Fast-tracking ERCP learning with the Boskoski-Costamagna Trainer: results of a multicenter randomized clinical trial

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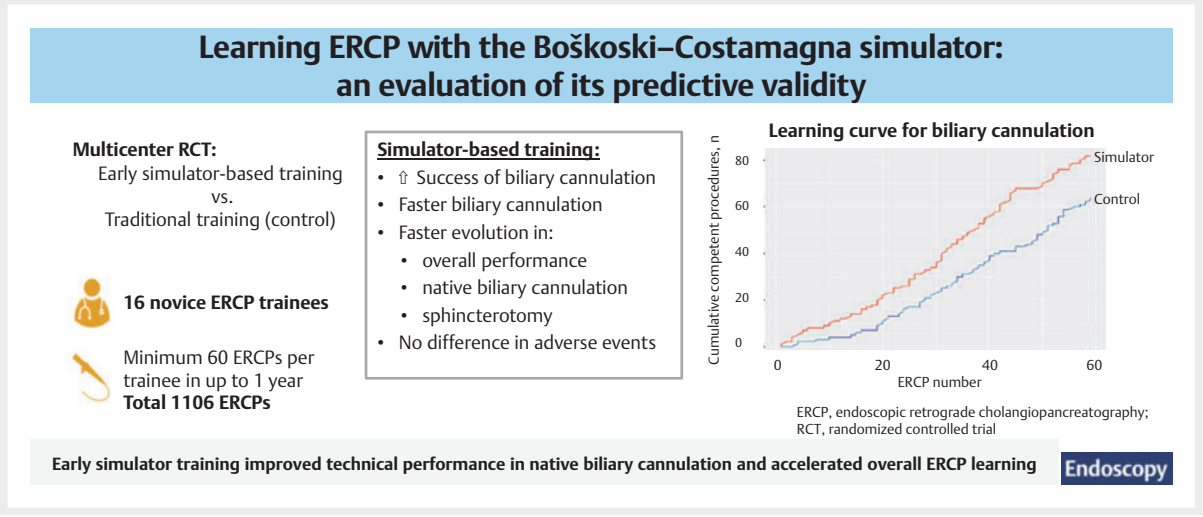
GRAPHICAL ABSTRACT



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ABSTRACT

Background Achieving competence in endoscopic retrograde cholangiopancreatography (ERCP) requires extensive training. Recognizing the potential of simulator-based education for safe and effective skill development, we aimed to assess whether initial training with the Boškoski–Costamagna ERCP Trainer (BCT) is beneficial compared with conventional training alone (i. e. predictive validity).

Methods A prospective multicenter randomized trial involving 16 novice ERCP trainees, randomly assigned to intervention or control groups, was performed. Both underwent hands-on training, with the intervention group receiving additional simulation training during the first 3 months. Each trainee was required to complete a minimum of 60 ERCPs in up to 1 year. The TEESAT score evaluated rates of global overall competence (primary outcome), biliary cannulation, and adverse events (AEs; secondary outcomes). Mixed-effect logistic regression models assessed differences in between-group ERCP procedure competence and success. Learning curves were generated cumulatively over the training period.

Results 1106 ERCPs (562 simulator group; 544 control group) were included. Although no statistically significant difference in global overall competence was observed between the groups, possibly owing to data heterogeneity, simulation training demonstrated higher success for native biliary cannulation (52% vs. 42%; $P<0.001$) and faster median (interquartile range) biliary cannulation times (3 [6] vs. 5 [8] minutes; $P<0.001$). The simulator group also showed faster improvements in overall performance, native biliary cannulation, and sphincterotomy. No statistical difference was found in overall AEs between the groups.

Conclusion Early simulation training with the BCT improved technical competence in native biliary cannulation and accelerated overall ERCP learning. This approach has the potential to enhance ERCP training programs.

Introduction

Traditional endoscopy teaching typically follows an apprenticeship model in the endoscopy unit, with trainees undergoing supervised hands-on training on patients. However, the prolonged learning curve to reach competency poses challenges for both endoscopists and patients, potentially increasing risks for the latter. To address this, various gastrointestinal (GI) endoscopy simulators [1, 2] have been developed to accelerate the learning curve [3, 4, 5]. Simulator-based education aims to enhance training efficiency and effectiveness by providing a dedicated learning environment where trainees can acquire skills at their own pace, without increasing procedural times and risks.

