

**THE STUDY OF THE EFFECT OF BOWEL
PREPARATION AGENT ON THE QUALITY OF
COLONOSCOPY IN HOSPITAL USM KUBANG
KERIAN.**

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LIST OF ABBREVIATIONS

ADR	Adenoma detection rate
ANCOVA	Analysis of covariates
ASR	Age standardized rate
BBPS	Boston bowel preparation score
CRC	Colorectal cancer
CI	Confidence interval
gFOBT	Guaiac-based fecal occult blood test
WHO	World health organization
iFOBT	Immunochemical fecal occult blood test
MLR	Multiple logistic regression
OD	Odds ratio
OSP, NaP	Oral sodium phosphate , FLEET
PEG	Polyethylene glycol , FORTTRANS
ROC	Receiver operation characteristics
SD	Standard deviation
SLR	Simple logistic regression

ABSTRAK

Latar belakang: Kanser kolorektal adalah salah satu barah yang paling lazim di seluruh dunia dan di Malaysia. Pemeriksaan kolonoskopi dapat mengesan peringkat awal kanser dan mengurangkan kematian akibat kanser usus rektal. Penyediaan usus yang optimum adalah salah satu faktor utama yang mempengaruhi kualiti kolonoskopi. Objektif kajian kami adalah untuk membandingkan kesan PEG berbanding OSP terhadap kualiti kolonoskopi yang diukur dengan skor penyediaan usus boston, kadar intubasi cecal, dan jumlah masa prosedur.

Kaedah: Kajian keratan rentas ini dilakukan pada bulan November 2020 hingga Februari 2021 Universiti Sains Malaysia. Seramai 171 pesakit yang menjalani kolonoskopi di unit endoskopi hospital. 80 pesakit menerima OSP sementara 91 menerima persiapan usus PEG. Semua maklumat pesakit seperti umur, jantina, komorbiditi, tahap kreatinin, tujuan untuk kolonoskopi dikenal pasti. Indikator kualiti kolonoskopi termasuk tahap penyediaan usus (bowel preparation), kadar intubasi cecum, jumlah masa prosedur dibandingkan antara kedua-dua kumpulan ini. Untuk analisis statistik, data kategorik ditunjukkan sebagai frekuensi dan peratusan sementara data berangka disajikan sebagai min dan sisihan piawai (SD). Kami mengaplikasikan Independent t-test, chi square, Fisher test, dan Simple Logistic Regression (SLR) dengan tepat dalam analisis univariat. Kemudian, kami menggunakan Analisis Covariates (ANCOVA) untuk ujian objektif satu dan tiga dan Logistik Regresi Pelbagai (MLR) untuk menganalisis objektif kedua kami. Semua andaian untuk ujian dipenuhi.

Keputusan: Di antara 171 pesakit yang menjalani kolonoskopi, 90 (52.6%) daripadanya menerima persiapan usus PEG, dan 81 orang (47.4%) menerima

persiapan usus OSP . 150 pesakit (87.7%) mempunyai intubasi cecal yang berjaya. Sementara, 21 pesakit (12.3%) gagal intubasi cecal kerana persiapan usus yang tidak memuaskan . Skor min BBPS 5.69 (± 1.86). Purata masa kolonoskopi adalah 50.18 (± 23.24) minit. Bagi Skor Persediaan Bowel Boston (BBPS) tiada perbezaan ketara (min disesuaikan 5.68 vs. 5.69, $p = 0.987$) antara PEG dan OSP setelah mengawal usia dan tahap kreatinin. Regresi logistik dilakukan untuk memastikan kesan PEG dan OSP dengan tahap usia dan kreatinin sebagai kovariasi kemungkinan intubasi caecal berjaya. Model ini tidak signifikan secara statistik ($p = 0.93$) tetapi diklasifikasikan dengan betul 87.1% kes dan mempunyai 64.7% kawasan di bawah kurva ciri operasi penerima (ROC). OSP 4% lebih cenderung untuk mencapai intubasi caecal yang berjaya daripada PEG ketika usia dan tahap kreatinin dikendalikan. Tiada perbezaan ketara bagi jangka masa prosedur kolonoskopi (rata-rata disesuaikan 50.12 vs. 50.29, $p = 0.963$) antara PEG dan OSP setelah mengawal tahap usia dan kreatinin.

