

**The precision of hand-held ultrasound machines for the diagnosis of
bowel inflammation in intestinal ultrasound**

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Introduction

Technological advances in the field of ultrasonography and the growing experience of ultra-sonographers have contributed to the advent of ultrasound as a clinically important, noninvasive imaging modality in inflammatory bowel disease (IBD). High-resolution assessment of the bowel layers as well as visualization of possible intestinal and extraintestinal pathologies (such as stenosis, abscesses, or fistulas) can be attained plainly using intestinal ultrasound (IUS).

Intestinal ultrasound can be used for the initial evaluation and follow-up of patients with clinically suspected IBD. Thickening of the bowel wall is the most significant ultrasonographic feature of Crohn's disease (CD) and is found to be a valid marker of inflammation in CD. Transmural remission of the small and large bowel is defined by bowel wall thickness (BWT) ≤ 3 mm. Other ultrasonographic signs of active disease including pseudo stratification of the bowel wall, mesenteric and adipose hypertrophy, enlargement of lymph nodes, and enhancement of blood flow in the bowel wall.

One of the major obstacles in implementing intestinal ultrasound services for IBD patients is the costs related to ultrasound machines. The costs of the mid-range (and higher levels of quality) ultrasound machine are considerable, and although large medical centers in developed countries can obtain ultrasound machines, smaller centers and centers in undeveloped countries may struggle with the cost of the machines. The inability to perform a point-of-care intestinal ultrasound impedes IBD patients' medical treatment.

Recently, some large US companies (such as GE and Philips) developed new models of hand-held small ultrasound machines. Those machines are affordable, and if their quality will be proven to be good enough for the detection of bowel inflammation and complication, the use of intestinal ultrasound can potentially increase, allowing better care for IBD patients.

Our idea is to compare the quality of hand-held US machines and that of mid-range and high-end US machines for the detection of bowel wall inflammation in IBD.

Methods

The project will examine the precision of 2 different handheld US machines (GE VSCAN air and Philips Lumify) for the detection of bowel inflammation and complication in Crohn's disease patients.

Study population

The study population will include 150 consecutive Crohn's patients undergoing intestinal ultrasound exams at the discretion of their treating physician.

All patients will go through an examination by a hand-held ultrasound machine. All exams will be followed by a high-end ultrasound machine (GE-S8 OR GE-E9) by the same performer.

Intestinal ultrasound

All exams will be performed using the same method: starting with a low-frequency curved array transducer, followed by examination using a high-resolution linear array transducer. All examinations will be performed without any preceding preparation, using a consistent technique and protocol, beginning the examination with the terminal ileum and the proximal to distal colon, followed by a complete examination of the small bowel. Assessment will be performed for features of inflammation, especially bowel wall thickness (>3 mm). Bowel wall thickness ≤ 3 mm is significantly associated with endoscopic and transmural remission, as measured by magnetic resonance imaging and normal C-reactive protein levels.

Comparison will include the ability to image each bowel segment (rectum, sigmoid colon, left colon, transverse colon, right colon, terminal ileum, and other small bowel segments) by each ultrasound machine type using convex and linear transducers.

Other parameters to be reported and compared between machines will include:

1. Bowel wall thickness of each segment (numerical in mm)
2. Disappearance of bowel wall layers (pseudosratification) (Y/N)
3. Blood flow within the bowel wall (as described by the Limberg score 0-3)
4. Mesenteric fat hypertrophy (Y/N/Uncertain)
5. Lymph node enlargement (Y/N, maximal size)
6. Complications: stricture, fistula abscess (Y/N)

Each patient will go through 2 exams- one using the handheld machine and the other using the regular machines. Images and cineloops of each segment in transverse and cross sectional planes will be stored in the ultrasound (handheld and high end\premium) for further re-evaluation. All images will be anonymized automatically or by cropping the metadata.

The images will be coded by the study coordinator and will be stored in 3 different places: A hospital computer, the study coordinator's computer and in a cloud drive. Only the investigators and the study coordinator will have permissions to access the stored data.

Images and cineloops from each segment will be stored (see later) and re-evaluated by one of the other investigators for signs of inflammation as described earlier.

The ultrasonographic finding on the high-end ultrasound machine (GE S8) will be regarded as the gold standard for comparison with the other types of ultrasound machines.

Inclusion criteria:

1. Age>18
2. Previously known or suspected Crohn's disease.
3. BMI< 30.

Exclusion criteria

1. Any kind of stoma.
2. Inability to demonstrate any bowel segment using the gold standard high-end ultrasound machine.
3. Pregnancy.

Hand-held US machines evaluation

Prior to the initiation of the study, each investigator will perform 20 exams on each of the hand held machines as a learning curve phase.

The ease of the operation of each system and the overall satisfaction for the use of each machine will be graded after each exam by all investigators using a lickert scale of 0 to 10

Primary outcome

1. The capability to imagine each bowel segment (rectum, sigmoid colon, left colon, transverse colon, right colon, terminal ileum, and other small bowel segments) using hand-held and mid-range ultrasound machines type using convex and linear transducers.
2. The capability to detect bowel wall thickening using hand-held and mid-range ultrasound machines type using convex and linear transducers.

Secondary outcomes

1. The accuracy of bowel wall thickness measurements using hand-held US and mid-range US machines when compared to the gold standard.
2. The capability to detect other signs of inflammation using hand-held US and mid-range US machines when compared to the gold standard, including:
 - i. Disappearance of bowel wall layers (pseudosratification) (Y/N)
 - ii. Blood flow within the bowel wall (as described by the Limberg score 0-
 - iii. Mesenteric fat hypertrophy (Y/N/Uncertain)
 - iv. Lymph node enlargement (Y/N, maximal size)
3. The capability to detect complications (stricture, fistula and abscess) using hand-held US and mid-range US machines when compared to the gold standard.

Data management:

All images will be anonymized automatically or by cropping the metadata.

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