Bowel preparation for colonoscopy: is diet restriction necessary?

Randomized pilot study

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DECLARATION

I, Dr. Hung-Jou Chang, hereby declare that the work on which this dissertation is based is my original work and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

Background: Bowel preparation is essential for quality colonoscopy. Although most bowel preparation regimens recommend dietary restriction for 24 to 48 hours before the procedure, the evidence for this is poor.

Objectives: To establish whether dietary restriction during bowel preparation improves the quality of bowel preparation.

Methods: A prospective single blind, randomised controlled pilot study. The dietary restriction (DR) group was instructed not to ingest high fibre foods for 48 hours prior to the use of a polyethylene glycol (PEG) bowel preparation. The non-dietary restriction (NDR) group was not given any dietary modification, but received instructions for the use of the PEG-based preparation solution. On the day of colonoscopy, the quality of the bowel effluent was assessed, and additional preparation given as necessary. The primary endpoint was quality of bowel cleansing using the Harefield Cleansing Scale during colonoscopy. The secondary endpoint was the need for additional bowel preparation and quantity of additional bowel preparation given prior to endoscopy. Data were analysed on an intention to treat basis.

Results: Twenty-three participants were randomised to the intervention group and thirty-four to the control group. Patient demographics were similar in both groups. Dietary restriction did not influence the success rate of bowel preparation: 97% successful bowel preparation in the DR group, vs 91% successful bowel preparation in the NDR group (p=0.559). Additional bowel preparation requirement were similar in both groups: 35% in DR group vs 39% in NDR group (p=0.768). Mean amount of additional bowel preparation required was similar: 560 ml in the DR group vs 460 ml in the NDR group (p=0.633).

Conclusion: The quality of bowel preparation was comparable in patients with and without dietary restrictions prior to colonoscopy. Non-restrictive diets prior to bowel preparation should be considered to increase compliance. The sample size of this pilot study prohibited definite statistical conclusions but demonstrated this to be a

reasonable methodology for a larger study.

Keywords: bowel preparation, colonoscopy, regular diet, non-dietary restriction.

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CHAPTER 1 – LITERATURE REVIEW

INTRODUCTION AND LITERATURE REVIEW

History of Colonoscopy

Retrograde colonoscopy, using fibre-optic technology as a light source, was first developed in June 1969. Three months later, an endoscopic polypectomy was successfully performed using an electrocautery device designed by Hiromi Shinya. Colonoscopy was initially called "Colonofiberoscopy" to distinguish from "Coloscopy". Coloscopy was the original way to examine the colon lumen, prior to the development of the colonoscopy, a procedure which involved a laparotomy and insertion of a rigid sigmoidoscope into the bowel lumen.[1]

Introduction

Colonoscopy is a valuable tool in diagnosis, screening, and treatment of lower gastrointestinal tract pathologies. It has the ability to detect colonic diseases, such as lower gastrointestinal cancers, polyps, inflammatory bowel disease, diverticular disease, rectal ulcers and haemorrhoids. Unlike radiology, colonoscopy can also be therapeutic and polypectomy, stenting of strictures, cauterising of ectatic or bleeding vessels, can all be performed during colonoscopy.[2,3] Colonoscopy has also been frequently used to investigate various non-specific abdominal symptoms and suspected occult bleeding which may result in iron deficiency anaemia.[2] However, the most obvious value of colonoscopy is in the detection and removal of early-stage cancers or dysplastic polyps, thus decreasing morbidity and mortality from colorectal cancer.[3]

Benefits of Colonoscopy in Early Detection of Colorectal Cancer

An average risk population can be defined as a population without any pre-existing diseases or genetic conditions that would increase their lifetime risk in developing colorectal cancer.[4] Although there are no randomised controlled trials to evaluate the efficacy of colonoscopy in average risk patients, observational studies have suggested

a benefit. The current guidelines recommend that individuals who are at average population risk and older than 50 years of age should undergo a colonoscopy at ten-year intervals.[4,5] A colonoscopy with no adverse findings should typically offer a ten-year protection interval for average-risk individuals, since the time for adenomatous polyps to transform into a cancerous lesion is estimated to be at least ten years.[4] Unfortunately, about 6% of adenomas are overlooked during colonoscopy. This incidence is higher at the hands of inexperienced operators or as a result of inadequate bowel preparation. The time interval should be shortened for the high-risk population, which includes a family history of colorectal cancer at a young age, genetic disorders or previously detected adenomatous polyps.[4]

Options for Investigating Colonic Anatomy

Both contrast enema and colonoscopy are frequently used for lower gastrointestinal tract investigation. Computed Tomographic Colonography (Virtual Colonoscopy) was developed more recently as a third modality to assess the colon. There are various reasons why a contrast enema study is still used as a screening tool despite the invention of colonoscopy. Firstly, the fluid contrast enema can flow through a narrowed colon more easily and painlessly. Secondly, X-ray film of the contrast study provides a permanent image record, whereas colonoscopies are not routinely video-recorded. The main advantages of colonoscopy, however, are the ability to view of the mucosal lining close-up and perform therapeutic interventions.[4,5]

Virtual colonoscopy has a sensitivity of 94% and a specificity of 96% for adenomatous polyps larger than 10mm. Large systemic reviews and meta-analyses have shown comparable sensitivity in polyp detection between virtual colonoscopy and optical colonoscopy. The benefits of virtual colonoscopy over optical colonoscopy include the avoidance of sedation and the cardiopulmonary risks associated with anesthesia, as well as a lower risk of colon perforation and a quicker procedure.
The disadvantages of virtual colonoscopy are its inability to perform therapeutic polypectomies, the exposure to radiation, and the need for more frequent follow-up screening - every five years as compared to every ten years in optic colonoscopy.[5]

Indications and Contraindications of Colonoscopy

The indications for colonoscopy can be classified into the following main categories:

1. Abnormal or suspicious imaging/contrast study;
2. Symptomatic complaint, most commonly rectal bleeding;
3. Surveillance, i.e. colon polyp, colitis;
4. Post-operative examination of anastomosis or stoma;
5. Intra-operative identification of lesion;
6. Interventions, i.e. dilatation, stenting.

