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Original Article

Sodium Picosulphate with Magnesium Citrate versus Polyethylene Glycol for Bowel Preparation in Children: A Systematic Review

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The authors have no financial conflicts of interest.

ABSTRACT

Purpose: To compare the effectiveness, tolerability, acceptability, and safety of sodium picosulphate with magnesium citrate (PS/Mg) and polyethylene glycol (PEG) in children (≤18 years) preparing for colonoscopy.
Methods: Three electronic databases (MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials) were searched till July 2020. Only randomized controlled trials (RCTs) were included. At least two authors independently selected studies and performed risk of bias assessment and data extraction.
Results: Four RCTs (n=390), with overall good quality were included. A meta-analysis of two trials (n=224) found no statistically significant difference between the groups with respect to the proportion of patients who had excellent and good scores (≥6 points) according to the Boston Bowel Preparation Scale (relative risk: 0.99; 95% confidence interval [CI]: 0.90 to 1.08). Excellent and good scores were observed in both groups in approximately 90% of children. A meta-analysis of two other trials (n=150) showed no significant difference between the groups with respect to the mean total score for the Ottawa Bowel Preparation Scale (mean difference: 0.20; 95% CI: −0.74 to 1.14). Both regimens provided a comparable safety profile; however, PS/Mg was significantly superior to high volume PEG in terms of tolerability (abdominal pain, nausea, vomiting, bloating/flatulence/fullness) and acceptability (ease of formulation consumption, taste acceptance, need for nasogastric tube, compliance with full dose).
Conclusion: PS/Mg provides a quality and safety profile similar to PEG for bowel cleansing; however, it has better acceptance and tolerance in children preparing for colonoscopy.

Keywords: Endoscopy; Therapy acceptance; Drug tolerance; Safety; Bowel preparation solution

INTRODUCTION

In children, colonoscopy is performed to assess a variety of gastrointestinal conditions such as chronic diarrhea, lower gastrointestinal bleeding, unexplained anemia, or polyposis syndrome [1]. The success of colonoscopy relies mainly on appropriate bowel preparation; inadequate colon cleansing increases the risk of adverse events, the overall procedure time, and the need for repeated colonoscopy while it decreases cecal intubation rate [2]. From

the children's perspective, bowel preparation is the most difficult part of the procedure [3]. They are forced to drink a relatively large amount of poorly acceptable fluid in a short period of time. Because of the lack of compliance for this, the cleansing regimen is sometimes administered through a nasogastric tube that increases the child discomfort. Numerous studies have evaluated the efficacy, acceptability, and safety of different bowel preparation protocols in children. These studies showed that 10% to 30% of colonoscopies are associated with suboptimal bowel preparation and substantial patient discomfort [4-6]. The current (2017) ESGE (European Society of Gastrointestinal Endoscopy)/ESPGHAN (European Society of Pediatric Gastroenterology, Hepatology and Nutrition) guidelines on pediatric gastrointestinal endoscopy recommends either polyethylene glycol (PEG) or picosulphate with magnesium citrate (PS/Mg) for bowel preparation [7]. The lack of available evidence at the time of guideline release prevented the recommendation of the best regimen for bowel preparation of the two. Therefore, we performed a systematic review to compare the effectiveness, safety, tolerability, and acceptability of PS/Mg with PEG for bowel preparation in children prior to colonoscopy.

MATERIALS AND METHODS

We followed the Cochrane Collaboration guidelines and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement for this review [8]. No ethical approval was needed to perform this systematic review.

Criteria for considering studies for this review

1. Type of studies

Randomized controlled trials (RCTs) were considered for inclusion.

2. Type of participants

All children under the age of 18 who underwent bowel preparation before colonoscopy.

3. Type of interventions

We included trials that compared the administration of PS/Mg with PEG which were given as monotherapy in all delivery formulations and vehicles, at any dose.

4. Type of outcomes

Our primary outcome measure was efficacy of total colon cleansing before colonoscopy as assessed by investigators. If a study used more than one method of quality evaluation of bowel preparation, we extracted all available methods for comparison.

Secondary outcome measures included tolerability, acceptability, and safety of bowel preparation. Acceptability was defined as the child's or caregiver's assessment of ease of intake, taste acceptance, need for nasogastric tube, and willingness to repeat the formulation. Tolerability outcomes were evaluated as the child's/caregiver assessment of gastrointestinal or extraintestinal symptoms during bowel preparation such as nausea, vomiting, abdominal pain, abdominal bloating, dizziness, apathy, or headache. Safety included adverse events such as electrolyte disturbances, hypotension, or serious adverse events. We decided to combine secondary outcome measures which were differently defined but may essentially be summed under the same outcome. All outcome measures had to be assessed during or after bowel cleansing but before colonoscopy.

