Objective Benefit of a 1-day Training Course in Endoscopic Hemostasis Using the "compactEASIE" Endoscopy Simulator

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Background and Study Aims: The Erlangen Active Simulator for Interventional Endoscopy (EASIE) was introduced in 1997 as a training model for interventional endoscopy. Objective evidence of the benefits of training with this model has not previously been published. As part of two long-term projects, the benefits of a 1-day training course with the "compactEASIE" simulator were evaluated.
Materials and Methods: Fourteen American and 18 French gastroenterology fellows were enrolled. These fellows were participants in the intensive groups performing training in endoscopic hemostasis, with a total number of 28 fellows in New York and 36 in France. Gastrointestinal endoscopy faculty members in New York and France evaluated and timed the fellows in four disciplines to establish baseline skills (manual skills; injection and coagulation; Hemoclip application; and variceal ligation) with the compactEASIE simulator. The trainees were reevaluated after an intensive 1-day course (with two or three fellows and one instructor per station), also including preparation and assistance for each procedure. The assessment (overall and parts) was done by expert tutors using an ordinal scale ranging from 1 to 10 (1 = poorest, 10 = best), recording also mistakes and performance time. The compactEASIE simulator, equipped with an upper gastrointestinal organ package and an artificial blood perfusion system, was used as the training tool.
Results: A highly significant improvement ($P \leq 0.001$) was observed in the performance of all endoscopic techniques. A significant reduction in performance time was also observed with three of the four endoscopic techniques. Successful hemostasis was significantly improved in two out of three techniques.
Conclusions: A 1-day training course on endoscopic hemostasis using the compactEASIE simulator is capable of improving the performance of hemostasis procedures. Long-term effects of repeated training sessions are currently subject of collaborative studies in New York and France.

Introduction

Severe upper gastrointestinal hemorrhage often requires prompt intervention by a skilled endoscopist to arrest the bleeding and avoid surgery or death. Successful control of this emergency situation requires expertise both in setting up the hemostasis equipment and in carrying out specific techniques.

All over the world, gastroenterology trainees typically learn hemostasis skills by performing real, supervised cases during their fellowship period [1,2]. This approach has several limitations. Firstly, this training method does not allow the fellow to learn in a calm, controlled environment. Secondly, the frequency of opportunities to apply specific techniques is accidental and limited in any particular institution and time period. Finally, if the patient is in an unstable condition, the time available to trainees may be limited before the supervisor takes over the procedure.

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With the development of simulator technology, intensive hands-on instruction in hemostasis procedures using simulators may represent a new option. In 1996, Hochberger et al. introduced an endoscopic training model that for the first time allowed realistic simulation of spurting bleeding [3,4]. The simulator uses a specially prepared upper gastrointestinal organ package from the pig, with vessels sutured to the stomach wall and fed by a pulsatile perfusion system (Figure **1**). Prospective evaluations using questionnaires, conducted during structured training workshops on endoscopic hemostasis, have shown that 96% of the participants rated the training overall as being excellent or good [5]. However, a prospective validation of the benefits of practical hemostasis training in 1-day courses with expert tutors using the compactEASIE model has not yet been performed, although 1-day courses are one of the most commonly used training programs throughout the world [6,7].

The aim of the present study was therefore to obtain objective data on progress in learning different techniques of endoscopic hemostasis during a 1-day training course. For this purpose, learning progress was evaluated during the initial training workshops forming part of two prospective long-term trials (in New York in 2000 – 2001 and in France in 2001 – 2002) on endoscopic hemostasis using the compactEASIE system [8,9].

