 17% using reinforced staple loads (12).
Stapler cartridges pre-loaded with buttress material may improve operating room efficiency and reduce the risk of handling errors while also providing the benefits associated with staple line reinforcement in various types of procedures such as thoracic, gastrointestinal, colorectal, and solid organ procedures (i.e. liver, pancreas).
The Endo GIA* Reinforced Reload with Tri-Staple* Technology utilizes a

pre-attached, porous, synthetic polymer buttress material during stapling and resection. This product is used in multiple therapeutic areas, including abdominal and thoracic surgery procedures for resection, transection of tissue, and creation of anastomoses.
Covidien has proposed a prospective two-arm, multicenter, post-market study to obtain data on subject outcomes following the routine clinical use of Endo GIA* Reinforced Reload with Tri-Staple* Technology (Universal Handle) in indicated procedures.

Study objective

The primary objective of this prospective, two-arm, multicenter, post-market study is to evaluate safety through the incidence of reported device-related adverse events (AEs) through 30 days following use of the Endo GIA* Reinforced Reload with Tri-Staple* Technology in subjects undergoing indicated abdominal or thoracic procedures.

Study design

This study is a prospective, two-arm, multicenter, post-market study evaluating the use of the Endo GIA* Reinforced Reload with Tri-Staple* Technology (Universal Handle) in indicated abdominal and thoracic surgery procedures (e.g., resection, transection of tissue, and creation of anastomoses).
Subjects who meet the eligibility criteria will be considered for study participation and will be followed through 30 days post-surgery.
Subjects will be evaluated at screening/baseline, during the procedure, at discharge, and at 30 days post-surgery.

Study burden and risks

9.0 Risk/Benefit Analysis
This is an observational study with the intent of collecting data on post-operative outcomes associated with the use of Endo GIA* Reinforced Reload with Tri-Staple* Technology (Universal Handle).
Subject assessment methods, procedures and follow-up visits noted in this evaluation are believed to be within the scope of contemporary medical practice, and in themselves do not compromise the rights or safety of subjects. There is a slight possibility of a breach of confidentiality. All precautions will be taken to ensure that subjects* protected health information is secured, including: (1) not using any identifying information in study records other than subject identification number; and (2) removing identifiers from all medical record information submitted to Covidien.
9.1 Anticipated Surgical Risks
Surgeons participating in this study are experienced with the known risks related to standard of care for abdominal and thoracic surgeries. Reported risks associated with the use of Endo GIA* with Tri-Staple* Technology Stapler

in abdominal and thoracic procedures include, but are not necessarily limited to: adhesions, air leak, anastomotic leakage, atelectasis, bile leak, biliary fistula, bleeding, bronchopneumonia, cardiac complications, death, gastric leak, heart failure, hematoma, infection, inflammation, intra-abdominal fluid collection, liver failure, pleural effusion, pneumothorax, pulmonary embolism, stricture, ulceration, and wound dehiscence (21, 31-42).
9.2 Potential Benefits to the Subject
The information obtained from this study will be used to evaluate outcomes from the use of the Endo GIA* Reinforced Reload with Tri-Staple* Technology (Universal Handle). This information may or may not lead to findings that could result in a reduction of complications for future patients.
9.3 Minimization of Risks
This study will be monitored to ensure the identification, documentation, and analysis of all reportable adverse events, compliance with the protocol, terms of the participating IRB/EC, and applicable local and international regulations to protect the safety and rights of all subjects are upheld. A Medical Monitor will be utilized to provide ongoing safety oversight for the study.
Moreover, Safety Review Meetings will be conducted by Clinical Affairs to review adverse events according to the safety plan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The subject must be 18-80 years of age
2. The subject must be willing and able to participate in the study procedures and to understand and sign the informed consent
3. The subject is undergoing an indicated primary abdominal or thoracic procedure where the Endo GIA* Reload with Tri-Staple* Technology device will be used per its Instructions For Use
-For Thoracic procedures, these may include, but are not limited to wedge resection and lobectomy, and may include video assisted thoracic surgery (VATS) or open procedures (not in The Netherlands)
-For Abdominal procedures, these may include, but are not limited to, laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (LRYGB), and biliopancreatic diversion, as well as hepatic and pancreatic resection
4. For thoracic subjects: the subject has a FEV1 *40% (Not in The Netherlands)

Exclusion criteria

Subjects undergoing cardiac and vascular procedures
2. The procedure is an emergency procedure
3. The procedure is a revision/reoperation for the same indication
4. Any female subject who is pregnant. Females of child-bearing potential will be required to provide either a urine pregnancy test or serum pregnancy test (except for subjects who are surgically sterile or are post-menopausal for at least two years)
6. Any subject who is considered to be part of a vulnerable population (e.g. prisoners or those without sufficient mental capacity)
7. The subject is unable or unwilling to comply with the study requirements or follow-up schedule
8. The subject has comorbidities which, in the opinion of the investigator, will not be appropriate for the study or the subject has an estimated life expectancy of less than 6 months
9. The subject has been diagnosed with a bleeding disorder and/or is undergoing active and not reversed anticoagulant treatment.
10. The subject is concurrently enrolled in another investigational drug or device research study

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	endo gia reinforced reload with tri-staple technology
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52126.100.15