

**FACTORS INFLUENCING IMPLEMENTATION OF AN ENHANCED  
RECOVERY PROGRAMME IN COLORECTAL SURGERY**

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## **Dedication**

**To Anwuri, Nicole and Amanda**

# **Abstract**

## **Introduction**

Major recent advances in modern surgery have focussed on processes and pathways relating to perioperative recovery. Optimising patients perioperatively is essential in improving outcomes. The enhanced recovery programme is an integrated pathway that combines evidence based practice in a synergistic manner to improve outcomes.

This research concerns perioperative recovery for patients undergoing major abdominal surgery.

## **Aim**

The aim of this study was to investigate the factors that influence the implementation of an enhanced recovery programme in patients undergoing elective colorectal surgery.

## **Method**

The study was done in four phases. The first phase was to assess the feasibility of introducing fast track surgery in our unit by recruiting patients undergoing reversal of loop ileostomy so as to reduce hospital stay.

The second phase, compared laparoscopic colorectal surgery with open colorectal surgery with regards to hospital stay and complication rates. Both groups of patients were followed up over a two year period to compare incisional hernia rates.

The third phase, compared the use of video education in the psychological preparation of patients undergoing elective colorectal resection with information leaflets and verbal information.

The fourth phase, compared short term outcomes between patients undergoing elective colorectal resection early in the week(Monday to Wednesday) with those later in the week(Thursday to Friday).

## **Results**

Early discharge is safe and achievable following reversal of loop ileostomy. Laparoscopic surgery does not improve short term outcomes following colorectal surgery compared with open surgery. Long term outcomes (incisional hernia rates) are similar. Supplementing video education with oral and written information prepares patients better psychologically for surgery although it does not improve short term outcomes. Operating on patients earlier in the week improves short term outcomes.

## **Conclusion**

The enhanced recovery programme is feasible and safe and should be practiced by individual units offering colorectal surgery. Patients benefit from preconditioning using video education and being operated upon early in the week.

## Acknowledgements

**I would like to acknowledge the support and advice of the following people who made the experience such an enjoyable one. Without their encouragement this thesis would not have been possible.**

My wife Anwuri and my children Nicole and Amanda for their love and patience and for allowing me the time and space to complete this work.

Mr Sanjay Chaudhri (Consultant Surgeon, University Department of Surgery, Leicester) who was one of my supervisors for the work included in this thesis. I would like to thank him for his encouragement and enthusiasm which I found invaluable during my research.

Professor Liz Anderson (Professor of Interprofessional Education, Department of Medical and Social Care Education) who was one of my supervisors for my thesis. I would like to thank her for her encouragement and enthusiasm which I found invaluable during my research.

Professor Patrick O'Dwyer (Professor of Surgery, University Department of Surgery, Glasgow) who was one of my supervisors for the work included in this thesis. He was very encouraging and offered very good advice on how to complete the thesis as there was an initial financial difficulty and hence registration was not done in Glasgow University.

Miss Jacqueline Mastermann (Stoma care nurse, Leicester General Hospital) who worked exclusively on the randomised trial helping with patient information, recruitment and data collection. I also want to thank all the other stoma nurses at Leicester General Hospital who helped whenever Jacqueline was off.

The following surgeons who allowed their patients to be entered into the randomised trial: Mr Baljit Singh (Consultant Surgeon, University Hospitals of Leicester), Mr Adam Scott (Consultant Surgeon, University Hospitals of Leicester), Mr Mike Thomas (Consultant Surgeon, University Hospitals of Leicester) and Mr John Jamieson (Consultant Surgeon, University Hospitals of Leicester).

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The majority of this work was carried out while I was employed as a Registrar at the University Hospitals of Leicester. The randomised trial which makes up the main body of my research was funded by the Charitable Trust, Leicester General Hospital.

# CONTENTS

	<b>Page:</b>
Title page	1
Dedication	2
Abstract	3
Acknowledgements	4-5
Contents	6-8
List of tables	9
List of figures	10
Statement of collaboration	11
List of work published and presented	12-18
Chapter 1:	
Introduction	
1.1 Introduction	20
1.2 History of colorectal surgery	35
1.3 Advances in colorectal surgery	40
1.3.1 Enhanced recovery	43
1.3.2 Laparoscopic colorectal resection	54
1.3.3 Psychological preparation of patients for surgery	58
Chapter 2:	
Methods	
2.1 Study aims	66
2.2 Methods	66
2.3 Ethical permission	67
2.4 Sample	68
2.5 Intervention	69
2.6 Data collection	73
2.7 Statistical analysis	74
2.8 Summary of stages of the study	76
Chapter 3:	
Closure of loop ileostomies: Is early discharge safe and achievable?	
3.1 Results (Phase I)	78

# CONTENTS

	Page:
Chapter 4: Laparoscopic colonic resection in fast-track patients does not enhance short term recovery after elective surgery	
4.1 Results (Phase II)	83
Chapter 5: Incisional hernia rates in laparoscopic colorectal resections compared with open colorectal resections	
5.1 Results (Phase II)	89
Chapter 6: Preparation for elective colorectal surgery using a video: A questionnaire based observational study	
6.1 Results (Phase III)	94
Chapter 7: Patient education videos for elective colorectal surgery: Results of a randomised controlled trial	
7.1 Results (Phase III)	98
Chapter 8: Enhanced recovery programmes in colorectal surgery are less enhanced later in the week	
8.1 Results (Phase IV)	108
Chapter 9: Summary of results	113
Chapter 10: Discussion	115-123
Chapter 11: Conclusions	125-126
Chapter 12: References	128-147

## CONTENTS-APPENDIX

	<b>Page:</b>
Appendix I: Randomised video education trial information sheet	149-151
Appendix II: Randomised video education trial consent form	152
Appendix III: Video education questionnaire	153-154
Appendix IV: Randomised video education trial protocol	155-159
Appendix V: Data collection form	160-163
Appendix VI: Ethics approval letter	164
Appendix VII: Research and Development approval letter	165-167
Appendix VIII: Short form 36 questionnaire	168-170



