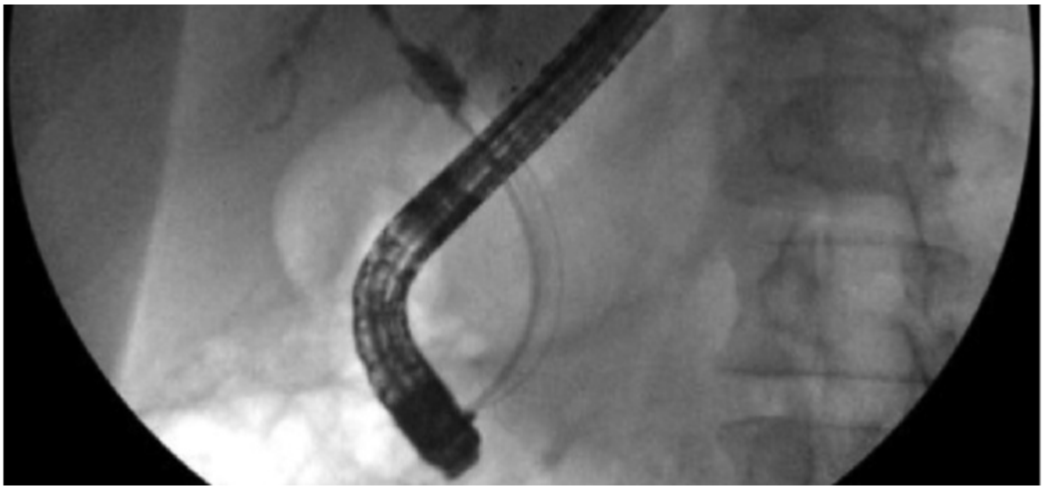

[Review] The Use of Simulation in Endoscopic Retrograde Cholangiopancreatography training: A Literature Review

Mohammad Fawad Khattak[1]

1 Brighton and Sussex University Hospitals NHS Trust

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Abstract

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopy procedure that has become the gold standard minimally invasive method of diagnosing and treating a vast variety of hepatopancreatobiliary diseases. It is associated with a significantly higher rate and wider range of adverse events compared with standard Upper GI endoscopy, with fewer of these procedures being performed in most centres and with procedure specific equipment and skills that most novice endoscopists will not be familiar with. These issues make training in ERCP challenging.

Aims: This literature review aims to look at the existing information available in the literature on the use of endoscopy simulators in ERCP training to see whether simulation training has a role in ERCP training, the main benefits and drawbacks of endoscopic simulation training, and how simulation training can be integrated into the learning process for achieving competence in ERCP.

Method: Study searches were conducted in the MEDLINE, EMBASE, CENTRAL/Cochrane Library databases, Web of Science, Google Scholar, LILACS and FINDit. Studies assessing simulation training against traditional training or against other methods of simulation were identified for inclusion in this literature review.

Results: Eight studies met the criteria for inclusion in this literature review with five of these being randomised control trials, where the primary outcome was biliary cannulation rates in simulation training against a control group.

Conclusion: Simulation training has the potential to make trainees more knowledgeable about the basics of ERCP and help develop the technical skills required to perform ERCP competently, as shown by all four RCTs demonstrating that trainees in the simulation group had a statistically higher rate of achieving biliary cannulation against control groups. Endoscopic simulation training should be embedded in ERCP training programmes to act as an important part of the initial development of skills in a safe environment, where trainees can achieve a satisfactory level of proficiency before performing procedures on patients to limit the risk of adverse events and complications. Further trials are required to assess EMS and ECS against traditional methods of learning.

1.1. Introduction

Gastrointestinal (GI) endoscopy has long been thought of as the gold standard in the detection of luminal gastrointestinal disease and GI cancers, however there is an increasing recognition of the therapeutic interventions that can be offered endoscopically and advanced endoscopy has now been established as a sub-speciality of gastroenterology with increasing number of programmes and fellowships being developed in this area worldwide[1].

Endoscopic retrograde cholangiopancreatography (ERCP) is an advanced endoscopic procedure which combines the use of endoscopy and fluoroscopy to diagnose and treat pancreatobiliary disease[2]. The first successful reported endoscopic biliary cannulation was done by McCune et al. in 1968, and over the last sixty years ERCP has become the preferred minimally invasive method of diagnosing and treating a vast variety of hepatopancreatobiliary diseases[3].

ERCP is a technically challenging procedure to perform and is associated with a significantly higher rate and wider range of adverse events compared with standard Upper GI endoscopy[4]. The Joint Advisory Group on GI Endoscopy (JAG) highlight how ERCP carries a recognised complication rate of between 10 and 14%, and a death rate of 0.1 to 1%[5].

1.2. Standard Technique for selective Biliary Cannulation

The standard technique for selective biliary cannulation, which is the first part of performing an ERCP, involves using a side-viewing endoscope/duodenoscope (Figure 1) and advancing this to the second part of the duodenum in a very similar manner to a conventional gastroscopy procedure. A side viewing endoscope is used to allow easy visualisation of the major papilla in the duodenum in order to perform biliary cannulation, however for beginners learning ERCPs this poses the first challenge as most endoscopists are used to performing forward viewing endoscopic procedures for both upper and lower GI endoscopy.

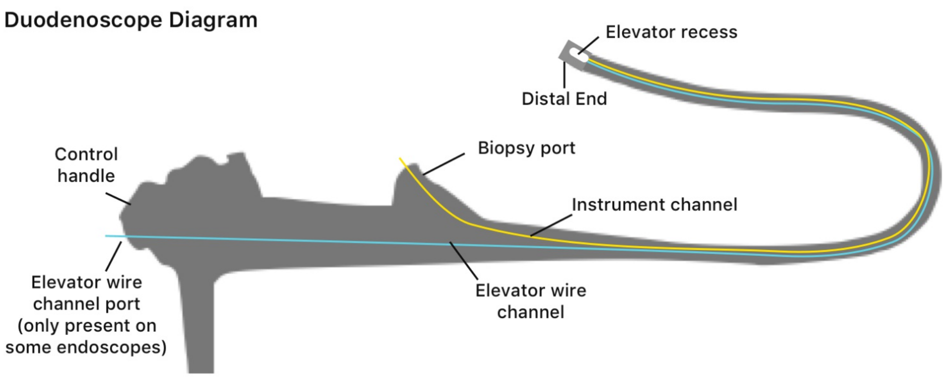

Figure 1. *Labelled side-viewing endoscope/duodenoscope*[6]

The initial process of ERCP is otherwise similar to standard Upper GI endoscopy and involves oesophageal intubation, navigation through the oesophagus and stomach and entering the duodenum via the pylorus.

In the second part of the duodenum, the next step involves identifying the major papilla in the duodenum in order to perform biliary cannulation. The first step involves positioning the duodenoscope so that the lens and working channel are located below the major papilla. Once properly positioned, a sphincterotome or an alternative cannulation catheter is engaged into the orifice of the major duodenal papilla, aiming usually towards the 11 o'clock position in order to achieve common bile duct (CBD) cannulation, with a guide-wire commonly used to assist advancement of the sphincterotome as demonstrated in figure 2[7]. Once suitably advanced, contrast injections can be given and this allows x-ray images to be obtained which can serve as a diagnostic test to look for pancreatobiliary pathology and also enable planning for any therapeutic interventions.

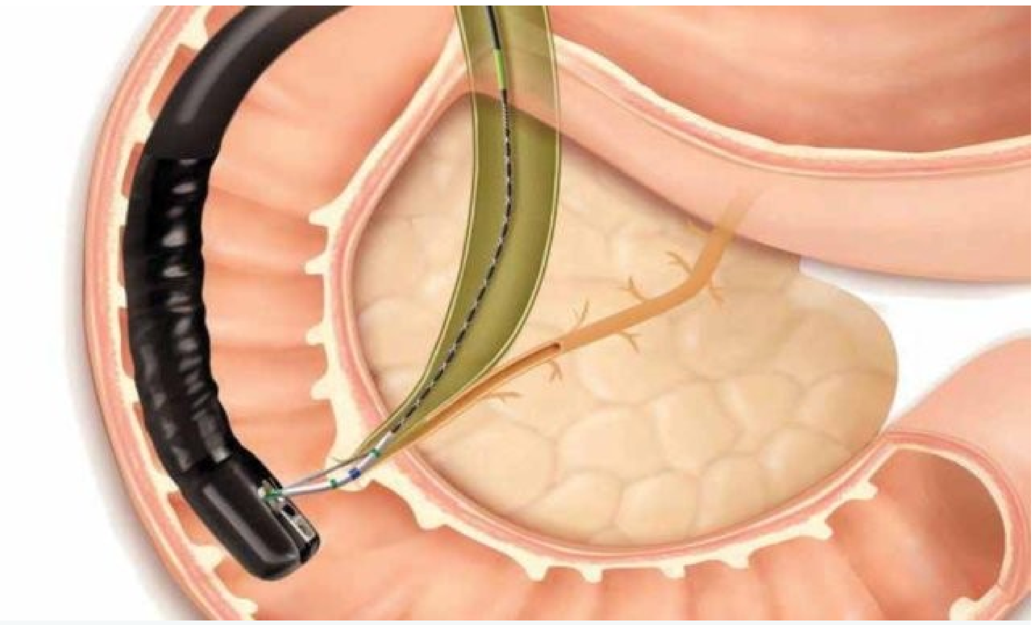

Figure 2. *Cannulation of the common bile duct*[7]

1.3. Sphincterotome

A sphincterotome consists of a metal wire covered by an insulating sheath, with the distal 20–30 mm of wire exposed, and a short radio-opaque, tapered tip. This is a piece of equipment which will also be foreign to the novice ERCPist and a variety of different types of sphincterotome are available, all with different properties and features.