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Search methods for identification of studies

We searched the Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library), MEDLINE via PubMed, and EMBASE databases from January 1980 to July 2020. The principal search text included word terms and MeSH headings as well as terms describing populations of interest. We did not apply any language restrictions to our search strategy (supplementary materials). Additionally, we screened the reference lists from all identified studies and systematic reviews of interest. We also searched The ClinicalTrials.gov and ClinicalTrialsRegister.eu websites to identify potentially relevant unpublished RCTs. We did not consider letters to the editor, abstracts, and proceedings from scientific meetings for inclusion.

Data collection and analysis

Two independent reviewers (MR, PD) used standardized approach and EndNote® software (Endnote™, Clarivate, Philadelphia, PA, USA) to search the literature, perform data extraction, and make quality assessment. Any disagreements were resolved by discussion.

Assessment of risk of bias in included studies

Assessing the risk of bias in the identified studies that met the inclusion criteria was performed by all the reviewers independently using the Cochrane Collaboration's tool (Cochrane Collaboration, London, UK) [9]. If the evaluation was not feasible due to missing information, we rated the respective item as unclear risk of bias.

Assessment of heterogeneity and reporting biases

Heterogeneity was quantified by X^2 and I^2, which are interpreted as the percentage of the total variation between studies that is attributable to heterogeneity rather than to chance. No observed heterogeneity is indicated by a value of 0%, whereas larger values show increasing heterogeneity. We planned to assess publication bias using the funnel plot proposed by Egger et al. [10]. However, given the small number of studies (<10) included in the analyses, this was not performed.

Data synthesis (statistical methods)

We analyzed the data with the use of Review Manager (RevMan [Computer program] Version 5.3 Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). The dichotomous outcomes, individual study results, and pooled statistics were reported as risk ratio (RR) between the experimental and control groups with 95% confidence intervals (95% CI). The mean difference between the treatment and control groups with 95% CI was reported for all continuous outcomes. If the 95% CI was provided in the original study, we calculated standard deviation according to the method described in Cochrane Handbook [9]. The random-effects model was applied in all analyses.

RESULTS

Fig. 1 shows the flow diagram documenting the identification process of eligible trials. There was no disagreement between authors on inclusion and exclusion of studies. Finally, four RCTs that randomized 380 participants (190 in the PS/Mg and 190 in PEG group) with age from 2 to 18 years were identified [11-14]. The sample size of trials ranged from 71 to 144 participants. Three studies used the same age adjusted doses of PS/Mg. One RCT used unified dose of PS/Mg for children >10 years [13]. Four trials provided PEG in the dose which was rated by authors as high volume and one trial used low volume PEG for bowel cleansing [12].

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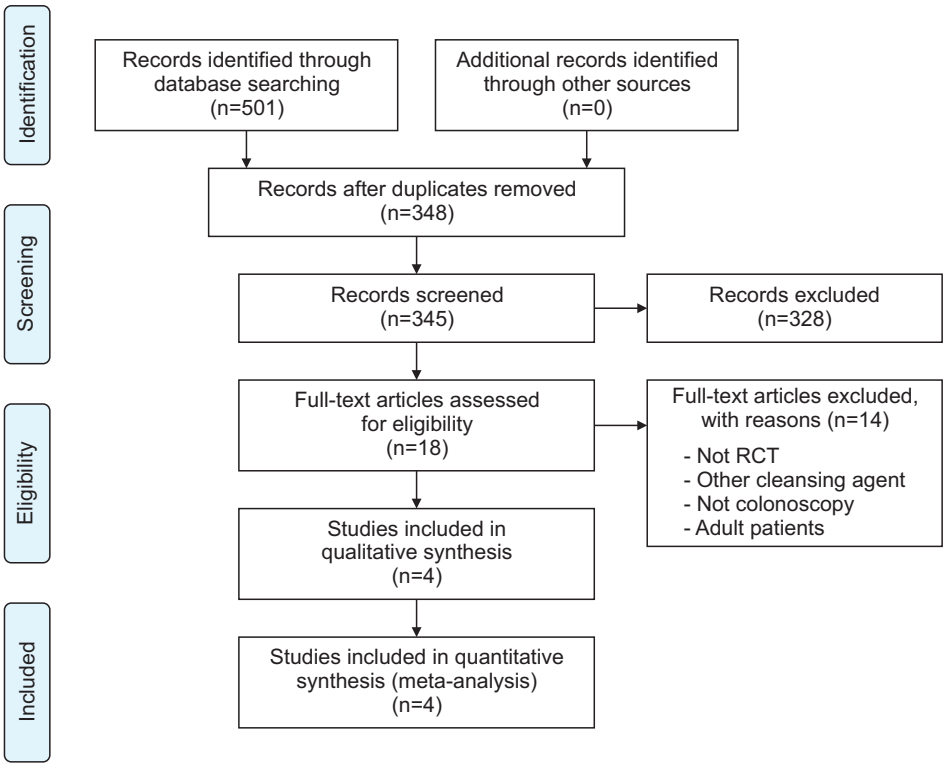

