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Digestive and Liver Disease
Digestive and Liver Disease 39 (2007) 70–78
www.elsevier.com/locate/dld

Digestive Endoscopy

The compactEASIE® is a feasible training model for endoscopic novices: A prospective randomised trial☆

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Received 16 March 2006; accepted 10 July 2006
Available online 30 August 2006

Abstract

Background. The objective benefit of a training using the compact Erlangen Active Simulator for Interventional Endoscopy-simulator was demonstrated in two prospective educational trials (New York, France). The present study analysed whether endoscopic novices are able to reach a comparable level of endoscopic skills as in the above-described projects.

Methods. Twenty-seven endoscopic novices (medical students, first year residents) were enrolled in this prospective, randomised trial. The compact Erlangen Active Simulator for Interventional Endoscopy-simulator with an upper GI-organ package and blood perfusion system was used as a training tool. Basic evaluation of endoscopic skills was performed after a practical and theoretical course in diagnostic upper GI endoscopy followed by a stratified randomisation according to the rating in endoscopic skills into intensive ($n = 14$) and control group ($n = 13$). The intensive group was trained 12 times every second week over 7 months in 4 endoscopic disciplines (manual skills, injection therapy, haemoclip, band ligation) by skilled endoscopist (three trainees/simulator). Assessment was performed (single steps/overall) using an analogue scale from 1 to 10 (1 = worst, 10 = optimal performance) by expert tutors. The control group was not trained. Blinded final evaluation of all participants was performed in January 2003.

Results. We observed in all techniques applied a significant improvement of endoscopic skills and of the performance time in the intensive group compared to the control group ($p < 0.001$). The comparison with the previous projects showed that the intensively trained novices achieved comparable levels of performance to the GI fellows in the New York and France Project (at least 80% of the median score in three out of four techniques).

Conclusion. Endoscopic novices acquired notable skills in interventional endoscopy in the simulator by an intensive, periodical training using the compactEASIE®.

Keywords: Education; Endoscopic haemostasis; Endoscopy; Training in endoscopy

1. Introduction

Practical education in medicine optimising patient care is of growing interest. The increasing number of minimal invasive procedures in surgery and gastroenterology stimulated the discussion on learning curves and quality assurance [1,2]. Legal and ethical considerations have enhanced the pressure on the medical community to show proofs of competence and to increase the efforts in training and education.

☆ Part of this study was part of a poster presentation at the UEGW 2003, Madrid, Spain, November 2003: Maiss J, Millermann L, Heinmann K et al. Evaluation of the compactEASIE®-simulator for the education in endoscopic hemostasis of endoscopic novices—a prospective randomized training trial. Endoscopy 2003;35(Suppl. II):A140.

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doi:10.1016/j.dld.2006.07.007

Nevertheless, only minimum requirements exist in most countries on the number of endoscopies to be performed (e.g. gastroscopy, colonoscopy, ERCP). The American and British Society of Gastroenterology, have published guidelines on training in GI endoscopy [3,4]. But especially in interventional endoscopy, no detailed curricula or learning steps exist. Moreover, no guidelines on the usage of simulator training exist at the moment even though there are interesting implications about the clinical learning pyramid in endoscopy and the use of simulators in this context [1].

Since the early 1970s, various types of simulators have been developed to improve practical training in endoscopy and to reduce the potential harms for patients. Particularly in upper GI endoscopy, a great variety of simulators exist, thus allowing the simulation of nearly all interventional procedures including active bleeding scenarios [5–10]. At present, the compactEASIE® (compact Erlangen Active Simulator for Interventional Endoscopy) is the best-suited simulator for interventional endoscopy especially for training in endoscopic haemostasis [1]. It has been shown that the training in haemostasis techniques was well accepted by the trainees even though this was only a subjective impression [10].

Subsequently, the objective benefit of the popular 1-day training courses in endoscopic haemostasis could be proven [11]. Until now, two long-term training project in endoscopic haemostasis were conducted in 2000/2001 in New York [12] and 2001/2002 in France [13] comparing the value of an additional repeat hands-on simulator training (3 single-day workshops in 7 month) and solely clinical endoscopic education. Both projects were performed as a cooperation of the Friedrich-Alexander University of Erlangen, Germany and the *New York Society of Gastrointestinal Endoscopy (NYSGE)* and *the French Society for GI Endoscopy (SFED)*. Both projects showed a significant improvement in skills of the simulator-training group in four haemostasis procedures at blinded final evaluation as well as a lower complication rate in the clinical follow-up. Thus, an objective proof of the value of training in emergency techniques in the simulator was demonstrated [12,13].

