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Research Article

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Validation of a Hybrid *Ex Vivo* Integral Colon Simulator in Basic and Advanced Endoscopic Procedures

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Abstract

Introduction: *Traditionally, training in gastrointestinal endoscopy has been performed directly on the patient under expert supervision, but this practice is not free of errors and risks to the patient. With the growing development of ever more complex therapeutic endoscopic techniques, an ex vivo hybrid integral colon simulator for the teaching of basic and advanced endoscopic procedures was a necessity. It would allow for the necessary repetitions required to overcome the learning curve, with the advantages of accessibility, low cost, reproducibility and with which the use of real accessories was feasible on human-like tissues and therefore, obtain effective training and the development of endoscopic techniques with no risk to the patient.*

Aim: *To validate the ex vivo hybrid integral colon simulator in basic and advanced procedures by experts in colonoscopy.*

Material and Methods: *We developed a questionnaire as a measuring instrument to determine the simulator´s realism. Twenty-nine (29) expert endoscopists were selected and each was exposed to the simulator and performs a colonoscopy and different therapeutic procedures. The questionnaire was then applied.*

Statistics: *The sum of skill mastery and the overall mastery was calculated, defining "close to reality" as at least, a 90% of responses in its favor. To identify the specialty effect and the level of experience (total colonoscopies) in terms of realism and the simulator´s usefulness, we used the Chi2 test and logistic regression models, considering a $p<0.05$ statistically significant.*

Results: *Twenty-nine (29) experts evaluated the simulator: 15 were gastroenterologists, 14 were surgeons, with an average of 2683 total colonoscopies. From a maximum overall score of 79 (100%), 9 experts (31%) gave it 79 points (100%), and 13 experts (44%) attributed it a score of 78 points (98%). In terms of the identification of anatomical structures and the simulator´s morphological characteristics, 96.6% considered them to be close to reality. As to the mastery of basic maneuvers and the evaluation of advanced procedures, 100% of the experts considered the simulator useful in terms of reproduction and close to reality. The categorization of realism, usefulness of the simulator by specialty and the number of total colonoscopies were analyzed and no difference was detected.*

Discussion: *Although in the overall score 100% of the experts considered the simulator experience to be close to reality and useful (cutoff point of at least 90%), the following items had greater variability: identification of the ileocecal valve and the hepatic flexure, and the mucosal appearance. We concluded that the simulator is not dependent on the physician´s level of experience nor on the specialty.*

Conclusion: *The simulator is realistic and useful when reproducing basic and advanced procedures, using real equipment and accessories. It is therefore a valuable tool when training in different therapeutic procedures that are a technical challenge and are associated with a broad range of complications if not successfully performed. It offers the possibility of repeating the required procedure to further develop or improve the student´s psychomotor abilities with no risk to the patient.*

Introduction

Traditionally, training in gastrointestinal endoscopy has been performed directly on the patient, under expert supervision; however, this practice is not free of errors and risks to the patient. Endoscopists with less experience have a greater risk of complications than those with greater experience [1,2]. Training in endoscopy ideally requires supervised practical experience to master procedures safely, but this is a difficult endeavor [3-5].

The American Society of Gastrointestinal Endoscopy (ASGE) refers that practicing therapeutic procedures on endoscopic simulators with no risk to the patient, has advantages and the European Society of Gastrointestinal Endoscopy (ESGE) recommends that if simulators are available, they should be used in endoscopy training [6,7].

With the growing development of endoscopic therapeutic techniques that have progressively increased in complexity, the need arose to develop an *ex vivo* hybrid integral colon simulator for the practice of basic and advanced endoscopic procedures (Figure 1 and 2), and that would permit the necessary number of repetitions to overcome the learning curve; it would be advantageous due to its low cost, its availability, the possibility of using real accessories on human-like tissues and thus, obtain effective training and develop abilities without risk to the patient.

