



ALL-SAFE PRELIMINARY VALIDITY EVIDENCE

Laparoscopic Appendectomy Module 2

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Part A. Internal Evaluation of Measures of ALL-SAFE Laparoscopic Appendectomy (Lap Appy) Cognitive Testing Tool

METHODS

Study. 24 participants from 4 sites completed the web-based module. Participants included 15 novice, 6 intermediate, and 3 expert participants. All participating sites were represented (Mbingo, n=9; MRS, n=1; Soddo, n=6; UM, n=8).

Scoring and Statistical analyses.

The identical (but shuffled in presentation) 10-item pre- and post-module quizzes were scored dichotomously (1=correct, 0=incorrect) and summed for each participant, with a maximum score of 10. Pre- and post-module summed scores were compared using paired student-test, while differences between novice, intermediate, and expert participants was tested using one-way ANOVA, both with SPSS Statistics for Windows v.25 (IBM, Armonk, NY) Item-level analyses were performed using a many-facet Rasch model using Facets software v. 3.50 (Winsteps.com, Beaverton, OR) following anchoring on subjects to accommodate for nested design across sites.

RESULTS

Test of Score Change Following Training.

For all. Paired Student T-Test Comparison of pre- and post-intervention Quiz (Appendix I) summed scores from all 24 participants indicated that there was not a statistically significant improvement in mean summed scores from Pre (M=7.13, SD=1.6) to Post (M=7.15, SD = 1.9), p=.55

Rasch analysis at item-level was consistent with this finding, indicating no statistical difference from pre- (M=0.7) and post (M=.8) training, p=.99. Deeper analysis indicated score improvement for both novice and intermediate participants.

*****For novice participants.*** Paired Student T-Test Comparison of pre- and post-intervention Quiz summed scores from all 15 novices indicated that there was a statistically significant improvement in mean summed scores from Pre (M=5.87, SD=2.03) to Post (M=7.47, SD = 1.58), p<.001.

*****For intermediate participants.*** Paired Student T-Test Comparison of pre- and post-intervention Quiz summed scores from all 6 intermediate participants indicated that there was a statistically significant improvement in mean summed scores from Pre (M=7.83, SD=.98) to Post (M=9.50, SD = .84), p=.032.

