The TOKYO Criteria 2014 for Transpapillary Biliary Stenting

Shomei Ryozawa, M.D., Ph.D.
Department of Gastroenterology, Saitama Medical University International Medical Center, Saitama, Japan

Introduction

It is difficult to carry out meta-analyses or to compare the results of different studies of biliary stents because there is no uniform evaluation method. Therefore, a standardized reporting system is required. We propose a new standardized system for reporting on biliary stents, the ‘TOKYO criteria 2014’, based on a consensus among Japanese pancreatobiliary endoscopists (Hiroyuki Isayama, Tsuyoshi Hamada, Ichiro Yasuda, Takao Itoi, Shomei Ryozawa, Yousuke Nakai, Hirofumi Kogure and Kazuhiko Koike).

Main Body

1. Technical and Functional success

We recommend that technical success is defined as successful deployment of a SEM/PS in the intended location with sufficient coverage of the stricture. Functional success is defined as a 50% decrease in or normalization of the bilirubin level within 14 days of stent placement.

2. Time to recurrent biliary obstruction

We recommend that recurrent biliary obstruction is defined as a composite endpoint of either occlusion or migration, and time to recurrent biliary obstruction refers to the time from SEMS/PS placement to the recurrence of biliary obstruction. We recommend that the time points of occlusion and migration be defined as the points at which symptoms associated with occlusion or migration are observed. In the estimation of time to recurrent biliary obstruction, patient death and complications other than recurrent biliary obstruction requiring SEMS removal are treated as censored cases at the time of death or SEMS removal, respectively.

3. Survival time

The survival time should be reported for each study arm in comparative studies. Note that time to recurrent biliary obstruction is underestimated when premature patient death without recurrent biliary obstruction is treated as censored in the Kaplan-Meier method.
4. Causes of recurrent biliary obstruction

The details of recurrent biliary obstruction should be clarified in the evaluation of biliary stent, rate of each cause and median time from the placement.

Occlusion

We recommend that stent occlusion is defined as present when there is biochemical evidence of cholestasis. The causes of SEMS/PS occlusion can be categorized as follows: tumor ingrowth/mucosal hyperplasia; tumor overgrowth; sludge with/without stones; hemobilia; food impaction; bile duct kinking; and others.

Migration

Stent migration is diagnosed when a reintervention reveals a completely or partially migrated SEMS/PS as a cause of recurrent biliary obstruction. We recommend that the time point of symptomatic migration be defined as the point when symptoms associated with stent migration are observed.

1. Complications other than recurrent biliary obstruction

Complications other than recurrent biliary obstruction can be categorized as follows: pancreatitis; cholangitis (non-occlusion cholangitis); cholecystitis; and others (bleeding, ulceration, penetration, perforation etc.). These complications are categorized as early (within 30 days) and late (31 days or later). The severity of pancreatitis, cholangitis, cholecystitis, bleeding, and perforation is graded using the system proposed by Cotton et al. The severity of pancreatitis was defined based on both Cotton’s grading and the Atlanta classification 2012.2,3

Conclusions

We propose a standardized system, TOKYO criteria 2014, for reporting endoscopic transpapillary biliary stenting for biliary stricture. These consensus-based criteria include definitions of complications and appropriate evaluation of stent quality.

References