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A Simulation Study to Investigate the Usefulness of a Novel Stricture Tool for Training Wire Guided Balloon Dilation

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Abstract

Background and Aims The training in esophageal stricture dilation is difficult to obtain and have few simulation models. The aim of the study was to evaluate a novel stricture simulation for training a wire-guided, controlled radial expansile (CRE) balloon dilation.

Methods The study was a pretest–posttest design without a control group involving a novel simulation device for esophageal stricture. The training session involved 12 final year gastroenterology fellows from five different centers. The trainees received 2 hours of education sessions featuring didactic content, a live demonstration of step-by-step demonstration of wire-guided CRE balloon dilation and a study material on the procedure. The simulation device used was a single-use hose pipe along with a red color nonhardening modeling clay with a 5.0-to-8.0-mm hole in the center.

Results All the trainees and instructor uniformly rated the model as excellent or good with simulation device being mild stiffer in haptics than of the real tissue. The mean (%) pretest scores of 39 (21.6%) improved significantly to 160 (88.8%) in mean (%) posttest questionnaire ($p < 0.05$). There was a significant improvement in the questionnaire of the dilation procedure after the simulation training episode.

Conclusion The novel stricture simulation model had good performance evaluation and can be used to train CRE balloon dilation procedure.

Keywords
- CRE
- dilation
- simulation
- stricture

Introduction

Simulation environment allows the trainee to practice repetitive procedural steps in a nonpatient risk-free environment. In endoscopic training, simulators include virtual reality computer simulators, ex vivo in vivo animal tissue models, and mechanical simulators.[1]

Background and Aims

Mastering endoluminal procedures requires a high level of hand–eye coordination through hands-on experience. The endoscopic training system includes standard trainee/mentor learning programs. In this context, the novice progressively learns a procedure by first assisting the expert clinician

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and later by practicing on the patient.[2] The way to reach independent practice and expertise in gastrointestinal endoscopy is mastered through continuous training, set in a framework that ideally includes progress monitoring, focused feedback, motivation enhancement, and instructional planning.[3] Training in endoscopic skills is more important due to reduced endoscopic numbers and demand to cope with many novel coronavirus disease 2019 (COVID-19) pandemic patients.[2]

Esophageal stricture leads to severe dysphagia, malnutrition, and cachexia. The primary aim of dilation is to alleviate symptoms, permit adequate oral nutrition, and reduce pulmonary aspiration.[4] Esophageal dilation is simple, safe, and economic option for treatment of symptomatic benign and malignant strictures of esophagus.[5] Esophageal dilation is associated with overall perforation rate of 2.8% (2% in benign strictures and 4.3% in malignant strictures) with 0.7% of mortality.[6,7]

But there are only a few reports in literature of simulation for esophageal stricture dilation. A tourniquet inflated around the outside of the esophagus on a mechanical model (OGI Phantom AC4, Adam, Rouilly Ltd., Sittingbourne, Kent, United Kingdom) or use of paper cylinder, and foam filler did not produce a realistic simulation due to poor deformability of the stricture.[7] The use of stricture simulation for practicing controlled radial expansion (CRE) balloon can improve the technical skills of the trainee without harm to the patient.

The aim of the study was to evaluate a novel stricture simulation for training wire-guided CRE balloon dilation.

Methods

Objectives and Design

The study was a pretest–posttest design without a control group involving a novel simulation device for esophageal stricture balloon dilation. Primary measurements were obtained at baseline (pretest) and after the hands on intervention (posttest).

Study Participants

Study participants included 12 final year gastroenterology fellows from five different centers across Bangalore. The intervention was an intensive hands- on exercise held in Mathikere Sampangi Ramaiah Medical College and Hospitals, Bangalore. The study was approved by institutional ethical review board. All the participants had two vaccinations of ChAdOx1 nCoV-19 Recombinant Corona Virus Vaccine, Covishield, and provided informed consent before the baseline assessment.

Study Procedure

All the trainees were kept as an intact group during the study. In first phase, the trainees had a pretest for baseline knowledge and procedural skill. The trainees received 2 hours of education sessions featuring didactic content, a live demonstration of step-by-step procedure of wire-guided CRE balloon dilation and a study material on the procedure.

The didactic content was of patient selection, indication and contraindications, knowledge of CRE balloon and alliance gun, stricture identification and interpretation of results of the procedure, and management of early and delayed complications of the procedure.