Figure 1: Superior View of the *Ex Vivo* Hybrid Colon Simulator

Figure 2: Fiberglass Simulator. In its Interior, Flexible Polymer with Echotransmitting Gel

The colon simulator was designed to teach the main basic procedures, identify different anatomical structures (Figure 3 and 4) during colonoscopy, loop reduction, cutting maneuvers, rectal retrovision (Figure 5), polyp identification (Figure 6), and biopsy procedures. Other therapeutic techniques include polypectomy with a hot snare (Figure 7), injection, clip placement, stent placement (Figure 8) and the use of argon plasma (Figure 9).

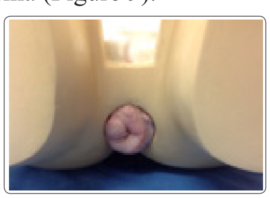

Figure 3: Pelvic View of the Anus in the Simulator

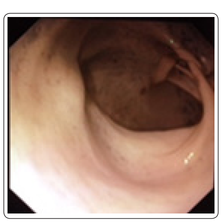

Figure 4: Cecum and Ileocecal Valve

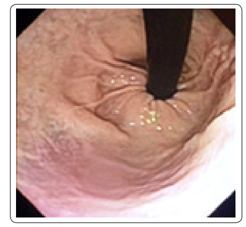

Figure 5: Rectal Retrovision

Figure 6: Fabricated Colonic Polyps

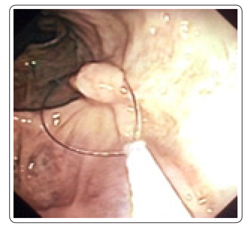

Figure 7: Snare Polypectomy

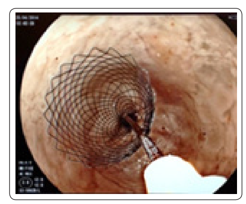

Figure 8: Release of Self-Expanding Metal Stent in the Colon

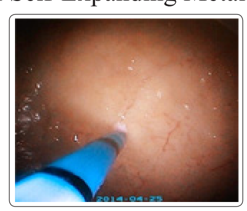

Figure 9: Mucosal Changes Secondary to Argon Plasma

Aim
To validate the *ex vivo* hybrid integral colon simulator in basic and advanced procedures, by experts in colonoscopy.

Material and Methods
Since no scale is available, we developed a questionnaire as a measuring instrument, based on the one published by Hill A, et al., in order to determine how realistic the colon simulator was in terms of the most relevant features of basic colonoscopy and in advanced therapeutic procedures applied in humans [8]. We evaluated the appearance, content and criterion validity by reviewing the questionnaire as a validation tool, by 8 experienced experts in the area of application; they approved the usefulness of the scale by identifying an acceptable degree of understanding of each item, the lack of ambiguity of the items and the answer choices, as well

as the instrument´s factibility and practicality.

The 33 items in the questionnaire were grouped to evaluate 4 skill mastery domains (Addendum 1):

1. Identification of anatomical structures in the simulator (anus, rectum, sigmoid, descending colon, splenic flexure, transverse colon, hepatic flexure, ascending colon, cecum and ileocecal valve).
2. Morphologic characteristics of the simulator (length of the colon, rectal examination, visualization of the mucosal circumference, aspect of the mucosa).
3. Basic maneuvers in colonoscopy (loop formation, loop reduction, reproduction of the cutting maneuver, tissue resistance, insufflation, aspiration, polyp identification, biopsy technique).
4. Advanced procedures (injection, hot snare polypectomy, visualization of the remnant, tattooing, clip placement, obtaining specimens, stenosis identification, placement of self-expanding metallic stents, mobilization/ retrieval of stents and the use of argon plasma).

We selected 29 expert endoscopists that were exposed to the simulator to perform a colonoscopy and different therapeutic procedures; all sessions were supervised by an investigator and at the end, the questionnaire was applied.

Statistics

The overall and the sum of each mastered skill were calculated; "close to reality" was established if at least 90% of responses were favorable.