Kesimpulan: kami membandingkan dua agen penyediaan usus, PEG dan OSP, dari segi kualiti kolonoskopi. Analisis kami tidak menunjukkan perbezaan yang ketara antara kedua-dua agen ini dari segi kualiti penyediaan usus dan jangka masa prosedur. Tahap intubasi cecal keseluruhan tidak memenuhi piawai, dan kumpulan OSP (4%) lebih cenderung untuk mencapai intubasi caecal yang berjaya daripada kumpulan PEG ketika usia dan tahap kreatinin menjadi factor pembaur dikawal serentak.

Kata kunci:

Kolonoskopi, kebersihan usus, intubasi cecal, agen penyediaan usus (PEG, OSP), waktu-prosedur.

ABSTRACT

Background: Colorectal cancer is one of the most common cancers worldwide and Malaysia. Screening colonoscopy reduces overall incidence and death due to CRC. Proper bowel cleanliness is one of the main factors that directly affect the quality of the colonoscopy. The objective of our studies is to compare the effect of PEG versus OSP on the quality of colonoscopy measured by Boston bowel preparation score, cecal intubation rate, and total procedural time.

Methods: This comparative cross-sectional study was conducted in November 2020 till February 2021 Universiti Sains Malaysia. A total of 171 patients underwent colonoscopy in the hospital endoscopy unit. 80 patients received OSP, while 91 received PEG bowel preparation. All patients' information such as age, gender, comorbidities, creatinine level, and indication for colonoscopy were recorded and saved. The quality indicators of colonoscopy including the efficiency of bowel cleanliness, the cecal intubation rate, and the total procedural time were compared between these two groups. For statistical analysis, categorical data was presented as frequency and percentage while numerical data was presented as mean and standard deviation (SD). We applied Independent t-test, chi square, Fisher exact and Simple Logistic Regression (SLR) appropriately in the univariate analysis. Then, we used Analysis of Covariates (ANCOVA) for objective one and three and multiple Logistic Regression (MLR) test to analyze our second objective. All assumptions for the tests were met.

Results: Among 171 patients that underwent colonoscopy, 90 (52.6%) of them received Fortrans bowel preparation, and 81(47.4%) received fleet bowel preparation. 150 patients (87.7%) had a successful cecal intubation while 21 patients

(12.3%) failed cecal intubation due to poor bowel preparations. The BBPS mean score 5.69 (± 1.86). The mean colonoscopy time was 50.18 (± 23.24) minutes. The Boston Bowel Preparation Score (BBPS) was not significantly different (adjusted mean 5.68 vs. 5.69, $p = 0.987$) between PEG and OSP after controlling age and creatinine level. A logistic regression was performed to ascertain the effects of PEG and OSP with age and creatinine level as covariates on the likelihood of successful caecal intubation. The model was not statistically significant ($p=0.93$) but correctly classified 87.1% of cases and has 64.7% of area under receiver operating characteristic (ROC) curve. OSP was 4% more likely to achieve successful caecal intubation than PEG when age and creatinine level were controlled. The colonoscopy procedural time was not significantly different (adjusted mean 50.12 vs. 50.29, $p = 0.963$) between PEG and OSP after controlling age and creatinine level.

Conclusion: we compared two bowel preparation agents, PEG and OSP, in terms of quality of colonoscopy. Our analysis showed no significant difference between these two agents in terms of bowel cleanliness efficiency and total procedural time. The overall cecal intubation rate was below standard, and the OSP group was 4% more likely to achieve successful caecal intubation than the PEG group when age and creatinine level were controlled as confounders

Keywords:

Colonoscopy, bowel cleanliness, cecal intubation, bowel preparation agent (PEG, OSP), procedural time

CHAPTER 1: INTRODUCTION

Colorectal cancer (CRC) is the third most diagnosed cancer and is the fourth leading cause of death worldwide. Considering the demographic estimates, the global burden of CRC is expected to increase by 60% and reaches more than 2.2 million new cases and 1.1 million deaths by 2030 (1) .

Colorectal cancer (CRC) is the commonest cancer in Malaysian men (age-standardized incidence rate 14.8/ 100, 000), and it's the second most common cancer in Malaysian women (age-standardized incidence rate 11.1/ 100,000) (2) , and the third commonest cause of cancer deaths in Malaysia. About 66% of male and 65% of female CRC cases are detected at a late stage (stage 3 or 4) thereby leading to an increased risk of cancer death (3). The GLOBOCAN project report demonstrated that the over- all incidence of CRC in Malaysia was the third highest (18.30 per 100,000) in South East Asia.