Materials and Methods

Study Design

The study was conducted as a prospective trial. Approval was obtained from the local institutional ethics committees. The evaluation results were analyzed before and after the first 1-day training workshop with the “intensive training groups” of two identically designed long-term trials [8,9] on training and education in endoscopic hemostasis (New York, September 2000 – April 2001; Limoges/Paris, September 2001 – June 2002). Fourteen gastroenterology fellows (in their first to third years) at nine New York hospitals were enrolled in the American part, and 18 gastroenterology fellows (in their final year) at various universities were enrolled in the French part. The two projects used the same training contents and evaluation criteria. The faculty in New York and in the French Society for Gastrointestinal Endoscopy (*Société Française d’Endoscopie Digestive,* SFED) had at least 5 years’ experience in interventional endoscopy. All of the participating experts met before the evaluation and training to standardize practical teaching methods and jointly review the evaluation forms and criteria. Training and evaluation were carried out in four sections: 1, manual skills; 2, injection and coagulation; 3, Hemoclip application; and 4, variceal ligation. Skills achieved were rated by the tutors using a 10-point ordinal scale (1 = poorest, 10 = best) for each section. Data were recorded for overall performance as well as for the parts of each technique – e. g., setting up of the device, proper bleeding localization, correct instructions to the assistant, and successful application of a particular technique. All steps were timed. For safety reasons, accurate performance was emphasized more than speed. Evaluation was stopped and a maximum time of 600 seconds was noted if a trainee was not able to prepare the device.

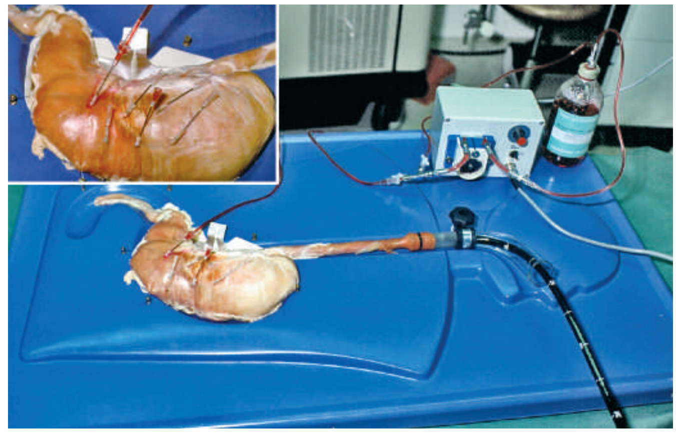

Figure **1** The compactEASIE model in its complete setting for training in endoscopic hemostasis. The upper gastrointestinal organ package with sutured-in vessels to simulate bleeding is connected via intravenous tubes to a roller pump and a reservoir holding a blood surrogate. A detailed view of the stomach preparation is seen at the upper left.

Immediately after the baseline evaluation, the intensive training unit started. This included both the theoretical background and practical application of the specific procedure. One instructor trained two or three fellows in 60-minute blocks in each section. The fellows underwent reassessment by different tutors in each technique at the end of all sections. For organizational reasons, blinding with completely new tutors was not possible. To overcome this problem, the experts rotated for the post-training evaluation. The tutors (two per section) thus evaluated a different topic after the training session, and specifically not the one they had taught.

Training Simulator

The compactEASIE model was used in this study (Figure **1**) [1,10]. A special organ preparation was used to simulate upper gastrointestinal bleeding. Six bleeding sources were placed in each specimen and connected to an artificial blood perfusion system driven by an adjustable pulsatile roller pump (Otto Huber, Ltd., Böttingen, Germany) using regular infusion lines (Figure **1**). The blood surrogate was obtained from a cherry-red food colorant solution (Brauns-Heitmann, Ltd., Warburg, Germany). Artificial varices were created directly before treatment by submucosal injections of the blood surrogate, seen from inside as a longitudinal livid swelling on the esophageal wall (Figure **2**).

Materials

Endoscopes. The video endoscopes used were the Olympus GIF-1T130, GIF-145 (Olympus Germany, Ltd., Hamburg, Germany), Fujinon EG-250D (Fujinon Europe, Ltd., Willich, Germany), and Pentax EG-2930 and EG-3430 (Pentax Europe, Ltd., Hamburg) dedicated for animal use alone.

Accessories. The electrosurgical generators used were the Erbe ACC-300 (Erbe Elektromedizin, Ltd., Tübingen, Germany) and Valleylab Force 1C (Valleylab, Inc., Boulder, Colorado, USA) devices.

