The Aer-O-Scope™ Colonoscopy System is Safe and Effective for Colonoscopy in Humans

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Background:
The self-propelled, disposable Aer-O-Scope™ Colonoscope (AOS) with 360° view is designed to enhance visualization as well as minimize risk for perforation and infection transmission, while shortening operator training time associated with conventional colonoscopy (CC) (Figures 1, 2 and 3).

Objective:
Testing the AOS for efficacy and safety.

Design: Single center, prospective study with AOS immediately followed by CC.

Setting: Gastroenterology unit at tertiary care hospital.

Patients: Adults presenting for colorectal cancer screening. Initial patients necessary for AOS operators to achieve proficiency made up the "training cohort". Subsequent enrolled patients made up the "study cohort".

Interventions: AOS was performed to the cecum, where anatomic landmarks were photographed and distinctive mucosal suction-marks made. During AOS withdrawal, polyps were recorded and similarly marked. At second-pass CC, any potential mucosal damage and suction-marks from the AOS, as well as polyps, were recorded (Figures 4 and 5).

Main Outcome Measurements: 1) AOS cecal intubation rates, confirmed by anatomic landmarks and/or residual marks seen at subsequent CC. 2) Frequency and severity of adverse events and mucosal damage with AOS.

Secondary Endpoints: 1) Subjective procedure-propriety, evaluated by physician-operator based on training cohort 2) Documenting pathologies visualized with AOS.

Results:
56/58 enrolled patients completed the study. Proficiency with AOS was attained after 8-10 procedures. Cecal intubation was successful in 98.2% (55/56 subjects, 95%CI 90.4-99.9%), including 100% (95%CI 90.7-100%) of study cohort and 94.4% (95%CI 72.7-99.9%) of training cohort.

Table 1. Aer-O-Scope™ Cecal Intubation & Safety Results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>Number of training procedures per physician (Training Cohort)</td>
<td>8</td>
</tr>
<tr>
<td>Total number of Aer-O-Scope™ procedures (Study Cohort)</td>
<td>40</td>
</tr>
<tr>
<td>Number of procedures not counted (poor prep)</td>
<td>2</td>
</tr>
<tr>
<td>Total number of confirmed cecal intubations</td>
<td>38</td>
</tr>
<tr>
<td>Average cecal intubation time</td>
<td>10min</td>
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<tr>
<td>Cecal intubation success rate</td>
<td>100%</td>
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No significant adverse events, immediate or delayed, in all procedures

Cecal intubation was confirmed by second-pass CC in 52/55 (94.5%) patients (Table 1). No mucosal damage or adverse events were reported. AOS detected 87.5% of polyps seen in tandem CC, including all polyps >5mm.

Conclusions:
AOS was highly successful and safe in attaining complete colonic intubation, a prerequisite for effective colorectal cancer screening in humans.