NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis

Acute calculous cholecystitis happens when a gallstone blocks an opening (the cystic duct) that drains fluid (bile) from the gallbladder. Bile builds up in the gallbladder causing pain, nausea, vomiting and fever. In this procedure, a stent is inserted into or across the cystic duct, through the catheter that was inserted into the gallbladder through the skin (percutaneous cholecystostomy) to relieve the acute cholecystitis. The aim is to allow bile to flow through the tube, bypassing the blockage and preventing further obstruction.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in April 2021 and updated in November 2021.

Procedure name

- Percutaneous insertion of a cystic duct stent for acute calculous cholecystitis

Professional societies

- Association of Upper Gastrointestinal Surgery of Great Britain and Ireland
- British Society of Gastroenterology
- British Society of Interventional Radiology
- British Association for the Study of the Liver
- Royal College of Radiologists.

Description of the procedure

Indications and current treatment

Acute calculous cholecystitis is inflammation of the gallbladder caused by a gallstone or biliary sludge that blocks the cystic duct. The blockage in the cystic duct causes bile to build up in the gallbladder, increasing the pressure inside it and causing it to become inflamed. Symptoms include pain, fever, nausea and vomiting.

Treatments include intravenous fluids, medicines (analgesics and antibiotics), endoscopic or percutaneous biliary drainage, and surgery (laparoscopic or open cholecystectomy). NICE's guideline on gallstone disease recommends offering

early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to patients with acute cholecystitis.

What the procedure involves

This procedure places a stent via a cholecystostomy tract into the cystic duct to provide antegrade gallbladder drainage and prevent further obstructive episodes of cholecystitis. This procedure is suitable for patients who otherwise need long-term external drainage.

Before the procedure, a percutaneous cholecystostomy and drainage is done to resolve the acute episode. This procedure is usually done using conscious sedation. The cholecystostomy drain is used for cholangiography to confirm cystic duct obstruction. Under fluoroscopic guidance, a guidewire and catheter are passed through the cholecystostomy tract, through the cystic duct and into the duodenum. A stent is then inserted and placed in or across the cystic duct.

After the procedure, an external gallbladder drain is usually left in situ for a few days to ensure that there is good antegrade drainage of bile into the duodenum. The external drain can then be removed after a satisfactory cholangiogram.

Efficacy summary

Technical success

In a case series of 33 patients with an acute presentation of stone disease (acute cholecystitis, n=21; gallbladder perforation, n=10; necrotising pancreatitis, n=1; acute cholangitis, n=1), the rate of technical success (successful insertion) was 91% (30/33; Hersey 2015). For the 21 patients with acute calculous cholecystitis, technical success was reported in 90% of patients (19/21).

In a case series of 5 patients with cholecystitis (acute cholecystitis, n=4 [calculous cholecystitis and concomitant advanced oesophageal carcinoma, n=1; malignant biliary obstruction, n=3]; chronic calculous cholecystitis, n=1), the rate of technical success was 100%, with complete resolution of gallbladder symptoms, correction of serum inflammatory markers and normalisation of ultrasound appearances (Brown 2015).

Symptom relief

In the case series of 33 patients, for the 21 patients with acute calculous cholecystitis, 15 patients became well (well without subsequent cholecystectomy,

n=10; well after additional treatment, n=4; well after recurrent cholecystitis, n=1) at a median follow up of 11.6 months (Hersey 2015).

In the case series of 5 patients, the 1 patient with acute calculous cholecystitis (and concomitant advanced oesophageal carcinoma) remained symptom-free for 5 months after the procedure, indicating ongoing stent patency (Brown 2015).

In a case report of a patient with acute calculous cholecystitis, the patient remained asymptomatic for 3 months after percutaneous cystic duct stenting, adjacent to the pre-existing common duct stent which was inserted for jaundice secondary to a cholangiocarcinoma of the distal common bile duct (Comin 2010).

