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North Avenue, Diliman, Quezon City

Assessment of the Learning Curve for Image Enhanced Endoscopy in the diagnosis of *Helicobacter pylori* infection using a Web-based teaching module

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ASSESSMENT OF THE LEARNING CURVE FOR IMAGE ENHANCED ENDOSCOPY IN THE DIAGNOSIS OF *HELICOBACTER PYLORI* INFECTION USING A WEB-BASED TEACHING MODULE

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SIGNIFICANCE

Gastric cancer is the fourth most common cancer worldwide with Helicobacter pylori (Hp) infection as its primary etiologic agent. Hence, eradication is of paramount importance. Image Enhanced Endoscopy (IEE) has been used in detecting pre-malignant lesions in the stomach, however, teaching IEE has not been standardized yet. The use of a web-based teaching module is expected to become a promising training resource in this field.

METHODOLOGY

This is a single-center, prospective study evaluating the effectiveness of a web-based teaching module in the diagnosis of Hp infection using IEE. After receiving a pre-test, the participants were asked to study the teaching module. Post-tests were taken immediately after the teaching module and 1 month after. The change in accuracy between the pre-test and the post-test was the primary outcome of this study.

RESULTS

Ten gastroenterologists were invited, of which 8 participants were included in the analysis. Significant increase in accuracy between pre-test and post-test 1, and pre-test and post-test 2 were observed among all the participants (*p* value 0.000009 and 0.00003, respectively). Durability of the learning gained was also observed as demonstrated by a significant increase in accuracy between post-test 1 and post-test 2 (*p* value 0.01). Subgroup analysis according to endoscopy experience did not show a significant difference between the changes in accuracy.

CONCLUSION

This study has successfully demonstrated that the web-based teaching module is highly effective in teaching and improving the knowledge of the participants with regards to the detection Helicobacter pylori infection using image-enhanced endoscopy.

Keywords: Prospective study, Learning Curve, Helicobacter pylori infection, Image enhanced endoscopy

INTRODUCTION

Gastric cancer is the fourth most common cancer worldwide and is the second leading cause of cancer-related mortality in the world (1,2). The highest incidence of gastric cancer has been reported from Asia, although a decreasing overall incidence has been shown in several studies (2,3). Helicobacter pylori (Hp) infection affects nearly half of the world's population. It is a widely recognized risk factor for gastric cancer, peptic ulcer disease (PUD), chronic gastritis and gastric mucosa-associated lymphoid tissue lymphoma (2,3, 4). Hp has been classified as a class I (or definite) carcinogen by the WHO and it is considered as the primary etiologic agent for gastric cancer (1,2). Hence, early diagnosis and eradication of Hp infection is crucial in eradicating cancer risk.

The Image Enhanced Endoscopy (IEE) is an endoscopic imaging technique for enhanced visualization of mucosal microscopic structure and capillaries in the superficial mucosal layer. Images are obtained by using narrower bands of red, blue, and green filters, which are different from conventional red-green-blue filters (4,5). Several studies have shown that IEE is useful for predicting the presence of Hp infection as well as histological severity of inflammation and atrophy (4,5,10,11,12). A web-based learning system in IEE has been reported in several studies (6,7). The aim of this study is to address the learning curve of gastroenterologist for this new system through the use of a web-based teaching module.

OBJECTIVES

GENERAL OBJECTIVE

To evaluate the impact of a web-based teaching module in the diagnosis of Helicobacter pylori infection using Image Enhanced Endoscopy.

SPECIFIC OBJECTIVES

1. To create a web-based teaching module on IEE patterned after the teaching modules created by the pioneers in the field of IEE.
2. To evaluate previous knowledge of the field through a test given before the introduction of the web-based teaching module.
3. To determine the subjects' immediate knowledge on IEE after watching the teaching module.
4. To test durability of learning gained from the web-based teaching module by comparing the subjects' scores on the post-test immediately given after the teaching module from that of their scores on the post-test given 1 month after.
5. To determine differences in the impact of the web-based teaching module between consultants and fellows-in-training.

SIGNIFICANCE OF THE STUDY

Image Enhanced Endoscopy (IEE) has been used in detecting pre-malignant lesions in the stomach. Teaching IEE has not been standardized yet. There is limited resource materials and teaching modules available for acquiring knowledge on IEE. The available web-based resource materials were mostly created by the pioneers of IEE in first world countries like Japan.

