

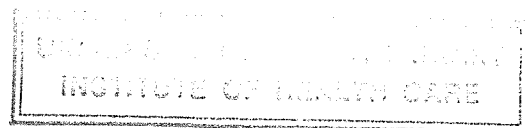
BARIUM ENEMA PREPARATIONS

**A BLIND PROSPECTIVE TRIAL OF STANDARD
PREPARATION VERSUS 'KLEAN PREP®' FOR DOUBLE -
CONTRAST BARIUM ENEMA BOWEL PREPARATION.**

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DECLARATION

I, hereby declare that I have carried out this dissertation and this is entirely my own work.

Claude Portanier Mifsud

3rd May, 1999

To
~Myriam~

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ABSTRACT

Bowel preparation is an important prerequisite prior to performing a double contrast barium enema, its aim being the removal of faeces and any residual particles so that the large bowel is completely empty.

This research project was designed to compare two different preparatory regimes, one of which is currently in use at St Luke's Hospital (Malta), with the aim of finding which preparatory regime is most effective.

The research instrument were a set of evaluation criteria used for the evaluation of barium enema preparations.

The researcher concluded that the preparations were equally effective and produced good results with regards to both faecal clearance and mucosal coating.

On the basis of the findings, recommendations are proposed with the aim of improving the diagnostic quality of barium enemas.

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CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION TO STUDY

Bowel preparation is an important prerequisite prior to performing a barium enema. The aim of bowel preparation is the removal of faeces and any residual particles so that the large bowel is completely empty (Bontrager, 1993).

1.2 BACKGROUND TO THE STUDY

A barium enema examination is a diagnostic X-ray procedure performed in order to examine the colon. It is a relatively common examination and constitutes 5% of all X-ray examinations performed in St Luke's Hospital (Radiology Services - Annual Report for 1997, 1998). Thomas (1998) stated that it is the primary imaging modality of choice when suspecting lesions in the colon.

Patients have to be well prepared and hence prior to the examination they have to undergo a preparatory regime. This ensures that the colon is free of faeces and residue. Cleaning the colon prior to a barium enema is important since any material remaining in the bowels may either mask or mimic pathologies (Smith, 1997).

At St Luke's Hospital (Malta) the standard preparatory regime consists of a special 3-day diet taken prior to the examination. Laxatives are prescribed and a cleansing enema is also performed. However, after performing a study to evaluate the barium enema versus colonoscopy, Tabone (1996) deduced that

patients undergoing barium enemas at St Luke's Hospital were not being prepared adequately. He recommended that

“a study should be carried out to investigate existing preparation regimes together with their documentation formats, possibly introducing new approaches based on the antegrade method.....”
(Tabone, 1996: 57).

These observations instigated the researcher to perform this study.

1.3 LITERATURE REVIEW

Barium enema and colonoscopy are the two major diagnostic procedures used when examining the entire large bowel (Brady, Stevenson & Stevenson, 1994). The barium enema is however the most cost - effective of the two (Karasick, Ehrlich, Levin, Harford, Rosetti, Ricci, Beam & Gigliotti, 1995).

Although the barium enema has been performed for more than 90 years the preparatory regimes used are still under scrutiny and controversial in nature. There are many methods of bowel preparation for barium enema and up to 44 different combinations of dietary restriction, purgatives and cleansing enemas were reported in one survey (Gelfand, Chen & Ott, 1991 a). It is with no surprise therefore that Kember, McBride, Tweed & Collins (1995) stated that the preparation for a barium enema is the least standardised part of the whole procedure.

The majority of research studies agree that the colon must be clean prior to a barium enema (Smith, [1997], Ott, [1993], and Gelfand et al, [1991 a]). However there are conflicting views on how this can be achieved. Gelfand et al (1991 a) stated that a standardised preparation utilising a cleansing enema

produces the cleanest colons and therefore images of highest diagnostic quality may be obtained. Conversely Hageman & Goei (1993) stated that cleansing enemas are unnecessary and time consuming. More recent publications entice the use of oral bowel cleansing solutions without the use of a cleansing enema, the concept being that they are more simple and convenient to use while at the same time obtaining good results (Lai, Kwok, Man, Lau, Chan, 1996).

1.4 STATEMENT OF THE PROBLEM

The barium enema is an important radiological examination used for the detection of colonic lesions. However, its sensitivity and specificity may depend, besides others, on an effective preparation. It was observed by Tabone (1996) that patients undergoing barium enemas at St Luke's Hospital are not being prepared adequately with the result that the examination is inconclusive and of low diagnostic value.

1.5 OBJECTIVES

The research evaluates two different preparatory regimes in patients undergoing double - contrast barium enemas. The objective is to determine the effectiveness of the two different preparations with regards to faecal content and mucosal coating. Recommendations based on the findings of the study will then be proposed.



1.6 AIMS

The aims of the study are:

- to improve the quality of barium enema examinations being performed in St Luke's Hospital (SLH),
- to increase the diagnostic potential of the barium enema examination.

1.7 RESEARCH QUESTIONS

(i) Will 'Klean Prep®', an oral bowel cleansing solution, produce the same or cleaner colons than the standard preparation currently in use at SLH which utilises a cleansing enema?

(ii) Is a cleansing enema crucial for barium enema preparations?

1.8 METHODOLOGY

1.8.1 LITERATURE REVIEW

The methods used in this research included a detailed literature review. Sources used for this literature search included the Institute of Health Care Library, using the CINAHL database, the Medical School Library, using the Medline database and the internet. Key words used included: **Barium enemas; Cleansing/Preparatory enemas/colonic lavage; Colonoscopy.**

1.8.2 RESEARCH DESIGN

This research involved an experimental study involving patients undergoing a double - contrast barium enema. Patients were assigned in two groups using a table of random numbers. The control group underwent the standard preparatory regime utilising a cleansing enema while the study group underwent an oral bowel cleansing solution - 'Klean Prep®'. Information describing the 3-day preparation for the barium enema was provided for both groups. The radiographs were evaluated independently by two radiologists using the scoring criteria developed by Hageman & Goei (1993) and Dodds, Scanlon, Shaw, Stewart, Youker & Metter (1977).

1.8.3 DATA ANALYSIS

The data collected were analysed by using both descriptive and inferential statistics. The Mann - Whitney test and Cronbach's alpha were used in order to perform statistical analysis of the data obtained.

1.8.4 ETHICAL CONSIDERATIONS

Written consent was sought and obtained from the Acting Manager of the Radiology Department at St Luke's Hospital (Appendix A-1). Permission was also granted by the dissertation panel to perform the study. Besides, consent from the patients in the study was also obtained. Confidentiality was guaranteed to all patients by not divulging any information obtained during the study.

1.9 DEFINITION OF KEY CONCEPTS

For the purpose of this study:

Barium enema: 'a rectal infusion of barium sulphate, a radioopaque contrast medium, which is retained in the lower intestinal tract, for diagnosing obstruction, tumours or other abnormalities during radiographic examination' (Anderson & Anderson, 1995).

Cleansing enema: is a procedure consisting 'of filling the colon with liquid to aid in dislodging and flushing out any faecal contents remaining in the lower intestinal tract' (Ehrlich & McCloskey, 1993)

Faeces: 'the waste material that is eliminated through the anus. It is formed in the colon and consists of a solid or semisolid mass of undigested food remains (chiefly cellulose) mixed with bile pigments (which are responsible for the colour), bacteria, various secretions (e.g. mucus), and some water' (Concise Medical Dictionary, 1990).

False negative: 'an incorrect result of a diagnostic test or procedure that falsely indicates the absence of a finding, condition or disease' (Anderson & Anderson, 1995).

False positive: 'a test result that wrongly indicates the presence of a disease or other condition the test is designed to reveal' (Anderson & Anderson, 1995).

Laxative: 'a drug used to stimulate or increase the frequency of bowel evacuation' (Concise Medical Dictionary, 1990).

Polyp: 'a growth usually benign, protruding from a mucous membrane' (Concise Medical Dictionary, 1990).

Sensitivity: 'the proportion of people who truly have a specific disease and are so identified by the test' (Thomas, 1993).

Specificity: 'the proportion of people who are truly free of a specific disease and are so identified by the test' (Thomas, 1993).

Standard

preparation (SLH): the preparation currently in use at St Luke's Hospital (Malta).

1.10 COURSE OF STUDY

This study is composed of the following components; an introductory chapter which includes background information on the topic being investigated together with the reasons for performing the study. The second chapter includes a literature review of barium enemas and its preparation. Chapter 3 explains the methodology of the study while chapter 4 presents the results of the study together with a discussion. This is followed by chapter 5 which includes the researcher's conclusions and recommendations. The final chapter is a concluding statement to the study.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter a review of the literature related to the diagnostic value and relevance of barium enema, the importance of good preparation, and various types of preparatory regimes will be analysed.

2.2 THE DIAGNOSTIC PROCEDURES USED WHEN EXAMINING THE ENTIRE COLON - BARIUM ENEMA AND COLONOSCOPY

The barium enema and colonoscopy are the predominant diagnostic methods used for visualising the entire colon (Smith, [1997], Brady, Stevenson & Stevenson, [1994] and Theoni & Margulis, [1988]). The **barium enema** is a radiological examination performed in order to visualise the entire large intestine. Two different methods of barium enema exist - the single and double contrast barium enema (DCBE). In the single contrast barium enema (SCBE), barium sulphate is instilled into the colon via the rectum until all the large intestine is visualised. A series of X-rays are then taken. In the double contrast barium enema, the colon is first filled with barium sulphate but some of it is then evacuated to be replaced by air. The reasoning behind the DCBE is to first coat the mucosal lining with barium and then distend the bowel by introducing air with the aim of visualising small pathological changes. Both the barium and the air act as contrast agents and hence the name double contrast barium enema (Culmer, 1995).

Another procedure used to examine the entire colon is **colonoscopy**. Colonoscopy is a procedure used to examine the entire large intestine and

rectum by means of a flexible illuminated instrument. It is a direct visual examination using a flexible tube containing light transmitting glass fibres or a video transmitter that returns a magnified image. The examination is a diagnostic examination however it enables the surgeon to perform biopsies using flexible forceps and to remove polyps using a diathermy snare (Concise Medical Dictionary, 1990).

2.2.1 OBJECTIVES OF THE DIAGNOSTIC PROCEDURES

Nearly all colonic carcinomas originate from adenomas (Ott, 1993). Severe epithelial dysplasia within an adenoma is the precursor to invasive carcinoma and the prevalence of malignancy is related to the size of the adenoma (Ott, 1993). Smith (1997) stated that there is a 10% chance that a polyp of 1cm in size harbours an invasive malignancy while polyps larger than 2 cms have a 50% chance of being malignant. Diminutive polyps less than 6mm are now believed to be of little practical significance and have a 0.1% chance of being malignant. With this evidence in mind, both Ott (1993) and Rice (1990) concluded that polyps of 1cm in size or greater should be targeted for detection.

2.2.2 IS THERE STILL A NEED FOR BARIUM ENEMA?

It is generally considered that colonoscopy is more sensitive and specific when compared to the barium enema examination (Tabone, 1996). Without any doubt, colonoscopy has a number of advantages over the barium enema one of which is that it has a high specificity because false positives rarely occur (Gelfand, 1997). This is due to the fact that the colonoscopist can visualise the colon directly and can therefore differentiate between the

presence of stool and segmental spasm of the colon. Furthermore, malignant-appearing lesions can be biopsied or removed during the diagnostic examination itself and therefore the patient will not be subjected to a second examination for the purposes of establishing its histology or for the purposes of removing it.

However, colonoscopy has its own disadvantages when compared to the barium enema. Smith (1997) stated that colonoscopy carries a greater risk of perforation than barium enema. Colonoscopy has a perforation rate of 1:200 to 1:5000 and a mortality rate of 1:2000 to 1:5000 while barium enema has a perforation rate of 1:2500 to 1:12500 and a mortality rate of 1:50000 (Smith, 1997). This risk factor alone should heavily influence the choice of which diagnostic procedure to choose primarily for examining the colon. Besides colonoscopy requires sedation with all its associated risks (Gelfand, 1997).

On comparing pain and costs, the barium enema examination was found to be a less painful and a much cheaper examination than colonoscopy (Karasick, Ehrlich, Levin, Harford, Rosetti, Ricci, Beam, & Gigliotti, [1995] and Steine, [1994]).

