Difficult Stone Management

Palle Nordblad Schmidt
Dept. of Gastroenterology and GI Surgery,
Copenhagen University Hospital Hvidovre,
Denmark

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CONFIDENTIAL 秘

Agenda

- Definition – difficult stones
- Endoscopic Papillary Large Balloon Dilatation (EPLBD)
- Endoscopic Lithotripsy
  - Mechanical (fluoroscopic guidance)
  - Electrohydraulic or laser (cholangioscopic guidance)
- Extracorporeal Lithotripsy (ESWL)

Difficult stones - definition

- Large stones (> 15 mm)
- Squared or barrel shaped stones
- Multiple stones
- Localization of stones (intrahepatic, cystic duct)
- Disproportion between stone and distal CBD (incl. biliary stricture with stone upstream)

ENDOSCOPIC PAPILLARY LARGE BALLOON DILATION (EPLBD)

(= SPHINCTEROPLASTY)

Definitions

- **Endoscopic Papillary Balloon Dilation (EPBD): Max. 10 mm**
- **Endoscopic Papillary Large Balloon Dilatation (EPLBD): 12-20 mm**

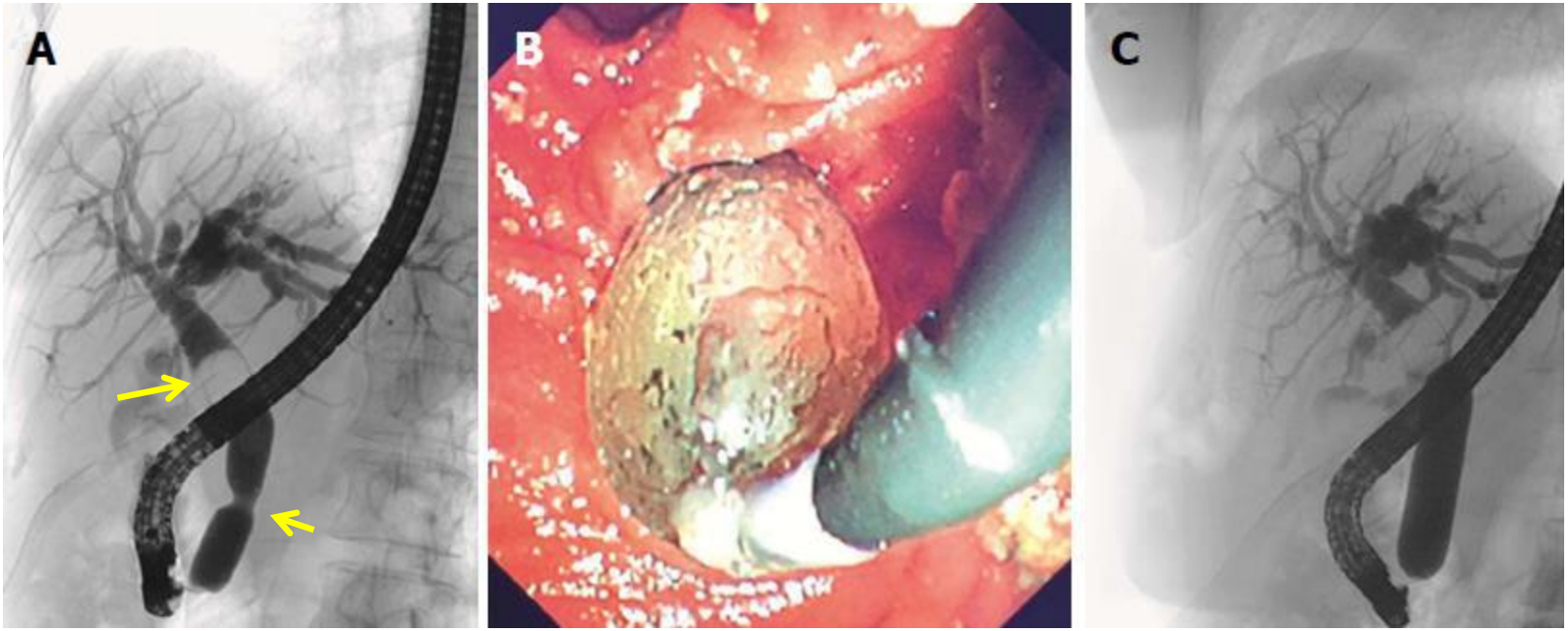
EPBD vs. EST

Papillary balloon dilation alone, however, remains unpopular and is not advocated for routine use as it is associated with **a lower technical success for stone clearance**, the **need for mechanical lithotripsy more frequently** than with endoscopic sphincterotomy, and a **presumed increased risk of pancreatitis**.

At present, the use of primary papillary balloon dilation without endoscopic sphincterotomy is considered mainly in patients with **coagulopathy** or with **altered anatomy who have stones smaller than 8mm.**

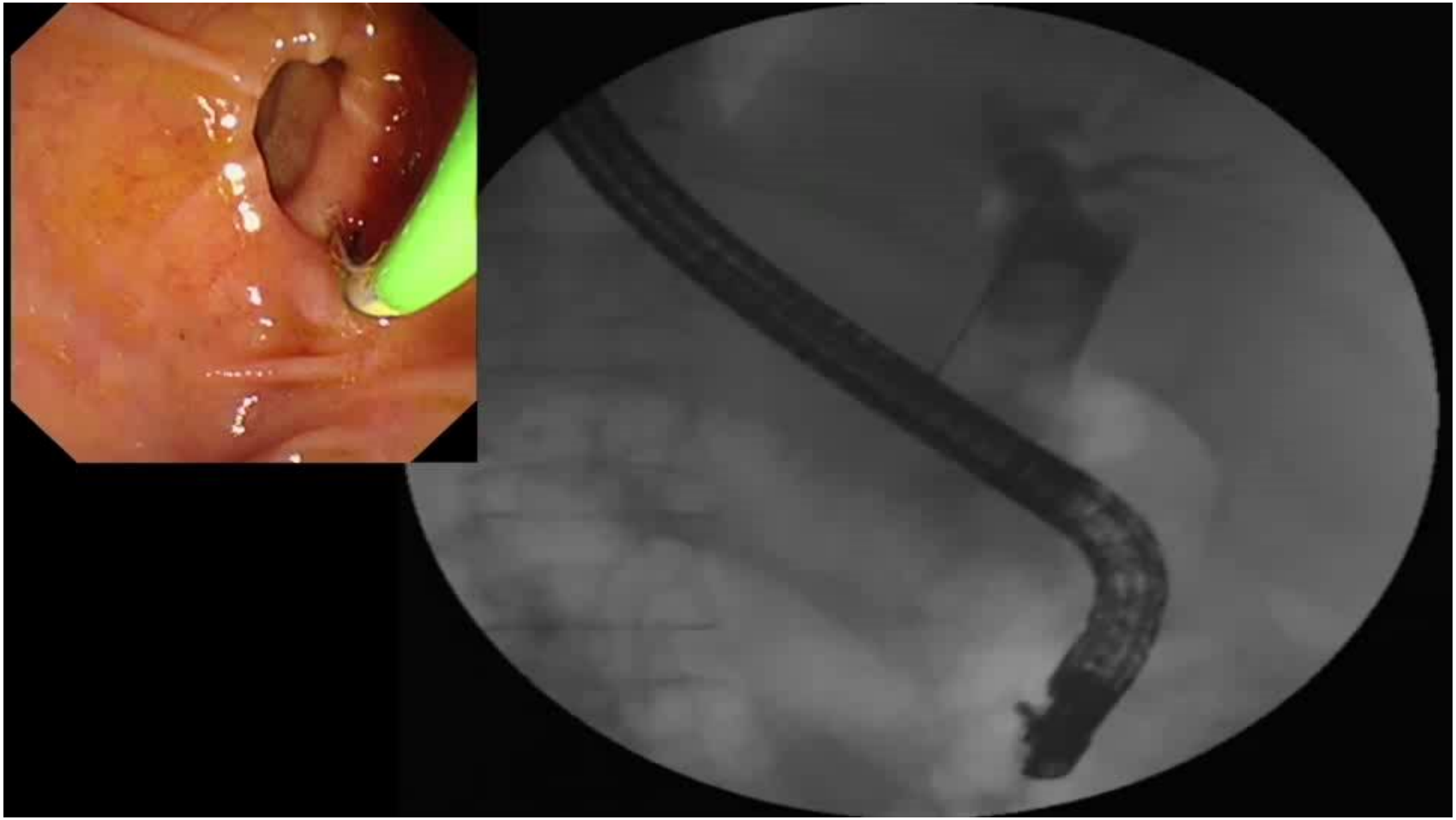
Manes et al, Endoscopy 2019;51:472-91

EPLBD



World J Gastroenterol 2017; 23: 8597-8604

EPLBD



Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract

Galip Ersoz, MD, Oktay Tekesin, MD, Ahmet Omer Ozutemiz, MD, Fulya Gunsar, MD

Izmir, Turkey

- Review of patients treated for bile duct stones 1998-2001: N = 942

- Standard ES + balloon/basket extraction successful: N = 854 (91%)
- Surgery: N = 26 (No CBD cannulation (16), refused balloon dilation (10))
- Stenting: N = 4
- **EPLBD: N = 58**
  - **Large, squared or barrel shaped stones N = 40**
  - **Tapered distal CBD: N = 18**

- **12-18 mm or 15-20 mm balloon**
- **Contrast in balloon, fluoroscopy, 45 sec**
- **If unsuccessful: Nasobiliary drain until repeated at another session with larger balloon**

Gastrointest Endosc 2003;57:156-9

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Results (EPLBD):

- **Large, squared or barrel shaped stones:**
  - Stone diameter: median **18 mm (16-28)**
  - Stone removal successful at:
    - First session: 87.5%
    - Second session: 7.5%
    - Mechanical lithotripsy: 5%

- **Tapered distal CBD:**
  - Stone diameter: median **16 mm (12-25)**
  - Stone removal successful at:
    - First session: 72%
    - Second session: 17%
    - Mechanical lithotripsy: 11%

Gastrointest Endosc 2003;57:156-9

Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract

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Complications (EPLBD):

- **Large, squared or barrel shaped stones: 3/40 (7.5%)**
  - Mild bleeding 2
  - Mild pancreatitis 1

- **Tapered distal CBD: 6/18 (33%)**
  - Moderate bleeding 3
  - Cholangitis 2
  - Mild pancreatitis 1

Gastrointest Endosc 2003;57:156-9

International Consensus Guideline for EPLBD

Definition:

- **EPLBD** is used to dilate the biliary orifice with a **large-diameter balloon (≥ 12 mm)**

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Definition:

- **EPLBD** is used to dilate the biliary orifice with a **large-diameter balloon (≥ 12 mm)**
- Can be performed **with or without EST**.

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Indication：

- In the removal of large or difficult bile duct stones, **EPLBD can be used as an alternative to EML** (1+, B).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

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- **EPLBD can be used as the initial method** when large bile duct stones have been identified on ERC or cross-sectional imaging (1+, B).

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- **When conventional stone removal after EST fails, EPLBD can be considered** (1+, B).

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- **When conventional stone removal after EST fails, EPLBD can be considered** (1+, B).
- **In patients with obvious distal bile duct strictures or a nondilated bile duct, EPBLD is not recommended because of the increased risk of perforation** (2+, C).

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- **EPLBD can be used as the initial method** when large bile duct stones have been identified on ERC or cross-sectional imaging (1+, B).
- **When conventional stone removal after EST fails, EPLBD can be considered** (1+, B).
- **In patients with obvious distal bile duct strictures or a nondilated bile duct, EPBLD is not recommended because of the increased risk of perforation** (2+, C).
- **EPLBD without EST is preferred over EPLBD with EST in patients with coagulopathy** (4, D).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Techniques:

- **The maximal diameter of the balloon should not exceed the diameter of the distal bile duct** (3, D).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

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- **The maximal diameter of the balloon should not exceed the diameter of the distal bile duct** (3, D).
- The balloon should be **inflated slowly in gradual steps** (3, D).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Techniques:

- **The maximal diameter of the balloon should not exceed the diameter of the distal bile duct** (3, D).
- The balloon should be **inflated slowly in gradual steps** (3, D).
- The usual duration of balloon dilation is approximately **30 to 60 seconds after disappearance of the waist** (1, C).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Outcomes:

- The initial and overall **success rates of EPLBD with EST are comparable to those of EST alone** (1+, A).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

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- The initial and overall **success rates of EPLBD with EST are comparable to those of EST alone** (1+, A).
- Overall **success rates of EPLBD with and without EST for bile duct stone clearance are comparable** (2++, B).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Outcomes:

- The initial and overall **success rates of EPLBD with EST are comparable to those of EST alone** (1+, A).
- Overall **success rates of EPLBD with and without EST for bile duct stone clearance are comparable** (2++, B).
- **EPLBD with EST can reduce the need for EML** (1+, B)

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Specific cases:

- The presence of a periampullary **diverticulum may not increase the risk of adverse events** in patients who undergo EPLBD (2++, B).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Specific cases:

- The presence of a periampullary **diverticulum may not increase the risk of adverse events** in patients who undergo EPLBD (2++, B).
- In patients with **surgically altered anatomy**, EPLBD may be an **effective and safe procedure** to remove bile duct stones (3, D).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Specific cases:

- The presence of a periampullary **diverticulum may not increase the risk of adverse events** in patients who undergo EPLBD (2++, B).
- In patients with **surgically altered anatomy**, EPLBD may be an **effective and safe procedure** to remove bile duct stones (3, D).
- In patients with a previous EST, EPLBD without repeated EST may be **effective and safe for the removal of recurrent stones** (2, D).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Adverse events:

- The rate of overall **adverse events for EPLBD with EST is lower than that for EST alone** in patients with large or difficult stones (1, C).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Adverse events:

- The rate of overall **adverse events for EPLBD with EST is lower than that for EST alone** in patients with large or difficult stones (1, C).
- **EPLBD may not increase the risk of pancreatitis** (1+, B).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Adverse events:

- The rate of overall **adverse events for EPLBD with EST is lower than that for EST alone** in patients with large or difficult stones (1, C).
- **EPLBD may not increase the risk of pancreatitis** (1+, B).
- EPLBD with **large EST may increase the risk of bleeding** (2++, C).

Gastrointest Endosc 2016;83:37-47

International Consensus Guideline for EPLBD

Adverse events:

- The rate of overall **adverse events for EPLBD with EST is lower than that for EST alone** in patients with large or difficult stones (1, C).
- **EPLBD may not increase the risk of pancreatitis** (1+, B).
- EPLBD with **large EST may increase the risk of bleeding** (2++, C).
- EPLBD with EST has a perforation rate similar to that of EST. **A distal CBD stricture is a major risk factor for perforation** (1+, B).

