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## Obesity does not affect sodium picosulphate bowel preparation

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#### Key words

Obesity, sodium picosulphate, bowel preparation, colonoscopy.

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### Abstract

**Background:** A previous study utilising oral polyethylene-glycol by Borg *et al.* concluded that obesity is an independent predictor of inadequate bowel preparation at colonoscopy.

Aim: To compare bowel preparation quality between obese and non-obese individuals as assessed by Boston bowel preparation scale (BBPS) after using sodium picosulphate.

**Methods:** Prospective recruitment of patients at a day surgical unit in a New South Wales academic hospital. Bowel preparation was with Picoprep in all patients. Body Mass Index and epidemiological details were collected. Bowel preparation efficacy was assessed using the Boston Bowel Preparation Score.

**Results:** One hundred and four patients were enrolled prospectively. Five (4.8%) were excluded owing to poor mental capacity. Sixty-three (64%) were non-obese, and 36 (36%) were obese. Fifty-seven (90%) non-obese and 32 (89%) obese patients had good bowel preparation. There was no statistical difference for sodium picosulphate bowel preparation between obese and non-obese individuals (P > 0.99) using Fisher's exact probability tests. The BBPS score in the left colon predicted the overall BBPS score in all patients (P < 0.001). Three of 99 patients (3%) did not tolerate sodium picosulphate, with nausea being the most common side-effect.

Limitations: Non-randomised study

**Conclusions:** There was no difference in bowel preparation quality between obese and non-obese patients using a low-volume bowel preparation (sodium picosulphate) and without dose modification of the bowel preparation. Sodium picosulphate was a well-tolerated and an effective bowel preparation for obese individuals. With an increasing incidence of obesity and expanding colonoscopic indications within Australia and other Western countries from government-sponsored programs, it is paramount that procedural quality not be compromised in the obese patient.

## Introduction

Successful visualisation of colonic mucosa depends on a good bowel preparation, the position of lesions in respect to colonic folds (distal vs proximal), the skill of the endoscopist and colonoscopic withdrawal time. Good bowel preparations are essential in colonoscopy for the identification and therapy of relevant abnormalities with emphasis upon pre-cancerous and cancerous lesions. Trautwein *et al.*<sup>1</sup> determined that an imperfect bowel preparation can prolong procedure time, increase the chance of an aborted examination and increase costs by 22%. In response to the earlier, professional bodies such as the American Society of Gastrointestinal Endoscopy (ASGE) produced a consensus statement on multiple bowel preparation options.<sup>2</sup> Although multiple commercial preparations exist, none fulfils all the goals of a perfect bowel preparation, as described by the Society of American Gastrointestinal and Endoscopic Surgeons<sup>2</sup> in 2006.

Obesity remains a significant public health concern in Australia and other parts of the developed world. In gastroenterology, obesity is associated with an increased incidence of diverticular disease, gastroesophageal reflux disease, colonic polyps and colonic cancer.<sup>3</sup> The National Institutes of Health - American Association for Retired Persons Diet and Health study<sup>4</sup> on 307 708 man and 209 436 women over 4.5 years had shown a strong positive correlation of body mass index (BMI) with colon cancers.<sup>5</sup> While several studies had noted an inverse relationship between colo-rectal cancer screening compliance and obesity (odds ratio 0.75; 95% confidence interval 0.62–0.91),<sup>6,7</sup> conclusive evidence of the effects of obesity on preparation quality remains elusive. Examples of conflicting evidence include Borg et al.8 who described obesity as an independent predictor of inadequate bowel preparation and Ness et al.9 who found no impact of obesity on bowel cleanliness.

Early studies<sup>10</sup> looking to quantify bowel preparation cleanliness utilised a subjective visual grading scale (Aronchick scale<sup>11</sup>) as described in Table 1. Although recommended by the American College of Gastroenterology Taskforce on Quality in Endoscopy, a lack of standardised definitions that were open to subjective interpretation had limited its utility in research.<sup>12</sup> Addressing these deficiencies, the Boston bowel preparation scale (BBPS)<sup>13</sup> has minimal interobserver variability and scores the right, transverse and left colon separately (Table 2), with a composite final score of >5 defining an inadequate bowel preparation. Table 1 Bowel preparation visual grading scale (Aronchick scale)

Subjective terminology	Subjective description
Poor	Large amounts of faecal residue, unacceptable
Fair	Enough faeces to prevent a completely reliable examination
Good	Small accumulation not interfering with a thorough examination
Excellent	No more than small bits of adherent faeces

Picoprep is a mixture of cathartic agents (citric acid and magnesium oxide) and a low volume picosulphate cleansing solution in the form of sodium picosulphate. The efficacy of picosulphate cleansing has been shown to be non-inferior to phospho-soda-buffered saline (Fleet)<sup>14</sup> with superior taste and tolerability compared with Fleet.<sup>14</sup>

The current study aims to determine whether a difference exists in bowel preparation quality as assessed by the BBPS between obese and non-obese individuals with a low-volume bowel preparation (sodium picosulphate – Picoprep).