Fig. 1. Flow diagram.
RCT: randomized controlled trial.

The trials were carried out in Canada, Italy, Poland, and Sweden. The detailed characteristics of the included RCTs are presented in **Table 1**.

Risk of bias within studies

Overall, the methodological quality of the 4 RCTs was similar and good (**Fig. 2**). Sequence generation and allocation concealment was unclear in one trial. Blinding of participants and personnel was impossible because of the nature of the intervention. However, it is unlikely that this affected the primary outcome since it was scored by an endoscopist, for whom blinding of the outcome assessment was ensured in all trials.

Quality of colon cleansing

The meta-analysis of two trials (n=224) found no difference (relative risk [RR]: 0.99; 95% CI: 0.90 to 1.08) between PS/Mg and high-volume PEGs in the proportion of patients who had excellent and good scores (≥6) according to Boston Bowel Preparation Scale (BPPS) (**Fig. 3**). In both groups, successful colon cleansing (BPPS≥6) was observed in approximately 90% of patients (PS/Mg: 89%, PEG: 90%) [12,14].

The meta-analysis of the other two trials (n=150) showed no statistically significant difference between groups on mean total score in the Ottawa Bowel Preparation Scale (MD: 0.20; 95% CI: −0.74 to 1.14) (**Fig. 4**) [11,13].

The other bowel preparation quality outcomes were assessed in single studies. Except for enema requirement (RR: 0.36; 95% CI: 0.14 to 0.91) favoring the PS/Mg group, none of them found any significant difference between the analyzed group (**Table 2**). One trial comparing

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Table 1. Characteristics of the included studies

