# **Publication Summary**

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

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# **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 represented 79.6% of the total analysis population. After CapsoCam SV-2 was released, investigators switched to SV-2 until November 2015 (20.4%). Each patientwas 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 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 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.