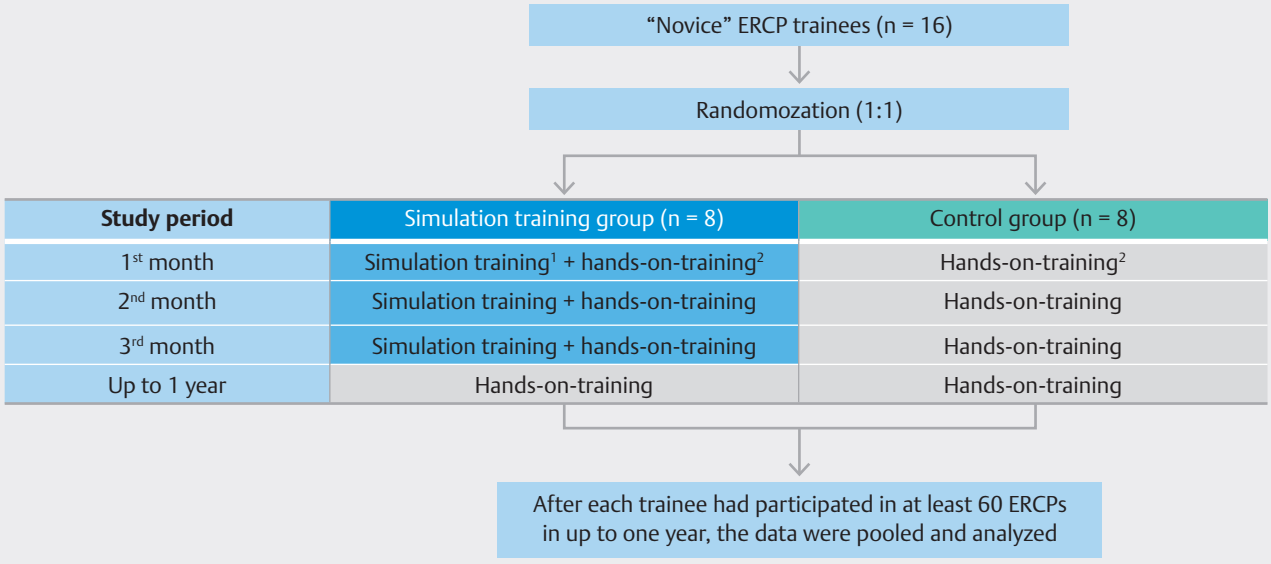
Endoscopic retrograde cholangiopancreatography (ERCP) is among the most challenging endoscopic procedures, requiring a long learning curve to achieve competence [6, 7]. Simulator-based training appears well suited for ERCP, with several models developed [1, 2, 8, 9] and suggested by the European Society of Gastrointestinal Endoscopy (ESGE) guidelines [10]. The Boškoski–Costamagna ERCP Trainer (BCT) [11, 12] offers a mechanical simulator with a simulated patient, featuring portability, varied patient positions, and realistic papillary anatomy. Unlike biological models, the simulator avoids ethical concerns and additional material costs. This simulator has demonstrated good face and construct validity, and has been endorsed by ERCP experts [13]. The next validation step is to assess the simulator's ability to transfer skills to trainees (i. e. its predictive validity) [14].

This study hypothesized that early ERCP simulator-based training with the BCT can enhance clinical performance in novice ERCP trainees. This prospective multicenter randomized controlled trial (RCT) aimed to analyze the impact of ERCP simulation training on the basic skills of novice ERCP trainees by assessing its additional benefit compared with standard training in terms of achieving technical competence.

Methods

Study design and participants

This first prospective multicenter exploratory parallel-arm RCT involved gastroenterology trainees without prior ERCP experience, who had completed basic endoscopy training (at least 300 gastroscopies and meeting the ESGE quality measure for upper GI endoscopy [15]), had participated in fewer than 30 ERCPs (with no hands-on experience), and were prepared to start advanced endoscopy training in recognized high volume ERCP centers. Informed consent was obtained from all participants.



▶ **Fig. 1** Study flowchart for training in endoscopic retrograde cholangiopancreatography (ERCP) with or without use of the Boškoski–Costamagna ERCP Trainer (BCT), according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [16].
[1] Simulation training consisted of a 2-day intensive course held monthly during the first 3 months of training.
[2] During hands-on training, the trainee's performance was systematically evaluated in all ERCPs with any degree of hands-on involvement

The study protocol adhered to the Helsinki Declaration and Good Clinical Practice guidelines. It was approved by the Ethics Committee at the coordinating Institution (N2022/034, Erasme Hôpital, Brussels, Belgium) and at each participating unit, as per local regulations. All patients provided informed consent before ERCP, with data collection compliant with anonymity and General Data Protection Regulations. No intervention to patient care was made, and all patients received the exact same routine care, regardless of the current study.

