



Assessment of the Learning Curve for Single-Use Disposable Duodenoscope for a Single Operator

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BACKGROUND/AIMS

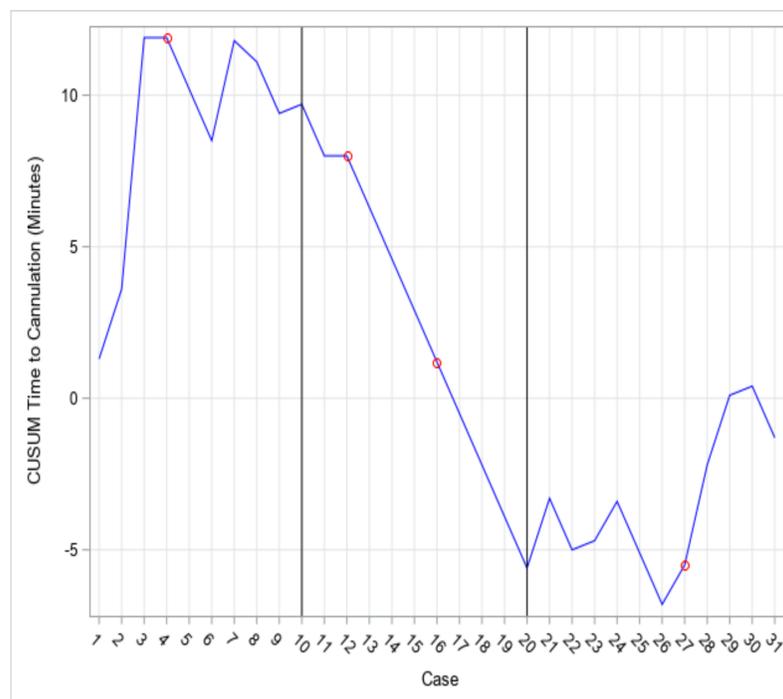
- In response to reports of duodenoscope-related infectious outbreaks of multidrug-resistant organisms, the Food and Drug Administration (FDA) has recommended a transition to duodenoscopes with innovative designs that may include disposable components or fully disposable duodenoscopes.
- We aim to characterize the learning curve (LC) for single-use disposable duodenoscopes, to ensure the adoption of these innovative devices in a safe and thoughtful manner.

METHODS

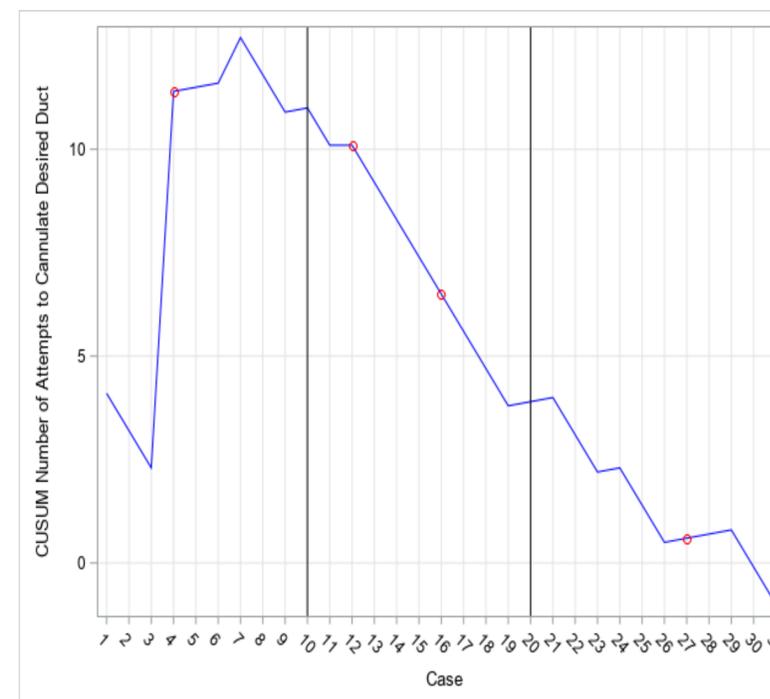
- We performed a retrospective review of data from 31 patients who underwent ERCP by a single, experienced operator using the EXALT Model D® disposable duodenoscope at a single tertiary referral center.
- The LC for this device was described by the number of cases needed to achieve proficiency using cumulative sum (CUSUM) analysis.
- Number of attempts to cannulate and time to cannulate the desired duct were assessed separately using CUSUM analysis.
- The overall mean number of attempts and overall mean time to cannulation were used as the target values in the respective CUSUM analyses.
- Proficiency was defined as the number of procedures where an inflection point was reached in the CUSUM graph.
- This observation indicates improving operator performance as shown by a decrease in the number of attempts and shortening of cannulation time after the defined number of procedures.

Table 1. Patient demographics, procedural characteristics, outcomes and complications (n = 31)

Variable	n (%)
Demographic data	
Mean age (years)	61 (35-84)
Female	14 (45)
Procedural characteristics	
Native papilla	6 (19)
ASGE complexity level	
1	6 (19)
2	14 (45)
3	11 (35)
Procedural outcome	
Technical success – procedure completion using disposable duodenoscope	27 (87)
Cases which required switching to a reusable duodenoscope	4 (13)
Procedural complications	
Post-ERCP pancreatitis	1 (3)
Post-procedural abdominal pain	13 (42)
Intra-procedural or post-procedural bleeding	1 (3)
Visceral perforation	0 (0)



Cumulative sum curve on time to cannulation to achieve proficiency



Cumulative sum curve on the number of cannulation attempts to achieve proficiency

RESULTS

- Overall, 31 patients underwent ERCP using the EXALT Model D disposable duodenoscope by a single experienced endoscopist (Table 1).
- 6 (19%) patients had a native papilla and the majority of these procedures were classified as ASGE complexity level 2 or above.
- The procedure was completed using solely the disposable duodenoscope in 27 patients (87%), while a reusable duodenoscope was required for procedure completion in 4 patients (13%). The cross-overs were distributed evenly across the performance period.
- Procedure-related complications are described in Table 1.
- Number of attempts to cannulate the desired duct and time to cannulation are illustrated by CUSUM plots in Figure 1.
- The risk of major procedural complications was comparable to those associated with the use of reusable duodenoscopes.
- In both endpoints, an inflection of the CUSUM curves is achieved at approximately 10 cases, indicating sustained shortening of cannulation attempts and time to cannulation.

CONCLUSIONS

- Among an experienced ERCP endoscopist, approximately 10 ERCPs can be considered the threshold to achieve proficiency with the use of a disposable duodenoscope.
- Procedure-related complications are consistent with those expected with reusable duodenoscopes.
- The need to cross-over from single-use duodenoscope to reusable duodenoscope did not appear to be related to the learning curve.
- These results can be used to guide adoption of single-use duodenoscopes into clinical practice.