The aim of the underlying study was to further assess the impact of the compactEASIE®-simulator training in endoscopy education. It should be analysed, if an intensified training (compared to the French and New York Project) leads to similar skills and equivalent performance scores in endoscopic novices.

2. Materials and methods

2.1. Study design

The study was designed as a prospective randomised controlled trial. Twenty-seven volunteers (26 medical students, and 1 first year resident) without previous endoscopic experience were enrolled.

2.2. Project outline (Fig. 1)

In May 2002, the project started with four theoretical session (2.5 h weekly) on endoscope handling, theory of upper GI endoscopy, pictures and video examples of pathologic findings, use of endoscopic accessories, cleansing/desinfection of endoscopes and accessories and patient care during endoscopy (Fig. 1). An initial practical training course was conducted on diagnostic upper gastrointestinal endoscopy at the first weekend in June 2002. All participants were trained 3 h/day for 3 days using and applying an endoscope in diagnostic gastroscopy in different simulators

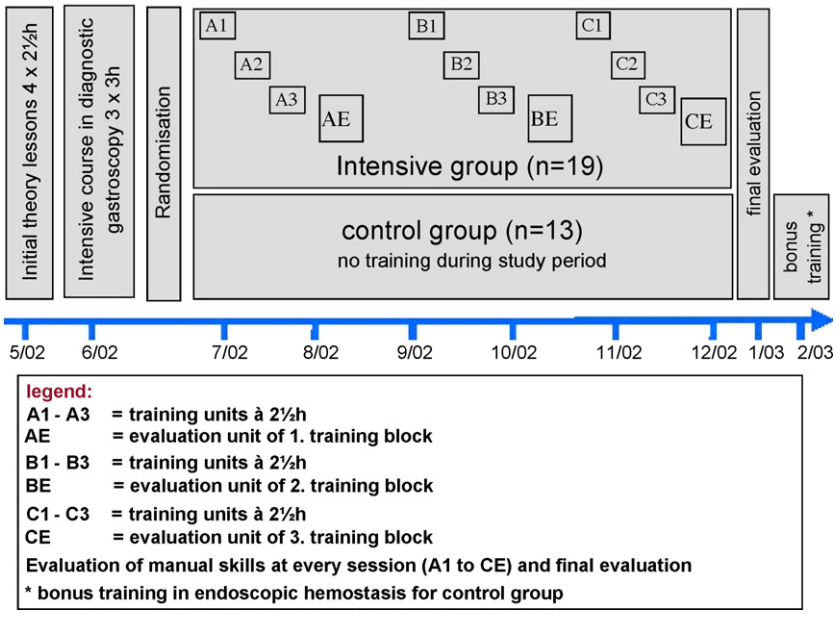

Fig. 1. Project outline: overview over the complete setup of the study.

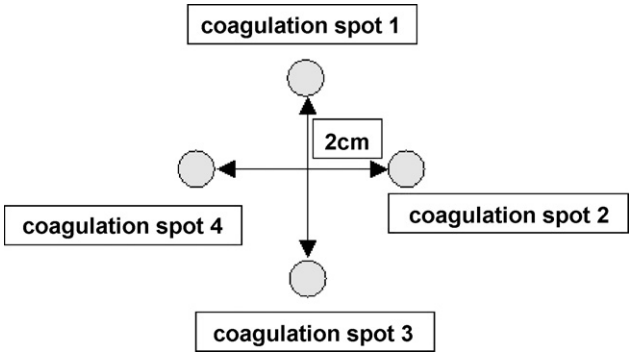

Fig. 2. Test arrangement of the 'manual skills' station: four 2 mm dots arranged as a square standing on one corner were placed on the anterior wall of the corpus using an APC probe before the test. The aim of this exercise was to evaluate how precisely the participant is able to manage three-dimensional work by brain–hand coordination when manipulating the endoscope only with his left hand and by body movement while the right hand had to precisely move the catheter forward and backward. The placement of the catheter tip on the determined spots was assessed according to precision, speed and smoothness of movements. After touching clockwise each mark in succession, the trainee was asked to 'paint' a circle through the four points with the probe always about one millimeter above the oblique stomach wall.

(plastic phantom [5], GI-Mentor, compactEASIE®). At the end of this unit, an assessment was performed consisting of a test in basic endoscopic 'manual skills' (see description in Fig. 2). Endoscopic skills were rated independently by experienced tutors (expert assessment) using a 10 point visual analogue scale (1 = worst, 10 = optimal performance). Data were recorded for the overall performance as well as for the single components. Afterwards, we started the assessment in three different endoscopic haemostasis techniques: (1) ulcer bleeding: 'injection therapy'; (2) ulcer bleeding: 'haemoclip application'; and (3) 'variceal ligation'.