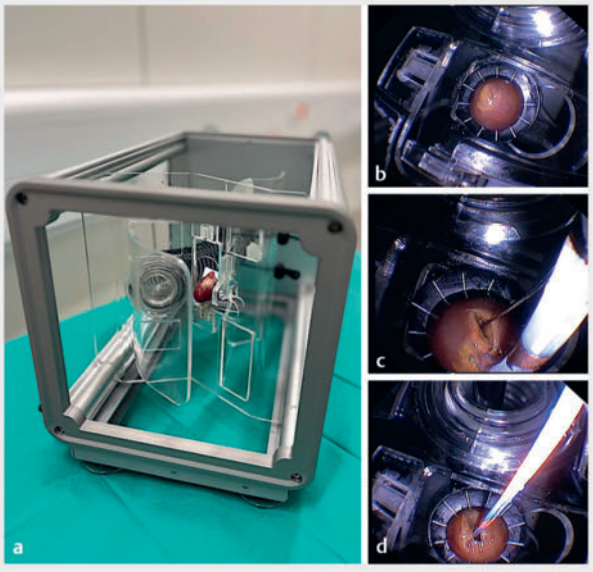
Participants were randomly assigned to the intervention or control groups in a 1:1 ratio, stratified by study site to avoid site-specific bias. Both trial arms had equal numbers of participants, and trainees were equally distributed between the intervention and control groups in centers with two participants.

The study was designed to last a duration of 1 year, involving at least 60 procedures per trainee. Trainee performance was systematically evaluated for each ERCP with any degree of trainee involvement. If a trainee completed 60 ERCPs before the end of the study, further participation was encouraged, but not required. ▶ **Fig. 1** summarizes the study protocol [16].

Training protocol

All participants completed a basic theoretical ERCP course before beginning the study. The course included video presentations covering fundamental aspects of ERCP, such as biliary cannulation, sphincterotomy, stone extraction, and stent placement, ensuring all trainees had the necessary foundation knowledge, regardless of their study group.

Both groups underwent traditional hands-on clinical ERCP training at their respective institutions, supervised by expert endoscopists and following established educational practices. Trainees in the simulator group received additional structured simulator-based training sessions using the BCT ▶ **Fig. 2a**) [11, 12]. The BCT included a recently validated biological papilla



▶ **Fig. 2** Photographs showing: **a** the Boškoski–Costamagna ERCP Trainer with a specific papilla; **b** the biological papilla made out of chicken heart tissue; **c** simulated sphincterotomy being performed; **d** simulated cannulation.

made of chicken heart tissue for sphincterotomy training (▶ **Fig. 2b–d**) [17].

Simulation training occurred over 2 full days, supervised by senior ERCP trainers at Fondazione Policlinico Gemelli, Rome, with monthly sessions in the first 3 months. This structured program gradually covered different ERCP aspects: scope handling, positioning, cannulation, sphincterotomy, stone removal, and stent placement. The training protocol was developed by a team of ERCP experts with extensive experience in ERCP training.

Performance evaluation

Trainee performance was assessed after each procedure using the ERCP TEESAT score [6], which is endorsed by the ESGE [10] and American Society for Gastrointestinal Endoscopy (ASGE) [7]. The ERCP TEESAT questionnaire evaluates basic maneuvers, and technical and cognitive aspects of ERCP with a four-level supervision scoring system. A score of 1 or 2 is defined as success, while a score of 3 or 4 is considered a failure. In the global overall assessment (GOA), a score of 3 or 4 indicates competence, while 1 or 2 indicates noncompetence. This dichotomization into competent/noncompetent and success/failure was defined in the TEESAT score validation study [6].

Successful biliary cannulation was defined as deep guidewire placement into the common bile duct (CBD), with contrast visualization. The cannulation time was measured from the first attempt to successful cannulation, and total procedural time from initial scope insertion to final scope withdrawal. The trainer or nurse monitored the time taken for each step. Adverse events (AEs), defined on the basis of the ESGE guideline [18], were assessed up to 72 hours post-procedure by the trainer.

Study data were collected and managed using REDCap electronic data capture tools, hosted at Erasme Hôpital, Brussels [19, 20]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing: (i) an intuitive interface for validated data capture; (ii) audit trails for tracking data manipulation and export procedures; (iii) automated export procedures for seamless data downloads to common statistical packages; and (iv) procedures for data integration and interoperability with external sources.