In a case report of a patient with acute calculous cholecystitis, the patient remained asymptomatic for 18 months after discharge from percutaneous cholecystoduodenal stenting (a metal stent in the cystic duct and another mental stent from the mid-cystic duct through the ampulla of Vater into the duodenum; Bonner 2018).

Recurrent cholecystitis

In the case series of 33 patients, 1 patient with acute calculous cholecystitis had recurrent cholecystitis at 6 weeks postprocedure (Hersey 2015). This recurrence was because of the absence of the stent, which was presumed to have passed per rectum.

In the single case report, the patient represented symptoms of acute cholecystitis at 3 months postprocedure, which was treated by another percutaneous cholecystostomy (Comin 2010). A subsequent cholecystogram showed patency of the cystic duct stent, and free communication between the cystic duct and common bile duct stents through their interstices. This recurrence was presumed to be a result of the heavy stone burden, in spite of maintenance of cystic duct patency. The patient was discharged with the cholecystostomy drain in situ.

Safety summary

Stent migration was described in 2 patients with acute calculous cholecystitis at a median follow up of 11.6 months in the case series of 33 patients (Hersey 2015).

Abdominal wall collection was reported in 1 patient with acute calculous cholecystitis in the case series of 33 patients (Hersey 2015). This event was caused by a no covering external cholecystostomy drain being left in situ for a short post procedural period.

Acute small bowel obstruction was reported in 1 patient with acute calculous cholecystitis at 13 months after the procedure in the case series of 33 patients (Hersey 2015). This obstruction was caused by gallstone ileus with stent migration. Laparotomy was done for gallstone ileus and this event subsequently resolved.

Pericholecystic abscess was reported in 1 patient at 3 months after the procedure in a case series of 8 patients with acute calculous cholecystitis (Franklin 2021). This patient needed drain placement and subsequent open cholecystectomy despite pulmonary hypertension.

Recurrent pain was described in 1 patient at 11 days after the procedure in the case series of 8 patients (Franklin 2021). This patient needed new percutaneous cholecystostomy tube placement, ultimately having laparoscopic partial cholecystectomy despite advanced age and known peritoneal adhesions.

Fever was described in a patient with acute calculous cholecystitis in the case report (Bonner 2018). This event was likely because of haematogenous septic showering from the stent insertion procedure and minor leakage from the cholecystostomy. The patient experienced this ongoing fever for 48 hours. She then became afebrile and pain resolved, along with normalisation of inflammatory markers and white cell count.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, professional experts listed the following anecdotal and theoretical adverse events: biliary sepsis, biliary leak, soft tissue collections, failure of procedure, and dislodgement of the external cholecystostomy drain.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis. The following databases were searched, covering the period from their start to 9 November 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature

search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with acute calculous cholecystitis who otherwise need long-term external drainage.
Intervention/test	Percutaneous insertion of a cystic duct stent after cholecystostomy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 48 patients (of these, 32 patients had acute calculous cholecystitis) from 3 case series (including 1 abstract reporting safety events) (Brown 2015; Franklin 2021; Hersey 2015) and 2 case reports (Bonner 2018; Comin 2010).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on percutaneous insertion of a cystic duct stent for acute calculous cholecystitis

Study 1 Hersey N (2015)

Study details

Study type	Case series
Country	UK
Recruitment period	2008 to 2013
Study population and number	n=33 (acute cholecystitis, n=21; gallbladder perforation, n=10; necrotising pancreatitis, n=1; acute cholangitis, n=1) Patients with an acute presentation of stone disease
Age and sex	Median 75 years (range 43 to 96); 45% (15/33) female
Patient selection criteria	Inclusion criteria: patients with an acute presentation of stone disease who were unfit for surgery were considered for cystic duct stent insertion.
Technique	The initial stage was to insert a percutaneous cholecystostomy under ultrasound guidance via either a transhepatic or transperitoneal route. A double-pigtail stent (Renal transplantation ureteral stent [OptiSoft] 8Fr 12 cm, Optimed) was then inserted percutaneously and the 2 pigtail ends were positioned in the gallbladder and the duodenum, respectively. A covering external nonlocking gallbladder drain was left in situ. A cholangiogram was done 48 to 72 hours after the procedure. If there was good flow and drainage internally, the external gallbladder drain was removed.
Follow-up	Median 11.6 months (range 1 to 76)
Conflict of interest/source of funding	None

Analysis

Study design issues: This case series presented the role of cystic duct stents in managing benign gallbladder disease in those patients unfit for surgery. The outcomes included technical success (defined as successful insertion of a cystic duct stent) and complications.