With IEE now integrated in the current video-endoscopy equipment, acquiring knowledge on IEE is now a necessity. It is currently integrated into the training of fellows. Assessing the effectiveness of a web-based teaching module created by consultants trained in IEE is paramount in improving the knowledge of our consultants and fellows-in-training.

Helicobacter pylori infection is a common risk factor in the development of peptic ulcer disease, gastric cancer, and gastric mucosa-associated lymphoid tissue lymphoma; hence, eradication is of paramount importance. IEE allows for simple and clear visualization of mucosal microscopic structure and its capillary patterns. IEE can also help in selecting suspicious areas for biopsy. With the use of IEE, detection of Hp infection could be achieved in cases in which false-negative results occur such as when bleeding is present or when there is recent antibiotic or proton pump inhibitor use. With these in mind, broadening our knowledge on the use of IEE system is imperative. The use of a web-based teaching module is expected to become a promising training resource in this field.

SCOPE OF THE STUDY

This study is a single-center study in which only the presence of Hp infection using IEE was studied. IEE findings of other gastric diseases, such as complications arising from Hp infection like ulcer, adenocarcinoma, and lymphoma, were not included in this study. The motivation of the participants to learn this new classification, which cannot be controlled by the investigators, were assumed to have a great impact on the results of this study.

REVIEW OF RELATED LITERATURE

Helicobacter pylori infection is the most common chronic bacterial infection in humans, affecting more than 50% of the world's population (2). Recent studies suggest that there has been an overall decline in the prevalence of Hp infection (1,3,8,9). Wong, et al showed that there was a significant decline in the prevalence of peptic ulcer disease from 35.87% in 1996 to 18.8% in 2002, in a tertiary hospital in Manila, Philippines. This decline was significantly related to the decrease in Hp infection (8). A similar study done by Leow, et al in Malaysia showed a steady decline in the prevalence of duodenal ulcer and gastric ulcer over a 20-year period along with the significant decline in the prevalence of Hp infection (9). Studies from

other countries show similar declining trends. The overall seroprevalence rate was 58.07% in China, 39.3% in Japan, 59.6% in South Korea, 54.5% in Taiwan, and 15.1% in Australia (3). The decreasing prevalence in Asia could be attributed to improvement in sanitation, public health measures, personal hygiene and living conditions, as well as, increased awareness of both patients and physicians regarding the risk of gastric cancer with Hp infection and appropriate eradication practices (1,3). Despite the decreasing prevalence of Hp infection, it is still an established risk factor for gastric cancer, hence, early diagnosis and eradication is of paramount importance.

Hp is a gram-negative bacterium ideally suited to live in the acidic environment of the stomach (2). Chronic Hp infection has a well-established association with chronic active gastritis, PUD, gastric adenocarcinoma, and gastric lymphoma (MALToma) (2,4,5,10). Hp infection is the primary cause of gastric inflammation, a feature for both the initiation and progression to gastric cancer. It widely recognized as the principal etiologic agent for gastric cancer (2). The inflammatory process leads to the development of atrophic gastritis followed by progression to intestinal metaplasia, and dysplasia which have been shown to be strong risk factors for the development of gastric cancer (2,5).

Standard indications for Hp testing include patients with active PUD (gastric or duodenal ulcer), history of PUD (with or without prior treatment for Hp), gastric MALT-lymphoma, following endoscopic resection of early gastric cancer, and those with uninvestigated dyspepsia (if population prevalence is 20%). Endoscopic and non-endoscopic means are available to diagnose Hp infection. These include histology, stool bacterial antigen, culture, urease detection and presence of antibody response (2). Histopathology remains the gold standard for diagnosing Hp infection. However, detection of Hp associated gastritis by random biopsy sampling of gastric mucosa may lead to sampling errors, missed pathology, and increased costs of work-ups (4). Studies have shown that rapid urease tests (RUT) and histology might miss 10% of the true Hp positive cases. Active gastrointestinal bleeding, recent antibiotic and proton pump inhibitor use may result in false-negative RUT-based tests. Additionally, a low bacterial burden and concomitant atrophic gastritis may also result in falsely-negative histology (8).