Study	Age of patients (y)	Picosulphate/magnesium citrate: product and manufacturer name, dose, preparation regimen, number of patients	Polyethelene glycol: product and manufacturer name, dose, preparation regimen, number of patients	Efficacy outcomes	Tolerability outcomes	Acceptability outcomes	Safety outcomes
Turner et al., 2009 [11]	4–18	Picosalax (Ferring Pharmascience Inc., Montreal, Canada): <6 y: 2x1/4 sachet*; 6–12 y: 2x1/2 sachet; >12 y: 2x1 sachet; diluted in 150 mL of water at 6 PM the day before colonoscopy and at 8 AM the day of colonoscopy, n=43	PEG 3350 with electrolytes (Pharmascience Inc., Montreal, Canada) 100 mL/year of age/h (max 1 L/h up to 4 h) starting 6 h before colonoscopy, n=40	Ottawa Bowel Preparation Score (total); physician impression of bowel preparation, enema requirement, time required to reach cecum, proportion of completed colonoscopy, proportion of patients with failed preparation for colonoscopy	Occurrence of gastrointestinal or extraintestinal symptoms during colonoscopy preparation (e.g., nausea, vomiting, fullness), need for nasogastric tube	Ease of taking colon cleansing preparation, taste acceptance, compliance with full dose of preparation, satisfaction with colon cleansing regimen	Any adverse event including laboratory parameters except those assessed as tolerability outcomes
Di Nardo et al., 2014 [12]	2–18	Picoprep, Ferring Italia, <6 y: 2x1/4 sachet*; 6–12 y: 2x1/2 sachet; >12 y: 2x1 sachet each diluted in 150 mL of water, at 4 PM and 5 hours later in the evening before the colonoscopy, n=72	High dose: PEG 4000 with electrolytes with simeticon (PEG-ELS, Selg Esse Promefarm, Italy) starting 4 PM the day before colonoscopy max. 4 L for 4–6 hours, n=72 Low dose: PEG 3350 with ascorbic acid (Moviprep Norgine Ltd, Harefield, UK) starting at 4 PM the day before colonoscopy 50 mL/kg (max. 2 L) with additional 25 mL/kg clear fluid (max. 1l), n=72	BBPS for: right colon, medium colon, left colon, proportion of patients >6 pts for total BBPS; physician impression of bowel preparation cecal intubation rate; time to reach cecum	Occurrence of gastrointestinal or extraintestinal symptoms during colonoscopy preparation (e.g., nausea, vomiting, abdominal pain, anal discomfort) need for nasogastric tube	Ease of taking colon cleansing preparation; willingness to repeat the same intervention; compliance with >75% dose of preparation	Any adverse event or exacerbation of preexisting symptoms including abnormalities in laboratory parameters except those assessed as tolerability outcomes
Vejzovic et al., 2016 [13]	10–18	Manufacturer name not provided 2x1 sachet, first sachet mixed with water at 8:00 AM the day before the colonoscopy. The second sachet was taken 6 to 8 hours later, n=36	PEG 3350 with electrolytes (BioPhausia, Stockholm, Sweden): 25–35 mL/kg body weight per hour until clear intestinal fluid was obtained, either orally or by nasogastric tube, n=35	Ottawa Bowel Preparation Score (right colon, medium colon, left colon, total), proportion of completed colonoscopy, time to reach cecum	Occurrence of gastrointestinal or extraintestinal symptoms during colonoscopy preparation (e.g., nausea, vomiting, abdominal pain, anal discomfort, sleeping problems)	Ease of taking colon cleansing preparation, taste acceptance	Not provided
Szaflarska-Popławska et al., 2019 [14]	1–18	Citrafleet (Takeda Pharmaceutical Company Limited, Tokyo, Japan) 2x1† sachet diluted in 150 mL of water, n=39	PEG 4000 with electrolytes (Fortrans Ipsen Pharma) 100 mL/kg (max. 4 L)+simethicone (80 mg/1 L solution), n=43	Proportion of patients with >6 pts for total BBPS, need for repeated colonoscopy	Occurrence of gastrointestinal or extraintestinal symptoms during colonoscopy preparation (e.g., nausea, vomiting, abdominal pain, anal discomfort, sleep disturbances, sleeping problems)	Ease of taking colon cleansing preparation; taste acceptance, willingness to repeat the same intervention, compliance with >75% dose of preparation	Not provided

PEG: polyethylene glycol, BBPS: Boston Bowel Preparation Scale.
*Each sachet contains: sodium picosulfate 10 mg, magnesium oxide 3.5 mg, citric acid 12 g. †Each sachet contains: sodium picosulfate 10 mg, magnesium oxide 3.5 mg, citric acid 10.97 g.

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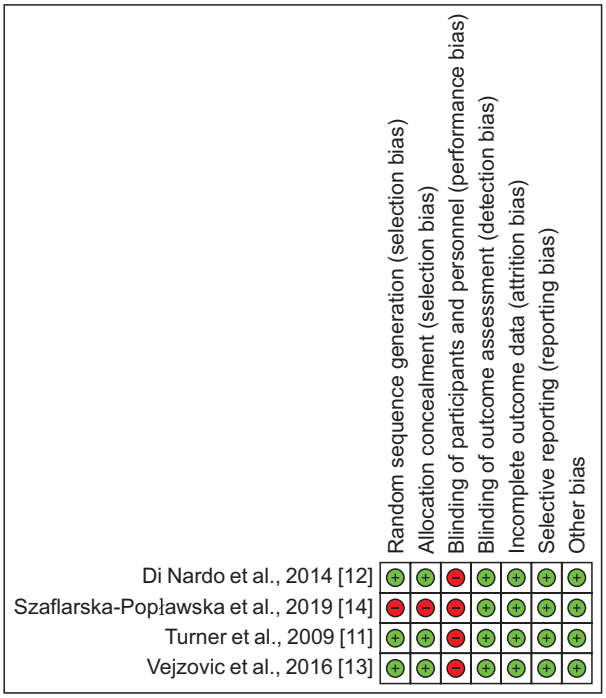

Fig. 2. Risk of bias summary.