A recent study to explore Incidence and mortality rates of colorectal cancer in Malaysia with 34 participating centers including at least one representative hospital from each of the 14 states of Malaysia found the overall incidence rate for CRC was 21.32 cases per 100,000. Those of Chinese ethnicity had the highest CRC incidence (27.35), followed by the Malay (18.95), and Indian (17.55) ethnicities. The ASR incidence rate of CRC was 1.33 times higher among males than females (24.16 and 18.14 per 100,000, respectively) (4) .

Another study done in Malaysia by (Sajesh K. Veetil et al 2016) exploring the burden of colorectal cancer noted that even though incidence is higher in developed Asian countries such as Japan and Singapore compared to developing nations such as Malaysia . The improving socioeconomic status and increasingly

westernized life style in developing countries in Asia, including Malaysia, could be expected to be associated with an increasing incidence of colorectal cancer (5) . The estimated economic burden of colorectal cancer management of new cases alone is estimated to be around RM108 million per year , excluding costs for non-incident cases, like detection and management of recurrences, and ongoing palliative care of Stage 4 patients , and the cost of new biologic drugs that are provided for some patients (6) .

Patients with colorectal cancer present mostly with altered bowel habit (41.7%) followed by blood in stool (35.5%), abdominal pain (31.5%), weight loss (31.0%), anemia (9.8%) and intestinal obstruction (9.3%). The target of CRC screening is to diagnose premalignant lesions such as colon polyps or CRC at earlier stages in average-risk adult population, when there is a higher rate of successful treatment and survival.

According to the recent Malaysian clinical practice guidelines screening for CRC in the average risk population defined as population with no known risk, CRC should be offered at the age of 50 years and continues until 75 years old. Immunochemical faecal occult blood test (iFOBT) is the preferred method to screen for CRC in average risk population. If iFOBT is positive, an early colonoscopy is necessary. If iFOBT is negative, yearly test should be performed.

However, in moderate to high risk population asymptomatic individuals with positive family history should be screened for colorectal carcinoma. Additionally, all individuals whose family history is suggestive of a hereditary colorectal cancer syndrome should be referred to a clinical genetics service for genetic risk assessment, where accessible (7) .

Multiple tests are available for CRC screening. Each test has its own strengths and weaknesses. To mention a few, 1st is Immunochemical FOBT (iFOBT) and guaiac-based FOBT (gFOBT) are two methods of qualitative FOBT. The sensitivities of iFOBT and gFOBT are 0.67 (95% CI 0.61 to 0.73) and 0.54 (95% CI 0.48 to 0.60) respectively.

Other investigations to use for CRC screening are Sigmoidoscopy and colonoscopy. Flexible sigmoidoscopy needs less rigorous bowel preparation and can be performed as a clinic-based procedure without the need for sedation. Small polyps can be biopsied during procedure but excision of larger lesions (>1 cm) may be performed during subsequent colonoscopy. Sigmoidoscopy reduces the CRC incidence by 18-32% and mortality by 26-38% in general population. There is low incidence of bowel perforations associated with it.

Colonoscopy is the screening modality that has the ability to visualize the colonic mucosa directly, perform biopsy and excise polyps. It can detect proximal lesions that would be missed by screening sigmoidoscopy and has been shown to reduce risk of cancer in the right colon. Screening colonoscopy reduces overall CRC incidence significantly by 56% and death by 68%. For those who have had colonoscopy especially for screening, the risk of CRC is strongly reduced by 91% up to 10 years (7) . To compare sensitivity between the most commonly used Standard guaiac fecal occult-blood test, using a three stool samples shows a sensitivity rate of 33- 50 % , comparing it to colonoscopy which is > 95% sensitive in detecting Colorectal cancer and advanced adenoma(8) .

Population-based CRC screening through a faecal occult blood test was identified by the World Health Organization (WHO) as a ‘best buy’ for the

prevention and control of NCDs. In Malaysia, in the absence of a population-based CRC screening, Malaysia opted for a nationwide opportunistic screening in its health facilities rolled out in an organized manner. This structured program offered a significant screening method, follow-up and data collection methods. There were high-level documents for governance and guidelines for implementation. However, since its initiation in 2014 up to 2018, the coverage of screening remained low.