For each of these stations, skills were also rated independently by tutors (expert assessment) using a 10 point visual analogue scale as described previously [11–13]. Data were recorded for the overall performance as well as for the single components of each technique. These included the steps for setting up and testing of the equipment, proper localisation of the bleeding site, correct instructions to the assistant and finally successful application of the particular haemostasis technique. All steps in this process were timed.

Subsequently, participants were randomised using a random list based on the rankings in the 'manual skills' test as assessed by experts in two groups: intensive training group (group A) and control group (group B).

2.2.1. Intensive Group A (n = 14)

Directly after initial evaluation, we started the training program with the intensive group. Over a period of 7 months we had three blocks of training (A, 6/02–8/02; B, 9/02–10/02; C, 11/02–12/02). Each training block consisted of three standardised intensive hands-on training and one evaluation unit (2 h for each unit) (Fig. 1). Each training session was conducted under the supervision of two experienced endoscopists. Evaluation in haemostasis techniques (see above) was performed at the end of each block (after three training sessions) using the same visual analogue scale used in the initial assessment. 'Manual skills' was tested at the end of every training and evaluation unit. Final evaluation in all techniques for both groups was conducted in January 2003. This time, aside from the initial study tutors, a new group of blinded faculty (at least 10 years experience in interventional endoscopy) independently rated the performance of the trainees using the same assessment criteria. All tutors met prior to each training session to standardise practical teaching in the simulator and were briefed to the evaluation forms and criteria.

2.2.2. Control Group B (n = 13)

After baseline evaluation, participants of group B returned to merely clinical education or university education but were not restricted to attend endoscopic education or examinations elsewhere.

After 8 months (1 month after the last training session), participants of group A and group B came together and were mixed for re-evaluation by the study tutors and the new blinded faculty tutors. Group B received, after final evaluation in February 2003 as a grant for participation in this study, an intensive hands-on training weekend in the compactEASIE® in above-mentioned haemostasis techniques.

2.3. Material

Training simulator: The compactEASIE® used in this study and setting for the training (Fig. 3) has been described previously [10,11]. *Endoscopes*: GIF 1T 100 and GIF 100 (Olympus Optical Europe Inc., Hamburg, Germany) dedicated for animal use only were used. *Accessories*: Electrosurgical Generator, ERBE ICC 200 and APC 300 (ERBE, Tuebingen, Germany). *Endoscopic devices*: APC-probe (ERBE, Tuebingen, Germany) for 'manual skills'. UNO-JECT® injection needle (MTW Endoskopie, Germany) for 'injec-

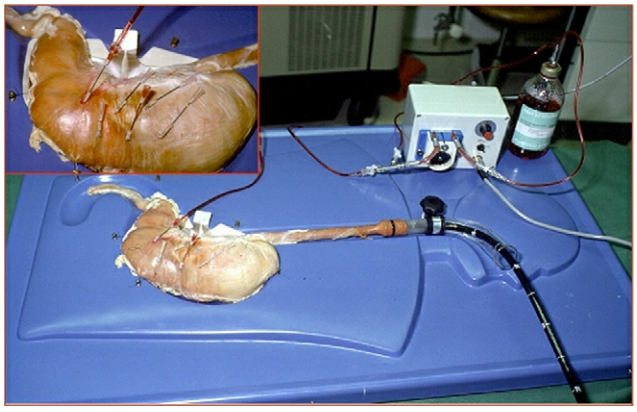

Fig. 3. CompactEASIE® model in complete setting for training in endsocopic haemostasis: upper GI-organ package with sewed-in vessels for bleeding simulation connected by i.v. tubes to a roller pump and a reservoir for blood surrogate. Details of the stomach preparation are shown on the small image in the upper left angle.

tion therapy'. Reusable Haemoclip-applicator (HX-5LR-1, HX-600-90, Olympus Endotherapy, Hamburg, Germany) for 'haemoclip application'. Mounting of a ligation device and application in the simulator was performed the Six-shooter™ multiband ligation device (Wilson-Cook, Limerick, Ireland).

2.4. Training and skills sections

Four topics were trained and evaluated: (1) 'manual skills'; (2) 'injection therapy'; (3) 'haemoclip application'; and (4) 'variceal ligation'. The training and evaluation in each section was performed as described before in the New York and French Training Project [11–13]. This included proper setting up of the device, proper bleeding localisation, correct instructions to the assistant and successful application of a particular technique. The performance for each step as well as for overall performance was rated by using an ordinal scale from 1 to 10 point (1 = worst, 10 = optimal performance) [11,13]. The time to complete the task was also measured. Mistakes were noted for generating the overall score. Precision was weighted more heavily than speed. In addition, the faculty recorded whether or not the trainee performed successful haemostasis unassisted within 10 min.