Contraindications to performing colonoscopy include: acute toxic conditions or acute severe colitis such as ulcerative colitis, Crohn's disease, ischaemia, or severe acute diverticulitis. These conditions increase the risk of colonic perforation during colonoscopy.[6,7]

Complications of Colonoscopy

Abdominal distention and pain are commonly reported during and after colonoscopy, which can reduce patient adherence to future colonoscopies. Perforation is a more severe but less common complication occurring in less than 0.1% of cases.[8] Infrequent complications include cardiopulmonary events related to sedation such as cardiac arrhythmia or myocardial infarction; haemorrhage associated with polypectomy; postpolypectomy electrocoagulation syndrome; transient bacteremia; and gas explosion due to incomplete colonic cleansing. Even less common are splenic rupture, acute appendicitis, diverticulitis, subcutaneous emphysema and tearing of mesenteric vessel.[6,8]

Influence of Bowel Preparation on Colonoscopy

The quality of colonoscopy is influenced by the quality of bowel preparation. Poor bowel preparation can result in incomplete or suboptimal colonoscopy, increased procedure time, increased theatre and administrative time and shortening of the duration of protection. This decreases the interval for surveillance from ten to five years if there is inadequate mucosal visualization, translating into both financial and

patient health costs.[9]

A study by Harewood *et al*. reported that inadequate bowel preparation, which occurs 20-30% of the time, hinders detection of smaller lesions. This inadequacy can be compensated for if the screening interval is shortened to less than five years.[10]

Factors that influence the quality of bowel preparation include patient factors (male gender, advanced age, increased BMI, comorbidities and concomitant medication such as opioids), palatability of the purgative solution, timing of the purgative solution and possibly the type of diet prior to colonoscopy.[11]

Types of Bowel Preparation

There are many different bowel preparation regimens, which can be divided into three main categories:

1. Iso-osmotic or hypo-osmotic polyethylene glycol (PEG) preparations;
2. Hyper-osmotic agents (sodium sulfate, sodium phosphate), and
3. Combination regimens including both a stimulating laxative and a osmotic laxative.[11]

PEG bowel preparation is the most commonly accepted safe regimen due to its minimal fluid and electrolyte shifts.[12]

Historical Bowel Preparation Regimen

Historically, prior to 1980, conventional bowel preparation consisted of 48 - 72 hours of clear liquid diet, laxatives (castor oil, Senokot, Dulcolax, magnesium citrate, magnesium sulphate, mannitol or liquid paraffin) and enemas (tap water, saline, hypertonic solutions or purgative agents such as Dulcolax).[13-16] This conventional bowel preparation was then replaced by whole-gut lavage - a large volume, approximately 7 to 12 liters of isotonic saline or mannitol (electrolyte solution) given orally or via nasogastric tube until the effluent was clear.[13,14,17] However, whole bowel lavage was associated with significant issues. Firstly, electrolyte and fluid absorption could result in fluid retention and electrolyte imbalance. Secondly, gas

explosion during electrocautery, specifically associated with fermentation of non-absorbable carbohydrate (mannitol or lactulose), could result in production of hydrogen and/or methane above explosive concentration levels. Several case reports have described colonic explosion secondary to the use of mannitol in whole-gut lavage. Mannitol is thus no longer used as a colonic cleansing solution.[17,18] Thirdly, this high-volume lavage is often associated with poor patient tolerance.[16] PEG bowel preparations were introduced after the abovementioned preparation methods were found to be unsuitable. PEG soon gained popularity because of its safe profile, and now it is regarded as the gold standard in bowel preparation for colonoscopy.[19]

Current Guidelines for Bowel Preparation

Current European Society of Gastrointestinal Endocospy (ESGE) 2013 guidelines recommend bowel preparation as follows:

1. Low fiber diet on the day before colonoscopy;
2. Split regimen of four litres PEG solution or split regimen of two litres PEG plus ascorbate or of sodium picosulphate plus magnesium citrate;
3. The delay between the last dose of bowel preparation and colonoscopy should be minimized to no longer than four hours;
4. ESGE advises against the routine use of sodium phosphate for bowel preparation because of safety concerns.[19]

Evidence Behind Current Bowel Preparation Guidelines

In Kilgore *et al*.'s 2011 meta-analysis, full-dose PEG was compared to split dose PEG (four litres of full-dose PEG solution in the afternoon or evening before colonoscopy as opposed to split-dose PEG solution, half dosage in the afternoon before and half on the morning of colonoscopy). Kilgore *et al.* found that split-dose PEG bowel preparation was superior to a single dose of PEG in terms of the following:

1. Bowel preparation quality (resulting in a more thorough examination of the mucosa);
2. Patients' willingness to drink a purgative solution;
3. Decreased nausea or vomiting;
4. Decreased patient discontinuation of bowel preparation;

5. Increased willingness to repeat the same preparation.[12]

In a study done by Seo *et al*. to determine the best timing interval between the last dosage of bowel preparation and colonoscopy, three to five hour intervals yielded the best bowel cleansing quality throughout the whole colon.[20] This study concluded that three to seven hour interval was the most acceptable timing. The ascending colon becomes concealed by opaque small-bowel effluent after seven hours. Therefore, an interval of less than three hours or more than seven hours should be avoided.

Markowitz *et al*. found the use of oral sodium phosphate purgative as a bowel preparation could result in irreversible kidney damage.[21] Heher *et al*. further described three adverse effects of sodium phosphate purgative usage:

1. Metabolic disturbances such as hyperphosphatemia, hypocalcaemia, hyponatremia, metabolic acidosis and dehydration;
2. Phosphate nephropathy due to intra-tubular calcium-phosphate deposits, especially in patients of advanced age or those who are taking ACE inhibitor or angiotensin receptor blockers who appear to be at increased risk;
3. Innate immune system mediated inflammatory response towards crystal deposition in the kidney can result in permanent chronic renal failure.[22]

Challenging Current Guidelines

Over the past few years, some studies have challenged the previously mentioned guidelines: A study by Park *et al*. concluded that magnesium citrate low volume (two-litre) PEG was better tolerated by patients than the conventional four-litre PEG regimen.[23] Ell *et al*. concluded that two-litre PEG plus ascorbic acid was more acceptable to patients than the four-litre PEG regimen.[24] Longcroft-Wheaton *et al*. concluded that a same-day bowel cleansing regimen is superior to a two-day split-dose regimen for afternoon colonoscopies. The same-day regimen avoided a "wasted day", resulting in fewer side effects and impacts less on daily living activities.[25]

The above-mentioned studies have one common theme - attempting to simplify bowel preparation, without sacrificing colonic cleansing quality, by removing unnecessary

instructions from bowel preparation to improve patient cooperation and compliance.