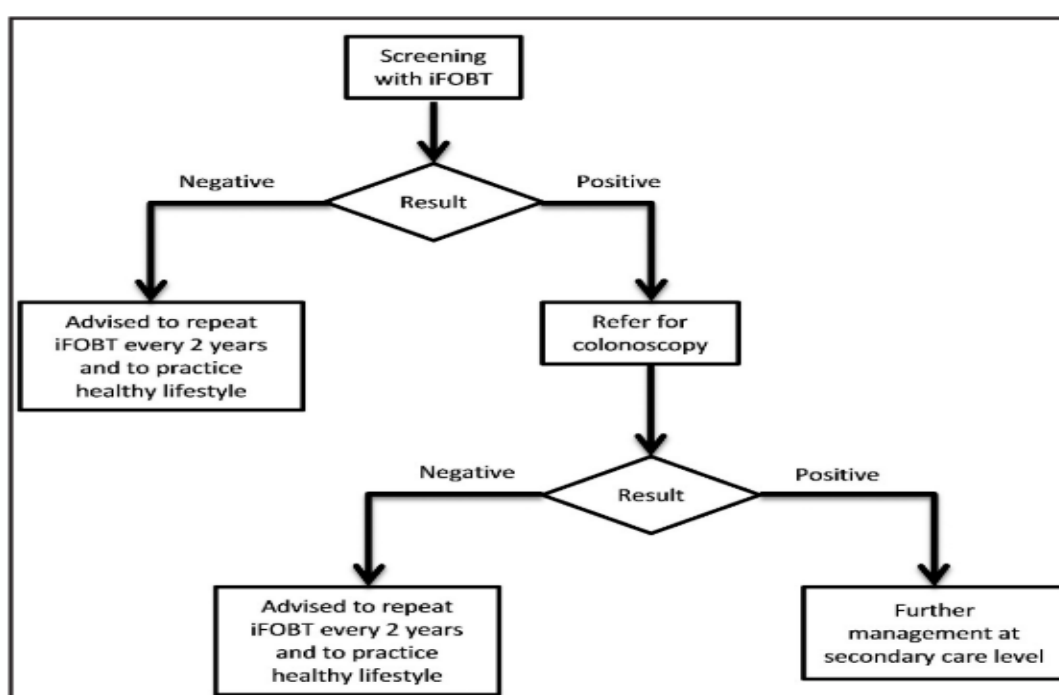


Fig. 1: Flowchart of the colorectal cancer screening programme in Malaysia

However, successful implementation depends on many factors. The effectiveness of colonoscopy is directly affected by many factors such as patient compliance, skill of the Endoscopist, and most importantly the Quality of bowel preparation. The preparation quality affects completing the procedure, the duration of the procedure, the need to cancel and repeat the procedure (9) .

Cancelled colonoscopy procedure due to imperfect bowel preparation does have a direct effect on the patients due to the need to undergo another bowel preparation which can be an uncomfortable procedure and reschedule another

colonoscopy appointment. Additionally, cancelled procedure results in financial burden on the health care system. A study performed in 10 Indiana University Medical Center aiming to measure the impact of bowel preparation on total direct cost resulted in a 12% increase in cost at a university hospital, and 22% increase in public hospital. Colonoscopy in both centers was performed by experienced attending physicians

Proper cleaning is one of the main factors. It's usually defined as one that allows the detection of colonic polyps 5 mm or larger. The cecal intubation rate and adenoma detection rate are two of the main quality endoscopic indices, both of which are directly related to the quality of preparation (10).

Inadequate colonic preparation is associated with reduced adenoma detection rates (ADRs). A large prospective European study of 5832 patients enrolled in 21 centers across 11 countries examined the association of preparation quality and polyp identification during colonoscopy performed for a range of common indications. High-quality preparation was associated with identification of polyps of all sizes (odds ratio [OR], 1.73; 95% confidence interval [CI], 1.28–2.36), and with polyps greater than 10 mm in size (OR, 1.72; 95% CI, 1.11–2.67) (11).

Many scores were created to standardize the assessment of bowel cleanliness during colonoscopy. Of those many scores, The Boston bowel preparation score is a valid and reliable instrument for assessing bowel cleanliness during colonoscopy. Bowel Segment scores represent a standardized way to determine bowel preparation adequacy (12).

Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve, so that the entire cecal caput, including the medial

wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. Effective colonoscopists should be able to intubate the cecum in >90% of all cases and >95% of cases when the indication is screening in a healthy adult.