The maximum and minimum overall possible scores were 79 and 23, respectively. Those for each mastered skill were: 1 (10-0), 2 (12-4), 3 (27-9) and 4 (30-10).

To identify the effect of specialization and level of experience (total number of colonoscopies) in terms of realism and usefulness of the simulator, we used the Chi2 test and logistic regression models; a p value < 0.05 was considered statistically significant.

Results

Twenty-nine (29) experts evaluated the simulator; 15 were gastroenterologists and 14 were surgeons with an average total number of performed colonoscopies of 2683 according to their accumulated experience.

Overall, with a maximum score of 79, 9 experts (31%) assigned a score of 79 points, 13 experts (44%) assigned 78 points, 4 experts assigned 77 points, 2 assigned 76 points and one assigned 75 points.

In terms of anatomical structure identification, 96.6% considered that the representation of the different colonic segments in the simulator was close to reality (Table 1). One hundred percent (100%) identified the anus, rectum, sigmoid, descending and ascending colon. 96% identified the transverse colon and cecum, and 93% identified the splenic flexure. 89.7% were able to identify the hepatic flexure and 86%, the ileocecal valve (Table 2).

Table 1

Skills	Valid n (%)	Not Valid n (%)
Identification of anatomical structures	28 (96.6%)	(3.4%)
	28 (96.6%)	(3.4%)
Basic maneuvers	29 (100%)	0
Advanced procedures	29 (100%)	0

Table 2

1. Identification of Anatomical Structures	
Item	**%**
Anus	29 (100%)
Rectum	29 (100%)
Sigmoid	29 (100%)
Descending colon	29 (100%)
Splenic flexure	27 (93%)
Transverse colon	28 (96.6%)
Hepatic flexure	26 (89%)
Ascending colon	29 (100%)
Cecum	28 (96.6%)
Ileocecal valve	25 (86.2%)

As to the simulator´s morphological characteristics, 96.6% of experts considered them to be close to reality (Table 1). One hundred percent (100%) referred that the colon´s length was adequate, that the consistency of the anal sphincter was appropriate and that the complete colonic circumference could be observed during the colonoscopy. Seventy-nine percent (79%) of the experts believed that the mucosal appearance was very much like the human, one expert (3.4%) considered that the aspect of the mucosa was not very similar to the human's and 5 experts (17%) attributed an intermediate score to the simulator.

In terms of mastering basic maneuvers, 100% of experts evaluated the simulator as useful for the reproduction of procedures and close to reality (Table 3, 4 and 5). All experts agreed on its usefulness in performing rectal retrovision with similar movements to those used in humans; they could reproduce the handle with paradoxical movements, tissue resistance during the colonoscopy was adequate, the loop could be reduced with realistic movements, the cutting maneuver could be performed, and insufflation and aspiration were possible with an adequate mucosal response. Ninety-six percent (96.6%) considered that polyps could be identified and that their appearance was comparable to the human´s. One expert (3.4%) believed that polyps could indeed be identified but that their appearance was not comparable to the human´s. Ninety-six percent (96.6%) referred that the mucosa could be clamped and biopsies could be obtained. One expert (3.4%) referred that the tissue can indeed be clamped with a real accessory, but that biopsies could not be obtained.

Table 3

2. Morphologic Characteristics of the Simulator		
Item	**Point**	**n %**
Colon length	3	29 (100%)
Rectal examination	3	29 (100%)
Visualization of the mucosal circumference	3	29 (100%)
Mucosal appearance	3	23 (79.3%)
	2	5 (17.2%)
	1	1 (3.4%)

Table 4

3. Basic Maneuvers During Colonoscopy		
Item	**Points**	**n %**
Rectal retrovision	3	29 (100%)
Loop formation	3	29 (100%)
Loop reduction	3	29 (100%)
Cutting maneuver	3	29 (100%)
Tissue resistance	3	29 (100%)
Insufflation	3	29 (100%)
Aspiration	3	29 (100%)
Polyp identification	3	28 (96.6%)
	2	1 (3.4%)
Biopsy	3	28 (96.6%)
	2	1 (3.4%)