The exposed aspect of the sphincterome acts as a cutting wire and is connected to an electrode connector of a monopolar electrosurgical unit on the handle and functions as a knife when current is applied[8]. This allows endoscopic sphincterotomy, which is a therapeutic intervention commonly done to facilitate extraction of common bile duct (CBD) stones.

A high level understanding of the equipment and effective training in sphincterotomy is vital to limit the numerous short term and long term complications seen with this procedure including bleeding, perforation, pancreatitis, cholangitis, hepatic abscess, papillary stenosis and biliary stricture.

A number of advanced ERCP techniques are available for biliary cannulation when the standard techniques fail, and these include double guidewire techniques, pancreatic stent-assisted technique, precut techniques and rendezvous techniques.

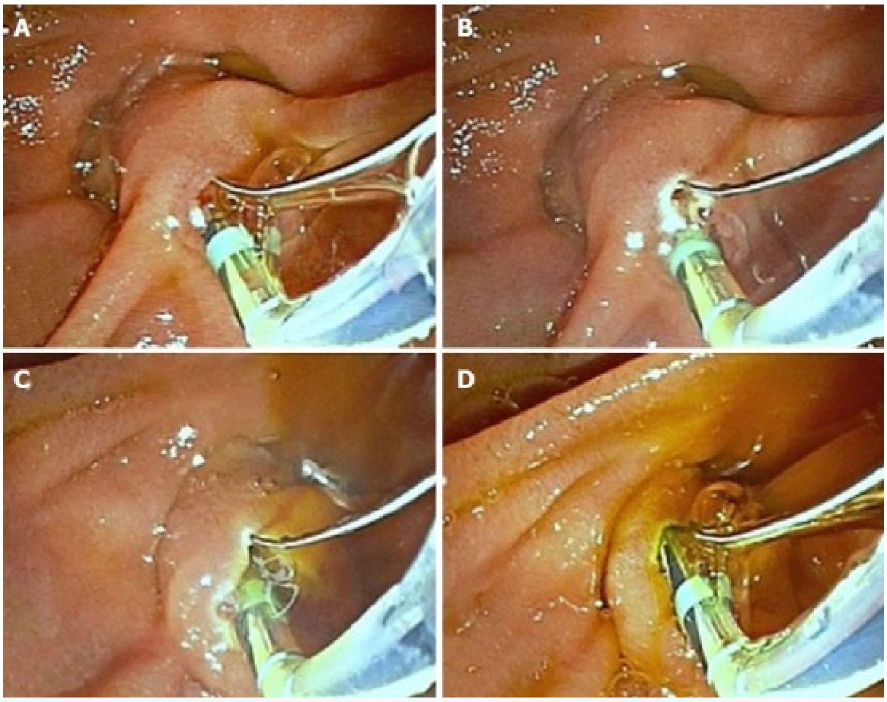

Figure 3. *Endoscopic Sphincterotomy*[9]

1.4. Therapeutic ERCP

With increasing availability of magnetic resonance cholangiopancreatography (MRCP), ERCP use as a solely diagnostic test has dwindled and it is now performed primarily as an interventional tool in those with proven pancreaticobiliary disease on radiological investigations.

The increased use of MRCP has seen a significant decrease in the overall ERCP workload at most centres, which has the knock-on effect of reducing the number of training opportunities available to gastroenterology trainees. Trainees in ERCP still need significant training in interpreting fluoroscopy images in order to identify hepatobiliary pathology and thereby plan how and where to perform interventional ERCP techniques.

The most common indication for therapeutic ERCP is the removal of gallstones or other biliary debris from the biliary system using a number of equipment and commonly alongside a sphincterotomy.

Plastic and metal stents can be inserted in both the common bile duct and pancreatic duct to relieve an obstruction and strictures can be dilated using balloons.

1.5. Endoscopy Training

Endoscopy training is a long and complex process which is traditionally done via a mixture of observation, attendance at educational courses and hands-on experience[10]. The hands-on experience typically starts by the trainee assisting the trainer initially, to learn the basic steps and theory of the process, before performing the procedure with significant assistance from the trainer. This assistance slowly reduces as the trainee becomes more competent and the trainer's role switches to a more observational and hands-off role as the trainee becomes more comfortable with the procedure, with most national endoscopy accreditation process involving trainees completing a certain number of procedures with evidence of a paper or electronic logbook before being deemed competent. With more complex endoscopic procedures, this learning process is even more challenging and longer in duration with the additional factor of introducing higher risks of adverse events.

Gastroenterology trainees wishing to do ERCP commonly have to do additional year/s of training in dedicated advanced endoscopy fellowships after completing their gastroenterology training to learn both basic and more advanced ERCP procedures. The European Society of Gastrointestinal Endoscopy (ESGE) recommend a minimum of twelve months of dedicated ERCP training in a high volume training centre with access to learn and perform more advanced ERCP procedures, with a suggested minimum of 300 procedures being recommended[11].

Achieving competence in ERCP undoubtedly requires significant hands-on supervised training. However, a number of drawbacks exist with the traditional learning model. Especially at the beginning stages, having a novice endoscopist perform procedures increases the risks of causing discomfort or adverse events to the patient with associated patient dissatisfaction[12]. Trainee endoscopists at the beginning of the learning process will take significantly longer to perform the procedure, which can lead to prolonged discomfort for patients and delays even if using a dedicated training list with reduced procedures[13]. More advanced procedures such as ERCP may not be performed as regularly in a lot of hospitals, leading to fewer training opportunities for trainees in certain centres.

The ESGE in its curriculum recognises that simulation-based training may have a role in the learning process for ERCP training as it allows trainees to learn in a risk and stress-free environment[11]. Simulation-based training involves using artificial representation of a real world process to achieve educational goals through experiential learning[14].

1.6. Simulation Based Training

Simulation in ERCP training may have an important role in the early stages of learning to become familiar with the equipment used and the process of performing ERCP. The trainee can learn the key steps, of performing the procedure in a risk-free environment at their own pace, with the ability to do far more simulated procedures than would be possible via hands-on training allowing a more rapid progression up the early learning curve. Having simulator training before hands on training therefore has potentially very important trainee and patient benefits, allowing a more knowledgeable and confident trainee performing procedures under supervision rather than a complete novice with minimal experience.

Simulation training for endoscopy stretches back to 1969 when the first documented simple mannequin for sigmoidoscopy training was developed[15].

Over the last fifty years, these simulators have developed in realism and complexity, representing a valid and smart alternative to standard trainee/mentor learning programs, and currently endoscopy simulators are available in a variety of different formats including; mechanical simulators animal models – in vivo and ex vivo (hybrid) computer-based/virtual reality simulators.

1.7. Mechanical Simulators

Mechanical simulators for endoscopy involve a mannequin which reproduces either the upper or lower GI tract using a combination of soft and hard materials. A real endoscope can then be used on these models to replicate a procedure and allow a trainee to practice scope handling, equipment use, relevant techniques and recreate the full process of performing an endoscopic procedure.

One of the main problems with mechanical simulators is that they only show one variation of the GI tract and offer limited opportunities for practising therapeutic procedures and therefore are best used for early-stage training of endoscopy where a trainee is learning how to use the scope and learning the relevant steps that are performed in a procedure[16].

There are two mechanical simulators available for ERCP training; the ERCP mechanical simulator (EMS) and the X-vision ERCP simulator[17][18].

Both of these systems involve a rigid model upper GI tract with special papillae adapted to a mechanical duodenum. The x-vision system allows selective cannulation using an injection of a colour solution or using a sphincterotome, whereas the EMS system allows selective cannulation using a guide wire or a sphincterotome.

The EMS system has bile duct models which allow practice of therapeutic ERCP such as balloon dilation of strictures, brush cytology, stenting, basket stone extraction and mechanical lithotripsy.

1.8. Animal Models

Simulation training involving animal models is a popular method for endoscopy training and can involve both live animals and explanted organs.

In-vivo models consist of practising a complete endoscopic procedure on an anesthetised live animal. Large animals such as pigs have similar GI anatomy and dimensions when compared to humans and therefore allow an accurate simulation experience as a full live procedure using actual endoscope equipment is performed on a live animal.

In-vivo model endoscopy is now becoming less commonly used due to high costs, resource use and ethical concerns. Therefore, the use of in-vivo model simulation is becoming limited to more complex endoscopic procedures, such as ERCP, where the increased realism and simulation when compared to mechanical simulation has the most benefits.

Ex-vivo animal models for GI endoscopic training are similar to mechanical simulators except that, rather than an artificial model replicating the GI tract, an explanted animal GI tract is used within a plastic frame. Ex-vivo animal samples are commonly obtained from companies slaughtering animals for the meat industry and therefore represent a slight improvement from an ethical standpoint.

For ERCP training, ex-vivo porcine stomachs with attached biliary systems are commonly used within a plastic frame. These allow a more realistic and tactile experience when compared to a mechanical simulator, with different animal samples offering different experiences for the trainee[19].

1.9. Computer Based Simulators

The area of simulation training which will probably be of the most importance over the next decade is that of computer-based simulators and virtual reality simulators.