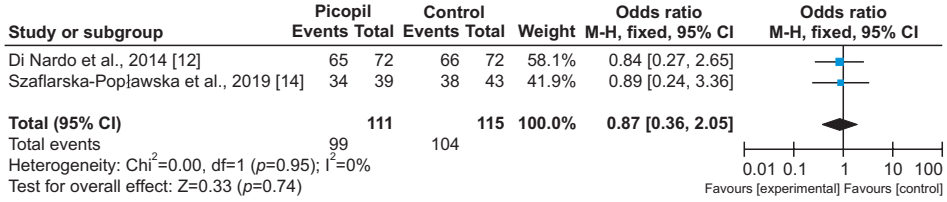

Fig. 3. Sodium picosulphate/magnesium vs. high volume polyethylene glycol. Meta-analysis of efficacy outcome measures: Boston Bowel Preparation Scale.
CI: confidence interval.

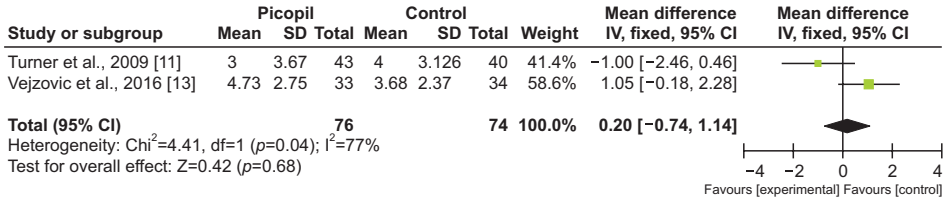

Fig. 4. Sodium picosulphate/magnesium vs. high volume polyethylene glycol. Meta-analysis of efficacy outcome measures: Ottawa Bowel Preparation Scale.
SD: standard deviation, CI: confidence interval.

PS/Mg with low volume PEG showed no statistically significant differences in any of the quality outcome measures (**Table 2**) [12].

Acceptability

The meta-analyses found that PS/Mg is superior to high volume PEG in taste acceptance, ease of drinking, decreased need for nasogastric tube, willingness to repeat formulation, and compliance with the full dose of study formulation (**Fig. 5**). One study showed that 7/31 patients badly tolerated the nasogastric tube [11].

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Table 2. Quality of bowel preparation in single center studies

Outcome	PS/Mg (n/N)	PEG (n/N)	RR (95% CI)
PS/Mg vs. high volume PEG			
Good or excellent preparation according to physcian	33/40	32/40	1.03 (0.84 to 2.7)
Enema requirement	5/43	13/40	0.36 (0.14 to 0.91)
Failed preparation	1/43	2/40	0.49 (0.05 to 5.19)
Good or excellent preparation according to physcian	65/72	66/72	0.98 (0.89 to 1.09)
Colonoscopy completed	35/36	36/36	3 (0.12 to 71)
PS/Mg vs. low volume PEG			
Good or excellent preparation according to physcian	65/72	60/72	1.08 (0.95 to 1.23)
BPPS≥6	63/74	56/76	1.15 (0.98 to 1.36)
Cecal intubation rate	71/72	71/72	1 (0.96 to 1.04)

PS/Mg: picosulphate/magnesium, PEG: polyethtylene glycol, BPPS: Boston Bowel Preparation Scale, RR: relative risk, CI: confidence interval.

