

Small-bowel capsule endoscopy with panoramic view: results of the first multicenter, observational study (with videos)

Tontini GE, et al. *Gastrointestinal Endoscopy* 2017; (85)2: 401-408e

Objective

To assess the efficacy and safety profile of CapsoCam® SV capsule's 360° panoramic view in a large series of consecutive patients from 7 European institutions. This was the largest clinical study on CapsoCam to date.

Study Design

The study included 172 patients with reports of suspected small-bowel bleeding without ongoing, overt bleeding or Crohn's disease. Patients underwent VCE with CapsoCam SV-1 between January 2011 and January 2015, which broke down to 79.6% of the total n value. After CapsoCam SV-2 was released, investigators switched to SV-2 until November 2015 (20.4%). Each patient was assessed on technical, clinical and safety data. The study had four readers. Patients were divided into 2 groups:

- Patients with anemia or obscure GI bleeding
- Patients with suspected or established Crohn's disease

Findings:

Clinical Outcomes

- 685 lesions found in 172 VCEs including 125 small-bowel lesions in one outlier patient
- Excluding the outlier, 45% of lesions were high probability (P2) findings
- 80% of lesions were in the small bowel
- 25% of lesions were in the upper GI, 4% in the lower GI
- Diagnostic Yield
 - 69 VCEs had at least one P2 finding (40.1%)
 - OGIB patients = 42.2%
 - Crohn's patients = 30.0%

Technical Outcomes

- Video reliability was adequate in 99% of patients
- Capsule failure occurred in 4 cases (2.3%): 3 had downloading issues & 1 damaged by an investigator
- Complete enteroscopy rate = 90.2%
- Mean GTT = 30 min, Mean SBTT = 268 min
- Identification of ampulla of Vater = 32.7% of patients

Safety Outcomes

- In four patients, the VCE was released under endoscopic assistance according to the history of gastric surgery or previous VCE affected by prolonged GTT
- Capsule retention occurred in one patient (0.58%)
 - CT showed patient had a stricturing small-bowel mass
- No additional incidents or AEs were reported

Study Limitations

The study had an observational design, therefore all results are merely descriptive. Since data from the frontal-view capsule examinations was performed in the study timeframe at the participating centers were not collected systematically, the centers could not perform head-to-head comparisons of lateral-view and standard frontal-view VCE systems. The participating studies collected data pertaining to the two most common clinical indications for capsule endoscopy, so it possible that this approach generated selection bias.

Conclusions

This study confirmed that CapsoCam SV-1 and SV-2 is safe and provides clinical and technical performances comparable to frontal-view VCEs. The authors also pointed out that CapsoCam SV appears to be effective in scoping areas such as the proximal small bowel and upper GI tract.