With regards to accuracy, a good quality barium enema examination was found to have a sensitivity which ranged from 90% to 95% for polyps of 1cm or larger and a sensitivity of between 92% and 100% for larger polypoid and annular carcinomas of the colon. This was found to be comparable to that of colonoscopy (Smith, [1997] and Ott, [1993]). With regards to polyps under 1cm in size it was found that colonoscopy is more sensitive, however, the clinical importance of these polyps is minimal since carcinoma is rare in polyps smaller than 1cm (Ott, 1993).

Thomas (1998) and Schiller, Cockel, Hunt, Ashby & Stevenson (1986) stated that the barium enema examination is the primary imaging modality used when suspecting lesions in the colon. Colonoscopy is indicated when radiological appearances are equivocal, when biopsy or polypectomy are necessary, or when radiology is normal despite significant symptoms, especially rectal bleeding. Thomas (1998) concluded that using colonoscopy as a first line investigation is inappropriate and uneconomic. However, Karasick et al (1995) found that colonoscopy has been replacing the barium enema examination as the initial colorectal examination since 1985. Karasick et al (1995) further stated that this was due to the guidelines issued by hospital administrators and physicians who emphasised the identification and removal of all polyps irrespective of size and pathologic status. This was being done so that colonoscopy examinations are performed more frequently than barium enema examinations since physician and hospital reimbursement amount to much more. The authors also emphasised the fact that

“the barium enema and colonoscopy are so similar with respect to accuracy in the detection of treatable disease that, until superior cost-effectiveness of colonoscopy can be demonstrated in a randomised trial, the trend towards increased use of this procedure as the initial line of investigation should be re-evaluated...”

(Karasick et al, 1995: 783)

Smith (1997), Rice (1990) and Bolin, Franzen, Nilsson, & Sjudahl (1988) were of the same opinion. They stated that the barium enema and colonoscopy should not be considered competitive because, ideally, the two methods compliment one another. A case in point is a study performed by Thoeni and Petras (1982) where the accuracy of colonoscopy was found to be 76% and that of the barium enema was found to be 83%. However, when these two procedures were combined the accuracy was found to be 97%.

2.2.3 THE BARIUM ENEMA AND COLONOSCOPY WITH REGARDS TO THE CAECUM AND ASCENDING COLON

Thoeni and Petras (1982) demonstrated that double contrast barium enema (DCBE) is slightly better than colonoscopy for evaluating well prepared patients with suspected polypoid lesions in the ascending colon. In a study performed on 53 patients who had polypoid lesions in the caecum and ascending colon, the authors deduced an accuracy rate of 76% for colonoscopy and an 83% accuracy rate for DCBE. If both modalities were combined they had an accuracy of 97%. Brady et al (1994) agreed with Thoeni and Petras (1982) and stated that the proportion of cancers detected in the caecum and ascending colon was higher with barium enema than with the use of colonoscopy. This may seem unusual since Smith (1997), Brady et al (1994), and Goyal (1994) stated that colonoscopists can visualise the entire colon up to the caecum in 95% of patients. However, in daily practice it was reported that in 10% - 30% of colonoscopic examinations, the colon was not entirely visualised with the consequence and risk of missing lesions. The barium enema therefore has an increased potential in this area (Brady et al, 1994). This factor is of great importance since the incidence of cancers found in the caecum and ascending colon is increasing (Kelvin, Maglinte, & Stephens, 1988). One of the reasons given for this increase in incidence rate is the longer lifespan, and therefore the implications of detecting these cancers is significant (Kelvin et al, 1988).

2.3 THE BARIUM ENEMA: THE MALTESE SITUATION

It has been shown that the barium enema is highly sensitive for the detection of colon abnormalities (Smith, 1997). However, in the only study performed in

Malta on this subject, Tabone (1996) demonstrated that the barium enema has a sensitivity of 59.1% whilst colonoscopy has 100% sensitivity. Tabone (1996) concluded that colonoscopy should be used as the first diagnostic tool in investigating colonic lesions. However, the researcher thinks that the study has a number of limitations which Tabone (1996) did not take into account when arriving to his conclusions. First of all the study was performed in retrospect and as Fork (1981) pointed out, such studies have the disadvantage that the colonoscopist is aware of the radiological findings whereas the radiologist is not. Secondly, the study does not verify whether any false negative results were obtained by colonoscopy since no follow up was carried out to confirm if the patients had any recurrent symptoms. In fact, Thoeni and Petras (1982) stated that colonoscopy may miss lesions previously reported as radiographic false positives and which were later found to be in actual fact colonoscopic false negatives. Another factor which Tabone (1996) failed to mention was that most of the lesions missed by the barium enema were smaller than 10mm and therefore were of minimal clinical importance.

However, after having stated this, these limitations may not be the only reason behind the big discrepancy in sensitivity between the barium enema and colonoscopy. In fact, Tabone (1996) stated that:

“ Inadequate bowel preparation was probably the main factor related to false positive missed rates, however, poor preparation could have accounted for a number of negative missed rates as faecal matter may have concealed fine mucosal structures.”

(Tabone, 1996: 44)

Similarly, Rice (1990) stated that there was a big discrepancy between published reports demonstrating a high sensitivity and the everyday practice of radiology. He stated that many of the barium studies are of poor quality, and it would be impossible to confidently diagnose or exclude 1cm polyps. He concluded that this was mainly due to inadequate bowel preparation.

2.4. BOWEL PREPARATION

Inadequate bowel preparation due to the presence of stool in the bowel and poor mucosal coating was found to be one of the main causes of missed diagnosis on the barium enema. Stool was found to be the most common cause of false positives and false negatives when interpreting barium enemas (Ott, 1996). Mucosal coating with barium may depend on retained fluid in the colon and this depends on the type of preparation used. Therefore, thorough bowel preparation is the most important prerequisite for an accurate radiological examination of the colon (Ott & Gelfand, [1993], Rice, [1990] and Ott, Scharling, Chen, Gelfand, & Wu, [1989]. In fact,

“researchers have estimated that 10% - 40% of colon cancers are missed on the initial barium enema, mainly because of poor bowel preparation”.
(Ott & Gelfand, 1993: 491)

This occurs because faecal material may mimic or mask polyps or cancers and therefore may cause significant errors. Poor mucosal coating on the other hand makes it more difficult for the radiologist to visualise the bowel lumen and therefore any abnormalities on the mucosal wall may be missed. Unfortunately Brady et al (1994) and Bolin et al (1988) demonstrated that bowel preparation is poorest in the caecum and ascending colon and therefore most of the cancers and polyps missed on the barium enema are in

this region. Colonoscopists may also find it difficult to visualise this region and therefore a good quality barium enema free of any faecal matter and with adequate mucosal coating is highly important.

As previously stated, the objective of the barium enema is to exclude polyps of 1cm or larger. If it is impossible to exclude polyps of this size due to poor bowel preparation, then the examination should be postponed or else repeated (Rice, 1990). Ott (1996) stated that the adequacy of colon cleansing must be evaluated at the beginning of the examination. This, however, is not always possible because the plain film may not always indicate faeces and it does not give any indication with regards to mucosal coating (Pietila, Bondestam, Hartel & Suramo (1990). Therefore, it is important that patients undergo a good preparation on their first appointment. A good preparation technique saves personnel and equipment time. It should not be forgotten that when a patient is appointed for a barium enema a radiographer is called, equipment is scheduled for use and previous films are retrieved. Therefore, there is considerable loss of time and waste of money for the institution if patients are reappointed, besides the considerable inconvenience to the patient (Tjon A Tham, Korte, Bom, van Kints, & Zwinderman, [1993] and Rice, [1990]).

2.5 PRODUCING A GOOD QUALITY BARIUM ENEMA - A 'SYSTEMS' VIEWPOINT

The effectiveness and quality of the barium enema depends on many other factors besides a good preparation. Gelfand, Chen & Ott (1987) stated that a 'systems' analysis approach can be used in order to minimise errors at each stage of the diagnostic process.

Stamatis (1993) defined a 'system' as

“ an arrangement of separate and independent components sharing a relationship for the purpose of attaining a common goal and predetermined objectives”.

(Stamatis, 1993: 22)

The 'systems' approach is a holistic way of studying things. For the purpose of attaining a good quality barium enema, it is important to understand the interrelationships of the essential elements in the system. Therefore, making wise decisions about what and how to improve the quality of barium enema requires combining information on the various elements in the system (Stamatis, 1993). In the barium enema these include the preparatory regime, fluoroscopic and radiographic equipment, the resolution of the film-screen combination, the density and stability of the barium suspension, the examination technique and quality controls (Gelfand, Chen & Ott, 1991 b). To maximise the results of the barium enema with the aim of detecting polyps of 1cm or more in size, all factors must be brought to an optimal state. However, for the purpose of this study, preparatory regimes only will be analysed.

2.6 PREPARATORY REGIMES

It is accepted that a clean colon well coated with barium is essential for accurate interpretation (Chakraverty, Hughes, Keir, Hall, Rawlinson, 1994). The increasing incidence of colorectal cancer in the western world and the excellent results obtainable by early treatment demonstrate that a high standard DCBE is of extreme importance. This can only be achieved if bowel cleanliness is also of high standard (Lai, Kwok, Man, Lau, Chan, 1996).

There are many methods of bowel preparation but no universally accepted standard of what constitutes excellent, good, acceptable, or unacceptable preparation. There is no consensus on the optimal methods for bowel preparation in patients undergoing barium enema and every institution has its own preferences (Chan CC, Loke, Chan JCS, LO 1997).

Three principal factors are involved in cleansing the colon of faecal material:

- dietary restriction,
- laxatives, and
- cleansing enemas.

The relative importance of these factors has not been established despite the large number of barium enema examinations performed (Lee and Ferrando, 1984). Dietary restriction involves having a low residue diet for a number of days with the aim of reducing the amount of faecal residue in the large bowel. At the same time liquid intake is encouraged so that waste and faeces is quickly forced to move along the digestive tract. Laxatives are given to promote defecation. Various types of laxatives exist. Stimulant or irritant laxatives such as 'Dulcolax®' and 'Picolax®' act on the sensory nerve endings of the mucosa producing peristalsis of the bowels. Osmotic or saline laxatives such as magnesium citrate and sodium phosphate contain inorganic ions which draw fluid into the bowel lumen by osmosis. The resulting large volume of fluid retained in the large intestine stimulates peristalsis and therefore colonic contents are expelled. A variant form of saline laxatives are oral bowel cleansing solutions (OBCS) or gut irrigation solutions such as 'Golytely®' and 'Klean Prep®'. In this case, a large volume (approximately 4 litres) of an isotonic solution is administered for the purpose of flushing the colon contents. Despite the massive volume of fluid ingested there is no net absorption or

secretion of water or salts and therefore these solutions cause no dehydration or overhydration (Culmer, [1995] and Gelfand et al, [1991 a]). The cleansing enema consists of filling the colon with liquid retrogradely with the aim of dislodging and flushing any faecal material (Ehrlich & McCloskey, 1993).

2.6.1 DIETARY RESTRICTION

Several preparatory regimens exist and each method has its own merits and drawbacks. The use of dietary restriction is practised in 97% of all leading institutions surveyed (Thoeni & Margulis, 1988). Both Chakaverty et al (1994) and Lee & Ferrando (1984) performed separate studies and concluded that dietary restriction lessens the amount of faecal residue in the large bowel much more than a cleansing enema does. However, Kember et al (1995) stated that a 3 day low residue diet offers no advantage in the preparation of the colon for barium enema, and hence should be abandoned thus simplifying the preparation and thereby improving patient compliance.

2.6.2 CLEANSING ENEMA

The most significant point of contention for bowel preparation prior to a barium enema is however, the use of a cleansing enema. Numerous studies have been performed with the aim of assessing preparatory regimes, some utilising a cleansing enema and others not. Unfortunately, as Gelfand et al (1991 a) stated, many published reports on the effectiveness of various preparatory regimes are inconclusive. This is due mainly to variability in the criteria used to define what constitutes a clean colon. Indeed, in most of the articles noted, the criteria for a clean colon are not mentioned, except for stating whether the

participating radiologists believed a preparation was satisfactory or unsatisfactory (Gelfand et al, 1991 a).

Gelfand et al (1988) undertook a study where patients received a 24hr clear-liquid diet, hydration, the laxatives magnesium citrate followed by castor oil four hours later and a cleansing enema on the morning of the examination. Satisfactory cleansing of the colon with faecal particle sizes of less than 5mm was demonstrated in 97% of the examinations. To date, this study following the above-mentioned preparatory regime, produced one of the best preparatory regimes ever. The authors concluded their study by stating that the cleansing enema was the crucial element in this regime. However, this conclusion may not be correct, since theirs' was not a comparative study comparing the regimen with or without a cleansing enema and therefore their arguments may not be valid in this context.