Study outcome measures

The primary outcome was the overall trainee competence rate, measured by the GOA in the ERCP TEESAT score. Secondary outcomes included biliary cannulation performance and AE rates.

Statistical analysis

Based on the literature [21], a power analysis for logistic regression was conducted using $\alpha = 0.05$ and a power of 80%, and assuming a 15% difference in GOA between the groups. With an assumed intraclass correlation of 3%, 60 procedures per trainee, and 16 trainees (8 per group) were required.

Trainee characteristics are presented as medians and interquartile ranges (IQRs) for continuous variables, and as counts and percentages for categorical variables.

Primary and secondary analyses

Mixed-effect logistic regression univariate models were used to assess differences in ERCP procedure competence and success between the groups. Each trainee was treated as a random effect to account for the grouping factor.

To assess the learning progress of trainees in each group, learning curves were graphically designed, based on the accumulation of competence and success in each group from procedure 1 to 60. Additionally, the probabilities of observing a positive outcome (e. g. competence in the GOA, or success in biliary cannulation or stent placement) in the control and intervention groups were inferred based on mixed-effect logistic regression models. These predictive probabilities and their 95%CIs were generated for each outcome, focusing on the initial 60 procedures for each trainee.

Supplementary analysis

An analysis of potential confounding factors was conducted as a supplementary analysis, to evaluate their influence on the observed differences in success and failure between the groups (**Appendix 1s**, see online-only Supplementary Material).

Multiple testing was accounted by using the Sidak method and the statistical threshold was set to 0.007.

Results

Baseline trainee characteristics

Sixteen trainees (eight in each group) were included, and their characteristics are detailed in ▶ **Table 1**.

Primary outcome: ERCP overall performance

Of the 1174 registered ERCPs, 1106 were included (562 simulator group; 544 control group); 68 were excluded owing to unassessed GOA (46 for ductal cannulation not achieved, 17 for no trainee participation, and five for major papilla not reached/identified). We recorded a median of 79 procedures per trainee (range 17–106) in the simulator group and 75.5 procedures (range 41–85) in the control group. One trainee from each group did not achieve the 60 ERCP threshold during the 1-year study period.

▶ **Table 2** shows ERCP performance (complete analysis is shown in **Table 1s**, see online-only Supplementary Material). There was no significant difference in GOA between the two groups (odds ratio [OR] 1.47, 95%CI 0.0–692.0; $P = 0.90$). Notably, high heterogeneity was observed for GOA within both the simulator group, with overall competence varying between 13% and 88% (IQR 36.5%, variance 698.2), and the control group (IQR 12.6%, variance 575.7).

Secondary outcomes

Statistical differences were noted between the groups in terms of native biliary cannulation (simulator group 52% vs. control group 42%; $P<0.001$) and faster biliary cannulation in the simulator group (3 [6] vs. 5 [8] minutes; $P<0.001$) (▶ **Table 2**). The simulator group had a longer total procedure time. No difference was found in the grade of difficulty (OR 0.65, 95%CI 0.0–764; $P = 0.90$).

▶ **Table 1** Baseline characteristics of the 16 trainees who were randomly assigned to the simulator and control groups.

Baseline trainee characteristics	Simulator group (n = 8)	Control group (n = 8)	Total
Sex, male, n (%)	5 (63%)	5 (63%)	10 (63%)
Age, median (IQR), years	30.5 (3.5)	32.5 (4.5)	31.5 (4)
Number of nationalities	4	4	4
Number of departments	8	8	10
Medical career stage			
▪ Gastroenterology fellow in training	8 (100%)	7 (88%)	15 (94%)
▪ Gastroenterologist	0	1 (13%)	1 (6.3%)
Gastrointestinal endoscopy experience, median (IQR), years	2 (2)	2 (1.5)	2 (2)
Previous experience in other advanced endoscopy procedures, n (%)	2 (25%)	3 (38%)	5 (31%)

IQR, interquartile range.

Overall AE rates were not significantly different between the groups (OR 1.08, 95%CI 0.0–8325.2; $P = 0.99$).