Simulation Device Characteristics

The characters of the simulation device should be cheap, reusable, have realistic haptic feedback and should not have animal tissue. The device should have a lumen big enough only for passage of guidewire and balloon dilator but not the endoscope. On balloon inflation, it should dilate and maintain the lumen for passage of endoscope.

The simulation device used was a hose pipe of 35 cm in length and 25 mm in diameter. A red- and orange-colored nonhardening modeling clay (Koolclay; Kores [India] Limited; Mahim [W]; Mumbai) was packed for 40 mm at one end of the pipe. A hole was made with a blunt tube of either 5 or 8 mm in diameter after the insertion of clay. The 5.0-to-8.0-mm hole created in the center of the clay was the stricture simulation for dilation. The video gastroscope (Olympus GIF-Q150) with slim 9.2-mm diameter and working channel diameter of 2.8 mm connected with CV-170 video processor was used for the study. Two wire-guided CRE balloons were used in the study (11–13 mm Olympus America INC, PA & 12–15 mm Microvasive, Boston Scientific Co., Natick, Massachusetts, United States). The Alliance II integrated inflation single-use syringe/Gauge assembly device (Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland) was used for balloon inflation.

Teaching and Testing Sessions

Four trainees with a faculty instructor were present for each dilation session and the remaining fellows have to verify the checklist (►**Supplementary Appendix S1**; available in the online version). The trainees were expected to pass the lubricated endoscope through the pipe to the proximal end of the clay. They have to assess the stricture during endoscopy, choose the correct size of balloon, and assemble the balloon with water-filled alliance gun. After the initial passage of wire, balloon position should be maintained during inflation to create a lumen of 10 to 12 mm allowing the passage of endoscope. The proximal and distal ends of the stricture were measured for reporting. The procedure steps as performed by the trainees are depicted in ►**Figs. 1–3**. The situational awareness, team work, problem solving, and management plan were discussed with other fellow trainees.

During each training session, two trainees have to mention the steps of dilation correctly and support the pipe. Two other trainees have to coordinate and show the steps of balloon dilation with one performing the endoscopic end and other acting as an endoscopy assistant. They were then asked to complete a short questionnaire regarding the performance of the simulator (►**Supplementary Appendix S2**; available in the online version). The questions were scored on a 5-point Likert's scale regarding visual appearance, haptic feedback, usefulness in training, an overall opinion, and a section for free-text comments.

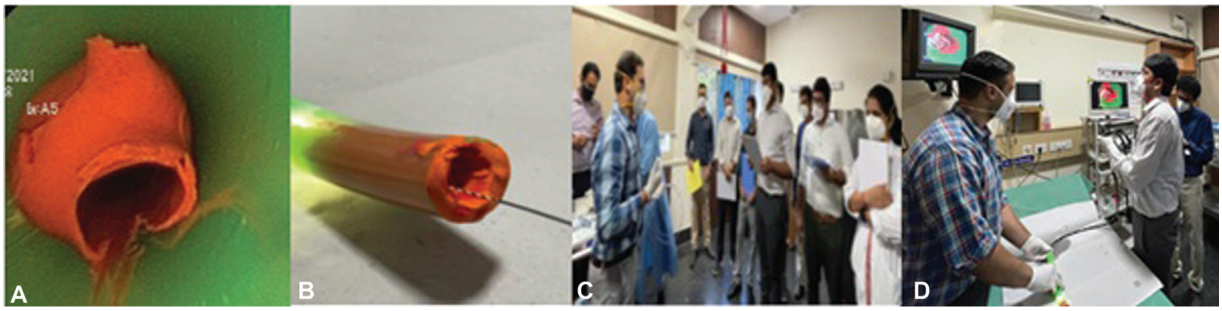

Fig. 1 (**A**) Endoscopic image of proximal end of the clay with the hole. (**B**) The wire is passed across the clay under endoscopic vision. (**C**, **D**) Students explaining and demonstrating the procedural steps and working as a team.