## LIST OF TABLES

	<b>Page:</b>
Table 3.1	Table comparing time of discharge with readmission rate
Table 3.2	Table comparing complication rate with time
Table 3.3	Indication for ileostomy construction
Table 4.1	Baseline characteristics for patients in the laparoscopic/open surgery study
Table 4.2	Times to study endpoints for patients in the laparoscopic/open surgery study
Table 4.3	Complications for patients in the laparoscopic/open surgery study
Table 5.1	Baseline characteristic for patients in the hernia study for laparoscopic/open surgery
Table 5.2	Risk factors for development of incisional hernia between the laparoscopic and open colorectal resection
Table 5.3	Number of patients with incisional hernia from an intention to treat basis and actual treatment received
Table 6.1	Summary of result from the video observational study questionnaire
Table 7.1	Baseline characteristics for patients in the video trial
Table 7.2	Mean Short Form 36 (SF-36) scores at 3 months after surgery for patients in the video study
Table 8.1	Baseline Characteristics comparing effect of day of surgery on short term outcomes in an enhanced recovery programme
Table 8.2	Complications for patients in the study comparing effect of day of surgery on short term outcomes in an enhanced recovery programme
Table 8.3:	Operations by day of surgery in the study comparing effect of day of surgery on short term outcomes in an enhanced recovery programme

## LIST OF FIGURES

	<b>Page:</b>
Figure 1	20
Average number of new cases per year and age specific incidence rates per 100,000 population UK	
Figure 7.1	102
Trial profile for the randomised video study	
Figure 7.2	103
Length of hospital stay for both groups of patient in the randomised video study	
Figure 7.3	104
Pain scores at rest from day 1 to 4 postoperative days in both groups in the randomised video study	
Figure 7.4	105
Pain scores on movement from day 1 to 4 postoperative days in both groups in the randomised video study	
Figure 7.5	106
Epidural use in both groups in the randomised video study	
Figure A	24
Extended right hemicolectomy	
Figure B	25
Hartmann's procedure	
Figure C	26
Abdominoperineal resection	
Figure D	27
Low anterior resection	
Figure E	28
High anterior resection	
Figure F	29
Sigmoid colectomy	
Figure G	30
Left hemicolectomy	
Figure H	31
Right hemicolectomy	
Figure I	32
Subtotal colectomy	
Figure J	33
Total colectomy	
Figure K	34
Transverse colectomy	

## **Statement of collaboration**

Although this project was conceived within a surgical team, this statement confirms the role I played as lead researcher.

The randomised trial comparing the effect of video education in the psychological preparation of patients for colorectal surgery was initially conceived by Mr Sanjay Chaudhri. I was involved in the submissions for ethical approval. In conjunction with Mr Chaudhri, I helped with the initial study to get patients views on the video and the enhanced recovery programme. I designed the data collection sheets and all other material used in the running of the trial.

I supervised the operational elements of the study including the day to day running of the trial, and all data collection with help from Jacqueline Mastermann. Follow up of patients following inpatient stay was performed by both myself and Jacqueline Mastermann. I collected data from patients during their inpatient stay and outpatient follow up and entered the data into a database.

Short Form 36 health survey questionnaires which are quality of life validated questionnaires were posted to patients by Jacqueline Mastermann.

Analysis of the results of the trial was carried out by myself with help from Simon Vaughan.

The first draft of the randomised video paper was reviewed by both Mr Chaudhri and Mr Singh who offered a fresh perspective on the results prior to submission for publication in Colorectal Disease.

The composition of this thesis is my work and has not been submitted previously for another degree or to any other institution. The thesis was typed by me using a Windows PC running Windows XP operating software. The following software were used in the production of this work: Microsoft Word 2003, Microsoft Excel 2003, Minitab version 14 and SPSS version 15. All references used in the text were reviewed by me personally.

## **List of work presented and published**

### **Original Articles:**

1. U Ihedioha, S Vaughan, J Mastermann, B Singh, S Chaudhri

Randomised trial of video versus traditional printed patient education for  
elective colorectal surgery

Colorectal Disease 2013 Nov;15(11):1436-41

2. U Ihedioha, S Sangal, J Mastermann , B Singh, S Chaudhri

Use of video education in the psychological preparation of patients undergoing  
elective colorectal surgery.

J R Soc Med Sh Rep August 2012 3:58;

3. U Ihedioha, S Muhtaseb, K Kalmar, L Donnelly, V Muir, A Macdonald

Closure of loop ileostomies: is early discharge safe and achievable?

Scott Med J 2010 : 55 : 27-9

4. U Ihedioha, G Mackay, E Leung, R Molloy, P J O'Dwyer

Laparoscopic colonic resection does not reduce incisional hernia rates when  
compared with open surgery

Surg Endoscopy 2008 : 22 : 689-92

5. G Mackay, U Ihedioha, A McConnachie, M Serpell, R G Molloy, P J O'Dwyer

Laparoscopic colonic resection in fast track patients does not enhance short  
term recovery after elective surgery.

Colorectal Disease 2007 : 9 : 368-72

## **List of work presented and published**

6. U Ihedioha, F Esmail. G Lloyd, A Miller, B Singh, S Chaudhri

Enhanced recovery programmes in colorectal surgery are less enhanced later  
in the week

Submitted to Journal of The Royal Society of Medicine

## **Letters:**

1. U Ihedioha, G Mackay, E Leung, R Molloy, P J O'Dwyer

Laparoscopic colonic resection does not reduce incisional hernia rates when compared with open surgery.

Reply to letter

Surg Endoscopy 2008 : 22 : 2767

2. G Mackay, U Ihedioha, A McConnachie, M Serpell, R G Molloy, P J O'Dwyer

Laparoscopic colonic resection in fast track patients does not enhance short term recovery after elective surgery.

