Needle-knife fistulotomy (NKF) for primary biliary access in patients with choledocholithiasis; a *real world* prospective multicenter pilot study

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To explore the safety and efficacy of NKF as the primary cannulation technique in patients with an indication for sphincterotomy in tertiary as well as teaching centers after standardized training on an ex-vivo ERCP model.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bile duct disorders
Study type	Interventional

Summary

ID

NL-OMON56974

Source
ToetsingOnline

Brief title
INCISION

Condition

- Bile duct disorders

Synonym
choledocholithiasis, gallstones

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biliary cannulation, Choledocholithiasis, ERCP, Fistulotomy

Outcome measures

Primary outcome

The primary outcome is safety and feasibility of NKF. Feasibility is defined as successful biliary cannulation via the fistulotomy. Safety is defined as absence of ERCP related complications (perforation, bleeding, post ERCP pancreatitis).

Secondary outcome

Secondary outcomes will include:

- Individual components of the primary endpoint
- Clinical success
- Successful CBD stone removal
- PD cannulation/contrast injection
- Time from first contact with the papilla until successful cannulation
- Total cannulation time and total procedure time
- Other ERCP-related adverse events, such as cholangitis, cholecystitis and abscess within 30 days
- Mortality within 30 days
- Objective structured assessment of technical skills (OSATS)
- Association between OSATS based graded performance on ex vivo model and learning curve (as measured by procedural time and outcome) in patients

Study description

Background summary

Selective biliary cannulation is an essential first step in a successful endoscopic retrograde cholangiopancreatography (ERCP). However, conventional cannulation techniques fail in 5%-20% of cases.(1, 2) Difficult biliary access leads to repeated cannulation attempts, mechanical injury to the papilla and/or pancreatic duct cannulation.(3) Previous studies have reported that these actions might facilitate the most common procedure-related adverse event, post-ERCP pancreatitis (PEP). (4, 5)
In the last decades, various rescue methods have been developed to overcome the issue of difficult biliary cannulation, such as precut sphincterotomy and Needle-Knife Fistulotomy (NKF). As opposed to precut sphincterotomy, NKF requires an incision a few millimetres above the papillary orifice without trauma to the papilla.
Although NKF was initially developed as a rescue technique, it could reduce PEP rates to zero if it would be used as primary biliary cannulation technique instead of the standard technique. There is now considerable evidence to support this hypothesis, with multiple RCTs showing low PEP rates (0 - 2.0%).(5-7) Despite these encouraging results in tertiary care centres, NKF as primary technique has not been implemented in daily clinical practice. This is probably due to lack of experience of this rescue technique and thereby not feeling comfortable using it.

Study objective

To explore the safety and efficacy of NKF as the primary cannulation technique in patients with an indication for sphincterotomy in tertiary as well as teaching centers after standardized training on an ex-vivo ERCP model.

Study design

Prospective, multicenter, single-arm, interventional pilot study.

Intervention

needle-knife fistulotomy as primary cannulation technique after hands-on training on an ex-vivo ERCP model provided by the researchers.

Study burden and risks

Because this technique requires an incision above the papilla, direct contact with the pancreatic duct is avoided, reducing the risk of post-ERCP pancreatitis. Apart from this alternative method of primary biliary

cannulation, they receive standard care.

Contacts

Public
Amsterdam UMC

Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Amsterdam UMC

Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with an indication for ERCP with sphincterotomy (e.g. choledocholithiasis)
- Sedation with administration of propofol or general anesthesia during ERCP
- Naive papilla
- Capable of written informed consent
- Age >= 18 years

Exclusion criteria

- Low risk of pancreatitis: (1) definite chronic pancreatitis according to M-ANNHEIM criteria
(15), (2) previous sphincterotomy, and (3) routine biliary stent exchange. In case of a pancreatic duct intervention, chronic pancreatitis and previous sphincterotomy are not exclusion criteria
- Acute pancreatitis, according to the Atlanta classification
- Altered anatomy (defined as anatomical variations in which bile and/or pancreatic secretions (in case of pancreatic duct interventions) do not enter the duodenum by way of the ampulla of Vater (e.g., Roux-en-Y reconstruction, surgery for chronic pancreatitis)
- Pregnancy
- Severe liver disease (ascites)
- Contraindications for rectal NSAIDs, including allergy, active gastrointestinal bleeding, ulcer disease, renal insufficiency (glomerular filtration rate < 30 mL/min) and NSAID use for other indications (other than cardioprotective aspirin)
- Coagulopathy or anticoagulant use, except for antiplatelet monotherapy
- Type I (flat papilla without oral protrusion) and type IIIA (papillary orifice inside the diverticulum) according to the Viana classification (18), and all others without an intraduodenal segment
- Active cholangitis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL86953.018.24