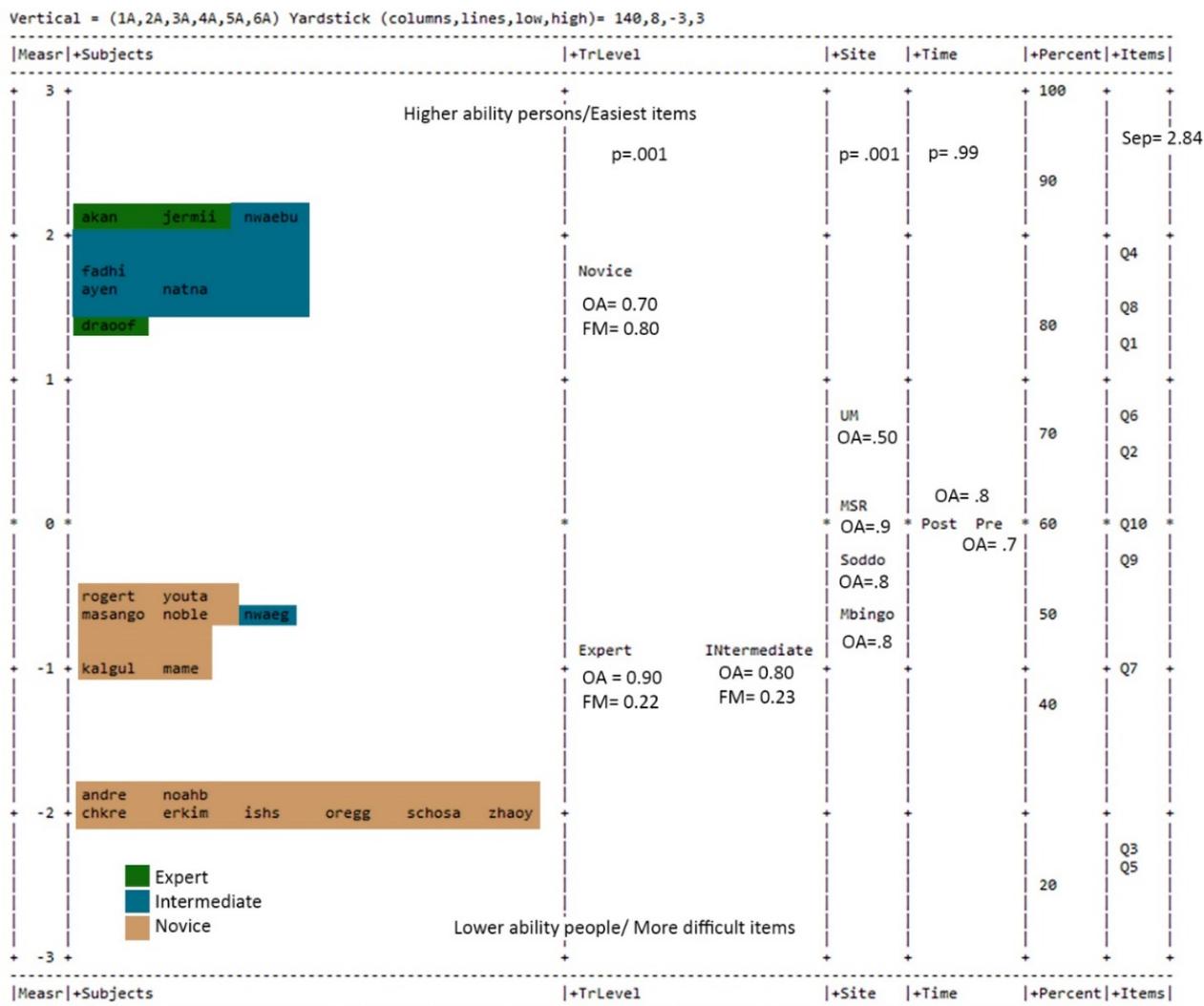
*****Discrimination across novice, intermediate, and expert participants.*** One-way ANOVA test indicated summed scores were able to discriminate between novice (M=6.67, SD=1.97), intermediate (M=8.67, SD=1.23), and expert (M=8.83, SD=.40) participants, p<.001. Rasch analysis supported this finding, $X^2(2,X)=70.8$, p=.001

Bias analysis

One-way ANOVA indicated statistical differences in mean summed scores across sites, $M_{UM}=5.38$, $M_{MSR}=8.50$, $M_{Soddo}=8.08$, $M_{Mbingo}=8.50$, $p < .001$. Rasch analysis supported this finding, $M_{UM}=0.5$, $M_{MSR}=0.9$, $M_{Soddo}=0.8$, $M_{Mbingo}=0.8$, $p=.001$.

Although these findings could suggest item or test bias, because the majority of medical students (the lowest performers) in the UM cohort, differences can be rationalized.

Figure 1. Rasch Variable Map Cognitive Test, questions 1-10



Cognitive Test Item discrimination

Review of item discrimination showed reasonable distribution of item difficulty for items, with items 3 and 5 as the most difficult item (item discrimination=.15 and .67, respectively), and Qs 4 and 8 as the easiest (item discrimination= .81 and .86, respectively) (Table 1)

Table 1. Item discrimination values for ALL_SAFE cognitive test items, ordered highest to lowest.