## Methods

Ethics approval for the study was obtained from the Sydney South West Area Health Service Human Ethics Committee (QA2010/19).

Prospective recruitment occurred over 3 months (March 2010 to May 2010) from outpatient colonoscopies performed in the day surgery unit at Campbelltown Hospital (CTH). All colonoscopies were performed by gastroenterologists.

Picoprep (Australian Pharmaceutical Industries, Camelia, Australia) was used for all bowel preparations as per three-sachet (30 mg picosulphate) protocol at CTH.

Weight and height data were identified at admission to CTH, and BMI was calculated (BMI = weight(kg)/

Table 2 Boston bowel preparation scale (BBPS) scoring

BBPS score	Score description
0	Unprepared colon segment with mucosa not seen because of solid stool that cannot be cleared
1	Portion of mucosa of the colon segment seen, but other areas of the colon segment are not well seen because of staining, residual stool and/or opaque liquid
2	Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment is seen well
3	Entire mucosa of colon segment seen well, with no residual staining, small fragments of stool or opaque liquid

height (m<sup>2</sup>)). Obesity was defined as a BMI  $\geq$  30 kg/m<sup>2</sup> in Caucasians<sup>15</sup> and  $\geq$  27.5 kg/m<sup>2</sup> in Asians.<sup>16</sup> Patient characteristics, time of procedure (morning vs afternoon), history of diabetes mellitus, cardiovascular comorbidities, medications (specifically narcotics, antidepressants, anti-hypertensive agents, proton pump inhibitors), mental capacity, diverticular disease and a history of inflammatory bowel disease were recorded. BBPS scores were obtained for the right colon, transverse colon and left colon. Ancillary history of tolerability, effectiveness and compliance with Picoprep was obtained pre-anaesthesia.

Bowel preparation efficacy was graded during colonoscopy with the BBPS for the right, transverse and left colon. All three gastroenterologists used the BBPS. Scores were agreed on between the gastroenterology advanced trainee and the supervising consultant gastroenterologist for the procedure. A composite score was derived from adding the three scores. Poor bowel preparation was defined as a BBPS score >5.<sup>14</sup> Patients with poor mental capacity from a history of dementia or intellectual impairment were excluded from analyses on the basis that bowel preparation compliance would be of issue.

Polyp detection was recorded. Polyp detection rates were calculated and used as a surrogate for colonoscopy quality.<sup>17</sup>

The measured primary outcome was a BBPS score relating to bowel preparation effectiveness, with secondary outcomes of tolerability and polyp detection. Time of procedure (morning vs afternoon) was investigated with respect to bowel preparation quality.

Because of the observational nature of this study, blinding was not possible.

Statistical analyses were performed on Statistical Package for the Social Sciences (SPSS) for Windows version 12 (SPSS, Inc., Chicago, IL, USA). Fisher's exact probability tests were performed on continuous and categorical variables. A *P* value of >0.05 was considered significant.

## Results

Within 3 months, 104 patients were recruited, with five (4.8%) excluded from analyses for reasons of poor mental capacity (intellectual disability and dementia). The median age of the 99 patients was 51.5 years old (range 16–77 years old) with 60.6% female and 93% Caucasian (Table 3).

Thirty-six per cent of recruited patients met the definition for obesity in this study. The composite BBPS was  $\geq$ 5 in 89% of patients with a colonoscopy completion rate of 97%. Of the 62 non-obese patients, 57(90%) had a good bowel preparation, and of the 37 obese patients, 32(89%) had a good preparation. There were no statis-

Table 3 Population characteristics

Total number of patients	99
Median age (years)	51.5
Female/male	56/43
Caucasians (%)	93
Comorbidities (%) Cardiovascular risk factors	17.1
Diabetes mellitus (Type 1 and 2)	11.1
Diverticular disease	27.2
Inflammatory bowel disease	5.1
Mean BMI (kg/m²)	28.8 ± 6.7
Percentage non-obese (%)	63.6
Good bowel preparation (BBPS $\geq$ 5) (%)	89
Morning/afternoon procedure(%)	50/49
Polyp detection rate (%)	37.4
Adenoma rate	26.3
Previous abdominal surgery (%)	19.2

BBPS, Boston bowel preparation scale; BMI, body mass index.

tical differences for Picoprep bowel preparation between obese and non-obese patients (P > 0.99) using Fisher's exact probability tests, with further data in Table 4. There were no correlations seen between BBPS scores and BMI, as seen in Figure 1.