Reply to letter

Colorectal Disease 2007: 9: 760-1

## **Published Abstracts:**

1. U Ihedioha, G Mackay, A McConnachie, M Serpell, R G Molloy, P J O'Dwyer  
Laparoscopic colonic resection in fast track patients does not enhance  
recovery after elective surgery  
Surgical Endoscopy 2007:21:1-106
  
2. G Mackay, U Ihedioha, A McConnachie, M Serpell, R G Molloy, P J O'Dwyer  
Laparoscopic colonic resection in fast track patients does not enhance  
recovery after elective surgery.  
Colorectal Disease 2006:8:1-31
  
3. U Ihedioha, S Mutaseb, K Kalmar, L Donnelly, A MacDonald  
Early discharge after closure of loop ileostomy: Is it safe and achievable?  
Colorectal Disease 2004:6:37-85

## **Presentations to Learned Societies:**

1. U Ihedioha, S Vaughan, J Mastermann, B Singh, S Chaudhri

Patient education videos for elective colorectal surgery: Results of a randomised controlled trial.

Association of Coloproctology of Great Britain and Ireland

Dublin, Ireland, 2-3rd July 2012

2. U Ihedioha, G Gravante, A Miller, B Singh, S Chaudhri

Enhanced Recovery Programmes in Colorectal surgery are less enhanced later in the week.

Association of Coloproctology of Great Britain and Ireland

Dublin, Ireland, 2-3rd July 2012

3. U Ihedioha, S Vaughan, J Mastermann, B Singh, S Chaudhri

Patient education videos for elective colorectal surgery: Results of a randomised controlled trial.

Association of Surgeons of Great Britain and Ireland

Liverpool, UK, 9-11th May 2012

4. U Ihedioha, G Gravante, A Miller, B Singh, S Chaudhri

Enhanced Recovery Programmes in Colorectal surgery are less enhanced later in the week.

Association of Surgeons of Great Britain and Ireland

Liverpool, UK, 9-11th May 2012



## **Presentations to Learned Societies:**

5. U Ihedioha, G Gravante, A Miller, B Singh, S Chaudhri

Enhanced Recovery Programmes in Colorectal surgery are less enhanced later in the week.

East Midlands Surgical Society Meeting

King's Mill Hospital, Sutton-In-Ashfield, 4th May 2012

6. U Ihedioha, G Gravante, A Ali, G Lloyd, B Singh, S Chaudhri

Enhanced Recovery Programme: Does day of surgery affect length of hospital stay?

European Colorectal Congress, St Gallen, Switzerland, 29th Nov-2nd Dec 2011

7. U Ihedioha, S Sangal, J Mastermann, J Jameson, B Singh, S Chaudhri

Use of video education in the psychological preparation for colorectal surgery.

Tripartite Colorectal Conference, Cairns, Australia, 3-7th July 2011

8. U Ihedioha, S Sangal, J Mastermann, B Singh, S Chaudhri

Psychological preparation for colorectal surgery: Does a video help?

1<sup>st</sup> International Conference on Enhanced Recovery, Bristol, UK. Sept 2010.

9. U Ihedioha, S Sangal, J Mastermann, B Singh, S Chaudhri

Use of video education in the psychological preparation for colorectal surgery.

The West Midlands Enhanced Recovery Workshop, Birmingham, UK. Sept 2010

**Invited Speaker**

## **Presentations to Learned Societies:**

10. U Ihedioha, G Mackay, E Leung, R G Molloy, P J O'Dwyer

Laparoscopic colorectal resection does not reduce incisional hernia rates compared with open colorectal resection.

European Hernia Society, Athens, Greece. May 2007

11. U Ihedioha, G Mackay, E Leung, R G Molloy, P J O'Dwyer

Laparoscopic colorectal resection does not reduce incisional hernia rates compared with open colorectal resection.

British Hernia Society, Nottingham, UK. Nov 2006

12. U Ihedioha, G Mackay, A McConnachie, M Serpell, R G Molloy, P J O'Dwyer

Laparoscopic colonic resection in fast track patients does not enhance recovery after elective surgery.

European Association of Endoscopic Surgeons, Berlin, Germany. Sept 2006

13. U Ihedioha, G Mackay, E Leung, R G Molloy, P J O'Dwyer

Laparoscopic colorectal resection does not reduce incisional hernia rates compared with open colorectal resection.

West of Scotland Surgical Scientific Association, Glasgow, UK. Oct 2006

14. U Ihedioha, S Mutaseb, K Kalmar, L Donnelly, A Macdonald

Early discharge after closure of loop ileostomy: Is it safe and achievable ?

Association of Coloproctology of Great Britain and Ireland, Birmingham, UK.

