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## The impact of fair colonoscopy preparation on colonoscopy use and adenoma miss rates in patients undergoing outpatient colonoscopy

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### Abstract

**Background**—The impact of fair bowel preparation on endoscopists' recommendations and adenoma miss rates in average-risk patients undergoing colonoscopy is unknown.

**Objective**—To assess the impact of fair bowel preparation on endoscopists' interval colonoscopy recommendations and miss rates in colonoscopies performed within 3 years of the index colonoscopy in average-risk patients undergoing colorectal cancer screening.

**Design**—Retrospective chart review.

**Setting**—Tertiary-care center.

**Patients**—Average-risk patients undergoing index colonoscopy for colorectal cancer screening between 2004 and 2006.

**Intervention**—Colonoscopy.

**Main Outcome Measurements**—Endoscopists' interval recommendations, adenoma miss rates.

**Results**—A total of 16,251 colonoscopy records were reviewed over a 2-year period. Of these cases, 1943 colonoscopies were performed for the sole indication of *average risk* or *screening*. Of these, fair bowel preparation was reported in 619 patients (31.9%). A repeat colonoscopy within 5 years was recommended in 70.4% of patients. The follow-up colonoscopy compliance rate within 3 years was 55.9%. Adenoma detection rates at index and follow-up colonoscopy were 20.5% and 28.2%, respectively. Of the 39 patients with follow-up colonoscopy within 3 years, the overall adenoma miss rate was 28%. Of the patients with an adenoma identified on follow-up colonoscopy, 13.6% had normal colonoscopy results on index examination.

**Limitations**—Retrospective design.

**Conclusion**—Fair bowel preparation led to a deviation from national guidelines with early repeat colonoscopy follow-up recommendations in nearly 60% of average-risk patients with normal colonoscopy results. In patients who returned for repeat colonoscopy within 3 years, the

overall adenoma miss rate was 28%. Further guidelines on timing for repeat colonoscopy for fair bowel preparation are needed.

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States.<sup>1</sup> In an effort to reduce CRC rates, national guidelines recommend specific CRC screening modalities starting at age 50 in average-risk patients. Colonoscopy is the only modality that has been shown to not only identify but also prevent CRC. In the National Polyp Study, colorectal cancer incidence was reduced by colonoscopic removal of adenomatous polyps.<sup>2</sup> In the follow-up study, Zauber et al<sup>3</sup> demonstrated a 53% reduction in long-term mortality with colonoscopic polypectomy of adenomatous polyps. Additionally, declining CRC incidence and mortality rates have been attributed to reduced exposure to risk factors and early detection and prevention through polypectomy.<sup>4</sup>

Over 14 million colonoscopies are performed yearly. Approximately 50% of these are ordered for CRC screening and surveillance. Adequate bowel cleansing is crucial to performance of quality colonoscopy.<sup>5</sup> Retained stool in the colon limits the detection of adenomas during colonoscopy. If the cleansing is inadequate, then repeat colonoscopy is required. The 2012 CRC screening guidelines now cite specific follow-up recommendations for poor bowel preparation and state that “in most cases the examination should be repeated within 1 year.”<sup>6</sup> Additionally, the new guidelines also give recommendations on bowel preparation that is graded as fair but adequate with the finding of small adenomas (< 10 mm); follow-up at 5 years should be considered. However, if cleansing is suboptimal, endoscopists often recommend repeat colonoscopies at shorter intervals (3-5 years) regardless of the presence of polyps.<sup>7-9</sup> Furthermore, prospective surveys of gastroenterologists also demonstrate that many gastroenterologists recommend follow-up colonoscopy sooner, specifically influenced by bowel preparation.<sup>10,11</sup>

Follow-up data in patients with suboptimal or inadequate bowel preparation is limited. Lebowhl et al<sup>12</sup> performed a retrospective review of colonoscopies for all indications with poor or fair bowel preparation and follow-up for 3 years. The authors found that among those with repeat colonoscopies, the adenoma miss rate was 27%. In another study by Chokshi et al<sup>13</sup> that reviewed the records of average-risk patients presenting for screening colonoscopy with inadequate bowel preparation, 33.8% had at least one adenoma missed, and the peradenoma miss rate was 47.9%. However, data on the impact of fair bowel preparation on endoscopists’ recommendations and the findings on repeat colonoscopy are lacking. Therefore, the aim of our study was to assess the impact of fair bowel preparation on interval colonoscopy recommendations and adenoma miss rates in follow-up colonoscopies performed within 3 years of the index colonoscopy in average-risk patients undergoing CRC screening. We hypothesized that fair colonoscopy preparation would affect recommendations for repeat colonoscopy in colonoscopies in the outpatient setting and lead to an increased adenoma miss rate.