Role of Diet Restriction in Bowel Preparation

There are insufficient data pertaining to the value of dietary restriction in bowel preparation. In a study by Wu *et al*., three diet groups were compared using the Ottawa Bowel Preparation Scale: high residue, normal residue and low residue diet. Even though Wu *et al*. concluded that the 48 hour low residue diet prior to colonoscopy would provide better bowel cleansing than an unrestricted diet, there were no significant differences in polyp detection rate or caecum intubation time between these three groups.[26] This implies that there may not be any clinically significant differences in terms of bowel cleansing between the different diet groups.

There is no strong evidence for diet restriction in bowel preparation. Specifically, there is a lack of evidence to support either compulsory diet restriction or low fibre diet. There is also not strong evidence to support bowel preparation initiated one to two days prior to the procedure. Many colonoscopy centres still include strict diet instructions for patients prior to colonoscopy: 48 hours of a low fibre diet (free of seeds, no high fibre vegetable) and clear fluids only for 24 hours prior to colonoscopy.[15] A clear fluid diet means strictly no solids or turbid fluid, only transparent-coloured juices, energy drinks or water. Such a highly restrictive diet does not contain sufficient calories and is significantly inconvenient for patients, thereby reducing patient compliance.

New Trend: Diet Liberalisation

Current trends in bowel preparation favour a low residue/fibre diet (LRD) rather than a clear fluid/liquid diet (CLD). Over the past decade, many randomised controlled trials have evaluated the possibility of diet liberalization prior to colonoscopy. As shown by Melicharkova and colleagues, a low residue breakfast diet started a day prior to the procedure does not compromise the quality of bowel preparation.[15] Some believe the LRD might result in better bowel preparation when compared to the clear fluid diet group.[27]

Meta-analysis and systematic review studies have evaluated the low residue diet in depth and reached the following five conclusions:

1. Although some studies suggested CLD was superior to LRD in bowel cleansing, a meta-analysis showed there is no difference in colon cleansing efficacy.
2. Pooled results revealed LRD regimen was better tolerable by patients. However, results indicated no difference in terms of dietary compliance between the groups.
3. In terms of adverse events, there is no significant statistical difference between groups.
4. Tolerance and willingness to repeat the same bowel preparation in future were better in LRD group.
5. CLD has no role in bowel preparation and should be replaced by LRD.[27,28]

So far, studies have concluded the LRD is preferred over CLD. To date, there are no standard guideline for timing or duration of LRD prior to colonoscopy, and no studies to address this question. In a study by Ell *et al*., (primarily aimed at comparing low-volume PEG to four litre PEG) patients received a regular diet breakfast, a light diet lunch and a liquid diet supper the day before the procedure. The final bowel cleansing success rate was comparable to other studies with diet restrictions, a 95% and 89% success rate in the four litre PEG group and low-volume PEG group, respectively.[24] A meta-analysis by Nguyen *et al*. identified four studies allowing LRD meals on the day before the procedure: a specific analysis was done comparing these four studies to CLD group, and the adequacy of bowel preparation was found to be similar.[27]

Extended Diet Liberalisation Until Dinner

Jung *et al*. conducted a randomised controlled trial comparing LRD until dinner and CLD as part of bowel preparation. The study arm was allowed to have a LRD until 20h00 the day before the procedure, while the control arm was only allowed to have CLD the day before procedure. Comparison between the CLD and LRD groups showed that the quality of bowel cleansing (83.5% vs 83.3%, p-value = 0.963), the caecal intubation time (7.4±7.9 min vs 7.4±6.8 min, p-value = 0.917), the polyp

detection rate (51.6% vs 49.2%, p-value = 0.504), and the adenoma detection rate (33.6% vs 35.1%, p-value = 0.48) were all statistically similar. Therefore, restriction to a CLD should therefore not be compulsory prior to colonoscopy.[29]

Conclusion

In summary, the ideal bowel preparation process as a whole should include a tasty, tolerable oral agent to ensure patients are willing to repeat the procedure; smaller purgative volume to prevent vomiting or bloating; minimal or no adverse effects to ensure patient safety; shorter preparation duration to limit disruption to daily routine; minimal dietary restriction to allow sufficient energy intake; and most importantly provide good bowel cleansing to allow successful colonoscopy visual evaluation for polyp detection and removal, providing a full ten-year's protection against colorectal cancer.

The aim of this study was to compare the quality of bowel cleansing between two groups: dietary restriction group and non-dietary restriction group. The primary endpoint was adequate bowel cleansing quality for screening colonoscopy as determined by Harefield Cleansing Scale during colonoscopy. The secondary endpoint was the administration of additional bowel preparation and the quantity of additional bowel preparation given prior to endoscopy. We hypothesised there is no difference between the dietary restriction and non-dietary restriction groups.

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CHAPTER 2 – PUBLICATION-READY MANUSCRIPT

PUBLICATION-READY MANUSCRIPT

Title: Bowel preparation for colonoscopy: is diet restriction necessary?

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REVIEW

Bowel preparation for colonoscopy: is diet restriction necessary?