2.4.1. Statistical analysis

SPSS 11.0 software and 'R'-software (http://www.r-project.org/) was used for data analysis. Estimation of sample size was performed on the basis of the results in New York and French pilot study [12,13]. A case number of 14 participants was calculated to be sufficient (level of power 0.8, odds ratio 5.5, $\alpha = 0.05$).

Medians and interquartile ranges (25th and 75th percentile) were determined. Mann–Whitney *U*-test was applied for comparison of the scores of group A and group B at the basic and final evaluation owing to ordinal data level. Longitudinal data analysis concerning the learning progress for each group was calculated with the Wilcoxon signed rank test. Results were considered to be statistically significant if $p < 0.05$.

Mann–Whitney *U*-test was used to compare the results of group A with the scores of the intensive training groups of the projects in France and New York. Equivalence testing was performed by two one-sided comparisons of median scores using Mann–Whitney *U*-test. A median score of $80\% \leq x \leq 120\%$ of the scores of the intensive groups in the French and the New York Training Projects was considered to be an equivalent rating. After Bonferoni correction results were estimated as equal, if *p*-values of each one-sided testing were below 0.025.

3. Results

Twenty-six medics and one first year resident of the Department of Medicine I were drawn by lot out of 70 volunteers to participate in this project (intensive group A [$n = 14$], control group B [$n = 13$]). All participants had no experience in upper gastrointestinal endoscopy. A basic evaluation could be established only in 'manual skills'. A median overall score of 3.0 (range 1.0–7.0) was achieved in the whole group. Owing to a lack of knowledge and skills in the three other techniques, all trainees received the lowest mark 1.0 and the maximum time level of 600 s in these disciplines because nobody was able to setup a device.

Owing to stratification on the results in baseline assessment of 'manual skills', there was no significant difference between both groups as well as in the performance score (group A 4.0 (3.3–4.0) versus group B 3.0 (2.0–4.3) $p = 0.10$) and in the total time ($p = 0.132$) for the exercise.

3.1. Learning progress during the study period

None of the participants had prior experience in therapeutic endoscopy. Thus, both the lowest mark 1.0 was given to all trainees in the disciplines 'injection therapy', 'haemoclip application' and 'band ligation' and maximum time (600 s) was recorded in these techniques.

3.1.1. Intensive group A (n = 14)

All trainees completed the study. Overall, we found a significant increase in the performance scores in all disciplines. The median level in 'manual skills' advanced from 4.0 to 8.0 points ($p < 0.001$). The median score increased also significantly up to final evaluation for 'injection therapy', 'variceal ligation' and 'haemoclip application' ($p < 0.001$ each) (Tables 1 and 2). The most evident improvement was seen between the initial evaluation and the assessment after the first block of training sessions except 'injection therapy'. Owing to lack of time, there was no efficient training possible for 'injection therapy' in the first training block. Therefore, we noted a marked increase in 'injection therapy' – results almost reaching the final assessment – after the second training block. The results (median and interquartile range) for all assessments are shown in detail in Table 1.

Table 1
Development of skills in the intensive group ($n = 14$) during the study period (median and interquartile range)

	Intial evaluation 6/02	First evaluation 7/02 (AE)	Second evaluation 10/02 (BE)	Third evaluation 1/03 (CE)	Unblinded final evaluation 2/03
Manual skills	4.0 (3.0–4.25)	8.0 (7.0–8.0)	8.0 (7.0–8.5)	8.5 (8.0–9.0)	8.0 (7.0–9.0)
Injection therapy	1.0 (1.0–1.0)	1.0 (1.0–1.0)	8.0 (7.0–8.0)	8.0 (7.5–8.0)	8.5 (7.75–9.0)
Haemoclip application	1.0 (1.0–1.0)	6.0 (4.75–7.25)	8.0 (6.0–8.25)	8.0 (7.0–9.0)	8.0 (7.0–8.25)
Variceal ligation	1.0 (1.0–1.0)	8.5 (6.75–9.0)	8.0 (6.75–8.25)	8.0 (6.75–9.0)	8.0 (8.0–8.25)

Table 2
Longitudinal comparison of skills in all tested endoscopic disciplines at baseline and after 8 months of training at the final evaluation (significant results in bold letters)