With this in mind, Hageman & Goei (1993) undertook a comparative study where the patients chosen were given the same preparatory regime with the exception that some had the cleansing enema while others did not. The best regimen was found to be the one having no cleansing enema and these patients were found to be almost completely clean with faecal particle sizes of less than 5mm in 60.5% of the cases. Compared with the study performed by Gelfand et al (1988) where 97% of the patients had a clean colon, 60.5% may be deemed to be a poor result. However, Hageman & Goei (1993) stated that this discrepancy was only due to the fact that they evaluated the films on DCBE while Gelfand et al (1988) evaluated them on both DCBE and SCBE. They stated that the DCBE is much more sensitive for the detection of small stool particles than single contrast studies and hence the discrepancy in the

results. They concluded their study by stating that a time consuming cleansing enema may be omitted.

Other results, such as those reported by Lee & Ferrando (1984) support the study performed by Hageman & Goei (1993). Lee & Ferrando (1994) found that dietary restriction improved bowel cleansing and gave better results than mechanical lavage. On the other hand, Present, Jansson, Burhenne, Dodd, Goldberg, Goldstein, Miller, Nelson, & Stewart (1982) insisted that cleansing is less effective when the cleansing enema is not prescribed.

Chakaverty et al (1994) stated that the cleansing enema does not improve the quality of bowel preparation. This is mostly due to water retention which causes poor barium coating. However, Gelfand et al (1991 a) stated that the effectiveness of a cleansing enema is entirely a function of the care with which it is administered. They explained that if the barium enema examination is performed 30 minutes and 60 minutes after the cleansing enema for the SCBE and DCBE respectively, the barium enema examination would have adequate mucosal coating because the water would have been absorbed by the colon. However, both Pietila (1990) and Freimanis (1989) detected no significant decrease in retained fluid in the colon after 30, 60 or 90 minutes. On the other hand, if patients wait excessively from the time they are given the cleansing enema to the time they undergo the barium enema examination, faecal small bowel contents may be dumped into the large bowel through the ileocaecal valve resulting in debris obscuring the ascending colon (Freimanis, 1989).

Lai et al (1996) stated that standard bowel preparation utilising a cleansing enema is as effective as a non - washout regimen. Therefore, they concluded

that in a hospital or country with limited nursing staff and where time is money, the cleansing enema may be omitted and reserved only for patients undergoing barium enema at short notice and for elderly patients. The only added advantage found by the authors for the use of the cleansing enema was due to the fact that it was under the control of the department and therefore patients' compliance was guaranteed. Tjon A Tham et al (1993) stated that compliance depended on the energy content given in the diet. The authors performed a study in which the patients were given a commercially - available liquid diet which satisfied their criteria and provided the patients with sufficient caloric content to keep them in optimal condition. Laxatives were prescribed, however, a cleansing enema was not performed. Ninety two percent of all barium enemas were excellent with regards to the presence of stool and mucosal coating. Patient compliance was high. They concluded that successful preparation schemes depend not only on restriction of intake on certain kinds of foods and liquids, but also on patient tolerance. The authors stated that

“if hunger pangs were avoided through provision of enough calories, the patients will not experience the preparation schemes as a torture and will not eat foods or drink liquids that are not prescribed”.

(Tjon A Tham et al, 1993: 580)

This may eliminate the need for the cleansing enema and thus patients can be examined immediately upon their arrival and not wait for a cleansing enema to be performed. This will increase patient efficiency, reduce costs and maximise the potential effectiveness of all human resources (Tjon A Tham et al, 1993).

Authors in favour of the cleansing enema such as Gelfand et al (1988) however state, that besides ensuring that any faecal material remaining in the

bowels after the action of the laxatives is removed, the cleansing enema is a means of determining whether the colon is sufficiently clean to proceed with the examination. If it is not clean, the initial cleansing enema may be safely repeated. Besides, it may indicate whether the patient can easily retain an enema, thereby helping to determine whether a DCBE or a SCBE should be performed (Gelfand et al, 1988).

As can be seen, arguments in favour and against the use of the cleansing enema are numerous with various studies contradicting one another and therefore no consensus has been reached on a standardised preparation. One reason is due to the variability in criteria used for the evaluation of the radiographs making most of the studies non - comparable. Certainly, the trend is towards not performing the cleansing enema (Thoeni & Margulis, 1988), the reasons being that it increases costs, wastes time besides being uncomfortable for the patient (Lai et al, [1996] and De Lacey, Benson, Wilkins, Spencer, & Cramer [1982]).

2.6.3 ORAL BOWEL CLEANSING SOLUTIONS

Oral bowel cleansing solutions (OBCS) are the preferred method of cleansing used in colonoscopy (Gelfand et al, 1991 a). 'Golytely®', one brand of OBCS, is a macromolecule and is not absorbed by the small intestine. It cleans the bowel rapidly by inducing diarrhoea. 'Golytely®' has the theoretical advantage of causing minimal transmucosal flux of sodium and water and therefore is theoretically safe in the elderly and in patients with cardiac, renal or hepatic insufficiency (Fitzimons, Shorvon, Frost, & Stevenson, 1987). In a study performed by Davis & Smith (1983) and cited by Fitzimons et al (1987) it was revealed that standard preparation resulted in a mean weight loss of 1.7kg

whereas 'Golytely®' produced a weight loss of only 1kg. Although all patients in the study seemed to tolerate this degree of weight loss over a short period of time, it certainly represents some extracellular, intracellular volume contraction (dehydration) which may be poorly tolerated by elderly or debilitated patients (Chan et al, 1985).

In order to evaluate the effectiveness of OBCS, Ernstoff, Howard, Marshall, Jumshyd & McCullough (1983), performed a study where they compared standard preparation (laxatives, 2 days of clear liquids and a cleansing enema) versus 'Golytely®'. They found no significant difference between the 2 groups with regards to stool particle size. Similarly, Lai et al (1996) found no statistically significant differences for bowel cleanliness and degree of mucosal coating between standard preparation and 'Golytely®'. However Gelfand et al (1991 a) pointed out that in the majority of cases, OBCS retain a significant amount of fluid in the colon with the result of degrading mucosal coating. This was confirmed by Hawkins, Bezuidenhout, Shorvon & Hine (1996) who found that 'Klean Prep®', another brand name of OBCS, was similar with respect to 'Picolax®' (a well-accepted laxative [Swarbick, Collins, Moore & McBride, 1994]) as regards faecal clearance, but was significantly worse as regards retained fluid and mucosal coating. Hawkins et al (1996) recommended that a study is performed in which 'Klean Prep®' is prescribed several hours earlier than their study where 'Klean Prep®' was given at 17:00 hrs the day before examination. They presumed

“that if Klean Prep were to be commenced and finished several hours earlier, the excess fluid may be absorbed by the colon, reducing the coating difficulties”.

(Hawkins et al, 1996:238)

Indeed, this may explain the findings of Chan, Diner, Fontenot & Davidson (1985), who found comparable results to a standard regimen for barium enema.

Chan et al (1997) stated that more research is needed to determine the best preparation of OBCS. Such solutions are routinely used for bowel preparation of the barium enema because of their convenience and simplicity when compared to the traditional method of colonic washout. However, OBCS have to be taken in large volumes and this may be a disadvantage since some patients may find it uncomfortable. Lee & Ferrando (1984) however, view this as an advantage and state that frequent drinks reduce the appetite and this helps the patients to adhere to food restriction and therefore increase patient compliance.

2.7 CONCLUSION

The literature reviewed has shown that the barium enema is still a valid and relevant diagnostic tool for imaging clinically important pathologies of the colon. Colonoscopy and the barium enema are not competitive but complementary. The sensitivity and specificity of the barium enema however depends on a number of factors one of which is adequate bowel preparation. No consensus has been reached on an ideal preparation and therefore there is controversy on which is the ideal preparation. Due to this fact no standardisation for barium enema preparation exists across the globe and every institution has its own preferences. Some authors believe that the crucial element in the preparation is the cleansing enema, on the other hand, others think that this is useless, time consuming and utilises human resources badly.

In the next chapter, the methods used for the gathering of the data in the process of this study will be analysed.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

Several studies have been conducted world - wide with the aim of studying different preparatory regimes for barium enema. No standard preparatory regime exists and there is controversy on which are the best preparations. A study performed in Malta by Tabone (1996) comparing barium enema examinations with colonoscopy found that the barium enema has a very low sensitivity when compared to colonoscopy. In this same study, the author observed that the barium enema preparation was ineffective and concluded that the low sensitivity for barium enema was due to inadequate bowel preparation. No study has, as yet, been performed to evaluate the different preparatory regimes utilised in Malta.

These factors prompted the researcher to perform a study on barium enema preparations. In order to perform this, two groups of patients who were about to undergo a double - contrast barium enema examination were each given a different preparation prior to the examination. The radiographs of each examination were then evaluated by two radiologists. This chapter will discuss the research design used in the formulation of this study.

3.2 RESEARCH DESIGN

“The aim of scientific research is to understand the
nature of relationships among phenomena.”
(Polit & Hungler, 1995: 157)

In order to understand the effect of two different preparatory regimes for barium enemas, an experimental study was chosen. In an experimental study

“the researcher plays an active role by introducing the intervention.”

(Polit & Hungler, 1995: 139)

Polit & Hungler (1995) characterises true experiments by three properties:

- 1) Manipulation
- 2) Control
- 3) Randomisation.

All these 3 properties were observed in this study.

3.2.1 MANIPULATION

“Manipulation involves doing something to at least one group of subjects.”

(Polit & Hungler, 1995: 158)

In this study, two groups of patients were chosen. One group of patients - the control group - was given the preparation currently used at St Luke’s Hospital (Malta) - standard preparation for barium enema. This consisted of: a low residue diet for 3 days prior to the examination; hydration with no food intake a day prior to the examination; 2 Dulcolax® pills (Remidica - Cyprus) taken orally 2 days prior the examination at midday; 2 Dulcolax® pills taken orally 1 day prior the examination at 6:00 am; a Dulcolax® suppository placed at midday 1 day prior to the examination; and a cleansing enema undertaken by a community nurse at home in the afternoon 1 day prior to the barium enema examination. The second group of patients - the study group - was given an alternative preparation. This consisted of: a low residue diet for 3 days prior to the examination; hydration with no food intake a day prior to the examination;

Four sachets of Klean Prep® (Norgine - France) topped up with 1 litre of water each starting at 10:00 am one day prior to the examination and taken in approximately 4 hours.

In this way, the effect of two different preparations could be compared.

3.2.2 CONTROL

“Through control, the influence of extraneous variables (variables which are not being studied but which could influence the results of the study by interfering with the actions of the ones being studied) is reduced.”

(Cormack, 1996: 140)

Control involves manipulation, randomisation, carefully preparing experimental protocols and using a control group (Polit & Hungler, 1995). In this study, various factors were observed with the aim of making the two groups comparable. These factors included randomisation, the use of eligibility criteria, and similar environmental settings for the two groups were observed as much as possible. In this way, any variation caused in the amount of bowel cleanliness can be attributed to the preparations and not to other extraneous variables.

3.2.3 RANDOMISATION

“Randomisation involves the placement of subjects in groups on a random basis.”

(Polit & Hungler, 1995: 159)

In this way every subject has an equal chance of being assigned to any group.

“The primary function of randomisation is to secure comparable groups with respect to extraneous variables.”

(Polit & Hungler, 1995: 211)

“However there is no guarantee that the groups will, in fact, be equal.”

(Polit & Hungler, 1995: 159)

In this study thirty - two subjects were chosen to form part of the study. They were each randomly assigned using a table of random numbers obtained from Polit & Hungler (1995). In this way, extraneous variables such as age, sex, literacy and health status were controlled as much as possible.

3.3 RESEARCH METHODOLOGY

3.3.1 TARGET POPULATION

“The target population is the total group of subjects about whom the investigator is interested and to whom the results could reasonably be generalised.”