Study population issues: The route of percutaneous cholecystostomy puncture was transhepatic in 29 patients and transperitoneal in 4 patients. The median interval between cholecystostomy and cystic duct stent insertion was 9 days (range 0 to 180 days). For the 21 patients with acute cholecystitis, the transhepatic route was done in 19 patients and the transperitoneal route in 2 patients.

Key efficacy findings

Number of patients analysed: 33 (acute calculous cholecystitis, n=21)

Technical success rate: 91% (n=30)

Technical failure: n=3

- Extremely tortuous cystic duct: n=2
- Stricture of the common bile duct secondary to pancreatitis: n=1

Outcomes at a median follow up of 11.6 months (n=30)

- Stent remained in situ: 73% (n=22)
- Well enough to have subsequent cholecystectomy: 20% (n=6; including acute cholecystitis, n=3; gallbladder perforation, n=2; necrotizing pancreatitis, n=1)
- Stent migration: 7% (n=2 patients with acute cholecystitis)

Outcomes after insertion for acute cholecystitis (n=21)

- Technical success: n=19
- Technical failure because of extremely tortuous cystic duct: n=2 (1 patient died of biliary sepsis 12 days following attempted stent insertion and the other died 8 months later of metastatic gastric carcinoma)
- Final outcomes:
    - Well without subsequent cholecystectomy: n=10
    - Death: n=6 (metastatic cancer colon, n=2; biliary sepsis, n=1; posterior inferior cerebellar artery infarct, n=1; metastatic gastric carcinoma, n=1; unknown [reason not reported], n=1)
    - Well after additional treatment:
        - Laparoscopic cholecystectomy for porcelain gallbladder, n=1
        - Laparotomy for gallstone ileus, n=1
        - Laparoscopic cholecystectomy, n=2
    - Recurrent cholecystitis and then becoming well: n=1

Key safety findings

Complications: n=3 patients with acute cholecystitis

- Abdominal wall collection because of no covering external drain: n=1
- Recurrent cholecystitis at 6 weeks because of stent passed per rectum: n=1
- Acute small bowel obstruction at 13 months because of gallstone ileus with stent migration: n=1

Study 2 Brown N (2015)

Study details

Study type	Case series
Country	Australia
Recruitment period	Not reported
Study population and number	n=5 (acute cholecystitis, n=4 [calculous cholecystitis and concomitant advanced oesophageal carcinoma, n=1; malignant biliary obstruction, n=3]; chronic calculous cholecystitis, n=1) Patients with cholecystitis
Age and sex	Mean 64 years; 40% (2/5) female
Patient selection criteria	Not reported
Technique	Technique included ultrasound-guided cholecystostomies for draining cholecystitis, removing gallstones, traversing and straightening the cystic duct, and placing metallic stents across the cystic duct. Self-expanding, uncovered nitinol or steel stents ranging in size from 6 to 10 mm in diameter and 40 to 100 mm in length (Pulsar 18 and Astron Pulsar [Biotronik, Berlin, Germany] or Wallstent [Boston Scientific]) were deployed in all patients. Stents were positioned from the gallbladder neck, along the cystic duct, through the ampulla of Vater, and into the D2 segment of duodenum. Stents were placed across the ampulla to reduce the risk of further blockage by biliary debris at the distal common bile duct. Precautionary external drains were then inserted into the gallbladder to allow confirmation of stent patency and antegrade gallbladder drainage by checking cholecystograms at 1 to 7 days after the procedure.
Follow-up	3 to 22 months
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Of the 5 patients, 4 patients were followed up ranging from 3 to 22 months and 1 died from nonhepatobiliary complications of malignancy 4 weeks after cystic duct stent placement.

