

The Benefit of an Intensive Training Course on ERCP Artificial Simulator on Decreasing the Cannulation Time Achieved by the Trainees

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Abstract

Background: ECRP is an advanced endoscopic technique with a high learning curve requiring effective and standardized training programs to ensure competency.

Aim of Study: Test the benefit of an intensive course on ERCP artificial simulator on decreasing the cannulation time achieved by trainees.

Patients and Method: Forty trainees were divided into two groups. Twenty were enrolled in a clinical training program only and the other twenty were enrolled in an intensive two-week intensive course using a simulator for ERCP training. Ten expert endoscopists represented to control group.

Results: Forty trainees were included in the final analysis. Cannulation time was 18.69 ± 9.21 (mean \pm SD) in group 1 and 9.36 ± 5.14 in group 2 ($p=0.001$).

Conclusion: Intensive course including hands-on training on an ERCP simulator can be an alternative for traditional training programs.

Key Words: ERCP – Training – Simulators.

Introduction

ENDOSCOPIC retrograde cholangiopancreatography (ERCP) is a technique that uses a combination of luminal endoscopy and fluoroscopic imaging to diagnose and treat conditions associated with the pancreatobiliary system. The endoscopic portion of the examination uses a side-viewing duodenoscope that is passed through the esophagus and stomach and into the second portion of the duodenum [1].

It is an advanced endoscopic technique that is challenging for trainees for several reasons such

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as the use of side view endoscope, procedural complexity, and risk of complications. As a result, proficiency in using an upper gastrointestinal endoscope is imperative and a precise understanding of the pancreatobiliary anatomy and physiology is essential [2]. For these reasons, a study in the United States has shown that only 23% of the fellows who completed ERCP training have experience completing >180 cases yearly, meaning that appropriate ERCP training is very difficult in real practice [3].

Given the complexity of the procedure, it is associated with a higher frequency of serious complications than other endoscopic procedures are. Accordingly, specialized training and equipment are required, and the procedure should be reserved for appropriate indications [4].

The aim of this study is to test the benefit of a two weeks intensive course on ERCP artificial simulator on decreasing the cannulation time achieved by trainees.

Patients and Methods

Study setting and population:

Twenty trainees were evaluated by ten expert endoscopists in this study to evaluate if there is a difference between two training programs. The study was conducted in two gastroenterology centers including Theodor Bilharz Research Institute and Al-Demerdash University between February 2021 to February 2022. An informed written consent was obtained from all participants of the study.

Eligibility criteria of the trainees:

- Age: More than 33 years.
- Performing upper GI procedures independently.
- Performing lower GI procedures independently.
- Observed at least 50 ERCP cases under supervision from an expert endoscopist.

Exclusion criteria:

- Age: Less than 33 years.
- Performing upper GI endoscopy procedure under supervision of an expert endoscopist only.
- Performing lower GI endoscopy under supervision of an expert endoscopist.
- No prior exposure to ERCP procedures.

Study design:

This prospective, observational, single blind study involved independent operators (control group) and their trainees (trainee group 1 and 2). The subjects in this study were divided into 3 groups to assess the benefit of intensive 2 weeks training course on ERCP artificial model and comparing the results of the two trainee groups to the control group. ASGE assessment criteria was used to evaluate the performance and to assess immediate post-ERCP adverse events [2].

- Group (1): 10 trainees were enrolled in a clinical training program only.
- Group (2): 10 trainees were enrolled in an intensive two-weeks hands on training on Boskoski-Costamagna ERCP trainer followed by clinical training.
- Control group (3): 10 expert endoscopist were enrolled in this study, defined as expert endoscopist who performed more than 1000 independent ERCP procedures.

One hundred and fifty (150) ERCP patients were included in this study, they were classified into three groups:

- Group (1): Fifty (50) patients were performed by 10 trainees of group (1); 5 cases each trainee.
- Group (2): Fifty (50) patients were performed by 10 trainees of group (2); 5 cases each trainee.
- Group (3): Fifty (50) patients were performed by 10 expert endoscopist of group (3); 5 cases each endoscopist.

The following tools were used in this study:

- Boskoski-Costamagna ERCP Trainer.
- Model description: Manufactured by COOK medical (Limerick, Ireland).

- Model definition: The model is a useful tool for ERCP training, particularly in improving the position of the scope, handling the wheels and the elevator, targeting the papilla, selectively cannulating the biliary and pancreatic ducts, extracting stones, and placing plastic and metal stents.