Table 5

4. Advanced Procedures		
Item	**Points**	**n %**
Snare polypectomy		
Injection	3	27 (93.2%)
	2	2 (6.8%)
Use of hot snare	3	29 (100%)
Visualization of remnant	3	29 (100%)
Tattooing	3	27 (93.2%)
		2 (6.8%)
Clip placement	3	29 (100%)
Specimen retrieval	3	29 (100%)
SEMS placement	3	29 (100%)
Use of real accessories	3	29 (100%)
Technique	3	29 (100%)
Mobilization and retrieval	3	29 (100%)
Use of argon plasma	3	29 (100%)

When evaluating advanced procedures, 100% of participants considered that the simulator was useful and close to reality. When performing a hot snare polypectomy, 93.2% agreed that during injection and tattooing, the mucosa is of adequate consistency, the needle could be inserted and elevate appropriately. Six percent (6.8%) considered that the needle could be inserted but the mucosa was not elevated, 100% agreed that the polyp could be treated with laser and perform a polypectomy with a real accessory; the polypectomy remnant could be identified and was similar to those observed in humans. Clips could be adequately placed and the mucosal closure could be observed, specimens could also be retrieved using real accessories. When placing enteral self-expanding metal stents, 100% agreed that stenosis could be simulated, the simulator allowed the use of real accessories to place stents following the same steps used in the technique in humans, it self-expanded adequately and once placed, and it was useful in the retrieval or mobilization of the stent with a loop and clamp. The simulator was exposed to argon plasma and all of the experts agreed that the use of argon plasma to observe mucosal changes was feasible.

The categorization of the realism determination and the simulator´s usefulness in terms of the number of total colonoscopies performed by the physicians exposed to the simulator, were analyzed and no differences were detected.

Discussion

In the overall scores, 100% of the experts considered that the simulator was close to reality and useful, based on a cutoff point of at least 90% responses in favor of the total number of items; however, the following items displayed greater variability.

In structure identification, although 96.6% of participants considered it close to reality, the ileocecal valve was the most difficult to identify, followed by the hepatic flexure. In the evaluation of morphologic characteristics, we observed that in terms of the mucosal appearance, 79% of the experts considered that it was very similar in appearance to that in humans, 5 experts (17%) gave it an intermediate score and only one expert considered that it was not human-like. One expert (3.4%) believed that the aspect of the polyps was not comparable to humans and that although the mucosa could be clamped with real accessory, biopsies could not be obtained and the needle did not become elevated during injection. The remaining items received a maximum score.

We analyzed whether categorization of the different items had any relation with the specialty and the past number of colonoscopies performed by the participants, and we concluded that the simulator was not dependent on experience nor on the specialty.

In accordance with the results obtained, we believe that the simulator mimics circumstances close to reality and it is useful to reproduce and repeat basic and advanced procedures, using real accessories. It is therefore a valuable tool that fosters training in different therapeutic procedures that are technically a challenge and that are associated with a broad list of complications, if unsuccessful. It offers the possibility of repeating the procedures as necessary to further develop and improve psychomotor abilities with no risk to the patient. It presents clear advantages over virtual simulators in terms of cost, likeness of the tissues, the use of real accessories and the possibility to perform therapeutic procedures.

Conclusion

In accordance with the obtained results, we concluded that the *ex vivo* hybrid integral colon simulator is close to reality and is useful in the reproduction of basic and advanced procedures. It is a tool that facilitates the development of abilities in all stages of aerospatial location, psychomotor coordination, it also allows the evaluation of risks and complications during the procedures with real accessories and real equipment without exposing patients to the risk inherent to specialist training in advanced colonoscopy techniques [9].

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