There are a number of virtual reality simulators available on the market and these combine the use of a model endoscope which mirrors a real endoscope and the movement and use of this model endoscope correlates with movements in a virtual environment, allowing a trainee to perform endoscopies in a variety of different virtual intraluminal scenarios. Figure 4 highlights the key components that make up a computer-based simulator.

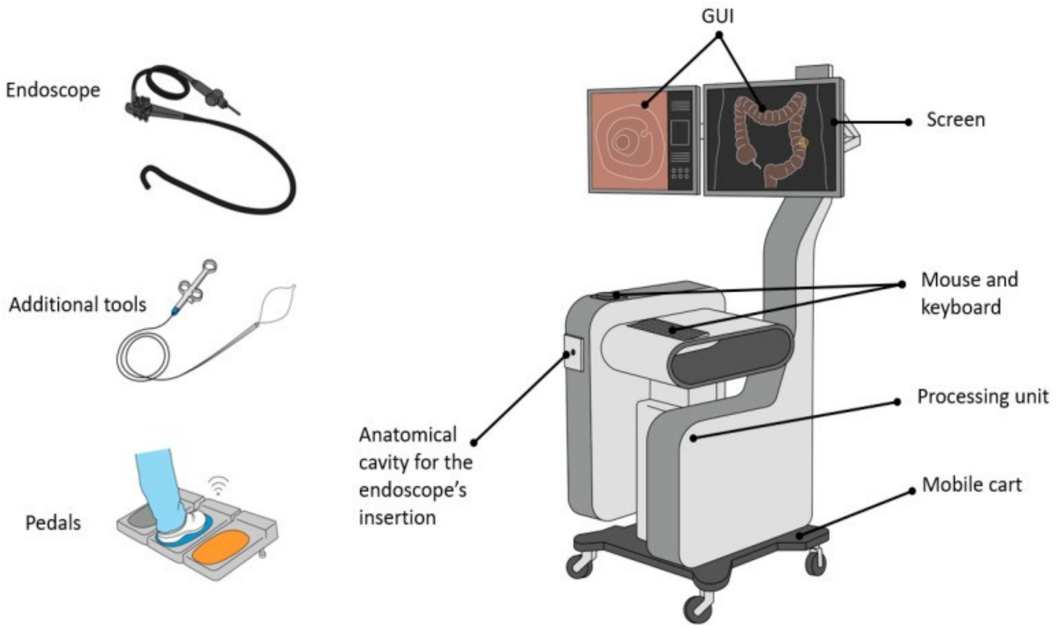

Figure 4. Computerised simulators for GI endoscopy: main components [10]

Computerised simulators are currently not as realistic or similar to an actual procedure when compared to ex-vivo or in-vivo animal models, but with increasing technology and the adoption of virtual reality in medical education, this is an area where a significant improvement is anticipated in the coming years.

Computerised simulators have the advantage of being able to replicate a wide variety of different GI anatomies and can therefore come up with different simulations allowing trainees to be challenged in different ways.

1.10. Virtual Reality Simulators

Over the last decade there has been significant advancement of extended reality technologies, including Virtual and Augmented reality (VR and AR respectively), which have created new human-computer interfaces that are continually becoming more realistic in terms of replicating human and equipment movements, interactions, environments and experiences[20].

Hann et al. (2019) describe a VR system created for performing gastroscopies using a three-dimensional VR headset and a modified gastroscope with sensors to direct the VR headset to the location of the scope so that this corresponds to movements in the headset[21]. An EMS stomach model was used to insert this modified scope. However, this was used mainly as a vessel for the endoscope with the VR headset showing a unique three-dimensional stomach where movement in the EMS model resulted in similar movements in the headset.

This technology has significant potential in allowing for trainees to experience a variety of realistic and immersive three-dimensional endoscopic simulation with a higher level of fidelity and realism than current ECS.

Similar systems are already established for laparoscopic surgery and this is an area with the most potential for growth in the next decade.

1.11. Use of Endoscopic Simulators Currently

Endoscopic Simulation training is already becoming increasingly more popular in generic endoscopic education curricula, especially in basic upper and lower GI endoscopy training, where novices can engage in deliberate practice without fear of making mistakes or harming a patient[22].

In the United Kingdom, all trainees wishing to become competent in Oesophago-Gastro-Duodenoscopy (OGD) or colonoscopies must complete the corresponding JAG Basic skills course at the beginning of their training. These basic skills courses involve significant model and simulation-based training before delegates then perform real life procedures on patients under supervision. Feedback from the integration of simulation training into these skills courses has demonstrated the increased confidence candidates have when subsequently performing the procedures on actual patients[23].

A key thing to consider with extrapolating the success of simulation training for basic endoscopic procedures with ERCP training is that simulator-based training has long been considered most optimal for novices or trainees with minimal practical experience of a procedure. Most trainees embarking on ERCP training will have already completed hundreds of basic endoscopic procedures and therefore may not benefit as much from simulator-based training, particularly current computer-based/virtual reality simulators.

2.1. Aims/Hypothesis

This literature review aims to look at the existing information available in the literature on the use of endoscopy simulators in ERCP training to see whether simulation training has a role in ERCP training, the main benefits and drawbacks of endoscopic simulation training, and how simulation training can be integrated into the learning process for achieving competence in ERCP.

This literature review centres around the hypothesis that Endoscopic Simulation training has a valuable role in the initial attainment of relevant skills required to competently perform ERCPs before the use of intensive training on patients.

3.1 Method

This literature review was conducted to summarise and critically analyse the current literature available on the use of simulation-based training for ERCP. There is a lack of systematic reviews and literature reviews done in this area. Therefore, as opposed to a “review of reviews”, this literature review will look at randomised control trials or crossover studies assessing simulation-based training for ERCPs versus a control group. Identified studies will be assessed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[24].

3.2. Eligibility Criteria

Studies comparing the use of simulation-based training versus a control group who receive either no simulation training or a different format of simulation training in the development of ERCP skills will be included in this literature review, with no location or year of publication restriction applied.

The PICO criteria for the literature review are highlighted below;

- Population: Gastroenterology trainees/Endoscopy trainees
- Intervention: Simulation based ERCP training
- Control: Trainees who receive either no simulator training, less simulator training or an alternative method of training
- Outcome: Biliary cannulation rates and competency scores post training

Exclusion criteria include; non-English publication, inability to access study

and the presence of high risk of bias.

3.3. Selection of studies

In order to identify relevant studies for this literature review, the following databases have been searched for: MEDLINE, EMBASE, CENTRAL/Cochrane Library databases, Web of Science, Google Scholar, LILACS and FINDit.

The search criteria used the following keywords combined with Boolean logical operators, appropriate for each database: "ERCP," "Endoscopic Retrograde cholangiopancreatography", "simulator(s),' "simulation", 'training(s)," and "model(s)." Where possible a filter for 'trials' was applied to the searches in the relevant databases.

The studies identified from the above search were screened by a single reviewer and only those studies which are randomised control trials or crossover studies analysing simulation training for ERCP against a control group are listed in the subsequent analysis to ensure that only English articles with accessible full tests were selected. Any studies which fulfil the above criteria but are subsequently excluded ,e.g duplicate articles or high risk of bias, have been reported in the literature review.

3.4. Data Extraction and Quality Assessment

A number of key data have been extracted from each study and presented in a summary table in order to allow quick comparison between the different trials. The study design, types of participants in terms of speciality and experience, type of simulators used in the study, description of training method, types of participants in the control group and the various outcomes of each study will be displayed in the summary table.

An important aspect of this literature review will be identifying whether each study has a low risk of bias, a high risk of bias or whether an uncertain risk of bias exists in each of the trials analysed. This conclusion will be determined after analysing the methodological quality of each trial using the Cochrane Collaboration Risk of Bias 2 tool, which measures nine different bias categories (i.e., selection bias, allocation, masking of data and statistical collectors, performance, detection, attrition, selective reporting of outcomes, and other biases)[25].

The initial piloting search of the literature identifies biliary cannulation rates and other measures of trainee competency as primary outcomes for the clinical trial. This literature review is both a qualitative and quantitative analysis, with the risk ratios and odds ratios of each outcome highlighted alongside the respective confidence intervals for each data set. Tables and plots have been used where possible to help illustrate these results in a clear manner.

The discussion on the literature review will use both primary and secondary outcomes of each trial to analyse how simulation training may be of benefit in the training process, recognising that with advancing technologies particularly in virtual reality and artificial intelligence, future trials with these technologies may demonstrate different results from the conventional simulators currently in use.

The discussion will also look at a few other clinical trials of particular importance, e.g an RCT comparing the different types of simulators available to allow a more in-depth review of the subject.

3.5. Ethical considerations

Prior to initiating this literature review, ethical approval was obtained from the University of South Wales Ethics Sub Group and Faculty Research Ethics Committee, with this literature review being a low-risk study due to the study using only existing data already publicly available.

4. Results

4.1. Study Selection

The above-described search strategy was used on the databases until the 10th March 2022, with 547 studies being identified. After excluding 56 duplicate papers and 430 articles where it was clear that they did not fulfil the predefined inclusion criteria. 61 articles were included in the screening process, of which 52 were excluded with the vast majority of these not being trials comparing simulator training against a control group, thereby not fulfilling the inclusion criteria. 10 articles were subsequently successfully sought for retrieval.