Gastrointest Endosc 2016;83:37-47

Smaller vs. larger balloon

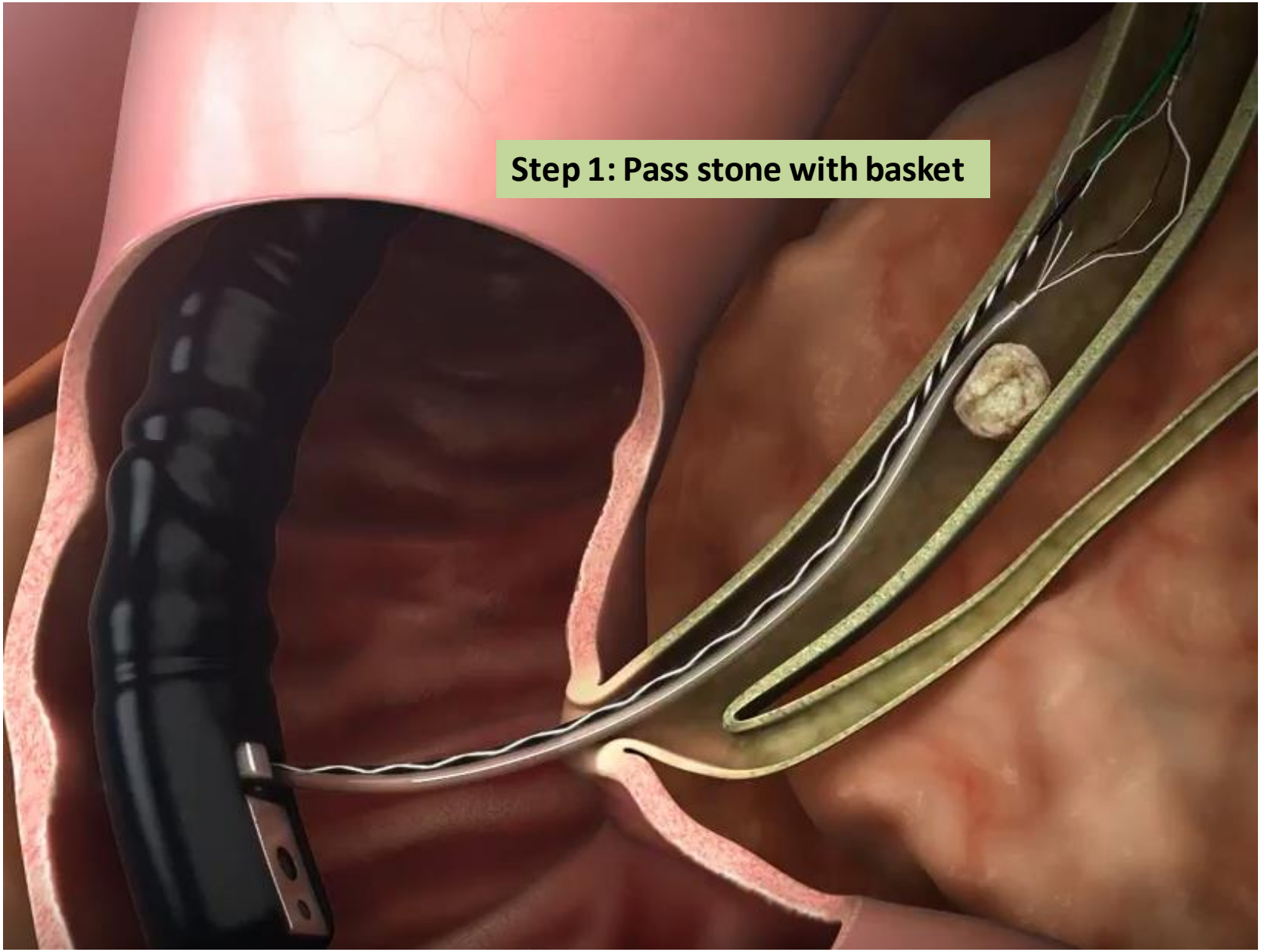
Table 3 Comparison of adverse events between smaller balloon (12–15 mm) and larger balloon (> 15 mm) groups

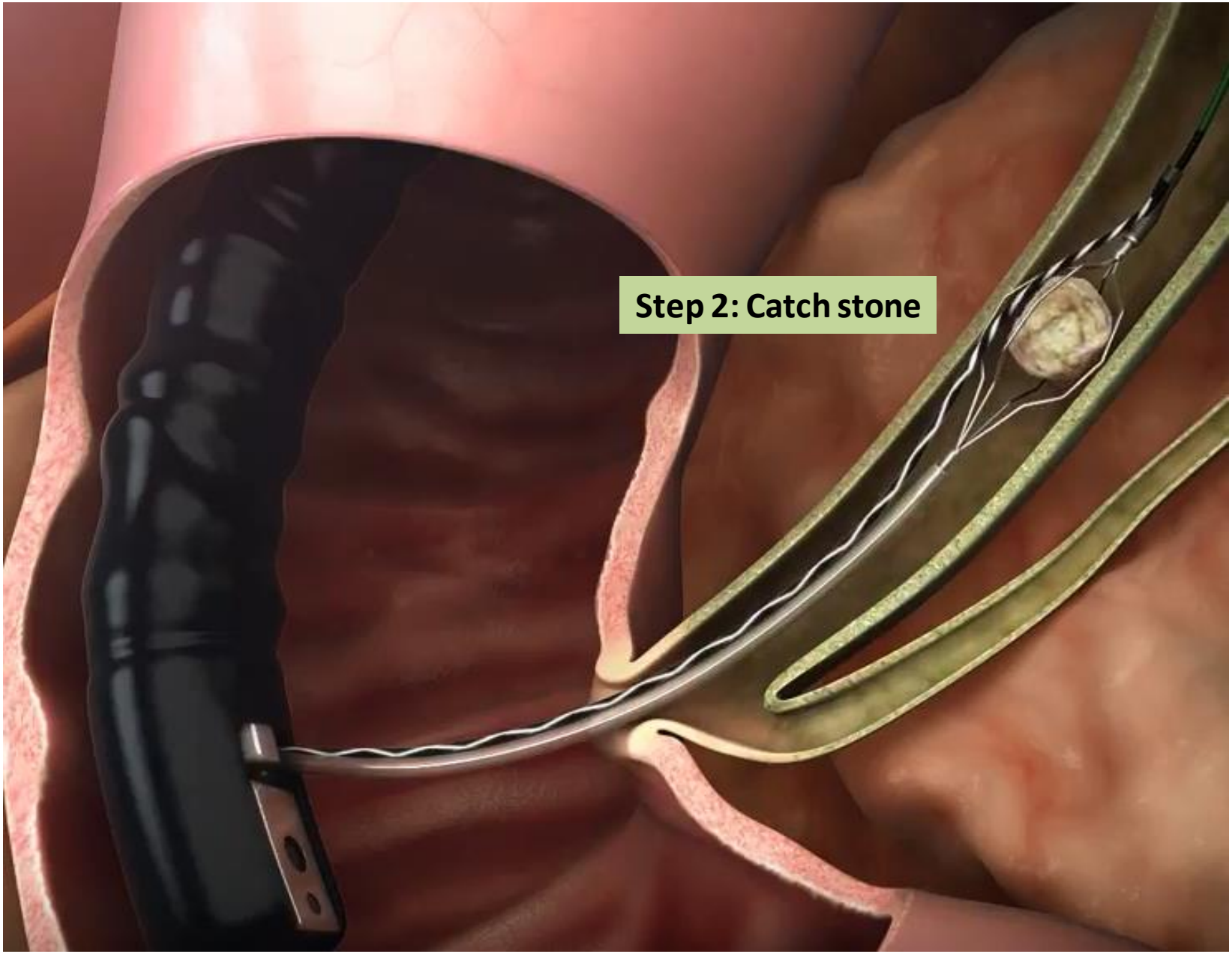
	S-EPLBD (n = 490)	L-EPLBD (n = 182)	P value
Overall adverse event[†]	22 (4.5)	13 (7.1)	0.169
Bleeding, M/Mod/S/F	3 (0.6), 3/0/0/0	3 (1.6), 2/0/1/0	0.352
Pancreatitis, M/Mod/S/F	17 (3.5), 12/5/0/0	6 (3.3), 6/0/0/0	0.913
Perforation, M/Mod/S/F	2 (0.4), 1/1/0/0	2 (1.1), 0/0/0/2	0.297
Others	1 (0.2)	3 (1.6)	0.063
Severe-to-fatal event	0 (0.0)	3 (1.6)	0.020

(18-20 mm balloons)

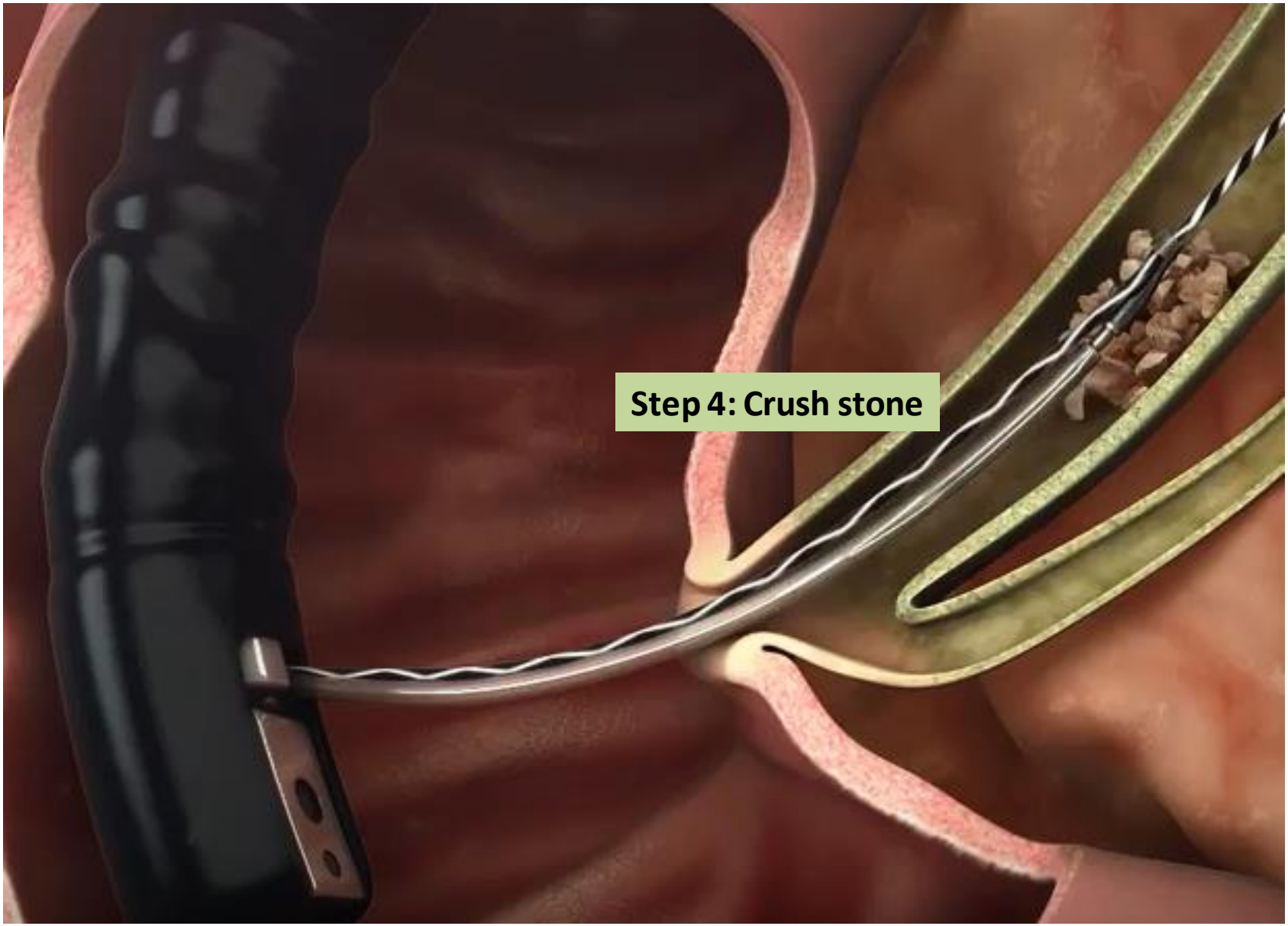
Lee et al, J gastroenterol Hepatol 2019; 34: 1450-3

ENDOSCOPIC MECHANICAL LITHOTRIPSY


Step 1: Pass stone with basket


Step 2: Catch stone


Step 3: Bring stone down to metal sheath tip

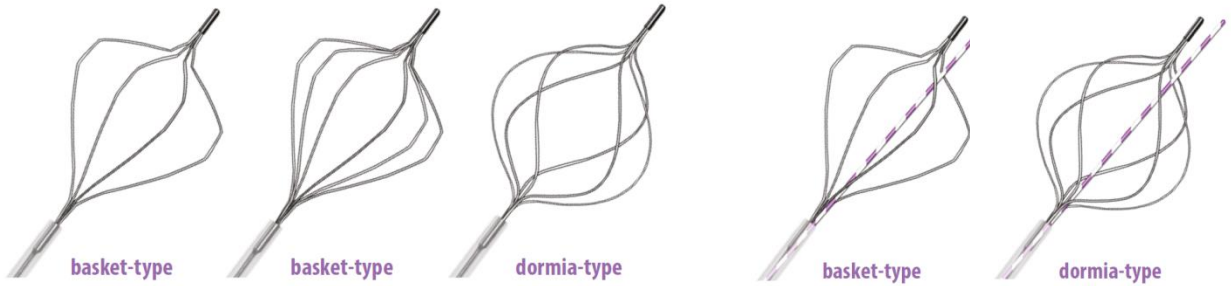

Step 4: Crush stone

Mechanical lithotripsi

- Through the scope (TTS)
- Out of the scope (OTS)

Olympus Mechanical Lithotriptor (TTS)

Endo-Flex Mechanical Lithotriptor (TTS)

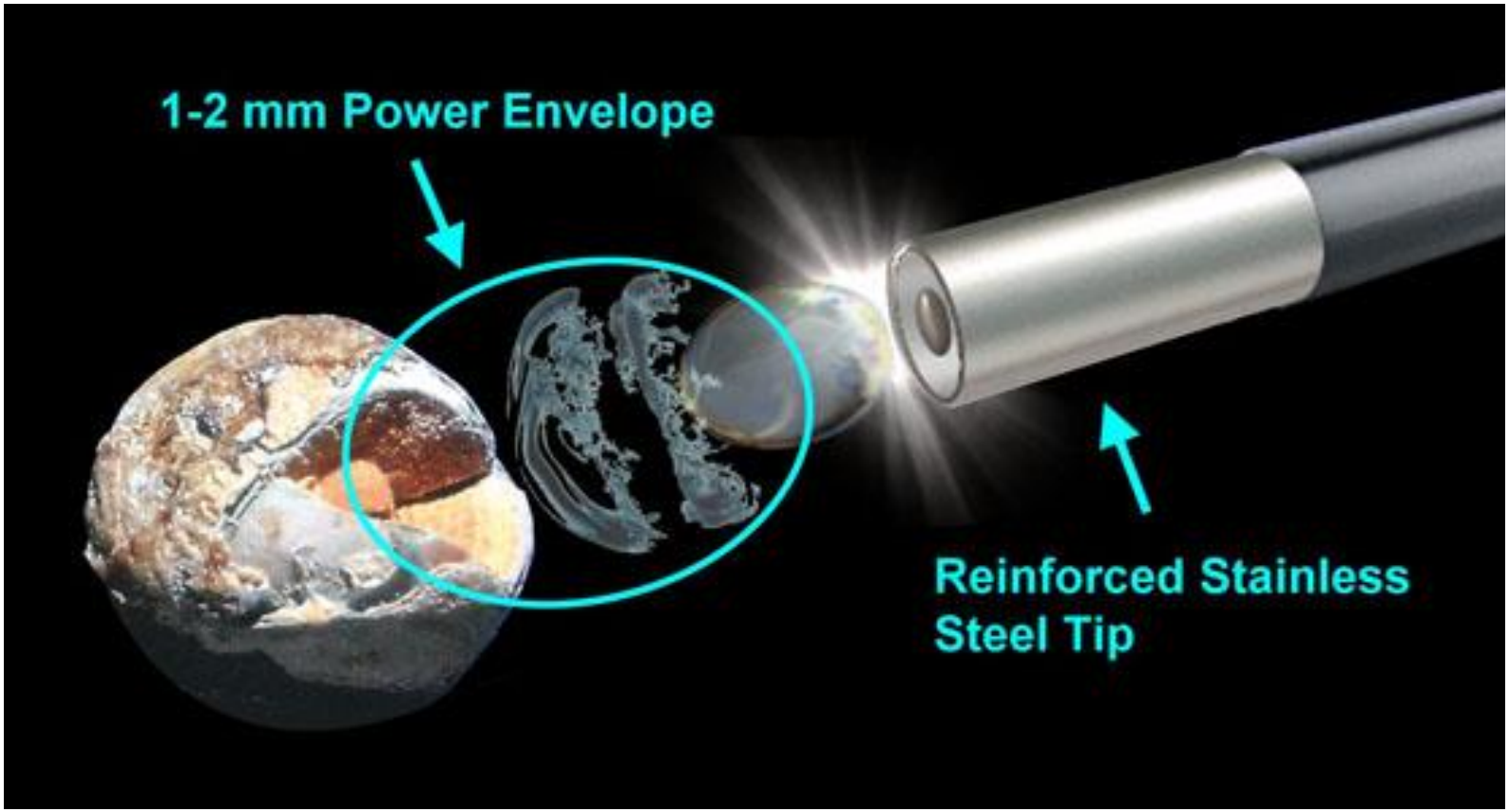


Emergency Lithotriptor Handle (OTS)

ENDOSCOPIC ELECTROHYDRAULIC LITHOTRIPSY (EHL)

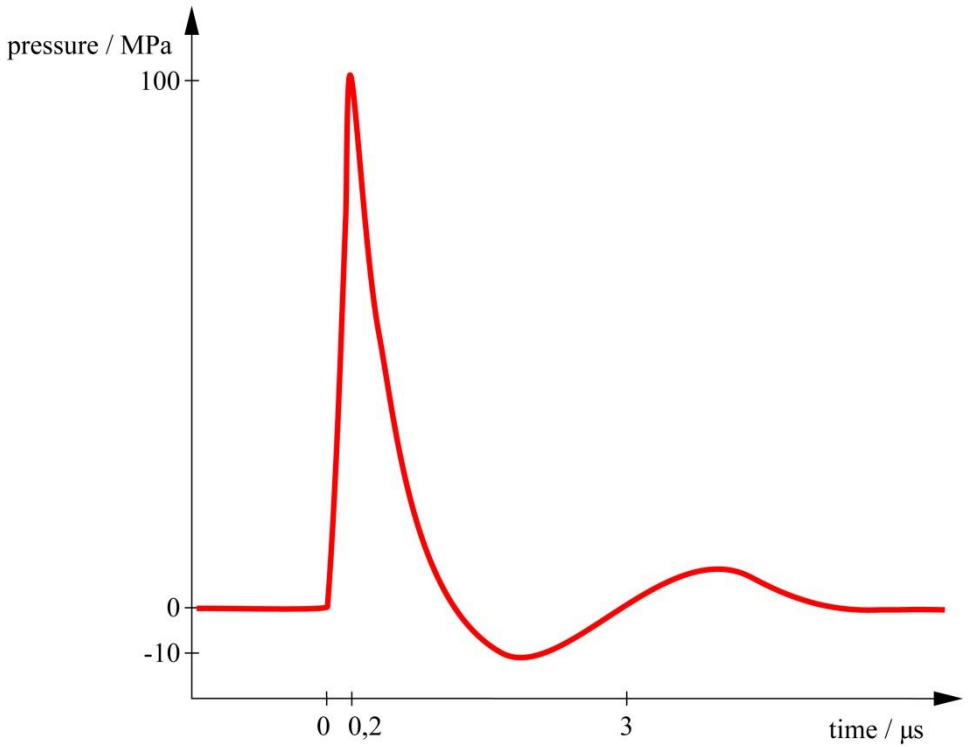
SpyGlass DS animation

Electrohydraulic Lithotripsy (EHL)