Colonic polyps were identified in 37.4% of all patients, with an adenoma rate of 26.3% (26.7% female; 25.5% male).

A past history of intra-abdominal surgery did not affect preparation quality (P > 0.99). A good bowel preparation in the left colon predicted a good bowel preparation in the whole colon (P < 0.01). Although the presence of diabetes suggested a difference between BBPS scores

Table 4 Primary and secondary outcomes

	п	Р
Obese vs non-obese	37 vs 62	>0.99
Number of obese (female vs male)	25 vs 12	
Number of non-obese (female vs male)	32 vs 30	
Diverticular disease (obese vs non-obese)	14 vs 13	0.28
Inflammatory bowel disease (obese vs non-obese)	0 vs 5	0.42
Previous abdominal surgery	19	>0.99
Patients with polyps found (female vs male)	21 vs 16	_
Patients with adenomas found (female vs male)	15 vs 11	_
Females with adenomas (obese vs non-obese)	8 vs 7	0.18
Males with adenomas (obese vs non-obese)	0 vs 11	0.31
Females with hyperplastic polyps (obese vs non-obese)	1 vs 5	0.18
Males with hyperplastic polyps (obese vs non-obese)	1 vs 4	0.31
Medication use (B-blockers, anticholinergics, antidepressants, anti-emetics, constipation medications)	45	0.72
Time of day of procedure (morning vs afternoon)		0.32
Obese	50	_
Non-obese	49	_

— , not significant.



Figure 1 Scatterplot showing no relationship between body mass index and Boston bowel preparation scale (BBPS) scores. (

(6 vs 7) (P = 0.013), it did not affect the overall effectiveness of bowel preparation. Opinions on bowel preparation effectiveness by the patient were not a reliable indicator of bowel preparation cleanliness (P > 0.99) (Table 3).

This study was underpowered to analyse if diverticular disease (P = 0.28) or inflammatory bowel disease (P = 0.42) predicted a poor bowel preparation. Medication effects (narcotics, antidepressants, antihypertensive agents, proton pump inhibitors) on bowel preparation quality were insignificant (P = 0.72), as was the time of day of procedure (morning vs afternoon) (P = 0.32).

Ninety-seven per cent of patients tolerated Picoprep. Nausea was the most common side-effect. There was no difference in Picoprep tolerability between obese and non-obese groups.

## Discussion

In this prospective study, we demonstrated that BMIs  $\geq$  30 in Caucasians and  $\geq$ 27.5 in Asians were not independent predictors of inadequate bowel preparation with sodium picosulphate. A good bowel preparation in the left colon predicted a good preparation in the whole colon, and a past history of abdominal surgery did not affect bowel preparation quality. The study of Borg *et al.*<sup>8</sup> was important in suggesting that clinicians might not be performing colorectal cancer screening as effectively as they could for a higher risk population group (obese patients); our results differ and reassure that excellent colonoscopy viewing can be achieved with a standard picosulphate preparation in obese as well as non-obese individuals.

The strengths of this study include its prospective design with the use of a highly reproducible bowel preparation scoring tool between gastroenterologists with scoring performed by a small group of three consultant gastroenterologists adequately trained in the use of the BBPS prior to subject recruitment. Comparatively, Borg et al. (the only other significant study in this area) was conducted retrospectively with a significant recall bias where the quality of bowel preparation was extracted from a descriptive procedural report using the Aronchick scale. As recognised by Borg et al., the descriptive use of the Aronchick scoring system in retrospective records with procedures done by 26 different gastroenterologists had meant that interobserver variability was a significant confounding factor with unclear, subjective interpretations of what constitutes an 'adequate preparation'. Inherent flaws within a retrospective data set also challenged a definitive conclusion of an association between a high BMI and poor bowel preparation given confounders of compliance, socioeconomic status and education level.8 While Borg BB et al. had looked at several different bowel preparation options in their study (a significant confounding factor), the current study looked at the adequacy of bowel preparation with one bowel preparation product only - Picoprep thus reducing the influence of compliance on study conclusions. Previous studies had shown that 5-15% of patients do not complete their prescribed preparation because of poor palatability and/or the large volume needed compared with Picoprep.<sup>18,19</sup> It is a strength of the current study that the best tolerated bowel preparation has been studied to determine obesity's influence on bowel preparation.