Study design issues: This case series presented a series of 5 patients unsuitable for surgery who had nonretrievable self-expanding metallic stents deployed along the cystic duct as treatment for acute and chronic cholecystitis.

Key efficacy findings

Number of patients analysed: 5 (acute calculous cholecystitis, n=1)

IP overview: Percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis

Time between presentation and insertion of cystic duct stents: range 2 to 8 weeks

Technical success with complete resolution of gallbladder symptoms, correction of serum inflammatory markers and normalization of US appearances: 100%

Patients' characteristics and clinical outcomes

Age (year), sex	Acuity	Aetiology of cystic duct obstruction	Other clinical details	Gallstones	Gallstones removed/crushed	CBD stent in situ	Cystic duct stent positioning	Follow-up stent patency
57, male	Acute gallbladder empyema	Malignant biliary obstruction	Pancreatic carcinoma	No	NA	Yes	Through interstices of CBD stent wall; proximal end of stent positioned inside gallbladder distal end landed inside CBD	4 weeks (unrelated death from advanced malignancy)
71, female	Acute	Malignant biliary obstruction	Pancreatic carcinoma	No	NA	Yes	In parallel with CBD stent; from gallbladder to duodenum	22 months symptom-free; no complications
62, male	Chronic	Benign impacted calculous cholecystitis	CBD calculi; viral cirrhosis, renal failure after nephrectomy, cardiac failure	Yes	Yes	No	From gallbladder to duodenum	6 months symptom-free; fungemia and pain, resolved completely after treatment
64, male	Acute gallbladder rupture	Benign calculous cholecystitis	Advanced oesophageal carcinoma	Yes	Yes	No	From gallbladder to duodenum	5 months symptom-free; no complications
66, female	Acute	Malignant biliary obstruction with CBD stent	Metastatic cholangiocarcinoma	Yes	No	Yes	Parallel deployment alongside existing CBD stent; stent	3 months symptom-free; recurrent pain from

		and calculous cholecystitis					placed from gallbladder to duodenum	untreated cholelithiasis; stent patency confirmed on cholecystogram

CBD, common bile duct; NA, not applicable.

Procedural pain was minimal, and postprocedural symptoms were controlled with low-dose oral opioid agents and intravenous metoclopramide.

Drainage catheters were removed and cholecystostomy tracts closed by secondary intention without complication.

Stent patency: Follow-up ranged between 3 and 22 months, with ongoing stent patency inferred from a lack of recurrent gallbladder symptoms.

Key safety findings

No procedural complications and stent failures.

Study 3 Comin JM (2010)

Study details

Study type	Case report
Country	Australia
Recruitment period	Not reported
Study population and number	n=1 patient with acute cholecystitis
Age and sex	66 years; female
Patient selection criteria	Not reported
Technique	After removing the cholecystostomy drain, a biliary Wallstent (Boston Scientific, Natick, Massachusetts, USA) was deployed from the gallbladder neck, through the cystic duct and through the common bile duct into the duodenum, adjacent to the pre-existing common duct stent. A drainage catheter was replaced in the gallbladder. A cholecystogram the following day showed passage of contrast into the duodenum. The drain was removed and a gauze dressing applied. The patient was discharged the following day.
Follow-up	3 months
Conflict of interest/source of funding	None

Analysis

Study design issues: This case report described the technique used for percutaneous cystic duct stenting in a patient and its effectiveness.

Study population issues: Previous treatments included endoscopic stenting (Wallstent) for jaundice because of a cholangiocarcinoma of the distal common bile duct (multiple hepatic metastases were also noted) and percutaneous drainage with the catheter in situ for acute cholecystitis. Contrast studies, done at 1 month post drainage catheter insertion, showed persistent obstruction of the gallbladder neck by a large calculus. Given the patient's discomfort from the drain and her unsuitability for surgery, a decision was made to attempt percutaneous stenting of the cystic duct.

Key efficacy findings

Number of patients analysed: 1

The patient remained asymptomatic for 3 months postprocedure before re-presenting with symptoms of acute cholecystitis. Another percutaneous cholecystostomy was done. A subsequent cholecystogram demonstrated patency of the cystic duct stent, and the cystic duct and common bile duct stents were shown to communicate with each other freely through their interstices. It was presumed that the development of cholecystitis was a

result of the heavy stone burden, in spite of maintenance of cystic duct patency. The patient was discharged with the cholecystostomy drain in situ.

Key safety findings

Not reported.

Study 4 Bonner BC (2018)

Study details

Study type	Case report
Country	Australia
Recruitment period	Not reported
Study population and number	n=1 patient with acute calculous cholecystitis
Age and sex	84 years; female
Patient selection criteria	Not reported
Technique	A cholecystogram was done to guide insertion of a catheter and wire to cannulate the cystic duct under fluoroscopic guidance. A balloon was used to remove obstructing stones. A 6 × 60 mm bare metal stent was inserted into the cystic duct, and an 8 × 100 mm bare metal stent was inserted from the mid-cystic duct through the ampulla of Vater into the duodenum. An 8-French cholecystostomy drain was capped and left in situ. A cholecystogram the next day showed that the stents remained patent with prompt antegrade drainage of contrast, and the cholecystostomy drain was removed.
Follow-up	18 months
Conflict of interest/source of funding	None

Analysis

Follow-up issues: The patient was followed up at 2 weeks, 3 months, 6 months, 11 months and 18 months after discharge.

Study design issues: This case report described describe percutaneous cholecystoduodenal stenting following cystic duct stone disimpaction and removal. The procedure aimed at preserving the patency of the cystic duct to prevent recurrent obstructive cholecystitis.

Study population issues: The patient had multiple comorbidities. For acute calculous cholecystitis, conservative treatment with intravenous antibiotics was initially successful. However, she subsequently re-presented with an empyema of the gallbladder. She was readmitted for further intravenous antibiotics and had percutaneous gallbladder drainage. She did not want a permanent catheter for drainage, nor the prospect of repeat drainage procedures in the future for recurrent cholecystitis. She finally decided to have cholecystoduodenal stent placement following disimpaction and removal of cystic duct stones.

Key efficacy findings

Number of patients analysed: 1

A postoperative CT scan confirmed appropriate positioning and sizing of the metallic stents and revealed a collapsed gallbladder with no discrete collection.

The patient was discharged on day 22 from admission. She was followed up at 2 weeks, 3 months, 6 months, 11 months, and 18 months after discharge and remained asymptomatic.

Key safety findings

The patient experienced ongoing fevers for 48 hours, likely because of haematogenous septic showering from the stent insertion procedure and minor leakage from the cholecystostomy. She became afebrile and her pain resolved, along with normalization of her inflammatory markers and white cell count.

Study 5 Franklin A (2021)

Study details

Study type	Case series (abstract)
Country	Not reported
Recruitment period	Not reported
Study population and number	n=8 Patients with acute calculous cholecystitis
Age and sex	Median 70 years; 75% (6/8) female
Patient selection criteria	Not reported
Technique	Cholecystoduodenal stenting placement was done with a single 6-8 French double-pigtail stent via the pre-existing cholecystostomy tract, extending from the gallbladder lumen to the duodenum
Follow-up	At least 3 months
Conflict of interest/source of funding	Not reported

Analysis

Study design issues: This study evaluated the safety, feasibility and outcomes of internal cholecystoduodenal stenting. Relevant laboratory values were trended at follow-up.

Study population issues: Patients initially had percutaneous cholecystostomy tubes for acute calculous cholecystitis and were deemed non-operable after surgical evaluation.

Key efficacy and safety findings

Number of patients analysed: 8

No immediate complications.