At this point, an article by Meng et al. (2016) was excluded from the literature review as it appears that this was a pilot for a subsequent trial in 2019 by the same authors using the same method. A study by Khouli et al. (2021) compared how well novices, intermediate, and expert endoscopists compared on endoscopic simulators, and although this did not fully fulfil the inclusion criteria, it has been included in the analysis and discussion as the article gives further information which helps explore the aims of the study.

Eight studies have therefore been included in this literature review.

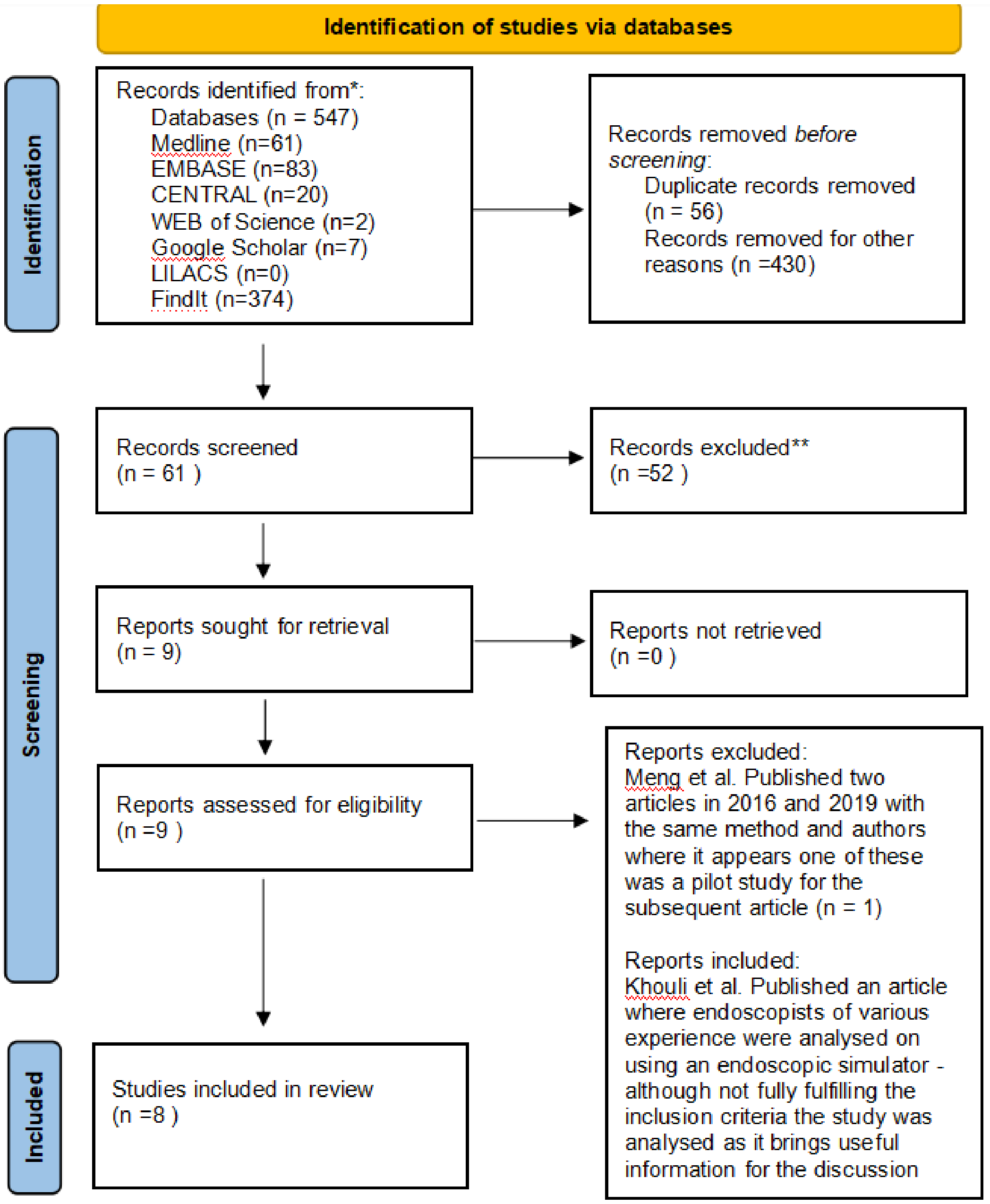

Figure 5. *PRISMA 2020 flow diagram*[26]

4.2. Results of Individual Studies

Eight studies have been identified in this review, with four of these studies being randomised control trials comparing simulation training against a control group with no simulation training. Two of the studies are crossover trials comparing the different types of simulation training against one another. One study looks at the use of motion training using EMS against standard EMS training and one study looks at whether performance on a simulator can be used as a surrogate marker for competency in ERCP.

All the included clinical trials were designed according to the Declaration of Helsinki and were approved by the respective ethics committees in the institutions that they were completed in. All of the trials have disclosed that written informed consent was obtained from all participants enrolled into each trial.

Lim et al. (2011) - Effect of ERCP Mechanical Simulator (EMS) Practice

on Trainees ' ERCP Performance in the Early Learning Period: US Multicenter Randomized Controlled Trial

This study was a randomized controlled trial involving six US academic centres where 16 participants were recruited and randomised to receive either didactic teaching plus two sessions of teaching on an ERCP mechanical simulator (EMS) or receiving didactic teaching without EMS training[27]. These two sessions were spaced 8 weeks after one another, with the EMS training centring around selective CBD and pancreatic duct cannulation on four different example papillaes.

Following the training sessions participants clinical performances were monitored in the subsequent 16 weeks, with the primary outcomes for the study being successful biliary cannulation, and secondary outcomes were cannulation time and competency scores given by the supervising ERCPist (1=poor, 5=excellent).

The study participants were all beginners in ERCP with the average number of ERCPs performed by these early stage trainees being < 30 in both groups.

Randomisation was stratified across the different training sites in order to reduce any bias being introduced from the trainees receiving training at the various different sites, and ERCP's supervised by the EMS instructor were excluded from the study in order to limit any potential bias from this.

There was 265 ERCPs included in the analysis of this study, with 251 (95%) of these being therapeutic procedures. The mean number of ERCPs performed by a trainee during the follow-up period was 17.

Overall cannulation success rate was 47.1 % for the control group and 69.6 % for group receiving EMS training, demonstrating a statistically significant higher rate of biliary cannulation in the EMS training group (p= 0.021).

The EMS cohort also had a statistically significant lower mean cannulation time when compared to the control group 4.7 ± 4.2 min vs. 10.3 ± 14.1 min (p< 0.001).

However, there was no statistically significant difference in the trainee competency scores as assessed by supervising physicians who were blinded to the randomisation status.

Overall, this was a well designed RCTs which tried to limit potential bias from EMS instructors and chose participants all at similar points in their journey towards learning ERCP. The changes made to limit the EMS instructors' role in assessment of trainees is particularly important as Leung invented the ERCP EMS system used in this study.This multi-centre study used randomisation stratified by study site to avoid bias created by site specific differences.

Leung et al. (2012) - Head-to-head comparison of practice with endoscopic retrograde cholangiopancreatography computer and mechanical simulators by experienced endoscopists and trainees

This study is a head-to-head comparison between EMS and endoscopic computer based (ECS) simulators in the development of ERCP skills[17].

The study recruited 18 gastroenterology trainees and 16 trainers who were gastroenterology faculty members. The median number of ERCPs performed in the trainee cohort prior to the simulation training was 14 (range 0–120) whilst the median for the trainers cohort was 1550 (range 100–3000).

Both groups completed a questionnaire survey before and after practice with both an EMS simulator and a computer-based simulator.

The EMS simulator used in this study was similar to the one used by Lim et al. (2011) and involved the use of a duodenoscope on a detachable papilla and a model bile duct with a simulated distal common bile duct (CBD) stricture.

The computer-based simulator training was on the GI Mentor II (Simbionix USA Corp, Cleveland, OH,USA) simulator which simulated both the endoscopic and fluoroscopic images on one of 10 cases available on the system.

The study used pre and post simulator questionnaires to better understand the benefits of the simulator training. The participants reported their pre- and post-practice understanding and confidence (0 = none, 5 = very, max. score of 20) in: (i) selective bile duct cannulation; (ii) guidewire negotiation of a bile duct stricture; (iii) papillotomy; and (iv) stent placement.

In addition to this, all of the participants gave a score for an overall evaluation of both of the simulators (1 = very poor, 10 = very good) in the following areas ;(i) application of the simulation practice in learning ERCP (max. score = 40); (ii) realism of the simulation practice (max. score = 80); (iii) usefulness of the simulator as an instructional tool (max. score = 30); and (iv) respective application in ERCP training (max. score = 30).

Compared to pre-practice evaluation, both EMS and ECS received higher scores in the post training questionnaires.

These questionnaires demonstrated that EMS showed significantly greater improvement over ECS for both trainers and trainees in terms of understanding, confidence and credibility after the hands-on experience, with all of these categorises meeting statistical significance ($p<0.05$) apart from trainers' understanding of ERCP.

EMS also proved to show statistically significant better trainee and trainer scores for application in learning, realism, usefulness as an instructional tool and respective application.

This study is a well designed crossover study where all participants use both systems being assessed. It gives us a good overall assessment of participants' views of simulation training and the two platforms being assessed, but this study requires a randomised control trial to allow us to compare the effectiveness of ECS and EMS in development of ERCP skills. Currently no RCTs are available comparing different ERCP simulation platforms for ERCP training.