June 2004

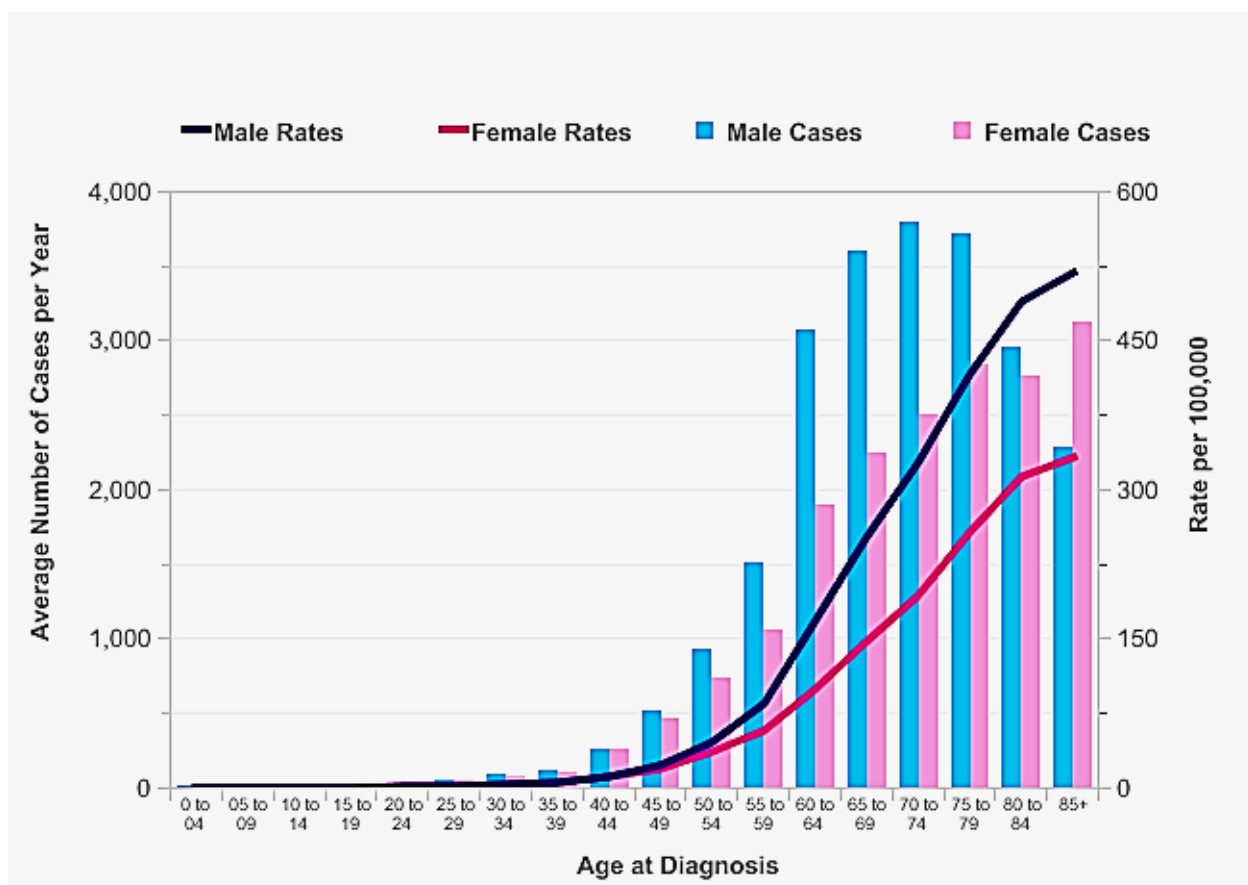
# **Chapter 1**

## **Introduction**

## 1.1 Introduction

Colorectal cancer is the third most common malignancy in both sexes with approximately 110 new cases diagnosed every day and a total of 39,991 new cases registered in the UK in 2008.<sup>(1)</sup> It is more common in the elderly as the incidence doubles for every decade of age after 40 years <sup>(2)</sup> and since there is a continuous improvement in life expectancy of the general population. In fact, this figure rose from 359/100.000 cases in the mid 70's to 379/100.000 cases in 2008 in the elderly population <sup>(3)</sup>. Fig 1 shows the incidence with increasing age.

Fig 1. Average number of new cases per year and age specific incidence rates per 100,000 population UK



Other risk factors for development of colorectal cancer include

- if a close relative has had colorectal cancer (genetic factor)
- inherited disorders such as familial adenomatous polyposis or hereditary non-polyposis colorectal cancer
- disease conditions of the colon such as crohn's disease or ulcerative colitis for more than 8-10 years
- obesity
- lifestyle factors such as little exercise, drinking a lot of alcohol <sup>(4,5,6)</sup>

Risk is reduced in women who take hormone replacement therapy (HRT) and those who eat a lot of fruit and vegetables. The risk is reduced by 2-11% with fruit and vegetables <sup>(7,8)</sup> and by 16% with HRT <sup>(9,10)</sup>

Patients can be asymptomatic and cancer incidentally picked up during bowel screening or present with rectal bleeding, anaemia, change in bowel habit, weight loss, abdominal pain, abdominal mass or bowel obstruction.

The bowel screening programme was introduced by the Department of Health to detect early cancer in people between the ages of 60 and 69 which is the peak age for colorectal cancer. People in this age range who are asymptomatic are given a faecal occult blood kit to check their stools for presence of blood. The test is done every 2 years and those who are positive with presence of blood in stool are offered further investigations such as colonoscopy to view the lumen of the bowel.

Management of colorectal cancer in most cases involves surgery and whenever possible the avoidance of complications such as perforation and obstruction.

Apart from cancer, benign conditions of the colon and rectum similarly require surgery whenever possible and the avoidance of complications.

For cancers and benign conditions, surgical options include extended right hemicolectomy for distal transverse colon or splenic lesions (Figure A), Hartmann's procedure for sigmoid lesions (Figure B), abdominoperineal resection for low rectal or anal lesions (Figure C), low anterior resection for low rectal lesions (Figure D), high anterior resection for high rectal lesions (Figure E), sigmoid colectomy for sigmoid lesions (Figure F), left hemicolectomy for splenic or descending colon lesions (Figure G), right hemicolectomy for right sided lesions (Figure H), subtotal or total colectomy for lesions involving most or all of the colon (Figures I,J), transverse colectomy for colonic lesions (Figure K).

Several studies have shown that colorectal cancer accounts for 10% of all deaths due to cancer. The crude mortality rate in the United Kingdom shows that there are 28 bowel cancer deaths for every 100,000 males and 23 for every 100,000 females <sup>(11,12,13)</sup>. 30 day mortality following elective surgery is between 2.4% and 6.7%. This increases to between 10% and 15.7% with emergency surgery <sup>(14,15)</sup>. Generally patients become worried when they are made aware of these figures. They worry about immediate recovery, convalescence at home and return to normal activities <sup>(16,17)</sup>. Issues such as chemotherapy and radiotherapy are also a concern.