Effect of simulation training on key outcomes

Based on mixed-effect logistic regression models, probabilities for positive outcomes (e. g. competence in GOA or successful biliary cannulation) were inferred by study group. Mixed-effect models predicted probabilities for the first 60 procedures; however, one simulator group trainee performed only 17 procedures, and one control group trainee performed 41 procedures, which were included as observations in the analyses. The results showed the following probabilities for the simulator group vs. the control group, respectively: competent procedures by GOA rate, 38% (95%CI 17%–59%) vs. 18% (95%CI 6%–39%); successful native biliary cannulations, 46% (95%CI 32%–60%) vs. 37% (95%CI 20%–51%); successful biliary sphincterotomies, 67% (95%CI 42%–82%) vs. 42% (95%CI 20%–67%); successful stone removals, 79% (95%CI 61%–90%) vs. 76% (95%CI 58%–88%); successful stent placements, 69% (95%CI 52%–82%) vs. 58% (95%CI 41%–74%).

▶ **Fig. 3** presents learning curves depicting the progression within the simulator group (red lines) and the control group (blue lines). As shown, simulator group trainees learned faster for native biliary cannulation and sphincterotomy, achieving faster overall ERCP competence.

Supplementary analysis

No confounding factors were identified for any of the main outcomes. Details of this analysis can be found in **Appendix 2s** and **Table 2s**.

Discussion

This RCT is the first multicenter prospective trial to assess the impact of simulator-based training using the BCT on novice ERCP trainees starting their advanced endoscopy training. Results revealed an increase in technical performance based on the TEESAT score, particularly for biliary cannulation in native papilla cases (52% competence vs. 42%). Furthermore, simulator group trainees demonstrated faster acquisition of key technical skills such as biliary cannulation and sphincterotomy, as shown by learning curves, although cumulative differences between the groups did not attain statistical significance. These findings highlight the potential of simulator-based training to fast-track ERCP learning, a critical consideration given the procedure's inherent complexity [6, 7].

The primary outcome measure was the GOA of trainee competence as assessed by the TEESAT score. The simulator group had a higher percentage of competent procedures (49% vs. 33%), although the difference was not statistically significant. This lack of significance may be attributed, in part, to the subjective nature of GOA. The BCT enables learning of all of the steps of an ERCP procedure, and the GOA was chosen for its comprehensive evaluation of trainees' performance and robust validity evidence [22]. Nevertheless, we acknowledge the inherent subjectivity of a GOA, which could only be mitigated if a single trainer assessed all of the trainees in all of the ERCPs, which is impractical. The lack of statistical difference might be also attributed to the substantial heterogeneity in the hierarchical structure of the study. In this approach, groups were assessed based on procedure outcomes, yet each group comprised a diverse set of trainees with heterogeneous performances, posing a challenge when drawing robust conclusions from statistical assessments. This result suggests that our model was not able to estimate the true effect on the GOA, likely owing to heterogeneity, the small sample size. The wide confidence interval does not indicate the absence of a difference, but rather highlights the limitations of the dataset.

The success rate of biliary cannulation, a secondary outcome, revealed a statistically significant difference favoring simulation training, particularly in cases with a native papilla. Differences solely in native papilla cases may be attributed to the inherent simplicity of non-native papilla cases. Combining both dilutes the impact of simulation training, as non-native papilla cases were more numerous and easier to cannulate. Native biliary cannulation, a relatively objective parameter (even consid-

▶ **Table 2** Comparison of endoscopic retrograde cholangiopancreatography (ERCP) outcomes between the two groups.