	Intensive training group (A) ($n = 14$) (simulator training)				Control group (B) ($n = 12$) (no simulator training)			
	Baseline evaluation[a]	Unblinded final evaluation[a]	Blinded final evaluation[a]	p-value[b]	Baseline evaluation[a]	Unblinded final evaluation[a]	Blinded final evaluation[a]	p-value[b]
Manual skills								
Overall score[c]	4.0 (3.3-4.0)	8.0 (7.3-9.0)	8.0 (7.0-8.0)	**<0.001**	3.0 (2.0-4.3)	3.0 (2.0-4.0)	3,5 (3-5.3)	0.312
Time	174 s (122–215)	83 s (79–98)		**<0.001**	196 s (187–264)	246 s (209–410)		0.117
Injection								
Overall score[c]	1.0 (1.0–1.0)[c]	8.5 (8.0-9.0)	8.0 (7.3-9.0)	**<0.001**	1.0 (1.0–1.0)	2.0 (1.0–2.0)	3.0 (3.0–3.3)	**<0.001**
Time	600 s (600–600)	370 s (241–480)		**0.002**	600 s (600–600)	695 s (543–753)		0.195
Haemoclip application								
Overall score[c]	1.0 (1.0–1.0)[c]	8.0 (7.0-8.0)	7.5 (5.5-8.8)	**<0.001**	1.0 (1.0–1.0)[c]	3.0 (2.0-3.0)	2.0 (2.0-3.0)	0.25
Time	600 s (600–600)	182 s (167–202)		**0.001**	600 s (600–600)	436 s (355–566)		**0.01**
Variceal ligation								
Overall score[c]	1.0 (1.0–1.0)[c]	8.0 (8.0-8.0)	8.0 (7.0-9.0)	**<0.001**	1.0 (1.0–1.0)[c]	1.0 (1.0-1.0)	1.0 (1.0-1.3)	0.25
Time	600 s (600–600)	134 s (113-152)		**0.005**	600 s (600–600)	600 s (600–600)		1.000

[a] Median and interquartile range.
[b] Wilcoxon test, comparison between baseline evaluation and blinded final evaluation.
[c] Ordinary scale: 1, worst performance; 10, best performance.

Overall, we noticed an improvement of the scores in the different techniques as well as a significant decrease in the performance time in each discipline (blinded and unblinded evaluation). Results are summarised in Table 2. No significant differences existed between blinded and unblinded assessment.

3.1.2. Control group B (n = 13)

During the study period, one trainee was lost for follow-up. Final evaluation was completed for 12 trainees (92%). The control group had no endoscopy training but had no restriction to attend endoscopies until final evaluation. Nobody in the control group gathered practical training or experience in upper GI endoscopy. At the final evaluation every participant was allowed to make an attempt to prepare a device or to apply a technique. Thus, we found a significant reduction in the performance time of 'haemoclip application' ($p = 0.01$), because some participants achieved the right mounting of a clip and were allowed to place the clip. No significant changes in performance time were observed in the other techniques though a small increase in the performance time occured for the exercise 'manual skills' (Table 2). No significant differences existed between blinded and unblinded assessment.

Table 3
Comparison between control and intensive group at baseline and at the final evaluation after 8 months (significant results in bold letters).

Baseline skill comparison (t_0)				Comparison of blinded assessment at the end of study period (t_{7mo})		
Technique	Intensive group (group A)[a]	Control group (group B)[a]	p-value[b]	Intensive group (group A)[a]	Control group (group B)[a]	p-value[b]
Manual skills						
Overall score[c]	4.0 (3.3–4.0)[c]	3.0 (2.0–4.3)[c]	0.10	8.0 (7.0-8.0)	3.5 (3-5.3)	**<0.001**
Total time	174 s (122–215)	196 s (187–264)	0,132	83 s (79–98)	246 s (209–411)	**<0.001**
Injection						
Overall score[c]	1.0 (1.0–1.0)[c]	1.0 (1.0–1.0)[c]	1.000	8.0 (7.3-9.0)	3.0 (3.0–3.3)[c]	**<0.001**
Total time	600 s (600–600)	600 s (600–600)	1.000	370 s (241–480)	695 s (543–753)	**<0.001**
Haemoclip application						
Overall score[c]	1.0 (1.0–1.0)[c]	1.0 (1.0-1.0)[c]	1.000	7.5 (5.5-8.8)	2.0 (2.0-3.0)	**<0.001**
Total time	600 s (600–600)	600 s (600–600)	1.000	182 s (167-202)	436 s (355–566)	**<0.001**
Variceal ligation						
Overall score[c]	1.0 (1.0–1.0)[c]	1.0 (1.0–1.0)[c]	1.000	8.0 (7.0-9.0)	1.0 (1.0-1.3)	**<0.001**
Total time	600 s (600–600)	600 s (600–600)	1.000	134 s (113-15)	600 s (600–600)	**<0.001**

group A, $n = 14$; group B, $n = 12$.
[a] Median and interquartile range.
[b] Mann–Whitney U-test.
[c] Ordinary scale: 1, worst performance; 10, best performance.