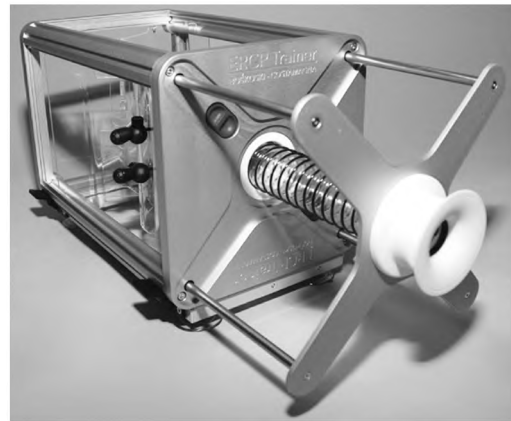


Fig. (1): The Boškoski-Costamagna ERCP Trainer [5].



Fig. (2): The Boškoski-Costamagna ERCP Trainer: Perspective from above [5].

The study was evaluating the benefit of a two weeks intensive training course on ERCP artificial simulator on decreasing the cannulation time achieved by the trainees.

In the trainee group (2), the duration of the training on the ERCP simulator was two weeks with intensive course: A rate of 5 working days each week with 6 hours daily and a total training period of 60 hours.

The two experts were considered as a part of the observation process and didn't know which of the two trainees' groups had received training on the simulator.

Both trainees' groups were assigned for evaluation for common bile duct (CBD) cannulation using a standard triple lumen sphincterotome preloaded with 0.035-inch hydrophilic guidewire.

The evaluation was stopped, and the scopes were handed to the expert if the candidate failed to cannulate the CBD within maximum of 15 minutes.

Patients:

All ERCPs performed in this study were part of a regular training program, and all were supervised by staff endoscopists. Patients are referred for ERCP for a variety of indications such as CBD stones, benign or malignant strictures or stent placement.

We selected 150 ERCP patients by a rate that allows each expert of the control group to perform ERCP on 5 patients and each trainee of both trainee groups to perform 5 ERCPs as well.

Assessment of the trainees:

The experts used the following scoring sheet to assess the trainees throughout the study.

Table (1): Scoring sheet based on ASGE guidelines.

Intubation	1	2	3	4	N/TN/A
Achieving the short position	1	2	3	4	N/TN/A
Positioning time: Time from insertion of the duodenoscope until introducing the endoscopic tools through the scope channel.					
Cannulation time (Time from introducing the endoscopic tool until cannulation of the desired duct was achieved)					
Identifying the papilla	1	2	3	4	N/TN/A
Native papilla?		Yes			No
Prior biliary sphincterotomy?		Yes			No
Prior pancreatic sphincterotomy?		Yes			No
Prior ERCP failure		Yes			No

Scoring key:

- 1 (Novice) = Unable to complete requiring trainer to take over.
- 2 (Intermediate) = Achieves with multiple verbal instruction or hands on assistance.
- 3 (Advanced) = Achieves with minimal verbal instruction.
- 4 (Superior) = Achieves independently.
- N/T= Not attempted for reasons other than trainee skill N/A= Not applicable.

Data analysis:

Data were analyzed using the statistical package SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). A normal distribution of variables was assessed using the Kolmogorov-Smirnov test. Three study groups were established based on the value of the mean ± SE.

The statistical differences between the three groups were analyzed using multiple analysis of variance (ANOVA) with the Bonferroni correction (post hoc comparisons). Linear regression was used to analyze the correlation coefficient (*r*) was determined. The Pearson correlation coefficient was also calculated to determine the relationship among the study variables. *p*-values <0.05 were considered significant.

Results

This is a prospective study including 20 trainees classified into 2 equal groups; group (1) included 10 trainees were enrolled in a clinical training program only, and group (2) included 10 trainees were enrolled in an intensive two-week hands on training on Boskoski-Costamagna ERCP trainer followed by clinical training. Another group (3) included 10 expert endoscopist represent the control group.

This table showed that the minimum age of trainees in the two groups was 33 years with mean of 41.7 ±6.42 and 42.1 ±5.96 years, in group (1) and group (2), respectively with statistically insignificant difference (*p*<0.05). The mean ages of patients were 51.4 ±2.19, 50.6±2.27 and 52.5±3.36 years, in groups (1), (2), & (3), respectively with statistically insignificant difference (*p*<0.05).

This table showed that the total biliary intervention performed in 85 cases (56.7%) and the pancreatic intervention was done for 65 patients (43.3%). Both techniques showed statistically insignificant difference in comparison between the three studied groups.