## METHODS

### Study population

We conducted a retrospective review of an endoscopic database and the electronic medical records of colonoscopies performed at the University of Michigan medical procedure unit and 2 university affiliated outpatient ambulatory surgery centers (Livonia, Michigan and Ann Arbor, Michigan). Electronic medical records of consecutive, average-risk patients aged 50 to 65 years undergoing colonoscopy between July 1, 2004 and June 30, 2006 were reviewed. Only preparation qualities rated as fair by the gastroenterologist were included. Patients were excluded for concurrent GI symptoms (ie, anemia, overt or obscure GI blood loss, abdominal pain, diarrhea, constipation, unexplained weight loss); family history of

CRC; personal history of CRC, colon polyps, hereditary CRC syndrome, or inflammatory bowel disease; or incomplete colonoscopies (ie, failure to visualize the appendiceal orifice and cecum). Patients with follow-up recommendations for barium enema also were excluded. Institutional Review Board approval was obtained at the University of Michigan before study initiation.

### Endoscopist index colonoscopy follow-up recommendations

Screening and surveillance follow-up colonoscopy recommendations were reported via the ProVation Medical Systems (Wolters Kluwer Health, New South Wales, Australia) at the University of Michigan endoscopy sites. Numerous recommendation interval descriptors were available to accommodate the multitude of intervals given in light of unknown tissue histology. Furthermore, endoscopists could provide multiple recommendations within the same endoscopy report to ensure issuance of a follow-up interval for a broad spectrum of histologic findings. If the endoscopist issued only one broad interval (eg, repeat colonoscopy in 3 years), then the follow-up recommendation was assigned the corresponding interval. If recommendations specified tissue histology (eg, adenomatous or hyperplastic/benign polyps), and the corresponding histology was identified, then that recommendation was assigned to the patient (eg, if adenoma, then repeat colonoscopy in 2 years).

Recommendations reported as *based on pathology* were assigned accordingly: hyperplastic and/or benign polyps at 10 years and adenomatous polyps at 3 or 5 years, depending on size and number.

### Follow-up colonoscopy compliance

Each instance of colonoscopy recommendation compliance was determined by a second documented colonoscopy within the specified interval period plus 1 year. A 1-year lag was added to capture data for patients who underwent a second colonoscopy but may not have been eligible for insurance reimbursement until the end of the specified interval. Patients who received recommendations of more than 5 years were not included in the compliance rate analysis. Those who were lost to follow-up (defined as having last documented medical visits at a University of Michigan Healthcare System clinic before the recommended follow-up time) also were excluded from the analysis.

### Adenoma detection and adenoma miss rate

To quantify the impact of fair bowel preparation quality on the detection of adenomatous polyps, we included all patients in whom the cecum was reached on the index and follow-up colonoscopy. The adenoma detection rate was calculated by the percentage of patients with at least one adenoma. The adenoma miss rate was calculated as the total number of patients with adenomas detected on the follow-up colonoscopy within 3 years divided by the total number of patients with adenomas detected on the index colonoscopy plus follow-up colonoscopy within 3 years. Only the data of those patients who underwent index colonoscopy as well as follow-up colonoscopy were included in this calculation. The adenoma miss rates were calculated for all (or any size) adenomas and advanced adenomas (adenoma  $\geq 10$  mm) for the follow-up colonoscopy in those patients with optimal bowel preparation (excellent, good, and adequate).

### Patient and procedure data

For the index and follow-up colonoscopy, demographic and clinical data were collected on patient age, sex, race and/or ethnicity, body mass index, concurrent narcotic usage, and diabetic status. Colonoscopy procedure data were collected on the number, size, and histology of polyps and procedural difficulty and completion status. Endoscopist-level (ie,

years in clinical practice, sex) data were not collected because of Institutional Review Board privacy concerns.