Table 4
Comparison of the blinded final assessment of the intensive group with the final evalation of the training groups in the New York and French Project in endoscopic haemostasis for GI fellows (significant results in bold letters)

		Manual Skills	Injection Therapy	Hemoclip Application	Variceal Ligation
	Median score (interquartile range) Erlangen project	8.0 (7.0-8.0)	8.0 (7.3-9.0)	7.5 (5.5-8.8)	8.0 (8.0-9.0)
New York Project	Median score (interquartile range) New York project	8.0 (7.0-9.0)	6.8 (6.3-8.0)	7.6 (6.0-8.4)	8.3 (8.0-8.6)
	p-value at upper bound performance score ≥ 120 % of the median score in New York	**<0.001**	0.328	**<0.001**	**0.002**
	p-value at lower bound performance score ≤ 80 % of the median score in New York	**<0.001**	**<0.001**	0.065	**0.002**
French Project	Median score (interquartile range) French project	8.0 (5.8-8.0)	7.0 (6.8-7.5)	6.8 (6.1-7.5)	9.5 (8.3-10.0)
	p-value at upper bound performance score ≥ 120 % of the median score in France	**<0.001**	0.328	0.044	**0.001**
	p-value at lower bound performance score ≤ 80 % of the median score in France	**<0.001**	**<0.001**	**0.004**	0.115

Looking at performance scores, we observed a small but significant improvement from 1.0 to 3.0 points in 'injection therapy' ($p < 0.001$). These results rely on the same fact as the reduction in performance time as described above. No significant changes were noticed in 'manual skills' and 'variceal ligation'. The data are shown in detail in Table 2.

3.2. Comparison intensive versus control group (Table 3)

As shown in Table 3, there was no significant difference between the intensive and the control group at the beginning of the study. This is true for the median scores as well as for the performance times in all tested disciplines. At the final assessment we observed significantly higher performance scores ($p < 0.001$) as well as significantly shorter performance times ($p < 0.001$) for the intensive group A in each discipline. We noted no significant difference between the blinded and unblinded final assessment in this context.

3.3. Comparison with the New York and the French Training Project on endoscopic haemostasis

To assess the effectiveness of the training the result of the intensive training groups were compared with the results of the GI fellows in the training groups of the New York and the French Training Project. A level between 80–120% of the performances scores was estimated to be equivalent.

3.3.1. New York

The comparison of our intensively trained group with the intensive group in New York showed for 'manual skills', 'injection therapy' and 'variceal ligation' comparable results for our novices at the end. Only for the section 'haemoclip application' the performance of novices reached not significantly the 80% level ($p = 0.065$ at lower bound). The score in the 'injection therapy' section now even showed no significant difference at the upper level, so that a higher scoring had to be stated in intensive group A compared to the New York training group. The results are summarised in Table 4.

3.3.2. French Project

Compared to the French fellows, the intensive group achieved at least 80% of the score of the intensive group in National French Training Project except for 'variceal ligation' ($p = 0.115$ at lower bound). The score in the section 'injection therapy' and 'haemoclip application' now even showed no significant difference at the upper level, so that a higher scoring had to be stated in our intensive group compared to the French group (Table 4).

3.3.3. Learning curves

Like in the projects in New York and France, we observed the steepest increase of scores from baseline to the first intermediate evaluation. The median scores achieved in the second evaluation were nearly equivalent to the assessment at the final evaluation (Fig. 4).