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Background: Bowel preparation is essential for quality colonoscopy. Although most bowel preparation regimen recommend dietary restriction for 24 to 48 hours before the procedure, the evidence for this is poor.
Objectives: To establish whether dietary restriction during bowel preparation improves the quality of colonoscopy.
Methods: A prospective single blind, randomised controlled pilot study. The dietary restriction (DR) group was instructed not to ingest high fibre foods for 48 hours prior to the use of a polyethylene glycol (PEG) bowel preparation. The non-dietary restriction (NDR) group was not given any dietary modification but received instructions for the use of the PEG-based preparation solution. On the day of colonoscopy, the quality of the bowel effluent was assessed, and additional preparation given as necessary. The primary endpoint was quality of bowel cleansing using the Harefield Cleansing Scale during colonoscopy. The secondary endpoint was the need for additional bowel preparation and the quantity of additional bowel preparation given prior to endoscopy. Data were analysed on an intention to treat basis.
Results: Twenty-three participants were randomised to the intervention group and thirty-four to the control group. Patient demographics were similar in both groups. Dietary restriction did not influence the success rate of bowel preparation: 97% successful bowel preparation in the DR group, vs 91% successful bowel preparation in the NDR group ($p = 0.559$). Additional bowel preparation requirement were similar in both groups: 35% in the DR group vs 39% in the NDR group ($p = 0.768$). Mean amount of additional bowel preparation required was similar: 560 ml in the DR group vs 460 ml in the NDR group ($p = 0.633$).
Conclusion: The quality of bowel preparation was comparable in patients with and without any dietary restrictions prior to colonoscopy. Non-restrictive diets prior to bowel preparation should be considered to increase compliance. The sample size of this pilot study prohibited definite statistical conclusions but demonstrated this to be a reasonable methodology for a larger study.
Keywords: bowel preparation, colonoscopy, regular diet, non-dietary restriction.

Introduction

The incidence and prevalence of colon cancer has decreased significantly with the advent of screening colonoscopy, which can detect and remove pre-cancerous polyps.[1,2] Detection of inconspicuous lesions such as sessile adenomas during colonoscopy relies on the quality of bowel preparation.[3] Inadequate bowel preparation results in incomplete examinations and reduces cost-effectiveness for both patient and endoscopy units.[4] There are three types of bowel preparation: 1) isosmotic/hypo-osmotic polyethylene glycol (PEG), 2) hyperosmotic agents, and 3) combination regimens (stimulating and osmotic laxatives).[3] PEG bowel preparations are the most commonly accepted safe regimens, due to their minimal fluid and electrolyte shift effects.[5]

Historically, bowel preparations for colonoscopy were accompanied by dietary restriction, typically 48 hours of clear liquids only prior to the procedure.[6,7] More recently, this protocol has been liberalised, and a low residue diet is now standard from two days prior to the procedure. Although, once bowel preparation commences, only a clear liquid diet is allowed.[8-10] Current bowel preparation guidelines from the European Society of Gastrointestinal Endoscopy (ESGE) recommends a low fibre diet on the day before colonoscopy and either one of the following bowel preparation regimens: 1) split-dose regimen of 4L PEG solution, 2) split regimen of 2L PEG plus ascorbate or sodium picosulphate plus magnesium citrate.[11] The delay between the last dose of bowel preparation and colonoscopy should be minimised and no longer than four hours. ESGE advised against the routine use of oral sodium phosphate for bowel preparation because of safety concerns (0.1% chance of acute phosphate nephropathy).[11]

The effect of dietary restriction (DR) on the quality of bowel cleansing is not well described. Wu et al. reported no significant difference in terms of polyp detection rate or caecum intubation time between three diet groups: high residual diet, normal residual diet, and low residual diet.[12]

Understanding the effect of DR on bowel cleansing prior to colonoscopy can potentially improve colon cancer screening. In the study of Jung et al., only 52.1% of patients were in compliance with the three meals of clear liquid diet; this shows poor patient willingness to follow diet restriction.

Removal of strict DR may improve patient participation in screening programmes.[13] Therefore, DR should be associated with a clear diagnostic benefit and improved treatment outcomes for patients to justify its use.

The aim of this study was to compare the quality of bowel cleansing between two groups: dietary restriction group (DR) and non-dietary restriction group (NDR). The primary endpoint was adequate bowel cleansing quality for screening colonoscopy as determined by Harefield Cleansing Scale during colonoscopy. The secondary endpoint was the administration of additional bowel preparation and the quantity of additional bowel preparation given prior to endoscopy. We hypothesised there is no difference between the dietary restriction (DR) and non-dietary restriction (NDR) groups.

Methods

The study population was a convenience sample from a cohort in the Northern Cape of South Africa (Figure 1) with hereditary colon cancer mutation and their first-degree high-risk relatives. In brief, these individuals are at increased risk of colon cancer and undergo screening colonoscopy annually to remove polyps and biopsy non-resectable lesions.[14] Since 1994, the Colorectal Unit of Groote Schuur Hospital at the University of Cape Town has provided an outreach screening colonoscopy programme for these individuals, aimed at early detection and removal of adenomas or early detection of adenocarcinomas.

This was a prospective, single-blind, cluster randomised controlled study conducted during an annual screening colonoscopy outreach of families with known hereditary colon cancer mutations in the Northern Cape Province, South Africa. Randomisation occurred by town. The study period was from 30 July 2017 to 1 September 2017.

Individuals with hereditary colon cancer mutation or their first-degree high-risk relatives who qualified for annual screening colonoscopy during the annual outreach trip in September 2017 were included. Individuals with previous colonic resection, under the age of 18 or who had an allergy to bowel preparation were excluded.

All individuals due to undergo elective annual colonoscopy were screened in person by the first author (HJC) to discuss eligibility and participation in the study in July 2017. Towns were randomised into two groups: Group A: dietary restriction (DR) and Group B: non-dietary restriction (NDR). Participants were not individually randomised because of the concern of significant crossover since many participants were from the same family.

DR was defined as low-fibre diet two days before the colonoscopy followed by a clear fluid diet only the day before colonoscopy (as per manufacturer instruction from MoviPrep®). The NDR group was not given any dietary restrictions until the commencement of the bowel preparation (Figure 2). Both groups were limited to clear liquids only from the commencement of the bowel preparation. Both groups received two litres of split dosed MoviPrep® (PEG + ascorbate solution): half ingested the afternoon/evening before (17:00–19:00) and half ingested the morning of colonoscopy (due to the fact that some patients lived up to four hours' drive from the hospital, it was not possible to give them uniform instructions).