Image Enhanced Endoscopy, such as Narrow Band Imaging (NBI), facilitates simple and clear visualization of microscopic structures of the superficial gastric mucosa and capillary patterns (5). This enhanced visualization allows for better targeting of biopsies, improved prediction of histology, appropriate therapeutic plan and improved patient outcomes (11). Several studies have shown that IEE accurately predicts the presence of Hp infection as well as the histological severity of inflammation and atrophy (4,5,10,11,12). A study done by Tongtawee et al in 2015 showed that gastric mucosal morphologic patterns in Hp infected

gastric mucosa can be consistently detected using NBI endoscopy with good correlation with histopathological severity. They studied 200 patients who underwent gastroscopy for which the evaluation of dyspeptic symptoms. They classified NBI endoscopic findings into 5 morphological findings with associated histopathological severity of inflammation: type 1: regular arrangement of collecting venules associated with regular arrangement of surface epithelium with no infiltration by inflammatory cells; type 2: cone-shaped gastric pits which corresponds to mild gastritis with mild glandular atrophy, mild infiltration by inflammatory cells, irregular arrangement of surface epithelium, and irregular opening pits; type 3: rod shape gastric pit with prominent sulcus which corresponds to moderate gastritis associated with moderate glandular atrophy, moderate infiltration by inflammatory cells, and irregular arrangement of surface epithelium; type 4: marked gastritis characterized by ground glass-like patterns with associated marked glandular atrophy, marked lymphocytic infiltration, lymphoid follicular hyperplasia, and mild intestinal metaplasia; type 5: brownish patches with bluish margin and irregular border which corresponds to marked intestinal metaplasia with marked gastric atrophy, indicating advanced gastritis. Types 1 and 2 patterns were statistically significant in predicting Hp negative status (58/60, $p<0.01$), whereas, types 3, 4, and 5 patterns were statistically significant in predicting Hp positive status (132/140, $p<0.01$) (4). Similar classification was used in the study by Alaboudy et al (12).

Two separate studies done by Tahara et al in 2009 and Okubo et al in 2011 showed similar correlation of image-enhanced endoscopic findings with Hp infection and histological severity of gastritis (5,10).A normal pattern was described as the presence of small, round pits surrounded by regular subepithelial capillary networks (SECNs) which are regularly interspersed with collecting venules. Abnormal gastric morphological patterns were classified into 3 types: type 1: slightly enlarged, round pit with unclear or irregular SECNs; type 2: enlarged oval or prolonged pit with increased density of irregular vessels; and type 3: well-demarcated, oval or tubulovillous pit with clearly visible coiled or wavy vessels. Hp infection was detected in 92.9% of patients with type1, 94.6% with type 2, and 66.7% with type 3 morphologies, whereas, Hp infection was not detected in 92.5% of patients with the normal pattern. Their study showed that gastric mucosal patterns seen on NBI endoscopy correlated well with histological severity of gastritis. Types 2 and 3 correlated with higher degree of chronic inflammation, whereas, type 3 correlated with the highest degree of atrophy and intestinal metaplasia (5).

Use of IEE improves the accuracy for the detection of gastric lesion, however, it lengthens the examination time and it needs more training and experience of the endoscopist. Several studies have shown that web-based learning modules significantly improves the accuracy of detecting gastric lesions with IEE (6,7). Dias-Silva et al studied the learning curve

of 6 gastroenterologists for NBI in the diagnosis of pre-cancerous gastric lesions by using a web-based video. A 10% increase in global accuracy was observed in all the participants. Sensitivity and specificity of 80% and higher for intestinal metaplasia were observed in 3 out of 6 participants and a specificity for dysplasia greater than 95% were achieved by all of the participants. However, with identification of Hp infection gastritis and sensitivity to dysplasia, a learning curve was not observed (7). Nakanishi et al evaluated the efficacy of an e-learning system for the diagnosis of gastric lesions with the use of NBI. The study was a randomized controlled trial comparing the changes in diagnostic accuracy between the e-learning group and the non-e-learning group. They observed a significantly higher change in diagnostic accuracy in the e-learning group and they concluded that an e-learning system is effective in improving the capabilities of diagnosing gastric lesions using NBI (6).

METHODOLOGY

Study Design

This is a single-center, prospective study evaluating the effectiveness of a web-based teaching module in the diagnosis of Helicobacter pylori infection using Image Enhanced Endoscopy among gastroenterology consultants and fellows-in-training from Veterans Memorial Medical Center.

Teaching Module

The teaching module was created based on current literature and existing learning videos created by experts and pioneers in IEE which are available online. The teaching module consists of 2 parts: Part 1 includes the introduction to IEE (i.e. what is IEE, how does it work, the technique, etc.); and Part 2 includes a discussion on the normal mucosa on IEE, how to detect Hp infection and intestinal metaplasia based on IEE. This includes images using IEE without magnification and high-resolution magnification IEE.

