

NER1006, a 1 Liter Polyethylene Glycol–Based Bowel Preparation, is an Independent Predictor of Adequate and High-Quality Cleansing Success in Adults Undergoing Colonoscopy: a Pooled Analysis of 2 Randomized Phase 3 Trials

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INTRODUCTION

- Adequacy of bowel preparation is critical for visualizing the colonic mucosa and maximizing the therapeutic benefits of colonoscopy^{1,2}
- High-quality bowel cleansing has been shown to improve adenoma detection rates for individual patients³
- Unlike data on predictors of inadequate bowel preparation,^{4,5} data are limited on potential predictors of high-quality colon cleansing
- NER1006 (Plenvu, Salix Pharmaceuticals, Bridgewater, NJ) is a 1 L polyethylene glycol (PEG)–based bowel preparation indicated in the United States for cleansing of the colon prior to colonoscopy in adults⁶
 - A multiple regression analysis showed that NER1006 was an independent predictor of overall cleansing success and right-colon, high-quality cleansing⁷

OBJECTIVE

- To determine predictors of both adequate and high-quality colon cleansing success in patients undergoing colonoscopy using optimized regression models

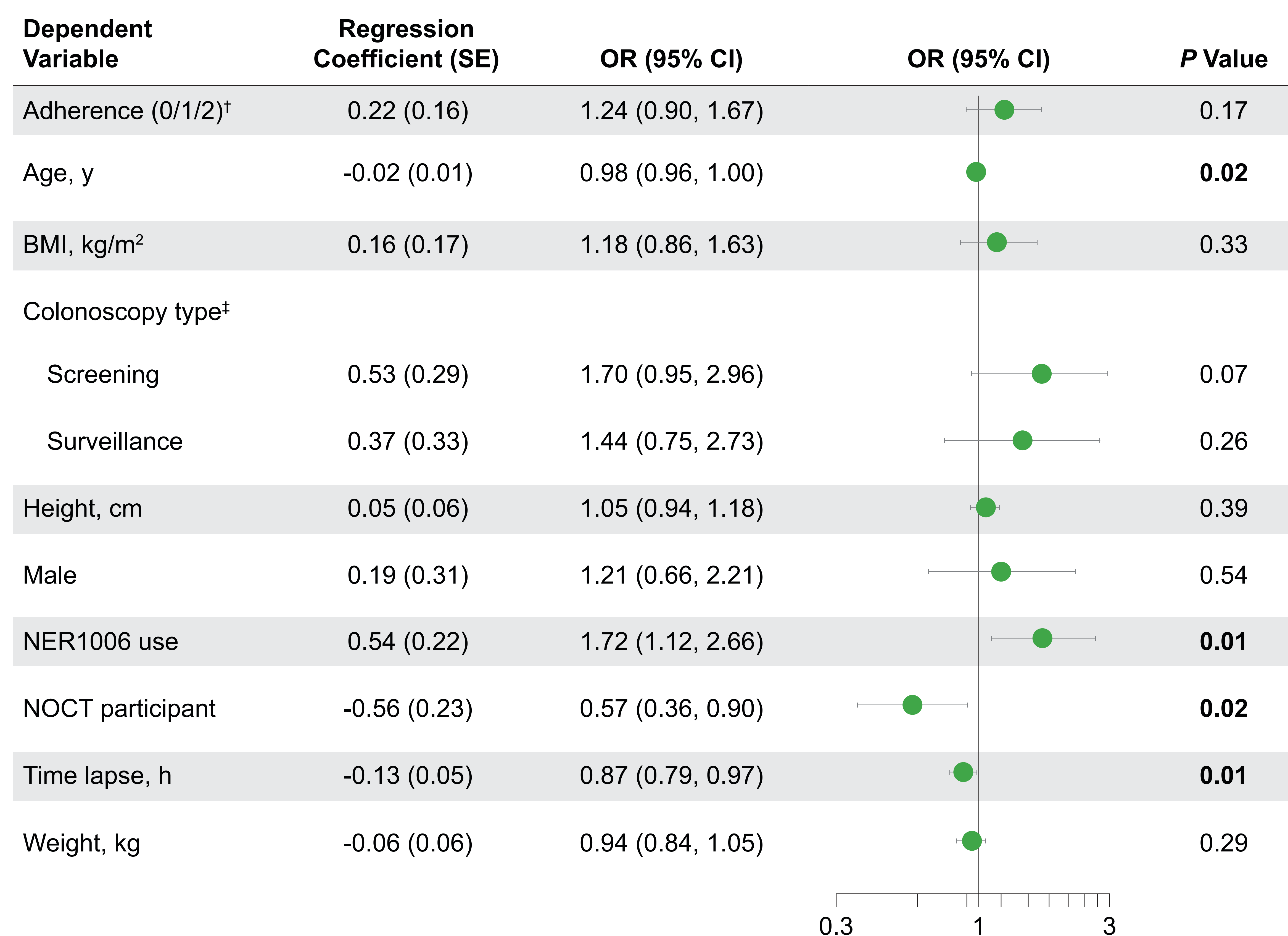
METHODS

- Pooled post hoc analysis of 2 published phase 3 trials (NOCT [NCT02254486] and MORA [NCT02273167])^{8,9}
- Adults were randomly assigned one of the following bowel preparations, administered as evening/morning split-dose regimens^{8,9}
 - NER1006, oral sulfate solution (OSS), or 2 L PEG plus ascorbate solution
- Boston Bowel Preparation Scale (score 0-3 for each of 3 colonic segments [right colon, which included ascending colon/cecum, transverse colon, and left colon])¹⁰ was used to assess colon cleansing
 - Overall adequate colon cleansing: total score ≥ 6 , with a score of ≥ 2 in each of 3 colonic segments
 - Overall high-quality colon cleansing success: total score 7-9, with a score of ≥ 2 in each of 3 colonic segments