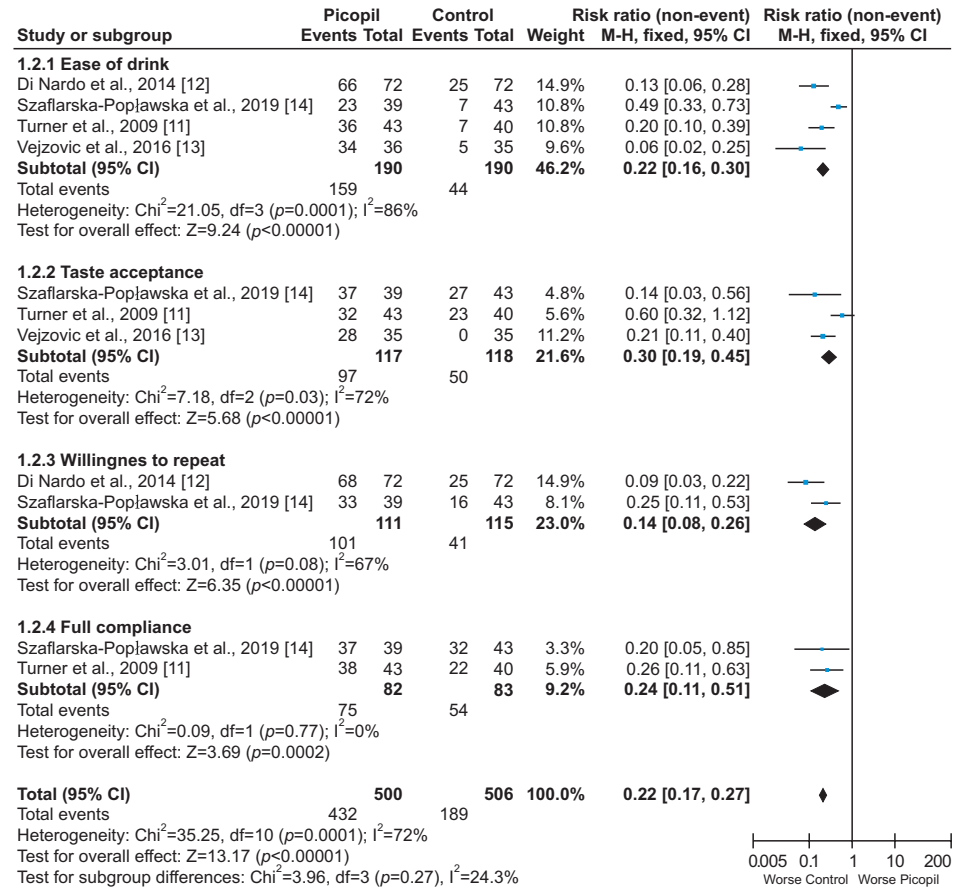

Fig. 5. Sodium picosulphate/magnesium vs. high volume polyethylene glycol. Meta-analyses of acceptability outcome measures.
CI: confidence interval.

The study comparing PS/Mg with low volume PEG showed that there is a significantly higher number of patients randomized to PS/Mg group who reported ease of taking formulation (RR: 1.41; 95% CI: 1.23 to 1.82), willingness to repeat the bowel cleansing regimen, and compliance with >75% of the prescribed dose (RR: 1.19; 95% CI: 1.05 to 1.35). Patients given low volume PEG had comparable need for nasogastric tube with patients given PS/Mg (RR: 0.25; 95% CI: 0.03 to 2.19).

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Tolerability

Six meta-analyses were performed on tolerability endpoints. PS/Mg had lower RR than high volume PEG for nausea, vomiting, bloating/flatulence/fullness, abdominal pain, and had comparable chance for anal discomfort and sleep disturbance (**Fig. 6**). Single center trials