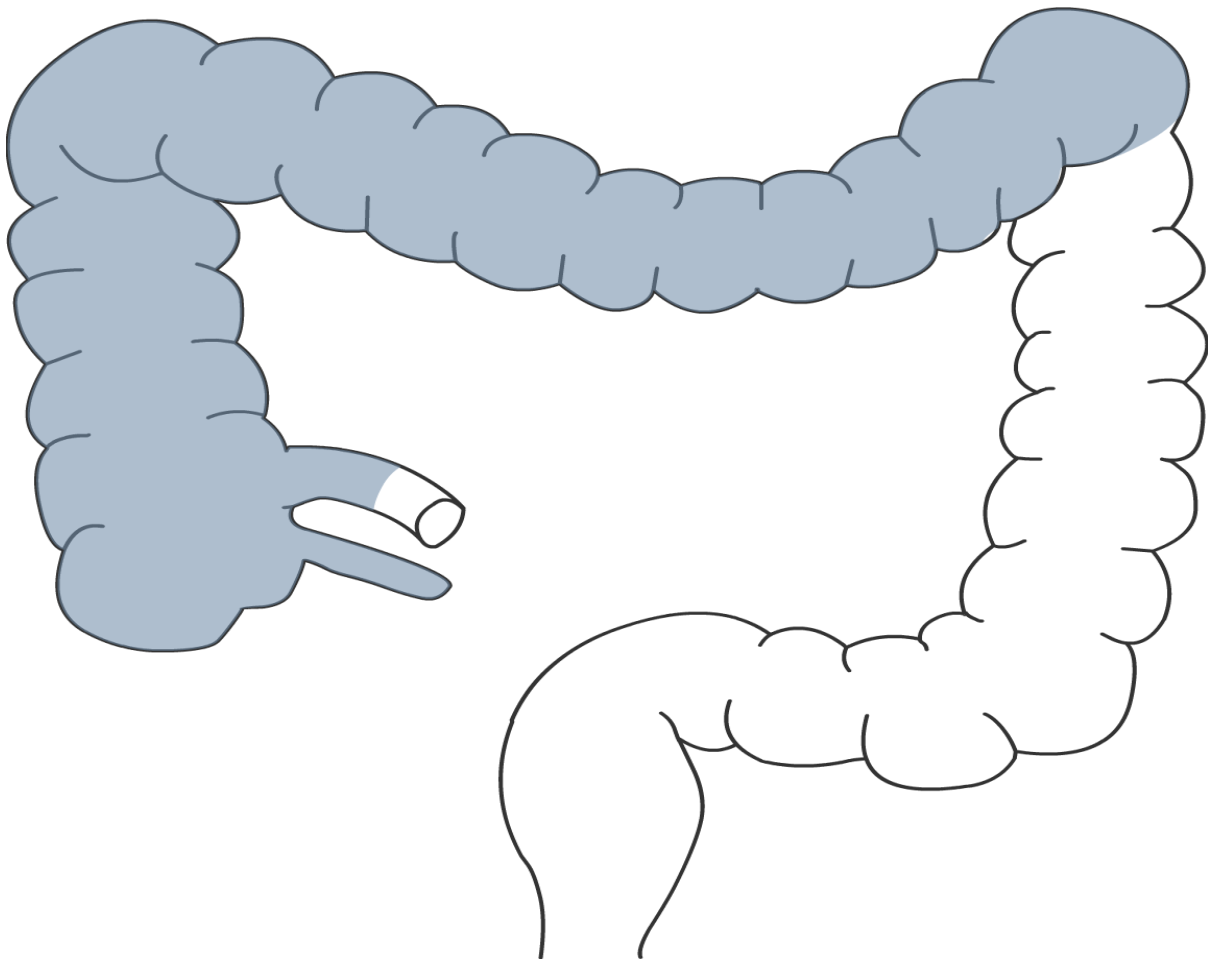
Total mesorectal excision which is a standard technique for rectal cancer devised 20 years ago by Professor Bill Heald has become the gold standard treatment for rectal cancer in the West <sup>(18)</sup>. It involves the en-bloc resection of the rectal cancer with a complete pararectal lymph node dissection as contained in the mesorectum. This has been found to reduce local recurrence and improve survival rates in patients with rectal cancer <sup>(19)</sup>. This concept was translated to colon cancer and complete mesocolic excision has now become the state of the art treatment for colon cancer. This technique

aims at the separation of the mesocolic from the parietal plane and true central ligation of the supplying arteries and draining veins right at their roots. Several studies have suggested an increased lymph node yield, reduced loco-regional recurrence and increased disease free survival <sup>(20,21,22)</sup>. There is however little information on serious adverse events and long term survival benefit has not been proven.

Surgeons over the years have looked at different methods to lessen the burden of surgery for patients. This has led surgeons and researchers to conduct several studies in the area of perioperative recovery. The work included in this thesis is in the area of perioperative recovery in patients undergoing elective colorectal surgery.

In the following pages, different types of colorectal operations are shown and explained using diagrams.