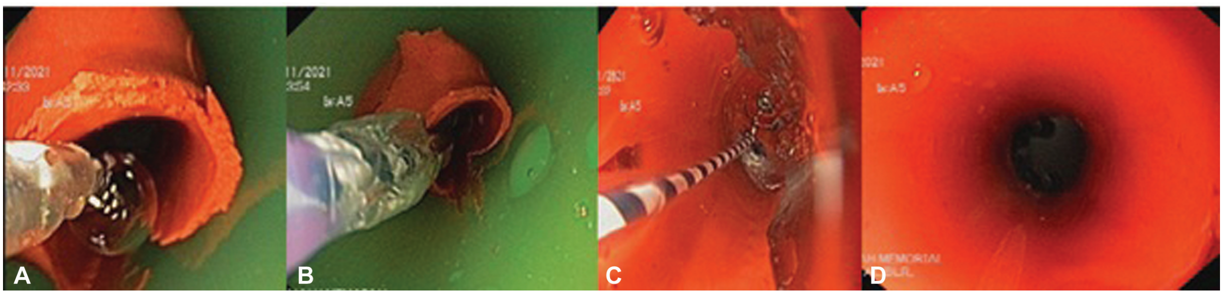

Fig. 2 (**A**) Endoscopic image of proximal end of the clay with passage of balloon over the guidewire positioned in the hole. (**B**) The wire guided balloon is positioned across the clay under endoscopic vision. (**C**) On inflation of the balloon, gastroscope is angulated to the balloon to note the stricture modulation (**D**) Endoscopic vision after balloon dilation.

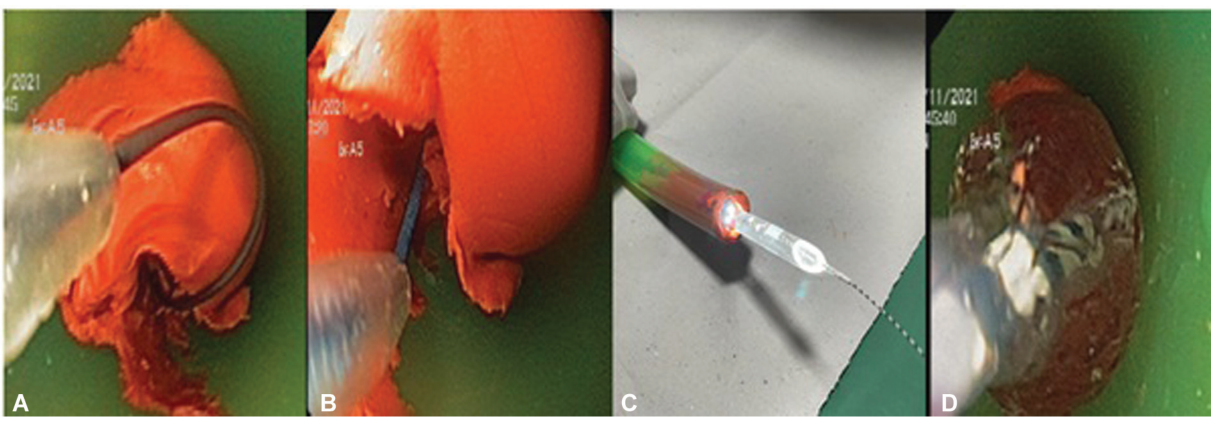

Fig. 3 Troubleshooting of the procedure: (**A** and **B**) Endoscopic image of proximal end of the clay with wrong position of the balloon and guidewire (**C**) Though the successful passage of balloon across, air column should have been avoided. (**D**) The endoscope was not positioned correctly during the inflation of the balloon.

Demography details of the trainees were obtained including age, gender, training hospital, number of balloon dilations performed prior to the study intervention, and the feedback of the program. Procedural skill checklist was prepared for the esophageal balloon dilation using relevant sources.

Pretest and Posttest Questionnaire and Scoring

The 15 questions and the procedure checklist were standardized by face and content validity with the trainers and an external expert. The pretest questionnaire contained 15 items, covering the key points pertaining to the CRE dilation. The procedure check list used for the hands on simulation was used for six times, following which a posttest comprising of similar set of questions was administered. Each correct answer was scored as 1 and mean (%) scores were calculated.

Statistical Analysis

Data were analyzed using SPSS software "SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc." The overall score was presented in terms of the mean after converting to percentage. Paired *t*-test was used to compare the mean score between pre- and posttest score. A p-value of <0.05 was considered as statistically significant.