(Polit & Hungler, 1995: 222)

In this study, the researcher was interested in patients who satisfied the following eligibility criteria:

- 1 - patients who were between 18 - 75 years of age
- 2 - ambulant patients
- 3 - outpatients
- 4 - persons who were capable of understanding instructions.
- 5 - patients who were about to undergo a barium enema at St Luke’s Hospital

Therefore, these criteria excluded persons with mental disabilities and frail institutionalised patients. The reason for excluding the former group was that such patients are unable to understand and comply with instructions. Moreover, the reason for excluding the latter group was that

“barium enemas performed in the institutionalised elderly population are inadequate more than 50% of the time.... due to poor bowel preparation”
(Gurwitz, Noonan, Sanchez, Prather, 1992: 43)

Frail institutionalised patients were therefore deemed to be variables and since randomisation does not guarantee comparable groups especially in a small sample such as the one chosen for this study, they were excluded from the study with the aim of attaining homogeneous and comparable groups. Outpatients aged between 18 - 75 years were chosen since several studies report that in this group of patients similar standards of bowel preparation were observed (Hawkins et al, [1996], Gurwitz et al, [1992], and Grad, Clarfield, Rosenbloom & Perrone, [1991]). St Luke's Hospital was chosen since this is the only general hospital in Malta. All these eligibility criteria were chosen with the aim of eliminating extraneous variables in order to acquire a homogenous target population (Parahoo, 1997).

Besides, patients who had phenylketunuria, gross bleeding per rectum, severe diarrhoea, colonic obstruction and those who had previous colonic surgery were excluded since the laxatives used in the study were contraindicated in these patients.

3.3.2 SAMPLING TECHNIQUE

Sampling refers to the process of selecting a portion of the target population to represent the whole target population.

In this study non - probability convenience sampling was used. Thirty - two consecutive patients who where about to undergo a double - contrast barium enema examination were chosen and randomised into the study and control groups.

3.3.3 THE RESEARCH INSTRUMENT

The instrument used in this study consisted of a set of scoring criteria by which each of the 4 segments of the colon; the ascending, transverse, descending and rectosigmoid, were evaluated for the amount of faecal matter present, adequacy of mucosal coating and an overall score was given based on the detectability of a 1 cm lesion. A detectability of a 1cm lesion was chosen since both Rice (1990) and Ott (1993) stated that 1cm lesions or greater should be targeted for detection since smaller lesion are of minimal clinical importance. This evaluation was carried out on double - contrast barium enema radiographs by two Radiologists chosen for their qualification and experience in reporting barium enemas. Both Radiologists were working in a blind manner and therefore they did not know which preparation was given to each patient and they did not consult with each other. Scores ranged from 1 to 5 and were based on the criteria used by Hageman & Goei (1993) and Dodds et al (1977) (Appendix C). Consent from Hageman & Goei (1993) was sought and obtained for the use of the scoring criteria (Appendix B). Double - contrast barium enema was chosen since this is the most common barium enema examination performed in St Luke's. Moreover double -

contrast barium enema is much more sensitive for the detection of stool particle size than single - contrast barium enema (Hageman & Goei, 1993) and hence the results of the study should be more accurate. In addition to the scoring criteria, the patient reference number, the date of examination, the Radiologist's name, the clinical indications and patient compliance to the preparation were also noted.

3.3.4 RELIABILITY AND VALIDITY OF THE RESEARCH INSTRUMENT

The establishment of reliability and validity are crucial when evaluating the research instrument (Talbot, 1995).

"The reliability of an instrument is the degree of consistency with which it measures the attribute it is supposed to be measuring."

(Polit & Hungler, 1995: 347)

On the other hand validity refers to

"the degree to which an instrument measures what it is supposed to be measuring."

(Polit & Hungler, 1995: 353)

The degree of validity and reliability of the research tool is difficult to determine. Talbot (1995) however emphasised that the use of a research tool which has already been tested provides many advantages,

"one of which is the preestablishment of critical reliability and validity information."

(Talbot, 1995: 74)

The scoring criteria used in this study were all previously used in whole or in part by other researchers such as Burchardt, Cartensen, Roikjaer & Burcharth

(1997), Hageman & Goei (1993), Lee (1984), Lee & Ferrando (1984), Erhstoff et al (1983) and Dodds et al (1977) and therefore these criteria have already been rigorously tested and accepted as valid and reliable tools for the evaluation of barium enema preparations.

3.3.5 THE PILOT STUDY

Although the criteria had already been tested, a pilot study was performed with the aim of ensuring that the Radiologists understood the scoring criteria. Another aim of the pilot study was to enable the Radiologists to become familiar with the evaluation sheet. Two barium enema examinations which were not part of the sample were chosen and given to the Radiologists to evaluate. No difficulties were encountered and no changes were deemed necessary.

3.3.6 ETHICAL CONSIDERATIONS

As previously stated in paragraph 1.8.4 written consent was obtained from the Acting Manager at the Radiology Department of St Luke's Hospital to perform the study. Approval from the dissertation panel to perform the study was also obtained (Appendix A-2)

The study group was given a preparation which is similar to the one given to patients undergoing colonoscopy in St Luke's Hospital and therefore is accepted by the authorities at the Hospital. Slight changes, based on the recommendations made on the literature were made in order to adapt the preparation to the barium enema examination. (Appendix D shows a copy of the preparation sheet given to patients undergoing colonoscopy at St Luke's Hospital). All participants were informed about the nature of the study and the

right to refuse or withdraw from the study was respected. Confidentiality was guaranteed to all participants by not divulging any information given at the time of data collection.

3.4 LITERATURE REVIEW

The literature review was conducted at the Medical School and Institute of Health Care, University of Malta. A computerised literature search was also performed on the internet and on the Medline Service.

3.5 THE RESEARCH SETTING

“It is generally good practice to make the conditions under which the data are collected as similar as possible for every participant in the study”

(Polit & Hungler, 1995: 209)

Therefore, several measures were taken in order to make conditions for the patients as similar as possible. The same barium suspension made up to a consistency of 75% w/v (Merck - Germany) was given to all patients taking part in the study. All participants in the study were given an explanation of the importance of bowel cleanliness by the same person at the reception desk. Furthermore, an identical diet sheet was also given to all participants. The only difference was in the intervention given, that is, the preparation (Appendix E-1 shows the preparation and diet sheets given to the patients in the ‘control group’ while appendix E-2 shows the preparation and diet sheets given to the patients in the ‘study group’). These factors are important because

“the more the research setting can be controlled, the more effective the researcher will be in reducing the influence of extraneous environmental variables, and the more accurate will be the examination of the cause - and - effect relationships of the variables studied”

(Cormack, 1996: 142).

The ‘time factor’ was also taken into consideration. Data was purposely collected from the 22nd of February 1999 to the 20th of March 1999, which may be regarded as a typical period of the year. Data was not collected during the Christmas period since during the festive period, compliance of the preparatory regimes may not be high and therefore results could be misleading.

3.6 ANALYSIS OF THE DATA

Both descriptive and inferential statistics were used for the analysis of the data which was computed by the Biomedical Data Package computer programme.

In this research study it was important to find if the scores obtained in the study group were statistically different from the scores obtained in the control group. In statistics, the word significant is used to demonstrate:

“that the obtained results are unlikely to have been the result of chance at some specified level of probability.”

(Polit & Hungler, 1995: 408)

On the other hand a non - significant outcome means:

“that any difference between an obtained statistic and a hypothesised parameter could have been the result of chance.”

(Polit & Hungler, 1995: 408)

In this research study a 0.05 level of significance was chosen. This level indicates that if the results are statistically significant then there is 5% probability that the results are due to chance. This was chosen since it is one of the most frequently used levels of significance (Polit & Hungler, 1995). In fact, all of the research articles reviewed by the researcher used a 0.05 level of significance.

The Mann - Whitney Test was used to analyse any differences between the two groups. The Mann - Whitney Test is a non - parametric test used to analyse the differences between two independent groups, based on ranked scores (Polit & Hungler, 1995). The assumptions required in making this test are that the two samples are independently and randomly drawn and that the level of measurement of the variables under investigation is at least ordinal (Polit & Hungler, 1995).

Correlations were obtained from the scores of the two radiologists. Cronbach's alpha was also calculated to examine the degree of reliability between the scores. Cronbach's alpha is an index of homogeneity. Indices of homogeneity estimate the extent to which different subparts of an instrument - in this case the radiologists - are equivalent in terms of measuring the critical attribute and therefore if they are reliable or not (Polit & Hungler, 1995).

3.7 LIMITATIONS OF THE STUDY

Due to both financial and time limitations on the part of the researcher, a sample size of 32 patients had to be chosen. This might be considered a small sample which might not be representative of the whole population. However, when the

“target population is relatively homogeneous with respect to the variables of interest, then a small sample may be adequate for research purposes”
(Polit & Hungler, 1995: 242).

The sample was also chosen using non - probability convenience sampling which is the weakest form of sampling because the subjects chosen might be atypical of the population with regards to the critical variables being measured (Polit & Hungler, 1995). However various measures were taken with the aim of selecting a homogeneous target population as possible since

“in cases .in which the phenomena under investigation are fairly homogeneous within the population, the risks of bias may be minimal.”
(Polit & Hungler, 1995: 233).

Another limitation of the study which, however, could not be controlled is the fact that the cleansing enemas were performed by different community nurses on different patients. Since there are various ways of performing the cleansing enema, different community nurses may vary in the method of undertaking and therefore this may be regarded as an extraneous variable since different ways of performing the cleansing enema may have a different effect on colon cleanliness. Furthermore, another limitation of the study is that while the cleansing enema is undertaken by all patients in the control group since this is done by the community nurse, the diet and the taking of laxatives may not be

observed by all patients. Since the preparation undertaken by the study group contains only the laxatives and the diet which depends totally on their compliance, this may effect the end results and it can be assumed as an extraneous variable. In order to minimise this, all patients were questioned prior to undergoing the barium enema with regards to compliance of the various preparations. Only those who complied were included in subsequent analysis.

Another factor which may limit the study is the radiographic technique. Radiographic technique may vary from one Radiographer to another and this may have an effect on the quality of the images. Under or overexposed films may influence the clarity of the images and this may effect the detection of faeces and mucosal coating. This may have slight influence on the results and may be regarded as an extraneous variable.

3.8 CONCLUSIONS

This chapter described the methods and research instrument used in the formulation and collection of the data for this study. The next chapter includes the presentation and analysis of the data collected.

CHAPTER 4

PRESENTATION AND DISCUSSION OF RESULTS

4.1 INTRODUCTION

After the data was collected, the results were compiled and analysed. Results for the amount of faecal content in each particular area of the colon, adequacy of mucosal coating and an overall score based on the detectability of a 1cm lesion will be presented, analysed and where possible, compared with similar studies performed abroad.

4.2 THE PARTICIPANTS

The population sample chosen for this study was 32 patients. Sixteen were intended to form part of the control group and another 16 were intended to form part of the study group. Out of these 32 patients, three failed to keep their appointment; two from the control group and one from the study group. Another five patients were found not to have complied with the preparation given. Three formed part of the control group while two formed part of the study group. Non - compliance involved mainly eating solid foods when patients were not supposed to and not taking the laxatives at the right time. All these five patients were re - appointed by the Radiologists in charge after evaluating their plain film. Non - compliance therefore amounted to 17.2% of those who turned up for the examination. This left the researcher with 24 patients whose films were evaluated by two Radiologists for the amount of faeces present, adequacy of mucosal coating and an overall score was given based on a detectability of a 1cm lesion. Eleven patients were in the control group and 13 patients were in the study group.

Gender distribution between the 24 patients in the research study and gender distribution between the control and study groups are shown below in figures 4.1 and 4.2 respectively .

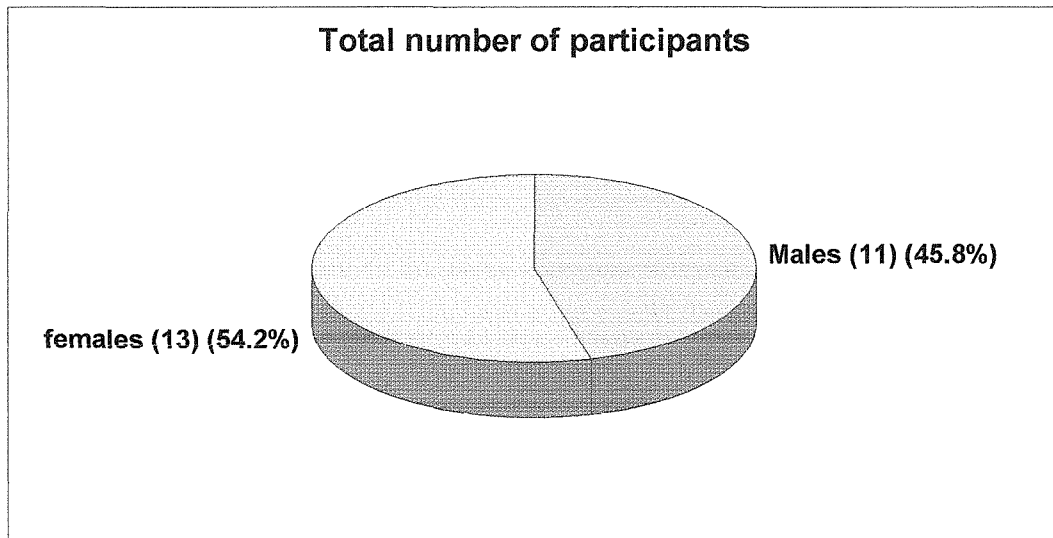


Figure 4.1 - Gender distribution in the patients whose films were evaluated in the study.