Image-enhanced endoscopic images are mostly created using endoscopes with high resolution magnification such as those taken from online videos. However, most local hospitals do not have the expensive high-resolution magnification endoscopes but rather have the IEE without magnification (conventional IEE). Still, conventional IEE has the capacity to detect Hp infection even without magnification because some characteristics of Hp-infected mucosa such as cone-shaped and rod-shaped gastric pits. Our center currently uses the conventional IEE endoscope (GIF-H170, Olympus) connected to a light source (Evis Exera III CV-190, Olympus). To make the teaching module applicable to the local setting, images captured using our endoscope with conventional IEE were added to the teaching module. The tissue samples

from which the images where based were validated by histopathology and rapid urease test for Hp infection.

Testing Module

The testing module was created based on high-resolution magnification IEE lifted from online videos. To make the testing module applicable to the local setting, images captured using our endoscope with conventional IEE were included. The tissue samples from which the images where based were validated by histopathology and rapid urease test for Hp infection.

The pre-test and the post-tests used the same questions but were arranged differently. A total of 45 questions were asked: 5 questions on basic knowledge of IEE, 9 images of normal gastric body mucosa, 9 images of normal gastric antral mucosa, 8 images on Hp positive gastric body mucosa, 7 images of Hp positive gastric antral mucosa, and 7 images of intestinal metaplasia.

Study Population and Study Flow

Ten gastroenterologists from Veterans Memorial Medical Center, 8 consultants without training in IEE and 2 fellows-in-training, were invited to participate in this study. Inclusion criteria were: 1) provision of an informed consent to participate in the study; 2) ability of a web browser on a participant's gadget (mobile phone, tablet, laptop, computer) to display the contents of the module; and 3) completion of the entire web-based teaching module beginning from the questionnaire to the second post-test. Two participants who were not able to complete the module were excluded from the study.

Data collected from the participants include years in practice, number of upper GI endoscopies done annually, and experience with IEE. The participants were asked to take a pre-test which involved identifying whether the gastric mucosal pattern shown is Hp-infected or not, as well as, their basic knowledge on IEE. After the pre-test, the teaching module was then shown. A post-test module was taken by the participant immediately after the teaching module. A second post-test was given 1 month after to assess durability of the learning obtained from the teaching module. Only 8 participants were able to complete the whole module (**Fig. 1**). Feedbacks were made available after the completion of each post-test which include the participants' answers corrected as right or wrong along with the correct answers for each. The whole module was done through a web-based system. Participants were asked to sign-up to the web application in order to gain access to the module and to enable results to be collected via the Internet.