This table shows that all indications for ERCP shows statistically non-significant difference (*p*>0.05) in comparison between the three studied group.

This table shows that all steps for ERCP shows successful ERCP steps of the three studied groups, however group (2) showed better improvement than group (1) as compared to group (3). None had failed for the overall technique.

Statistical analysis comparing the groups between each other showed that all steps for ERCP shows statistically significant difference (*p*<0.001). Group (2) had a highly significant difference than group (1) and group (3) had a highly significant difference than both groups (1) & (2).

This table showed that the total biliary and pancreatic procedure time were significantly different in the three groups.

All ERCP steps (cannulation, deep cannulation, sphincterotomy, correct wire placement, balloon, use of basket, mechanical lithotripsy, stone clearance, stricture dilation and stent removal) showed successful achievement in the three studied groups. However, group (2) had better success and group (1) in comparison to the control group (3). For all steps of ERCP, there was a statistically significant difference ($p < 0.001$) in comparison between the three studied groups. However, Group (2) had a highly significant difference than group (2) and group (3) had a highly significant difference than both groups (1) & (2), except in balloon usage

there is no difference between group (2) and control group (3), and stricture dilatation had no difference between the three groups.

All patients underwent ERCP in ambulatory setting. Patients with rehospitalization were 9 (18%), 6 (12%), and 5 (10%) in groups (1), (2) & (3), respectively, the cause of hospitalization was severe pain in 5 cases (4%), 4 (8%) and 3 (6%), respectively, pancreatitis was found in 4 (8%), 4 (%) and 3 (6%) of patients in the three groups respectively, while one perforation only presented in group (1). No cardiovascular complications nor mortality were present.

Table (2): Age distribution of the studied participants and the ERCP patients.

Age (years)	Group (1) (N = 10)	Group (2) (N = 10)	Group (3) (N = 10)	Test for Significance	
				t-test	p-value
Range	33-37	34-38	38-56	0.187	0.167
Mean ± SD	36.7±1.42	36.8±1.96	46.2±5.12		
Patients' age				F-test	p-value
Range	35-67	36-63	34-66		
Mean ± SD	51.4±2.19	50.6±2.27	52.5±3.36	0.152	0.115

t: Paired t-test (comparison between group 1 & 2).
 F: Fisher exact test (comparison between the three groups).
 $p > 0.05$: Statistically non-significant.

Table (3): Type of intervention for ERCP patients in the three studied groups.

Intervention	Group (1)		Group (2)		Group (3)		Significance	
	No.	%	No.	%	No.	%	χ^2	p
Biliary ERCP	28	56.0	27	54.0	30	60.0	0.028	0.357
Pancreatic	22	44.0	23	46.0	20	40.0	0.193	0.203
Total	50	100	50	100	50	100		

χ^2 : Chi square test. $p > 0.05$: Statistically non-significant.

Table (4): Indications for ERCP patients in the three studied trainee groups.

Indication	Total	Group (1)		Group (2)		Group (3)		Significance	
		No.	%	No.	%	No.	%	F	p
BDO	35	11	22.0	14	28.0	10	20.0	0.72	0.085
Benign mass	27	9	18.0	6	12.0	12	24.0	0.93	0.054
Malignancy	20	5	10.0	7	14.0	8	16.0	0.42	0.109
Pancreatitis	32	12	24.0	9	18.0	11	22.0	0.48	0.104
Others	36	13	26.0	14	28.0	9	18.0	0.66	0.093
Total	150	50	100	50	100	50	100		

F: Fisher exact test. $p > 0.05$: Statistically non-significant. BDO: Biliary duct obstruction.

Table (5): Evaluation of ERCP maneuvers of the 3 trainee groups.

ERCP steps	Group (1) (n=50)#		Group (2) (n=50)#		Group (3) (n=50)#	
	No.	%	No.	%	No.	%
Intubation	38	76.0	46	92.0	50	100
Short position achieve	31	62.0	45	90.0	50	100
Identifying structure	50	100	50	100	50	100
Native papilla	25	50.0	42	84.0	50	100
Prior biliary sphincterotomy	12/28	42.9	24/27	88.9	30/30	100
Prior pancreatic sphincterotomy	8/22	36.4	21/23	91.3	20/20	100
Prior ERCP Failure	0	0.0	0	0.0	0	0.0

#: Number of patients in each group.

Table (6): Comparison of cannulation time between the three studied groups.

