Supplemental Materials

- OCT-TCE procedure training

A half-day training was provided separately to each participating center on-site, by the same trainers from MGH. Training sessions included 1) a general overview of the TCE technology, 2) TCE imaging procedure training including general preparation, device preparation, capsule swallowing/imaging/removal, with exemplary images for tissue type identification, and 3) TCE capsule high-level disinfection and packaging training presentation with video guidance. The operators from the different sites practiced the TCE imaging procedure on a human body phantom after the presentations. In addition, the first TCE imaging procedure at each site was conducted under the supervision of a trainer from MGH.

Averaged learning curves from the external participating centers are shown in Fig. S1. Scores represent the key characteristics (time, SCJ and stomach imaged, and good quality images) that define a successful procedure. As can be seen in Fig. S1, after training, the external sites were immediately able to proficiently conduct the TCE procedure. Proficiency increased slightly with number of subjects imaged.
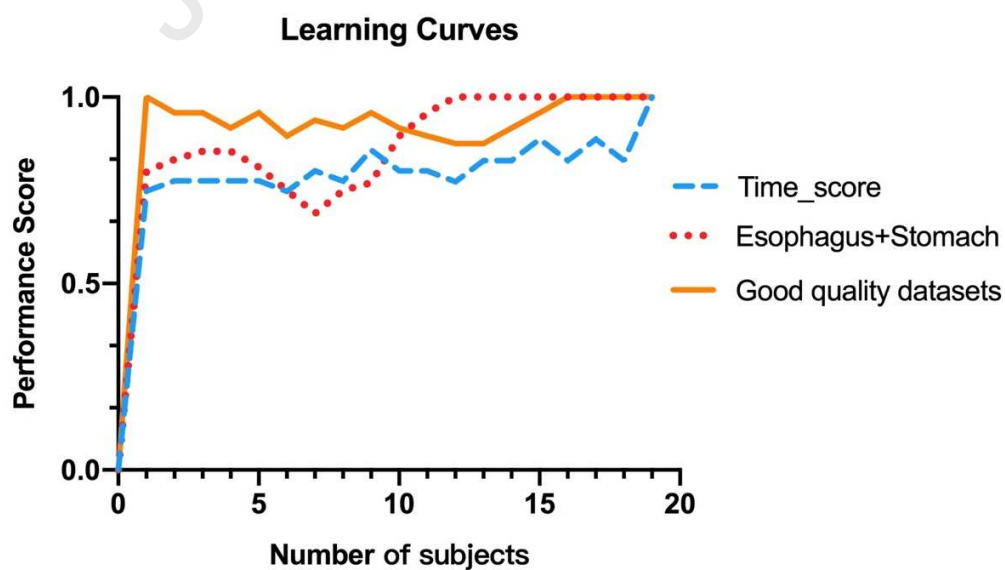
Fig. S1. The averaged learning curves of the external participating centers (Kansas City VA, Mayo Jacksonville, Mayo Rochester and Columbia University). Time_score = 1 if procedural time < average procedural time, 0.66 if average procedural time < procedural time < 1.5x average procedural time, 0.33 if 1.5x average procedural time < procedural time < 2x average procedural time, and 0 if procedural time > 2x average procedural time. The Esophagus+Stomach score is the percentage of pullback datasets that contained both esophagus and stomach. The good quality datasets score is the percentage of pullback datasets that had adequate image sensitivity and visible mucosa.

- Histograms of capsule number of swallow attempts, procedural duration, imaging duration, and post procedural questionnaire results.

Most patients who swallowed the capsule were able to do so in their first attempt (63.1%), whereas a minority required 2 (21.6%), 3 (9.0%), 4 (3.6%), or 5 (2.7%) attempts. The mean procedural duration was 8.01 ± 2.98 minutes, and the mean imaging duration was 5.47 ± 1.94 minutes. The post-procedural questionnaire showed that patients who swallowed the capsule experienced little overall discomfort (median = 2, IQR: 1-4, Scale 0 = none, 10 = severe) during the procedure, and the majority (84.7%) stated that they likely preferred TCE over endoscopy, including 70 (63.1%) patients reported extremely likely and 24 (21.6%) patients reported somewhat likely. The questionnaire also showed that 96.4% of patients would recommend TCE if it was approved for clinical use, including 81 (73.0%) patients who would definitely recommend and 26 (23.4%) patients who would probably recommend. The post procedural questionnaire results are listed in Table 2. Histograms of capsule number of swallow attempts,