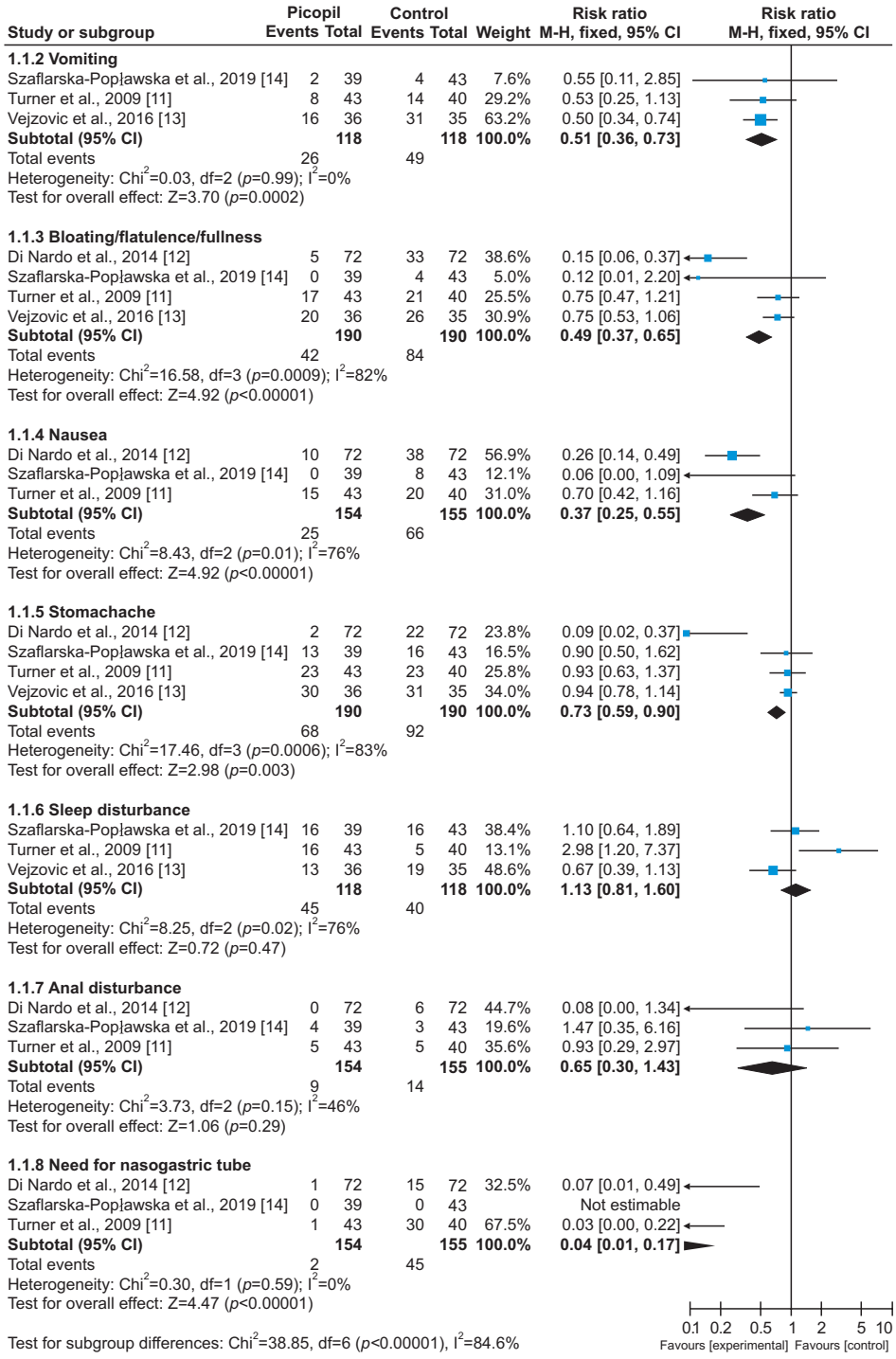

Fig. 6. Sodium picosulphate/magnesium vs. high volume polyethylene glycol. Meta-analyses of tolerability outcome measures.
CI: confidence interval.

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showed that there were no significant differences in the risk of headache, anxiety, dizziness, apathy, and sadness for both formulations (data not shown). However, one trial found that patients given PS/Mg had increased risk for the two defecation episodes during the night before colonoscopy (RR: 12.09; 96% CI: 1.66 to 88.28) [11].

PS/Mg compared with low volume PEG showed lower risk for nausea (RR: 0.34; 95% CI: 0.18 to 0.65), bloating (RR: 0.18; 95% CI: 0.07 to 0.44), and abdominal pain (RR: 0.17; 95% CI: 0.04 to 0.72) and comparable risk for anal discomfort (RR: 0.03; 95% CI: 0.01 to 6.05).

Safety

Two trials showed similar safety profile in both groups [11,12]. They reported no significant difference in the number of dehydration episodes, as judged by clinical signs and need for intravenous fluids (no data provided). Each study documented one temporary episode of lethargy and dehydration: one in PS/Mg group and one in high volume PEG group. One child treated with PS/Mg had a sodium level of 128 mmol/L without any clinical symptoms of hyponatremia [11]. One study reported a higher rate of mild hypokalemia (>2.7 mmol/L) in the high-volume PEG group (58% vs. 34%) and higher frequency of mild hypermagnesemia (<1.1 mmol/L) in the PS/Mg group (44% vs. 0%) [11]. There were no significant differences found for the other laboratory values [11,12].

DISCUSSION

Our systematic review of RCTs showed that PS/Mg for children is as effective as high-volume PEG for colon cleansing before colonoscopy regardless of the method of the of bowel preparation quality assessment. The meta-analysis of two studies which used BPPS, currently the most validated and reliable tool for the evaluation of bowel preparation quality, found that around 90% of children cleaned with each regimen had adequate colon cleansing [15]. However, our meta-analyses showed that PS/Mg is superior to high volume PEG for tolerability (abdominal pain, nausea, vomiting, bloating/flatulence/fullness) and acceptability (ease of formulation taking, taste acceptance, need for nasogastric tube, willingness to repeat the bowel cleansing regimen, compliance with the full dose of study formulation) outcome measures. We have not found any important differences in terms of safety measures between PS/Mg and PEG.