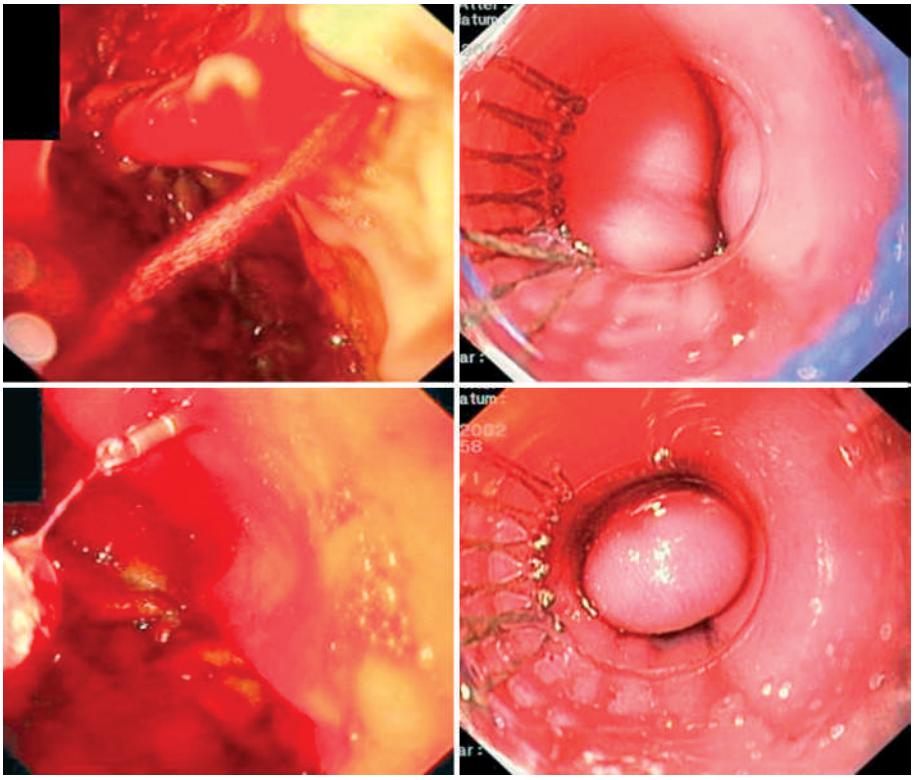

Figure **2** *Left:* simulation of spurting arterial bleeding and clipping in the compactEASIE simulator. *Right:* an artificial varix before and after band ligation.

Endoscopic devices. An argon plasma coagulation probe (Erbe Elektromedizin) was used for manual skills. A 10-Fr Injection Gold Probe (Boston Scientific Corporation, Natick, Massachusetts, USA) was used for injection and coagulation. A reusable applicator (Olympus HX-5LR-1) was used for Hemoclip application. The Six-Shooter ligator (Wilson-Cook Medical, Inc., Winston-Salem, North Carolina, USA) was used for mounting of a ligation device. Ligation was carried out in the simulator using Superview (Boston Scientific) or Six-Shooter ligators.

Training and skills sections. *Manual skills* (precision): a hand–eye dexterity exercise was developed for this purpose. Four dots (2 – 3 mm in size) were created with an APC probe before the training session and arranged as a square standing on a corner with a diagonal length of 2 cm at the anterior wall. Precision in brain–hand coordination was evaluated. After each mark was touched clockwise with the probe, the trainee had to "paint" a circle through the four points with the probe shortly above the oblique stomach wall. Performance was rated with an ordinal scale from 1 to 10 points (10 = best). The time taken to complete the task was measured. Mistakes were noted when generating the overall score. Precision was weighted more heavily than speed.

Injection and coagulation. The trainee had to set up the generator, adjust the power settings, and prepare the Injection Gold Probe. Correct commands to the assistant were required. Subsequently, the trainee had to identify the bleeding site, carry out a four-quadrant injection, and coagulate the central lesion. Each single section was rated with an ordinal scale from 1 to 10 points (10 = best). The mean score for all parts was calculated to generate the overall score. The performance time was recorded, as well as mistakes. In addition, the faculty member recorded whether or not the trainee was able to carry out successful hemostasis without assistance within 10 min.

Hemoclip application. Mounting of the Hemoclip on the applicator and placement of the clip were tested outside the simulator before a trainee was allowed to deploy a clip in the bleeding situation. The trainee thus had to demonstrate familiarity with the device. Subsequently, the tutor took the role of the assistant and assessed the accuracy of the trainee's endoscopic steps and commands while assisting the trainee. The mean score for all parts was calculated to generate the overall score. Successful hemostasis was documented (see above).

