**Cannulation Time is a More Accurate Measure of Cannulation Difficulty for ERCP than the Number of Attempts**

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**Abstract**

**Background**: Cannulation of the common bile duct (CBD) is the initial and often challenging step in this procedure.  Endoscopists often use cannulation attempts and cannulation time to grade cannulation difficulty but a standard system has yet to be established.

**Objective:** To evaluate cannulation time as a measure of cannulation difficulty.

**Design:** Prospective study.

**Setting:** Tertiary referral center.

**Patients:** 72 patients undergoing ERCP for a variety of indications.

**Intervention:** Cannulation time and the number of cannulation attempts were recorded for each patient.  A subset of 13 ERCPs had two observers assessing attempts at cannulation.

**Main Outcome Measurements:** Cannulation time, number of attempts, inter-observer variability in assessment of attempts.

**Results:** Number of cannulation attempts showed inter-observer variability.

**Limitations:** Small number of two-observer procedures.

**Conclusion:** Cannulation time is a more objective and more accurate assessment tool for grading cannulation difficulty than the number of attempts at the papilla.

**Introduction**

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic procedure that has been used in clinical practice for about four decades (1, 2). It is commonly used for the diagnosis and treatment of biliary and pancreatic diseases (1-5).  Deep cannulation of the common bile duct (CBD) is the critical first step to visualizing the pancreaticobiliary system during ERCP procedure.  Deep cannulation of the CBD at ERCP can represent a technical challenge, even to experienced pancreaticobiliary endoscopists (6-8).  In fact, the most common reason for an unsuccessful ERCP is the inability to cannulate the CBD (7, 8).

Previous studies have demonstrated that a difficult cannulation is a risk factor for post-ERCP complications, such as pancreatitis (8-10).  However, there has been no standardization of the assessment of cannulation difficulty.  Methods of estimating difficulty have been variable and subjective, incorporating measurements that are difficult to define such as the number of attempts at the papilla.  In an effort towards a standardized system for grading cannulation difficulty, we undertook a comparative study evaluating accurateness of cannulation time and the number of cannulation attempts.

**Methods**

Seventy-two patients undergoing ERCP for a variety of indications were evaluated in this study, which took place from February of 2005 to August of 2006.  Exclusion criteria included the following: pre-existing stent in CBD or pancreatic duct, history of endoscopic or surgical sphincterotomy, prior Billroth II surgery, Rouen-Y gastric bypass surgery, ERCP within 1 week prior to the study, and need for a biliary manometry study. All enrolled patients signed an informed consent document.  The study was approved by our university Institutional Review Board.

This study was carried out in a tertiary medical center where Gastroenterology fellows are trained in ERCP.  For each procedure, one of the ERCP fellows (trainee) was the first endoscopist.  If deep CBD cannulation was not achieved in 5 minutes, an attending (senior endoscopist) took the duodenoscope and continued the procedure.  Two senior endoscopists took part in the study.  Cannulation was performed using standard tapered or ball tip ERCP catheters with 0.035 guide wires (Boston Scientific, Natick, MA).  In this study, the physicians were allowed to continue using their usual cannulation techniques.  However, methods such as the precut and pancreatic guide-wire or stent placement were not allowed.

Two methods of grading cannulation difficulty were assessed: cannulation time and number of cannulation attempts.  Deep CBD cannulation time was defined as the time from starting cannulation to the time when the catheter has been introduced deeply inside the CBD, so that therapeutic procedures can be performed as needed.  During the selective deep CBD cannulation process, if the pancreatic duct was cannulated, the endoscopist would take out the catheter from the pancreatic duct immediately and continue deep CBD cannulation.  In this situation, the deep CBD cannulation time count was not interrupted.  Deep CBD cannulation time count was also not interrupted when the attending endoscopist continued cannulation if the fellow failed to cannulate the CBD.  Hence, the cannulation time recorded for the attending included the initial time utilized by the fellow.

The number of cannulation attempts was tallied for each patient by a bystander. The bystander was a MD with two years of ERCP experience.  For fourteen patients, an additional observer who was an experienced pancreatobiliary endoscopist and had performed thousands of ERCPs was brought in to separately record the number of cannulation attempts. Those two individuals were instructed on how to count the cannulation attempts before the study. Each cannulation attempt was defined as the ERCP catheter or the guide wire through the catheter touched the major papilla, injected/attempted to inject contrast or advanced/attempted to advance the guide wire through the ERCP catheter.

Cannulation failure was defined by the following criteria:  the attending physician terminated the procedure, the major papilla could not be located or visualized in a suitable position, and the patient became agitated and unsafe to complete the procedure.  Failure was also recorded if cannulation time exceeded 30 minutes.

A scoring system was used to grade cannulation difficulty based on the amount of time elapsed and attempt number: Easy = total cannulation time less than 5 minutes.  Moderate = total cannulation time of 5 to 10 minutes.  Difficult = total cannulation time greater than 10 minutes.  Scoring based on attempt number was defined as: Easy = cannulation achieved in 1 attempt.  Moderate = cannulation achieved in 2 to 5 attempts.  Difficult = cannulation achieved in 6 or more attempts.

**Results**

Of the seventy-two patients referred for ERCP, fifty-eight patients met the inclusion criteria and deep cannulation was successfully performed. Forty-four of these ERCPs were performed with a single observer recording the number of attempt count.  The mean cannulation time was 11 +/- 15 minutes (Table 1). Cannulation was achieved within 5 minutes in 40% (23/58), and in more than 5 minutes and less than 10 minutes in 41% (24/58). The mean number of attempts calculated by the single observer ERCPs was 9 +/- 14 counts (Table 1).

