ERCP training – the potential role of simulation practice

Joseph W. Leung^{1,2}, Danny Yen^{1,2}

¹Section of Gastroenterology, Sacramento Veterans Affairs Medical Center, Veterans Affairs Northern California Healthcare System, Mather, CA

²University of California, Davis Medical Center, Sacramento

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Abbreviations: ERCP, Endoscopic Retrograde Cholangiopancreatography; MRCP, Magnetic Resonance Cholangiopancreatography; GI, Gastrointestinal; CCTV, Close circuit television; EMS, ERCP mechanical simulator; CBD, common bile duct; RCT, randomized controlled trial; ACGME, Accreditation Council for Graduate Medical Education; ASGE, American Society for Gastrointestinal Endoscopy

Clinical ERCP training is limited by the availability of patients. Different ERCP simulators are available to supplement the basic training of novice trainees. An IDEAL simulation practice should provide trainees with the opportunity to Improve basic skills, Demonstrates realism, with Ease of incorporating into a training program and Application in teaching therapeutic techniques, and allows Learning with real scope and accessories including the use of simulation fluoroscopy. Whether simulation practice will impact trainee performance and clinical outcome of ERCP procedures will require prospective evaluation with randomized controlled studies.

Background

Endoscopic Retrograde Cholangiopancreatography (ERCP) is an established treatment for patients with pancreaticobiliary disorders and provides an alternative treatment to surgical management of biliary or pancreatic pathologies.¹ ERCP is a high risk procedure and may carry significant morbidity as well as mortality secondary to post procedural complications including post ERCP pancreatitis, bleeding, infection and less commonly, perforation.² The advent of Magnetic Resonance Cholangiopancreatography (MRCP) has replaced ERCP as the primary diagnostic modality for the evaluation of patients with abdominal pain and suspected pancreaticobiliary pathologies. Some centers noted MRCP can potentially replace 44% of diagnostic ERCP with a 13% reduction in the overall ERCP workload,³ others have seen a 25% reduction of ERCP numbers when MRCP was actually utilized in the evaluation of the patients.⁴ As ERCP procedures are now mostly performed for therapeutic reasons, many training centers lack a sufficient number of ERCP procedures for fellowship training and there are concerns that trainees are inadequately trained.

The lack of sufficient training experience may result in an increase in procedural failures and complications.⁵ What is more important is that the malpractice lawsuits that follow ERCP complications often reflect improper techniques and a lack of indication raising a question on the endoscopist's experience.⁶

Why - The need for ERCP training?

ERCP is one of the most challenging endoscopic procedure performed by gastroenterologists. Optimal performance requires broad knowledge of pancreaticobiliary pathologies, understanding the indications and contraindication for the procedures, considerable manual dexterity, proper handling of the equipment being used and familiarity with alternative diagnostic and therapeutic approaches. ERCP also carries substantial risks, even in the hands of experts. For these reasons, it has become clear that one should be properly trained both clinically as well as technically in order to be competent with ERCP and to minimize risks to the patients.

How – Training methods?

In general, diagnostic and therapeutic ERCP consist of different steps and trainees acquire experience with the procedures and mastering the skills of operating various accessories in coordination with the assistant through repeated practice. Traditional ERCP training takes the form of a hands-on approach (master/apprentice) system where the trainee learns and performs different techniques on a patient under the supervision of the trainer. The trainer provides verbal instructions, demonstrations and hands-on assistance for the trainee as s/he practices the different steps, progressing from basic to advanced procedures with increasing training experience. Eventually, the trainee is able to combine such experience and complete an ERCP procedure.⁷

When – Timing?

ERCP is an advanced procedure and in most Gastrointestinal (GI) training/fellowship programs, ERCP training takes place

*Correspondence to: Joseph W. Leung; Email: jwleung@ucdavis.edu
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after at least one to two years of introductory or basic endoscopy training. Despite the fact that many trainees will have mastered endoscopy or colonoscopy skills, training in ERCP is still necessary as the trainees may not be familiar with handling the side-viewing duodenoscope and operating the different accessories in coordination with the assistant.

What – Training with real scopes and accessories?

Although trainees can learn and understand the different aspects of ERCP through studying books, slide atlases, watching teaching videos and observing live demonstrations, ERCP training and practice is ultimately conducted on patients during clinical training.⁸ The major limitation to clinical training is the limited availability of patients, but more importantly, concerns over safety of the patients when the procedures are performed by an inexperienced endoscopist. It would be better if the trainees can gain basic experience without involving a patient in order to minimize risks to the patient. Hands-on ERCP practice involving manipulation of real scope and accessories in coordination with an assistant would be most beneficial to the trainee. In this context, the use of alternative teaching media including simulator(s) may provide trainees with the practice opportunities.