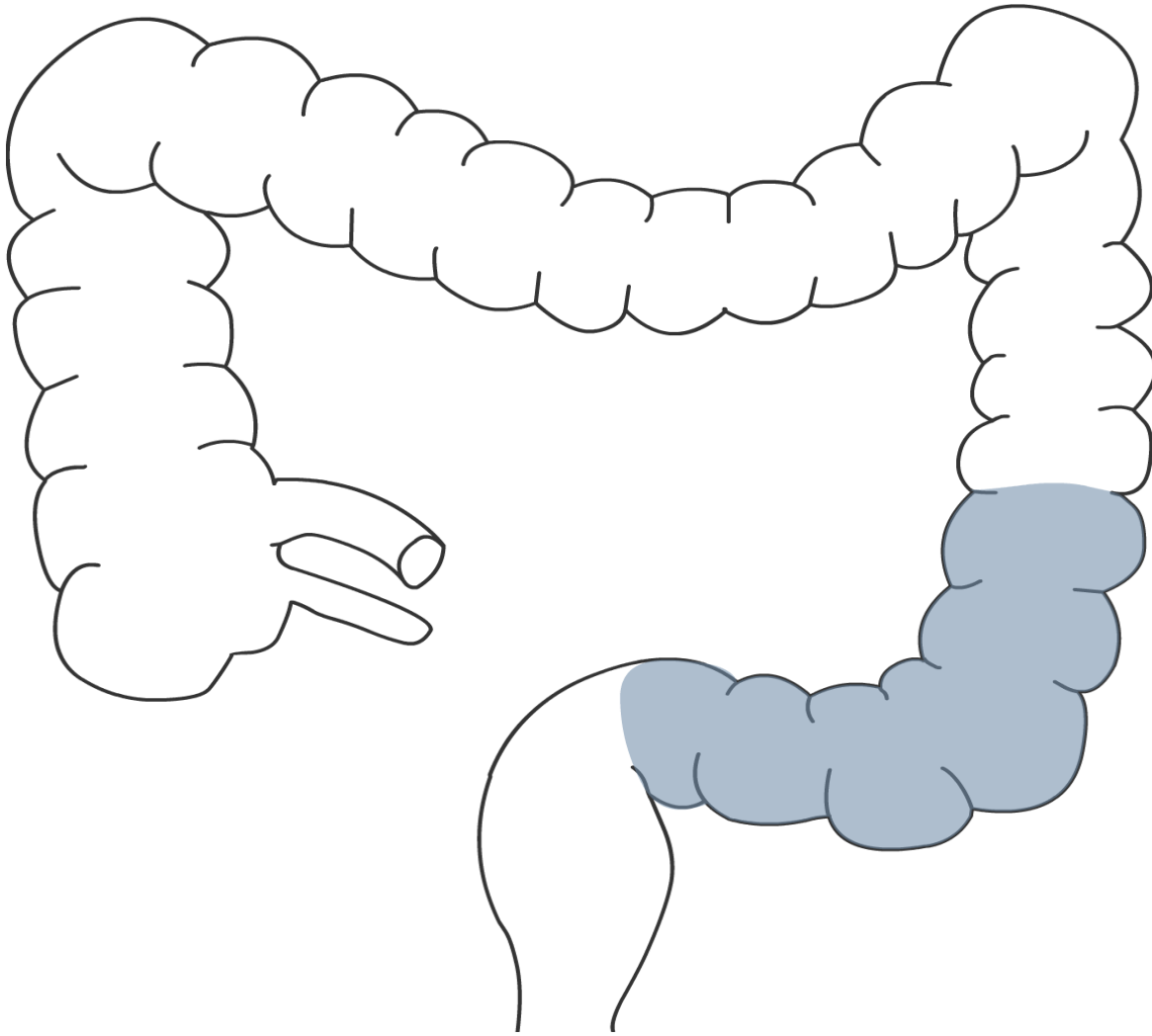
**Figure A: Extended Right Hemicolectomy**



**Explanation:** This is done for lesions affecting the distal transverse colon and the splenic flexure. The right colon and transverse colon are resected with formation of an ileocolic anastomosis in most cases.