Variceal ligation. The fellow had to explain the function of a Six-Shooter ligation device and mount it on an endoscope. In the simulator, he or she had to identify an artificial varix in the esophagus and carry out a ligation using a premounted ligator. The overall score was calculated as the mean of the scores for each part. Successful hemostasis was documented (see above).

Statistical methods. The Statistical Package for the Social Sciences (SPSS, Inc., Chicago, Illinois, USA), version 11.0, and the R Project for Statistical Computing suite (www.r-project.org) were used for data analysis. Medians and interquartile ranges (25th and 75th percentiles) were determined. Learning progress between the baseline evaluation and the post-training evaluation was assessed using Wilcoxon's signed-rank test (ordinal data level). This test was also used to compare changes in performance times. Differences between the New York and French groups were compared using the Mann-Whitney U test at the pretraining and post-training levels. To compare previous endoscopic experience in the two groups (New York vs. France), mean and standard error of the mean were determined and the Mann-

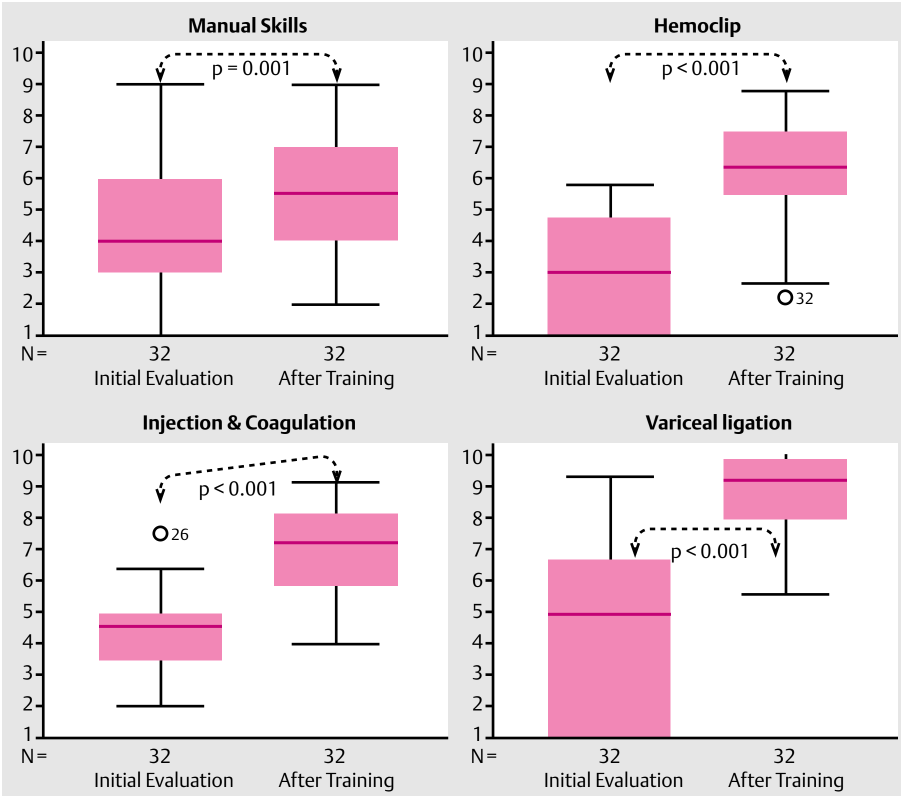

Figure **3** Learning progress among 32 trainees during a 1-day training course in four different interventional endoscopic hemostasis techniques.

Whitney U test was applied. The results were regarded as statistically significant at $P < 0.05$.

Results

Overall, 32 physicians took part in the training study. Fourteen gastroenterology fellows (seven in first year, five in second year, and two in third year) from nine New York City training programs took part, as well as 18 last-year gastroenterology fellows from various French universities.