The most important determinant of preparation quality is the interval between the end of the preparation ingestion and the start of the procedure. Quality diminishes as the interval increases, and the right side of the colon is particularly affected (13) . In a single-centre study Higher BBPS scores (>5 vs. <5) were associated with a higher polyp detection rate (40% vs. 24%, $P < .02$). BBPS scores were inversely correlated with colonoscope insertion ($r -0.16$, $P < .003$) and withdrawal ($r -0.23$, $P < .001$) times.

The consensus guidelines for the safe prescription and administration of oral bowel-cleansing agents performed in United Kingdom suggest that The ideal oral bowel cleansing agent would be easy to administer, tolerated by the patients , effective in cleansing, with an acceptable side-effects . No single agent is ideal in all clinical scenarios, and research into the ideal agent (or combination) continues (9) .

Bowel preparation agents can be divided into 3 groups: isosmotic, hyposmotic, and hyperosmotic agents. Isosmotic agents include high-volume polyethylene glycol (PEG) preparations, low-volume PEG preparations, and sulfate-free PEG-electrolyte solutions (ELS). Hyposmotic agents include a low-volume PEG preparation called PEG-3350 (PEG-SD) that requires an additional electrolyte solution (sports drink) and often combined with bisacodyl. Hyperosmotic agents include magnesium citrate, oral sodium sulfate, and sodium phosphate.

Polyethylene glycols (also known as PEG or macrogols) are non-absorbable iso-osmotic solutions, which pass through the bowel without net absorption or

secretion. Significant fluid and electrolyte shifts are therefore attenuated. The preparations must be diluted in large volumes of water (up to 4 liters) to achieve the desired cathartic effect, and often have an unpalatable taste (despite flavorings).

On the other hand, oral sodium phosphate preparations are hyper- osmotic and promote colonic evacuation by drawing large volumes of water into the colon (1.8 liters of water per 45 ml of preparation). They are typically diluted in much smaller volumes of water than the polyethylene glycols (250 ml).

Multiple clinical studies have been conducted to compare the effectiveness of many agents used for bowel preparation, few actually comparing the agents of interest in this study. A prospective single-centre randomized trial conducted in Finland by J. Kossi et al 2003 involving 111 patients, comparing the effect of bowel cleanliness in patient who took PEG as bowel preparation agent versus OSP . This study showed that the mean cleansing score was significantly higher in the NaP group than in the PEG-EL group (3.64 ± 0.16 versus 2.69 ± 0.13 , respectively) and the withdrawal time was significantly shorter in the OSP group. No significant differences were seen in caecal intubation time and total colonoscopy time (14). Another similar study conducted in china by yang et al 2020, involving 586 patients in a single-centre which show more effective cleanliness in group OSP versus group using PEG .

CHAPTER 2: OBJECTIVES OF STUDY

GENERAL OBJECTIVE:

To compare the effect of PEG versus OSP on the quality of colonoscopy measured by Boston bowel preparation score.

SPECIFIC OBJECTIVES:

1. To compare the mean outcome of bowel cleanliness using Boston bowel preparation score in patient who received PEG vs. OSP
2. To determine the proportion of success of cecal intubation in patient received PEG vs. OSP.
3. To compare the mean outcome of total procedure time in patient who Received PEG vs. OSP.

CHAPTER 3: MANUSCRIPT

JOURNAL: Malaysian Journal of Medical Sciences

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study.

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INTRODUCTION

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Multiple tests are available for CRC screening. Each test has its own strengths and weaknesses in being the best screening tool. To mention few, Immunochemical FOBT (iFOBT) and guaiac-based FOBT (gFOBT) are two methods of qualitative FOBT. The sensitivities of iFOBT and gFOBT are 0.67 (95% CI 0.61 to 0.73) and 0.54 (95% CI 0.48 to 0.60) respectively.

Other investigations to use for CRC screening are Sigmoidoscopy and colonoscopy. Flexible sigmoidoscopy needs less rigorous bowel preparation and can be performed as a clinic-based procedure without the need for sedation. Small polyps can be biopsied during procedure but excision of larger lesions (>1 cm) may be performed during subsequent colonoscopy. Sigmoidoscopy reduces the CRC incidence by 18-32% and mortality by 26-38% in general population. There is low incidence of bowel perforations associated with it.