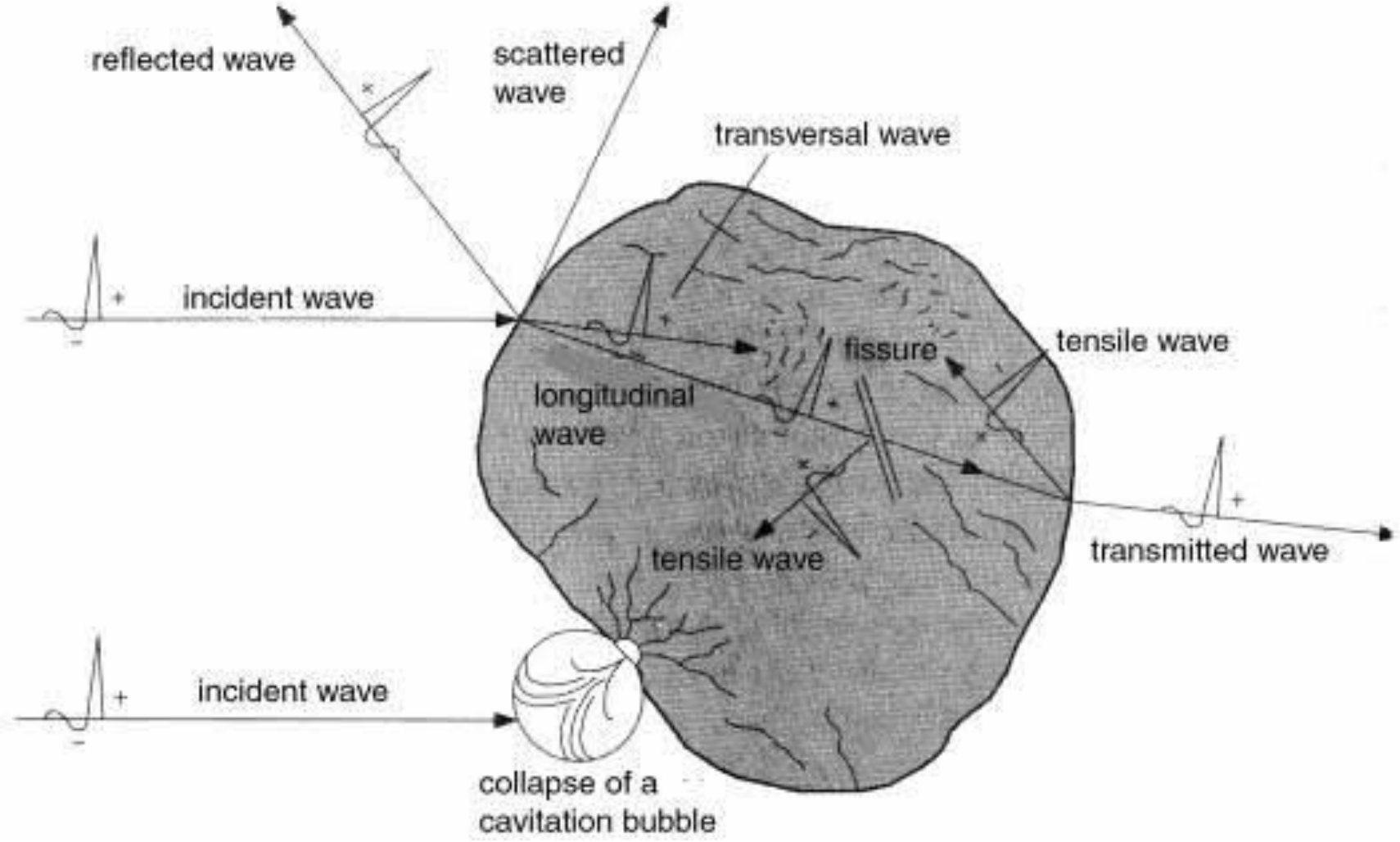


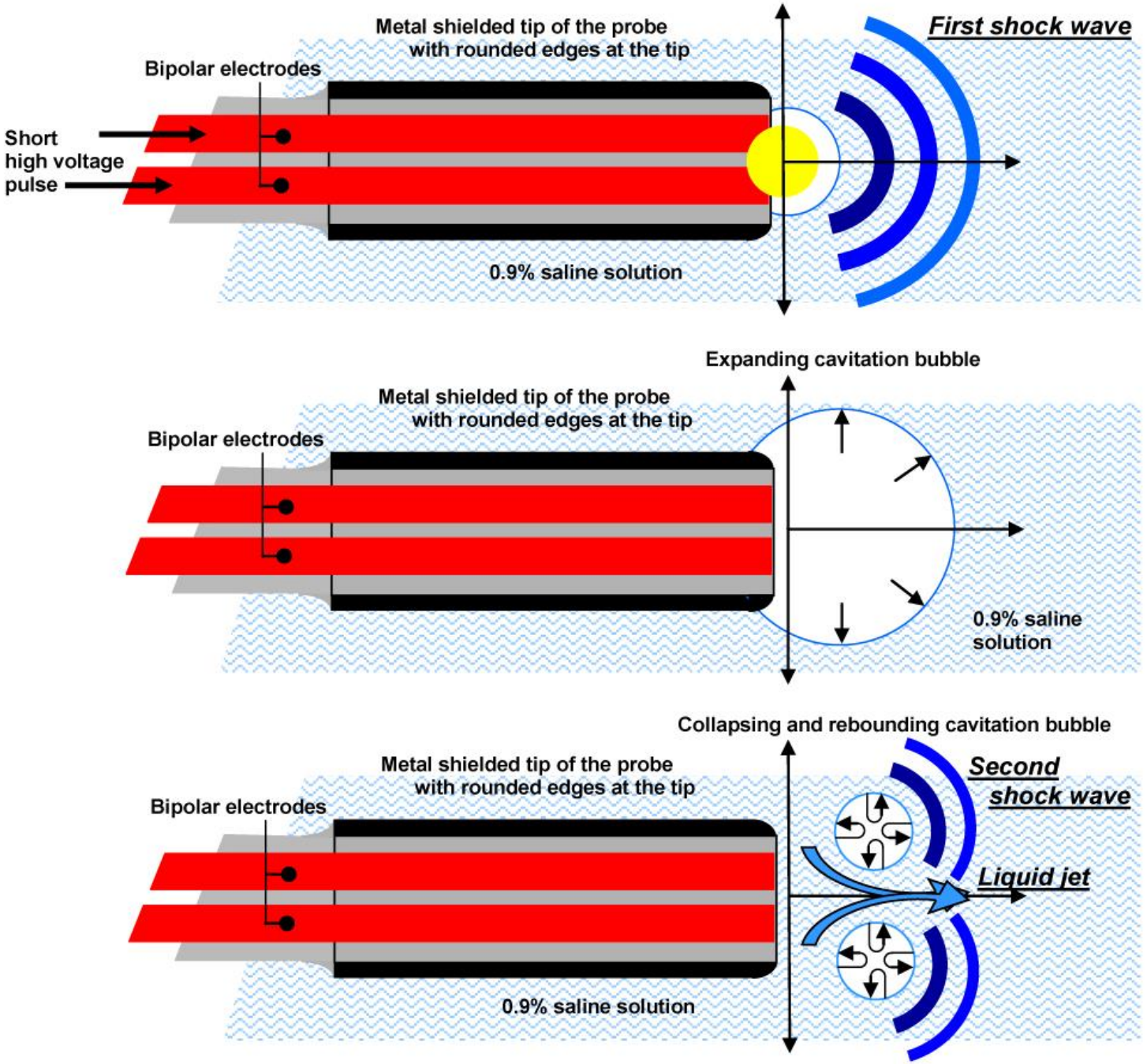
The shock wave

- High energy, high amplitude wave (may exceed 100 Mpa = 1000 bar)
- Extremely short build-up time
- Short duration (< 5 μs)
- Two phases:
  - Near instantaneous leap to PEAK POSITIVE PRESSURE: THE SHOCK (compressive phase)
  - Near instant drop to zero and below with a PEAK NEGATIVE PRESSURE (tensile phase)



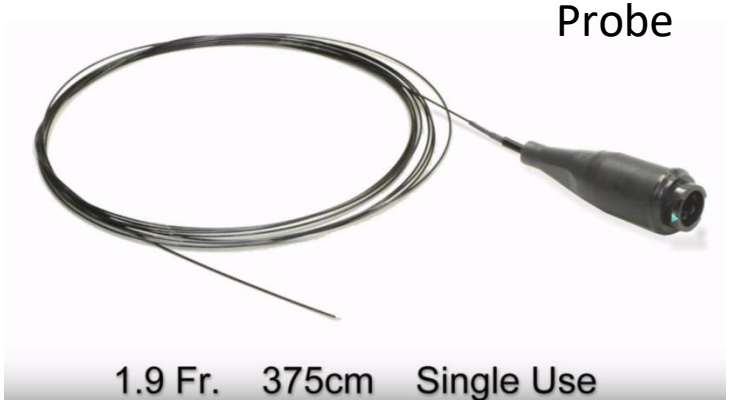
Shock wave lithotripsy




Metal shielded tip of the probe
with rounded edges at the tip
Bipolar electrodes
Short
high voltage
pulse
First shock wave
0.9% saline solution
Expanding cavitation bubble
Metal shielded tip of the probe
with rounded edges at the tip
Bipolar electrodes
0.9% saline
solution
Collapsing and rebounding cavitation bubble
Metal shielded tip of the probe
with rounded edges at the tip
Bipolar electrodes
Second
shock wave
Liquid jet
0.9% saline solution

