CLinical EValuation of the EndoRings: "The CLEVER study"

Interim results of a randomized, multicenter, tandem colonoscopy study

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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 (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

	EndoRings first	Standard first	P-value[1]
Subjects	57	59	-
Age (years), mean ± SD	57.9 ± 9.1	59.6 ± 9.3	0.322
Female sex, n (%)	16 (28.1)	29 (49.2)	0.020
BBPS, mean ± SD	7.8 ± 1.1	7.8 ± 1.1	0.838
Indication, n (%)			
Screening	17 (29.8)	17 (28.8)	
Surveillance	21 (36.9)	19 (32.2)	0.800
Diagnostic	19 (33.3)	23 (39.0)	

Primary outcome

Adenoma miss rates
Standard colonoscopy: 28 of 58 adenomas = 48.3%
EndoRings colonoscopy: 7 of 69 adenomas = 10.1% *P<0.001*

Secondary outcomes

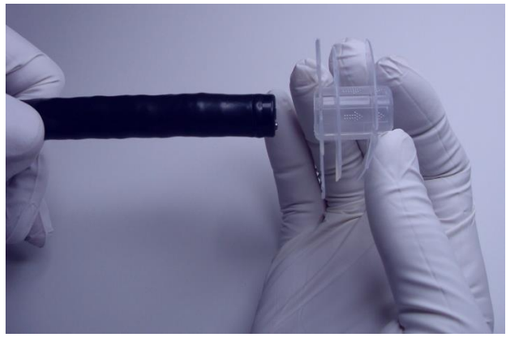
Polyp miss rates
Standard colonoscopy: 56 of 106 polyps = 52.8%
EndoRings colonoscopy: 11 of 121 polyps= 9.1% *P<0.001*

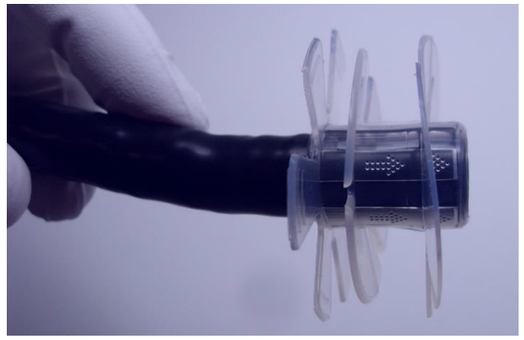
Adenoma detection rates (ADR)
Standard colonoscopy: 17 of 59 subjects= 28.8%
EndoRings colonoscopy: 29 of 57 subjects = 50.9% *P = 0.015*

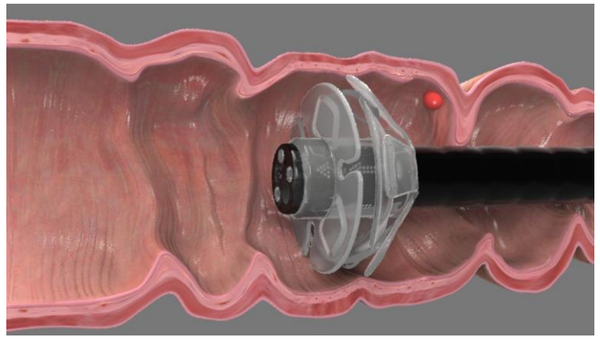
Polyp detection rates (PDR)
Standard colonoscopy: 24 of 59 subjects= 40.7%
EndoRings colonoscopy: 39 of 57 subjects = 68.4% *P < 0.001*

Time endpoints	Standard	EndoRings	P-value
Cecum intubation time	8.4 ± 5.6 min.	9.3 ± 7.3 min.	0.142
Withdrawal time	7.2 ± 2.2 min.	7.4 ± 1.9 min.	0.286
Total procedure time	18.5 ± 8.2 min.	21.6 ± 8.9 min.	*0.001*

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







Conclusion

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

References

[1] Van Rijn, Am. J. Gastroenterol. 2006. [2] Gralnek, Lancet Oncol. 2014.
[3] Leufkens, GI Endoscopy 2011. [4] Pickhardt, Ann. Intern. Med. 2004.

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