There was positive association between cannulation time and the number of cannulation attempts, where longer cannulation was associated with more cannulation attempts (Figure 1). [need measure of correlation such as an R statistic]  However, during twenty-one of the single-observer ERCPs (21/44, 48%), the time score did not correlate with the attempt score.  Specifically, eight ERCPs (8/44, 18%) had a higher time score whereas thirteen ERCPs (13/44, 30%) had a higher attempt score (Figure 2).

Of the fourteen ERCPs with two observers separately recording number of attempts, seven (7/14, 50%) had counts differing by at least two (Figure 3).  In three of these seven instances, the observers’ differing counts placed the same procedure in two different grades of cannulation difficulty (Figure 3).  In one of the fourteen two-observer ERCPs, one observer lost count and only the other observer’s count was available.

**Discussion**

ERCP remains an important therapeutic modality for pancreatobiliary diseases. Typically, the essential step in a successful procedure is cannulation of the CBD. The degree of difficulty during cannulation at ERCP is positively associated with post ERCP pancreatitis (8). Many studies have been published on the assessment of the degree of difficulty during cannulation at ERCP (9, 11-24). Among those published papers, most of them used cannulation attempts as the measure of difficulty during cannulation (9, 11, 13-16), three used cannulation time (12, 17, 18), some used cannulation attempts and cannulation time (19, 20) and a number of studies did not report the method of assessment of difficulty during cannulation (21-24). However, there is no study comparing these two measures of cannulation difficulty. To our knowledge, this is the first study to compare these two assessments.

Although cannulation attempts have been used by many authors, there is no uniform definition for cannulation attempts. In one study, a cannulation attempt was defined by any repositioning or wedging of the catheter tip or cannulation device in an attempt to cannulate the biliary or pancreatic duct (14). In another study, a cannulation attempt was defined as sustained contact between the cannulating device and the papilla for at least 5 seconds (20). The present study showed that the number of attempts is an unreliable measure and varies between observers despite an established definition for a cannulation attempt.  The large interobserver discrepancy (7/14, 50% plus one ERCP where an observer lost count) brings into question the feasibility of number of attempt scoring during complicated cannulations.  In three of seven ERCPs where a discrepancy was noted, one observer graded the ERCP as moderate while the other graded the same procedure as difficult based on their counts.  These differences were noted despite training and instruction in criteria for counting the cannulation attempts prior to study initiation.

In contrast, cannulation time is more objective and is not influenced by interobserver variation. In some situations, such as when a patient is unstable during cannulation, the cannulation may be interrupted and may make the cannulation time not measureable.

It is commonly believed that a difficult cannulation is associated with increased post-ERCP pancreatitis. As the level of cannulation difficulty increased, the observed incidence of post-ERCP pancreatitis also increased (8).  Notably, observed incidence of post-ERCP pancreatitis jumped from 4.3% to 10.3% when cannulation difficulty increased from easy to moderate (8). Since the aim of the present study was mainly to compare the cannulation attempts and the cannulation time, we did not follow up patients for post ERCP pancreatitis or other procedural related complications.

Our study also demonstrated poor correlation between the attempt score and total time score.  Thus, grading obtained by these methods should not be used interchangeably.  This result more importantly, supports a need for scoring standardization.

The main limitation of the study was the small sample size for the two-observer arm of the study.  However, interobserver differences were significant enough for us to recommend using total cannulation time as a more objective and therefore, more accurate assessment of cannulation difficulty.

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Table 1. Average cannulation time and attempt number

|  |  |  |
| --- | --- | --- |
| Scoring method | Mean | SD |
| Cannulation Time\* | 11 minutes | 15 |
| Cannulation Attempts\*\* | 9 counts | 14 |

\*n = 58 (single-observer and two-observer ERCPs)

\*\*n = 44 (single-observer ERCPs)

**Figure 1.** Grading cannulation difficulty in forty-four ERCPs by two methods: total cannulation time and number of cannulation attempts

**Figure 2.** Difference between the time score and attempt score for forty-four ERCPs. Each ERCP was graded on cannulation difficulty by total cannulation time and cannulation attempts

**Figure 3.** Interobserver count difference for fourteen two-observer ERCPs. In fourteen ERCPs, two observers were asked to separately record cannulation attempts.

Figure legends

**Figure 1**

Time score derived from the following criteria: easy/1= cannulation achieved within 5 minutes, moderate/2= cannulation achieved in 5 to 10 minutes, difficult/3= cannulation achieved in more than 10 minutes. Attempt score derived from the following criteria: easy/1= cannulation achieved in 1 attempt, moderate/2= cannulation achieved in 2 to 5 attempts, difficult/3= cannulation achieved in 6 or more attempts.

**Figure 2**

Time score derived from the following criteria: easy/1= cannulation achieved within 5 minutes, moderate/2= cannulation achieved in 5 to 10 minutes, difficult/3= cannulation achieved in more than 10 minutes. Attempt score derived from the following criteria: easy/1= cannulation achieved in 1 attempt, moderate/2= cannulation achieved in 2 to 5 attempts, difficult/3= cannulation achieved in 6 or more attempts. Difference obtained by subtracting the attempt score from the time score for each ERCP.

**Figure 3**

The count difference is the disparity in recorded attempts between two observers for each ERCP. For the 14th ERCP, the count difference is not calculable as one observer lost count. The asterisk \* denotes ERCPs where a count disparity placed the same procedure in different grades of cannulation difficulty. Cannulation difficulty graded by attempts is as follows: easy= cannulation achieved in 1 attempt, moderate= cannulation achieved in 2 to 5 attempts, difficult= cannulation achieved in 6 or more attempts.