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Surgical treatment of bile duct stenosis by a modified shunting of the biliary tract to the bowel with enhanced possibility to follow up and manage the shunt by the endoscope

Submission date
01/10/2011

Recruitment status
No longer recruiting

Registration date
13/10/2011

Overall study status
Completed

Last Edited
14/07/2016

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A biliary stricture is an abnormal narrowing of the common bile duct, the tube that moves bile from the liver to the small bowel. The treatment is usually surgery, where a shunt (small passage) is added between the blocked bile channels and the small bowel (hepaticojejunostomy) to overcome the narrowing. This shunt is liable for complications, especially repeated narrowing of the shunt which is a common and dangerous complication. If this occurs the treatment options include ERCP (Endoscopic Retrograde Cholangio-Pancreatography), where a bendable lighted tube (endoscope) is used to reach the shunt and widen it. Although ERCP is the best choice, the technique could be very difficult or even impossible due to the fact that the shunt has changed the anatomy of the bile channels and the small bowel in a way that makes it extremely difficult to reach the shunt site with the endoscope. Different techniques have been tried to solve this. One of these involves performing the shunt between the bile channel and the small bowel and adding a shunt between the small bowel and the stomach (bilio-entero-gastrostomy, or BEG). The aim of this study is to assess the performance of a modified surgical shunt (BEG) in the treatment of benign biliary stricture.

Who can participate?
Patients with a benign biliary stricture (i.e., not caused by a malignant tumour)

What does the study involve?
All participants undergo surgery to receive a modified surgical shunt to treat the bile channel narrowing using bilio-entero-gastrostomy (BEG). One month after the operation participants undergo an endoscopy to access and evaluate the shunt. Thereafter, they are followed for five years to detect any possible complications and treat them promptly.

What are the possible benefits and risks of participating?
The possible benefits are treatment of the problem of narrowed bile channels. If the shunt get narrowed in the future it can be treated by the endoscope without doing another risky major

surgery. The possible risks include: stomach inflammation (gastritis) caused by bile in the stomach, longer operating and anesthesia time, leakage, shunt narrowing, bile channel inflammation (cholangitis), and liver cirrhosis caused by bile obstruction.

Where is the study run from?
Assiut University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
October 2008 to December 2015

Who is funding the study?
Assiut University Hospital and The National Health Care System (Egypt)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Bilio-Entero-Gastrostomy: prospective assessment of a modified biliary reconstruction with facilitated future endoscopic access

Study objectives
1. Would this modified bilio-enteric shunt (BEG), that entails some form of gastric access loop, result in successful endoscopic access to the biliary anastomosis and hence endoscopic management of its possible future anastomotic complications?
2. Which of the three reported types of bilio-entero-gastrostomy (BEG type I, II, or III) is more efficient in adressing question number 1?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Assiut Faculty of Medicine, September 2008

Study design
Single-centre interventional study with a single arm

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Benign biliary stricture

Interventions
The trial is interventional trial with single arm. All participants will have surgical bilioenteric shunt in the form of Bilio-Entero-Gastrostomy (BEG), which is a modified bilioenteric shunt that entails some form of gastric access loop.

Surgical Details:
Under general intubation anesthesia after administration of prophylactic antibiotic in the form of third generation cephalosporin, a generous right subcostal incision was performed and could be extended on demand upward to the xyphoid process and/or to the left subcostal area. Thorough dissection and adesiolysis was performed to reach the CBD and prepare the unaffected proximal part for anastomosis. The Roux jejunal loop was prepared with lengthening of the mesentery and then passed retrocolic to reach the porta hepatis. Afterwards, BEG was constructed depending on the type; I, II or III. In all types, the hepaticojejunostomy (HJ) is end to side anastomosis using interrupted sutures of polyglactin 910 of 4-0 size. The level of HJ is dependent on Bismuth classification of the level of the stricture and also on the diameter of

