Flushing of internalized percutaneous transhepatic biliary drainage catheters

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To compare the median time-to-symptom-onset in patients with an internal external PTBD catheter without daily flushing compared to median time-to-symptom-onset in patients with an internal external PTBD catheter who daily flush the catheter.Symptoms...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON54445

Source
ToetsingOnline

Brief title
Flush study

Condition

- Hepatic and hepatobiliary disorders

Synonym
biliary obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: drainage catheter, Flushing, percutaneous, transhepatic

Outcome measures

Primary outcome

Median time-to-symptom-onset in patients with an internal external PTBD

catheter without daily flushing compared to patients with an internal external

PTBD catheter who daily flush the catheter

Secondary outcome

- Comparison of the number of re-interventions

- Comparison of the events of cholangitis

- Comparison of the decrease in bilirubin

- Comparison of the quality of life

- Comparison of the cost-effectiveness

- Comparison of the mortality rate

- Comparison of the number of catheter complications

- Therapy adherence

Study description

Background summary

Bile is synthesized and secreted by the liver and transported into the peripheral bile ducts, to the left or right hepatic duct which join together in the common hepatic duct and more distally in the common bile duct. Secreted bile is stored in the gall bladder. During a meal, the bile is secreted into the duodenum.
Obstruction of the biliary tract will result in cholestasis with symptoms as jaundice and pruritus and cholangitis in case of infection, usually related to prior biliary intervention. Causes of biliary obstruction are benign or

malignant.

Percutaneous transhepatic biliary drainage (PTBD) is a drainage method for biliary obstruction. The procedure starts with percutaneous puncture under fluoroscopic or ultrasound guidance and cannulation of the peripheral biliary tree, which is confirmed by contrast injection in the biliary tree. The needle will be exchanged for a guidewire which can be advanced into the biliary tract. When the correct position is reached, a drainage catheter with side holes is placed.

There are two types of PTBD techniques: placement of an external biliary drain and placement of an internal external biliary drain. The external biliary drain is positioned in the bile duct above a stenosis and drains the bile externally into a bag outside the patient. Capping of an external biliary drain will stop the drainage of bile into the bag and forces the bile to drain towards the digestive tract. The internal external biliary drain is placed in the bile duct and the tip of the internal external biliary drain is localised in the duodenum allowing both bile flow through the drain to the digestive tract (internal) or into the bag (external). Capping of an internal external biliary drain will stop the external drainage and results in internal drainage only.

Complications of PTBD are bleeding (usually during or shortly after the procedure), infection (cholangitis, abscess, peritonitis, cholecystitis, pancreatitis), catheter obstruction and catheter dislocation. Catheter obstruction will result in cholestasis resulting in jaundice, drain leakage and finally cholangitis. The exact prevalence of PTBD catheter obstruction is not described in literature, however the prevalence of cholangitis in patients with a PTBD catheter is reported as high as 59%. Subsequently, the PTBD catheter often needs a revision (re-intervention), i.e. exchanging the catheter for a new one. If catheter obstruction is assessed during re-intervention, attempts can be made to remove the obstruction or the obstructed PTBD catheter can be exchanged for a new PTBD catheter.

After PTBD catheter placement, flushing of the PTBD catheter is not standard protocol in our center. In clinical practice, when obstruction of PTBD catheter occurs, we advise patients to start with daily flushing of the PTBD catheter which we believe will decrease the extent of obstruction and omits re-intervention. We performed a literature search and we did not find any clinical trial on the efficacy of flushing of PTBD catheters. Guidelines of the Society of Interventional Radiology on percutaneous biliary drainage do not mention flushing of the catheter. We did find some publications in which an advice with regard to flushing of a PTBD catheter was mentioned, however without any scientific substantiation.

There is no scientific evidence for or against PTBD catheter flushing. Flushing is a simple, low-cost and low-risk procedure. Complications or side-effects of PTBD catheter flushing are not reported in literature. PTBD re-interventions on

the other hand are associated with risks and are invalidating for the patient. We hypothesize that daily flushing of an internal external biliary catheter will increase the median time-to-symptom-onset requiring hospital visits and re-interventions in this patient group.

Study objective

To compare the median time-to-symptom-onset in patients with an internal external PTBD catheter without daily flushing compared to median time-to-symptom-onset in patients with an internal external PTBD catheter who daily flush the catheter.

Symptoms of catheter obstruction is defined as:
- signs of cholestasis defined as: rising bilirubin level and/or increase in catheter localized pain and/or leakage of bile along the catheter and/or resistance while flushing the catheter
- and/or signs of cholangitis defined as: elevation in temperature more than 38.5°C thought to have a biliary cause

Study design

Non-blinded randomized controlled trial with 1:1 allocation.

Intervention

- Intervention group: flushing of internal external PTBD catheter 3 times a day.
- Control group: no flushing of PTBD catheter.

Study burden and risks

The potential value of this study is that flushing of an internal external PTBD catheter may result in a longer symptom free period for the patient.

Flushing of the catheter is a low-risk procedure, complications or side-effects are not reported in literature. Flushing is currently not standard of care.

When obstruction of a PTBD catheter occurs, treating physicians often advise patients to start with daily flushing of the PTBD catheter.

Participants in this study need to fill in questionnaires on quality of life and study procedures at baseline, 3 weeks and 6 weeks after randomization. This study requires no extra site visits.

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

- Patient with obstruction of the bile duct(s) planned for internal external PTBD;
- Proficient in Dutch language;
- Written informed consent.

Exclusion criteria

- Age < 18 years;
- No informed consent;
- Pregnancy;
- Obstruction caused by gall stones;

- External PTBD catheter (without internalization);
- Patient has already a PTBD catheter;
- More than 1 PTBD catheter is placed at intervention.
- If the patient is non-communicative.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-06-2022
Enrollment:	91
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-10-2024

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL77857.078.21