Meng et al. (2019) - Impact of Simulation practise on clinical ERCP performance of novice endoscopists

This randomised control trial involved 12 Chinese surgical trainees with no endoscopy experience being randomised to either EMS training (n=6) or no EMS training (n=6)[28][29].

Both groups received didactic teaching on the basics of ERCP before the EMS group received 20 hours of training on

EMS focused on scope insertion, positioning, biliary cannulation and stent placement.

Following this initial training phase all trainees had supervised clinical hands-on training where successful biliary cannulation was the primary outcome for the study.

Secondary outcomes included time to achieve cannulation and trainer questionnaires on trainee performance (below average, average, above average).

A total of 300 ERCPs were included in the results with the mean ERCPs for a trainee being 25.

The EMS group had a statistically significant successful cannulation success rate (70% vs. 54.7%, p= 0.006), a faster biliary cannulation time (10 vs. 15 min, p<0.001) and higher trainer questionnaire ratings (40.7% above average vs 20%, p<0.001). In addition to this the study found fewer post ERCP pancreatitis and cholangitis in the EMS group (p<0.05).

This is a well designed RCT where the participants performed a higher mean number of ERCPs during follow up compared to other RCTs, allowing analysis of a larger data set. This RCT featured trainees with no previous endoscopy experience as opposed to the others, where trainees all had significant experience in performing upper GI endoscopy. Most current viewpoints surrounding simulation training highlight how it is more useful for the novice trainee and this study's results further back up this viewpoint.

Hritz et al. (2013) - Assessment of the effectiveness of ERCP mechanical simulator (EMS) exercise on trainees' ERCP performance in the initial learning period: multicenter randomized controlled trial.

Hritz et al. recruited 15 participants with experience in performing Upper GI endoscopy but with no ERCP experience. Trainees were randomised to receive either ECS using an AccuTouch Endoscopy Simulator (Immersion Medical, USA) alongside didactic teaching (n=6) or to receive only didactic teaching (n=9)[30].

The ECS group used 7 different computer simulated ERCP cases on the Accutouch simulator with 10 repetitions on each case.

59 ERCPs were included in the study with a mean ERCP per trainee of 3.93.

This study found that deep papillary cannulation control was superior in the ECS group compared to the control group (score 2.84 vs. 2.36; p=0.04) and the time required to reach the papilla was also significantly quicker (129.4 vs. 179.4 sec; p=0.03).

One of the key limitations with this study are that the mean ERCPs per trainee was particularly low and full data for biliary cannulation rates were not disclosed by the authors limiting interpretation of the results. The authors have stated that statistical analysis was performed with Student's t-test and non-parametric Mann-Whitney test however in terms of biliary cannulation they only disclosed the scores listed above with no raw data disclosed limiting analysis and comparison with other studies.

Liao et al. (2013) - Coached practice using ERCP mechanical simulator improves trainees' ERCP performance: a randomized controlled trial

This Taiwanese randomised control trial recruited 16 trainees with experience in Upper GI endoscopy but with no ERCP experience. Trainees were randomised to receive EMS training (n=8) and didactic teaching or only didactic teaching (n=8)[31].

The EMS training group received biweekly teaching on the simulator for 12 weeks apart from a cohort in 2008 who received only a single 6 hour session on the EMS.

The study included 190 ERCPs with the mean ERCPs per participant being 11.875.

The primary outcome measure for the trial was successful deep biliary cannulation. Secondary outcome measures were an overall performance score as rated by blinded trainers, during the subsequent 12 weeks of clinical practice.

The study found that EMS training in both the single session and multiple sessions cohorts resulted in statistically significant higher rates of biliary cannulation by trainees (single: adjusted odds ratio [aOR] 2.89, 95 % confidence interval [CI] 2.21 - 3.80 [$p < 0.001$]; multiple: 3.09, 95 %CI 1.13 - 8.46 [$p = 0.028$]) and to have superior overall performance scores aOR 3.29, 95 %CI 1.37 - 7.91 [$p = 0.008$] and 6.92, 95 %CI 3.77 - 12.69 [$p < 0.001$], respectively).

A key thing to consider with this RCT is that the training approach in the EMS group varied from the initial cohort who received only a single 6 hour session, to later cohorts who received biweekly teaching. Nonetheless the study was able to show statistically significant benefits for EMS in both the initial cohort with the limited training and subsequent cohorts so although this stands out as a potential bias in terms of study design, it is at least limited by the authors' ability to show statistically significant improvement in interventional cohorts for both initial and subsequent methods of EMS training.

Sedlack et al. (2003) - A direct comparison of ERCP teaching models

This trial randomly selected 20 endoscopists attending an advanced ERCP training course to the study. 10 of these endoscopists were trainees with varying ERCP experience, whilst 10 faculty members who were trainers were also selected[32].

Each of the endoscopists attempted to perform ERCPs on three different simulators.

The first simulation involved performing ERCPs on live anaesthetised pigs. The second simulator was a simulator using a harvested porcine organ model. The third simulator was a GI Mentor ECS.

After using all three of the simulations the endoscopists were asked to do Likert scale surveys that graded aspects of the simulated realism of each model in comparison to ERCPs in patients (1 = very unrealistic, 7 = very realistic). Another similar survey was used to assess the utility of each model for teaching of basic or advanced ERCP techniques.

The simulator using harvested porcine organs ranked highest in most realism indices with scores for the ECS being significantly lower ($p < 0.05$) when compared to the harvested porcine and live pig cases.

The harvested porcine organs also ranked highest in terms of usefulness for ERCP training with the ECS again being seen as significantly less useful (*p*< 0.05) than the other two simulators.

It was however found that ECS was identified as the modality most easily incorporated into a fellowship training programme.

Similar to Leung et al. (2012) this study is a well designed crossover study where all participants use all three systems being assessed. This type of study allows us to analyse participants' views on the systems being assessed but nonetheless warrants randomised control trials to better ascertain the potential benefits of each system and also see how the views extracted from the study extrapolate in terms of better clinical outcomes.

Voiosu et al., (2021) - Motion training on a validated mechanical ERCP simulator improves novice endoscopist performance of selective cannulation: a multicenter trial

This multicentre randomised control trial recruited 36 trainees with experience in GI endoscopy but with no ERCP experience. Trainees were randomised to receive either motion training followed by standard cannulation training on an EMS or to receive only standard cannulation training on an EMS[33].

Trainees randomised to the intervention group (n=16) received motion training which consisted of completing five tasks, such as writing and drawing, using an EMS with a modified 10Fch catheter with a graphite tip and a piece of white paper. The main hypothesis behind motion training is that it allows trainees to develop their skills in handling and manoeuvring a duodenoscope.

Those in the control group (n=20) received only standard EMS training to develop skills in handling a duodenoscope and achieving biliary cannulation.

Following the training participants were asked to complete a total of 20 cannulation attempts on four different papilla models on the EMS. The primary outcome was achieving selective biliary cannulation within five minutes, with secondary outcomes being time to achieve cannulation and supervisors scoring on a four-point scale.

A total of 720 supervised attempts at selective biliary cannulation on the EMS were included in this study. There was no significant difference in achieving biliary cannulation between the two study groups (96.5% motion training group vs. 97.25% Standard cannulation group, *p*= 0.66). The study did however demonstrate that the motion training group had significantly lower median cannulation times when compared to the control group (36 vs. 48 seconds, P < 0.001). The motion training group also received significantly better supervisor scores for technical performance (*p*=0.009).

This was a high quality study looking at the use of motion training with EMS against standard EMS which found that motion training had potential in the development of technical skills for ERCP. One could however hypothesise that the participants in the interventional group had better outcomes due to the increased overall training that they received rather than specifically due to the use of motion training. Having control groups who received additional standard EMS training to compensate for the additional motion training that the control group received may have resulted in different overall findings in this study and thereby changed the conclusion derived by the authors.

Khouli et al. (2021) - Development of virtual reality training curriculum for ERCP

Thirty nine participants with varying ERCP experience were included in this study[34]. The participants were divided into three groups; novices, intermediate and experts. All of the participants were asked to do a case on the GI Mentor II and following this data was collected from the case alongside a questionnaire done by the participants.

Metrics collected from the task included the time taken to complete the case,

the number of papillary contacts before cannulation and number of pancreatic duct (PD) cannulations.

The expert group was found to have completed the task quicker on average compared to the other groups (264.4 sec); intermediates (321.14 sec), and novices (822.05 sec). The expert group was also found to have less papilla contacts before cannulation and less pancreatic duct cannulations.

The authors used the expert results and by eliminating results +/- 1 SD of the mean they were able to generate benchmark results for time to complete task, number of papilla contacts, number of PD cannulations and number of contrast injections to both PD and CBD. The authors conclude that the ECS showed statistically significant differences between novice, intermediate, and expert groups and that the use of benchmarks can be used to identify proficiency in ERCP.

One of the limitations with this study was how the authors categorised their participants into the “novices”, “intermediates” and “experts” group, with the authors giving overviews how they categorised their participants but without clearly defined rules. The authors also did not disclose the specific benchmarks that the made for the curriculum at the conclusion of the study. This observational study should ideally be followed up by a randomised control trial where participants who achieve EMS benchmarks as highlighted by Khouli et al. are compared with participants who have not received EMS training to ascertain whether a EMS based training curricula results in better ERCP biliary cannulation rates and lower mean time to achieve selective cannulation.