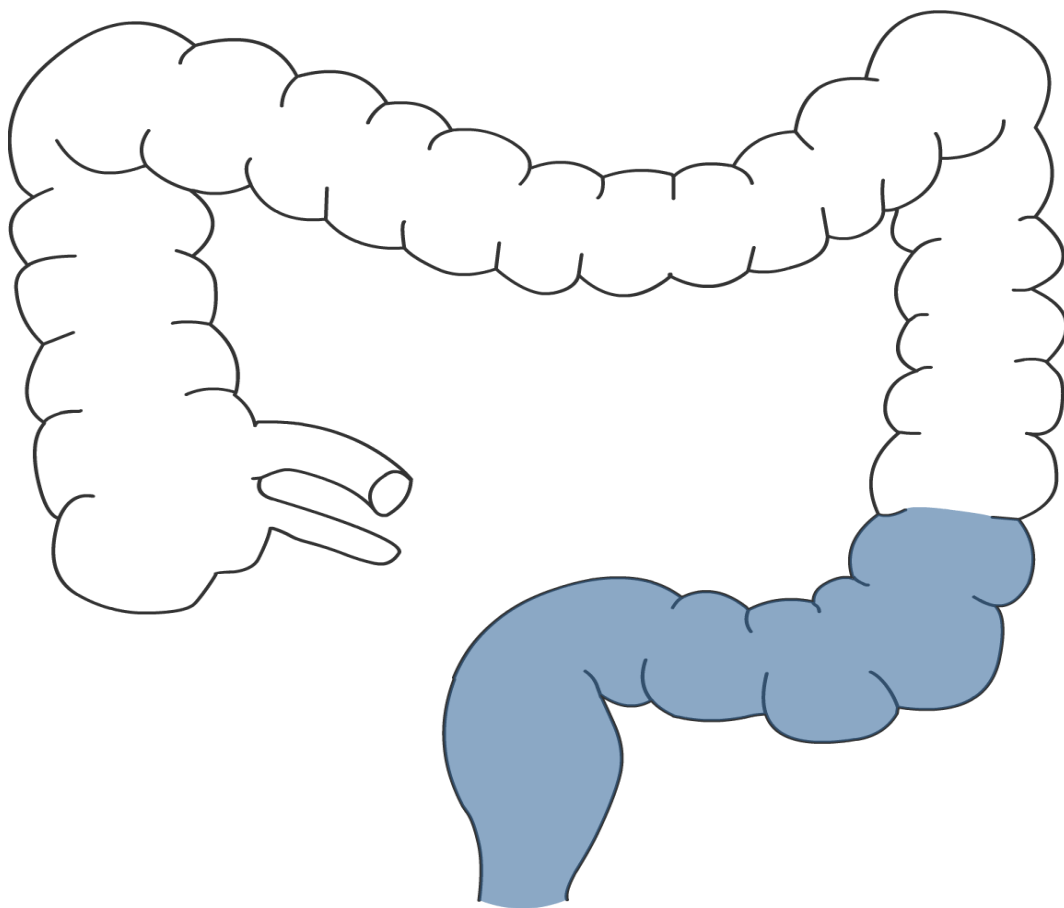


**Figure B: Hartmann's Procedure**



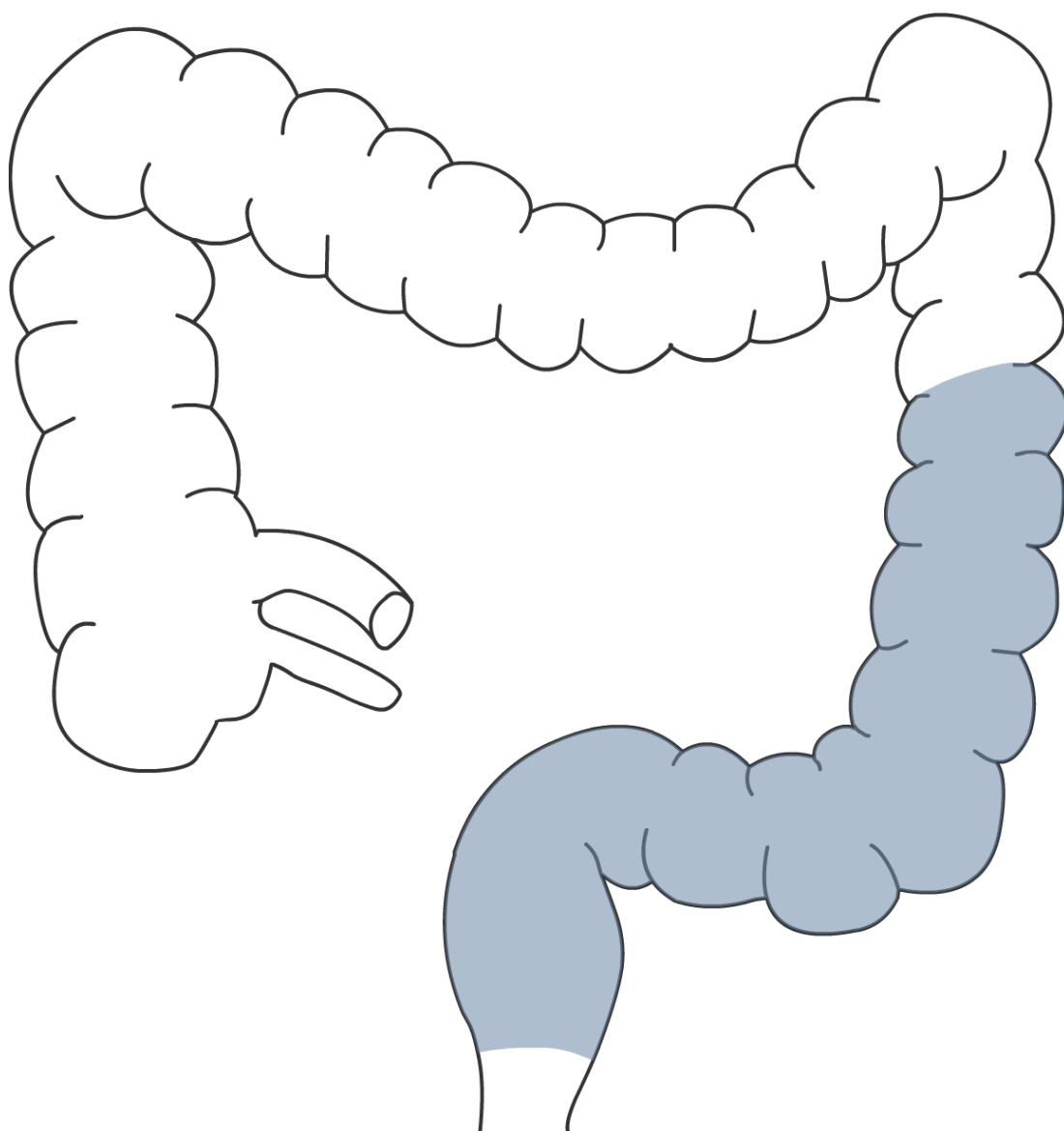
**Explanation:** This is done for sigmoid lesions. Indicated in emergency situations with perforation and contamination or in elective cases in frail patients. The sigmoid colon is resected with formation of an end colostomy. The proximal part of the rectum is stapled off.

**Figure C: Abdominoperineal Resection**



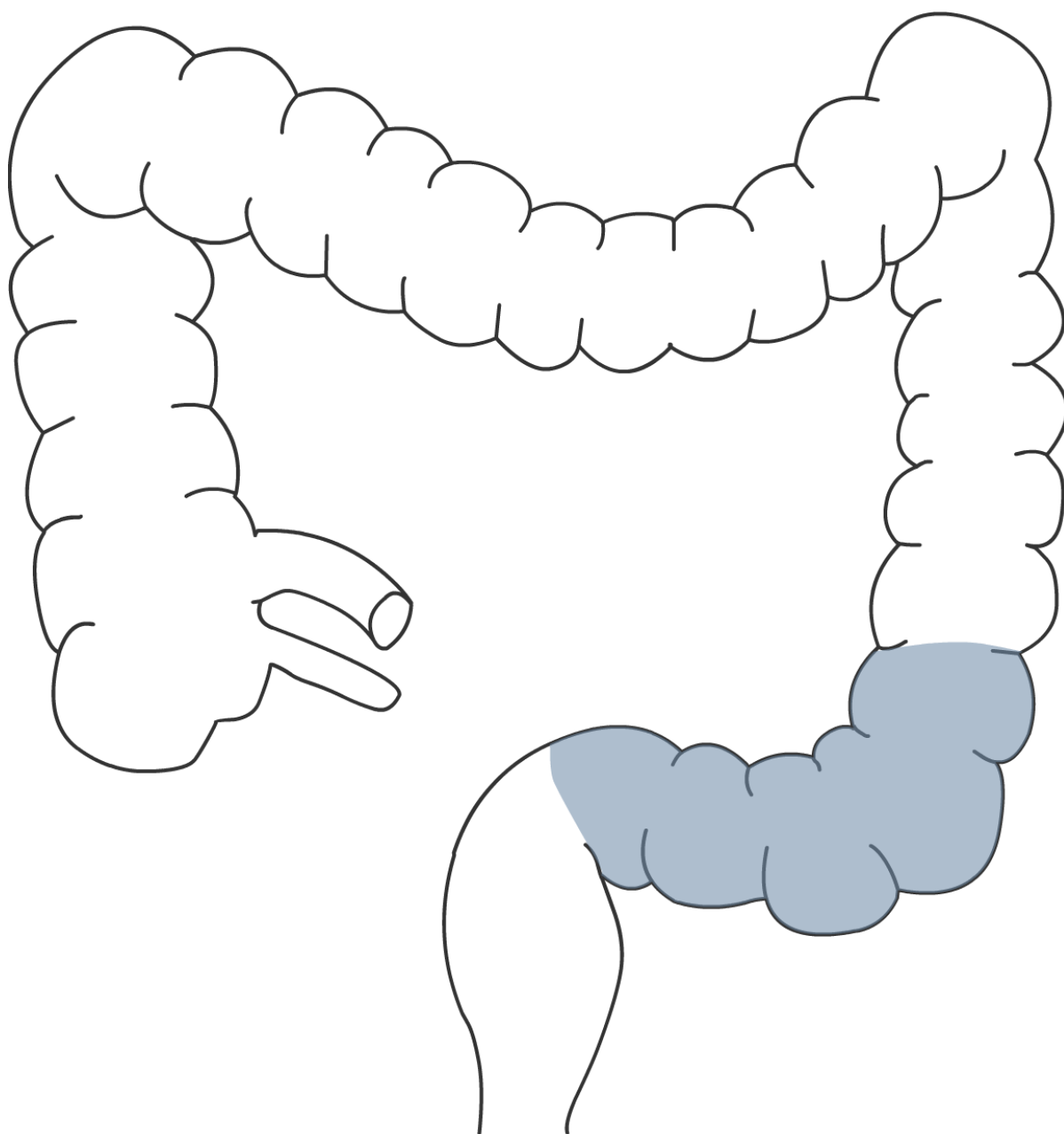
**Explanation:** This is done in low rectal lesions where sphincter preservation is difficult or in anal lesions. The rectum and anus are resected with formation of an end colostomy