The participants' endoscopic experience before entering the study did not significantly differ between the French and New York groups with regard to diagnostic and supervised therapeutic procedures (no emergency cases). However, a significant difference was noted in the numbers of emergency endoscopies conducted. The French group had performed 20.3 ± 6.3 emergency examinations, compared with 1.4 ± 0.7 in the New York group ($P = 0.008$).

Comparison of the New York and French groups (Figure **3**, **4**). There were no significant differences in simulator performance between the New York and French groups at the baseline evaluation for the sections on manual skills ($P = 0.316$) and injection and coagulation ($P = 0.808$). Significant differences were observed in the sections on Hemoclip application ($P < 0.01$) and variceal ligation ($P < 0.01$) (Figure **4**); the French trainees had higher baseline scores in both of the latter techniques. Notable changes were evident after the participants had received training. The previous significant difference in the evaluation of variceal ligation disappeared, due to a strong improvement in the New York group. Similarly, significantly better performance was observed in the section on manual skills at the final evaluation in the New York group compared to baseline. The evaluation of Hemoclip application was significantly better in the French group both at baseline and at final assessment. Both the French and American groups showed a strong improvement in the clip section (Figure **3**, **4**). However, the baseline evaluation had to be stopped with the New York trainees even in the preparatory part, as none of the participants knew how to mount or apply a clip. Accordingly, all of the single steps in this technique were rated with the minimum score. At the end, the American fellows still had scores significantly lower than those of the French group (Figure **4**).

The widely used injection technique combined with the coagulation method showed no significant differences at the baseline evaluation. The French group showed a significant improvement in performance in this section at the end in comparison with the American fellows.

Learning progress. A highly significant improvement ($P < 0.001$) was observed in the assessment of all four endoscopic techniques in each group and for every technique after 1 day of intensive training (Figure **3**, **4**). Focusing only on the endoscopic part of each hemostasis technique (bleeding discovery, positioning, and application), significant improvement was observed both in the overall group and in the New York and French subgroups for each technique. The mean evaluation for injection and coagulation increased from 4.6 to 7.0 points ($P < 0.001$), for variceal ligation from 4.75 to 9.0 points ($P < 0.001$), and for Hemoclip application from 3.6 to 6.3 points ($P < 0.001$) for the whole group.

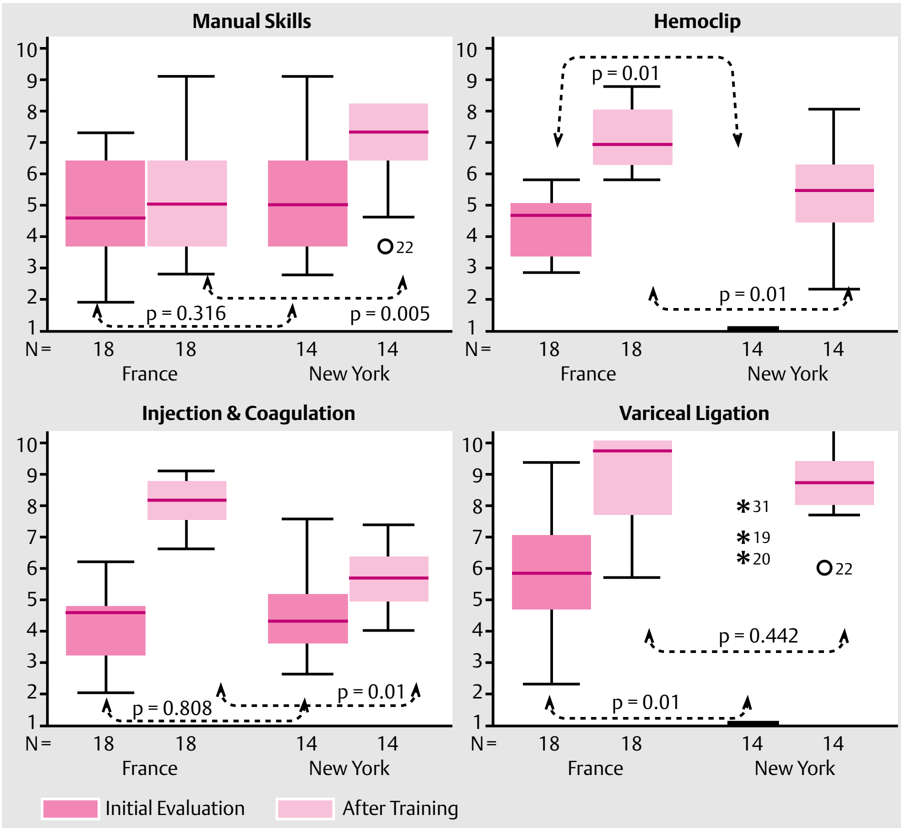

Figure **4** Comparison of the baseline evaluation and post-training evaluation in the French group (18 trainees) and the New York group (14 trainees).