### Statistical analysis

Descriptive statistics of patient characteristics were reported, and any comparisons between groups were done by using analysis of variance and  $\chi^2$  tests, as appropriate. Because of the descriptive nature of this study, we reported follow-up recommendation intervals and follow-up compliance by categorical colonoscopy findings (ie, normal, only hyperplastic polyps, 1-2 small adenomas, and 3+ small and/or 1+ large adenoma). Statistical analyses were performed by using SAS 9.2 (SAS Institute Inc, Cary, NC).

## RESULTS

Between July 1, 2004 and June 31, 2006, a total of 16,251 colonoscopies were performed at the University of Michigan endoscopy units, of which 1943 colonoscopies were performed for the sole indication of average-risk or screening. Of these, 619 outpatient colonoscopies (31.9%) had a fair bowel preparation quality and were included in our study (Table 1). The mean ( $\pm$  standard deviation [SD]) age of the patients was  $55.3 \pm 4.3$  years, and the mean ( $\pm$  SD) body mass index was  $30.1 \pm 6.6$ . The patients were predominantly white (84.6%) and male (54.0%). The colonoscopies were performed by 35 gastroenterologists, with a mean of  $11.2 (\pm 7.2)$  years in clinical practice (range 1-27 years). Gastroenterology fellows participated in 49.9% (309/619) of cases for the index colonoscopy and in 25.6% (10/39) of cases for the follow-up colonoscopy. The mean time-to-repeat for colonoscopy was 4.0 years (SD = 1.7 years). The adenoma detection rate on index colonoscopy was 20.5% (127/619), with a mean number of adenomas of 1.62 (SD = 1.52, range 1-11) in patients with adenomas detected. A total of 17 patients (17/619, 2.7%) had at least 1 advanced ( $>10$  mm) adenoma detected, with a mean number of advanced adenomas of 1.3 (SD = 0.69, range 1-3) in patients with advanced adenomas detected on the index colonoscopy. No colorectal cancers were identified on index or follow-up colonoscopy. Male patients and diabetic patients were more likely to have at least 1 adenomatous polyp ( $P < .05$ ). There were no other predictors of histologic findings in index colonoscopy patients.

### Endoscopist follow-up colonoscopy recommendations

Of the initial 619 patients with fair bowel preparation in index screening colonoscopy, 436 patients (70.4%) received a recommendation for a repeat colonoscopy within 5 years (Table 2). The most common recommendation for follow-up screening or surveillance colonoscopy varied by the risk associated with colonoscopy findings: the most common recommendation was 5 years (45.9%) for normal colonoscopy, whereas it was follow-up colonoscopy before or at 1 year (44.8%) for patients with 3 small adenomas and/or 1 large adenoma. In those with normal colonoscopy results, 57.4% were recommended to undergo a screening colonoscopy within 5 years, whereas 23.1% received a 10-year recommendation. When a colon polyp was detected, 77.9% of patients received a recommendation for follow-up colonoscopy within 5 years of the index colonoscopy. For patients with 1 to 2 adenomas, 98.0% were recommended to undergo follow-up surveillance colonoscopy within 5 years, with 15.3% to receive a 1-year follow-up repeat colonoscopy.

### Follow-up colonoscopy compliance

Of the 619 patients with fair bowel preparation in index screening colonoscopy, 145 patients (23.4%) received a recommendation for a follow-up colonoscopy within 3 years, but 18 patients were lost to follow-up before their recommended screening times. In the remaining 127 patients, the compliance to follow-up colonoscopy was 55.9% (N = 71). Of the noncompliant 56 patients, 29 eventually underwent a follow-up colonoscopy. The mean ( $\pm$

SD) duration between the recommended time of follow-up colonoscopy and the time of actual repeat colonoscopy was  $2.3 \pm 0.9$  years. In the 27 patients who did not have follow-up colonoscopies, the mean duration between the recommended time of follow-up colonoscopy and the end of study follow-up time was 3.2 years (SD = 1.4 years). Of the 100 (71 + 29) patients who underwent follow-up colonoscopies (after exclusion of 2 patients who did not have quality reported), 58.2% had excellent and/or good and/or adequate bowel preparation, 21.4% had fair bowel preparation, and 20.4% had poor and/or inadequate bowel preparation. Patients with 3 small adenomas and/or 1 large adenoma had the highest recommendation compliance rate (87.0%), and compliance was 52.9% in individuals with 1 to 2 small adenomas, 43.3% in those with hyperplastic polyps, and 47.8% in those with normal colonoscopy results.