4.3. Risk of Bias Assessment

Five of the eight trials included in this review are randomised control trials and Cochrane Collaboration's risk of bias 2 (RoB 2) tool was used to assess the risk of bias in all of these trials and the summary of this analysis is demonstrated in figure 6 below.

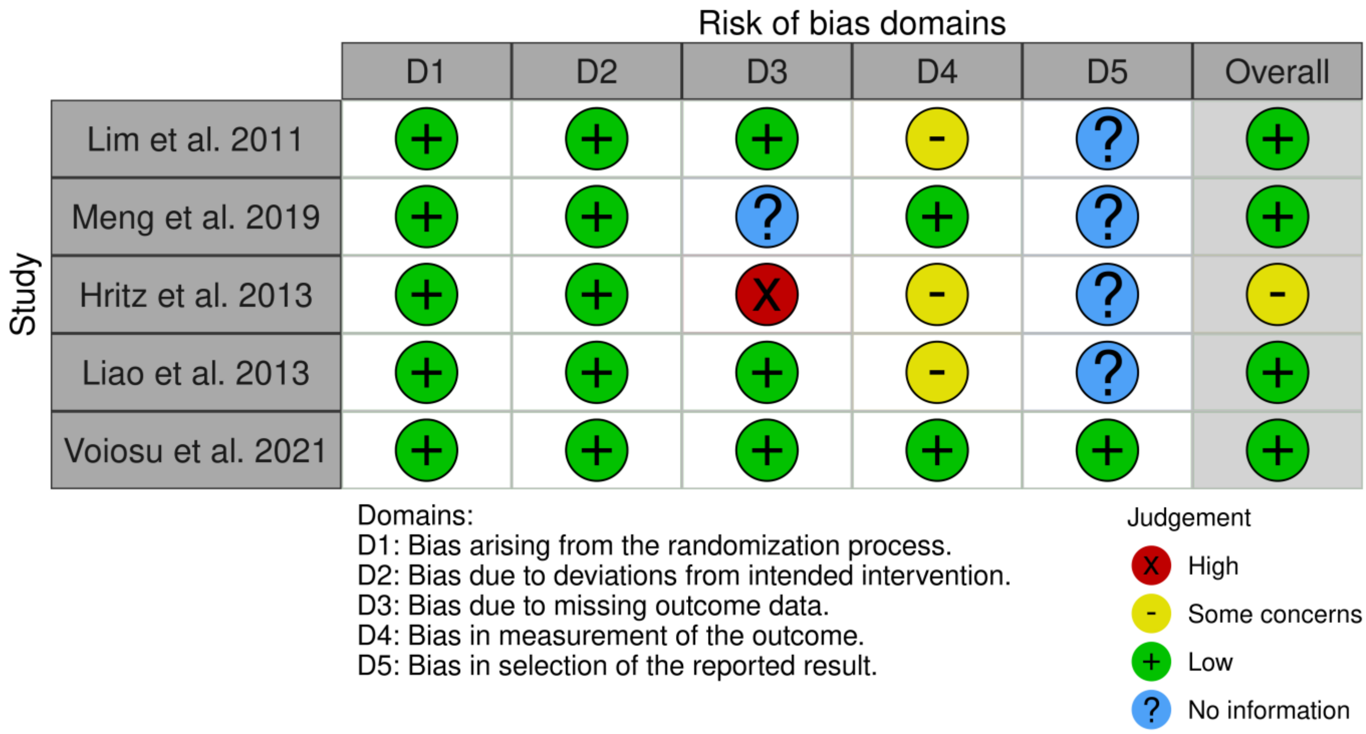

Figure 6. *Risk of Bias analysis of included randomised control trials*

The trials done by Leung et al. (2012) And Sedlack et al. (2003) were crossover trials where all participants received all the interventions available in the study, therefore selection bias is not as pronounced as would be seen in other non-randomised trials.

The study done by Khouli et al. (2021) has the highest risk of selection bias as it has recruited participants from experienced expert ERCPists to medical students and where subdivided into three groups based on the authors' opinions of whether they were “novices”, “intermediates” or “experts”.

4.4. Simulation Training vs. No Simulation Training Results

All four of the randomised control trials comparing simulation training in the form of EMS against a control group, who received only didactic teaching, used biliary cannulation post training as the primary outcome for the studies. All four trials demonstrated that the simulation training cohort had statistically significant lower rates of failed biliary cannulation as highlighted in figure 7. Hritz et al. (2013) did not provide exact rates of biliary cannulation but highlighted how papillary cannulation control was superior in the simulation group compared to the control group (score 2.84 vs. 2.36; p=0.04).

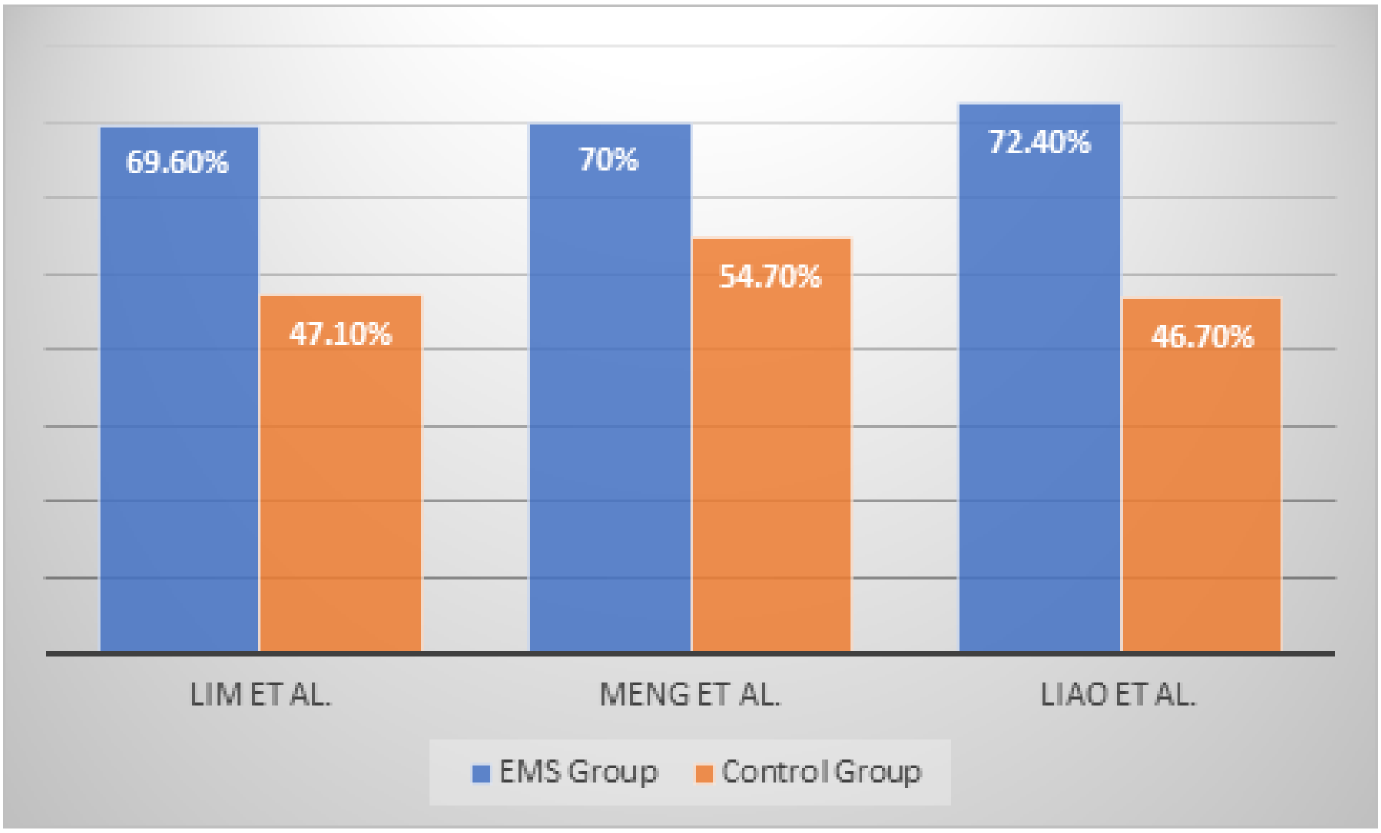

Figure 7. *Biliary Cannulation Rates in EMS groups vs Control Groups*

In terms of secondary outcomes the studies by Lim et al. (2011), Hritz et al. (2013) and Meng et al. (2019) found that trainees in the simulation cohort had statistically significant lower mean time to achieve cannulation, as demonstrated in figure 8, and all four RCTs apart from Lim et al. reported statistically significant mean trainee competency scores based on supervisor questionnaires. Lim et al. however, reported no significant differences based on the analysis of the questionnaires used in their study.