On the morning of the colonoscopy, nurses, who were blinded to the randomisation, visually assessed patients' effluent. Participants with solid, semi-solid or brown effluent were given an additional 500 ml of PEG solution every 30 minutes until their effluent was clear. The total amount of additional PEG solution required was recorded. Once visually assessed as 'clear effluent', participants proceeded to the next available colonoscopy theatre.

Colonoscopies were performed or supervised by one of the four consultants (two colorectal surgeons and two gastroenterologists) blinded to randomisation. All patients

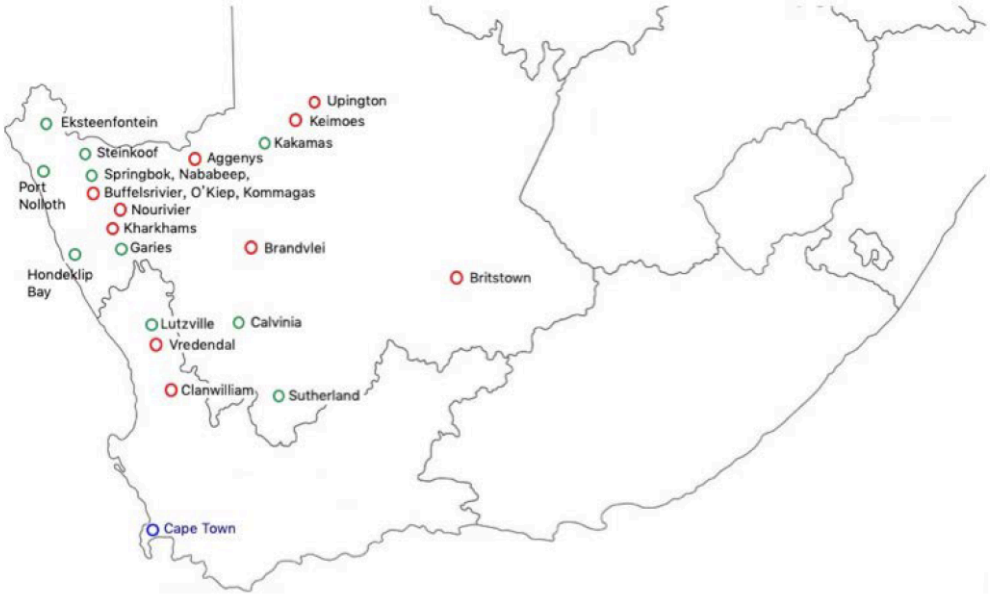


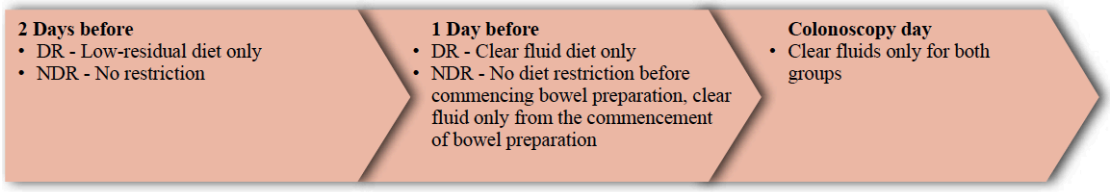
Figure 1: Study towns in the Northern Cape, South Africa
Green: Non-dietary restrictions. Red: Dietary restrictions

Table 1: Patient demographics and clinical outcomes in dietary restriction and non-dietary restriction bowel preparation groups for colonoscopy

	DR group	NDR group	*p*-value	Total
Participants	34	23		57
Female (%)	24 (71%)	21 (91%)		45 (79%)
Male (%)	10 (29%)	2 (9%)	0.097	12 (21%)
Median age	39	41	0.743	39
No. of people who vomited after ingestion of bowel prep (%)	3 (9%)	4 (17%)	0.423	7 (12%)
Median time (hours) from the start of bowel prep to scope	19.8	21.6	0.554	
Median time (hours) from last bowel prep to start of scope	8.25	3.5	0.182	
Harefield score A	24 (71%)	17 (74%)		41
Harefield score B	9 (26%)	4 (18%)		13
Harefield score C	1 (3%)	1 (4%)		2
Harefield score D	0 (0%)	1 (4%)		1
Compliant to dietary instruction (%)	17 (50%)	20 (83%)		37 (65%)
Non-compliant to dietary instruction (%)	17 (50%)	3 (17%)	0.0049	20 (35%)

DR - Dietary restriction; NDR – Non-dietary restriction. Harefield score A and B are successful bowel preparation.
p-value is derived by either independent t-test or Fisher's/Chi square test.

Figure 2: Timing of dietary restriction and non-dietary restriction groups



DR – Dietary restriction group, NDR – Non-dietary restriction group.