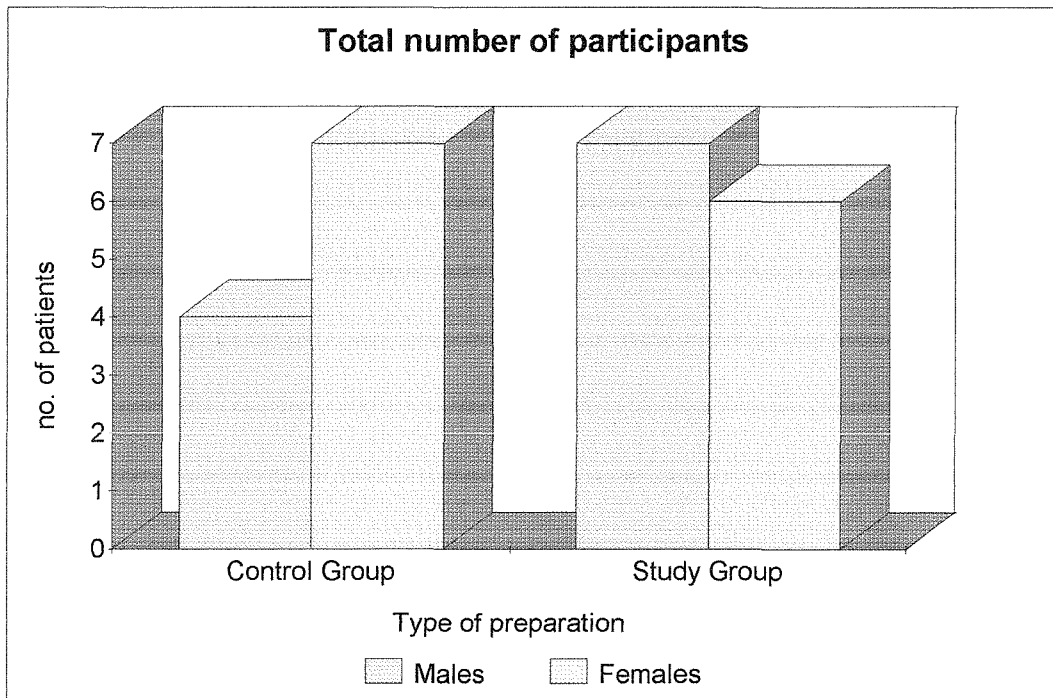


Figure 4.2 - Gender distribution between the control and study groups.

The mean ages between the two groups participating in the research study were comparable, with a mean age of 49 for the control group, and a mean age of 48 for the study group. Table 4.1 below shows the age distribution between the two groups.

AGE	CONTROL GROUP (n = 11)	STUDY GROUP (n = 13)
25 - 35 years	3	2
36 - 45 years	3	4
46 - 55 years	1	4
56 - 65 years	2	2
66 - 75 years	2	1

Table 4.1 - Age distribution between the two groups.

Radiological findings were also analysed in order to assess if any selection bias with respect to pathological status was present. Polit & Hungler (1995) stated that:

"selection biases should be analysed even when random assignment has been used to form groups because there is no absolute guarantee that randomisation will yield perfectly comparable groups."

(Polit & Hungler, 1995: 221)

The radiological findings indicated comparable groups with respect to pathological status. Table 4.2 below shows the radiological findings found in the two groups.

RADIOLOGICAL FINDINGS	CONTROL GROUP n = 11	STUDY GROUP n = 13
No abnormality detected	7	8
Diverticular disease	3	4
Constricting lesion/s	0	1
Polyp/s	1	0

Table 4.2 - Radiological findings in the participants of the study.

4.3 RESULTS

All the raw data obtained from the study for each particular variable was compiled and analysed. (Appendix F shows the raw data demonstrating the scores given to each particular patient by the two different Radiologists). All the scores were correlated together using Cronbach's alpha. The Cronbach's alpha for all variables was found to be 0.9065. Nachmias & Nachmias (1992) pointed out that a high alpha of 0.7 or more is an acceptable level which indicates that the variables are tightly connected. Since Cronbach's alpha was more than 0.7 the two Radiologists can be stated to be measuring the same characteristics. Therefore the results were amalgamated together to form two groups - the control group with 22 evaluations and the study group with 26 evaluations.

4.3.1 COMPARISON OF AMOUNT OF FAECAL CONTENT BETWEEN GROUPS

The study group, utilising 'Klean Prep®' as the laxative, was found to have higher mean scores with respect to the control group, utilising the standard preparation, in all four segments of the colon. However the differences were not statistically significant ($P = < 0.05$) when evaluated by the Mann - Witney Test. Table 4.3 overleaf shows the mean, standard deviation (Std. Dev.) and the standard error mean (S.E.M.) for each group in each particular segment.

REGION/COLON		CONTROL GP <i>n</i> = 22	STUDY GP <i>n</i> = 26	MANN-WHITNEY TEST <i>P</i> < 0.05
ASCENDING	Mean	3.55	4.12	0.0695 Not significant
	Std.Dev.	1.14	1.07	
	S.E.M.	0.24	0.21	
TRANSVERSE	Mean	4.1	4.54	0.0677 Not significant
	Std.Dev.	0.92	0.71	
	S.E.M.	0.2	0.14	
DESCENDING	Mean	4.27	4.46	0.7 Not significant
	Std.Dev.	1.08	0.76	
	S.E.M.	0.23	0.15	
RECTO-SIGMOID	Mean	4.41	4.54	0.3893 Not significant
	Std.Dev.	0.67	0.71	
	S.E.M.	0.14	0.14	

Table 4.3 - Scores for faecal content between groups for each particular region in the colon.

Similar to the findings of Present et al (1982) where the population sample for each group was 150, this study demonstrated that cleansing for both groups is best in the recto - sigmoid region, slightly worse but equally good in the descending and transverse region and worst in the ascending region.

On evaluating the raw data, it was evident that 88% of all the double - contrast barium enema (DCBE) studies performed in the study group, had a score of 3 or more in all parts of the colon and therefore these had no particulate matter greater than 5mms in any segment. On the other hand, 82% of all DCBE's performed in the control group had a score of 3 or more in all segments of the colon. The mean scores for all the segments in the study group for scores of 3 or more were 92% and 94% respectively. Table 4.4 overleaf shows the number of evaluations and the % scores for amount of faecal content of those DCBE's having scores of 3 or more (3+) and 2 or less (2-) in each particular segment for each particular group. Table 4.5 overleaf shows the number of evaluations and the % mean score.

REGION/COLON	SCORES	CONTROL GP		STUDY GP	
		n = 22	% SCORES	n = 26	% SCORES
ASCENDING	2-	4	18%	3	12%
	3+	18	82%	23	88%
TRANSVERSE	2-	1	5%	1	4%
	3+	21	95%	25	96%
DESCENDING	2-	2	9%	1	4%
	3+	20	91%	25	96%
RECTO-SIGMOID	2-	0	0%	1	4%
	3+	22	100%	25	96%

Table 4.4 - % scores for faecal content of those DCBE's having scores of 3 or more (3+) and 2 or less (2-) for each particular segment.

	SCORES	CONTROL GP		STUDY GP	
		n = 88	% SCORES	n = 104	% SCORES
MEAN	2-	7	8%	6	6%
	3+	81	92%	98	94%

Table 4.5 - Mean % scores for faecal content of those DCBE's having scores of 3 or more (3+) and 2 or less (2-).

These results are comparable to most of the studies performed abroad where Hawkins et al (1996), Lai et al (1996), Tomlinson, DiPalma, & Mangano (1988), Fitzimons et al (1987), and Ernstoff et al (1983) found no statistical significant difference between standard/conventional preparation and an OBCS being either 'Klean Prep®' or 'Golytely®'. In all of these research studies the population sample ranged from 16 - 57 participants per group.

Hawkins et al (1996) found that 76% of the patients utilising 'Klean Prep®' had mean faecal particle sizes of less than 2mm's. In this research study performed at St Luke's Hospital, 89% of the patients utilising 'Klean Prep®' had a mean score of 4 or 5 which corresponds to faecal particle sizes of 2mm's and therefore this indicates that in this study 'Klean Prep®' produced better results than in the study performed by Hawkins et al (1996). However, a major difference existed between the 2 studies since Hawkins et al (1996) had a population sample size of 47 participants in the 'Klean Prep®' group while in

this research study the population sample utilising 'Klean Prep®' was of only 13 participants and therefore the probability of inaccuracies due to deviant results is higher in this research study than in the one performed by Hawkins et al (1996). On the other hand, only 76% of those utilising the standard preparation (SLH) had a mean score of 4 or 5. Table 4.6 below shows the number of evaluations and the % scores for the amount of faecal content of those DCBE's having scores of 4 or more (4+) and 3 or less (3-). Table 4.7 below shows the number of evaluations and the % mean score.

REGION/COLON	SCORES	CONTROL GP		STUDY GP	
		n = 22	% SCORES	n = 26	% SCORES
ASCENDING	3-	10	45%	7	27%
	4+	12	55%	19	73%
TRANSVERSE	3-	6	27%	1	4%
	4+	16	73%	25	96%
DESCENDING	3-	3	14%	2	8%
	4+	19	86%	24	92%
RECTO-SIGMOID	3-	2	9%	1	4%
	4+	20	91%	25	96%

Table 4.6 - % scores for faecal content of those DCBE's having scores of 4 or more (4+) and 3 or less (3-) for each particular segment.

	SCORES	CONTROL GP		STUDY GP	
		n = 88	% SCORES	n = 104	% SCORES
MEAN	3-	21	24%	11	11%
	4+	67	76%	93	89%

Table 4.7 - Mean % scores for faecal content of those DCBE's having scores of 4 or more (4+) and 3 or less (3-).

Ernstoff et al (1983) found no significant difference between standard preparation and 'Golytely®', however, only 68.75% of the patients utilising 'Golytely®' had faecal particle sizes of less than 5mm's in all segments which is low when compared to the 88% achieved in this study. Tomlinson et al (1988), however achieved a higher score with no faecal particle sizes of more than 5mm's in all segments in 98% of the patients utilising 'Golytely®'. This

shows that results vary and it is difficult to give the exact reasons for these discrepancies. One main reason, however, is the difference in population sample sizes between studies. The smaller the sample, the more inaccuracies due to deviant samples. As the sample size increases, the probability of getting an inaccurate result diminishes as atypical values counter balance each other (Polit & Hungler, 1995). Moreover, there are other reasons which may influence the results of the study from one institution to another, one main reason being compliance which sometimes is difficult to disclose. Patient compliance may be affected by the educational background of the patients, the importance the institution gives to bowel preparation, the explanation given to the patients prior to undergoing their DCBE, the layout of the preparation sheets given to the patients, the length of the preparation and by the discomfort caused by the preparations. Moreover, the 'time factor', in other words the period of the year in which the study is performed may also influence compliance. Demographic factors such as lifestyle and eating habits may vary from one country to another and these may also influence the final results making studies more difficult to compare. These reasons however cannot be proved as this information was not included in the research articles analysis and therefore the researcher cannot give the exact reasons for the discrepancies in the results.

4.3.2 COMPARISON OF THE ADEQUACY OF MUCOSAL COATING BETWEEN THE TWO GROUPS

The quality of mucosal coating was similar in both groups and in all segments of the colon. Table 4.8 overleaf shows the mean, standard deviation and the standard error mean for each group in each particular segment. No statistically significant differences ($P = < 0.05$) were found between the groups using the Mann - Whitney test.

REGION/COLON		CONTROL GP	STUDY GP	MANN-WHITNEY TEST
		<i>n</i> = 22	<i>n</i> = 26	<i>P</i> < 0.05
ASCENDING	Mean	4.55	4.46	0.3956 Not significant
	Std.Dev.	0.67	0.51	
	S.E.M.	0.14	0.1	
TRANSVERSE	Mean	4.5	4.54	0.9526 Not significant
	Std.Dev.	0.67	0.58	
	S.E.M.	0.14	0.11	
DESCENDING	Mean	4.55	4.58	0.8849 Not significant
	Std.Dev.	0.67	0.5	
	S.E.M.	0.14	0.1	
RECTO-SIGMOID	Mean	4.55	4.54	0.7021 Not significant
	Std.Dev.	0.67	0.51	
	S.E.M.	0.14	0.1	

Table 4.8 - Scores for mucosal coating between groups for each particular region in the colon.

