Evidence Table

Clinical Area: Capsule endoscopy for obscure gastrointestinal bleeding.

Study Type: Comparison of diagnostic tests.

Study Aim: To investigate the role of wireless capsule endoscopy (CE) in detecting lesions of the small bowel in patients with unexplained iron deficiency anemia (IDA) after a negative endoscopic work-up.

Outcomes
- **Primary**: Diagnostic yield, and resolution of IDA.

Design
- **Number of subjects**: N=253 referred for IDA investigation, N= 51 underwent CE.
- **Description of study population**: These were patients referred to CE for the evaluation of IDA in a gastroenterology department in Athens, Greece, between December 1st 2003 and December 31st 2004. 53% were men and 47% women. Their median age was 53 years (range 19-81 years), the median duration for IDA was 19.7 months, and the mean hemoglobin level was 10.2 g/dl.
- **Inclusion criteria**: Patients with IDA defined as blood hemoglobin level <13.8g/dl for men, <11.5g/dl for postmenopausal women, and <11 g/dl for premenopausal women, a plasma ferritin level <30µg/l, and a mean corpuscular volume <80fl.
- **Exclusion criteria**: Evidence of active or obscure overt GI bleeding, epistaxis, menometrorrhagia, history of heavy menstrual loss, active alcohol or drug abuse, liver cirrhosis, prior gastrectomy, recent or chronic use of aspirin or nonsteroidal anti-inflammatory drugs, use of anticoagulants or antiplatelets, vegetarian diet, iron-deficient high risk diet, hematological disorders, or other non GI disease likely to cause IDA. Other exclusion criteria included history of bowel obstruction or major abdominal surgery, implanted pacemaker, or a psychiatric condition that would hinder providing consent or compliance with study.
- **Consecutive patients?**: The patients referred for IDA investigation were consecutive, but not those who underwent CE.
- **Intervention**: Eligible patients underwent diagnostic endoscopic work-up including esophagogastroduodenoscopy (EGD) with biopsies, ileocolonoscopy, and/or serological tests (upper GI series and push enteroscopy were not included among the diagnostic procedures performed) Those with negative results were examined by CE Given M2A video capsule system according to the manufacturer’s instructions. They also underwent enteroclysis examinations.
- **Follow-up duration**: Ranged from 8 to 18 months with a median of 12 months.
- **Completeness of follow-up**: 94.1% complete.
Validity

- **Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?** The results of CE were compared to enteroclysis not to the gold standard of intraoperative enteroscopy. The radiologists who reviewed the enteroclysis radiographic images were blinded to the results of the CE.

- **Was “normal” defined?** Yes.

- **Appropriate spectrum of disease?** No.

- **Methods described in enough detail to enable you to replicate the test?** Yes.

- **Reproducible results?** Probably.

**Conclusions regarding validity of methods:**

This small study had its advantages and limitations. It had well defined eligibility criteria, an average of 12 months of follow-up, and the results of CE were blindly compared to those of enteroclysis. However, the study was too small, was conducted among a highly selected group of patients, and no comparison was not made with the gold standard.

**Results**

253 patients were referred for evaluation of IDA during the study period. In 202 (80%) one likely cause for IDA was diagnosed with standard work-up, and 51 underwent CE

**Diagnostic yield**

<table>
<thead>
<tr>
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<th>Capsule endoscopy</th>
<th>Enteroclysis</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>29*/51 (56.9%)</td>
<td>6**/51 (11.8%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Angiodysplasia in 12 patients, multiple ulcers suggestive of Crohn’s in 6 patients, diffuse erosions in 4, solitary ulcers in 3, polyps in 2, and tumors in 2 patients.
**Multiple ileal ulcers in 3 patients, tumors in 2 patients and a polyp in one patient

**Adverse events:**

The capsule failed to reach the cecum during its battery life in 3 (5.9%) patients.

**Resolution of IDA after follow-up**

<table>
<thead>
<tr>
<th></th>
<th>Cases diagnosed with CE</th>
<th>Cases not diagnosed with CE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=29/51</td>
<td>n=22/51</td>
</tr>
<tr>
<td>No</td>
<td>29</td>
<td>15</td>
</tr>
<tr>
<td>%</td>
<td>100</td>
<td>68%</td>
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<tr>
<td>Complete resolution</td>
<td>29</td>
<td>15</td>
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Authors’ Conclusions

The authors concluded that capsule endoscopy is superior to enteroclysis in detecting small bowel lesions in patients with unexplained iron deficiency anemia. They recommended it as the diagnostic test of choice after unremarkable standard endoscopic evaluation.

Reviewer’s Conclusions

This was a small study performed on a highly selected group of patients which may limit generalization of the results. Those who underwent CE were not diagnosed with other standard work-up. Upper GI series and push enteroscopy were not included among the diagnostic procedures performed. The authors compared the yield of CE with enteroclysis which is not considered as a gold standard, and the results were presented as diagnostic yields not sensitivity and specificity. The long-term follow-up shows that all 29 patients (56% of the total) with a positive CE had their anemia resolved after receiving an intervention or iron therapy. Two thirds of the patients with negative CE findings also showed complete resolution of their anemia by the end of the follow-up duration.