procedural duration, imaging duration, and post procedural questionnaire results are shown in Fig. S2.
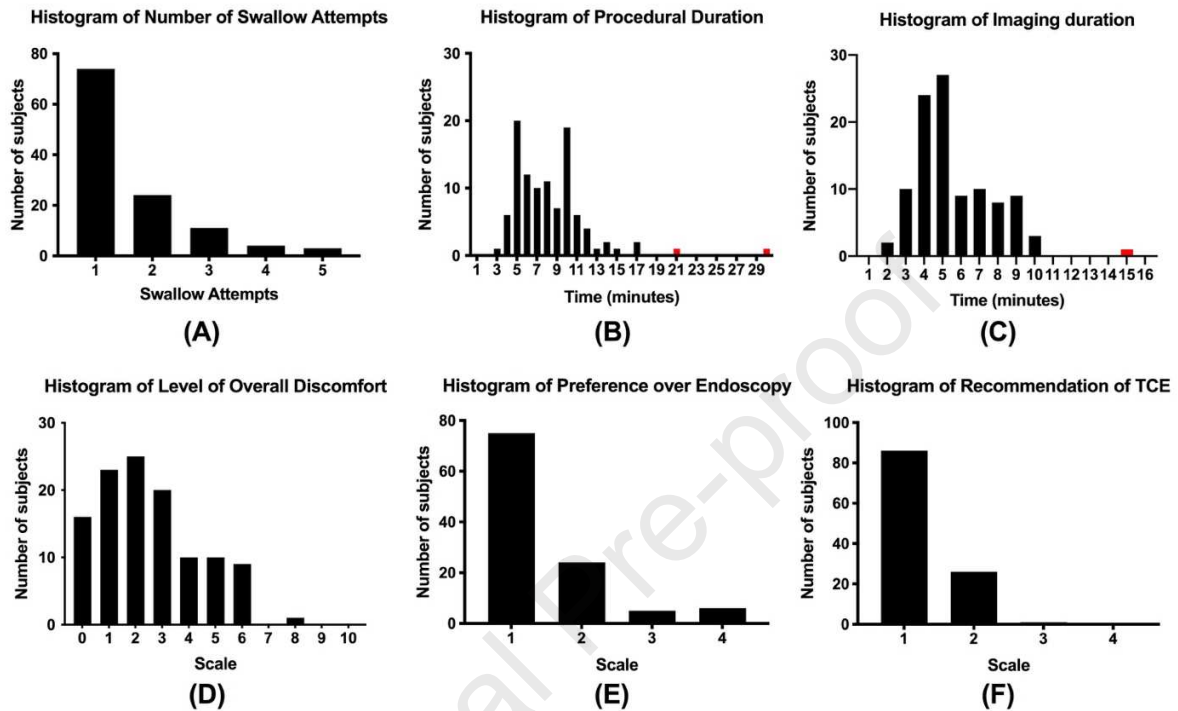

Figure S2. Distribution of (A) Number of capsule swallow attempts, (B) procedural duration, (C) imaging duration, (D) level of overall discomfort (Scale 0 = none, Scale 10 = severe), (E) procedure preference over endoscopy (Scale 1 = extremely likely, Scale 2 = somewhat likely, Scale 3 = somewhat unlikely, Scale 4 = extremely unlikely) and (F) whether patient would recommend TCE if it was approved for clinical use (Scale1 = definitely, Scale 2 = probably, Scale 3 = probably not, Scale 4 = definitely not). The red bars in (B) and (C) indicate outliers.