Successful hemostasis. The experts had to assess whether the application of a technique would have led to successful hemostasis (Table **1**). A significant improvement in the ability to achieve successful hemostasis was observed for injection and coagulation ($P = 0.003$) and variceal ligation ($P < 0.001$). Most of the trainees had not been familiar with Hemoclips before the training session. None of the New York fellows were therefore able to apply a clip. Only two of the 18 French fellows (11 %) were able to achieve successful hemostasis with a Hemoclip at the baseline assessment. At the end of the course, seven of the 32 fellows (22 %) were able to stop bleeding successfully using clip application. However, the increase was not significant.

Performance time (Table **2**). The training course significantly reduced performance time for three of the four procedures (manual skills, Hemoclip application, variceal ligation). There was only a slight, but not significant, time reduction in the injection and coagulation section.

Discussion

In recent years, substantial efforts have been made to improve facilities for simulator training and to enhance endoscopic training. Various types of simulator devices (the Tübingen Interphant, Simbionix GI Mentor, Immersion Medical AccuTouch, etc.) have been developed for this purpose [11 – 16]. Various studies have been carried out to assess the value of each simulator [1]. Plastic phantoms and computer simulators are the devices best suited for providing training in basic endoscopic skills [1]. Computer simulators have been assessed as useful in providing training in colonoscopy; they can be used to distinguish between different levels of skills among trainees [17,18] and significantly improved the performance level of endoscopic novices [18]. Training with the GI Mentor before the first clinical colonoscopy was found to lead to better performance in the first real cases and to less patient discomfort [19]. Since 1997, our own group has shown that simulators based on animal organs, such as the compactEASIE device, are well accepted by trainees [4, 5, 20, 21].

Nevertheless, the data on the compactEASIE 1-day training workshops represent only a subjective impression of the trainees' learning progress. Hardly any data are currently available regarding the objective benefit of structured 1-day training courses in interventional endoscopy in the compactEASIE and other simulators, even though such courses are widely used all over the world. The present study reports the first attempt to evaluate the EASIE training concept in an objective fashion [1,10]. Significant improvements were demonstrated for all of the techniques in which training was provided. In particular, trainees who had no prior knowledge of a specific technique (e.g., Hemoclip application and variceal ligation) showed strong improvements in skills (Figure **4**). These results indicate that the EASIE training approach is an effective one and underlines subjective impressions obtained with the method during the last 7 years.

For organizational reasons, completely blinded assessment by the tutors, by using new tutors for the final evaluation, was not possible (blinded final evaluation has been carried out in the long-term studies, however). To overcome the problem of potential bias, the experts were rotated for the final evaluation and assessed a different topic that was specifically not the one they had

Table 1 Pretraining and post-training assessment of the effect of hemostasis. The tutors were advised to evaluate whether the application of a technique led to successful hemostasis without any intervention on the part of the supervisor. Significant results (Wilcoxon's signed-rank test) are shown in **bold** type)

Technique	*Pretraining assessment (n = 32)*			*Post-training assessment (n = 32)*			*P**
	n	Σ	*%*	*n*	Σ	*%*	
Injection and coagulation	**11**	**32**	**34**	**25**	**32**	**78**	**0.003**
New York	8	14		10	14		
France	3	18		15	18		
Hemoclip application	**2**	**32**	**6**	**7**	**32**	**21**	< 0.096
New York	0	14		4	14		
France	2	18		3	18		
Variceal ligation	**16**	**32**	**50**	**28**	**32**	**87**	**< 0.001**
New York	3	14		12	14		
France	13	18		16	18		

* Wilcoxon's signed-rank test.