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significant screening method, follow-up and data collection methods. There were high-level documents for governance and guidelines for implementation. However, since its initiation in 2014 up to 2018, the coverage of screening remained low.

However successful implementation depends on many factors, proper cleaning is one of the main factors. It's usually defined as one that allows the detection of colonic polyps 5 mm or larger. The cecal intubation rate and adenoma detection rate are two of the main quality endoscopic indices, both of which are directly related to the quality of preparation (8) .

Inadequate colonic preparation is associated with reduced adenoma detection rates (ADRs). A large prospective European study of 5832 patients enrolled in 21 centers across 11 countries examined the association of preparation quality and polyp identification during colonoscopy performed for a range of common indications. High-quality preparation was associated with identification of polyps of all sizes (odds ratio [OR], 1.73; 95% confidence interval [CI], 1.28–2.36), and with polyps greater than 10 mm in size (OR, 1.72; 95% CI, 1.11–2.67) (9) .

Many scores were created to standardize the assessment of bowel cleanliness during colonoscopy. Among those many scores, The Boston bowel preparation score is a valid and reliable instrument for assessing bowel cleanliness during colonoscopy. Bowel Segment scores represent a standardized way to determine bowel preparation adequacy (10) .

Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve, so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible. Effective colonoscopists should be able to intubate the cecum in >90% of all cases and >95% of cases when the indication is screening in a healthy adult.

The most important determinant of preparation quality is the interval between the end of the preparation ingestion and the start of the procedure. Quality diminishes as the interval increases, and the right side of the colon is particularly affected (11) . The consensus guidelines for the safe prescription and administration of oral bowel-cleansing agents performed in United Kingdom suggest that The ideal oral bowel cleansing agent would be easy to administer, tolerated by the patients , effective in cleansing, with an acceptable side-effects . No single agent is ideal in all clinical scenarios, and research into the ideal agent (or combination) continues (12) .

Bowel preparation agents can be divided into 3 groups: isosmotic, hyposmotic, and hyperosmotic agents. Isosmotic agents include high-volume polyethylene glycol (PEG) preparations, low-volume PEG preparations, and sulfate-free PEG-electrolyte solutions (ELS). Hyposmotic agents include a low-volume PEG preparation called PEG-3350 (PEG-SD) that requires an additional electrolyte solution (sports drink) and often combined with bisacodyl. Hyperosmotic agents include magnesium citrate, oral sodium sulfate, and sodium phosphate.

Polyethylene glycols (also known as PEG or macrogols) are non-absorbable iso-osmotic solutions, which pass through the bowel without net absorption or secretion. Significant fluid and electrolyte shifts are therefore attenuated. The preparations must be diluted in large volumes of water (up to 4 liters) to achieve the desired cathartic effect, and often have an unpalatable taste (despite flavorings).

On the other hand, oral sodium phosphate preparations are hyper- osmotic and promote colonic evacuation by drawing large volumes of water into the colon (1.8 liters of water per 45 ml of preparation). They are typically diluted in much smaller volumes of water than the polyethylene glycols (250 ml).

Multiple clinical studies have been conducted to compare the effectiveness of many agents used for bowel preparation but few actually compared the agents of interest in this study. A prospective single-centre randomized trial conducted in Finland by J. Kossi et al 2003 involving 111 patients compared the effect of bowel cleanliness in patient who took PEG as bowel preparation agent versus OSP. This study showed that the mean cleansing score was significantly higher in the OSP group than in the PEG-EL group (3.64 ± 0.16 versus 2.69 ± 0.13 , respectively) and the withdrawal time was significantly shorter in the NaP group. No significant differences were seen in caecal intubation time and total colonoscopy time (13). Another similar study conducted in china by yang et al 2020, involving 586 patients in single centre showed more effective cleanliness in group OSP versus group using PEG.

METHODOLOGY

This cross comparative sectional study was conducted from November 2020 till February 2021 by comparing the outcome of bowel cleanliness in patients who received PEG bowel preparation agent versus group of patients who received OSP bowel preparation agent. Study populations were patients who underwent colonoscopy at the endoscopy unit in hospital university sains Malaysia. Patients were be divided into two groups based on the bowel preparation agent used (PEG vs. OSP) . This information was obtained from patients record in the pharmacy online portal / and patient medical folders. After identifying the bowel preparation agent used, inclusion criteria (age 18 years old and more, patient underwent colonoscopy in university hospital scope unit) and exclusion criteria (Patients with an obstruction, an incomplete obstruction, or a lower digestive tract hemorrhage, Patients with a history of colorectal resection, except appendectomy, ESRF patients and patients with advanced heart failure) was implemented to create two groups of patients based on bowel preparation agent used.