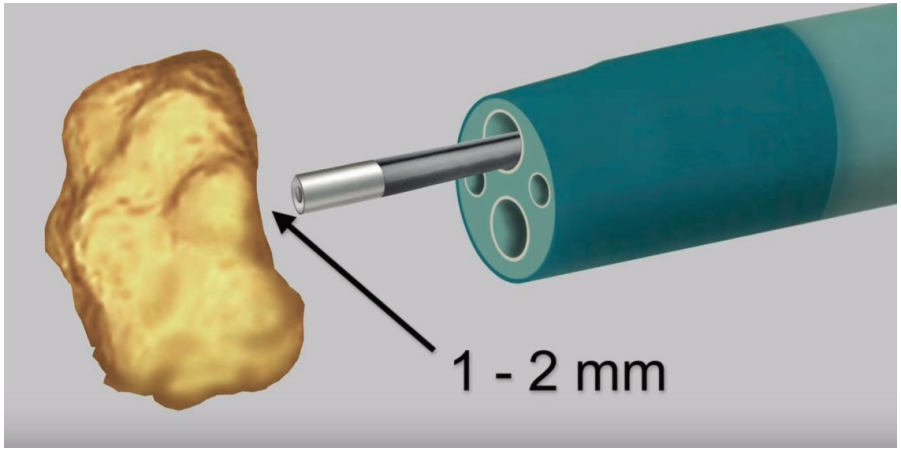
Prerequisites for EHL

EHL generator



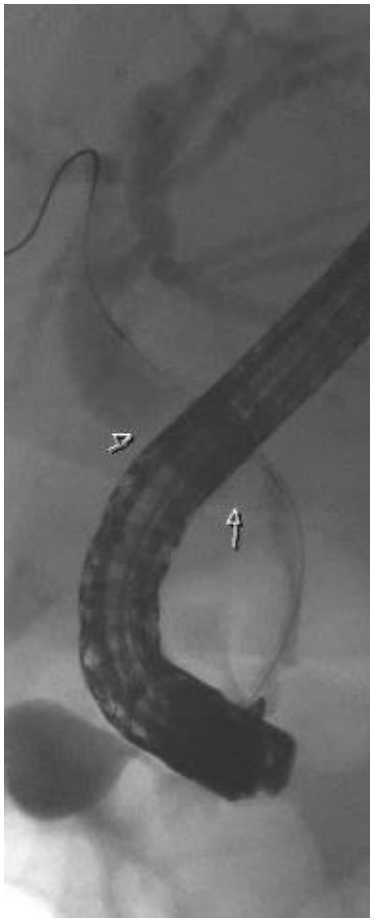
Probe

0.9% saline



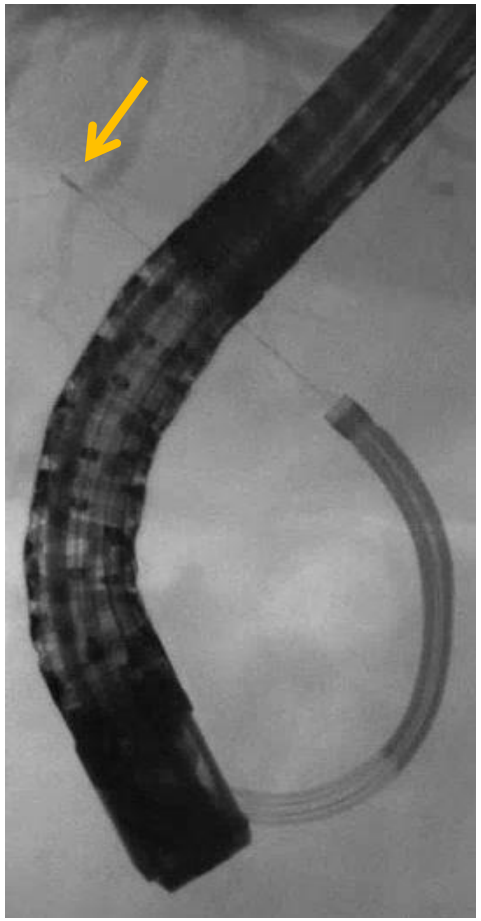
Large common hepatic duct stone

ERCP: Stone



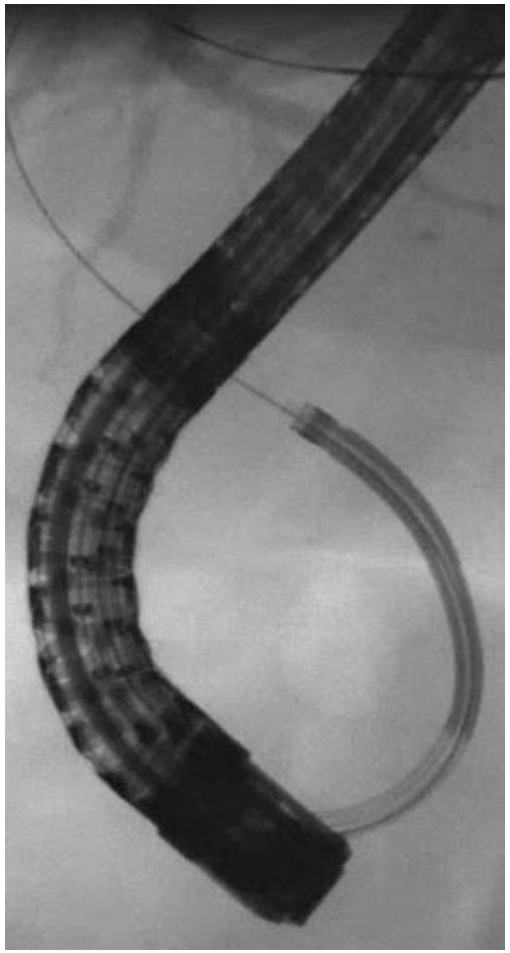
Cholangioscopy

EHL-probe through stone center

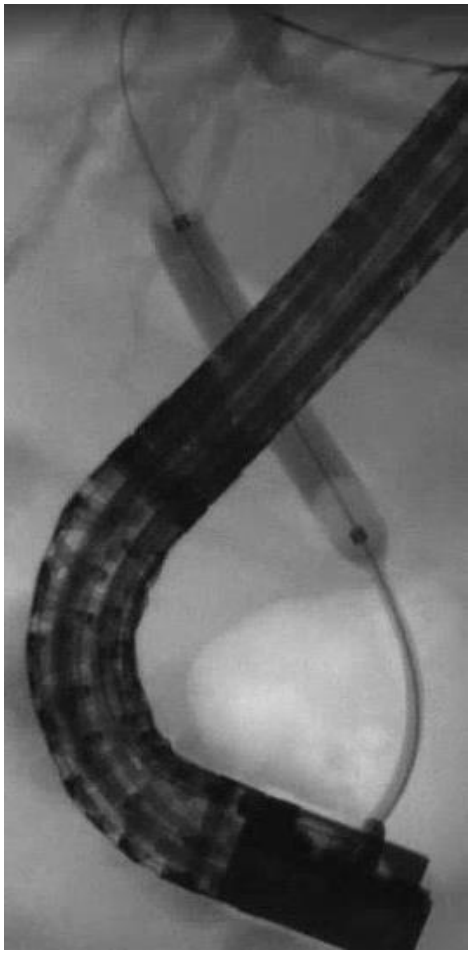


Large common hepatic duct stone

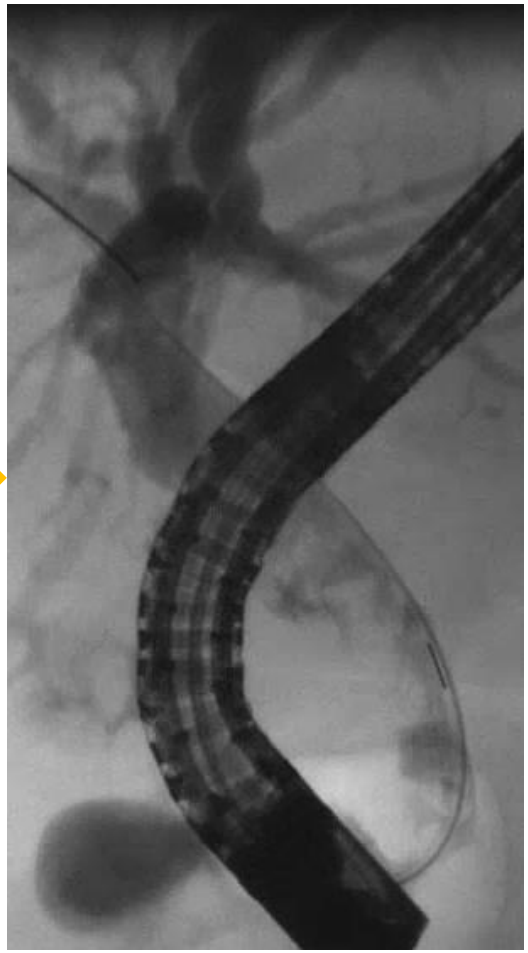
Guidewire through stone center



Balloon fragmentation

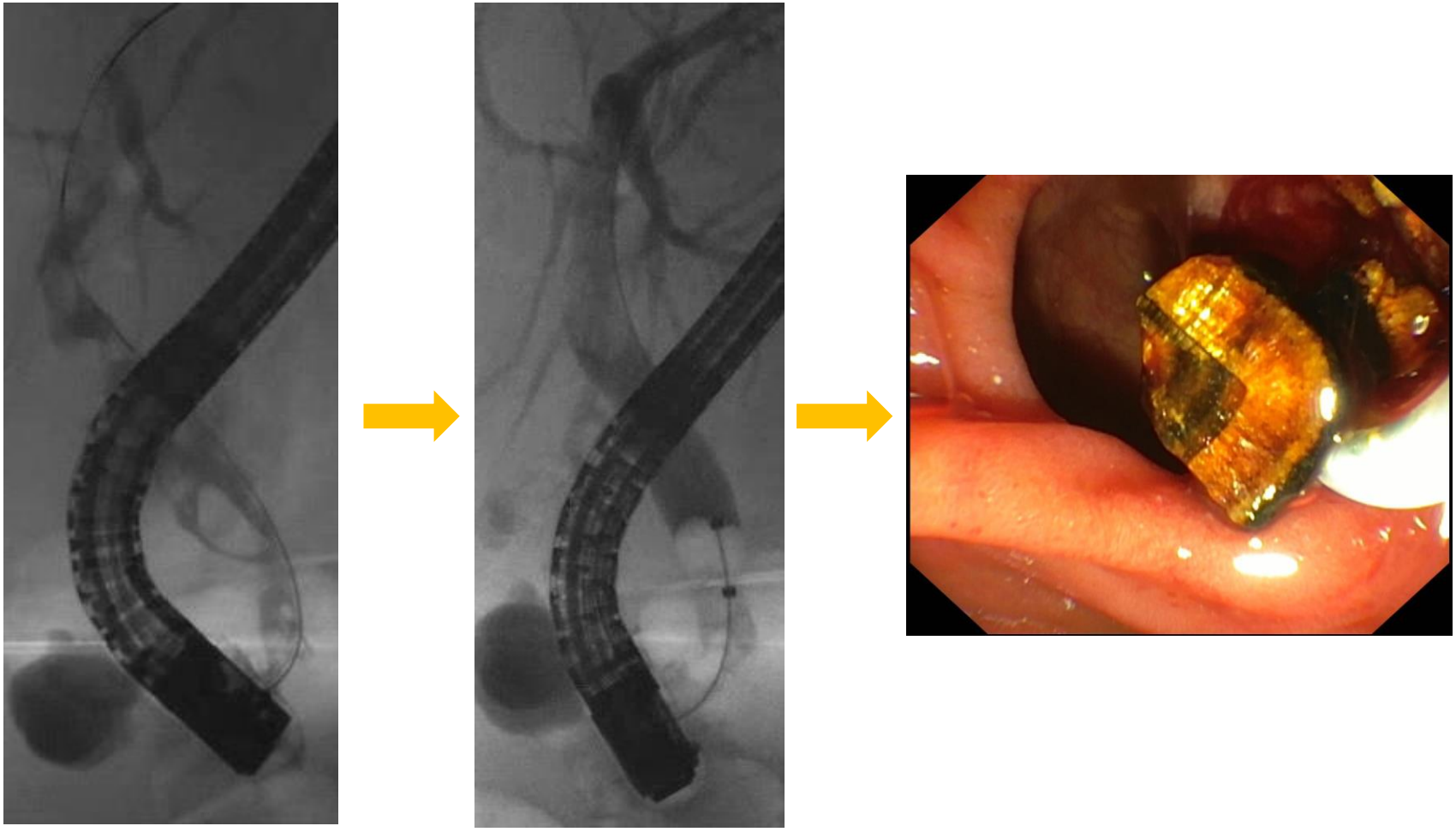


Stone fragments

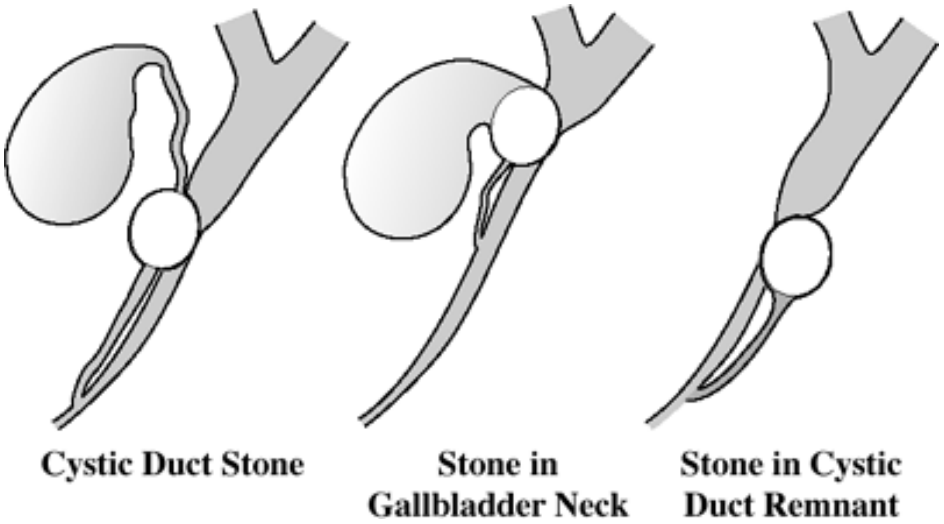


Large common hepatic duct stone

Large common hepatic duct stone



Mirizzi's syndrome

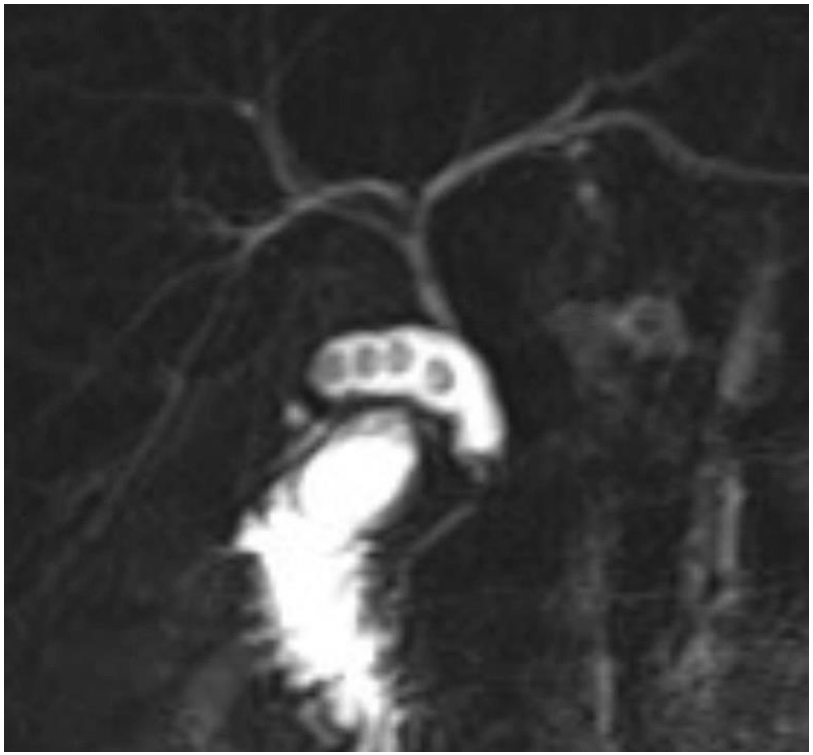


Obstruction of common hepatic duct by stone in cystic duct or gallbladder neck

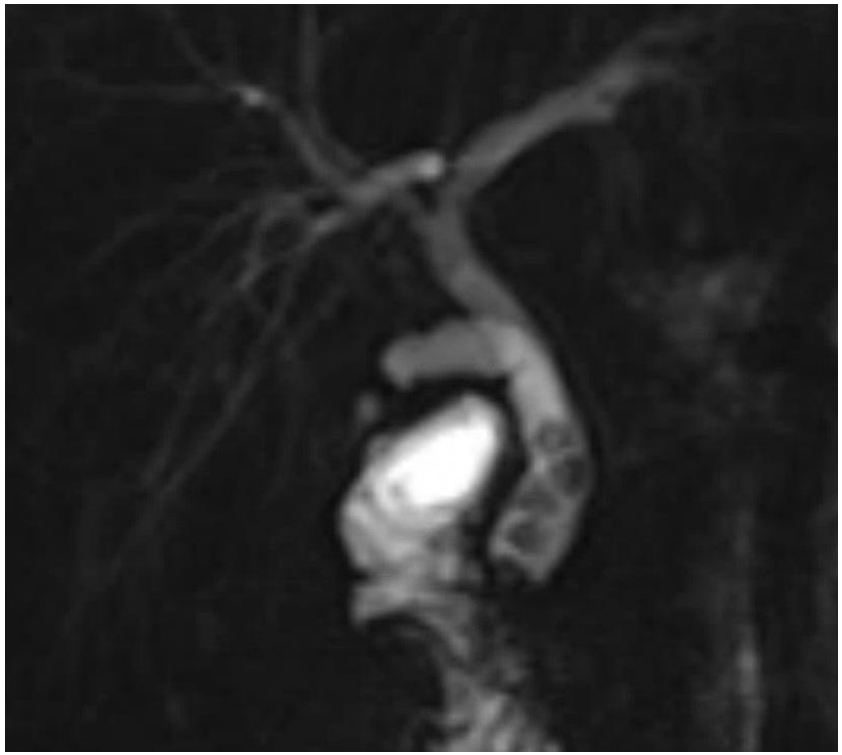
Prof. Pablo Luis Mirizzi (1893-1964)

Mirizzi's syndrome

Multiple stones in cystic duct remnant

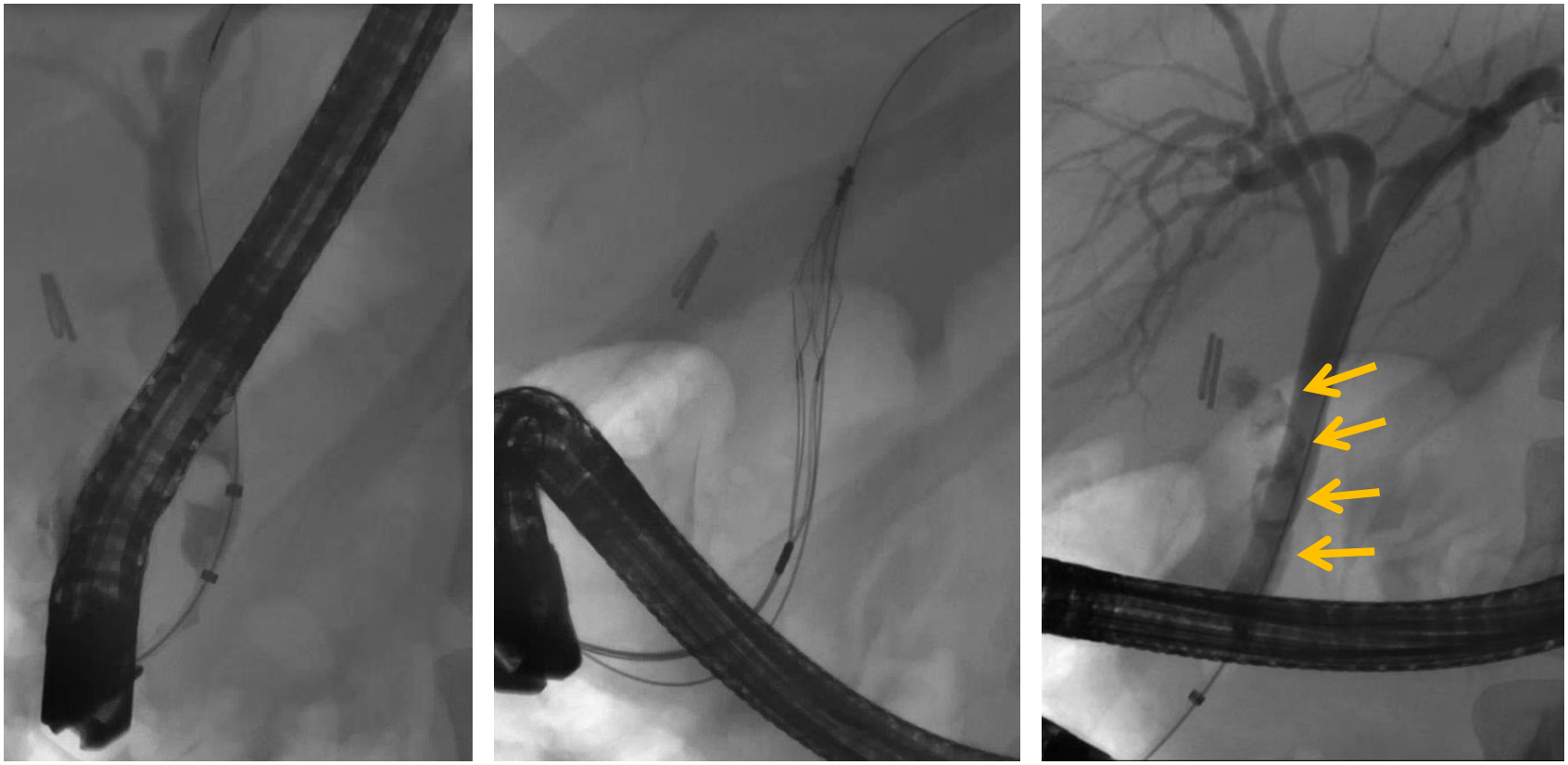


19.07.2016: No cholestasis



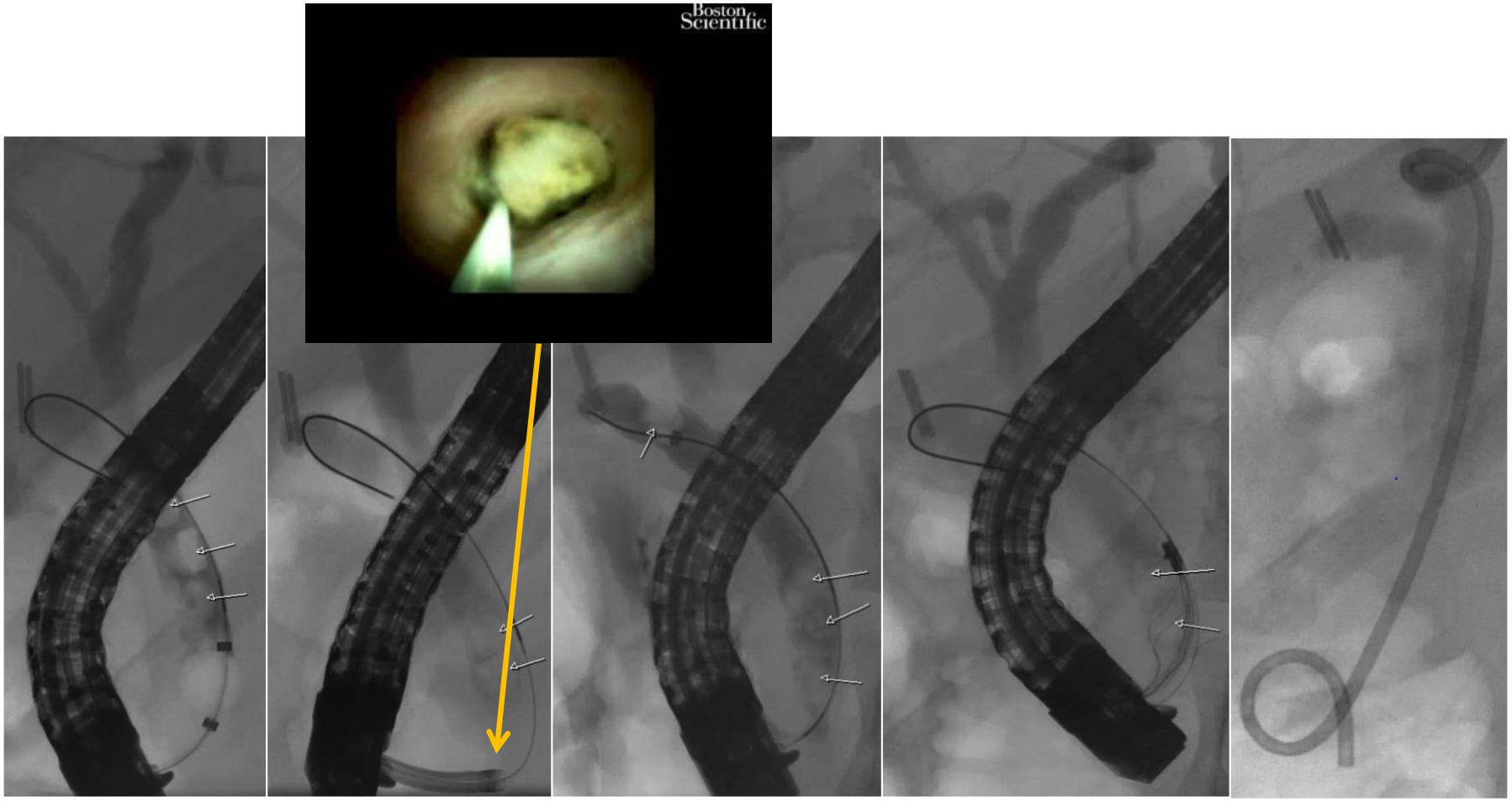
03.08.2016: Intra- and extrahepatic cholestasis

Mirizzi's syndrome



Cystic duct stones mimicking stones in distal common bile duct

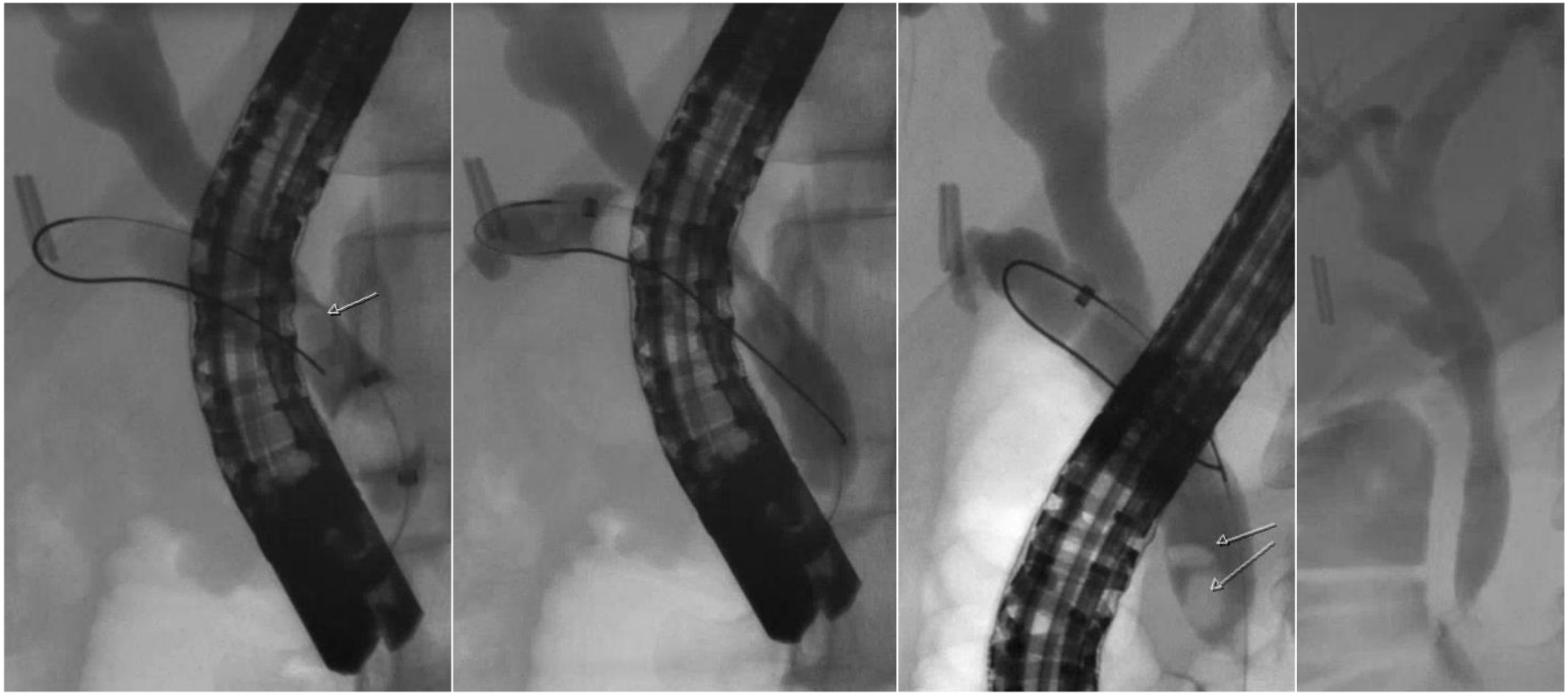
Mirizzi's syndrome



ERCP with cholangioscopy, EHL, extraction of stone fragments and finally stenting

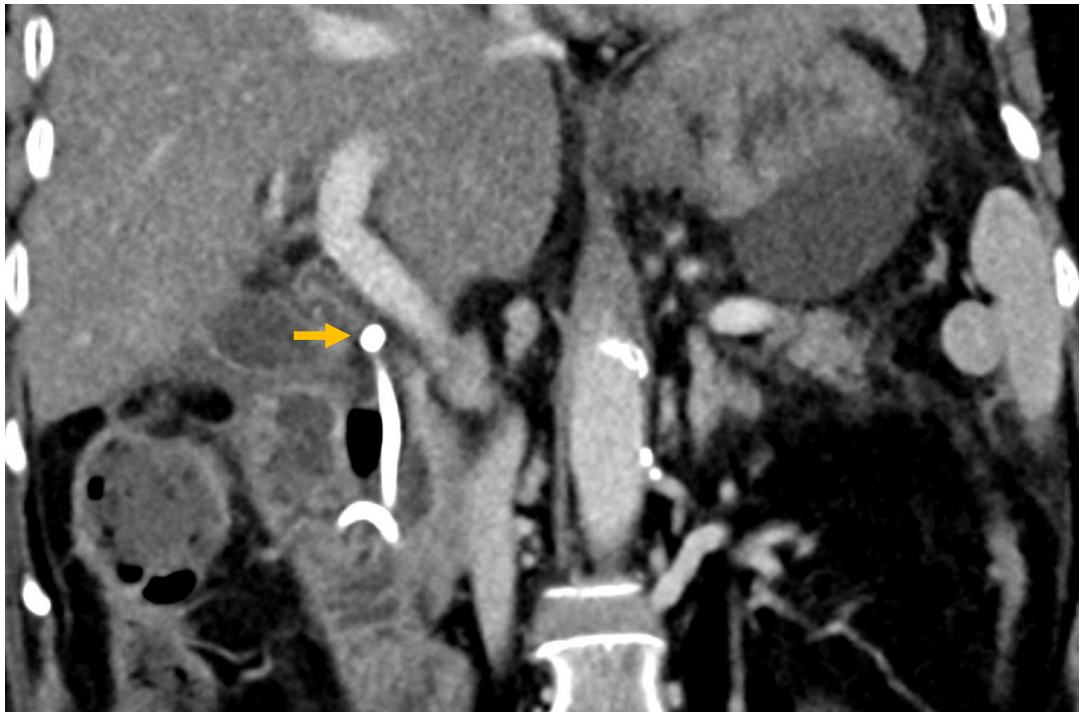
Mirizzi’s syndrome

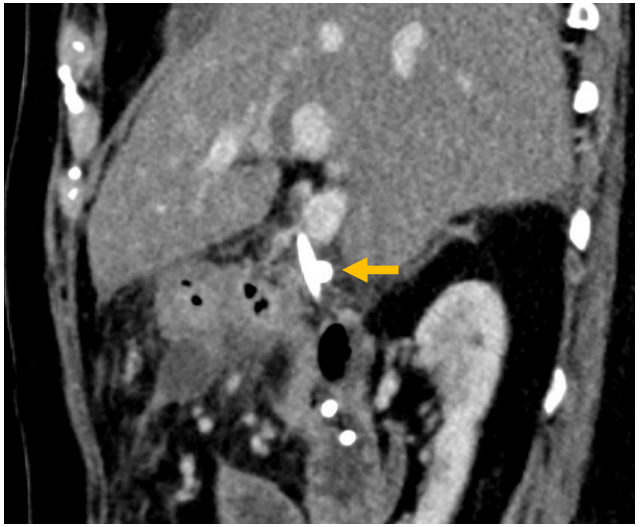
Mirizzi's syndrome

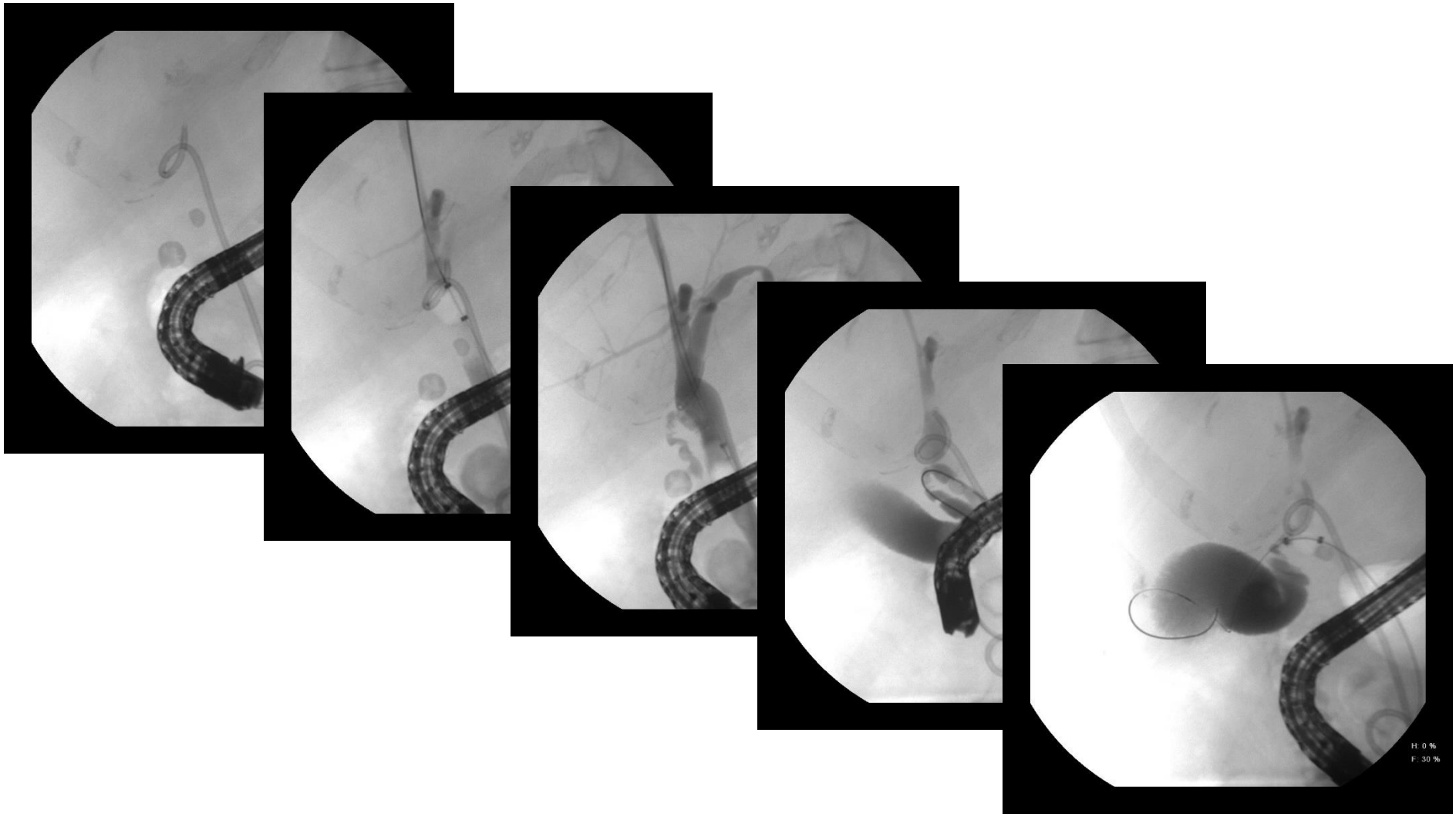


Balloon extraction of remnant stone fragments from cystic duct, relieving the obstruction

CBD stone or …?



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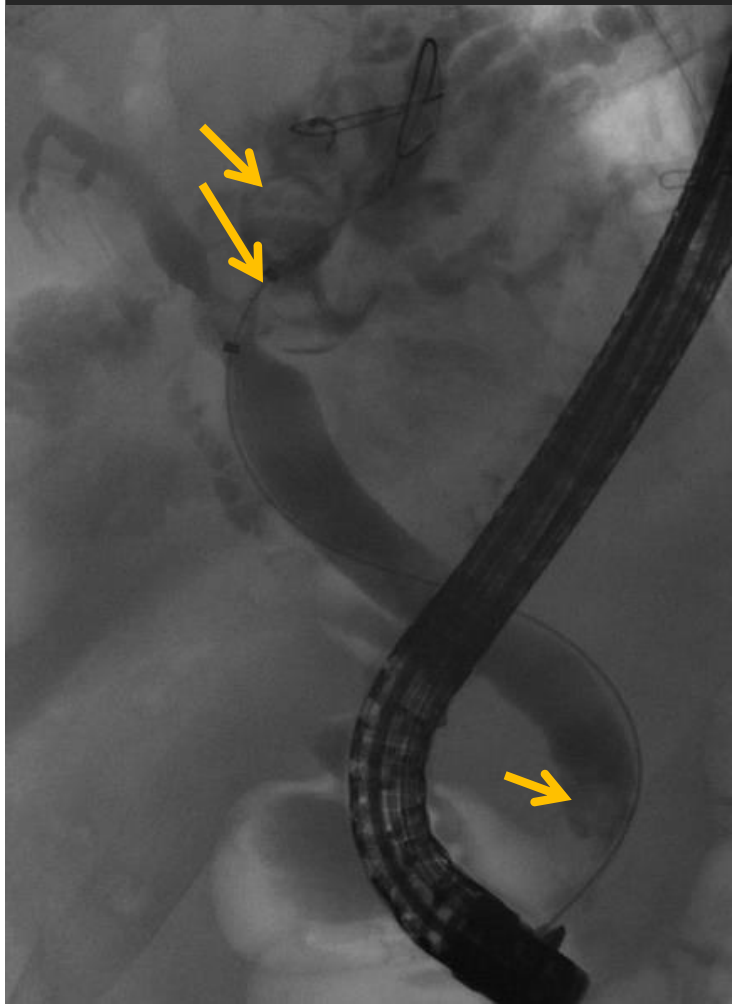
Intrahepatic stones

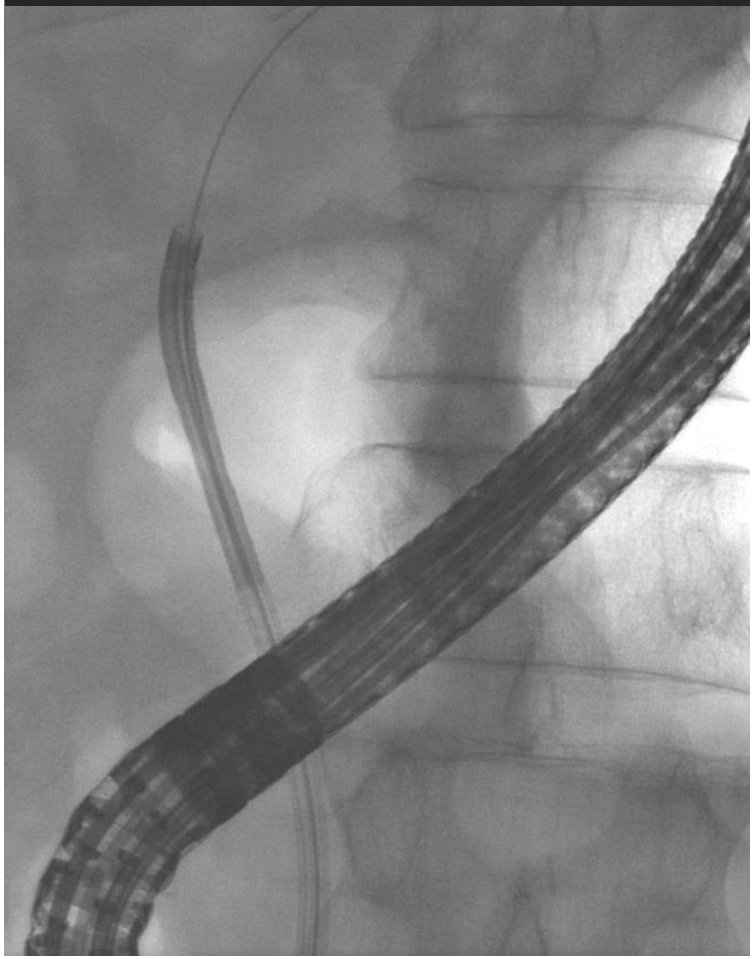
Index MRCP:
CBD and intrahepatic stones

Index ERCP:
CBD and intrahepatic stones

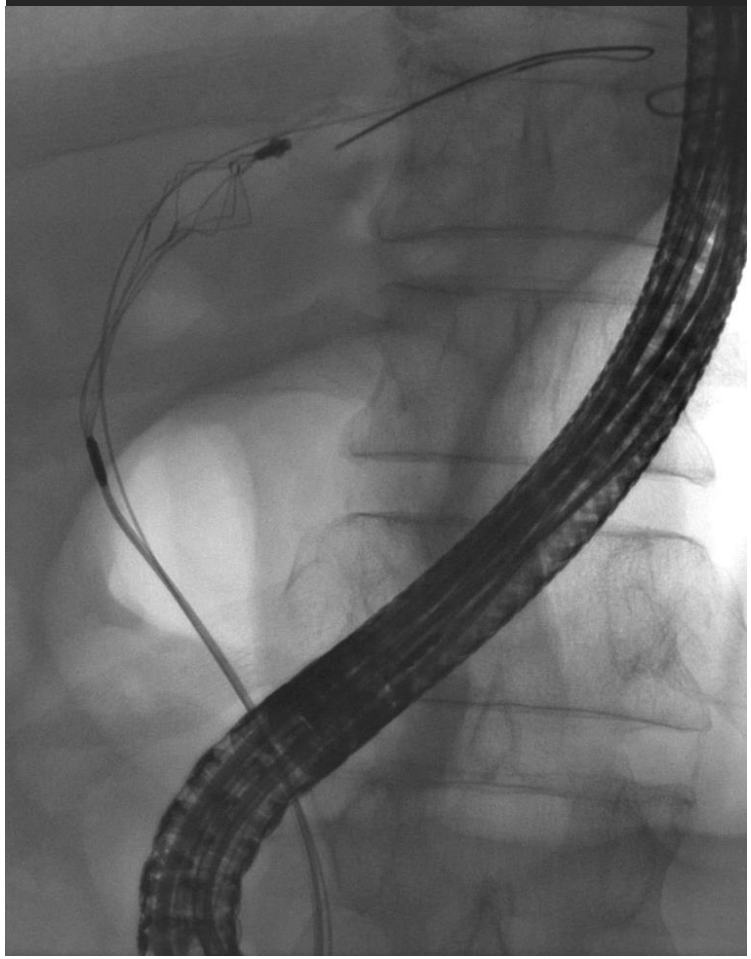


Intrahepatic stones

Index ERCP:
Cholangioscopy and EHL

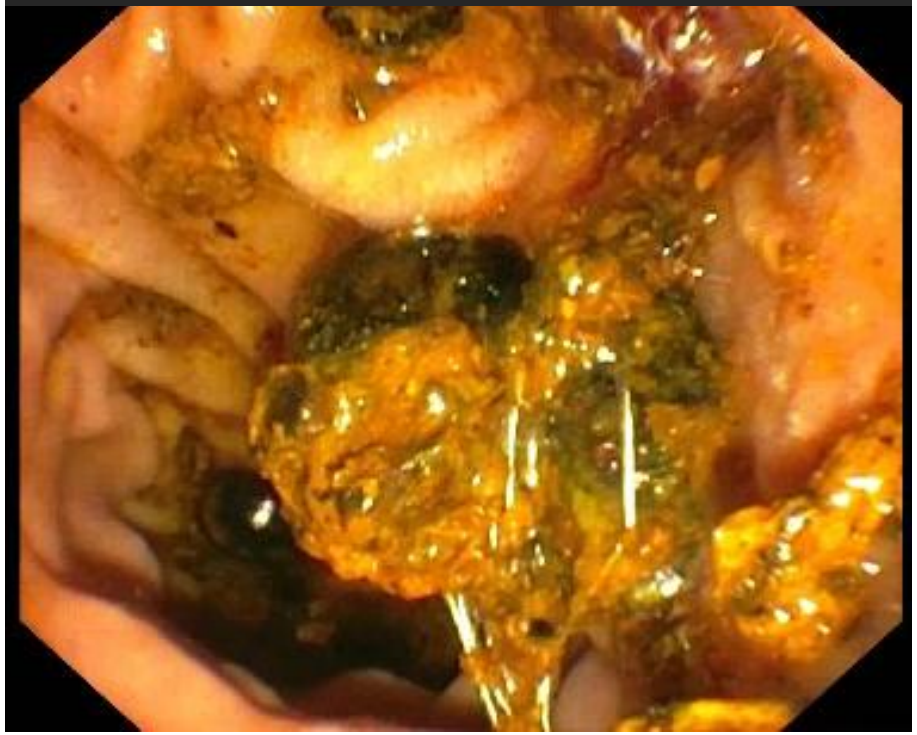


Index ERCP: Extraction of fragments from distal intrahepatic stone

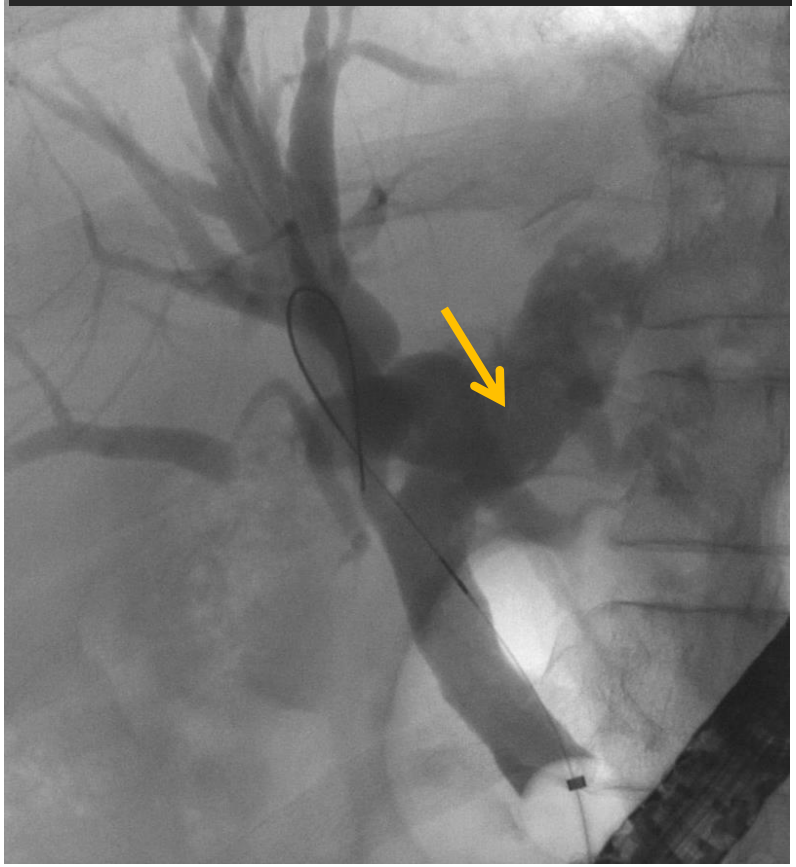


Intrahepatic stones

Index ERCP:
Extraction of stone fragments



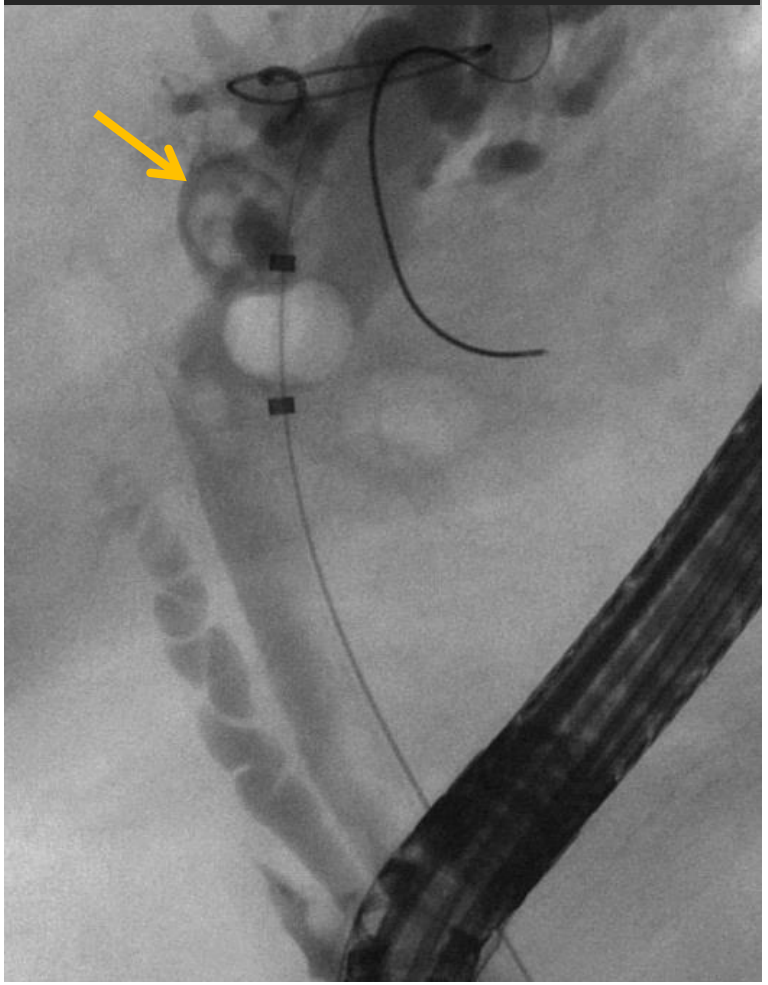
Index ERCP:
Clearance of distal left hepatic duct



Intrahepatic stones

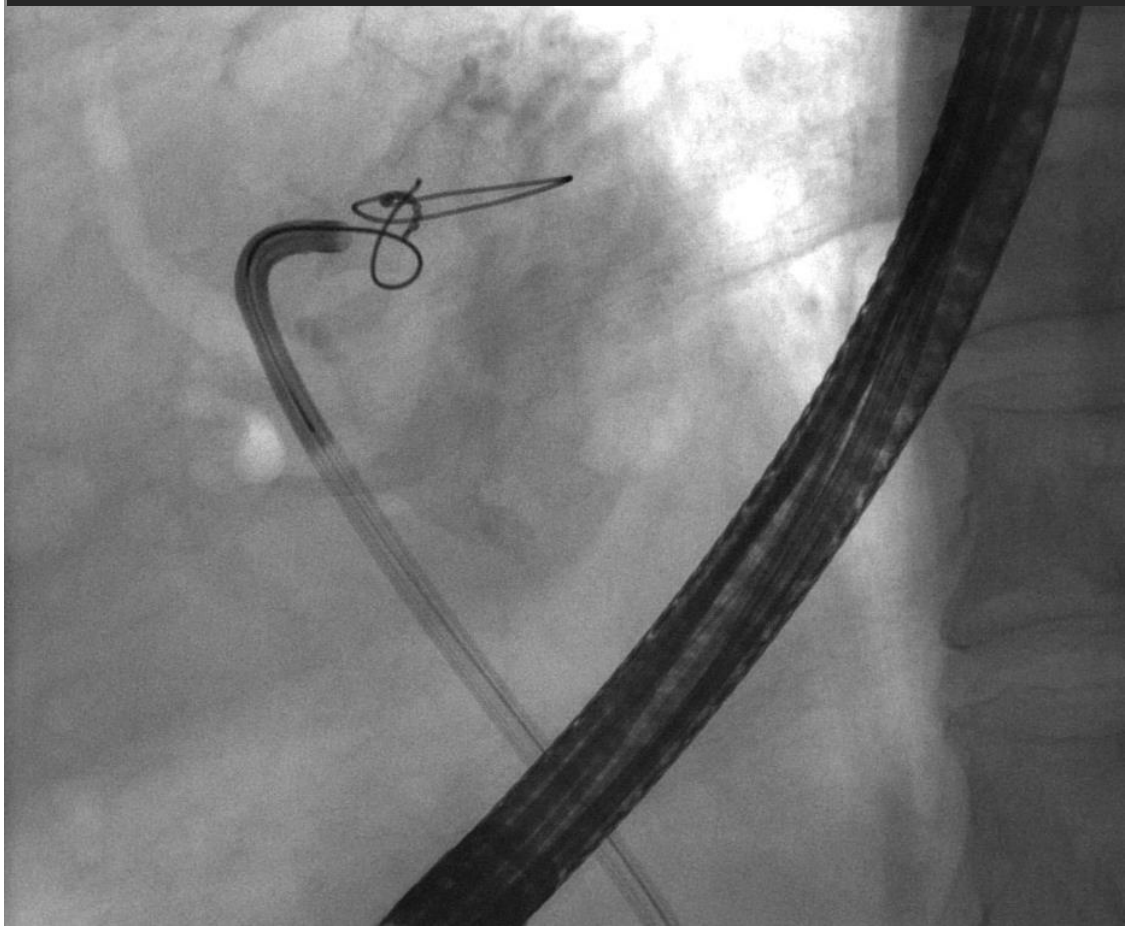
MRCP #2:
Remnant intrahepatic stone

ERCP #2:
Remnant intrahepatic stone

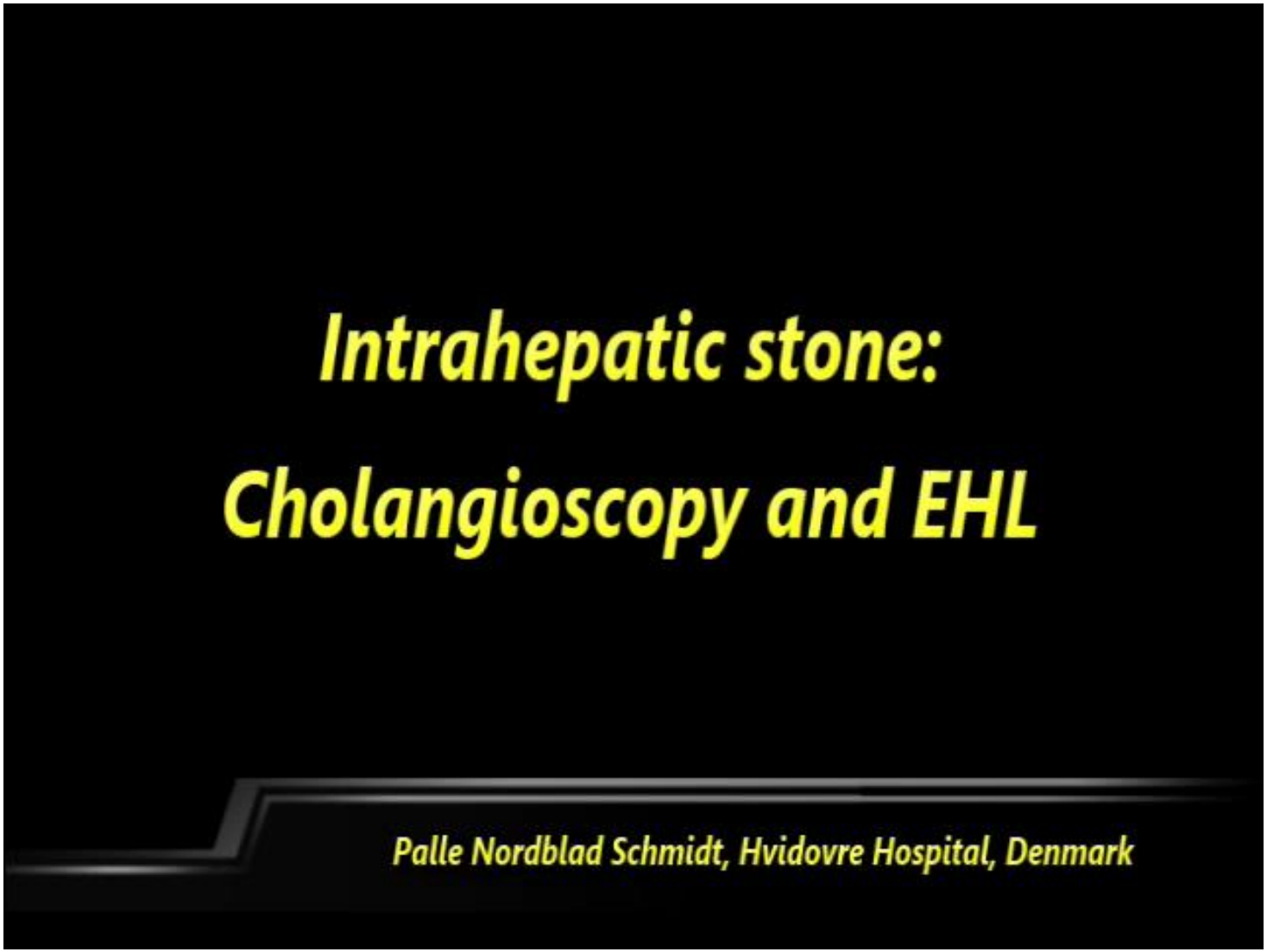


Intrahepatic stones

ERCP #2:
Cholangioscopy and EHL of remnant intrahepatic stone

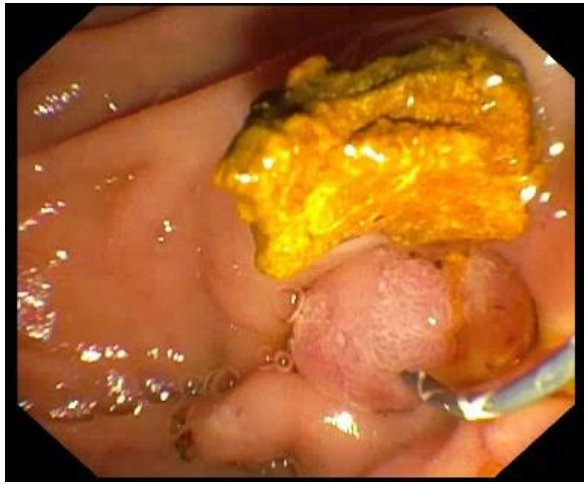


Intrahepatic stones

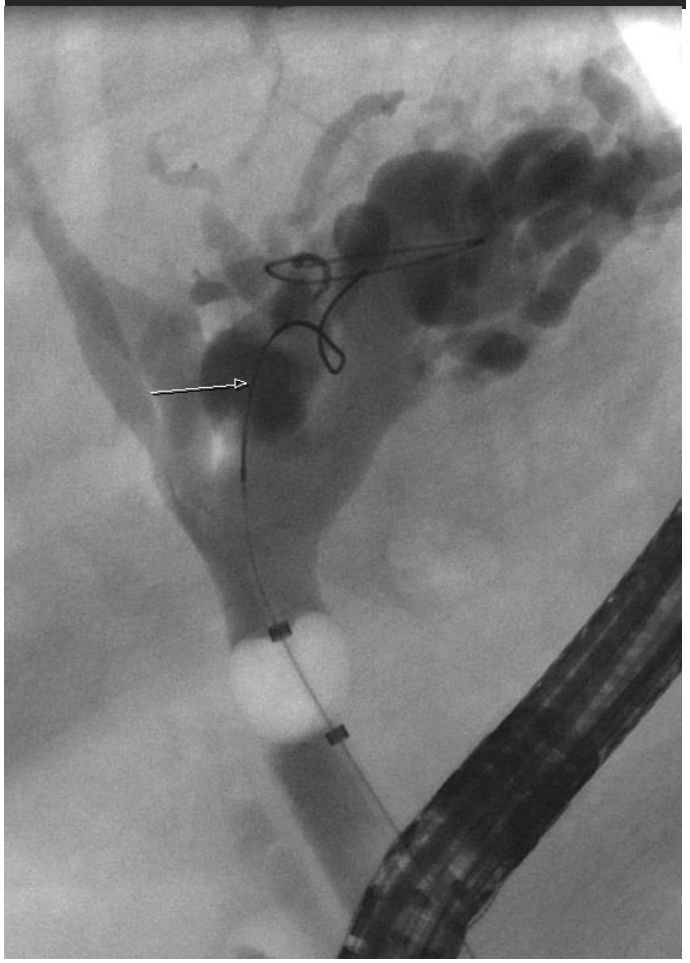


Intrahepatic stones

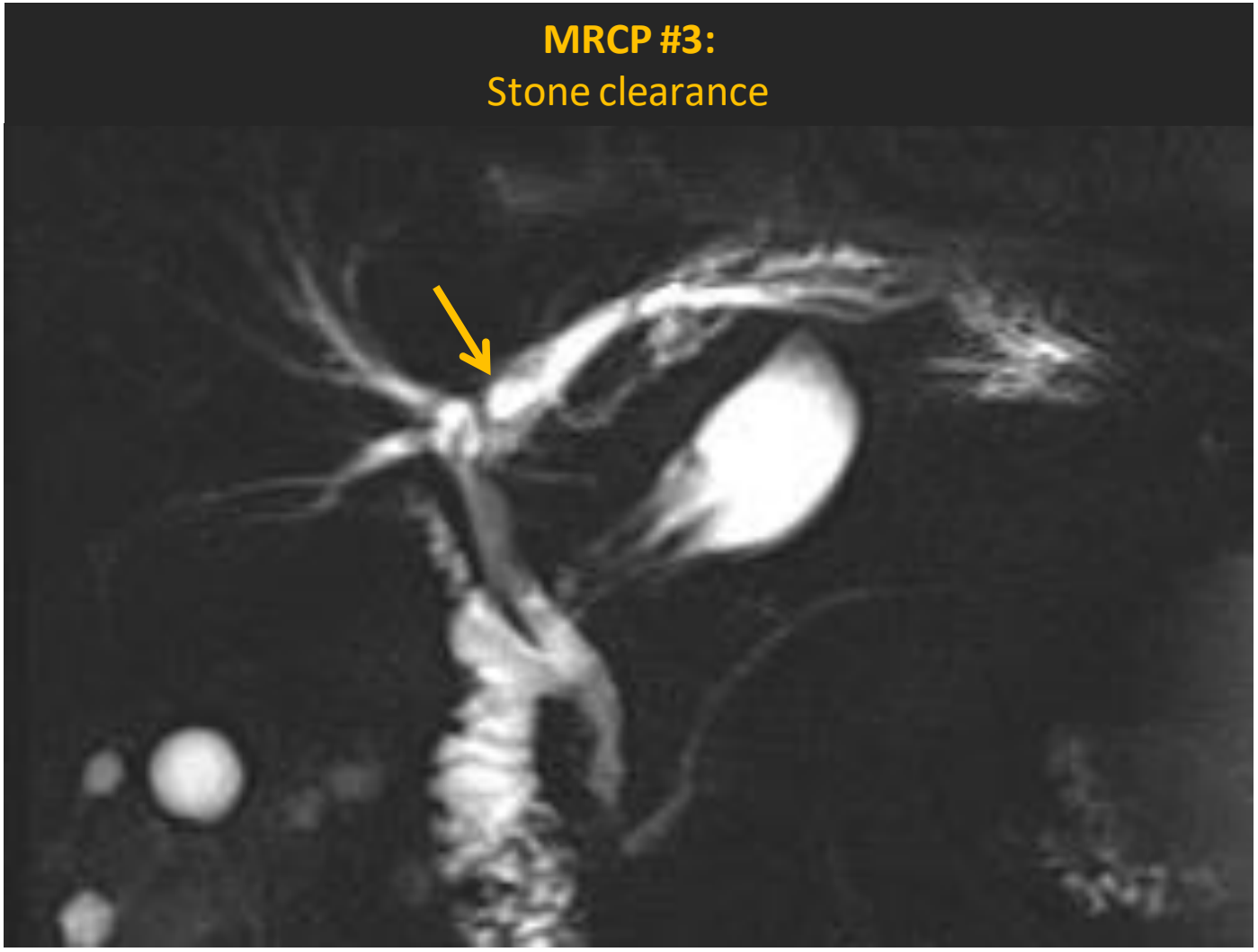
ERCP #2:
Extraction of stone fragments



ERCP #2: Stone clearance



Intrahepatic stones



Efficacy and Safety of Digital Single-Operator Cholangioscopy for Difficult Biliary Stones

- Retrospective, international, multicenter study on single-operator cholangioscopy + EHL/laser lithotripsy
- 22 tertiary center (USA, UK, Italy, Korea)
- 407 ptts
  - EHL (N = 306)
  - Laser (N = 101)

Brewer Gutierrez et al, Clinical Gastroenterology and Hepatology 2017, in press

Efficacy and Safety of Digital Single-Operator Cholangioscopy for Difficult Biliary Stones

Stone size, mm (mean ± SD)	**16.0 ± 7.1**
Stone number, *n* (%)	
1	**168 (41.3)**
2-3	**20 (4.9)**
> 3	**219 (53.8)**
Stone impaction	**155 (38.1)**
Stone proximal to stricture	**80 (19.7)**
Difficult cannulation/anatomy	**57 (14)**
Mirizzi syndrome	**35 (8.6)**

Brewer Gutierrez et al, Clinical Gastroenterology and Hepatology 2017, in press

Efficacy and Safety of Digital Single-Operator Cholangioscopy for Difficult Biliary Stones

Complete ductal clearance in single session, n (%)	**315 (77.4)**
Complete ductal clearance overall, n (%)	**396 (97.3)**
Need for ESWL and/or surgery	**11 (2.7)**
Procedure time, *min* (mean ± SD)	**67 ± 35**
EHL	**74 ± 34**
Laser	**50 ± 32**
AE (cholangitis (6), pancreatitis (1), bleeding (1), bile duct perforation (1), bacteremia (1), abdominal pain (5)	**15 (3.7)**

Brewer Gutierrez et al, Clinical Gastroenterology and Hepatology 2017, in press

Thieme

Complex biliary stones management: cholangioscopy versus papillary large balloon dilation – a randomized controlled trial

OPEN ACCESS

- 98 ptts with difficult biliary stones (> 10 stones, > 15 mm stones, disproportion between stone and distal CBD, biliary stricture with upstream stone)
- Randomized to EST + EPLBD (50) or peroral cholangioscopy + EHL (48)
- In case of failure: Crossover to the other treatment (in same or later session)
- No mechanical lithotripsy allowed
- Single dose antibiotic prophylaxis with ciprofloxacin 400 mg i.v. given

Endoscopy International Open 2018; 06: E131–E138

Thieme

Complex biliary stones management: cholangioscopy versus papillary large balloon dilation – a randomized controlled trial

	EST + EPLBD	Cholangioscopy + EHL
First session success, %	72	77.1
Overall success (after crossover), %	78	86
AE, %	12	4.2
AE , n	Bleeding (2), pancreatitis (2), CBD perforation (1), periampullary laceration (1)	Cholangitis (1), Pancreatitis (1)

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Thieme

Complex biliary stones management: cholangioscopy versus papillary large balloon dilation – a randomized controlled trial

OPEN ACCESS

" Single-operator cholangioscopic electrohydraulic lithotripsy as well as endoscopic papillary large balloon dilation are effective and safe techniques for endoscopic treatment of complex biliary stones, with high success rates and low incidence of AE…"

Endoscopy International Open 2018; 06: E131–E138

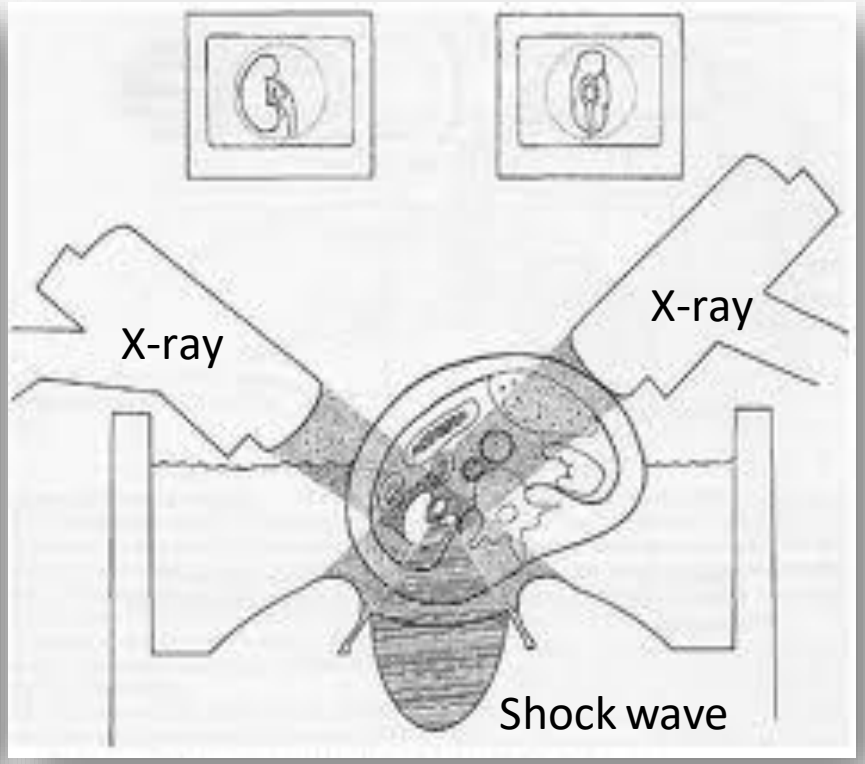
Extracorporeal Shock Wave Lithotripsy (ESWL)

History of ESWL

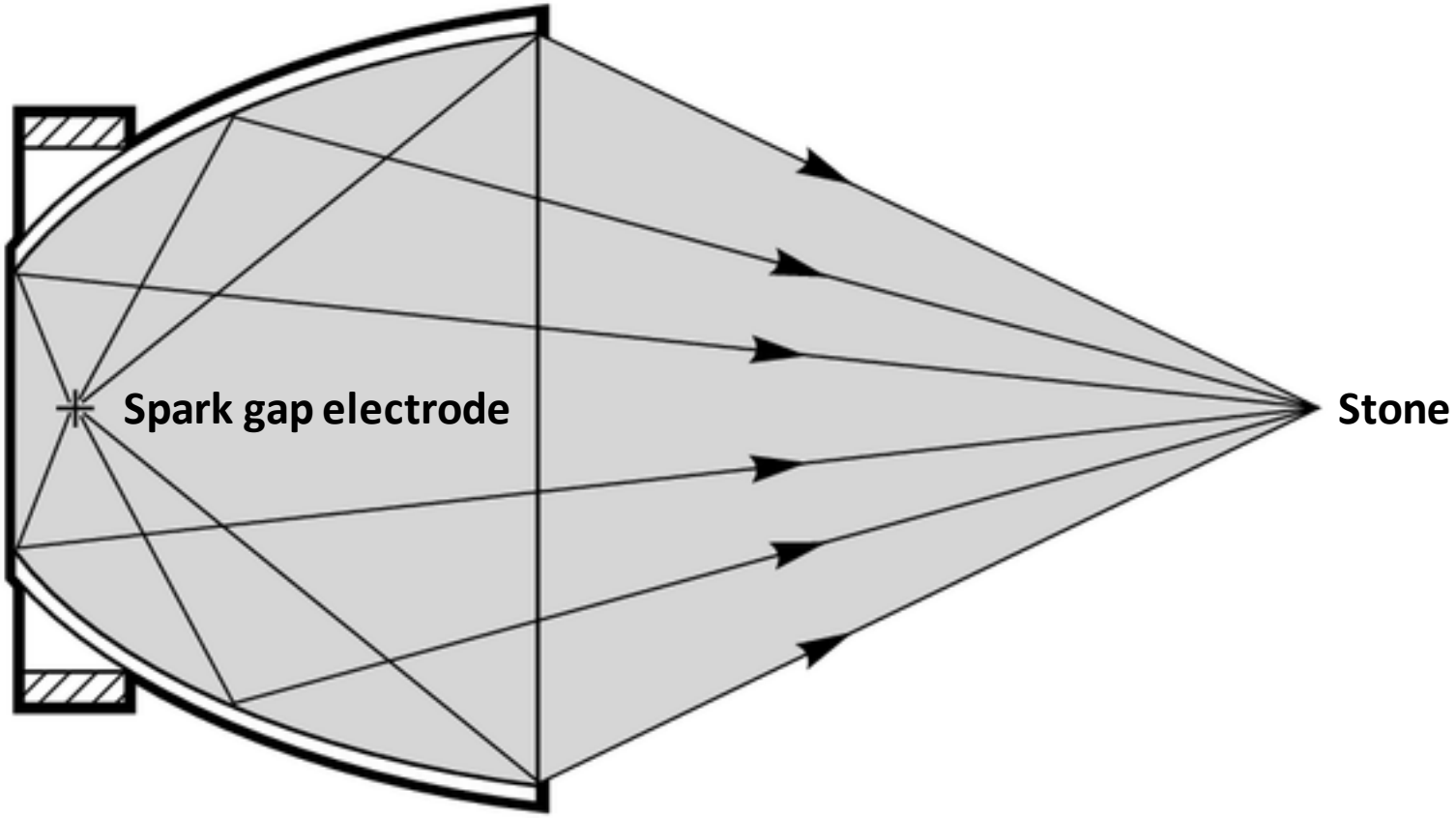
- **World War II:** Lungs of castaways were cracked from explosions of waterbombs without other signs of violance
- **1950s:** First systematic investigations of shock wave physics. First patent on electrohydraulic shock wave generator accepted (Frank Rieber, New York)
- **1966-71:** Dornier and Dept. of Defense in Germany perform experiments with shock waves
- **1971:** Haeusler and Kiefer, first report on in-vitro crushing of kidney stone
- **1980:** Chaussy et al. (München), first report on kidney stone treatment in humans with Dornier HM1 prototype
- **1986:** Sauerbruch et al. (München), first report on gallstone treatment
- **1987:** Sauerbruch et al. (München), first report on pancreatic stone treatment