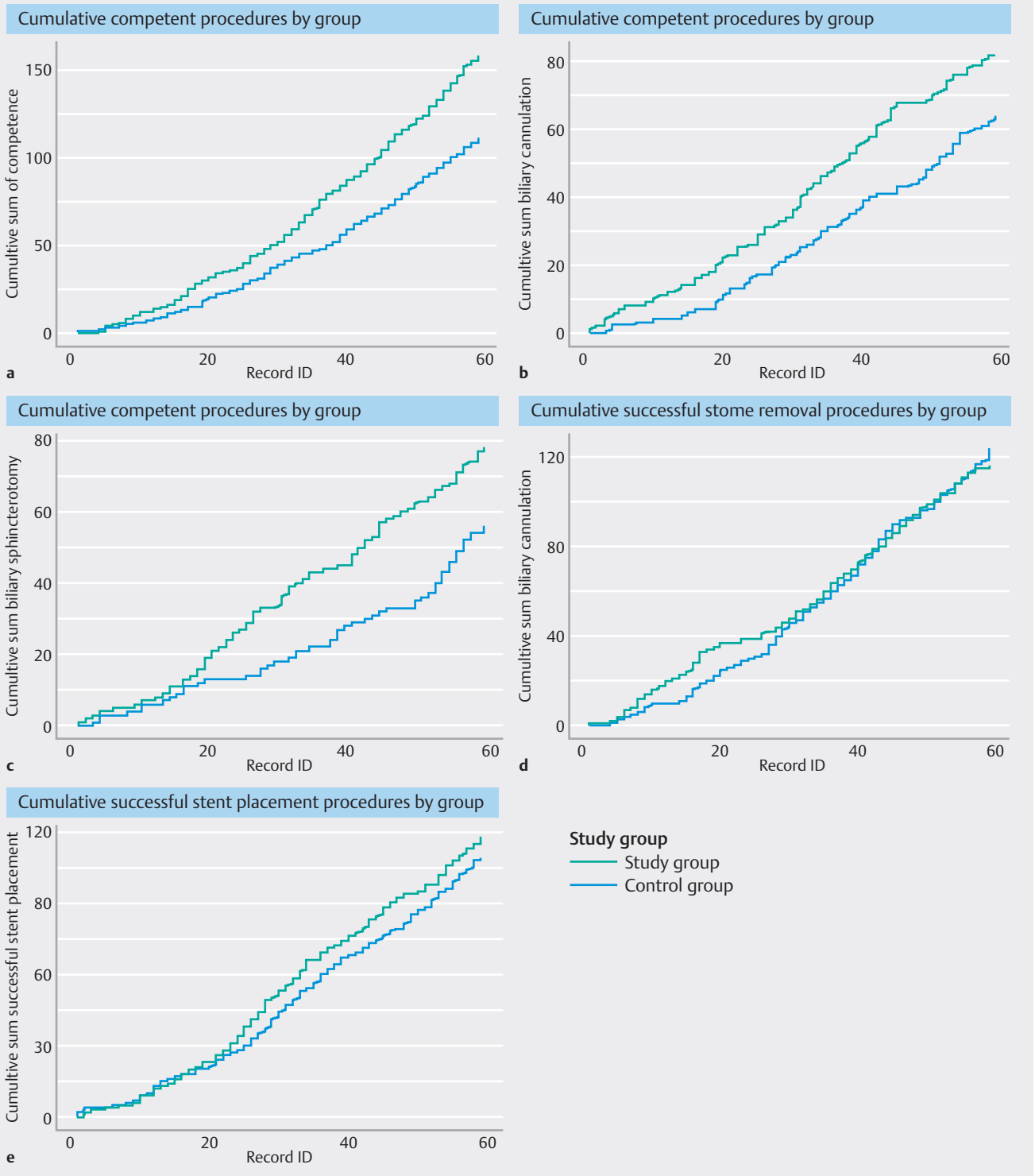
ERCP outcomes	Simulator group (n = 562)	Control group (n = 544)	Total (n = 1106)	OR (95%CI)	*P* value
Global overall assessment (GOA), n (%)				1.47 (0–692)	0.90
▪ Competent (TEESAT score 3–4)	274 (49%)	173 (32%)	447 (40%)		
▪ Noncompetent (TEESAT score 1–2)	288 (51%)	371 (68%)	659 (60%)		
Biliary cannulation achieved, n (%)				1.11 (0–334)	0.97
▪ Success[1]	358 (71%)	327 (65%)	685 (68%)		
▪ Failure[2]	149 (29%)	176 (35%)	325 (32%)		
Native biliary cannulation achieved, n (%)				1.05 (1.0–1.1)	**<0.001**
▪ Success[1]	115 (52%)	96 (42%)	211 (47%)		
▪ Failure[2]	105 (48%)	132 (58%)	237 (53%)		
Time for overall biliary cannulation, median (IQR), minutes	3 (6.0)	5 (8.0)	4.0 (6.0)	0.99 (0.98–0.99)	**<0.001**
Time for native biliary cannulation, median (IQR), minutes	6.0 (7.0)	8.0 (6.3)	7.0 (7.0)	0.99 (0.98–1.00)	0.20
Biliary sphincterotomy, n (%)				1.63 (0–803)	0.88
▪ Success[1]	111 (66%)	91 (60%)	202 (62%)		
▪ Failure[2]	54 (26%)	65 (33%)	119 (37%)		
Stone removal, n (%)				1.00 (0–425)	>0.99
▪ Success[1]	178 (86%)	158 (81%)	336 (84%)		
▪ Failure[2]	29 (14%)	37 (19%)	66 (16%)		
Stent placement, n (%)				NV	0.99
▪ Success[1]	172 (70%)	157 (69%)	329 (69%)		
▪ Failure[2]	73 (30%)	72 (31%)	145 (31%)		
Overall adverse events, n (%)				1.08 (0–8325)	0.99
▪ No	501 (89%)	491 (90%)	992 (90%)		
▪ Yes	61 (11%)	53 (9.7%)	114 (10%)		
Total procedure time, median (IQR), minutes	30 (23)	28 (28)	30.0 (27)	1.01 (1.01–1.02)	**<0.001**