Biliary time	Group (1)	Group (2)	Group (3)	F	p
Range (min)	14.5-27.2	5.18-15.6	3.25-6.55	-1.921	0.001
Mean ± SD	18.69±9.21	9.36±5.14	4.95±2.08		
Pancreatic	Group (1)	Group (2)	Group (3)	F	p
Range (min)	11.28-39.45	7.64-19.8	4.50-12.4		
Mean ± SD	23.65±12.8	10.32±5.84	8.18±4.32	-1.577	0.001

X²: Chi square test. F: Fisher exact test. p>0.05: Statistically non-significant.

Discussion

Teaching endoscopic retrograde cholangiopancreatography (ERCP) is the most difficult task in an endoscopic training program. As a consequence, attaining competence in ERCP necessitates extensive training (1). Selective cannulation of the common bile duct (CBD) and/or the main pancreatic duct (MPD) is fundamental to clinical success in the vast majority of the cases.

Invariably, high-quality ERCP is reliant on high-quality training. Prolonged training time is required for novices to transition into a competent independent practitioner capable of delivering a safe and high-quality service. Although guidance on ERCP credentialing exists outside the UK [6], these are typically based on minimum procedural numbers and key performance indicators (KPIs), with variable uptake within training systems [7].

The Boşkoski-Costamagna ERCP Trainer is a novel mechanical ERCP training model developed and produced by Cook Medical (Cook Medical, Limerick, Ireland) in close collaboration with the Digestive Endoscopy Unit of the Gemelli Hospital in Rome, Italy (Dr. Boşkoski and Prof. Dr. Costamagna) [5]. It is designed to guide trainees on how to correctly position the endoscope in front of the papilla in order to attain a proper axis and to achieve deep cannulation from where several therapeutic interventions can be performed, such

as plastic or metal stent placement and stone extraction [8]. An initial report has been published by Jovanovic et al showing the potential value of the model [9].

A recent systematic review by van der Wiel et al., [5] presented an overview of currently available simulators and their known potential in training novices. Only six simulators have previously been described in the literature [10-15]. The ERCP Mechanical Simulator has proven its training value in novice trainees [16].

Similar to our study, Voiosu et al., [17] found that the overall time of cannulation in advanced fine trainers than traditional trainees and the time to cannulation increased as the level of complexity increased, with median times of 36 seconds, 41.5 seconds, 46.5 seconds and 45 seconds for types 1 to 4, respectively, across the entire study population (p=0.005).

This study demonstrates the substantial variability in ERCP learning among trainees of intensive training course was better than other trainees, however both trainees groups achieve acceptable training program which are consistent with previous studies [18-23] and validate the proposed shift from relying on an absolute number of cases performed during training to determine competence to using well-defined performance thresholds with strong validity evidence [22].

Conclusion:

ERCP is a skill demanding procedure, therefore trainees who will train in ERCP should be selected between those who are likely to achieve competence and will make good use of the valuable skills.

The intensive two weeks hands on training on Boskoski-Costamagna ERCP trainer can be an alternative for traditional training programs the save time and good achievement of endoscopic skills.

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فائدة التدريب على المحاكاة الاصطناعية في تقليل وقت ادخال القناة المرارية الذي يحققه المتدربون في مناظير القنوات المرارية

الخلفية: تنظير القنوات المرارية هي تقنية تنظيرية متقدمة ذات منحنى تعليمي عالٍ تتطلب برامج تدريب فعالة وموحدة لضمان الكفاءة. الهدف من الدراسة: اختبار فائدة دورة مكثفة على المحاكاة الاصطناعية على تقليل وقت إدخال القناة المرارية الذي يحققه المتدربون. المرضى وطريقة العلاج: تم تقسيم أربعين متدرباً إلى مجموعتين. تم تسجيل عشرين منهم في برنامج تدريب سريري فقط بينما التحق العشرون الآخرون بدورة مكثفة لمدة أسبوعين باستخدام جهاز محاكاة لتدريب. تم تمثيل عشرة خبراء في التنظير الداخلي للمجموعة الضابطة. النتائج: تضمن البحث أربعين متدرباً في التحليل النهائي كان وقت إدخال القناة المرارية 9.21 ± 18.69 في المجموعة ١ و 5.14 ± 9.36 في المجموعة ٢ ($p=0.001$).

الخلاصة: يمكن أن تكون الدورة المكثفة بما في ذلك التدريب العملي على جهاز محاكاة بديلاً لبرامج التدريب التقليدية.