Table 2 Longitudinal analysis of performance time during pretraining and post-training evaluation in four endoscopic techniques. Significant changes (Wilcoxon's signed-rank test) are shown in **bold** type; data are shown as medians and interquartile ranges

Technique	*Median performance time before training (n = 32)*	*Median performance time after training (n = 32)*	P
Manual skills/ precision	251 s (186 – 310 s)	180 s (160 – 290 s)	**0.023**
Injection and coagulation	322 s (222 – 417 s)	250 s (178 – 340 s)	0.187
Hemoclip application	600 s (600 – 600 s)	336 s (226 – 600 s)	**< 0.001**
Variceal ligation	600 s (521 – 600 s)	256 s (157 – 331 s)	**< 0.001**

taught. In addition, all of the experts jointly reviewed the evaluation criteria before each evaluation. All of the experts were blinded to the baseline results. An attempt was thus made to ensure objectivity without blinded assessment by new tutors. The learning progress observed therefore appeared to represent objective progress resulting from the training provided on the course.

However, the data obtained regarding improvements in skills in 1-day courses do not answer important questions regarding whether certain techniques require repeated training to allow the trainee to reach a maximum level of skills, or how long the expertise achieved is sustained. This is important in particular for more complex techniques such as Hemoclip application. These issues have been addressed in the prospective randomized long-term trials in New York and France comparing additional training courses using the compactEASIE simulator with exclusively clinical training. For future reference, the preliminary analysis showed that this depends on the complexity of a technique [8,9]. The present study was only conducted to test the benefits of the popular form of 1-day courses with the compactEASIE simulator.

In addition, it was not intended that this study should be a demonstration of a specific type of simulator. Simulators are merely educational tools – a view supported by results in other medical disciplines. Matsumoto et al. demonstrated a significant improvement in skills using a simulator for urological endoscopy training [22], and the training effect observed was not dependent on the simulator hardware. For this reason, Matsumoto et al. compared a simplified endourological bench model (a "low-fidelity" bench model costing US $ 20) with the "high-fidelity" simulator originally used (costing US $ 3700). Comparable skills were also achieved with the simplified version [23]. These data correlate well with our own group's experience during the last 7 years using different types of biosimulation model. An equivalent level of acceptance from the trainees was obtained in training workshops, regardless of whether the EASIE model or the simpler compactEASIE simulator was used [10].

Another interesting topic in this study was the difference between the French and American fellows. The two countries have different systems for the study of medicine, as well as for medical specialist training. It was considered that a study including trainees from both countries was admissible if it could be proved that endoscopic experience was capable of being matched. The two groups had previously conducted comparable and not significantly different numbers of diagnostic and therapeutic procedures. The French fellows had only carried out a slightly higher mean number of emergency endoscopies (20.3 ± 6.3 vs. 1.4 ± 0.7; $P = 0.008$). Despite this difference in numbers of emergency procedures, any expert would agree in characterizing the members of both groups as beginners. The combination of the two groups of fellows therefore appeared to be feasible. The differences in the assessment of fellows from the two countries may be more influenced by regional and personal differences in prior knowledge. Reusable and single-use clips were hardly ever used in New York hospitals during the period of the study; none of the New York fellows therefore knew anything about clipping. In addition, only a few fellows had experience with band ligation. It was therefore not surprising that the French fellows showed significantly better baseline scores, because a substantial percentage of them had observed the techniques in their departments. However, the New York fellows showed a strong improvement in both skills sections. In variceal ligation, they were able to catch up with the French fellows and reach the same level. This may have been because the preparation of the clips and their application is more complex and requires more training than the ligation technique.

In conclusion, the results of this study demonstrated that differences were more influenced by personal prior knowledge than by the medical education system and that training is even capable of compensating for imbalances between different medical systems. Furthermore, it appears that a structured education program with access to training in different simulators, in addition to supervised real cases in the hospital, would increase the efficiency of endoscopic education, which is characterized by what has been termed a "learning pyramid" [1]. Assessment of the outcome of real procedures performed by trainees after intensive hands-on simulator training will ultimately be needed in order to confirm that innovative educational modalities can lead to the expected improvements in patient care and complication rates.

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Original Article

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