GOA, global overall assessment; IQR, interquartile range; NV, not valid, model failed to converge; OR, odds ratio.
[1] According to TEESAT (score 1–2).
[2] According to TEESAT (score 3–4).

ering occasional trainer input) compared with the GOA, was extensively practiced during simulation training courses. It stands out as a critical step in ERCP, a performance measure recognized by the ESGE [23]. Arguably the most challenging step in ERCP, native biliary cannulation is considered a key metric for assessing ERCP competence in the current literature [24].

The time required to complete each step of the procedure serves as a performance indicator. The overall biliary cannulation time was lower in the simulator group, indicating a small but positive impact of simulation training on technical skills. The lack of statistical significance in native papilla cannulation may be attributed to the smaller sample size, in comparison with the overall number of biliary cases.

AE rates did not differ significantly between the groups, consistent with other simulator-based training studies and large cohort studies of real-life training [25, 26]. This is expected because novice endoscopists were constantly supervised by experienced ERCP performers. The apprenticeship model has proven, for the most part at least, to be safe and reliable [27], and so no differences were anticipated. Furthermore, to avoid the "training center" being a potential confounding factor, trainees were paired by study site and, for all departments with two trainees, they were allocated to opposite study groups. The similarity in AE rates between the groups highlights the fact that training settings provided an equally high standard of practice for all trainees, although the study was not specifically powered to detect potential differences in AEs.



▶ **Fig. 3** Learning curves for: **a** global overall assessment; **b** successful common bile duct cannulation of a native papilla; **c** biliary sphincterotomy; **d** stone removal; **e** stent placement.
Green line, simulator group; blue line, control group.

A small, but statistically significant, longer total procedure time was observed in the simulator group compared with the control group. This may be because trainers were more inclined to allow additional time for competent trainees to complete the procedure before intervening, indicating an increased "perception of competence."

Analysis of the plotted learning curves, further supported by predicted probabilities in the first 60 procedures using mixed-

effect models, showed that trainees receiving simulator-based training accumulated successful procedures at a higher rate in terms of GOA, native biliary canulation, and biliary sphincterotomy compared with the control group trainees. This further reinforces the positive effect of ERCP simulator-based training, similarly to studies that have evaluated the ERCP Mechanical Simulator [21, 25]. The difference in terms of learning biliary sphincterotomy can be attributed to the recent BCT modification with a biological papilla, providing a more realistic training experience [17]. This holds particular significance, given that sphincterotomy is a high risk ERCP component associated with AEs, like perforation, pancreatitis, and bleeding [18]. Differences in the learning curves for stent placement and stone removal were minor or negligible after a certain number of procedures, suggesting a limited additional benefit of simulation training for these steps beyond a particular point.

The study's limitations should be acknowledged. First, despite all efforts, two trainees (one per group) were unable to complete the target of 60 procedures. The lack of statistical significance in GOA differences may be attributed to data heterogeneity and insufficient sample size to drive robust conclusions. High performing trainees in either group may have disproportionately influenced the overall results. Future research should focus on personalized training programs, targeting specific trainee weaknesses. Differences in the rates at which procedures were performed across various training centers, potentially impacting distinct opportunities, and learning paces, along with diverse evaluators and the subjective nature of GOA measurement, might have contributed to statistical heterogeneity. This variability underscores the challenges in detecting statistically significant differences with a small sample size, suggesting that a more homogeneous study group could have yielded different results. From a statistical perspective, this limitation could have been mitigated by increasing the number of trainees in each group; however, in practice, achieving this is challenging owing to the logistical constraints of organizing simulation courses. To minimize this limitation, we employed a mixed-effects logistics regression model, which is more robust than straightforward statistical analyses.

Second, it was also not possible to perform formal comparisons between specific AEs because of statistical restrictions related to multiple comparisons, which limit the number of comparisons performed to avoid increasing the risk of type I errors. Another limitation is that, while an ideal scenario would involve a blinded study for trainer evaluations, this was not feasible owing to the protocol of the simulation-training courses and the involvement of multiple training centers and trainers. To overcome this limitation, we used a validated competence tool, which was fully explained and discussed with the trainers prior to the start of the study to standardize the evaluation of the trainees' performance. This TEESAT score, despite having GOA as a potentially subjective parameter, includes a long list of measures that are objective and independent of the trainers' opinion or potential preferences for the trainees in the study group (e. g. rate of successful of biliary cannulation or time for biliary cannulation).