- 11 variables were analyzed: adherence, age, body mass index, type of colonoscopy (screening, surveillance), height, male sex, use of NER1006 bowel preparation, participation in NOCT trial, time lapse, and weight
 - Adherence rated as study drug compliance rate (based on patient diary; regardless of the amount of additional fluids consumed)
 - Rating of 0 (<75% of each dose of bowel preparation), 1 ($\geq 75\%$ of each dose of bowel preparation), or 2 (100% of each dose of bowel preparation)
 - Time lapse (range, 0-24 hours) was defined as the time from end of bowel preparation to start of colonoscopy
- Multivariate logistic regression performed and odds ratio with 95% confidence intervals were generated

RESULTS

- 1018 patients were included in the analysis (NER1006 [n=510]; comparator [OSS and 2 L PEG combined; n=508]
 - 50.3% of 1018 patients were male (45.7% in NER1006 and 54.9% in comparator groups)
 - Mean age (range) of patients was comparable between the 2 groups (NER1006: 57.0 [18-86] years; comparator: 55.6 [18-84] years)
- Variables shown to significantly affect the achievement of overall adequate cleansing success were age, NER1006 use, participation in the NOCT trial, and time lapse (Figure 1)

Figure 1. Linear Regression and Odds Ratio Analysis to Identify Variables Impacting Overall Adequate Colon Cleansing Success*



*Boston Bowel Preparation Scale total score ≥ 6 , with a score of ≥ 2 in each of 3 colonic segments.
[†]According to patient diary and regardless of additional fluids consumed: 0 = adherence rate <75% of each dose of bowel preparation, 1 = adherence rate $\geq 75\%$ of each dose of bowel preparation, and 2 = adherence rate of 100% of each dose of bowel preparation.
[‡]Diagnostic colonoscopy was not evaluated as a variable.
 BMI = body mass index; CI = confidence interval; OR = odds ratio; SE = standard error.

- NER1006 use and time lapse were the 2 variables significantly associated with achievement of overall high-quality colon cleansing success (Figure 2)