Study weaknesses include the lack of data on diabetic complications and of diabetic control. The study was underpowered to analyse for the effects of diverticular disease, inflammatory bowel disease, medication use or time of procedure on the adequacy of bowel preparation. The study was observational and lacked blinding; therefore, patient physical size could be observed with BMI estimated preprocedure potentially introducing bias into the study. However, the use of the BBPS in the study design as an objective measure does mitigate any significant impact on our study. The prevalence of obesity in the Macarthur region of New South Wales in this study of colonoscopy in adults was also higher than the 2008 national average of 24.8%,<sup>20,21</sup> which could hint upon different ethnic and lifestyle factors that could not be excluded in our study as potential confounding factors.

ASGE quality guidelines on minimum adenoma detection rates suggest a minimum adenoma pickup rate of 15% in females and 25% in males. Given that colonoscopies were performed by the advanced trainee in gastroenterology closely supervised at all times by experienced consultant gastroenterologists, it was likely that 25.5% represented the true male adenomas prevalence and 26.7% the true female adenoma prevalence in the Macarthur region in Sydney, New SouthWales indicating accurate colonoscopy results. The zero adenoma rate found in the obese male cohort can be attributed to a Type 2 error with this study not designed to prove an existing effect previously already well elucidated by other studies.<sup>4</sup>

These results show sodium picosulphate to be an excellent bowel preparation solution for obese patients with 3% of the obese study group failing bowel cleansing necessitating a repeat procedure and 89% of all patients achieving a good preparation where Picoprep failure rates are comparable with phospho-soda enemas in colonoscopy.<sup>14,18,19</sup>

Obesity has a significant impact on colonoscopies in Australia with 2005–2006 Medicare data estimating a total of 444 689 public and private colonoscopies done per year,<sup>22</sup> of which approximately 110 000 (24.8%) procedures are in obese patients.<sup>20,21,22</sup> This number is likely to be significantly higher now with an increasing population, the advent of the Australian National Bowel Cancer Screening Programme (NBCSP), and increased public awareness of bowel cancer screening. With the NBCSP currently funded for 1 million faecal occult blood testings or \$34 million over 4 years, any reduction in procedural repeat rates secondary to poor bowel preparation as high as 20%<sup>23</sup> can be of significant impact to the success of the former. The efficacy of sodium picosulphate on obese patients in the Macarthur region in New South Wales benefits bowel cancer colonoscopy screening programmes by demonstrating that a good colonoscopy preparation is readily achievable in obese patients as well as the nonobese population.

Future studies into bowel preparation in obese patients could compare high-volume and low-volume preparations with various dosing regimens.

## Conclusion

There was no difference in bowel preparation quality between obese and non-obese patients using a lowvolume bowel preparation (sodium picosulphate). Sodium picosulphate was well tolerated and effective in obese patients with favourable implications on NBCSP in Australia and similar programs overseas.With an increasing incidence of obesity and expanding colonoscopic indications within Australia and other Western countries from government-sponsored programmes, it is paramount that procedural quality not be compromised in the obese patient.

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# Relationships between HMG-CoA reductase inhibitors (statin) use and strength, balance and falls in older people

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#### Key words

statin, muscle strength, balance, accidental fall.

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#### Abstract

**Aims:** To investigate associations between HMG-CoA reductase inhibitor (statin) use and muscle strength, balance, mobility and falls in older people.

**Methods:** Five hundred community-dwelling people aged 70–90 years provided information about their medication use and undertook tests of lower limb strength, postural sway, leaning balance (maximal balance range and coordinated stability tests) and functional mobility. Participants were then followed up for 12 months with respect to falls.

**Results:** After adjusting for general health in analyses of covariance procedures, statin users had poorer maximal balance range than non-statin users (P = 0.017). Statin and non-statin users did not differ with respect to strength, postural sway, mobility or falls experienced in the follow-up year.

**Conclusion:** In a sample of healthy older people, statin use was not associated with muscle weakness, postural sway, reduced mobility or falls. Statin users, however, had poorer leaning balance which may potentially increase fall risk in this group.

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Conflict of interest: The Physiological profile Assessment (NeuRA FallScreen) is commercially available through Neuroscience Research Australia.

## Introduction

Atherosclerosis and atherosclerosis-associated conditions, such as coronary heart disease and ischaemic cerebrovascular disease, are major causes of morbidity and mortality among middle aged and older adults in developed countries.<sup>1–4</sup> Hyperlipidaemia and low levels of high density lipoprotein cholesterol (HDL-C) increase atherogenic risk.<sup>1,5</sup> Multiple well-controlled clinical trials have