• Comparison of OCT-TCE and VLE images from a patient with biopsy proven BE

The OCT-TCE images and VLE images that were acquired from a biopsy confirmed BE-positive patient on the same day were compared. The OCT-VLE images were obtained through an inflated 20 mm balloon. As shown in Fig. S3(A, C) and Fig. S3(B, D), cross-sectional OCT-TCE

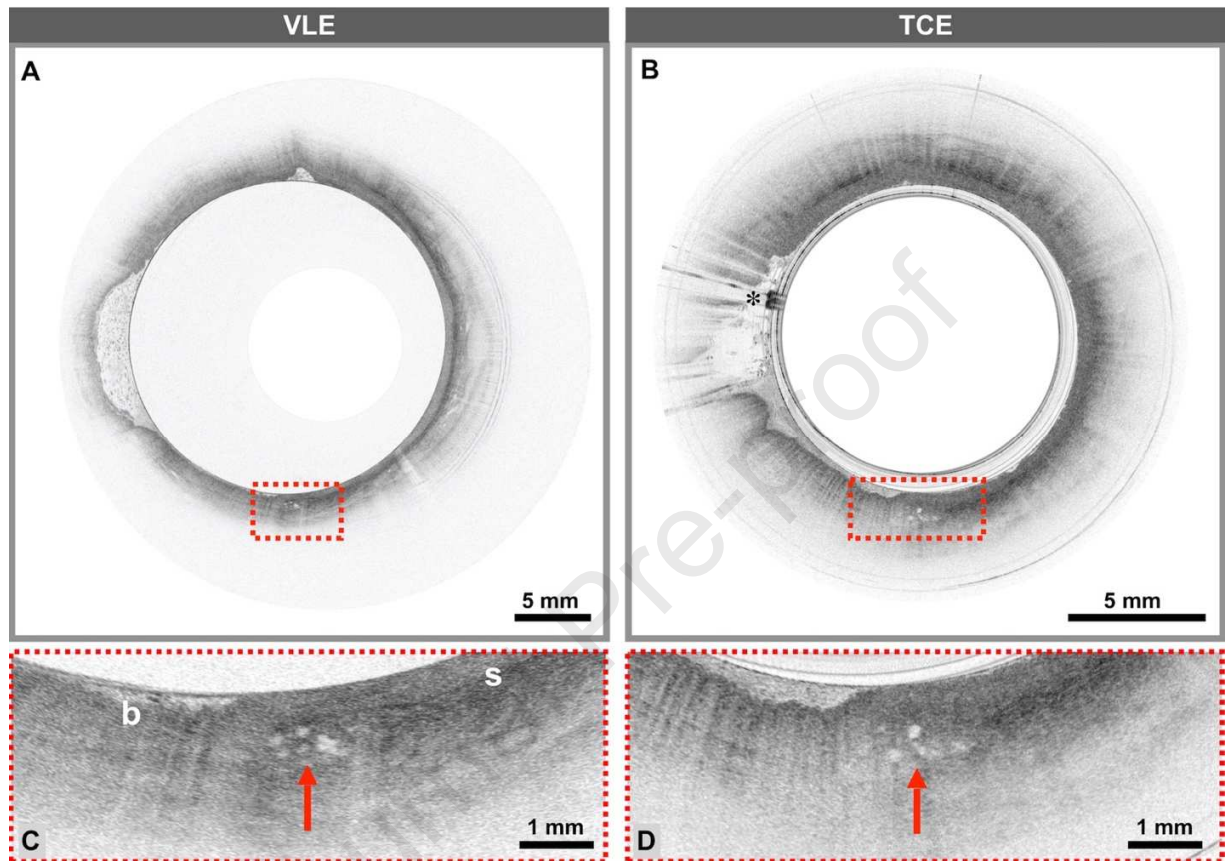enabled clear identification of the same tissue microscopic architectural features as that seen by VLE.

Figure S3. Comparison of VLE and TCE images from a patient with biopsy proven BE (images acquired on same day). (A) Cross-sectional VLE image. (B) Corresponding cross-sectional TCE image. (C) Magnified portion of VLE image (A, dotted box) showing BE on the left (b), squamous epithelium (s) on the right and an interposed cluster of glands (arrow). (D) Magnified portion of TCE image (B, dotted box) demonstrating the same cluster of glands (arrow) and BE (b), squamous epithelium (s). Scale bars, 5 mm for (A) and (B) and 1 mm for (C) and (D). The asterisk indicates the image shadows caused by electrical wires that power the distal micro-motor.