In the control group 91% of all patients had a score of 4 or 5 in all regions of the colon which corresponds to good or excellent mucosal coating. In the study group 96% had good or excellent coating in the transverse colon, while the coating in the ascending, descending and recto-sigmoid regions was good or excellent in all patients. Table 4.9 below shows the number of evaluations and the % scores of those DCBE's having scores of 4 or more (4+) and 3 or less (3-).

REGION/COLON	SCORES	CONTROL GP		STUDY GP	
		<i>n</i> = 22	% SCORES	<i>n</i> = 26	% SCORES
ASCENDING	3-	2	9%	0	0%
	4+	20	91%	26	100%
TRANSVERSE	3-	2	9%	1	4%
	4+	20	91%	25	96%
DESCENDING	3-	2	9%	0	0%
	4+	20	91%	26	100%
RECTO-SIGMOID	3-	2	9%	0	0%
	4+	20	91%	26	100%

Table 4.9 - % scores for mucosal coating of those DCBE's having scores of 4 or more (4+) and 3 or less (3-) for each particular segment.

These results are similar to the findings of Lai et al (1996), Fitzimons et al (1987) and Chan et al (1985) who found no statistically significant differences in the quality of mucosal coating between standard preparations utilising a cleansing enema and an OBCS. A factor which, however, makes these studies non - comparable to this study is the fact that in all the 3 studies mentioned the cleansing enema was performed 1-2 hours prior to the examination as opposed to this study where the cleansing enema was performed in the afternoon of the day preceding the examination.

A study which does not agree with the findings of this research study was the one performed by Hawkins et al (1996). The authors found that although 'Klean Prep®' produced comparable faecal clearance to 'Picolax®' (a well accepted laxative) it produced inadequate mucosal coating proximal to the sigmoid colon with the result that 'Klean Prep®' produced inadequate studies in 46% of the patients. This fact was also highlighted by Gelfand et al (1991 a) who stated that the major disadvantage of OBCS's was the retention of fluid in the colon which may cause poor mucosal coating.

A major difference however existed between the study performed by Hawkins et al (1996) and this research study which may explain the big discrepancy in the results for mucosal coating. This difference was due to the fact that 'Klean Prep®' was administered at different times of the day. In the study performed by Hawkins et al (1996) 'Klean Prep®' was commenced at 17:00 pm while in this research study 'Klean Prep®' was commenced at 10:00 am. Hawkins et al (1996) themselves had recommended that 'Klean Prep®' be commenced earlier after realising that not enough time had passed for the bowels to absorb the excess water. This research study therefore demonstrated that if the laxatives are commenced earlier and therefore finished earlier, mucosal

coating will be better since the remaining water would have been absorbed by the bowels.

4.3.3 COMPARISON OF THE OVERALL SCORES BETWEEN THE TWO GROUPS

The overall scores for the two groups were comparable with a mean of 4.05 for the control group and a mean of 4.23 for the study group. No statistical significant difference ($P = < 0.05$) was found between the two groups for the overall scores. Table 4.10 below shows the mean, standard deviation, and the standard error mean for the overall scores between the two groups.

		CONTROL GP <i>n</i> = 22	STUDY GP <i>n</i> = 26	MANN-WHITNEY TEST <i>P</i> < 0.05
OVERALL SCORE	Mean	4.05	4.23	0.4665
	Std.Dev.	0.79	0.59	Not significant
	S.E.M.	0.17	0.59	

Table 4.10 - The overall score between groups.

With a mean of more than 4 for each of the two groups, it is evident that in most of the patients a 1cm lesion could have easily been detected. In fact, in 92% of the study group and in 82% of the control group a 1cm lesion would have been detected. This is important since 10% of 1cm polyps harbour an invasive malignancy. Table 4.11 below shows the number of patients and the % scores of those who have scores of 4 or more (4+) and 3 or less (3-).

	SCORES	CONTROL GP		STUDY GP	
		<i>n</i> = 22	% SCORES	<i>n</i> = 26	% SCORES
OVERALL SCORE	3-	4	18%	2	8%
	4+	18	82%	24	92%

Table 4.11 - % Overall scores of those DCBE's having scores of 4 or more (4+) and 3 or less (3-).

A score of 4 or 5 demonstrates that a 1cm lesion can be detected and such scores are described by the criteria used in this study as good or perfect. On the other hand, a score of 3 or less demonstrates that a 1cm lesion can be missed in one or more segments due to the presence of faeces and/or due to poor mucosal coating. Examinations scoring 3 or less therefore reduce the sensitivity and specificity of the barium enema. In this study, 18% of the patients in the control group had a score of 3 or less and therefore a 1cm lesion, if present, could have been missed in these patients. On the other hand, only 8% of those patients in the study group had a score of 3 or less.

It is evident that results vary from one study to another especially with regards to faecal content. One of the reasons for this variation may be the population sample size. Although numerous studies were performed to investigate preparatory regimes, most of them utilised different evaluation criteria and this made the studies non - comparable (Gelfand et al, 1991 a). Indeed, in most of the articles reviewed, the criteria for a clean colon and adequacy of mucosal coating were not mentioned, except for stating whether the participating radiologist/s believed a preparation was excellent, good or bad, a factor which makes the studies highly subjective. Besides, only a few studies which utilised an OBCS gave an overall score based on the detectability of a 1cm lesion and moreover, they did not utilise the same set of scoring criteria as was utilised in this study. Therefore, these studies cannot be used for comparison. In this research study a set of criteria which were objective and easy to understand were chosen with the aim of understanding what is excellent, good or bad and therefore it is hoped that other similar studies follow suit and use these criteria making studies comparable.

4.4 CONCLUSION

This chapter presented and discussed the results of the study. In the next chapter the conclusions derived from this study will be highlighted and recommendations on how to improve the barium enema examination will be given.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

In this chapter the conclusions based on both the literature reviewed and the results obtained from this study are drawn. Recommendations based on the conclusions are then proposed.

5.2 CONCLUSIONS BASED ON BOTH THE LITERATURE REVIEWED AND ON THE RESULTS OBTAINED IN THIS STUDY

This study demonstrated that there was no significant difference between preparations with regards to faecal content, mucosal coating and the detectability of a 1cm lesion on the DCBE for the target population. However, the study group showed higher mean scores for faecal content in all segments of the colon compared to the control group. This provides an answer to the first research question posed in paragraph 1.7 (pg 5). A larger sample would have been more desirable in this study since Talbot (1995) stated that a small sample size may fail to demonstrate differences between groups, not because they do not exist, but because of a small sample size. However, due to both financial and time limitations a larger sample size was not feasible.

This study also demonstrated that the cleansing enema is not crucial in a preparatory regime for barium enema as Gelfand et al (1988) had insisted. In fact, the study group utilising 'Klean Prep®' as the only laxative with no cleansing enema, was found to produce similar preparations compared to the control group which included a cleansing enema in its regime. This provides the answer to the second question posed in paragraph 1.7 (pg 5).

A very important and interesting fact which can be concluded from this study is that both preparations produced good results which were comparable if not better than studies produced elsewhere. The results contradict the observations made by Tabone (1996) where he had found a very low sensitivity and specificity for barium enema when compared to colonoscopy and which he ascribed to as being due to poor bowel preparation. The effectiveness and quality of the barium enema depends on many other factors besides a good preparation (Gelfand et al, 1993) and therefore in order to improve the sensitivity and specificity of barium enema other factors such as quality controls, radiographic technique, flourosopic and radiographic equipment should be evaluated using a systematic approach. A point which should be highlighted is the fact that at St Luke's Hospital (Malta) barium enema examinations are not performed under screening and therefore the radiographs are produced in the 'blind'. Malpositioning which may obscure polyps and other lesions may therefore be one of the reasons for missed polyps and therefore the low sensitivity. This fact was emphasised by Ott & Gelfand (1993) who stated that careful flouroscopy is:

"important during the double - contrast examination to position the patient properly and to optimise spot filming of any lesions. A protocol for a Double - contrast barium enema that includes only limited series of routine large films obtained without the use of flouroscopy will be prone to error."

(Ott & Gelfand, 1993: 493)

A point which was confirmed in this study refers to the ascending colon where the ascending colon was found to be the least prepared region of the colon, a factor which was also demonstrated in other studies such as the ones performed by Brady et al (1994), Bolin et al (1988) and Present et al, (1982).

In fact due to this, Brady et al (1994) stated that the caecum and ascending colon are the areas in which most cancers and polyps are missed on the barium enema. This is an unfortunate situation since the barium enema has an increased potential in this region due to the fact that colonoscopy fails to visualise this area in 10 - 30% of all colonoscopic examinations (Smith, [1997] & Brady et al, [1994]).

This study also indicated a non - compliance rate of 17.2%. In 1997, 1509 DCBE's were performed (Radiology Services - Annual Report for 1997, 1998) and if 17.2% is taken as a baseline for non - compliance, 260 patients should have had a reappointment. Although this is not alarming, it still involves a considerable number of patients and therefore indicates a waste of money and resources, which can be utilised much better if non - compliance is reduced.

5.3 RECOMMENDATIONS BASED ON THE FINDINGS OF THIS STUDY AND ON THE LITERATURE REVIEWED

No statistically significant difference was found between standard preparation (SLH) and the preparation utilising 'Klean Prep®' for the target population. Therefore, until further research is performed using a larger sample size, it is recommended that for the time being, the standard preparation will remain in use at St Luke's Hospital.

Since 'Klean Prep®' was found to produce similar bowel preparations as the standard preparation (SLH) and both preparations were found to produce good results when compared to foreign studies, it is recommended that a cost - effective analysis is performed in order to determine which of the two is the

most cost - effective. The most cost - effective preparation should then be used to prepare the colon prior to a DCBE.

Unfortunately, in some patients adequate colon cleansing is not achieved and for these patients it is recommended that a cleansing enema is performed in the department on that same day of their appointment with the aim of dislodging the remaining faecal contents. If the cleansing enema cannot be performed in the department due to manpower or space limitations 'Klean Prep®' can be given as an alternative.

'Klean Prep®' should be used in those patients with a delicate fluid electrolyte balance such as those suffering from cardiac, renal, hepatic and diabetic disease since OBCS's are associated with minimal absorption of water and therefore are safer for the above mentioned patients (Fitzimons et al, 1987).

The aim of the department should be to reduce non - compliance. Therefore, a study should be performed in order to see which preparation of the two analysed preparations causes most side - effects. It was found that the more uncomfortable and unpleasant a preparation is, the less the patients are compliant (Bartram, 1994). After taking into consideration the costs and patient's acceptance of the two preparations, a decision on the best preparation can be taken.

Compliance can also be improved by introducing pre - packaged diets which reduce bulk in the colon and therefore are low fibre but at the same time provide sufficient caloric content to keep the patient in optimal condition. With modern lifestyle being so fast and hectic, outpatients often do not have the time to prepare an adequate diet. The aim of the use of pre - packaged diets

is to provide sufficient caloric intake and therefore keep the patient compliant (Tjon A Tham et al, 1993).

In order to improve sensitivity and specificity of the barium enema, it is recommended that a 'systems' analysis approach be used in order to minimise errors at each stage of the diagnostic process. It is therefore important to gather information and understand the various elements which are involved in a barium enema examination. With this intent, a study should be performed in order to determine why lesions, especially significant polyps and carcinomas, are missed with a barium enema. Ways and methods of minimising these errors could then be introduced.

Flourosocopy should be utilised when performing barium enemas in order to position the patient properly and to optimise spot filming of any lesions. It is hoped that this increases the sensitivity and specificity of the barium enema.

Finally, it would be interesting to determine whether a larger sample size would produce statistically significant results. A study with a larger sample which may include a subgroup of frail elderly institutionalised patients should therefore be performed.

5.4 CONCLUSION

In this chapter, the conclusions of the study were presented. A number of recommendations based both on the results and also on the literature reviewed were proposed with the aim of understanding the complexity of a barium enema examination, and increasing the diagnostic potential of the examination.

CHAPTER 6

CONCLUSION

The objectives of the study were to investigate two different preparatory regimes with the aim of improving the quality of the barium enemas being performed at St Luke's Hospital (Malta).

The study revealed that the two preparatory regimes produced similar results.