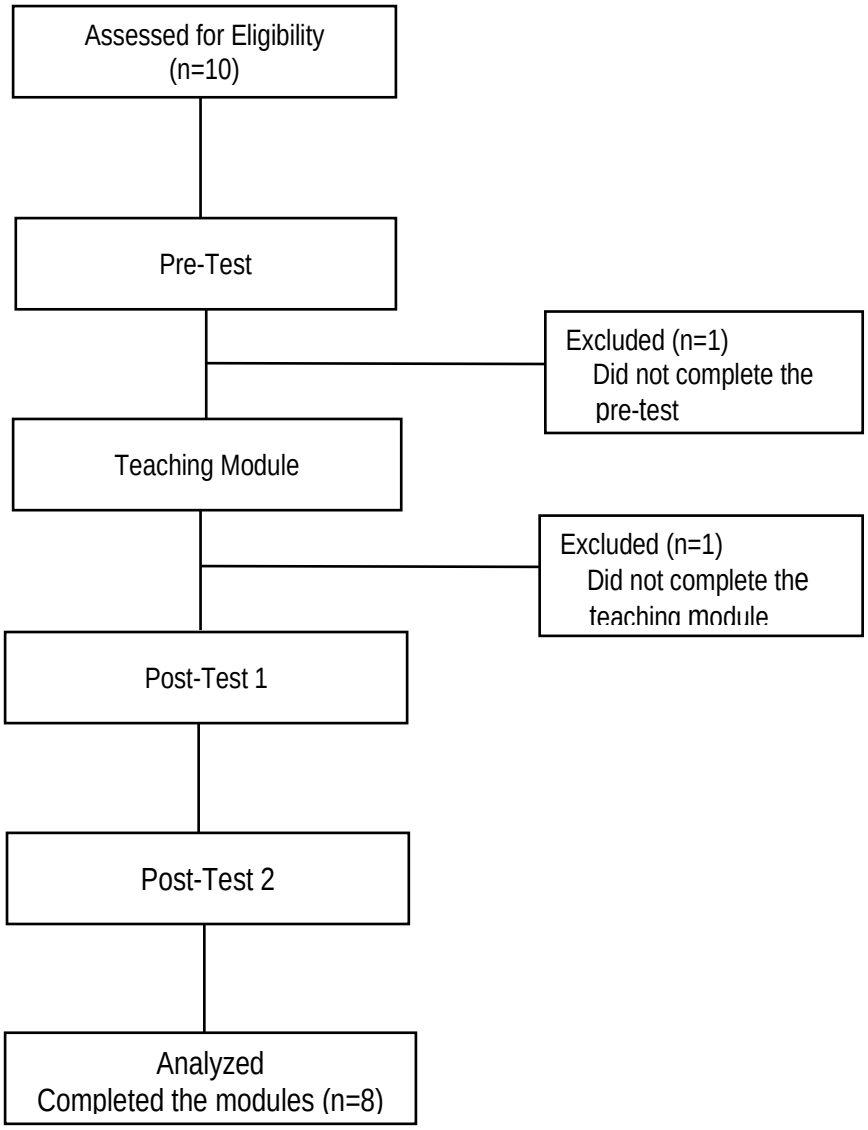

Fig. 1. Study flow

Study Outcomes

The primary outcome of the study was the increase in diagnostic accuracy between the pre-test and the post-test 1 among the participants. Secondary outcomes include increase in diagnostic accuracy between the pre-test and post-test 2, increase in diagnostic accuracy between the post-test 1 and post-test 2 to check for durability of learning gained from the web-based teaching module, and differences in degree of improvement based on experience on endoscopy (consultants vs fellows-in-training).

Statistical Analysis

Statistical analysis was performed using Excel Analysis ToolPak. The increase in diagnostic accuracy between pre-test and post-test 1, pre-test and post-test 2, and pre-test 1 and pre-test 2 among the participants were calculated using paired *t* test with a *p* value of

<0.05 indicating statistical significance. Subgroup analysis based on experience on endoscopy was done using unpaired *t* test.

RESULTS

Participants

A total of 10 gastroenterologists were invited to participate in the study, however, only 8 participants were able to complete the study and thus, were included in the analysis of results. **Table 1** shows the characteristics of participants at baseline.

Table 1. Baseline characteristics of participants.

	Participants (n=8)
Age	
<40 years	4
≥40 years	4
Gender	
Male	5
Female	3
Level of Training	
Consultants	6
Fellows-in-Training	2
Number of endoscopies conducted annually	
<100	3
≥100	5
Use of IEE-screening endoscopy	
Use	4
Do not use	4

Study Outcome

The increase in accuracy between the pre-test and the post-test 1, which was the primary outcome of this study, was significant among all the participants (*p* value 0.000009). Likewise, for the secondary outcomes, a significant increase in accuracy was noted between the pre-test and the post-test 2 (*p* value 0.00003), and between post-test 1 and post-test 2 (p value 0.01). The increase in the accuracy rate of each participant in both the pre-test and respective post-tests (post-test 1 and post-test 2) are shown in **Fig. 2 to 4**. The highest scores

in post-test 1 and post-test 2, with an accuracy of greater than 70% and 95%, respectively, were achieved by fellows-in-training (S8 and S7).

Subgroup analysis according to endoscopy experience (consultant vs fellow-in-training) did not show a significant difference between the changes in accuracy between pre-test and post-test 1, pre-test and post-test 2, and post-test 1 and post-test 2 (*p* value 0.097, 0.472, and 0.409, respectively) (**Fig. 5**).