Recurrent pain: n=1 at 11 days after cholecystoduodenal stenting. This patient needed new percutaneous cholecystostomy tube placement, ultimately having laparoscopic partial cholecystectomy despite advanced age and known peritoneal adhesions.

Pericholecystic abscess: n=1 at 3 months needing drain placement and subsequent open cholecystectomy despite pulmonary hypertension.

Validity and generalisability of the studies

- When reported, 1 study was carried out in the UK and 3 in Australia.
- Patients were followed up ranging from 1 to 76 months.
- A total of 48 patients were included, and of these, 67% (32/48) had acute calculous cholecystitis and 52% (25/48) were female.
- There was more than 1 device used for this procedure.
- All patients had comorbidities and most were unsuitable for surgery.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Single-incision laparoscopic cholecystectomy. NICE interventional procedures guidance 508 (2014). Available from https://www.nice.org.uk/guidance/ipg508

NICE guidelines

- Gallstone disease: diagnosis and management. NICE clinical guideline 188 (2014). Available from https://www.nice.org.uk/guidance/cg188

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public

consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaires for percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE a completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

References

1. Hersey N, Goode SD, Peck RJ et al. (2015) Stenting of the cystic duct in benign disease: a definitive treatment for the elderly and unwell. Cardiovascular and interventional radiology 38(4): 964-70
2. Brown NI, Jhamb A, Brooks DM et al. (2015) Percutaneous placement of permanent metallic stents in the cystic duct to treat obstructive cholecystitis. Journal of vascular and interventional radiology: JVIR 26(12): 1860-5
3. Comin JM, Cade RJ and Little AF (2010) Percutaneous cystic duct stent placement in the treatment of acute cholecystitis. Journal of medical imaging and radiation oncology 54(5): 457-61
4. Bonner BC, Brown NI, Joseph VP et al. (2018) Cholecystoduodenal stenting: an option in complicated acute calculous cholecystitis in the elderly comorbid patient. Case reports in surgery. Doi:10.1155/2018/1609601
5. Franklin A, Odu A, Quadri R et al. (2021) Cystic duct stenting via percutaneous cholecystostomy in non-operative calculous cholecystitis. Journal of Vascular and Interventional Radiology 32: 76-s77

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	09/11/2021	Issue 10 of 12, October 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	09/11/2021	Issue 10 of 12, October 2021
International HTA database (INAHTA)	09/11/2021	-
MEDLINE (Ovid)	09/11/2021	1946 to November 08, 2021
MEDLINE In-Process (Ovid)	09/11/2021	1946 to November 08, 2021
MEDLINE Epubs ahead of print (Ovid)	09/11/2021	November 08, 2021
EMBASE (Ovid)	09/11/2021	1974 to 2021 November 08
EMBASE Conference (Ovid)	09/11/2021	1974 to 2021 November 08

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	exp Cholecystitis/
2	cholecystitis.tw.
3	((gallbladder or gall bladder) adj4 (inflam* or empyema or infect* or irritat*)).tw.

4	biliary tract/ or bile ducts/ or cystic duct/ or gallbladder/
5	(obstruct* or block* or stenos* or stoppage* or narrow* or imped*).tw.
6	4 and 5
7	((Biliary or "Bile duct*" or gallbladder or gall bladder or "cystic duct*") adj4 (obstruct* or block* or stenos* or stoppage* or narrow* or imped*)).tw.
8	1 or 2 or 3 or 6 or 7
9	Cystic Duct/ and Stents/
10	(("cystic duct*" or Cholecystoduodenal or percutan*) adj4 (stent* or tube* or tubular*)).tw.
11	("biliary endoprosthes*" or (endoscop* adj4 biliar* adj4 prosthes*)).tw.
12	or/9-11
13	8 and 12
14	(gastrosoft or "Archimedes stent*" or (archimedes and stent*)).tw.
15	13 or 14
16	animals/ not humans/
17	15 not 16

Appendix

There were no additional papers identified.