

Perbandingan Bersihan Kolon Antara Polyethylene Glycol dan Sodium Phosphate Pada Persiapan Kolonoskopi : Uji Klinis Acak Tersamar Tunggal = Bowel Preparation for Colonoscopy with Polyethylene Glycol versus Sodium Phosphate Based Lavage : A Single Blind Randomized Clinical Trial

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Abstrak

Latar belakang. Bersihan kolon yang adekuat berkaitan dengan persiapan kolonoskopi yang baik namun hingga saat ini belum ada penelitian mengenai dua preparat bersihan kolon yang paling umum digunakan di Indonesia yaitu polyethylene glycol (PEG) dan sodium phosphate (SP).

Tujuan. Mengetahui perbandingan bersihan kolon antara PEG dan SP pada pasien yang akan dilakukan kolonoskopi di Indonesia. Metode. Uji klinis acak tersamar tunggal, satu sentral penelitian di pusat endoskopi saluran cerna (PESC) RS. Cipto Mangunkusumo (RSCM) pada pasien usia lebih dari 18 tahun yang menjalani kolonoskopi periode Maret ? September 2014. Randomisasi manual, teknik sampling konsekutif dilakukan untuk mengalokasikan preparat PEG dan SP, kemudian penilaian bersihan kolon secara tersamar tunggal dilakukan oleh dua orang dengan Boston Bowel Preparation Scale (BBPS). Nilai adekuat bila skor ≥ 5. Analisis dilakukan dengan intention to treat.

Hasil. Dari 135 subyek yang dirandomisasi, dieksklusi 14 subyek sehingga yang dianalisis 121 subyek (PEG n=62; SP n=59). Semua subyek menjalani penelitian hingga selesai. Bersihan adekuat pada PEG 88,7% dengan rerata skor BBPS 5,89, sedangkan pada SP 89,8% dengan rerata skor BBPS 6,34 (nilai p=0,84). Didapatkan nilai Control Event Rate (CER) 11,3%, Experiment Event Rate (EER) 10,17%, Absolute Risk Reduction (ARR) 1,13%, Relative Risk Reduction (RRR) 9,92%, dan Number Needed to Treat (NNT) untuk SP sebesar 90 subyek. Efek samping pada PEG adalah mual (19,4%), rasa tidak enak (3,2%), muntah (1,6%) sedangkan pada SP hanya rasa tidak enak (5,1%). Kedua kelompok tidak mengalami alergi.

Kesimpulan. Tidak ada perbedaan bermakna secara statistik dan klinis antara PEG dan SP dalam bersihan kolon yang adekuat menggunakan skor BBPS.

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Background. Adequate clearance of the colon is associated with a good preparation for colonoscopy. Up until now research on colon adequate clearance by using two of the most commonly used preparations in Indonesia, namely polyethylene glycol and sodium phosphate has not been done.

Aims. To compare the effectivity of PEG and SP in colon clearance for patients undergoing colonoscopy in Indonesia.

Design and Methods. A single blind randomized clinical trial in one centre at gastrointestinal endoscopy centre RSCM, was conducted on patients aged over 18 years old that had colonoscopy in the period from

March to September 2014. Consecutive manual randomization was performed to allocate the PEG and SP lavage and assessment of adequate colon clearance will be evaluated by two investigators using the Boston Bowel Preparation Scale (BBPS). Adequate score if > 5 . Analysis was done by intention to treat.

Results. From the 135 randomized subjects, 14 was excluded, and 121 subjects obtained (PEG n=62; SP n=59). All subjects completed the research. Adequate clearance in PEG was 88.7% with BBPS mean score 5.89. While, SP had adequate clearance of 89.8% with BBPS mean score 6.34 (p value=0.84). Analysis resulted in CER 11.3%, EER 10.17%, ARR 1.13%, RRR 9.92%, and NNT for SP was 90 subjects. Side effects in PEG participants were nausea (19.4%), unpleasant taste (3.2%), vomit (1.6%) while in SP participants only experienced unpleasant taste (5.1%). Both groups did not experience allergic reaction.

Conclusion. There was no significant difference in terms of adequate colon clearance preparation between PEG and SP using BBPS score.