The majority of patients (436 [70.4%]) who underwent index screening colonoscopies received a recommendation for follow-up colonoscopy within 5 years; however, 95 were lost to follow-up before their recommended screening times. In the remaining 341 patients, the compliance rate for follow-up colonoscopy recommendation to 5-years was 53.7% (N = 183). Of the noncompliant 158 patients, 45 eventually did a follow-up colonoscopy, and the mean ( $\pm$  SD) duration between the recommended time of follow-up colonoscopy and the time of actual repeat colonoscopy was  $2.0 \pm 0.9$  years. In the 113 patients who did not undergo a follow-up, the mean ( $\pm$  SD) duration between the recommended time of follow-up colonoscopy and the end of the study follow-up time was  $1.7 \pm 1.2$  years. Of 228 patients (183 + 45) who underwent follow-up colonoscopy, 67.3% had excellent and/or good bowel preparation, 17.7% had fair bowel preparation, and 15.0% had poor and/or inadequate bowel preparation. Patients with 3 small adenomas and/or 1 large adenoma had the highest recommendation compliance rate (83.3%), followed by individuals with 1 to 2 small adenomas (56.2%), hyperplastic polyps (51.6%), and normal colonoscopy results (49.0%).

### Three-year adenoma detection and adenoma miss rates

Of the 39 patients who had repeat colonoscopy within 3 years and an optimal bowel preparation (Table 3), 11 patients (28.2%) had at least 1 adenoma; the mean ( $\pm$  SD) number of adenomas in those with at least 1 adenoma was  $1.9 \pm 1.0$ , range 1-5). Among those who underwent repeat colonoscopy within 3 years, 22 patients had adenomas at the index colonoscopy. The overall adenoma miss rate was 28% (18%-39%). Of the patients with adenomas identified within 3 years on follow-up colonoscopy, 13.6% had normal colonoscopies on index examination. Of the 39 patients who underwent follow-up colonoscopy within 3 years, 6 patients (15.4%) had at least 1 advanced adenoma, with the mean ( $\pm$  SD) number of advanced adenomas of  $1.67 \pm 0.5$ , range 1-2). Among those who underwent repeat colonoscopy within 3 years and had advanced adenomas on index colonoscopy, no additional advanced adenomas were found.

## DISCUSSION

Fair bowel preparation limits colonoscopy visualization, leading to earlier rescheduling of procedures and missed adenomas. Our study is novel because it is the first to solely address the fair descriptor of bowel preparation that is used widely throughout endoscopy practice. Additionally, we specifically targeted the average-risk patient population, which accounts for a large percentage of colonoscopy usage. We found that in patients with fair bowel preparation, gastroenterologists recommend that the patients return for repeat colonoscopy earlier than guideline recommendations. In those patients who underwent repeat colonoscopy within 3 years of the index procedure, we found a 28% adenoma miss rate at the second colonoscopy.

Before the 2012 CRC screening guidelines, specific recommendations for repeat colonoscopy based on bowel preparation were lacking. There is no mention in the 2006 US Multi-Society Task Force guidelines; however, the 2009 American College of Gastroenterology guidelines acknowledged that inadequate bowel preparation is common but did not give a recommendation for timing of interval colonoscopy.<sup>14,15</sup> Within the literature, there was some prior direction for follow-up colonoscopy intervals in patients with inadequate or poor bowel preparation. The experts stated that follow-up colonoscopy should be scheduled at a “prompt” interval, “a relatively short interval,” “within 6 months,” or “repeat at 1 year or less.”<sup>9,16,17</sup> However, for fair bowel preparation alone, without the additional descriptor of adequate and the presence of small adenomas, there still is no consensus. For endoscopists, the meaning of a fair bowel preparation is variable. As defined by the Aronchick scale,<sup>18</sup> fair bowel preparation is equivalent to “80-90% of mucosa visualized.” With fair bowel preparation, close to 60% of endoscopists in our study recommended follow-up colonoscopy in 5 years or less in patients with normal colonoscopy results. This finding is more uniform than recommendations of the Ben-Horin et al<sup>19</sup> study, where gastroenterologists were presented with hypothetical patients undergoing screening colonoscopy associated with photographs of less than perfect bowel preparation. Close to 90% of gastroenterologists recommended follow-up in 5 to 10 years, although this interval was not broken down further. Similar to findings of the article by Ben-Horin et al, in our patients with 1 to 2 adenomas, 99% were recommended to return in < 5 years. Interval follow-up colonoscopy recommendations for 1 to 2 small adenomas (< 1 cm) has changed from 5 years in 2003 guidelines to 5-10 years in 2006 guidelines.<sup>20</sup> Accordingly, only 13% of our endoscopists complied with these recommendations. Over 75% of our endoscopists recommended repeat colonoscopies at 1 year and 3 years, demonstrating the overwhelming impact of fair bowel preparation on their confidence of clearing the colon for 5 years. In the future, endoscopist compliance with national guidelines may become quality indicators, and failure to comply may lead to punitive monetary impacts on gastroenterologists’ practices. With this, further comment by the multiple-society consortium for CRC screening on the recommended interval for follow-up colonoscopy for fair bowel preparation is needed.