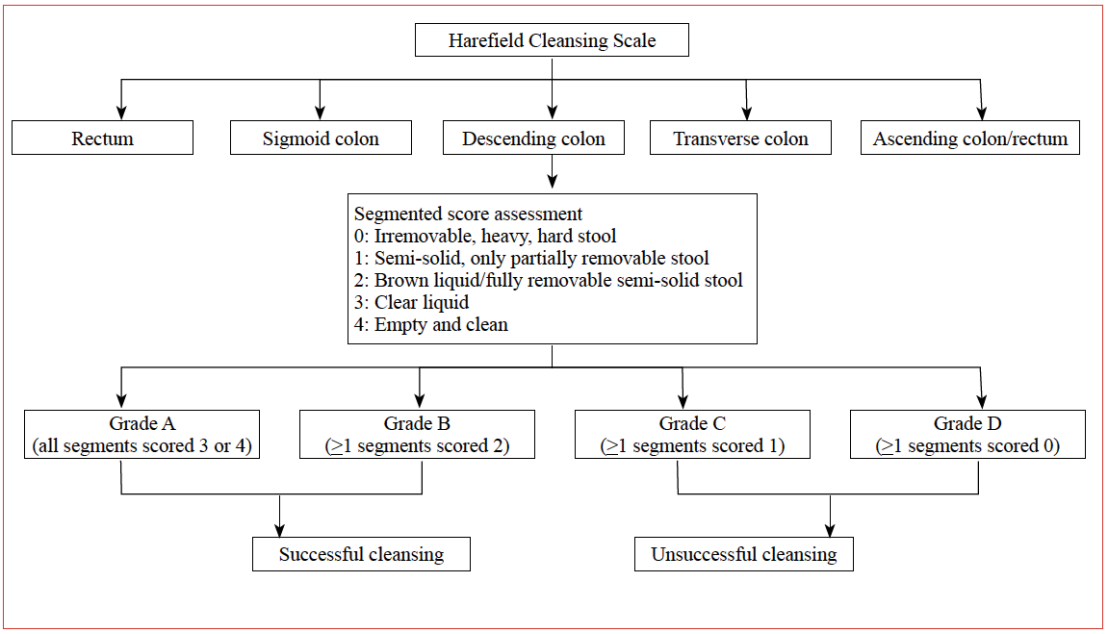


Figure 3: Harefield Cleansing Scale

Table 2. Comparison of primary and secondary endpoints between dietary restriction and non-dietary restriction groups

	DR group (34)	NDR group (23)	p-value	Total
Primary endpoint				
Successful preparation	33	21		54
Unsuccessful preparation	1	2	0.559	3
Secondary endpoint				
No. of people who had additional bowel prep (%)	12 (35%)	9 (39%)	0.768	21 (37%)
Mean amount (ml) of additional bowel prep	560	460	0.633	

DR - Dietary restriction: NDR, Non-dietary restriction.

received conscious sedation during the colonoscopy. Endoscopists rated the quality of bowel preparation using the Harefield Cleansing Scale. Only Olympus Exera III 190 endoscopy systems with ScopeGuide® (colonoscopy model) were used during this study to ensure consistent image quality.

The Harefield Cleansing Scale (Figure 3) is a visual scoring system, from A to D, to rate bowel preparation quality. This scoring system divides the colon into five segments and each segment receives a 'segmental score' given by the endoscopist. Scores A or B were considered successful and scores C or D were considered unsuccessful.[15]

Data collection and statistical analysis

Data was collected on a standard study intake sheet and entered into an electronic database. Variables included age and gender, randomisation group, time dietary modification commenced, time of last meal, time of first sachet of bowel preparation, time of second sachet of bowel preparation, estimated volume of vomitus after bowel preparation, additional amount of bowel preparation administered by nursing staff, time of colonoscopy, and Harefield Cleansing.

Data was analysed using SPSS®. Students T-test was used for parametric data and Fisher's Exact test, Chi-Square test and Mann-Whitney U test was used for non-parametric data as appropriate. A p-value of less than 0.05 was regarded as statistically significant.

Results

There were a total of 57 participants; 34 in the DR group and 23 in the NDR group; 45 (79%) were female (Table 1). The median age was 39 years (interquartile range 16). There was no significant difference in patient demographics between the two groups (Table 1). The bowel preparation was well tolerated; seven (12%) participants vomited some of their bowel preparation: three in the DR group and four in the NDR group (p-value = 0.423). According to estimation by patients, two participants vomited approximately one litre of bowel preparation, one vomited approximately half a litre, and the remainder vomited small amounts only (< 0.2 litre) (Table 1).

In total, 21 (37%) participants required additional bowel preparation; 12 (35%) in the DR group and 9 (39%) in the NDR group (p-value = 0.768). Mean additional bowel preparation ingested was 560 ml in the DR group, 460 ml in the NDR group (p-value = 0.633) (Table 2).

Median preparation-to-colonoscopy interval (the interval of time between the last PEG dose ingestion and the start of the colonoscopy) was 8.25 hours in the DR group and 3.5 hours in the NDR group (p-value = 0.182) (Table 1).

In the DR group, 50% of participants were non-compliant to their dietary instructions (those who failed to obey only clear fluid the day before colonoscopy), while only 17% of participants in the NDR group were non-compliant (those who only ingested clear fluid diet the day before colonoscopy; as majority of the patients had previous colonoscopy experiences, they still remembered dietary restriction instructions from previous years).

In total, 54 patients (95%) had successful bowel preparation: 33 in the DR group (24 grade A, 9 grade B Harefield score) and 21 in the NDR group (17 grade A, 4 grade B Harefield score) (Table 1). There was no statistical difference when comparing the adequacy of bowel preparation between the DR and NDR groups (p = 0.559) (Table 2).

One participant refused to have her effluent visually checked prior to colonoscopy. This resulted in her initial colonoscopy being abandoned due to inadequate bowel preparation (Harefield grade D). Although her repeat colonoscopy showed Harefield grade B score, only the first colonoscopy findings were included in the final data analysis.

Discussion

Bowel cleansing quality is an essential component of successful colonoscopy. Pre-procedure bowel preparation is time and energy-consuming with many instructions, restrictions and inconveniences.

Our results demonstrated no statistically significant difference in the success rate of bowel cleansing (primary endpoint) between the dietary restriction (DR) and non-dietary restriction (NDR) groups. The proportion of participants requiring additional bowel preparation and quantity of additional bowel preparation (secondary endpoint) were similar between the two groups.

In our study there was higher colonoscopy uptake among the female population, probably because females in this population are more compliant to the colonoscopy screening programme; this is in keeping with previous studies on this population.[16,17] Twelve per cent (12%) of patients vomited after drinking bowel prep. Whilst this number appears high, it is in keeping with other published studies.[18,19]

Our study has a few limitations. First, dietary instruction compliance in the DR group was significantly worse than in the NDR group. Fifty per cent (50%) of patients in the DR group did not follow the diet restriction instruction. This may be because, as part of the consent process, patients were informed about the nature of the study and lack of clarity regarding absolute necessity of dietary restriction. Second,

it is not an internationally standard procedure to check participants' effluent to assess bowel-cleansing adequacy prior to colonoscopy, and certainly, this is not suggested by any of the manufacturers of bowel preparation.