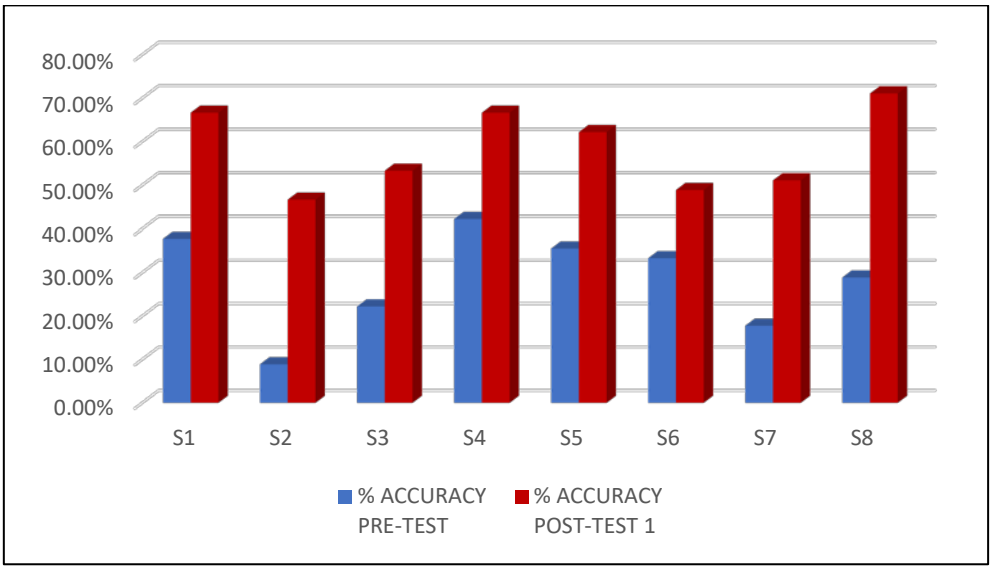

Fig 2. Changes in accuracy between pre-test and post-test 1 of each participant.

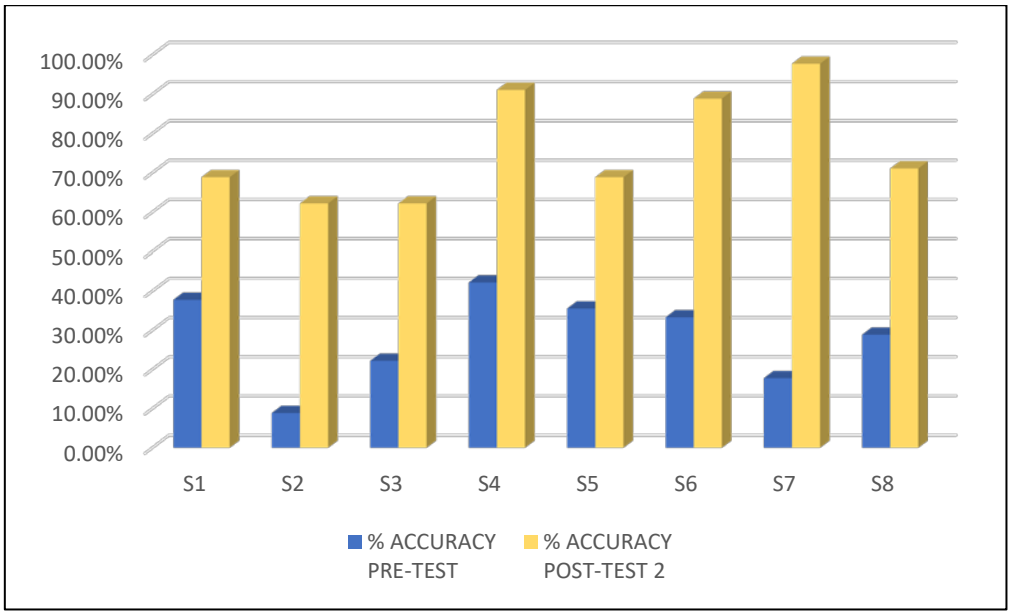

Fig 3. Changes in accuracy between pre-test and post-test 2 of each participant.