This research study was the first to be performed with respect to barium enema preparations in Malta and it gives an indication of the quality of preparations being performed in St Luke's. This study however was a very low scale study and therefore should not be considered conclusive even though it may give an indication of the situation involving the quality of barium enemas at St Luke's.

The findings of this study will be circulated to the relevant authorities and made available at the University Library with the intent of generating knowledge, interest and discussion.

The researcher augurs that the recommendations proposed will be given due consideration with the aim of improving the quality and diagnostic potential of barium enema.

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APPENDIX A -1

LETTER REQUESTING FOR CONSENT OF:

- Acting Manager at the Radiology Department

LETTER OF CONSENT OF:

- Acting Manager at the Radiology Department

'Id-Dwejra',
Triq il - Mingel,
Attard. BZN 12.
25th January, 1999.

Mr Joe Cassar,
Radiology Department,
St Luke's Hospital, G'Mangia.

I am a qualified Radiographer, currently undertaking a course leading to a B.Sc (Hons) degree in Radiography. The course involves carrying out a research - based project. My planned project will involve the study of patient's preparation for the barium enema procedure. The aim of the study is to compare two preparatory regimes, with the aim of improving on the existing preparation. In most hospitals abroad the trend is not to perform the cleansing enema prior to the barium enema and instead use oral bowel cleansing solutions. The idea is that such practices save money, are logistically easier, are more accepted by the patients and utilise manpower (nurses) in a more effective manner.

In order to obtain the required data I would need to perform my study on patients undergoing their examination in the X-ray department. Some patients will therefore not undergo a cleansing enema and instead be given an oral bowel cleansing solution (similar to the one given to patients undergoing colonoscopy). The length of period of the proposed study is approximately 2 weeks and this will involve approximately 30 patients. Patients confidentiality will be adhered to. This letter is intended to inform you about this study and also to obtain your consent in order to use the department's facilities to perform this study.

Should there be any queries, I would be delighted to discuss the matter further. I can be contacted at the above address or at the Division of Radiography, Institute of Health Care, St Luke's Hospital G'Mangia.

Whilst thanking you for your assistance, I look forward to your reply.

Yours sincerely,

Claude Portanier Mifsud

SPTAR SAN LUQA
Gwardamanga - Malta



ST. LUKE'S HOSPITAL
Guardamangia - Malta

OUR REF.

TELEPHONE: 621251 - 607860

YOUR REF.

Radiology department.
29 th January 1999.

Mr *Claude* Portanier Mifsud.
C/O Radiology Department.

Thankyou for your letter of the 25th January 1999, which I discussed with yourself and further with the Director of Radiology, Dr. MP Crockford.

Your same letter's request is now agreed to by the Radiology Department. Please note the essential departmental guidelines to follow while performing your project. It is also appreciated that you keep myself informed as to your project's progress in practice.

Your Sincerely

A handwritten signature in black ink, appearing to be 'J. Cassar', written in a cursive style.

Mr. J. Cassar.
A/Manager Radiology Services.

copy; Dr MP Crockford-Director of Radiology.

APPENDIX A -2

LETTER OF CONSENT OF:

- Dissertation panel - Radiographic Studies



REF. TAGHNA:
REF. TIEGHEK:

OUR REF:
YOUR REF:

7th October 1998

Mr Claude Portanier Mifsud
Id-Dwejra
Triq il-Mingel
Attard BZN 12

Re: Dissertation Proposal

The proposal that you have submitted for your dissertation has been reviewed at a meeting of the dissertation Panel, Radiography.

The subject area you have selected is researchable and the topic is valid.

I shall be your supervisor and you are kindly requested to organise a meeting with myself so that I may forward the recommendations by the Panel.

In the meantime you may commence your study.

Should you require further information please contact me.

Paul Bezzina
Co-ordinator
Division of Radiography

APPENDIX B

LETTERS REQUESTING FOR CONSENT OF:

- Dr Reginald Goei (Heerlen, The Netherlands)

LETTER OF CONSENT OF:

- Dr Reginald Goei (Heerlen, The Netherlands)

Claude Portanier Mifsud
"Id-Dwejra",
Triq Il-Mingel,
Attard BZN12
Malta.

22nd January 1999.

Reginald Goei MD
Department of Radiology,
De Wever Hospital,
Henri Dunantstraat 5, 6401 CX Heerlen,
The Netherlands.

I am a qualified Radiographer currently undertaking a course leading to a B.Sc (Hons) degree in Radiography at the University of Malta. The course involves carrying out a dissertation. My dissertation will involve the study of preparatory regimes prior to the barium enema. Barium enema films will be evaluated according to the amount of faeces present.

In my research design I am intending to use the same criteria used in your study which was published on **Radiology 1993: 109 - 112**. I would be greatly appreciated if you find no objection and could grant me permission to use the instrument.

I would also greatly appreciate if you could provide me with information on any further literature related to this subject area.

Whilst thanking you in anticipation for your assistance in this matter, I look forward to your reply.

Yours sincerely,

Claude Portanier Mifsud

Claude Portainer Mifsud
"Id-Dwejra"
Triq Il-Mingel
Attard BZN12
MALTA

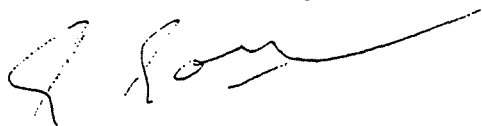
February 16, 1999

Dear Mr. Mifsud,

Thank you for your letter of January 22, 1999. I have no objection at all if you are intending to use the criteria which I used in my article on cleansing enemas. Enclosed is another paper dealing with the use of Antispasmodic drugs in Barium Enema Examination. In this paper we used criteria to quantify the quality of barium enemas. Perhaps you can use these criteria as well during the preparation of your dissertation.

I wish you very much succes with your work and if it is not very troublesome please send me a copy of your dissertation in due course.

Sincerely,



Reginald Goei
Department of Radiology
Atrium Medical Centre
Henri Dunantstraat 5
6401 CX Heerlen
The Netherlands.

APPENDIX C

SCORING (EVALUATION) CRITERIA USED IN THIS STUDY:

- For amount of faecal material present
- For quality of mucosal coating
- Overall quality of double - contrast barium enema

PATIENT NUMBER:

DATE OF EXAMINATION:

RADIOLOGIST:

CLINICAL INDICATIONS:

PATIENT COMPLIANCE:

Evaluation Criteria for amount of faecal material present.

POINTS	SCORE	DESCRIPTION	T A R E D S A E C N S R/S			
5	Excellent	No retained faecal material.				
4	Good	Minimal faecal material, few fine particles 1-2mm in diameter.				
3	Fair	Moderate faecal debris, particles 5mm or less, not sufficient to invalidate examination.				
2	Poor	Considerable faecal material, particles less than 1cm, sufficient to compromise examination.				
1	Unacceptable	Abundant faecal material, particles 1cm or more.				

The following key refers to the above and all evaluation criteria diagrams.

ASC = Ascending colon
TRAN = Transverse colon
DEC = Descending colon
R/S = Recto - sigmoid

Evaluation criteria - Mucosal coating

POINTS	SCORE	DESCRIPTION	A S C	T R A N	D E S	R/S
5	Excellent	Good coating in the whole segment.				
4	Good	Initially good coating in part of the segment and, later on, in the whole segment.				
3	Fair	Good coating in only part of the segment.				
2	Poor	Poor coating in the whole segment.				
1	Unacceptable	Unacceptably poor coating.				

Overall quality of the double contrast barium enema.

POINTS	DESCRIPTION	
5	Perfect.	
4	Good.	
3	Acceptable (a 1-cm lesion could be missed in one segment).	
2	Poor (a 1-cm lesion could be missed in more than one segment).	
1	Unacceptable (Inconclusive examination).	

APPENDIX D

PREPARATION SHEET:

- Given to patients undergoing colonoscopy at St

Luke's Hospital (Malta) both in English

(Researcher's Translation) and in

Maltese

ENDOSCOPY UNIT
TEL: 25951493 / 4.

COLON PREPARATION WITH 'KLEAN PREP'.

DATE OF EXAMINATION; / / AT 7:30 AM AT THE ENDOSCOPY UNIT.

One day prior to exam: (/ /) Your bowels should be clean before the examination.

7am: Have a toast with butter, and then start a LIQUID DIET. Example tea and coffee with sugar however WITHOUT MILK, lemonade or soft drinks, broth, squashes, juices and drink a lot of water.

DO NOT DRINK ANY MILK DURING THE DAY.

12:00 (Midday): Take some broth. You may take some jelly, however continue to drink.

2:00pm: Fill a bowl with 1 litre of water, open the first sachet of 'Klean Prep' and mix until all is dissolved. Then drink one glassful of the mixture every 15 minutes until you drink all the solution.

4:00/5:00pm: Do the same with the second sachet of 'Klean Prep'. After having drunk the second sachet, drink as much water or lemonade as you can until 8:00pm. It is very important for you to stay at home within easy reach of a lavatory.

The day of the examination: (/ /) You may take some tea or coffee WITHOUT MILK before coming to the department.

Please be at the Endoscopy Unit at 7:30am. It is best if another person accompanies you. You should bring the following with you:

1. The two remaining sachets of 'Klean Prep'.
2. Two 2 litre bottles.
3. Your ID card and your ticket of appointment.

IMPORTANT: After the examination you must not drive or use any mechanical machinery for the rest of the day.

UNIVERSITY OF MALTA LIBRARY
INSTITUTE OF HEALTH CARE

PREPARAZJONI GHALL-EZAMI TAL-MUSRANA BIL-'KLEAN PREP'.

DATA TA' L-EZAMI; / / fis- 7:30 ta' fil-ghodu L- ENDOSCOPY UNIT.

Gurnata qabel l-ezami: (/ /) Trid tibda tipprepara l-musrana ghal dan l-ezami.

7 am: Hu 'toast' bil-butir biss, wara ibda dieta ta' LIKWIDI BISS!
Ezempju: te' u kafe' biz-zokkor izda MINGHAJR HALIB, luminata jew 'soft drinks' ohra, meraq tal-brodu, 'squashes', 'juices' u HAFNA ILMA. TIEHUX HALIB IL-GURNATA KOLLHA.

12:00 (nofs in-nhar) : Hu ftit meraq tal-brodu msaffi. Tista tiehu ftit 'jelly'jekk trid, u wara kompli ixrob.

2:00 pm: Imla buqar bl-litru ilma (1 litre) , iftah l-ewwel pakkett 'KLEAN PREP" u hawwad sew mal-ilma sakemm jinhall kollu. Wara ixrob tazza (mit-tahlita biss) kull kwarta sakemm tixrobha kollha.

4:00 / 5:00 pm: Ghamel l-istess bit-tieni pakkett 'KLEAN PREP'.
Wara li tkun xrobt it-tieni tahlita ixrob kemm tista' ilma jew luminata sat-8:00 pm. Importanti li toqghod id-dar ghaliex ser ikollok tuza it-'toilet' spiss!

Gurnata ta' l-ezami: (/ /) Tista tiehu te' jew kafe' minghair halib qabel tigi.

Ejja L-Endoscopy Unit fis- 7:30 am, ma' xi hadd u gib mieghek:

1. Iz-zewg pakketti 'KLEAN PREP' li baqalek (jekk tawk erba').
2. Zewg fliexken ilma taz-zewg litri.
3. I.D. card u l-biljett tal-appuntament.

IMPORTANTI: Wara l-ezami ma' tkunx tista' issuq u lanqas thaddem magni il-gurnata kollha!

APPENDIX E-1

PREPARATION AND DIET SHEETS:

- Given to patients in the 'control group' of this study, in English and Maltese

BARIUM ENEMA

You are kindly requested to attend the X-ray department at St Luke's hospital on _____ at _____.

A **Barium Enema** is an examination of the large bowel. A small tube will be introduced into your back passage, and barium (a white fluid which will show on X-rays) will be run through the tube into your bowel. Several X-rays will then be taken.

Your bowel should be **clean** before doing the examination and therefore it is important that you follow these instructions for the success of your examination.

1. For the three days prior to the examination follow the enclosed diet sheet.
2. On _____ take two dulcolax pills after lunch
3. On _____ do not eat anything but drink plenty of water.
4. On _____ at 6:00 am take two dulcolax pills and at 12:00 pm of the same day place 1 suppository.
5. On _____ in the afternoon a community nurse will come and visit you in order to perform a cleansing enema. For the cleansing enema you need to prepare a bucket, a sheet, a soap, dettol, some oil and a small plate.

