CLinical EVAluation of the EndoRings device: “The CLEVER study”

Interim results of a randomized, multicenter, tandem colonoscopy study

Vincent K. Dik1, Ian M. Gralnek1,2,3, Ori Segol4, Alain Suissa2,3, Tim D.G. Belderbos1, Leon M. Moons1, Meytal Segev5, Sveta Domanov2,3, Douglas K. Rex6, Peter D. Siersema1

1 University Medical Center Utrecht, Utrecht, the Netherlands. 2 Rambam Health Care Campus, Haifa, Israel. 3 Elisha Hospital, Haifa, Israel. 4 Lady Davis Carmel Medical Center, Haifa, Israel. 5 EndoAid Ltd, Caesarea, Israel. 6 Indiana University Hospital, Indianapolis, IN, United States.

Introduction

Adenomas can be missed with standard colonoscopy due to inadequate visualization of proximal aspects of folds and inner curves of flexures.1-4 EndoRings device (EndoAid Ltd., Caesarea, Israel) is a silicone rubber device that is fitted onto the distal end of the colonoscope. Its flexible circular rings engage and mechanically stretch colonic folds during withdrawal.

Primary study aim

To compare adenoma miss rates of standard colonoscopy and colonoscopy with the EndoRings.

Secondary study aims were to compare

- Polyp miss rates, adenoma detection rates, polyp detection rates, cecum intubation times, withdrawal times, total procedure times and adverse events.

Methods

Study design

Multicenter, randomized tandem colonoscopy study between July 2013 and June 2014 with six endoscopists.

Inclusion criteria

Subjects between 40-75 years with an indication for screening, surveillance or diagnostic colonoscopy. Written informed consent was obtained.

Exclusion criteria

History of colonic resection, abdominal or pelvic radiation therapy, inflammatory bowel disease, polyposis syndrome, colonic stricture, acute lower GI bleeding, diverticulitis or toxic megacolon.

Randomization

Arm A: Standard colonoscopy > EndoRings colonoscopy
Arm B: EndoRings colonoscopy > Standard colonoscopy

Procedures

- Minimal withdrawal time 6 minutes.
- Polyps found during first procedure were immediately removed.
- Diminutive rectal polyps with hyperplastic appearance excluded.

Sample size calculation

Expected 25% difference in adenoma miss rates (per lesion analysis) with mean number of adenomas 0.75 per patient. Two-sided chi-square test with 80% power and alpha=0.05. With expected 10% drop-outs 126 subjects required.

Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>EndoRings first</th>
<th>Standard first</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>Subjects</td>
<td>57</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>Age (years), mean ± SD</td>
<td>57.9 ± 9.1</td>
<td>59.6 ± 9.3</td>
<td>0.322</td>
</tr>
<tr>
<td>Female sex, n (%)</td>
<td>16 (28.1)</td>
<td>29 (49.2)</td>
<td>0.020</td>
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<tr>
<td>BBPS, mean ± SD</td>
<td>7.8 ± 1.1</td>
<td>7.8 ± 1.1</td>
<td>0.838</td>
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<tr>
<td>Indication, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>17 (29.8)</td>
<td>17 (28.8)</td>
<td></td>
</tr>
<tr>
<td>Surveillance</td>
<td>21 (36.9)</td>
<td>19 (32.2)</td>
<td>0.800</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>19 (33.3)</td>
<td>23 (39.0)</td>
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Primary outcome

Adenoma miss rates

Standard colonoscopy: 56 of 106 polyps = 52.8%
EndoRings device colonoscopy: 11 of 121 polyps = 9.1%  P<0.001

Adenoma detection rates (ADR)

Standard colonoscopy: 17 of 59 subjects = 28.8%
EndoRings device colonoscopy: 29 of 57 subjects = 50.9%  P = 0.015

Polyp detection rates (PDR)

Standard colonoscopy: 24 of 59 subjects = 40.7%
EndoRings device colonoscopy: 39 of 57 subjects = 68.4%  P < 0.001

Time endpoints

<table>
<thead>
<tr>
<th></th>
<th>Standard</th>
<th>EndoRings</th>
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<tbody>
<tr>
<td>Cecum intubation time</td>
<td>8.4 ± 5.6 min.</td>
<td>9.3 ± 7.3 min.</td>
</tr>
<tr>
<td>Withdrawal time</td>
<td>7.2 ± 2.2 min.</td>
<td>7.4 ± 1.9 min.</td>
</tr>
<tr>
<td>Total procedure time</td>
<td>18.5 ± 8.2 min.</td>
<td>21.6 ± 8.9 min.</td>
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</tbody>
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Adverse events

No adverse events related to the EndoRings device occurred during the conduct of this study.

Conclusion

This randomized tandem study demonstrates that colonoscopy with EndoRings device is safe and has significantly lower adenoma and polyp miss rates as compared to standard colonoscopy.

References