Item No.	Item Difficulty	Estimated Discrimination*	Discrimination Power	Notes	Suggested Action
Q7	Moderate	1.66	High		—
Q6**	Easier	1.40	High	All Intermediate=1.0	—
Q1	Easiest	1.17	High	All Intermediate=1.0	—
Q2	Easier	1.16	High		—
Q9	Moderate	0.97	Good		—
Q10	Moderate	0.95	Good	Intermediate score declined after training (MPre=1.0, MPost=.83)	Review question for clarity/alignment with content. Focus groups with Residents to ID problem
Q8	Easiest	0.86	Good	All Intermediate=1.0	—
Q4	Easiest	0.81	Good	All Intermediate=1.0	—
Q5	Most Difficult	0.67	Low	All Intermediate=1.0 Novices; Remained difficult (Mpre=.27, Mpost=.53)	High Rasch MnSq Infit (1.67) suggests guessing from lower ability participants, so review question/content to ensure they align; review question to ensure clear
Q3	Most Difficult	0.15	Low	Novices; Remained difficult (Mpre=.13, Mpost=.47) Intermediate; No change in pre-post score.	Simply a difficult question that seems to be too hard for this targeted group of participants

*Values over 1 indicate this item has more discrimination power than expected for its difficulty while values under 1 indicate less discrimination power for its difficulty.

** Question 6 is the only question all novices answered correctly following training.

Considerations include:

- a) Review/modification of Q5 to avoid ambiguity. Ensure question target is indeed covered within content.
- b) Review Q3 to ensure it's clearly written and targeted content is covered
- c) ** Q6 is the only question all novices answered correctly following training.
- d) Likely, Intermediate participants came in with set knowledge (Pre-test means for Qs 1,4, 5, 6 = 1.0, SD=.00), which is expected
- e) Given that mean post-test scores are still low (M=7.47, SD = 1.58) for novices, it might be expected that they review the content until they achieve mastery (100%) or some expected target, after ensuring content indeed aligns with QUESTIONS 3 and 5.

FINAL SUMMARY

Case Scenario/ Associated Cognitive Test:

- Cognitive test effectively discriminated between novice, intermediate, and expert participants, and demonstrated benefit to novice and intermediate participants with statistically significant score improvements for novice and intermediate groups, $p \leq .032$.
- Item discrimination analysis suggests review/potential modification of 2 questions (Qs 3/5) to ensure questions target is indeed covered within content, and language is clear.
- Evidence suggests Intermediate participants came in with set knowledge (Pre-test means for Qs 1,4, 5, and 6 = 1.0, SD=.00), which is expected
- Given that mean post-test scores are still low (M=7.47, SD = 1.58) for novices, it might be expected that they review the content until they achieve mastery (100%) or some expected target, after ensuring content indeed aligns with QUESTIONS 3 and 5.

Suggested Next Steps

- 1) evaluate 1) low, 2) borderline, and 3) high performer, with automated feedback based on AI to test alignment with scoring/competency decisions
- 2) Improve evaluation matrix to maximize distribution, minimize nesting which could introduce unexpected score patterns/biases.
- 3) To minimize future bias from experienced "novice" participants, recruit from new/virgin "novice" groups if possible, or include true experts as "gold standard"
- 4) Also, to avoid potential issues from nesting, consider recruitment of residents at UM/SUI, and if possible, novices (med students?) from all participating sites (Soddo/ Mbingo/ Kijabi) and ensure that each operator that submits a video is evaluated by a) judges from another site, b) these judges are ideally, balanced
- 5) To test judging quality of novice (medical students), add attendings to allow comparison to 'gold standards.'

Appendix I

Pre/Post Test Appendectomy

1. Which of the following is the most common cause of appendicitis?

- Abdominal adhesions
- Colitis
- +Obstruction (fecalith)
- Traumatic injury

Correct Answer: Obstruction (fecalith)

Explanation: While acute appendicitis is an infectious process, it starts with an obstructive etiology. The appendix is a narrow, blind-ending pouch that can easily be obstructed from lymphoid hyperplasia in the pediatric population or from fecalith, food matter, pills, masses, parasites, or fibrosis in adults.

Obstruction results in impaired drainage, mucus production, secretions, and overgrowth of bacteria in the blind-ending lumen. This increases the pressure within the lumen leading to impaired venous and lymphatic drainage and local ischemia. Progression in the ischemic process (usually after 48 hours) may lead to full thickness gangrene and thus perforation.