CBD and the operative circumstances. If the level was at the carena (Bismuth type III), the HJ could be performed, using the Hepp-Couinaud technique, with widening of the stoma by extension through the wall of the left hepatic duct. When the two ducts constituted separate openings (Bismuth type IV), the septum in between, if applicable, could be sutured and cut to transform both ducts into single stoma. The rest of the anastomoses, including the enterogastrostomy (EG), are constructed according to the type of BEG. All JG are anastomosed to the anterior wall of the stomach as near as possible to the pyloric orifice. In BEG type I, a side loop of the Roux jejunum is anastomosed at its apex to the stomach with another side to side enteroenterostomy as a conduit of bile away from the stomach. In BEG type II, the Roux jejunum is transected about 10 to 15 cm from HJ without interference with its mesentery. The distal end is anastomosed to the stomach, while the proximal end is anastomosed to the side of the distal loop as a conduit of bile. In BEG type III, HJ is constructed leaving the distal end of the Roux jejunum long enough to be anastomosed to the side of the stomach. All the enterogastrostomies and enteroenterostomies were in the form of single-layer continuous sutures of polyglactin 910 of 3-0 size. An intraperitoneal drain was left in the hepatorenal pouch before closing the incision.

In the fourth postoperative week, endoscopic assessment of the BEG shunt with evaluation of the HJ was scheduled for all patients.

Endoscopic Technique:
Within the 4th postoperative week, gastroenteroscopy was performed using end-view gastroduodenoscope (pentax 3440, Tokyo, Japan). The aim was to assess the feasibility to access the HJ stoma and perform cholangiography. With the patient in the left lateral position, monitored anesthesia care (MAC) sedation with propofol was used with an initiation dose of 100-150 mcg/kg/min for a period of 3-5 minutes and a maintenance dose of 25-75 mcg/kg/min which was adjusted to clinical response. The endoscope was introduced through the oesophagus to the stomach where we assessed the amount of bile in the stomach on a scale of 0 to 2 where 0 meant no bile, 1 meant minimal amount of bile staining the gastric mucosa, and 2 meant large amount of bile accumulating and needed to be sucked out. The gastroenterostomy stoma was assessed as regard to its site, diameter, as well as the difficulties we faced to pass through it. We passed through the gastroenterostomy either directly with the scope or over a guiding catheter. Thereafter, when we reached the HJ stoma, we inject a diluted dye into the cannulated bile ducts using an ERCP catheter to obtain cholangiography. Time to reach the gastroenterostomy as well as time to reach the HJ was reported for each case. Failure of endoscopic access was defined as failure to reach the HJ and perform cholangiography. For failed cases, the cause of failure and the type of BEG performed were reported. After the end of each procedure, the endoscopist was asked to score the difficulty of it on a scale from 1 to 5 where 1 is the easiest and 5 is the most difficult.

The total duration of treatment for the preliminary report was 24 months. At the end of the trial, the total duration of treatment will be 5 years.

The follow up period for the preliminary report was 6-30 months. At the end of the trial, the follow up will range from 1-6 years.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Successful endoscopic access to the bilioenteric anastomosis in the fourth postoperative week with cholangiography performance.

Secondary outcome measures
1. Duration of the endoscopic procedure in minutes
2. Difficulty score to the endoscopist (score from 1-5)
3. Amount of bile in the stomach (score 0, 1, 2)
4. Efficiency of endoscopic management of biliary anastomotic stricture if encountered during follow up

Overall study start date
01/10/2008

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients suffering from benign biliary stricture
2. Patients indicated for surgical intervention in the form of bilioenteric shunt

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The total target number of participant is 50-60 patients at the end of the trial. A preliminary report of the results is intended after performing 15-20 cases.

Key exclusion criteria
1. Patients who were discovered intraoperatively or postoperatively to have malignant cause of the biliary stricture
2. Patients who died postoperatively due to non-surgical causes before performing the follow up endoscopy

Date of first enrolment
01/10/2008

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Egypt

Study participating centre
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Funder type
Hospital/treatment centre

Funder Name
Faculty of Medicine, Assiut University Hospitals, Assiut (Egypt)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration