Asian EUS Group guidelines for standardized reporting in publications of EUS-guided biliary interventions

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Introduction

- There is considerable heterogeneity in the terminology and reporting of methods as well as outcomes in studies published in EUS-BD as is the case in studies evaluating biliary stenting using ERCP.
- This creates confusion when data needs to be collated to know the exact utility of EUS-BD.
- As more clinical studies are emerging there is a need to standardize reporting of studies with regards to the terminology, indications, measures of technical and clinical success as well as complications that are associated with EUS-BD.
- Such standards would facilitate a better understanding of the procedure outcomes and allow comparison between studies as well as facilitate the conduction of meta-analyses. In this article we propose a standardized reporting system for EUS-BD.

Terminology

- Generally, EUS guided biliary interventions can be divided into; transluminal or transpapillary biliary drainage procedure . Transluminal biliary drainage includes; EUS guided choledocoduodenostomy (EUS-CDS); EUS guided hepaticogastrostomy (EUS-HGS); and EUS guided gallbladder drainage (EUS-GBD) while the transpapillary biliary drainage procedure refers to EUS-antegrade (EUS-AG) interventions or EUS-rendezvous technique (EUS-RV). Although EUS-RV is not a biliary drainage procedure on its own and rather facilitates access for an ERCP it remains a EUS guided biliary intervention.
- Furthermore, these procedures could be divided based on the site of initial access, either through the liver (trans-hepatic) or the duodenum(trans-duodenal). However these terminologies do not help us much
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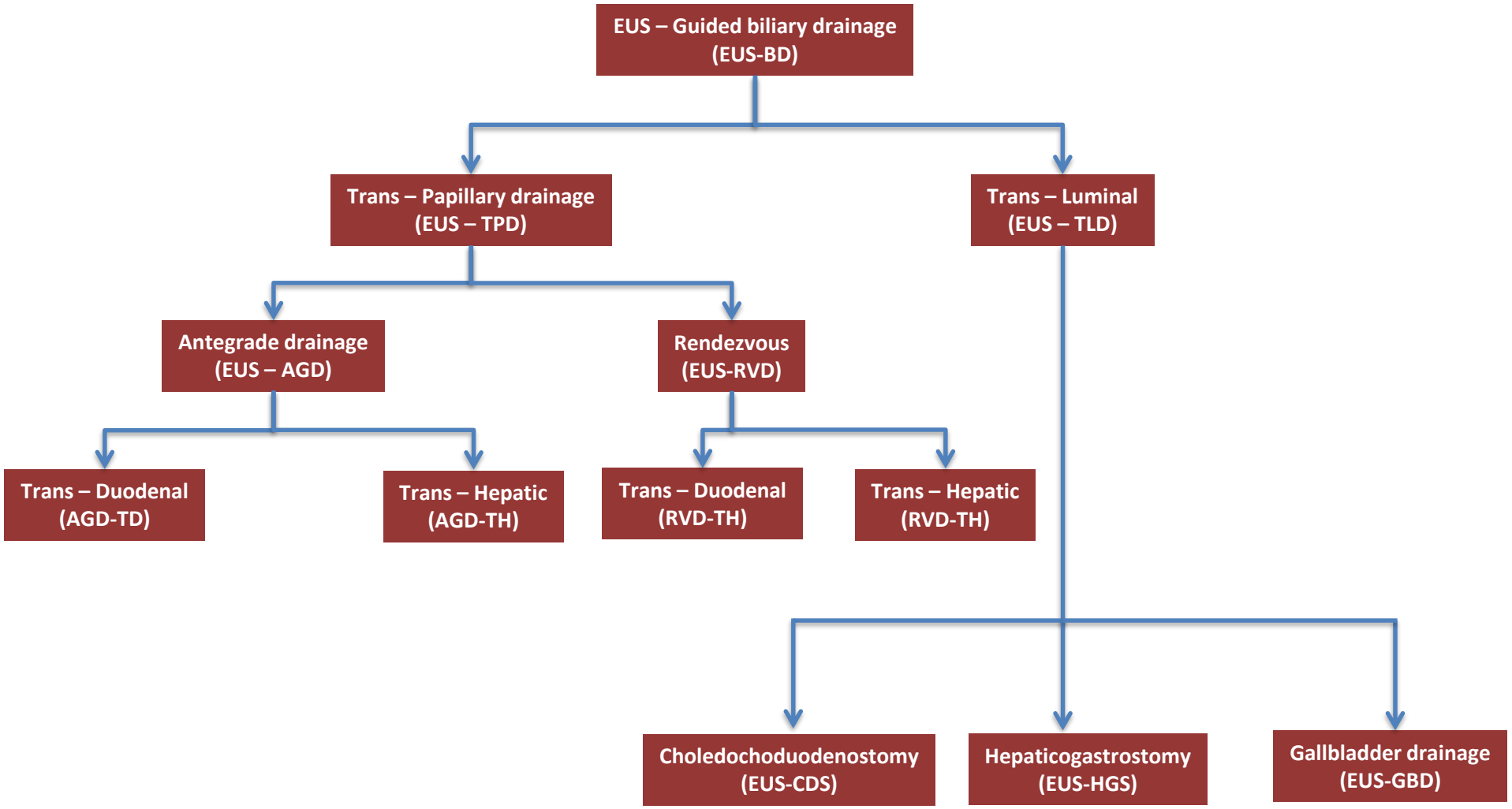
EUS – Guided biliary drainage (EUS-BD)
Trans – Papillary drainage (EUS – TPD)
Trans – Luminal (EUS – TLD)
Antegrade drainage (EUS – AGD)
Rendezvous (EUS-RVD)
Trans – Duodenal (AGD-TD)
Trans – Hepatic (AGD-TH)
Trans – Duodenal (RVD-TH)
Trans – Hepatic (RVD-TH)
Choledochoduodenostomy (EUS-CDS)
Hepaticogastrostomy (EUS-HGS)
Gallbladder drainage (EUS-GBD)

Indications

Standard indications

Patient's status

Palliation for MBO with difficulties in ERCP

Unavailable or refusal of PTBD/surgical procedures

Procedural status

Failed biliary access

Anatomical status

Inaccessible or difficult to access papilla

Altered GI anatomy

Malignant duodenal obstruction

Possible indications

High risk of complications for ERCP-BD

Tumor involvement of cystic duct (cholecysytitis)

Poor results in ERCP-BD

recurrent cholangitis due to stent block

Duodenal tumor infiltration

Presence of duodenal SEMS

Planning Multicenter trials

- Retrospective multicenter data collection should be avoided due to lack of uniformity in procedural variables and data collection at individual centers
- Expertise of participating centers should be clearly defined by specifying the number of procedures done per year at each center
- Centers doing fewer than 10 cases per year are unlikely to develop expertise for several years. Thus each expert center should contribute at least 10 cases per year of study recruitment
- Studies should mention the proportion of EUS-BD cases vis-à-vis ERCP cases at each Institute
- Studies should concentrate on one or two EUS-BD procedures. Multiple procedures in one study do not allow a fair conclusion about individual procedures

Reporting Patient related variables

- Co-morbidities
- Performance status
- Diagnosis
- Prior treatment

Pre-procedure	
	Patient Demographics
	Functional status
	Co-morbidities
	Indication
	Benign or malignant etiology
	Site of the primary tumor (if malignant)
	If duodenal obstruction is present is it type I, II, or III
	Is the papilla accessible or not
	Prior upper gastrointestinal surgery
	What decompression procedure was attempted prior to the EUS guided biliary intervention
	Preparation for the procedure
	Planned sedation: conscious sedation or general anesthesia
	Antibiotics use initiated pre- or post-procedure, rout and duration of administration.

