

ORIGINAL ARTICLE

Proposed standards for reporting outcomes of treating biliary injuries

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Abstract

Background: There is no standard nor widely accepted way of reporting outcomes of treatment of biliary injuries. This hinders comparison of results among approaches and among centers. This paper presents a proposal to standardize terminology and reporting of results of treating biliary injuries.

Methods: The proposal was developed by an international group of surgeons, biliary endoscopists and interventional radiologists. The method is based on the concept of “patency” and is similar to the approach used to create reporting standards for arteriovenous hemodialysis access.

Results: The group considered definitions and gradings under the following headings: Definition of Patency, Definition of Index Treatment Periods, Grading of Severity of Biliary Injury, Grading of Patency, Metrics, Comparison of Surgical to Non Surgical Treatments and Presentation of Case Series.

Conclusions: A standard procedure for reporting outcomes of treating biliary injuries has been produced. It is applicable to presenting results of treatment by surgery, endoscopy, and interventional radiology.

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Biliary injuries are usually complications of laparoscopic cholecystectomy and are both morbid and costly. Effective surgical, endoscopic and interventional radiologic techniques have

evolved to treat them and many reports of such treatment outcomes are available. However, there is no standard or widely accepted way of reporting outcomes. This hinders comparison of

results among approaches and among centers. Furthermore, heterogeneity among studies represents a major challenge in assessment of outcomes because of non-standard reporting methods. Adoption of standardized reporting of outcomes should allow determination of the degree of clinical heterogeneity that exists among studies and improve the ability to compare studies of biliary injuries.

The following is a proposal to standardize terminology and reporting of results of treating biliary injuries. The proposal is largely focused on the outcome of primary repairs of bile duct injuries. However there is a discussion on how the approach may be also used for evaluating patients who have had prior failed attempts at repair.

Methods

The proposal was developed by an international group of nineteen surgeons, biliary endoscopists and interventional radiologists. The method is based on the concept of “patency” and is similar to the approach used to create reporting standards for arteriovenous hemodialysis access.^{1,2} The schema was developed in an iterative fashion in which a series of plans and questions were emailed to participants for comment over a period of 18 months. Based on feedback the proposal was modified until this final document was produced.

The group considered recommendations under the headings: Definition of Patency, Definition of Index Treatment Periods, Grading of Severity of Biliary Injury, Grading of Patency, Metrics, Comparison of Surgical to Non Surgical Treatments and Presentation of Case Series.

Results

Definition of patency

The purpose of treating biliary injuries is to restore continuity of the biliary tree and bring patients into a state of cure that will be referred to as “patency”. Patients may stay in a state of cure or patency or fall out of that state temporarily or permanently. What is evaluated is how effectively “patency” is attained and conserved after treatment of a biliary injury, and if it is lost how effectively it is restored.

Patency is defined as an open functional biliary tree, free of stents,^a and free of the need for invasive interventions, in a patient who following completion of treatment has no episodes of cholangitis, liver abscess, jaundice or external biliary fistula. The biliary tree must be both open and functional to be in a state of “patency”. Although uncommon, a repair may be anatomically patent but nonetheless associated with cholangitis, liver abscess,

jaundice, or external biliary fistula. This type of result is not considered patency. Therefore, patency means not only anatomic but functional patency.

Primary patency: If the definition of patency is fulfilled after the completion of the index surgical or non-surgical treatment of a biliary injury then the patient is considered to have entered a state of “primary patency”. If after primary patency is attained an invasive intervention is required either by surgery, endoscopy or by interventional radiologic techniques then primary patency is lost. Similarly, if after primary patency is attained cholangitis, liver abscess, jaundice or external biliary fistula occur, then primary patency is lost. The duration of primary patency is the interval between attainment of patency and loss. Primary patency is the ideal outcome. A patient who does not achieve patency at the end of the index treatment period never attains primary patency. Abdominal pain alone i.e., in the absence of jaundice, cholangitis, liver abscess, or bile fistula is not considered to represent a loss of patency.

Secondary patency is a state that may be achieved in a patient who has either not attained primary patency at the end of the index treatment period or who has subsequently lost primary patency. In the former case, if patency is achieved after the treatment or, in the latter case, restored after additional treatment then the patient is considered to have entered a state of “secondary patency”. If during the period of secondary patency, a need for an invasive intervention develops or cholangitis, liver abscess, jaundice or external biliary fistula occur then secondary patency is lost. Secondary patency can be lost and regained more than once. The duration of secondary patency is the interval between achievement and loss.

It is common for surgical case series to include primary repairs and re-repairs of failed primary repairs, which are often called secondary repairs. The term “secondary repair” is undesirable as it may be confused with “secondary patency” and if two re-repairs are performed it would be necessary to refer to “tertiary” or more repairs. The term re-repair is suggested and can be used as first re-repair, second re-repair, and so on.

Definition of index treatment periods

Index treatment period

The index treatment period is the time during which a definitive attempt is made to obtain patency in an injured biliary tree by surgical, endoscopic or radiologic means. Surgical treatments differ from endoscopic or interventional radiologic (IR) procedures in that surgical repairs are usually accomplished in one procedure. The most common surgical procedure involves the formation of one or more biliary-enteric anastomoses. The surgical procedure is followed by a recovery period. Non-surgical treatments often require more than one intervention and these are commonly performed over several months. Recognizing that the treatments are fundamentally different in this manner the Index Treatment Period will be different for surgical and non-surgical treatments.

^a The word stent is used throughout to indicate any tube placed in the biliary tree. This includes short tubes that are entirely within the body and those that exit from the body and which sometimes are called drainage catheters.

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