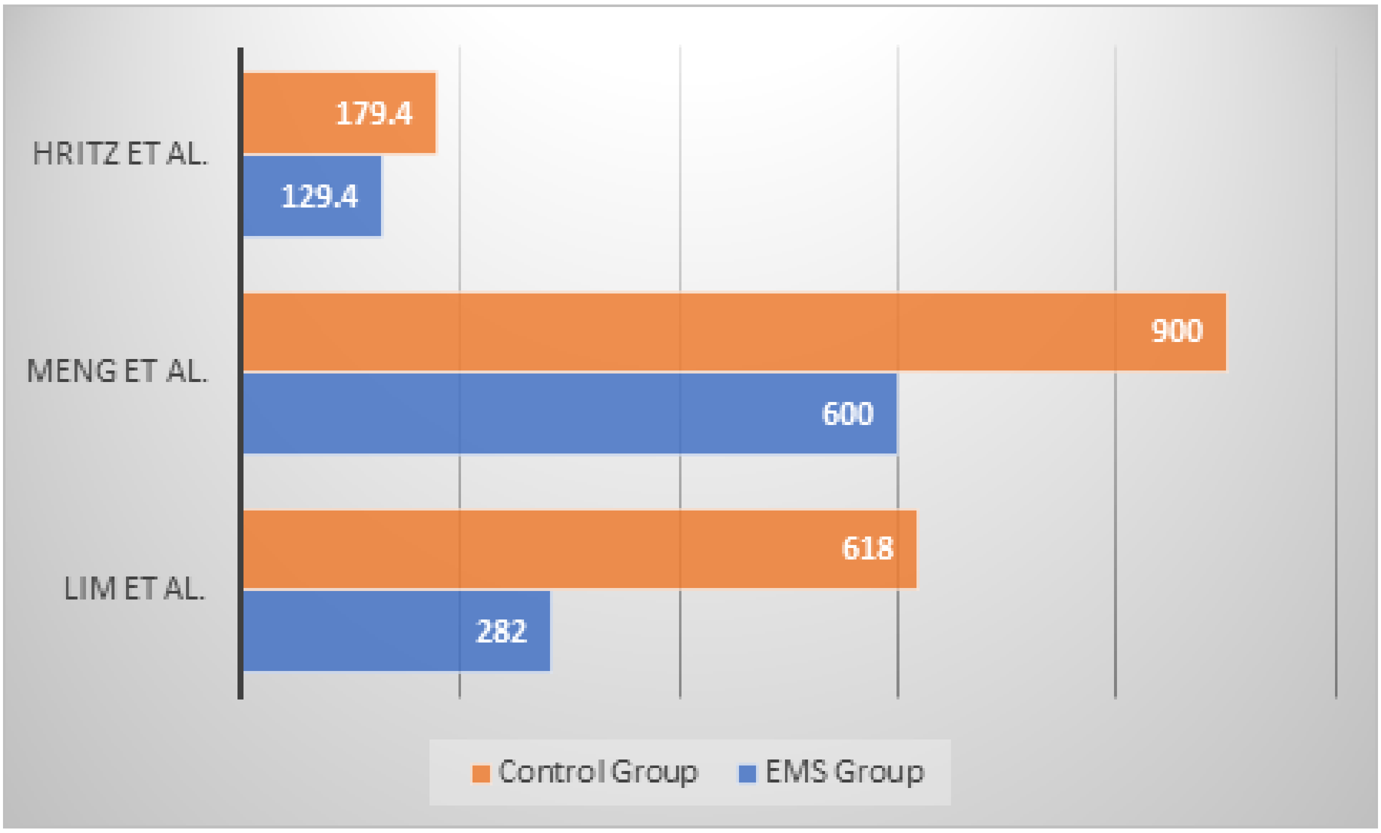

Figure 8. *Mean time to achieve biliary cannulation in EMS groups vs Control Groups*

4.5. Comparing the effectiveness of different forms of simulation training

The studies by Leung et al. (2012) and Sedlack et al. (2003) compared the different types of endoscopic simulator training options against one another.

Leung et al. (2012) compared EMS and ECS by the use of pre and post simulator use questionnaires. They found that participants had a better understanding

and confidence in performing the technical aspects of an ERCP such as selective biliary cannulation after the use of both EMS and ECS. However, they found that participant scores were significantly higher for EMS when compared to ECS for improving understanding on how to perform an ERCP.

Leung et al. (2012) also used questionnaires to assess participants views on the credibility of simulator practice on both of the platforms and how realistic and helpful they were for training. This analysis showed that participants scored EMS significantly higher in realism and usefulness as an instructional tool in the development of skills in ERCP.

Sedlack et al. (2003) compared ECS, live anaesthetised pigs and harvested porcine organ model using questionnaires completed by participants who used all three interventions to judge the realism, educational utility and ease of use of all three interventions. Sedlack et al. (2003) found that the harvested porcine organ model had the highest scores for realism and educational utility, followed closely by the live anaesthetised pigs. ECS was judged to be significantly less realistic and useful as an educational tool by the participants but it was recognised that it was the format most easily incorporated into a training programme as opposed to the porcine models and the live anaesthetised pigs.

Voiosu et al. (2021) compared EMS training with motion training against standard EMS training. They found that the motion training cohort had a similar rate of biliary cannulation when compared to the control group but had significantly lower median cannulation times (36 vs. 48 seconds, p=0.001) and better technical performance based on supervisor questionnaire competency ratings.

Khouli et al. (2021) did an analysis on the use of ECS and demonstrated that proficiency on ECS correlates with practical experience of ERCP and used data relating to this to develop a curriculum and benchmarks which could be used to judge when a trainee has achieved sufficient proficiency on the ECS to hopefully translate to better skills when performing ERCPs on patients.

4.6. Limitations of Studies

There are very few randomised control trials looking at the use of simulation training in ERCP training and the majority of these studies involve small sample sizes. Currently only RCTs are available which compare EMS with a control group, therefore all the other modalities of simulation training have no RCTs that support their use in training. Further larger scale multi-centre RCTs are required in order to better analyse the use of EMS in ERCP training.

Outside of RCTs the data available to support ECS or animal models are based on questionnaire-based perceptions of participants using these platforms, therefore high quality studies are required to support the use of these platforms.

5.1. Discussion

This literature review explored three basic research areas:

1. Does simulation training help in the development of skills required to competently perform ERCP.
2. How do the various different platforms for simulation training compare with one another.
3. What are the experiences of trainees when using simulation training.

Interest in the use of simulation for acquiring, maintaining, and assessing skills in GI endoscopy has grown substantially over the past decade with organisations such as

the American Society for Gastrointestinal Endoscopy (ASGE) and JAG incorporating the use of endoscopy simulation training in a number of guidelines relating to endoscopy training and training standards. However, despite this RCTs looking at the use of simulation training in endoscopy are still limited, particularly for areas of advanced endoscopy such as ERCP training.

The studies analysed in this review demonstrate that simulation training has the potential to make trainees more knowledgeable about the basics or ERCP and help develop the technical skills required to perform ERCP competently as shown by all four RCTs demonstrating that trainees in the simulation group had a statistically higher rate of achieving biliary cannulation. Additional benefits highlighted by these studies include lower mean time to achieve biliary cannulation, higher technical scores as judged by supervisors and one study highlighted lower rates of post ERCP complications in the simulation group.

Participants in Sedlack et al. (2003) and Leung et al. (2012) gave positive experiences of using endoscopic simulators, with EMS receiving particular praise for its realism and potential for use in training.

5.2. Integrating simulation training in a deliberate learning model

Learning a complex procedure such as ERCP requires the acquisition of a number of different skills including; cognitive (knowledge and recognition), technical (psycho-motor), and non-technical (expertise and behaviour) skills[35].

Traditionally attaining and developing these skills have been achieved by a mixture of initial observation followed by graded exposure and then by deliberative practice. In the United Kingdom most trainees wishing to embark in ERCP training will have achieved accreditation for performing independent diagnostic Upper GI endoscopy. One would then expect to observe a number of ERCPs to orientate themselves on how the procedure is performed, the differences between a standard upper GI endoscope and the duodenoscope used in ERCPs, the different accessories used in ERCP such as the sphincterotome and the ERCP specific technical aspects such as selective biliary cannulation. Once a trainee has achieved this basic orientation and receiving didactic teaching on how to perform an ERCP they would then be allowed to receive graded exposure on patients under supervision ranging from attempting intubation with a duodenoscope to actually performing biliary cannulation and sphincterotomy. Once a trainee is then able to perform a full ERCP under supervision, the next step would be to perform a large number of ERCPs under supervision in a large volume training centre in order to become confident and competent in performing the procedure, with regular feedback given by the supervisors in the form of an electronic logbook and the use of workplace based assessments such as Direct Observation of Procedural Skills (DOPS).

The development of endoscopy skills is centred around deliberate practice which involves focused repetitive performance of a skill which is coupled with constructive feedback which identifies strengths, weaknesses, areas which have been improved on previously and areas where further development is needed. This style of learning is centred around self-reflection with the aid of an expert supervisor and is focused on error correction in order to improve performance[36].

This method of learning is centred around feedback and involves a baseline assessment to determine the appropriate level of difficulty of initial simulation-based activities with plans to help decide subsequent learning objectives and areas of improvement. These learning objectives should be focused on development of the requisite technical and non-technical skills required to perform ERCPs at minimum passing standards (e.g cannulation rate, cannulation time) with serial formative assessments to gauge progress followed by summative assessments to gauge overall competency once minimum number of procedures and targets are achieved.

Receiving initial feedback on technique during the simulation training phase may allow a trainee to make the relevant changes so that they do not require constant feedback during their initial procedures. In the early stages of ERCP training constant feedback may place an increase cognitive load on novice endoscopists as they attempt to focus on both the procedure and their instructors' feedback and therefore may lead to errors or hinder learning[37]. This type of feedback may also lead to trainees becoming reliant on their supervisors' instructions to perform procedures limiting critical thinking and non-technical skills development.

Simulation based training without supervision and feedback did not augment endoscopic learning in a study done by Mahmood and Darzi (2004), with the study highlighting how learning occurs when trainees use feedback and educational goals to form their own cognitive schemas that they can readily access[38].