Even with optimal bowel preparation, adenomas and cancers can be missed. Data from a systematic review of tandem colonoscopy studies, in which 2 colonoscopies are performed back-to-back by different endoscopists, found a miss rate of 2.1% for adenomatous polyps 10 mm and a miss rate as high as 26% for smaller polyps.<sup>21</sup> Additionally, data from a randomized trial of cap-assisted colonoscopy performed in tandem showed a 21% versus 33% miss rate for all adenomas compared with that of standard colonoscopy.<sup>22</sup> Therefore, in less than an optimal setting, it is not surprising that we found an overall adenoma miss rate of 28% in patients with fair bowel preparation. Our findings are similar to those of studies of both Lebowitz et al,<sup>12</sup> which included colonoscopies done for all indications with bowel preparation of fair and/or poor and/or inadequate and/or unsatisfactory, and Chokshi et al,<sup>13</sup> which was performed in average-risk patients for CRC screening with inadequate bowel preparation.

Patient compliance with follow-up colonoscopy was less than optimal because only 53% to 59% followed recommendations. It was interesting that those with normal colonoscopy results were the most likely to comply, and the group rated next high in compliance was the group who had an adenoma >1 cm or 3 or more adenomas. In randomized, controlled, surveillance trials, patient compliance rates are as high as 83%, whereas other retrospective trials note rates anywhere from 52% to 85% for a 3-year follow-up.<sup>23-27</sup> Patient compliance with interval colonoscopy recommendations improves with shorter time intervals, which is concordant with our high-risk population because all had recommendations of 3 years.<sup>28</sup> Additionally, the majority of our normal colonoscopy result population was recommended 5 years or less for repeat colonoscopy. Likely, our findings reflect real-world clinical practice

despite electronic reminders to the referring physicians and letters sent to the patients at the recommended intervals.

Despite the novel findings of this study, we acknowledge the following limitations. Because this study is a retrospective study, information quality regarding preparation quality documentation, endoscopists' recommendations, and follow-up colonoscopy are limited to the medical records. Another limitation is the variability among physician reporting of fair bowel preparation quality that cannot be captured with the retrospective nature of this study. Last, the generalizability of our study results may be limited because it was performed in an academic setting.

In conclusion, fair bowel preparation leads to deviation from national guidelines, with earlier repeat colonoscopy recommendations. In patients who returned for repeat colonoscopy, the adenoma miss rate was close to 30%. Detailed guidelines that address appropriate follow-up interval recommendations relating to fair bowel preparation quality are currently lacking. As endoscopists' recommendations for follow-up colonoscopy are to be quality indicators and tied to gastroenterologists' financial gain or loss, further guidelines in this area are needed.

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## Abbreviation

**CRC** colorectal cancer



**Take-home message**

- Fair bowel preparation leads to early repeat colonoscopy follow-up recommendations.
- Seventy percent of patients receive a recommendation for a repeat colonoscopy within 5 years. In those patients who underwent follow-up colonoscopy, we found a 28% adenoma miss rate.