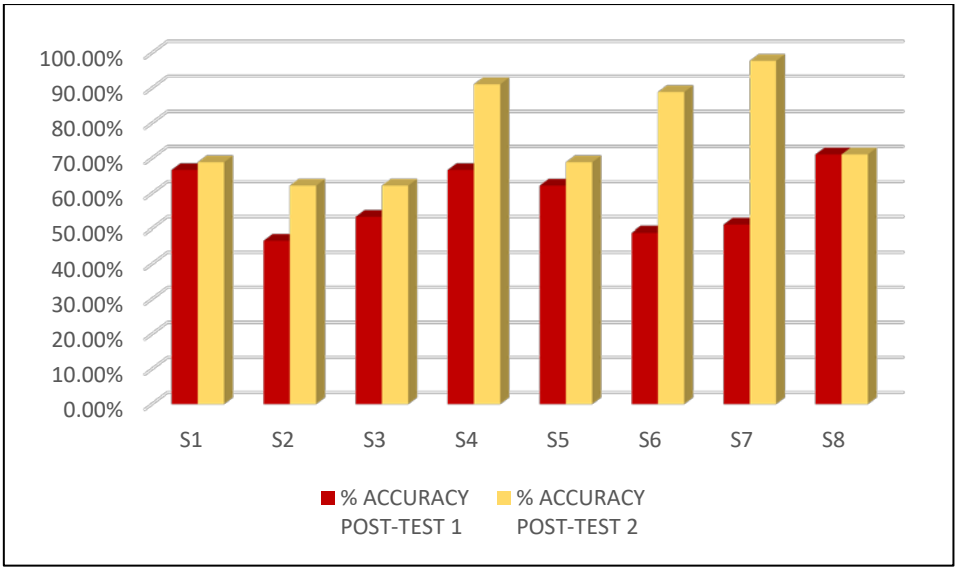

Fig 4. Changes in accuracy between pre-test and post-test 2 of each participant.

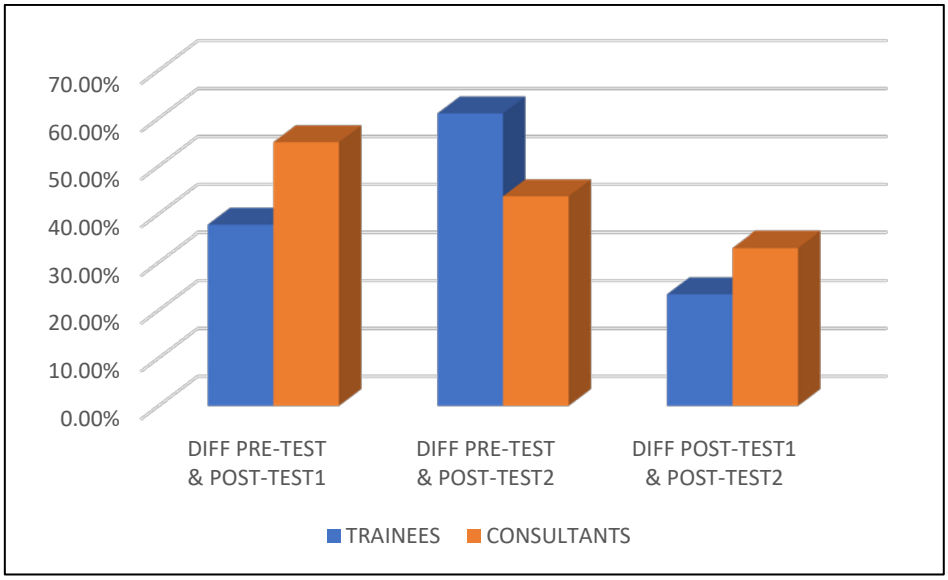

Fig 5. Subgroup analysis based on experience in endoscopy (Trainees vs Consultants).

DISCUSSION

Gastric cancer is the fourth most common cancer worldwide and is the second leading cause of cancer-related mortality in the world. Helicobacter pylori (Hp) infection is considered as the primary etiologic agent for gastric cancer (1,2). Hence, early diagnosis and eradication of Hp infection is crucial in eradicating cancer risk.

We developed a learning system based on the Internet to help gastroenterologists expand their knowledge on optical detection of Hp infection based on IEE. We assessed how much this web-based teaching module affect the learning of participants in identifying patterns

of normal and Hp infected gastric mucosa. We also, studied the differences in the learning curves based on experience in endoscopy.

Similar to other studies (6,7,13), our results showed that a web-based teaching module is effective in increasing the ability of detecting Hp infection using IEE. A significant increase in accuracy between the pre-test and the post-tests were observed. Likewise, a significant increase in accuracy was shown between post-test 1 and post-test 2 indicating durability of learning gained from the teaching module. This web-based teaching module offers several advantages over the conventional teaching methods in that it can be viewed anytime by the participant and that there is no limit on the number of participants who wish to expand their knowledge. The outcome of this study shows that this web-based teaching module is expected to become a promising training resource. However, it should be emphasized that continuous learning through repetition is paramount to achieve and maintain a high level of diagnostic ability in IEE.

A study done by Dias-Silva et al showed that less experienced endoscopists or trainees have more potential to benefit from the e-learning system. This is in contrast to our results in which there is no significant difference in the changes in accuracy between consultants and fellows-in-training. Perhaps all participants are motivated to gain knowledge on this field and all are open to this innovative technique.