Where – Training venue?

Most of the hands-on clinical ERCP training occurs in the ERCP room. The trainer is often present in the room giving advice, sometimes even working as an assistant to help the trainee with the procedure. Most established academic training programs may have special setup/facilities including close circuit television (CCTV) and intercom where trainees can observe and learn in a class room setting or alternatively perform the procedure under supervision of the trainer.

Who – The trainees and the trainer?

In general, ERCP is still performed mostly by gastroenterologists. However, the changes in today's clinical practice also meant that ERCP is no longer being performed only by gastroenterologists. Indeed, surgeons and more precisely minimal invasive therapists including surgeons, physicians or interventional radiologists have been involved with performing ERCP procedures. ERCP training is usually offered to senior trainees (in a GI fellowship) after they have completed the basic training. In special programs, it is being offered as an additional or fourth year of advanced endoscopy training.⁸

A skilled endoscopist may not necessarily be a good teacher. One may be good with technical skills but in order to be a good teacher, one has to be able to communicate clearly to the trainees the different skill sets and techniques involved with different procedures. The trainer needs to be able to recognize and correct the errors (mistakes) made by the trainee both in terms of technical operation as well as clinical judgment in the management of the patients.

Expectation – Experience versus risk?

Trainees undergoing ERCP training would want to acquire the necessary competency in performing a successful solo procedure. However, there is a learning curve with each technical procedure. Trainee often acquires the technical skills while working on a patient during the training process. Coordination and manipulation of the accessories also require familiarity with the equipment and it takes time. As a result, valuable time for learning could be lost in the early phase if the trainee is not familiar with the equipment nor accustomed to the function of different accessories. This will not only prolong the clinical procedure but may also put the patient at risk of technical failure and more importantly post procedural complications.⁵ A different format of basic training and orientation such as simulator practice may help to overcome this problem.⁹ Indeed, preliminary data indicated that simulator practice introduced as part of early ERCP training can improve the clinical performance of novice trainee endoscopists.¹⁰

Alternatives for clinical ERCP training

In recent years, credentialing and governing bodies have recommended or mandated the use of simulation in training as part of residency education.¹¹ Certain prerequisites are necessary when we consider alternative methods for ERCP training. The essence of simulation in ERCP training is to provide trainees with the opportunities to understand the basic anatomy; become familiar with the equipment (accessories) and learn the basic techniques of scope handling, manipulation of accessories and coordination with the assistant without involving a patient.¹² Unless the alternative practice method offers the opportunity to use real scope and accessories with hands-on experience, trainees may not be able to reap the benefits of additional or supplemental training.

The **I**DEAL simulator/simulation training should provide trainees with the learning opportunity to **I**mprove their basic skills, **D**emonstrates realism to help trainees understand the anatomy and motility, **E**ase of incorporating into a training program (i.e. inexpensive and portable system that allows repeated practices without special setup), **A**pplication in training including teaching therapeutic procedures, and **L**earning with real scope and accessories including use of simulation fluoroscopy.

ERCP simulation training

Different simulators are available to supplement ERCP training although there is limited information in the literature regarding the specific role of individual simulators. In particular, there is a lack of published data on the impact of simulator training on the trainees' clinical performance and outcome of their ERCP procedures.

While ERCP practice on a live anesthetized pig offers the closest resemblance to the human setting, it is expensive, labor intensive and often difficult to organize without special animal facilities, and carries potential ethical concerns regarding the use of live animals for teaching.¹² In general, three types of simulators – computer simulator, ex-vivo porcine stomach model, and

mechanical simulators are available for ERCP training. Computer simulator, (e.g. GI Mentor II), is useful for understanding the anatomy, duodenal motility and basic orientation for cannulation.¹³ However, the use of special probes instead of real accessories lacks realism and does not offer the tactile sensation when it comes to the manipulation of the “accessories” for therapeutic ERCP.

A more commonly used training model is the ex-vivo porcine stomach model with attached biliary system that allows trainees to practice with real scope and accessories.¹⁴ However, the anatomical variation i.e. close proximity of the papilla to the pylorus in the porcine model makes scope positioning and cannulation more difficult. Besides, there are separate biliary and pancreatic ductal openings making it suboptimal to practice selective cannulation. To facilitate proper practice of biliary papillotomy, the porcine model is further improved by attaching a chicken heart (Neopapilla model) to a separate opening created in the second portion of the duodenum which corrects for the anatomical difference and allows multiple (up to 3) papillotomy practices to be performed on each chicken heart (papilla).¹⁵

Another form of supplemental training involves the use of mechanical simulators namely the ERCP mechanical simulator (EMS) or the X-vision ERCP simulator.^{16,17} Both of these simulators utilize a rigid model with special papillae adapted to a mechanical duodenum. Selective cannulation can be achieved using injection of a color solution (X-vision)¹⁷ or using a guide wire with the help of a catheter or papillotome (EMS). The X-vision model allows practice papillotomy to be performed on artificial papillae made of a special molded material.¹⁸ The EMS allows practice papillotomy using a foamy papilla soaked with a special conducting gel.¹⁹ In addition, the built-in bile duct models for the EMS allow the performance of balloon dilation of stricture, brush cytology and stenting as well as basket stone extraction and mechanical lithotripsy.

Impact of supplemental simulator training

Simulation training is more commonly employed in the surgical discipline.²⁰ Despite different simulators being available to supplement clinical ERCP training, simulator practice has only been used in special teaching workshops. It has not been widely used in training programs because of a lack of clinical evidence or published experience to indicate that simulator training improves the clinical outcome. Much of the early studies were limited to commentaries on improving the skill set to perform different techniques²¹ or pilot studies to demonstrate that simulators are useful for basic teaching.⁸ Currently, there are two studies in abstract form that reported the results of controlled randomized studies on the impact of simulator training in trainees’ clinical performance. The first study conducted in Taipei showed that trainees who received simulator practice (with the EMS) plus usual (clinical) training achieved a higher success rate with selective and deep common bile duct (CBD) cannulation compared to the control group who received usual training only.²² In addition, the trainers’ (who were blinded to the randomization) subjective assessment score was higher for the simulator group than

the control group. A second study conducted in the US reported similar positive findings that indicated early practice with the EMS improved the clinical performance of trainees with a significantly higher deep CBD cannulation success rate and a faster cannulation time although the overall trainers’ assessment were not different.²³ Both studies took into the consideration of ongoing clinical training and expertise of the individual trainees during the study period. The results of these early studies further supported the use of simulation in ERCP training.

A more important question is whether repeat simulator practice can improve the clinical outcome with reduction in overall complications? This will require long term randomized controlled trial (RCT) with the study group trainees undergoing repeat simulator practice and measuring the clinical outcome i.e. success and complications to determine the benefits of simulator training.

Other prerequisites for simulation training include the willingness of the trainees to spend extra time practicing with the simulator(s). Initial orientation and coaching is still necessary in order for the trainee to gain maximum benefits with this type of training. A lack of interest in simulation practice may result in sloppy technique and even poor clinical performance.

Assessment of practice and clinical ERCP performance

Objective assessment of performance is easier to document with practice on simulators. Specific endpoints may include successful execution of the procedure; total procedure time taken including the use of simulation fluoroscopy during the practice.¹⁶ Documentation during computer simulation training is more complete with tracking of the time taken and number of attempts made to perform a particular procedure. Adjustment or modification in training can be done by using different computer software programs with varying levels of complexity, whereas the mechanical simulator can incorporate different setup including changing position of the papilla or level of the bile duct stricture. Such changes can cater for procedures with varying level of difficulties from basic cannulation to papillotomy and to the more advanced procedures such as multiple stents placement for a simulated bile duct stricture.²¹

Objective assessment of trainee clinical performance is determined by the clinical outcome, i.e. success/failure and complications. This to a great extent depends on ongoing clinical training. The overall outcome is affected by the degree of trainer involvement or if the trainee is allowed to perform a solo procedure. In a more refined way, assessment can be separated into the acquisition of clinical knowledge and its application. Clinical knowledge reflects on the understanding of underlying pathologies including interpretation of radiological findings which guide subsequent management. The second aspect is technical proficiency and competency in performing the procedure.

The Accreditation Council for Graduate Medical Education (ACGME) has devised objective endpoints for measuring the quality of ERCP training and success with the procedure, but strictly speaking, these endpoints cannot account for all of the

different aspects of this technical procedure. ACGME also does not stipulate that the trainee be certified for competence. Traditionally, the number of procedures performed is used as a surrogate for the trainee's experience. Jowell et al reported that a trainee will need 180 ERCPs to achieve competence i.e. an 80% success with selective cannulation²⁴ whereas Verma et al reported that it took 350-400 ERCP procedures for a single endoscopist to achieve 80% success with selective cannulation.²⁵ There is no consensus at present although the American Society for Gastrointestinal Endoscopy (ASGE) recommends that trainees should have performed 200 ERCP procedures with 80% success of cannulation and at least half of the procedures being therapeutic before they are considered competent.²⁶ The Australians have an even tougher criterion which requires trainees to have performed 200 successful solo procedures without trainer involvement.²⁷

Conventional assessment involves the local trainer who can evaluate the trainee performance based on his/her subjective assessment. To some extent, it reflects on their observation of the trainees' overall performance, both in technical proficiency as well as their knowledge in applying the ERCP procedures in the management of the patient.²⁸

Assessment of competence

Despite all of the objective assessment criteria, there is currently no exit examination or diploma for technical skills, especially for the high risk ERCP procedures. It can be argued that if one can successfully perform a live procedure in front of a panel, one proves his/her ability. However, there are so many variables including the stress of taking a test that can affect the trainee's performance which ultimately may hurt the patient. It would be of interest to know whether performing a procedure on a simulator with specific endpoints could suffice as an objective assessment for skills. An alternative approach is the commonly accepted proctoring system by an expert before granting individuals hospital privileges. Setting a limit and monitoring the success and complication rates like a report card system is another method of ongoing assessment for individual performance.²⁹ The ability to perform solo procedures successfully without trainer involvement or input reflects on the skill of the trainee. Cumulative data can be collected and analyzed over the whole training period to determine if the trainee shows any improvement. However, true assessment depends on solo performance and this may have to continue into

one's practice after graduation since the overall results during training may be attributed to the trainer.²⁵

The Trainee's Perspective

Up to now, the number of procedures is used as a surrogate for experience and a trainee would not be considered proficient if they are unable to attain the number of procedures required. As stated above, ASGE recommends a minimum of 200 procedures, with a >80% cannulation success rate.²⁹ But how does one assess the quality of a training program, presumably, not all training programs are alike?

Also the teaching philosophy of the trainers can vary even within one program. Some trainers are more involved while others would let the trainees keep trying till they succeed. Individual trainer's preference for accessories and variation in technique meant that the training method can be quite different between trainers. Depending on the availability of experienced GI assistants, trainees sometimes function as an assistant in the procedure. Under such circumstances, the trainee gets the opportunity to learn a different perspective of ERCP training i.e. assisting, which is quite different from being the endoscopist. This kind of exposure also helps the trainee to understand the essence of good coordination in achieving a successful ERCP procedure.

As to the overall assessment of training, the endpoints and expectation are similar between the trainees and the trainer. Objective assessment of experience, knowledge and competence is still dependent on surrogate markers such as total number of procedures and successful cannulation. Technical success/failure as well as complications should be monitored and recorded as well as the case mix and complexity. Training programs need to be held accountable once benchmarks are established to insure quality training and safety for the patients.

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Joseph W. Leung, MD is the inventor of the ERCP mechanical simulator (EMS).

The EMS is not commercially available. It is being used as a teaching and research tool.

Table. Summary of expectations and comparison between clinical and simulator training

Training	Clinical	Simulator
Why (Principle)	ERCP experience, competence, success and patient safety	Supplement clinical training, more practice opportunities
How (Approach)	Supervised hands-on practice on patients with ERCP trainer	Coaching/practice on simulator, supervised by trained personnel
When (Timing)	Advanced training after completion of basic training	Beginning of advanced training to compliment clinical training
What (Material)	Patients Real scope and accessories	Simulator(s) with real scope and accessories or modified probes
Where (Venue)	ERCP room	Training lab, class room or procedure room
Who (Individual)	GI fellows (senior)	GI fellows (any year), Assistants or technicians
Experience (Progress)	Learning curve depending on case complexity	Learning curve with gradation of difficulty
Risk (Patients)	Risk to patient from inexperienced endoscopist	Sloppy technique without proper supervision
Limiting factor	Patient availability	Trainees willingness to spend the extra time practicing, may need special facilities
Expectation (Endpoint)	Clinical competence and patient safety	Improve basic skills
Basic teaching	Technique and applications	Technique and basic skills

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