Additionally, it would be helpful to investigate the long-term effects of simulator-based training, determining whether the initial competence gain translates into sustained clinical proficiency and improved patient outcomes over extended periods of time, even beyond the formative period.

Nevertheless, and as previously noted [24, 28], trainees often face difficulties in meeting the procedure volume requirements during ERCP training. In our study, 12.5% of trainees did not achieve 60 ERCPs within 1 year, requiring an amendment to the initial study timeline and protocol to ensure that the study objectives remained achievable. The low trainee exposure to hands-on training observed in our study reinforces the need for simulator-based training. The last limitation concerns the optimal methodology of simulation training, which remains undetermined, presenting an avenue for future research.

Few studies have validated simulation training for ERCP [29], with research focusing on the ERCP Mechanical Simulator [21, 25, 30]. These studies demonstrate improvements in cannulation rates [21, 25, 30], reduced cannulation times [21, 25], and enhanced overall performance [25, 30] in the intervention group. Our study is the largest validation study of an ERCP simulator to date, with significant implications for gastroenterology training. Integration of simulator-based training in ERCP could reduce the time required for trainees to become competent, enhancing patient safety and optimizing training resources.

In conclusion, this exploratory multicenter RCT suggests that simulator-based training can be a valuable addition to traditional hands-on clinical training for ERCP. Although it was not shown to significantly improve global overall competence, possibly owing to data heterogeneity, simulation training accelerated the acquisition of critical skills and improved technical trainee competence, without affecting AE rates. Specifically, it enhanced the performance of biliary cannulation, particularly in native papilla cases, reduced biliary cannulation time, and accelerated the learning curve for overall competence, biliary cannulation, and biliary sphincterotomy.

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Conflict of Interest

I. Boskoski received a research grant from ERBE Elektromedizin and consultancy fees from Boston Scientific, Cook Medical, Pentax Medical, Siemens, Endotools, Nitinotes, and lecture fees from Microtech; he holds patents USA No. US D740,361 S (Endoscopy Training Apparatus) Oct. 6, 2015 and No. 0001426680, Class A61B1814 (Stent for

electrothermal treatment) Feb. 7, 2017, and has stock options from Myka Labs. T. Voiosu has received fees for lectures from Boston Scientific and an educational event from Cook Medical. G. Costamagna has received consultancy fees from Olympus, Waldner Group, and Alfa-Sigma, as well as speaker's and writer's fees from Malesci. J. Devière's received institutional support for IRB-approved studies and consultancy fees to his institution from Olympus and Cook Medical, as well as stocks from Endotools Therapeutics. M. Arvanitakis's has received consultancy fees from Olympus and honoraria from Pentax to her institution. J. van Hooft has received lecture fees from Cook Medical, Boston Scientific, Falk, and Fujifilm, and a consultancy fee from Olympus. G. Vanbiervliet has received lecture fees from Norgine, Tillots, Ambu, Fujifilm, and Pentax, and a consultancy fee from Boston Scientific. P. Fockens has provided consultancy for Cook Endoscopy and Olympus. R.P. Voermans received a research grant form Boston Scientific and Prion Medical, and his institution received consultancy fees from Boston Scientific and Cook Medical. J.-M. Gonzalez has received consultancy fees from Fujifilm and Boston Scientific. J.W. Poley has provided consultancy for MediGlobe GmbH, and Pentax Medical. M. Bruno has received consultancy fees from Boston Scientific, Cook Medical, Pentax, and AMBU, support for industry- and investigator-initiated studies from Boston Scientific and Cook Medical, and support for investigator-initiated studies from Pentax Medical, Mylan, AMBU, and ChiRoStim. P.J.F. de Jonge has received consultancy and lecture fees from Boston Scientific, Cook Medical, and Fujifilm. S.T. de Campos, M. Salmon, A. Langers, C. Gomercic, A. Lemmers, M. Barthet, W. Laleman, I. Tarantino, R. de Ridder, and JM Conchillo declare that they have no conflict of interests.

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Clinical Trial

ClinicalTrials.gov | Registration number (trial ID): NCT05533944 | Type of study: prospective, multicenter, randomized trial

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