Additionally, in the context of a study, a more direct comparison between DR and NDR would be achieved without visual effluent assessments and administration of additional bowel preparation. However, in the setting of an outreach screening programme, with limited time and resources, it would not be feasible to wait until the colonoscopy to discover inadequate bowel cleansing. Effluent assessment with or without additional bowel preparation has been our strategy for many years and anecdotally has improved colonoscopy completion rates with a successful bowel preparation rate of 95%, compared to 88–92% in the literature.[18,19]

Additionally, colonoscopy is not a procedure without complications. Although colonoscopic perforation rate is usually less than 0.1%, in certain situations it can be as high as 0.3%.[20] The use of a visual effluent assessment improved the adequacy of bowel preparation prior to colonoscopy and therefore avoids repeat colonoscopy for this reason. For example, one participant in our study who initially refused to have visual effluent assessment had Harefield score D initially (irremovable solids from descending colon and proximally). However, it became Harefield score B (successful cleansing) on repeat colonoscopy after our visual effluent assessment and additional bowel preparation strategy.

Our small sample size limits the generalisability of our findings. All patients who met the inclusion criteria for this study were successfully recruited and therefore our sample size represents the limitation of recruitment within a dedicated mobile screening programme. However this cohort did provide a young patient group (median age 39 years old) with minimal comorbidities which ensured less variability in bowel preparation efficacy due to patient factors.

Conclusion

Our results suggest that there was no significant difference in the adequacy of bowel preparation or need for additional bowel preparation solution with or without diet restriction. Visual effluent assessment with or without additional bowel preparation prior to colonoscopy is a useful and pragmatic adjunct tool to improve colon visualisation and completeness of colonoscopy.

Conflict of Interest

None

Funding and sources

None

Acknowledgement

Esther Platt

Ethics approval

The study was approved by the University of Cape Town Human Ethics Committee (HREC Ref: 277/2017). Written consent was taken from each participant prior to enrolment in the study.

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APPENDIX

1. Consent Form

Consent Form for Participation in a Research Study
University of Cape Town

Bowel preparation for colonoscopy: is diet restriction necessary?

Description of the research and your participation

You are invited to participate in a research study conducted by Dr. Hung-Jou Chang, Prof. Kathryn Chu, Sr. Ursula Agar, Prof. Paul Goldberg, from the Colorectal Surgery unit at Groote Schuur Hospital. The purpose of this research is to investigate if limiting your diet during the bowel preparation is necessary before colonoscopy.

You were selected as a possible participant because you are part of a group of patients with Lynch Syndrome. This syndrome involves certain genetic abnormalities, which put you and your family members at risk of developing colon cancer. As you know, a screening colonoscopy performed every year will reduce your risk of cancer.

Your participation will involve following the given instructions, in order to prepare your intestines for the procedure (colonoscopy). On the day of the procedure, we will perform an assessment of how well the preparation has worked. Depending on what we find, you may, or may not require additional preparation.

We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Aim of this study

The aim of this study is to shorten bowel preparation time, to make bowel preparation easier, to improve convenience.

Randomization

You have been computer randomized to a bowel preparation group (This is done by computer selection, i.e. equal chance to be chosen into either group.) - to compare against the other bowel preparation group. You will be chosen into either one of the following groups:

Routine group: 48hrs of light diet then bowel preparation the day before.
Study group: only bowel preparation the day before.

Risks and discomforts

There are no known additional risks associated with this research besides the risks of any colonoscopy. Possible risks/ discomforts of the colonoscopy procedure itself are described in the attached information booklet.

Potential benefits

Easier bowel preparation methods in future, if this study will show a significant result.

Protection of confidentiality

This study is anonymous. We will not be collecting or retaining any information about your identity. The records of this study will be kept strictly confidential.

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Dr. Hung-Jou Chang at the University of Cape Town at +27 726012636.

UCT Human Research Ethics Committee
E53, Room 46, Old Main Building, GSH
Tel: 021-4066346
www.health.uct.ac.za/fhs/research/humanethics/about

Consent

I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's signature_____ Date: _____

A copy of this consent form will be given to you.

SAGES  SAGEV

Information for patients undergoing colonoscopy

Your physician has asked that the inside of your colon (large intestine) be inspected by using a long flexible tube (colonoscope) so that he can know what disease, if any, is present.

Proper preparation is extremely important for this examination. The large intestine must be clean and empty for the doctor to make an adequate examination. The preparation requires the use of a clear liquid diet for one day before the examination. This is achieved by using a laxative, often "Golytely"; it is usual to use up to 4 litres to clean out the colon before the procedure; other preparations may be used by your doctor. Because many patients are apprehensive, Dormicum® and Pethidine® are often given intravenously at the time of the examination to relax the patient; once again, your doctor may use a different drug or combinations. Ask him/her about this. These drugs will not put you to sleep but may cause some lightheadedness. (See "Conscious Sedation: What you need to know") If you have had any unfavourable reaction to any of these drugs, you should tell the examiner before the injection is given.

The examination is carried out with the patient lying on his left side on the examining table. A lubricant is applied around the anus and the colonoscope is passed into the rectum. It is necessary for the doctor to use some air to aid him in the examination. This may cause you to feel distended and full. If you have the urge to pass this air by rectum, it is permissible to do so unless the doctor requests otherwise. The large intestine may be twisted and tortuous. As the instrument passes around some of these turns, it may cause a cramping or tugging sensation. This is usually relieved as the instrument is passed around a bend and straightened. The examination may take anything from 15 – 60 minutes. If polyps are to be removed, it may take longer. (Polyps are benign growths which have the potential to be malignant.) A nurse is present to help the doctor and to assist in monitoring the patient's condition. After the examination is completed, you will be asked to rest for an hour or two in an adjoining room until the effects of the medications have subsided and until you have passed much of the air which was introduced during the examination.

Polyps are removed by first locating them with the colonoscope and then placing a wire loop around the base of the polyp. An electric current is used to cut the polyp off at its stalk or base. You will not feel this current. The polyp specimen is usually retrieved by applying suction to the instrument and catching the polyp on the tip of the instrument. Polyp and instrument are then both withdrawn. If there is more than one polyp it is necessary to re-insert the instrument to remove the additional polyp.

There are certain risks to this procedure:

1. There is a very small risk of perforation of the colon. If, however, this should happen, surgery may be required for repair.
2. Following removal of a polyp, there is a small chance/risk of bleeding from the site. This may settle spontaneously, require re-examination or, rarely, surgical intervention. Blood transfusion may be required.
3. X-ray screening may be used during the procedure so it is important to inform the doctor if you suspect you might be pregnant.