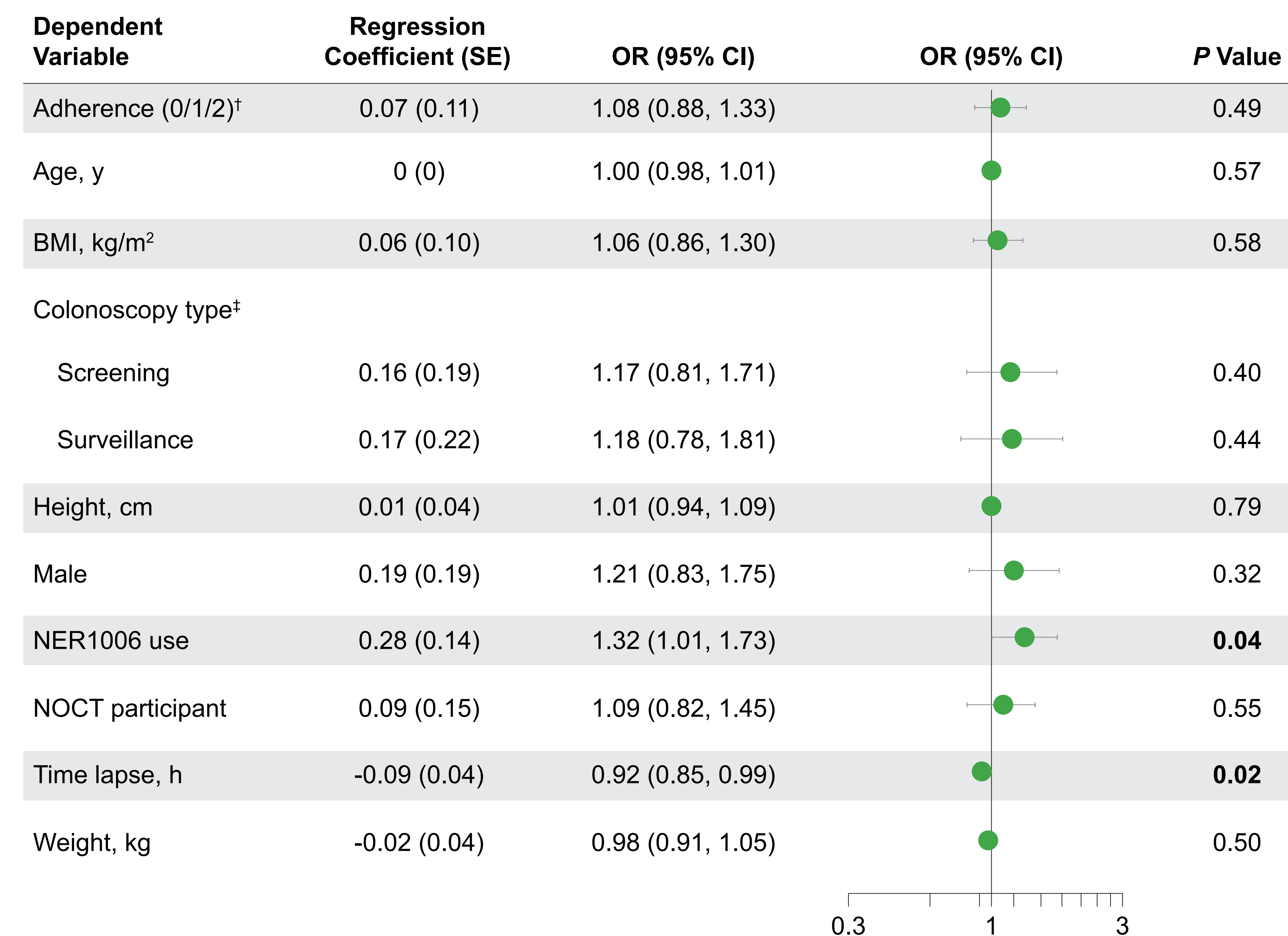
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DISCLOSURES: MSE reports being an investigator in the NOCT study, being a speaker for Amgen Inc., Pfizer Inc., and Pharmacosmos; and being a consultant for Nestlé Health Science. EDS reports having nothing to disclose. CA is an employee of Salix Pharmaceuticals. RB was an investigator in the MORA study and has received honoraria from Norgine Ltd. for speaking and advisory board attendance.

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Figure 2. Linear Regression and Odds Ratio Analysis to Identify Variables Impacting High-Quality Colon Cleansing Success*



*Boston Bowel Preparation Scale total score 7-9, with a score of ≥ 2 in each of 3 colonic segments.
[†]According to patient diary and regardless of additional fluids consumed: 0 = adherence rate <75% of each dose of bowel preparation, 1 = adherence rate $\geq 75\%$ of each dose of bowel preparation, and 2 = adherence rate of 100% of each dose of bowel preparation.
[‡]Diagnostic colonoscopy was not evaluated as a variable.
 BMI = body mass index; CI = confidence interval; OR = odds ratio; SE = standard error.

CONCLUSIONS

- NER1006 was the only independent, positive predictor of both adequate and high-quality colon cleansing success in patients undergoing colonoscopy
- NER1006 use had a greater effect than all other variables evaluated in this analysis
- Administration of NER1006 as a bowel preparation may provide improved cleansing quality, decrease colon cleansing failures, and maximize the therapeutic benefits of colonoscopy