2. Which of the following patient criteria would most strongly cause you to choose open surgical management over laparoscopic management of acute appendicitis?

- Patient has a leukocyte count greater than 20,000
- Patient has a morbid obesity with BMI>40
- Patient presents with a fever >40 C
- +Patient has multiple adhesions from prior lower abdominal surgeries

Correct Answer: Patient has multiple adhesions from prior lower abdominal surgeries

Explanation: There are multiple contraindications to laparoscopic appendectomy, including hemodynamic instability, hypotension, cardiovascular compromise, coagulopathy, abdominal wall sepsis, large ventral hernia, and extensive adhesions from previous RLQ or pelvic surgery. High leukocytosis, obesity, and fever may make laparoscopic appendectomy more difficult but, are not absolute contraindications.

3. How urgently must laparoscopic appendectomy be performed following diagnosis of acute appendicitis?

- Within 1 hour
- Within 12 hours
- +Within 24 hours
- Within 1 week

Correct answer: Within 24 hours

Explanation: Performing a laparoscopic appendectomy 12-24 hour safter diagnosis of appendicitis was not associated with an increased risk of perforation. However, delaying for > 48 hours was associated with increased risk of surgical site infections and other complications. As patients await surgery, they



should be admitted to the hospital and receive IV hydration, pain control, and antibiotics. For certain patients, interval appendectomy is the more appropriate choice. Interval appendectomies involve administering antibiotics and performing surgery 4-6 weeks later. For patients with perforated appendicitis with abscess or phlegmon, interval appendectomy allows local inflammation to subside and lowers the risk of postoperative abscess or enterocutaneous fistula.

4. Which of the following is an advantage of laparoscopic over open management of acute appendicitis?

- No requirement for perioperative antibiotics
- Use of spinal anesthesia
- Lower equipment cost
- +Decreased risk of wound infection

Correct answer: Decreased risk of wound infection

Explanation: Laparoscopic appendectomy is associated with lower wound infection rates compared to open appendectomy. However, there is an increased risk of intra-abdominal abscesses in laparoscopic appendectomy.

5. Which of the following is true regarding the use of antibiotic treatment versus surgical management of appendicitis?

- Overall complication rates are significantly lower in patients treated with antibiotics
- Antibiotic therapy for appendicitis decreases length of hospital stay
- Among patients who receive antibiotics for appendicitis, 100% will eventually undergo appendectomy
- +Antibiotics are a reasonable management option for both complicated and uncomplicated appendicitis

Correct answer: Antibiotics are a reasonable management option for both complicated and uncomplicated appendicitis

Explanation: Antibiotics have been shown to be noninferior to surgery in the management of acute appendicitis through various randomized control trials, including the CODA and APPAC trials. In the CODA trial, overall complication rates at 30 days were shown to be higher in patients receiving antibiotics, compared to those who underwent appendectomy (8.1% vs. 3.5%). In the APPAC trial, length of hospital stay was statistically significantly shorter in the surgical group than the antibiotics group. Among patients who initially receive antibiotics, 25%-30% will eventually undergo appendectomy for recurrent appendicitis. While more studies are warranted, we generally discourage the use of nonoperative management in resource-limited settings with hospital access problems.