This literature review has highlighted how data supports the use of EMS training to improve technical skills, shorten learning curves, and accelerate skills acquisition and how it can be used as an important adjunct to early conventional endoscopy training.

ERCPs are procedures which are not performed as commonly as OGDs and colonoscopies therefore, in a lot of centres, trainees will have limited opportunities to perform ERCPs under supervision. Therefore, having a platform which both allows a trainee to acquire the skills required to perform ERCPs and develop these skills is invaluable in the development of a competent advanced endoscopist. Simulation training at the start of ERCP training can ensure that before a trainee attempts an ERCP on a patient that they are fully familiarised with the equipment, how to perform the procedure and receive feedback on their performance on the simulator so that they can best identify what adjustments are needed so that they have attained some degree of proficiency prior to performance in a clinical setting. There is potential to use DOPS in simulated cases to allow a trainee to receive formal feedback on their performance and subsequently make improvements that correlate with existing quality metrics to ensure trainees achieve required competencies. Khouli et al. (2021) highlighted how performance on the simulator corresponded to how experienced endoscopists were and they were able to develop a curriculum for use on an ECS which allowed them to determine when trainees achieved relevant competencies for the various aspects of ERCP in each computer case.

5.3. Other applications of simulator teaching

Currently simulation training in endoscopy has mainly been focused around the beginner user where it has been recognised as a tool to allow trainees to acquire new skills and familiarise themselves with equipment in a safe environment and allow the process of deliberate learning to begin without associated patient risks.

This is perhaps even more of advantage in an advanced procedure such as ERCP where the risks of adverse events and complications are much higher than a basic upper GI endoscopy.

Simulation training also has a number of other areas where it can be useful including; the potential to prevent skill decay for specialists who may be at centres where the number of advanced procedures is limited; learning new technologies; simulating clinically rare events and as a tool to develop non-technical skills.

Non-technical skills are an important part of performing safe high quality endoscopy and simulation training can be used to develop skills such as communication and teamwork, judgement, leadership, and situational awareness. This can be achieved by using high-fidelity simulation alongside nursing staff and an actor to simulate real life scenarios. These scenarios are focused around emergencies or errors and focus more on developing the non-technical aspects that an endoscopist needs to be versed in. Menabawey et al. (2018) reported their experiences running a course on “Human Factors in Virtual Endoscopy” for five years and how this one day course led to a significant impact on trainees’ confidence in their non-technical skills[39].

5.4. Comparing different types of simulation training

One of the reasons that simulation training is not widely adopted is due to the costs associated with its use and its subsequent accessibility. Basic EMS systems are cheapest platforms, which is a large reason why they are the ones most encountered in the literature. Recently, mobile phone applications and online modules have been developed which introduce aspects of endoscopy and provide a basic simulation of performing an endoscopy procedure, although these are limited in their realism as they also rely on simulating the actual endoscope.

Existing ECS systems suffer due to inadequate haptic capabilities limiting their realism alongside having relatively simple cases which do not require advanced troubleshooting. Sedlack et al. (2003) and Leung et al. (2012) highlighted how trainees using the GI Mentor and GI Mentor II respectively found the systems to be less realistic and representative of ERCP when compared to EMS and found these systems less useful as a result.

Animal models appear to be the most realistic in terms of haptic feedback and similarity to actual ERCP procedures but there are significant ethical concerns associated with their use, especially for live anaesthetised pigs, alongside logistical and cost issues that have to be factored into getting the animals, veterinarian staff and anaesthetics.

EMS is the only simulation platform which has RCTs supporting its use, with all four RCTs comparing EMS against a control group showing statistically higher biliary cannulation rates in the EMS group with lower mean time to achieve cannulation and generally higher competence scores being given by supervisors. Voiosu et al., (2021) also highlighted how motion training to further develop technical skills using EMS had potential benefits over standard EMS.

As virtual reality simulation and computer-based simulators become more advanced and lifelike, they have the potential to allow trainees to learn and practise their skills in an immersive and realistic environment without the potential patient risks that come attached with performing complicated procedures in high pressure environments, although these systems will likely be even more expensive than current solutions.

5.5. Recommendations

Endoscopic simulation training should be embedded in ERCP training programmes to act as an important part of the initial development of skills in a safe environment, where trainees can achieve a satisfactory level of proficiency before performing procedures on patients to limit the risk of adverse events and complications.

Endoscopic simulation training should be supervised by experts who can give continuous formative feedback to trainees as they improve their skills via deliberate practice, and endoscopic simulation-based training curricula should be developed which allow trainees to develop their skills on increasing difficulty of simulations with criteria being developed to set minimum standards in a number of key areas ,such as biliary cannulation rates, in order to guide trainee learning.

Given the potential morbidity and mortality associated with ERCP related complications, trainees should receive significant supervised simulator training in addition to going to a formal ERCP course, such as the JAG basic ERCP course, early on in their training. Trainees should then proceed with hands on ERCP training once supervisors are confident that the trainee has the required skills to safely perform the procedure with assistance and supervision.

5.6. Developing Simulation Training Programme

Appendix 1 contains the JAG Formative DOPS for ERCPs, which is a tool used to judge competency in ERCP. This DOPS serves as a good basis to develop a simulation training programme around.

The first section of the DOPS covers the “pre-procedural aspects of ERCP” such as indication, risk, consent, sedation and procedure preparation. A lot of these aspects can be integrated into simulation training where a trainer can present a mock case prior to a trainee performing a simulated ERCP. This allows integration of didactic teaching into simulation training with a lot of this section containing knowledge based information, whilst the procedural checks and preparation can be carried out on the simulator endoscope. Using only simulation and didactic training, most trainees should be able to achieve “competent for independent practice” in all of the preparation sections apart from sedation, where practical experience is important in allowing a trainee to assess whether a patient has been adequately and safely sedated.

The second section covers “intubation of the oesophagus and duodenum as well as positioning”. The majority of trainees interested in learning ERCP will have significant experience in performing upper GI endoscopies where intubation of the oesophagus and duodenum are essential technical skills as well. However, ERCP uses a side-viewing endoscope and this is where repetitive practise and familiarising with a side viewing endoscope is achievable with simulation training. Prior to starting ERCPs on patients, a trainee should reliably be able to perform intubation and correct positioning of the side viewing endoscope during simulation training and receive feedback on acquiring only “minimal supervision”.

The third section involves “biliary cannulation and imaging”, and this is a section where trainees will have to learn new skill sets and techniques that they have not acquired during routine upper GI endoscopy training. Selective biliary cannulation is perhaps the area where trainees should focus the most amount of time on deliberate practise during simulation training as it is a key step to performing ERCPs and one of the main criteria used when assessing the competency of an ERCPist. This is the area where one would expect a significant amount of instructor feedback as trainees learn this key new step. As Sedlack et al. (2003) and Leung et al. (2012) highlighted, current ECS does not accurately mimic an actual biliary cannulation but the evidence base suggests that EMS has a key role in developing this skill. The imaging and biliary cannulation aspects are likely areas where trainees will need “maximal or significant supervision” even if they reach “minimal supervision” categorises in simulation training.

The fourth section of the DOPS covers “Execution of selected therapy” and is the area where current simulators are most limited in terms of replicating. Therapeutic ERCP is a challenging task and the area where a lot of the adverse events take place. Developments in virtual reality and ECS represent a potential avenue in the future to better simulate these areas. This is one of the areas where the most accurate simulations involve live anaesthetised pigs, a time-consuming, ethically debatable method of simulation training as previously discussed.

The fifth and sixth sections involve writing reports and non-technical skills. Similar to the first section, the simulation training can be incorporated in cases and this may require the trainee to identify pathology and explain to the trainer what pathology they have encountered and how they would manage it. Non-technical skills can be incorporated into simulation training is also highlighted above.

Using the DOPS forms during simulation training can allow trainees and trainers to assess the progress that has been made and identify areas where further improvement is required. It can also help guide when a trainee can then safely proceed to hands on practice e.g when they achieve DOPS where they require only “minimal supervision” in all areas of simulation.

6. Conclusion

ERCP is a technically demanding and high-risk advanced endoscopic procedure with serious life-threatening short-term and long-term complications including post-ERCP pancreatitis, post-sphincterotomy bleeding and perforation.

ERCP training commonly requires dedicated advanced endoscopy fellowship where trainees can focus a significant amount of time in developing their skills and performing an extensive number of procedures under supervision in order to achieve competency.

This literature review has highlighted that endoscopic simulation training has a valuable role in the early development of knowledge and skills relevant to ERCP in a safe environment, when done with expert oversight and with regular formal feedback, in order to allow deliberate practising.

EMS has proven to improve trainees’ rates of biliary cannulation, reduce mean biliary cannulation times and achieve higher supervisor competency scores in multiple RCTs.

With advancing technology, ECS and virtual reality are areas which hold much promise for future focus and we will undoubtedly see more realistic and educationally useful simulators in this area in the future.

Larger randomised control trials are required to assess endoscopic simulation training against control groups, particularly ECS, in order to better understand how useful these platforms are and also how they can be best used to develop trainees skills.

Endoscopic Simulation Training should follow a portfolio format similar to formal hands-on ERCP training, where competence in performing certain tasks is monitored via DOPS forms in order to allow trainees to develop their skills in a structured manner with regular feedback. This will ensure that trainees make full use of the educational opportunities available during this stage of training and thereby improving confidence and knowledge when performing supervised ERCPs on actual patients.

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