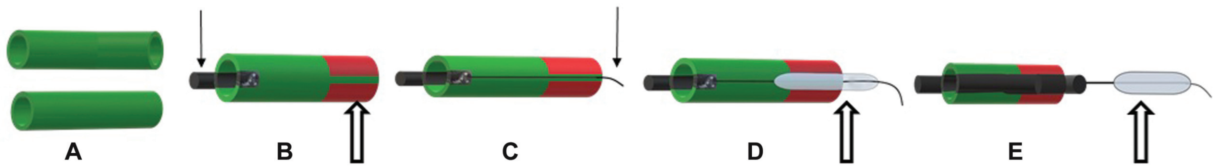

Fig. 4 Longitudinal section of the simulation model: (**A**) Picture showing a green hosepipe; (**B**) Red clay at one of the pipe (block arrow) & an endoscope at the other end (solid arrow); (**C**) Solid arrow showing a guidewire passed across the hole in the clay; (**D**) Block arrow showing CRE balloon in position dilating the hole in the clay with endoscope at one end; (**E**) Block arrow showing successful passage of balloon and endoscope after dilation.

Results

Trainee Validity

On Likert's scale, all the trainees rated visual appearance, haptic feedback, and usefulness in training as 5/5 except for one who rated it as 4/5 as the simulation was stiffer. All of them found that the skill development program to be useful with clear objectives and effective feedback. All of them were ready for repeat assignment on simulation model for improving their clinical skill and self confidence in performing an endoscopic procedure (►**Fig. 4**).

Instructor Validity

The most common problem encountered was that the simulation was stiffer than the haptics of real tissue. The clay has to be loaded just before the procedure for more realistic feel. The hole in the clay has to be at least 8 mm as smaller hole diameters had a problem of unsuccessful passage/buckling of the wire in the pilot models. Instead of clay, dough and plaster of Paris were used but were either soft or hard with cracking and not as realistic as clay for dilation. The clay remained fixed tightly to the pipe without any dislodgement during the dilation procedures.

Evaluation of the Training

All the trainees were in final year gastroenterology from different medical colleges. Ten men and two women comprised the study group. All of them had performed less than 10 CRE dilations. Two trainees wrote in free-text comments that the training program was interesting and wanted repeated sessions on different procedures for endoscopic skill training in COVID-19 times. All the scores improved after the study exercise as given in ►**Table 1** and the advantages of simulation model as perceived by trainees is given in ►**Table 2**.

The mean (%) pretest scores of 39 (21.6%) improved significantly to 160 (88.8%) in mean (%) posttest questionnaire ($p < 0.05$). There was a significant improvement in the questionnaire of the dilation procedure after the simulation training episode. The minimum and maximum scores obtained per trainee were 10 and 30, respectively.

Discussion

This study demonstrates that a skill exercise involving lecture, live demonstration, and hands-on training significantly enhanced the technical skills and knowledge of gastroenterology fellows in esophageal balloon dilation. All the trainees in the study had performed fewer than 10 esophageal balloon dilations. The use of small group training helped them in acquiring the knowledge and hands-on training with feedback of an instructor improved their confidence of the skill set. There are only few reports in literature of the use of simulation for training esophageal dilation technique.[7,8]

All the trainees had rated excellent in hands-on training on balloon dilation on simulation device. The simulation device is also cheap, reproducible, and does not involve animal tissue.

With the new normal and reality of pandemic, the early stage of training and enhancing the basic skill set in future endoscopists, curriculum is important.[2]

Virtual reality/mechanical simulator models do not have stricture simulation training module. Ex vivo animal models can provide haptic and visual feedback but explanted organs can lose the tissue elasticity and require appropriate disposal. A structured simulation-based training with progressive learning curriculum that sequentially increases the difficulty can improve the competency.[9]

The American Society for Gastrointestinal Endoscopy (ASGE) suggests that the introduction of a specific simulator into a training program is justified if its use by novices leads to a reduction of 25% of the clinical cases needed to learn the procedure.[10] In our study, the knowledge and hands-on skills were trained but how it improves the performance in real patient experience is not assessed.

The COVID-19 pandemic has disrupted endoscopy training with infection control measures to protect patients and health care personnel. More than 92.8% reported a negative impact on endoscopy training, with suspension of elective procedures (77.1%) being the most detrimental factor.[11] The decrease in number of elective endoscopies have reduced the training numbers during this period. Webinar-based teaching modules and video-based lectures had increased with hands-on training taking a backseat in this period.[12–14]

The gastroenterologist trainees need to carry out practical activities with the goal of balancing the safety of trainees and acquiring endoscopic skills in clinical practice. The implementation of hands-on courses for trainees may be a solution in COVID-19 pandemic.[15]

The future endoscopic training in India might constitute of various intrastate small-group simulation-based hands-on courses with defined skill set objectives and assessments.