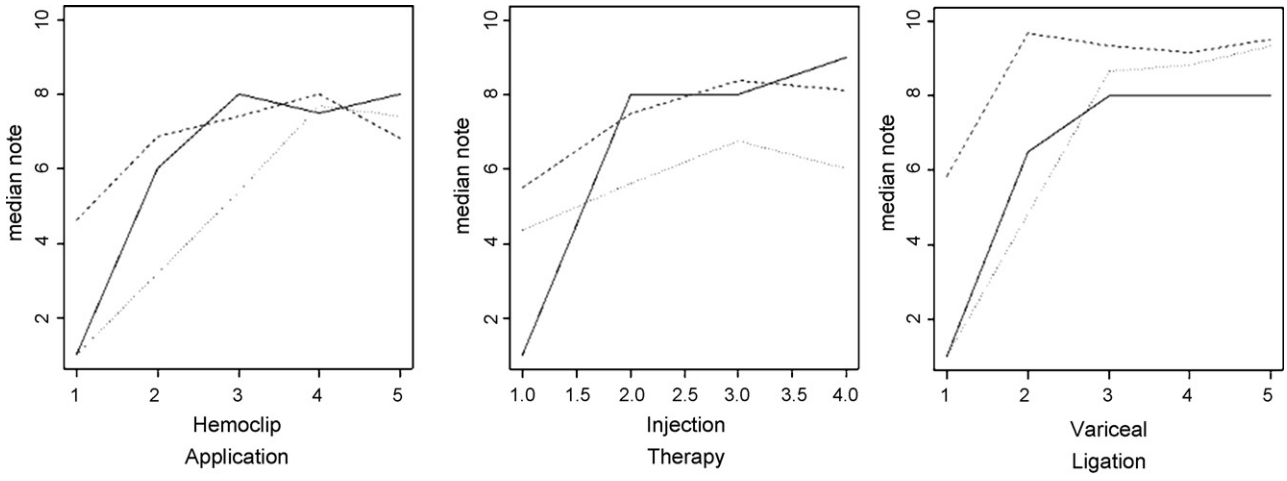

Fig. 4. Comparison of the learning curves (median scores) of the intensive training groups of the New York Project, the National French Training Project and the Erlangen Project of endoscopic novices. (solid line, Erlangen-Project; pointed line, New York Project; dashed line, French Project).

4. Discussion

The concept of teaching different endoscopic haemostasis techniques (preparation and application) employing the compactEASIE® model was applied to novices without any endoscopic experience. Intensive training in small groups with skilled tutors produced a level of performance in all techniques equal to GI fellows in the former prospective studies in New York and France after a comparable training. This demonstrates that the compactEASIE® model is an effective training tool irrespective of prior experience.

Our results corroborate subjective data gathered by prospective evaluation of workshops over the last 8 years [10,14,15]. compactEASIE® courses incorporate all aspects of an endoscopic technique like preparation of accessories, pathologic findings, application of the techniques, result of application and complications. Team-training of endoscopists and GI assistants is preferred to increase the mutual understanding of both professions [10]. Here, we could show that this could also be done on the novice level, at least in medical students.

Some statistical aspects of internal validity need to be considered. None of the participants had prior endoscopic experience, and differences including gender were controlled by randomisation. To increase the feeling of attention in the control group ('Hawthorne effect'), an intensive hands-on training weekend in the compactEASIE® in haemostasis techniques was offered and performed and so only one subject was lost for follow-up. Tutors were also raters, and this constituted an implementation threat. To control for this, the final evaluation was done in parallel by new blinded raters who had not participated in the trial. Blinded raters had no significantly different results (Table 2) showing the reliability of the scoring like in the former projects [12,13]. Important variables in relation to the hypothesis tested in this trial was location, instrumentation and testing. Every effort was made to standardise all aspects to increase internal validity. Therefore, the compactEASIE® was prepared identical to the New York and French settings by the same team. Scoring protocols were identical in all trials, and raters met regularly before training sessions to discuss scoring protocols. Thus, the comparison of the results from blinded final assessment of the present and the historical test sites (New York, France) seemed to be appropriate. As none of the participants had exposure to haemostasis instruments and techniques previously, regression threat was controlled by randomisation. There probably was some testing effect, as the results for assembly and performing two of the haemostasis techniques ('injection therapy' and 'haemoclip application') in the control group without any training exhibited significantly improved scores and time at final assessment (Tables 2 and 3). Some cross-contamination may also have played a role. In view of the highly significant results in this randomised trial internal validity appears to be well controlled and no threat to our interpretation.

A number of additional observations in our present study deserve consideration. In conformation to the projects in New York and France [11–13], we observed a steep increase of performance scores between baseline and second intermediate evaluation (Fig. 4, Table 1). Scores achieved in the second evaluation were almost equivalent to the results at final evaluation. Thus, like in the New York and French study, at least two separate intensive training periods seem to be mandatory to reach the plateau phase of the individual learning curve and to achieve a sustained skills level. This supports the goal of every simulator training to achieve a high level of performance by trainees outside the patient and thereby reduce complications and patients discomfort [16–18]. Up to now, evidence is available for computer simulators to be suitable tools in training basic endoscopic skills in a controlled, reproducible and riskfree setting [9,16–20]. However, there was a lack of training possibilities for interventional techniques; this could be solved by using the compactEASIE®-simulator and with newer static simulators like the Tuebingen