1st generation lithotriptor

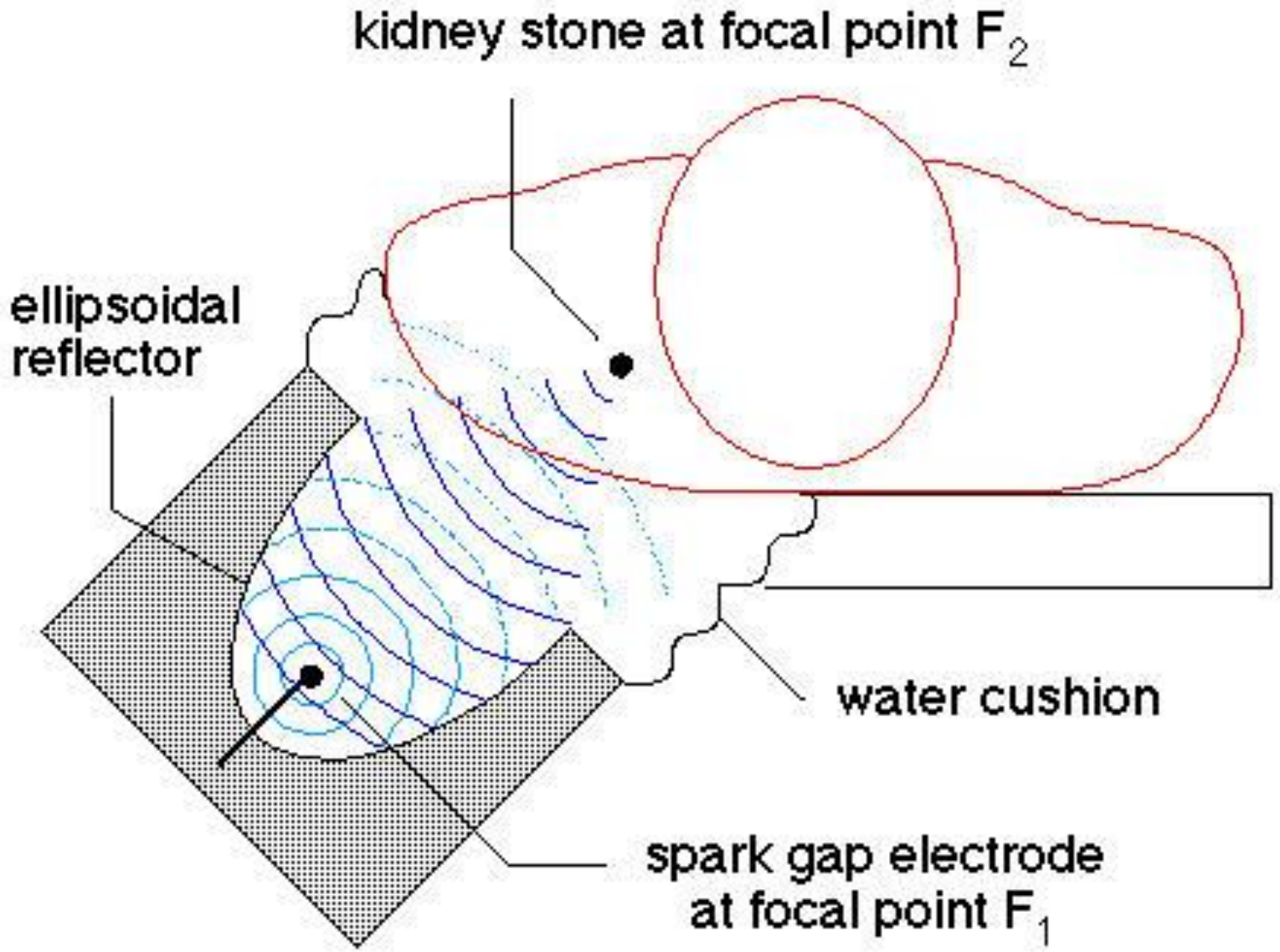
1st generation lithotriptor



Semi-ellipsodial reflector



2nd generation lithotriptor



Siemens Lithoskop

Stone localisation by in-line fluoroscopy

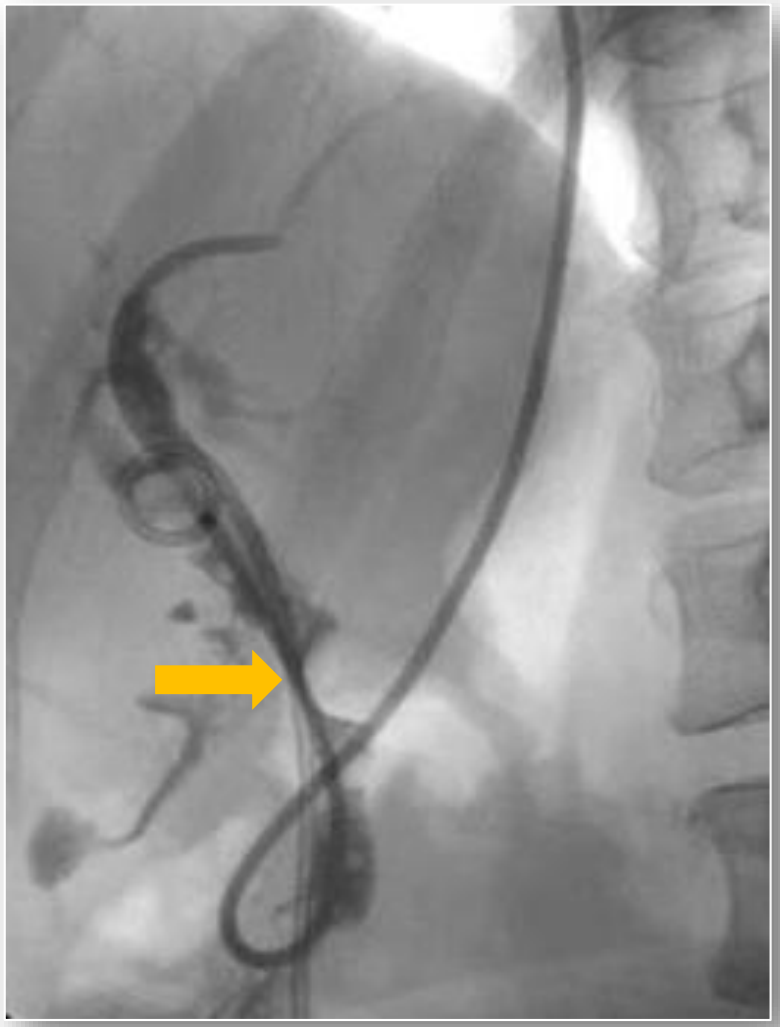
Image intensifier

Shock wave generator

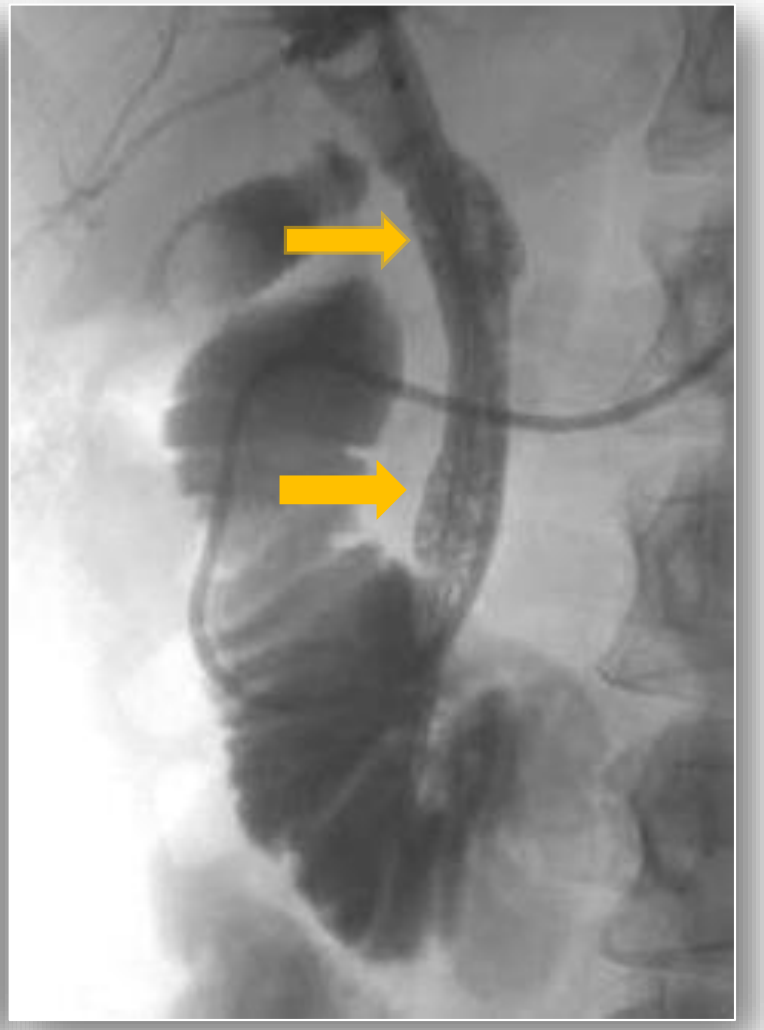
X-ray tube

Stone localisation by in-line ultrasound

ESWL: Large CBD/CD stone



Impacted CBD or cystic duct stone



Stone crushed by ESWL

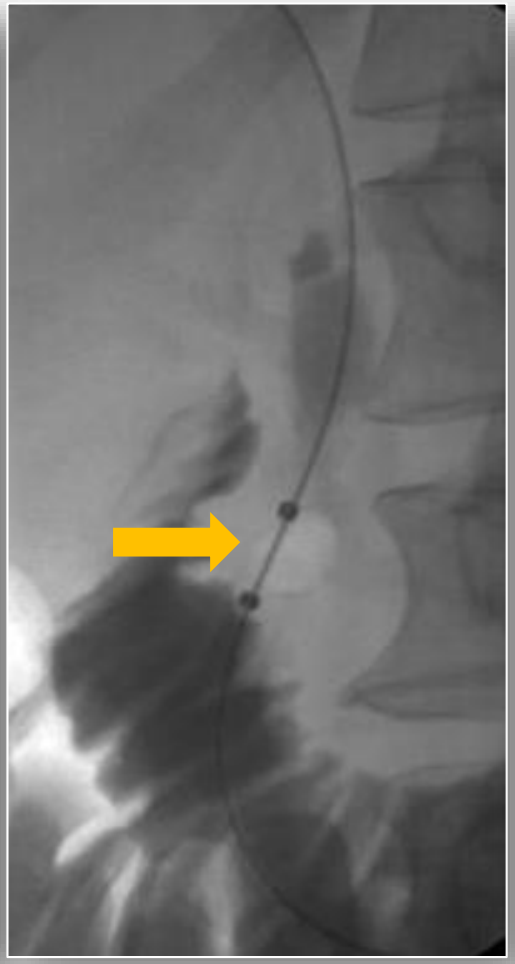
ESWL: CBD stone after gastric bypass

Percutaneous cholangiography

Stone crushed by ESWL

ESWL: CBD stone after gastric bypass

Remnant stone fragment



Stone removed by percutaneous balloon sweep

Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline

- ESGE recommends **limited sphincterotomy combined with endoscopic papillary large-balloon dilation as the first-line approach** to remove difficult common bile duct stones. Strong recommendation, high quality evidence.

Manes et al, Endoscopy 2019;51:472-91

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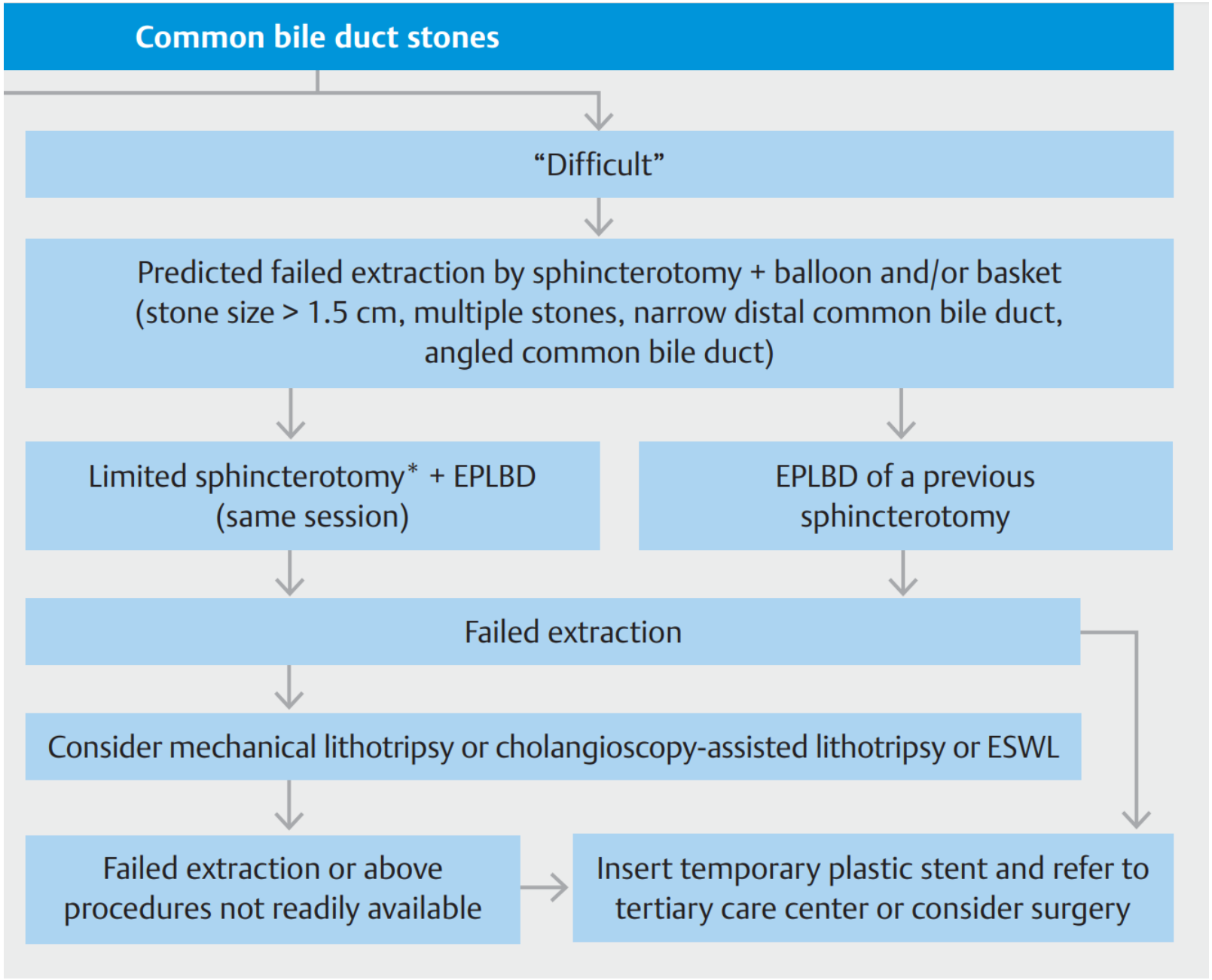
- ESGE suggests **considering extracorporeal shock wave lithotripsy when conventional techniques have failed** to achieve bile duct clearance and the intraluminal lithotripsy techniques are not available. Weak recommendation, low quality evidence.

Manes et al, Endoscopy 2019;51:472-91



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Summary

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- **Large balloon dilatation** reduces the need of mechanical lithotripsy
- **Large balloon dilatation is relatively contraindicated in ptts with a distal CBD stricture**
- **Single-operator cholangioscopy with EHL/laser lithotripsy** is a highly effective and safe supplemental treatment option
- **Extracorporeal shock wave lithotripsy** is slower and not as effective as intraductal EHL/laser lithotripsy but may have a role in selected patients with altered anatomy and inaccessible papilla