6. What is the standard pressure of pneumoperitoneum for a standard transabdominal laparoscopic procedure in adults?

- 5 mmHg
- 10 mmHg
- +15 mmHg
- 20 mmHg

Correct answer: 15 mmHg

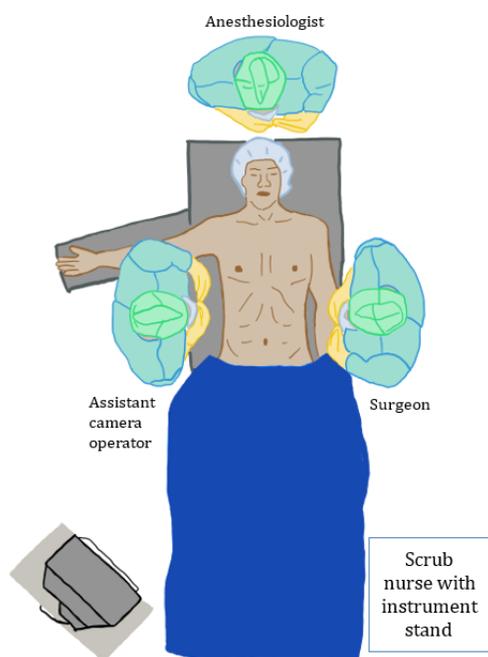
Explanation: A pressure of 15 mmHg is commonly used, allowing sufficient insufflation without compromising respiration or hemodynamics in a patient with normal cardiovascular reserve.

7. What is the proper positioning of a patient undergoing laparoscopic appendectomy?

- Supine position, Trendelenberg, left arm tucked with surgeon and camera on right side
- +Supine position, Trendelenberg, left arm tucked with surgeon and camera on left side
- Prone position, reverse Trendelenberg, both arms tucked with surgeon and camera on right side
- Supine position, reverse Trendelenberg, right arm tucked with surgeon and camera on right side

Correct answer: Supine position, Trendelenberg, left arm tucked with surgeon and camera on left side

Explanation: The patient should be placed in supine position. The right arm might be extended for IV line and BP cuff access by the anesthesia team. The left arm bearing a pulse oximeter can be safely tucked in at the patient's side. This allows for movement of the surgeon, who should be positioned at the left side of the table. The monitor is placed on the opposite side (right side), either directly across the operating team or towards the foot of the bed. The scrub nurse and instrument stand are positioned towards the foot of the bed. In order to have a good view of the appendix intraoperatively, the patient may need to be placed in Trendelenburg, with a left tilt of the table.



8. Which of the following trocars should be placed first during a laparoscopic appendectomy?

- Camera port at RUQ
- +Camera port at umbilicus
- Instrument port at LLQ
- Instrument port at suprapubic region

Correct answer: Camera port at umbilicus



Explanation: The most common site of entry for the first trocar is the periumbilical region due to the absence of fat or muscle between the skin and peritoneum at this location. The midline abdominal wall is absent of important vessels and nerves and is thus a preferred initial access site.

9. Which of the following demonstrates the basic steps of a laparoscopic appendectomy?

+Trocar placement, locate appendix, bluntly dissect cecum base, divide the mesoappendix, divide appendix base, remove appendix

-Locate appendix, trocar placement, bluntly dissect cecum base, divide appendix base, remove appendix

-Trocar placement, locate appendix, divide the mesoappendix, divide appendix base, bluntly dissect cecum base, remove appendix

-Trocar placement, locate appendix, divide appendix base, divide the mesoappendix, bluntly dissect cecum base, remove appendix

Correct answer: Trocar placement, locate appendix, bluntly dissect cecum base, divide the mesoappendix, divide appendix base, remove appendix

10. While performing a laparoscopic appendectomy, you quickly dissect the mesoappendix and notice mild bleeding. Which of the following is the next best step?

-Convert to open appendectomy

+Apply direct pressure with the instrument to control the bleeding

-Control the bleeding by ligating the ileocolic artery

-Turn down pneumoperitoneum and observe

Correct answer: Apply direct pressure with the instrument to control the bleeding

Explanation: Minor bleeding may be controlled laparoscopically. You can first try to apply direct pressure to the site of bleeding using an atraumatic laparoscopic grasper. For larger bleeding sites, direct tamponade with a gauze inserted through the larger port may help. Cautery is probably the most commonly used technique to control minor bleedings laparoscopically and controls the majority of cases. Mesoappendix ligation is also an alternative method to control intraoperative bleeding, although it might be technically difficult for many surgeons. If the bleeding cannot be controlled laparoscopically, then you would convert to open appendectomy. Ignoring the issue by reducing insufflation and observing would not be appropriate. Ligation of the ileocolic artery would cause ischemia to the cecum as it is part of the main trunk.