Our study has several limitations. One limitation of the study is that the teaching module was not available for review during the whole program. Having the teaching module available at all times to be viewed by the participants as frequently as they wish could prove to be more beneficial. A self-exercise program prior to the post-test would have also been helpful. Also, our study did not assess the improvement in using IEE in actual clinical practice after the learning period, we only assessed the improvement in test scores. In order to maintain the knowledge gained from the teaching module, the participants should apply what they have learned in their daily practice. We recommend further studies to be done involving more participants, longer duration of the learning period, and assessing the effect of the program in actual clinical practice. Furthermore, this web-based teaching module could be modified to include more images and to provide education regarding other pre-cancerous lesions of the stomach.

In conclusion, this study has successfully demonstrated that the web-based teaching module is highly effective in teaching and improving the knowledge of the participants with regards to the detection Helicobacter pylori infection using image-enhanced endoscopy. The use of a web-based teaching module is expected to become a promising training resource in this field.

APPENDIX A

PATIENT'S INFORMATION SHEET

Assessment of the Learning Curve for Image Enhanced Endoscopy in the diagnosis of *Helicobacter pylori* infection using a Web-based teaching module

ALMA M. AGUDA-PERDIGUERRA, M.D. (Principal Investigator)
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INTRODUCTION

I am Dr. Alma M. Aguda-Perdiguerra, a Fellow-in-training in the Section of Gastroenterology in the Department of Medicine, Veterans Memorial Medical Center (VMMC). The objective of this research is to determine effectiveness of a web-based teaching module in the diagnosis of Helicobacter pylori infection using Image Enhanced Endoscopy (IEE). The result could contribute more on the understanding of IEE and its impact on the society.

I am only affiliated with Veterans Memorial Medical Center. This study is not sponsored by any institution or companies. The expenses in the conduct of this study will come from personal funds. There may also be some foreseeable circumstances and reasons under which the participation in the study may be terminated. Should this happen, the subject will be duly informed beforehand.

Participating in this study is voluntary and refusal to join will not affect your current practice.

RESPONSIBILITIES OF THE PARTICIPANTS, RISKS and BENEFITS

Your responsibility as a participant in this study is to answer the self-administered questionnaires honestly and to give us as much accurate information as possible. Once included in this study, you are required to the following: take the pre-test, study the web-based teaching module, and then take the post-test. You may do the required tasks at your most comfortable time and place.

The outcome of this study will help us broaden our knowledge regarding the use of Narrow band imaging and its possible impact on the diagnosis for gastrointestinal disease through the use of web-based teaching modules. It would help gastroenterologists like us to broaden our knowledge on the said field.

There will be no rewards nor compensation given in joining this study.

CONFIDENTIALITY

I will keep all information confidential to the extent allowed by law. To protect your privacy, I will keep the records under a code number rather than by name. Only research staff related with this study will be allowed to look at your questionnaire. Your name or other facts that might point to you will not appear when we talk about this survey or publish its results.

RESULTS OF THE STUDY

The research is a part of the requirements of the fellowship program of Veterans Memorial Medical Center. Through your participation, you allow us to broaden our knowledge on IEE which we can use to improve our management of Helicobacter pylori infection. You also have the right to obtain a copy of the results of this study. Except for the results of this study, we assure you complete confidentiality of your medical records.

RIGHT TO REFUSE OR WITHDRAW

You are free to withdraw your participation anytime for whatever reason.

IF YOU HAVE ANY OTHER QUESTIONS
You can call or ask questions anytime regarding this study

Alma M. Aguda-Perdiguerra, MD
Mobile No.: 09256783227

All parts of this study were reviewed and approved by the Veterans Memorial Medical Center – Institutional Review Board, who is responsible in overseeing the rights of the study participants. For additional information regarding your rights as study participants and for grievances or complaints, you may reach,

Dr. Annielyn Beryl Ong-Cornel
Chair, VMMC IRB
VMMC-IRB, Ward 18, North Ave., Diliman, Quezon City
Tel. No.: +632 9276426 local 1368

APPENDIX B

INFORMED CONSENT FORM

I agree to participate in the above-mentioned study. I understood very well the purpose and the mechanics of the study which were clearly explained to me by Dr. Alma M. Aguda-Perdiguerra. My participation is voluntary and I am not forced or threatened by any means.

_____	_____
Signature of the Respondent	Signature of the Legally Authorized Representative
_____	_____
Date Signed	Date Signed

_____

Signature of Researcher

_____

Date Signed

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