Stratified sampling method was used. The population from which the sample was taken are patients who underwent colonoscopy from 01/01/2018 – 01/02/2021. The selection then was divided into strata based on the bowel prep agent used. Proportionate sampling was used to ensure equal numbers in each group. Then, another probability sampling was used to collect sample among each group using simple random sampling.

Both bowel preparation agents were represented equally. After that the proforma checklist was used to collect the data needed as the patient

sociodemographic characteristic (Number, Age, Gender, Medical comorbidities, Diagnosis on admission).

The bowel cleanliness score was given by the endoscopist using the bowel preparation score. This procedure was performed by a medical and surgical specialist or a third /forth year trainees to minimize the effect of performer variability, the ability to intubate the cecum in each colonoscopy, and the total duration from start to finish for each colonoscopy.

Total sample size required calculated using an online sample size calculator using two independent mean and ANCOVA sample size calculators for first and third objective , and two proportion sample size calculator for the second objective using Arifin calculator . With this sample size calculation, we would have 80% power to declare that the two groups have significantly different means, i.e. a two sided p-value of less than 0.05.

All the data collected were entered into a SPSS database. The statistical analysis was performed with IBM Statistic Program for Social Sciences (SPSS version 26) software. Demographic characteristics and prevalence of outcomes for both groups were tabulated for descriptive statistics.

For statistical analysis, categorical data was presented as frequency and percentage while numerical data was presented as mean and standard deviation (SD). We applied Independent t-test, chi square, Fisher exact and Simple Logistic Regression (SLR) appropriately in the univariate analysis. Then, we used Analysis of Covariates (ANCOVA) for objective one and three and multiple Logistic Regression (MLR) test to analyze our second objective. All assumptions for the tests were met.

Variables comparison with p-value less than 0.05 is considered as significant. The data was analyzed using SPSS software version 26.

Ethical clearance was sought from USM Human Research Ethics Committee (USM HREC). This study is pending approval by jpem .The study complied with acceptable international standards including the Declaration of Helsinki. Besides that, before obtaining the data and medical record review, permission from the hospital director and Secretariat Outcome Based Budgeting (OBB) were obtained.

RESULTS

Among the 171 patients that underwent colonoscopy, 90 patients (52.6%) received the PEG bowel preparation, and 81 patients (47.4%) received the OSP bowel preparation. The demographic characteristics of our sample were summarized in table 1. In the PEG group, the patient's ages were significantly different from the patient's ages of the OSP group (55.5 ± 15.03) and (47.57 ± 17.41) respectively, ($t(169) = 3.19$, $p = 0.002$). Male patients accounted for 52.2% in the PEG group and 44.4%. While female patients accounted for 47.8% in the PEG group and 55.6% in the OSP group. There was no statistically significant association between gender and type of Bowel preparation; $\chi(1) = 1.03$, $p = 0.31$.

Patients with no medical comorbidities represented 76.5% in the OSP group and 51.1% in the PEG group. The PEG group had a higher percentage of patients with comorbidities compared to the OSP group. There was a statistically significant association between comorbidities and type of Bowel preparation; $\chi(4) = 15.14$, $p = 0.004$. Creatinine levels in the PEG group (95.72 ± 61.98) were significantly higher than the OSP group (77.77 ± 17.77), ($t(169) = 2.52$, $p = 0.013$).

In the PEG group, chronic constipation, CRC screening, and others represented the most frequent indications with the percentage of 23.3%, 22.2%, and 22.2% respectively. However, in the OSP group, the indications other than CRC screening, and chronic constipation represented 29.6%. The second most frequent colonoscopy indication in the OSP group was CRC screening with 23.5%. In our analysis, there was no statistically significant association between colonoscopy indications and type of Bowel preparation; $\chi(5) = 9.07$, $p = 0.11$.

The prevalence of the measured outcomes is summarized in table 2. In our sample of 171 patients who underwent colonoscopy, 150 patients (87.7%) had successful cecal intubation and 21 patients (12.3%) failed cecal intubation due to poor bowel preparations. Patients who failed cecal intubation due to difficult angulation or an obstructing mass were excluded from our sample and analysis. As measured by the BBPS mean score 5.69 (± 1.86). The mean colonoscopy time was 50.18 (± 23.24) minutes.