Interphant for a wide range of interventions including the hepatobiliary system [7,10]. The trial addressed haemostasis techniques, which happen as an emergency and do not tolerate major mistakes and cannot offer a calm learning environment. The data shown here as well as in the French and New York Projects demonstrated the compactEASIE® model as a reproducible, controlled setting for teaching of endoscopic interventions without risk to patients in a relaxed atmosphere [11–13]. Since the presentation of the simulator and owing to the results of the New York and French study, various endoscopic centers in Europe have established compactEASIE®-simulator training courses regularly (e.g. in France, Austria, Germany, Switzerland, Italy, Poland). Further studies will have to be conducted to address the question, whether skills achieved by compactEASIE® training translate into better performance in patients. The New York data showed first evidence of a lower overall complication rate for the compactEASIE® training group during clinical follow-up of the fellows [12]. Additional studies are necessary to determine the best time for starting the training in interventional endoscopy. Our study shows that even novices increased their skills in different interventions. Accompanying training of interventional techniques in an early stage of clinical training may be used also a motivation tool and may consolidate the understanding of fundamental principles in interventional endoscopy from the beginning. Nevertheless, computer simulators and plastic phantoms are fully sufficient to train basic endoscopic skills and biological bench models like the compactEASIE® should be reserved for interventional techniques because of the higher logistic and financial efforts [1].

The underlying studies as well as the former projects included the preparation of accessories. There are different reasons for this: Not in all hospitals, specialised nurses are available in a 24 h service. Additionally, the knowledge of the preparation of a device enhances the comprehension of a procedure fundamentally and the understanding of the endoscopists for the problems of Gl assistants with a specific device (e.g. clipping). Last but not least, the tips and tricks of preparing a device can be trained best in a hands-on situation with a direct feedback of the tutor. Especially this could not be served by DVDs or CDs though they are also suitable training tools for teaching.

The training concept using the compactEASIE® model will offer additional advantages. Surgeons have a long tradition documenting their personal experience in a collection of operation protocols, and since 25 years surgical fellows were advised to collect their reports. At about the same time, national endoscopic societies began to deal with the question of how many procedures a trainee should do under supervision until a physcian is allowed to perform unsupervised endoscopies [21]. For gastroscopy and colonoscopy Cass et al. conducted a pilot study analysing competence attributes using a computer program after each single procedure [22]. Approximately 100 procedures were necessary to achieve reproducible success for 90% of objective criteria. In the future, instead of a fixed number of procedures, outcome criteria may be used for individual assessment and credentialing processes [1,23] using also different kinds of simulators for the assessment. Whereas computer simulators can play their part in basic skills training [18–20], the compactEASIE®-simulator will be most suitable for training endoscopic interventions or new methods. Simulators could not only play a major role in acquiring and measuring individual endoscopic skills, but may also offer a valid and reliable way for continuous education and objective re-certification in interventional endoscopic techniques.

In conclusion, training at regular intervals in the compactEASIE® model enhances skills in endoscopic haemostasis techniques even of endoscopic novices. Beginners achieved a conspicuous level of performance after an intensive training program using the simulator in three haemostasis techniques. The model offers a reliable and valid training tool for endoscopic haemostasis techniques for both elective and emergency simulation in a pre-clinical setting. This study was another step in the evaluation of the potential of the compactEASIE® in the so-called learning pyramid. It may also be used after further evaluation as an objective credentialing and re-certification instrument in further studies.

Practice points

- The compactEASIE-endoscopy simulator represents a reliable and valid training tool for endoscopic hemostasis techniques for both elective and emergency simulation in a pre-clinical setting.
- Training at regular intervals in the compactEASIE® model enhances skills in endoscopic hemostasis techniques even of endoscopic novices.
- Endoscopic beginners achieved a conspicuous level of performance after an intensive training program using the compact-EASIE-Simulator

Research agenda

- Further clinical trials comparing traditional endoscopic education with simulator assisted training programs in ERCP.
- Outcome measurement studies of simulator supported training programs measuring the complication rates, and success rates of only clinically trained and additionally simulator trained endoscopist.

Conflict of interest statement

None declared.

Acknowledgements

Special thanks for the support of this project had to be given to our industrial sponsor *Olympus Endotherapy Germany* and *Wilson & Cook Germany* for the allocation of accessories. Specimen were provided by the '*Association for the quality-oriented training in Endoscopy e.V. Erlangen*', a non-profit organization that aims at the research of the value of simulator-training especially in the EASIE-simulator. Thanks also to all endoscopy nurses and our charladies who cleaned and processed the training rooms, endoscopes and accessories carefully after each session. We also want to express our gratitude to our blinded evaluators Dr Muehldorfer, Dr Mayinger and Dr Preclik.

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