TABLE 1

Descriptive statistics of average-risk patients (n = 619) who underwent index colonoscopy with fair preparation quality

Characteristic*	Colonoscopy histologic findings			
	Normal result (n = 338)	Only hyperplastic polyps (n = 154)	1-2 Small adenomas (n = 98)	3 + Small and/or 1 large adenoma (n = 29)
Demographic				
Age, mean ( $\pm$ SD), y	55.3 ( $\pm$ 4.4)	55.2 ( $\pm$ 4.3)	55.2 ( $\pm$ 4.5)	55.8 ( $\pm$ 3.8)
Sex, no. (%)				
Male	167 (50.0)	83 (24.9)	63 (18.9)	21 (6.3)
Female	171 (60.0)	71 (24.9)	35 (12.3)	8 (2.8)
BMI, mean ( $\pm$ SD), kg/m <sup>2</sup>	29.3 ( $\pm$ 6.4)	30.7 ( $\pm$ 5.6)	31.5 ( $\pm$ 8.6)	30.9 ( $\pm$ 5.5)
Clinical				
Narcotic use, † no. (%)	11 (3.3)	6 (3.8)	2 (2.0)	0 (0)
TCA use, † no. (%)	13 (3.8)	8 (5.2)	5 (5.1)	0 (0)
Diabetic, † no. (%)	23 (6.8)	12 (7.7)	8 (8.1)	7 (24.0)
Procedural				
Afternoon procedure, † no. (%)	128 (37.9)	67 (43.5)	36 (36.7)	8 (27.5)
Procedure date, no. (%)				
7/1-12/31/2004	44 (50.0)	22 (25.0)	15 (17.1)	7 (8.0)
1/1-12/31/2005	191 (52.5)	94 (25.8)	58 (15.9)	21 (5.8)
1/1-6/30/2006	103 (61.7)	38 (22.8)	25 (15.0)	1 (0.6)
Aborted procedure, † no. (%)	6 (1.8)	1 (0.7)	1 (1.0)	2 (6.9)

*SD*, Standard deviation; *BMI*, body mass index.

\* Total may not add up to 619 due to missing data.

† Percentages calculated with column total as denominator.

**TABLE 2**  
 Frequency distribution of interval recommendations for follow-up colonoscopy by pathology findings on index examination

Pathology finding, no. (%)	Length of follow-up recommendation, y										Total	
	1	2	3	4	5	6	7	8	9	10		Missing
Normal result	8 (2.4)	2 (0.6)	16 (4.7)	13 (3.8)	155 (45.9)	9 (2.7)	22 (6.5)	14 (4.1)	6 (1.8)	78 (23.1)	15 (4.4)	338 (54.6)
Only hyperplastic polyps	10 (6.5)	5 (3.2)	18 (11.7)	3 (1.9)	84 (54.6)	1 (0.6)	6 (3.9)	0 (0)	0 (0)	23 (14.9)	4	154 (24.9)
1-2 Small adenomas	15 (15.3)	5 (5.1)	41 (41.8)	1 (1.0)	34 (34.7)	0 (0)	1 (1.0)	0 (0)	0 (0)	0 (0)	1	98 (15.8)
3+ Small and/or 1 large adenoma	13 (44.8)	6 (20.7)	6 (20.7)	0 (0)	1 (3.5)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3	29 (4.7)
Total	46 (7.4)	18 (2.9)	81 (13.1)	17 (2.8)	274 (44.3)	10 (1.6)	29 (4.7)	14 (2.3)	6 (1.0)	101 (16.3)	23 (3.7)	61

**TABLE 3**

Adenoma miss rate and advanced adenoma miss rate calculated by using only repeat colonoscopies with excellent, good, or adequate bowel preparation

Lesion	At index colonoscopy	At repeat colonoscopy	No. (%; 95% CI)
Adenoma			
Within			
1 y	20 (7)	14 (6)	14/34 (41; 25%-59%)
2 y	37 (15)	16 (8)	16/53 (30; 18%-44%)
3 y	55 (22)	21 (11)	21/76 (28; 18%-39%)
Advanced adenoma			
Within			
1 y	6 (2)	0 (0)	0/6 (0; 0%-46% <sup>*</sup> )
2 y	9 (5)	0 (0)	0/6 (0; 0%-46% <sup>*</sup> )
3 y	10 (6)	0 (0)	0/10 (0; 0%-31% <sup>*</sup> )

CI, Confidence interval.

<sup>\*</sup> One-sided 97.5% confidence interval.