The quality of bowel cleanliness adjusted mean of the PEG and OSP groups was calculated using covariate analysis (ANCOVA) after controlling age and Creatinine as shown in table 3 , figure 1 and 2 . The Boston Bowel Preparation Score was not significantly different between PEG and OSP after controlling age and creatinine level (adjusted mean 5.68 for PEG vs. 5.69 for OSP , $p = 0.987$).

A logistic regression was performed to ascertain the effects of PEG and OSP with age and Creatinine level as covariates on the likelihood of successful cecal intubation as summarized in table 4. The model was not statistically significant ($p=0.93$) but correctly classified 87.1% of cases and has 64.7% of area under receiver operating characteristic (ROC) curve. OSP was 4% more likely to achieve successful cecal intubation than PEG when age and Creatinine level were controlled.

The adjusted mean of colonoscopy procedural time for the PEG and the OSP groups was calculated using covariate analysis (ANCOVA) after controlling the age and the Creatinine level as summarized in table 5. detail description of the total procedural time in both groups shown in figure 3, 4. The colonoscopy procedural

time was not significantly different between PEG and OSP after controlling age and Creatinine level (adjusted mean 50.12 for PEG vs. 50.29 for OSP , $p = 0.963$).

DISCUSSION

Our study sample size of 171 patients who underwent colonoscopy consisted of both outpatient and inpatients and its size is comparable to the single-center study in Finland involving 111 patients comparing PEG versus oral sodium phosphate in regards to the quality of bowel preparation and colonoscopy procedural time (13) .

The mean age in the PEG group (55.5 ± 15.03) was significantly higher than the OSP group (47.57 ± 17.41), ($t(169) = 3.19$, $p = 0.002$) since older patients are more likely to have medical comorbidities that might limit the use of oral sodium phosphate. A similar trend showed in the single-center Chinese study in which the patients of the PEG group were also older than those of the OSP group ($46:4 \pm 9:8$ vs. $43:3 \pm 10:5$ years, $P \leq 0:001$) (14).

Both genders are equally represented in our sample since 47 (52.2%) patients and 36 (44.4. %) patients were male in the PEG and OSP group respectively and 43 (47.8%) patients and 46 (55.6%) patients were female. There was no statistically significant association between gender and type of Bowel preparation; $\chi(1) = 1.03$, $p = 0.31$. The mean creatinine level in the PEG group was $95.72 (\pm 61.98)$ which was significantly higher compared to the OSP group $77.77 (\pm 17.77)$. The standard deviation of mean creatinine level was significantly higher in the PEG indicating that the creatinine levels are respectively above and below the mean creatinine level, which can be explained by the Known side effect of oral sodium phosphate causing phosphate nephropathy.

There were more patients without medical comorbidities in the OSP group, 62 patients (76.5%), compared to the PEG group 46 patients (51.1%), which can be explained by phosphate nephropathy the well-recognized adverse event associated with oral sodium phosphate. Phosphate nephropathy is more likely to occur in patients older than 60 years old, female patients, hypertensives, patients on angiotensin converting enzyme inhibitors (ACE-I), angiotensin receptor block- ade (ARB), diuretics, and patients with underlying chronic kidney disease (15). There was a statistically significant association between comorbidities and type of Bowel preparation; $\chi(4) = 15.14$, $p = 0.004$.

Based on the 2010 data published by the American Society of gastrointestinal endoscopy, over 3.3 million outpatient colonoscopies are performed annually in the United States, with screening and polyp surveillance accounting for half of indications (20). In our study, CRC screening was the indication for colonoscopy in the PEG and the OSP with 20 (22.2%) and 19 (23.5%) respectively. There was no statistically significant association between colonoscopy indications and type of Bowel preparation; $\chi(5) = 9.07$, $p = 0.11$.

Among the 171 patients who underwent colonoscopy, 150 patients (87.7%) had successful cecal intubation, while 21 patients (12.3%) fail cecal intubation due to poor bowel preparation. Patients who failed the cecal intubation due to difficult angulation, intestinal mass obstructing the lumen were excluded from the study sample.

All of the colonoscopy procedures conducted on the patients of our sample were conducted by a specialist or a senior trainee. The U.S. Multi-Society Task