We only identified one study comparing PS/Mg with low volume PEG. This study found mixed results for efficacy endpoints favoring either PS/Mg (BPPS>6) and showed no difference between groups on the other quality colon cleansing outcomes (subjective score, mean BPPS in each of the segments, mean cecal insertion time). Low volume PEG, similar to high volume regimen, is also inferior in tolerability (nausea, bloating, abdominal pain) and acceptability endpoints (ease of taking, willingness to repeat, >75% compliance in taking regimens) but is comparable to PS/Mg on the need for nasogastric tube. The better acceptability and tolerability of PS/Mg appear to be the result of better taste, and probably to a lesser extent to lower volume of this agent. Considering the unique needs of the pediatric population, acceptability and tolerability of bowel cleansing formulation is vital. For this reason, it seems that PS/Mg can be an appealing alternative to PEG, which is currently the most commonly used formulation for bowel cleansing in children and adolescents [16]. However it must be emphasized that three out of four studies were designed to assess the efficacy but not the tolerability or acceptability. Moreover, these outcome measures were assessed with non-

validated scales and subjective measurement tools. Lastly, the data gathering was performed either in different ways or was not specified by the authors of primary studies, which limits the reliability of the results of our meta-analyses.

We also acknowledge other limitations of our study. (i) The evidence is based on a small number of trials; (ii) the bowel preparation regimens and diet restriction prior to colonoscopy were slightly different among individual studies, thus our pooled results may be biased; (iii) some outcomes in the present study were reported by a single RCT with a low number of participants; (iv) even pooled results were of relatively small sample size; and (v) there is high degree of heterogeneity for most of the meta-analyses on acceptability and tolerability. However, it must be emphasized that the low number of participants in these studies are mainly the result of the difficulties in enrolling pediatric patients [17]. Comparing to adult trials, there is a smaller pool of children available due to the lower burden of diseases. Besides, some parents perceive research studies as a threat and inconvenience to their children. Thus, they are reluctant to give consent for trial participation. Moreover, the assessment of subjective outcome measures is difficult in younger children and some of them have special compliance challenges, including acceptance of trial products which further limits the recruitment rate in this group of patients.

However, our systematic review has several strengths. The review was based on the methodology developed by the Cochrane Collaboration and reported according to the PRISMA statement with assessment of the risk of bias. Multiple efforts were made to decrease the risk of biases in trial inclusion (e.g., no language or date restrictions imposed and not yet published trials were searched for). The methodological quality of the individual trials was good. The meta-analyses on our primary outcome measures including validated scores such as Ottawa and Boston Bowel Preparation Scales were homogenous and compatible with each other. The results of our systematic review are d consistent and clear, which we believe are important for clinical practice.

Recently published systematic review on various bowel preparation formulations for all indications in children included only two trials at the time of search, comparing PS/Mg with PEG [6]. The authors of the study combined two different efficacy scoring systems and found that these two regimens were equally effective for bowel preparation. It must be acknowledged that putting different bowel cleansing measurement tools in a meta-analysis makes drawing reliable conclusions difficult. The authors of the aforementioned study also analyzed the proportion of patients who do not need a nasogastric tube and found that there was a significantly lower need for nasogastric tube in the PS/Mg group, which is similar to our meta-analysis results. Our systematic review also showed that both regimens have a comparable quality of bowel cleaning. We were able to perform meta-analyses on the effectiveness of colon cleansing with two objective and validated measurement tools. Moreover, our study provided a larger body of evidence due to the inclusion of more trials and analysis of more outcome measures. In other systematic review performed in adults, it was found that PS/Mg and PEG (either low or high volume) without additional agents was equally effective in colon cleansing, which was similar with our findings [18]. Moreover, this systematic review found that in almost all (7/8) available trials, PS/Mg based regimen was generally better accepted and patients were more compliant with the bowel cleansing protocol (pooled results of 2 studies). However, in contrast to our study, the risk for nausea, vomiting, and abdominal pain was not different between PS/Mg and PEG in adults. This could be the result of different methods of data collection in primary studies [18].

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Aside from giving some implications useful for clinical practice, the findings of this review also provides useful information for future research. The results of our study emphasizes the need for adequately powered RCTs comparing PS/Mg with low volume PEG. These should focus on tolerability and acceptability outcomes assessed with a validated questionnaire designed also for smaller children.

In summary, both PS/Mg and PEG provide adequate colon cleansing in approximately 90% of children. Both preparations are equally effective and safe, however most tolerability and acceptability measures seem to favor PS/Mg for bowel preparations in pediatric patients.

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