It is important to remember that this preparation causes diarrhoea and therefore it is advisable that you stay at home within easy reach of a lavatory.

In case that you cannot attend for the appointment please contact us on tel. no. 25951279 or 25951523.

DIET SHEET.

St Luke's Hospital

The barium enema examination depends on a preparation which aims at cleaning your bowel prior to the Barium enema.

It is very important that you follow the following instructions for the success of the examination. The following diet should be adhered to for the 3 days prior the examination.

Foods which **MAY** be taken:

Fresh fruit juice, tea or coffee (without milk), squashes, water.

White bread or toast, jam or marmalade, plain biscuits eg Rich tea, morning coffee.

Jelly.

Oxo/ bovril.

Chicken (prepared without fat or oil), Fish (prepared without fat or oil), boiled potato.

During the 2 days before the examination and also during the day of the examination drink plenty of fluids (approximately 5 pints or more).

Certain foods should **NOT** be taken:

ALL fruits and vegetables.

ALL fats, oils, butter and margarine, cheese, eggs, milk, yoghurt, ice cream, hamburgers, pastry, and sausages.

ALL fizzy drinks including beers and soft drinks.

EŻAMI TAL - "BARIUM ENEMA"

Inti ġentilment mitlub/a tattendi id-Dipartiment ta l-X-rays fl-isptar San Luqa nhar _____

fil-_____.

Il- "Barium Enema" huwa eżami tal-musrana l-kbira. Biex isir dan l-eżami, l-ewwel jitpoġġa pajp zgħir fill-warrani, u permezz ta` dan il-pajp, il- barium (likwidu abjad li jidher fuq l-X-rays) ikun jista` jgħaddi fill-musrana il-kbira. Wara jittieħdu l-X-rays li hemm bzonn. Huwa importanti li l-imsaren ikunu ndaf għall-dan l-eżami u għalhekk jeħtieġ li timxi ma` dawn l-istruzzjonijiet li ġejjin, biex l-eżami ma jsirx ta` xejn.

1. Matul it-tlett ijiem ta` qabel l-eżami, imxi mad-dieta li qed nibgħatulek ma` din il-karta.

2. Fil _____ hu żewg pilloli
DULCOLAX wara l-ikla ta` nofsinhar

3. Fil _____ tiekol xejn: imma ixrob
ħafna ilma .

4. Fil _____ fis-sitta ta` filgħodu ħu
żewg pilloli DULCOLAX, u f nofs-in-nhar ta`l-istess ġurnata poġġi
suppositorju.

5. Fil _____ għandha tiġi iżżurek in-
nurse tal-Community biex tagħmel il- "cleansing enema". Għal "cleansing
enema" għandek bzonn tlesti barmil, inċirata għal fuq is-sodda, sapuna,
dettol, żejt u plattina.

**FTAKAR! Din il-preparazzjoni tikkawża id-dijarea u għalhekk ikun
aħjar illi tibqa id-dar biex meta jkun hemm bzonn tmur it- "toilet".**

Jekk jogħġbok, għall-gid ta` pazjenti ohra, f`kaz li ma tkunx tista tiġi cempel
25951279 jew 25951523.

KARTA TAD-DIETA

L-eżami tal- "Barium Enema" jiddependi minn preparazzjoni li l-għan tagħha hu li jnaddaf l-imsaren qabel ma` jsir il- "Barium Enema".
Importanti hafna li timxi ma` dawn l-istruzzjonijiet biex l-eżami ma` jsirx ta` xejn. Għandek timxi ma` din id-dieta ta` hawn taħt għal tlett ijiem ta` qabel l-eżami.

IKEL LI TISTA` TIEHU:

Meraq tal-frott frisk, te` jew kafe` (mingħajr ħalib), "squashes", ilma
Hobz mill-abjad, jew ħobz mixwi, gamm jew marmalade,
Gallettini plain bħal "Rich Tea", "Morning Coffee"
Jelly
Oxo/Bovril
Tigieg (msajjar mingħajr xaħam jew żejt), ħut (msajjar mingħajr xaħam jew żejt)
Patata mogħllija

Fil-jumejn ta` qabel l-eżami, kif ukoll dakinhar ta` l-eżami, ixrob
ħafna likwidi (5 pinet jew aktar).

CERTU IKEL MA` JISTAX JITTIEHED:

Kull tip ta` ħaxix u frott frisk
Kull tip ta` xaħam, żejt, butir jew margarine, ġobon, ħalib, bajd,
ġelati, hamburgers, zalzett u ikel magħmul mill-għagina
Kull tip ta` xorb bill-gass, inkluż il-birra u luminati.

APPENDIX E-2

PREPARATION AND DIET SHEETS:

- Given to patients in the 'study group' of this study, in English and Maltese

BARIUM ENEMA

You are kindly requested to attend the X-ray department at St Luke's hospital on _____ at _____.

A **Barium Enema** is an examination of the large bowel. A small tube will be introduced into your back passage, and barium (a white fluid which will show on X-rays) will be run through the tube into your bowel. Several X-rays will then be taken.

Your bowel should be **clean** before doing the examination and therefore it is important that you follow these instructions for the success of your examination.

1. For the three days prior to the examination follow the enclosed diet sheet.
2. On _____ at 10:00 am open sachet number 1
3. Empty the contents in the container
4. Fill with one litre of water
5. Add the contents of sachet number 2
6. Cover the container with the lid and shake until dissolved
7. Drink the solution
8. Repeat process for each sachet. Drink the 4 solutions (4 litres) in about 4 hours.
9. No food should be taken after the start of drinking the solutions.

It is important to remember that this preparation causes diarrhoea and therefore it is advisable that you stay at home within easy reach of a lavatory.

In case that you cannot attend for the appointment please contact us on tel. no. 25951279 or 25951523.

DIET SHEET.

St Luke's Hospital

The barium enema examination depends on a preparation which aims at cleaning your bowel prior to the Barium enema.

It is very important that you follow the following instructions for the success of the examination. The following diet should be adhered to for the 3 days prior the examination.

Foods which **MAY** be taken:

Fresh fruit juice, tea or coffee (without milk), squashes, water.

White bread or toast, jam or marmalade, plain biscuits eg Rich tea, morning coffee.

Jelly.

Oxo/ bovril.

Chicken (prepared without fat or oil), Fish (prepared without fat or oil), boiled potato.

During the 2 days before the examination and also during the day of the examination drink plenty of fluids (approximately 5 pints or more).

Certain foods should **NOT** be taken:

ALL fruits and vegetables.

ALL fats, oils, butter and margarine, cheese, eggs, milk, youghurt, ice cream, hamburgers, pastry, and sausages.

ALL fizzy drinks including beers and soft drinks.

EŻAMI TAL - "BARIUM ENEMA"

Inti ġentilment mitlub/a tattendi id-Dipartiment ta l-X-rays fl-isptar San Luqa nhar _____

fil-_____.

Il- "Barium Enema" huwa eżami tal-musrana l-kbira. Biex isir dan l-eżami, l-ewwel jitpoġġa pajp zgħir fill-warrani, u permezz ta' dan il-pajp, il- barium (likwidu abjad li jidher fuq l-X-rays) ikun jista' jgħaddi fill-musrana il-kbira. Wara jittiehdu l-X-rays li hemm bżonn. Huwa importanti li l-imsaren ikunu ndaf għall-dan l-eżami u għalhekk jehtieg li timxi ma' dawn l-istruzzjonijiet li ġejjin, biex l-eżami ma jsirx ta' xejn.

1. Matul it-tlett ijiem ta' qabel l-eżami, imxi mad-dieta li qed nibgħatulek ma' din il-karta.
2. Fil _____ fl-għaxra ta' filgħodu iftaħ il-pakkett numru 1.
3. Izvojta l-pakkett fir-recipient li qed nagħtuk.
4. Żid litru ilma.
5. Żid il-kontenut tal-pakkett numru 2.
6. Għatti r-recipient bl-għatu u ħabbtu sewwa sakemm jinħall.
7. Ixrob it-taħlita.
8. Irrepeti dan il-process għal kull pakkett. B'kollox, għandek tixrob 4 litri f'erba' sigħat.
9. M'għandek tiekol xejn wara li tkun bdejt dan il-process.

FTAKAR! Din il-preparazzjoni tikkawża id-dijarea u għalhekk ikun aħjar illi tibqa' d-dar biex meta jkun hemm bżonn tmur it- "toilet".

Jekk jogħġbok, għall-gid ta' pazjenti ohra, f'każ li ma tkunx tista tiġi cempel 25951279 jew 25951523.

KARTA TAD-DIETA

L-eżami tal- “Barium Enema” jiddependi minn preparazzjoni li l-għan tagħha hu li jnaddaf l-imsaren qabel ma` jsir il- “Barium Enema”.
Importanti hafna li timxi ma` dawn l-istruzzjonijiet biex l-eżami ma` jsirx ta` xejn. Għandek timxi ma` din id-dieta ta` hawn taħt għal tlett ijiem ta` qabel l-eżami.

IKEL LI TISTA` TIEHU:

Meraq tal-frott frisk, te` jew kafe` (mingħajr ħalib), “squashes”, ilma
Hobz mill-abjad, jew ħobz mixwi, gamm jew marmalade.

Gallettini plain bħal “Rich Tea”, “Morning Coffee”

Jelly

Oxo/Bovril

Tiġieg (msajjar mingħajr xaħam jew żejt), ħut (msajjar mingħajr xaħam jew żejt)

Patata mogħllija

Fil-jumejn ta` qabel l-eżami, kif ukoll dakinhar ta` l-eżami, ixrob
ħafna likwidi (5 pinet jew aktar).

CERTU IKEL MA` JISTAX JITTIEHED:

Kull tip ta` ħaxix u frott frisk

**Kull tip ta` xaħam, żejt, butir jew margarine, ġobon, ħalib, bajd,
ġelati, hamburgers, zalzett u ikel magħmul mill-għagina**

Kull tip ta` xorb bill-gass, inkluż il-birra u luminati.

APPENDIX F

RAW DATA OBTAINED FROM STUDY

Patient number	Prep A/B	RADIOLOGIST 1								RADIOLOGIST 2									
		Faecal content				Mucosal coating				Overall	Faecal content				Mucosal coating				Overall
		asc	tran	des	r/s	asc	tran	des	r/s		asc	tran	des	r/s	asc	tran	des	r/s	
1	A	2	3	4	4	4	4	4	4	4	3	3	5	5	5	5	5	5	4
2	A	2	4	1	4	5	4	5	5	3	3	4	3	3	4	4	4	4	4
3	A	1	3	4	4	5	5	5	5	4	4	3	4	4	4	4	4	4	4
4	A	4	4	5	5	5	5	5	5	5	3	3	5	5	5	5	5	5	5
5	A	4	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
6	A	3	4	4	4	5	5	5	5	4	4	5	5	5	4	4	4	4	4
7	A	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
8	A	2	2	2	3	3	3	3	3	2	5	5	5	4	4	4	4	4	4
9	A	3	4	4	4	4	4	4	4	3	5	5	5	5	3	3	3	3	3
10	A	3	4	4	4	5	5	5	5	4	4	5	5	5	5	5	5	5	4
11	A	4	4	4	4	5	5	5	5	4	4	5	5	5	5	5	5	5	4
1	B	3	4	4	4	5	5	5	5	5	5	5	5	5	4	4	4	4	4
2	B	2	4	4	4	5	5	5	5	4	5	5	5	5	5	5	5	5	5
3	B	3	4	4	4	4	4	4	4	3	4	4	4	4	4	4	4	4	4
4	B	2	4	4	4	4	5	5	5	4	5	5	5	5	4	4	4	4	4
5	B	4	4	4	4	5	5	5	5	4	5	5	5	5	5	5	5	5	5
6	B	4	5	5	5	5	5	5	5	4	5	5	5	5	4	4	4	4	4
7	B	5	5	5	5	5	5	5	5	5	5	5	5	5	4	4	4	4	4
8	B	4	5	4	5	5	5	5	5	4	5	5	5	5	4	3	4	4	4
9	B	3	4	3	4	4	5	5	4	3	2	2	2	2	4	4	4	4	4
10	B	3	4	4	4	4	5	5	5	4	5	5	5	5	5	5	5	5	5
11	B	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
12	B	4	4	4	4	4	4	4	4	4	5	5	5	5	4	4	4	4	4
13	B	4	5	5	5	5	5	5	5	4	5	5	5	5	4	4	4	4	4

Key to the above diagram: Prep A = Control group; Prep B = Study group.
asc = ascending colon; tran = transverse colon; des = descending colon; r/s = recto - sigmoid colon.