Reporting Procedure related variables

- Accessories
  - Manufacturer, size (length and lumen), other details (covered etc)
- Anesthesia
- Procedure details
- Procedure time

Intra-procedure	Anatomical considerations
	Size of the CBD
	Level of the stricture
	Intrahepatic or extrahepatic biliary system approach
	Position of the scope; - Long (tip of the echoendoscope is in the cranial position) - Short (tip of the echoendoscope is in the caudal position)
	The site of puncture from the stomach (cardia or lesser curvature) or duodenum (first or second part).
	The segment of the liver that was used to access the biliary system
	Size of the needle used
	Length and caliber of the guidewire used as well as manufacturer
	Method used to dilate the tract between the enteric system and the biliary tree (boogie dilator, cystotome, or dilating balloon) and the size used.
	Was cautery used in the formation of the fistula.
	Stent used; - Plastic (length and French size) - Metal stent (length, manufacturer, fully covered or partially covered) - Lumen-apposing stent (length, manufacturer)
	In the case of EUS-HG - The length of the stent left protruding in the gastric lumen - If the left biliary system was only drained or the also the right - If the right system was drained was it through the left system (right to left system drainage) or through an independent puncture of the right biliary system.
	In the case of EUS-RV - Was cannulation of the CBD performed alongside the protruding guidewire or after retrieval of the distal end through the working channel of the duodenoscope.
	In the case of EUS-AG i - If a biliary balloon was used to dilate the area of stenosis prior to insertion of the SEMS
	Time from insertion of the scope till completion of the procedure
Miscellaneous	Was the EUS guided biliary intervention performed in a single session with an ERCP or was it scheduled at a latter date

Success of procedure

- Technical success is when a SEMS is deployed at the intended position as determined endoscopically and/or radiographically
- There have been variable definitions of clinical success in the literature with some defining functional success as a decrease in cholestatic indices to less than 75% of pretreatment values within 1 month of the procedure while others used a 50% reduction in total bilirubin after 7 days. We propose that clinical success be defined as a 50% decrease in serum bilirubin levels at 2 weeks post procedure

Reporting Adverse events

- Time of adverse events
  - Early
  - Late
- Severity
  - Mild
  - Moderate
  - Severe
  - Fatal
- Specific details

Complication	Definition
Perforation	Evidence of air or luminal contents outside the GI tract
Bleeding	Hematemesis and/or melena or hemoglobin drop > 2 g
Cholangitis	>38^{o}C for > 24 hours with cholestasis
Fever with no clear cause	>38^{o}C for > 24 hours without obvious source
Pancreatitis	Typical pain with amylase/lipase > 3 times normal
Cholecystitis	Right upperabdominal pain or fever >38°C occurs with supportive imaging studies
Hemobilia	Hemorrhage into the biliary tract
Intra-abdominal abscess	A pocket of infected fluid and pus located in the abdominal cavity
Biloma	A collection of bile inside the abdomen encapsulated with epithelial cells
Abdominal pain	This is in the absence of pancreatitis, cholecystitis, peritonitis, or perforation.

Severity grade	Complication
Mild	Procedure aborted (or not started) because of an adverse event
	Post-procedure medical consultation
	Unplanned hospital admission or prolongation of hospital stay for <3 nights
Moderate	Unplanned anesthesia/ventilation support, i.e. endotracheal intubation during conscious sedation
	Unplanned admission or prolongation for 4-10 nights
	ICU admission for 1 night
	Transfusion
	Repeat endoscopy for an adverse event
	Interventional radiology for an adverse event
	Interventional treatment for integument injuries
Severe	Unplanned admission or prolongation for >10 nights
	ICU admission >1 night
	Surgery for an adverse event
	Permanent disability (specify)
Fatal	Death

Specific adverse events

: Bleeding
  - Site
    - anastomotic site
    - intra bile duct(hemobilia)
  - Injured vessels
    - Arterial
    - portal venous
    - hepatic venous
    - unknown
- Peritonitis
  - Digestive perforation
    - Scope
    - Stenting
  - Other cause
    - Bile peritonitis
      - With stent
      - Without stent
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Long term outcomes

- The occurrence of stent migration, whether proximal (Into the biliary system, gallbladder or intra-abdominal cavity) or distal.
- The duration of stent patency and symptom free survival as well as recurrent biliary obstruction from overgrowth or ingrowth are important determinants.
- The need or repeat procedures or other modalities of biliary drainage (PTBD) should be recorded.
- Quality of life scores are important patient related outcomes