Table 1 The 15 test questions used for knowledge assessment of CRE balloon dilation

Sl. no.	Question: correct answer/total number of students (%)	Pretest	Posttest
1	What is the length of through the scope (TTS) wire-guided CRE balloon? Answer: 5.5 and 6.5 cm	3/12	11/12
2	What is French (Fr) to mm conversion: answer: 3 Fr = 1 mm[16]	5/12	12/12
3	Can biopsy and dilation be done simultaneously? Answer: yes with caution[17]	5/12	12/12
4	Can biopsy and dilation do prior or after dilation? Answer: biopsy should be done after dilation. Biopsy site can act like lead point for perforation if done prior to dilation[17]	2/12	12/12
5	What is the refractory stricture? Kochmann's criteria Answer: diameter: 14 mm; 5 sessions; 2-week intervals[18]	3/12	8/12
6	How to convert ATM to kPa? Answer: 1 ATM = 101.3 kPa	3/12	8/12
7	Prior dilation: 3 rules and the rule of three Answer: diameter of stricture, diameter of dilator and rule of 3: no more than three bougie dilators of sequentially larger size should be passed once moderate or greater resistance is evident[18]	0/12	12/12
8	In CRE balloon, what is used for dilation? Answer: Water with or without contrast by hand-held device[19]	4/12	12/12
9	What is the difference between fixed wire and wire-guided CRE balloons apart from wire? Answer: balloon is smaller to facilitate tortuous strictures and the wire fixes the balloon during dilation[20]	1/12	11/12
10	What are the differences in balloon material, shoulders, and length of wire-guided CRE balloon between Olympus, Wilson Cook (WC) and Boston Scientific (BS)? Ans: BS: Pebax; rounded shoulders; 5.5 cm WC: Petflex; squared shoulders; 5.5 cm Olympus: Nylon; rounded shoulders; 5.5 and 6.5 cm[21]	0/12	8/12
11	What are the scores of dysphagia? Answer: Bazaz score, Atkinson's score, Mellow–Pinkas score	0/12	10/12
12	What are the characteristics of simple stricture? Answer: symmetric, straight, short, and may allow passage of endoscope[22]	9/12	12/12
13	What are the characteristics of complex stricture? Answer: Length > 2 cm; tortuous, angulated stricture; complicated with tracheoesophageal fistula or diverticula; nontraversed stricture[22]	4/12	11/12
14	What are the dilation characteristics of CRE balloons? Answer: each balloon can be dilated for three dilation sizes controlled by alliance gun pressures[16]	0/12	9/12
15	What is the minimum time for CRE balloon inflation? Answer: 60 seconds[16]	0/12	12/12

Abbreviation: ATM, atmospheric pressure; CRE, controlled radial expansile; kPa, kilopascals.

Table 2 Benefits of simulation as compared with live patients as perceived by trainees

Sl. no.	Benefits of simulation model as compared with live patient as felt by trainees in learning CRE dilation
1	A check list for the procedure can stratify the risk and benefit analysis of dilation
2	Useful for the knowledge of the equipment and enhancing teamwork for successful completion of the procedure
3	No respiratory movements to interfere with dilation and there is no harm to the patient
4	No animal/human tissue was involved
5	Can take ample time to rehearse and repeat the steps of dilation without time frame
6	Useful to correct the trouble shooting that can happen during CRE (►**Fig. 3**)
7	Can be used repeatedly till the technique is mastered
8	Clay was stiffer to dilate as compared with live patient. But it was better if the clay was loaded just before the procedure
9	Feedback from mentor was crucial, as it is in a relaxed dedicated stress-free environment

Abbreviation: CRE, controlled radial expansile.

Limitations

The study is limited with the use of 15 questionnaire as pre- and posttest for validity. The objective evidence of improving clinical practice is not studied. But all the trainees had found the exercise useful and wanted similar single-day exhaustive skill training modules. The study used two different types of balloons but use of Savary-Gilliard dilators also could have been incorporated. The model is still under improvement with fixation to the board, as well as training the deployment of metallic stents.

Conclusion

The novel stricture simulator had good face validity and objectively improves trainee performance in attaining skill set. A low-cost model for hands-on training in endoscopy might be need of the hour in the pandemic era.

Conflict of Interest
None declared.

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