It is important to note that, if you are concerned regarding any symptoms which develop following this procedure, you should contact your doctor. He/she will most likely request that you present for assessment without delay.

If you have any questions, please ask your doctor.

2. Data Sheet

Assessor:			
Patient Code:		Town code:	

Gender:		Date of Birth: (or Age)	

Dietary modification: (Y/N)		Time started dietary modification:	
Time of last meal:		Type of food:	
Amount of bowel preparation drank:		Time started bowel preparation:	
Vomited after drank bowel preparation: (Y/N)			
Additional bowel preparation: (Y/N)		Amount of additional bowel preparation:	

Time of colonoscopy:		Number of polyps identified:	
Harefield Cleansing Scale: (0 – 4)	Rectum:	Boston Bowel preparation Scale: (0 – 3)	LC:
	Sigmoid:		
	Left colon:		TC:
	Transverse:		
	Right colon:		RC:
	Total: Grade		Total:

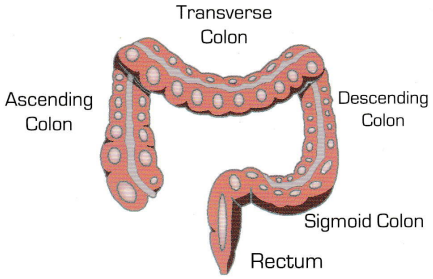
3. The Harefield Cleansing Scale

The Harefield Cleansing Scale©

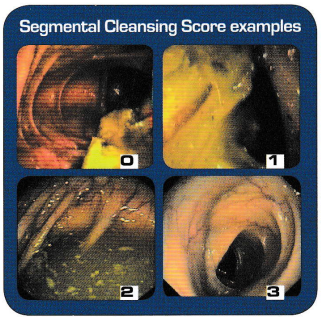
Objective Segmental Evaluation of Cleanliness

For each segment of the colon score the overall cleansing according to the following critera:

Segment Score	Description
0	Irremovable, heavy, hard stools
1	Semi-solid, only partially removable stools
2	Brown liquid/removable semi-solid stools
3	Clear liquid
4	Empty and Clean



Success Scores



Grade	Description
A	All 5 segments scored 3 or 4
B	1 or more segments scored 2
C	1 or more segments scored 1
D	1 or more segments scored 0

NORGINE

The Harefield Cleansing Scale, © Norgine® group of companies, 2008.

Appendix Removed Due to visible unremovable Signature

5. Human Research Ethics Committee Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

09 June 2017

HREC REF: 277/2017

Prof P Goldberg
Colorectal Unit
E-22 NGSH

Dear Prof Goldberg

PROJECT TITLE: BOWEL PREPARATION FOR COLONOSCOPY: IS DIET RESTRICTION NECESSARY? A PILOT STUDY: (MMed-candidate-Dr H Chang)

Thank you for your response letter dated 23 May 2017, addressing the issues raised by the Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 June 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student, Dr H Chang will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

HREC 277/2017

6. Instructions to Authors of the chosen journal

Author Guidelines

Submitted manuscripts that are not in the correct format and without the required supporting documentation specified in these guidelines will be returned to the author(s) for correction, and will delay publication.

AUTHORSHIP

Named authors must consent to publication **by signing a covering letter** which should be submitted as a supplementary file. Authorship should be based on substantial contribution to:

(i) conception, design, analysis and interpretation of data;

(ii) drafting or critical revision for important intellectual content; and

(iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**); and

(iv) exact contribution of each author must be stated.

CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute conflict of interest.

RESEARCH ETHICS COMMITTEE APPROVAL

The submitting author must provide written confirmation of Research Ethics Committee approval for all studies including case reports.

STATISTICAL ANALYSIS

Authors are advised to involve medical statisticians at the protocol stage of their research project: to plan sample size, and the selection of appropriate statistical tests for analysis and presentation.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

The rationale for analysis based on racio-ethnic-cultural categorisation should be indicated.

ETHNIC CLASSIFICATION

References to ethnic classification must indicate the rationale for this.

CATEGORIES OF SUBMISSIONS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Original articles

Original articles on research relevant to surgery should not exceed 3 000 words, references no more than 30, with up to 6 tables or figures. A structured abstract under the following headings: Background, Methods, Results, and Conclusions is a requirement and should not exceed 250 words.

Scientific letters/short reports

Short reports should not exceed 1500 words with a maximum of 10 references. Only one table or illustration is permissible. A structured abstract under the following headings, Background, Methods, Results, and Conclusions, is a requirement and should not exceed 250 words.

Case reports

Case reports should not exceed 1500 words with no more than 10 references. Figures are limited to 2 figures and may include images or photographs. The case report should have three headings: Summary (not exceeding 100 words), Case report (with no introduction) and Discussion. Case reports will be published online only. The summary and the URL will appear in the printed version.

Video Case reports (SAJS-VIDEO)

Video Case Reports should not exceed 1500 words with 10 references and 6 figures. Heading should include Summary (not exceeding 100 words) and Case Description (with three subheadings: Introduction, Case Presentation and Discussion). The video file format must be only MP4 or MOV and should not exceed 300 MB and 8 minutes. Use the Video Case Report Template to format your submission, which can be found at Video Case reports will be published online only. The summary and the URL will appear in the printed version.

Editorials

Opinions, etc. should be about 1000 words and are welcome, but unless invited, will be subjected to the SAJS peer review process.

Review articles

Review articles relevant to surgery should not exceed 5 000 words, with a maximum of 50 references and no more than 6 tables or figures. A summary of 250 words or less is required.

Letters to the editor

Letters to the editor should be 400 words or less with only one image or table.

Obituaries

Obituaries should be 900 words or less and should be accompanied by a photograph.

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

Qualification, affiliation and contact details

This information must be provided for ALL authors and must be submitted as a supplementary file.

Abbreviations

All abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

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Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age'. The same applies to ± and º, i.e. '35±6' and '19ºC'.

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Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]

Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101. *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

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