**Figure D: Low Anterior Resection**



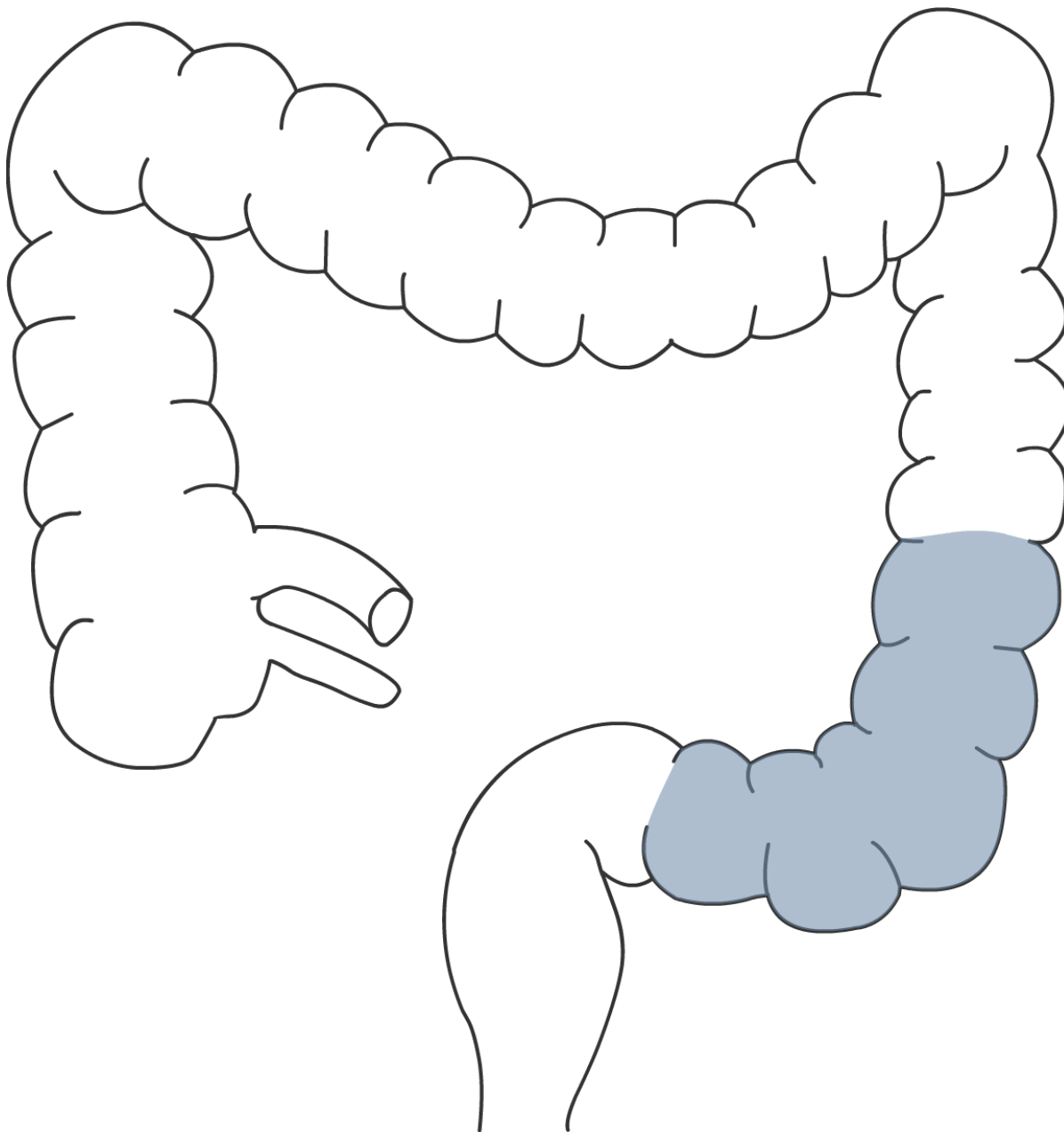
**Explanation:** This is done in low rectal lesions where sphincter preservation is possible. The lower third of the rectum is resected with coloanal anastomosis

**Figure E: High Anterior Resection**



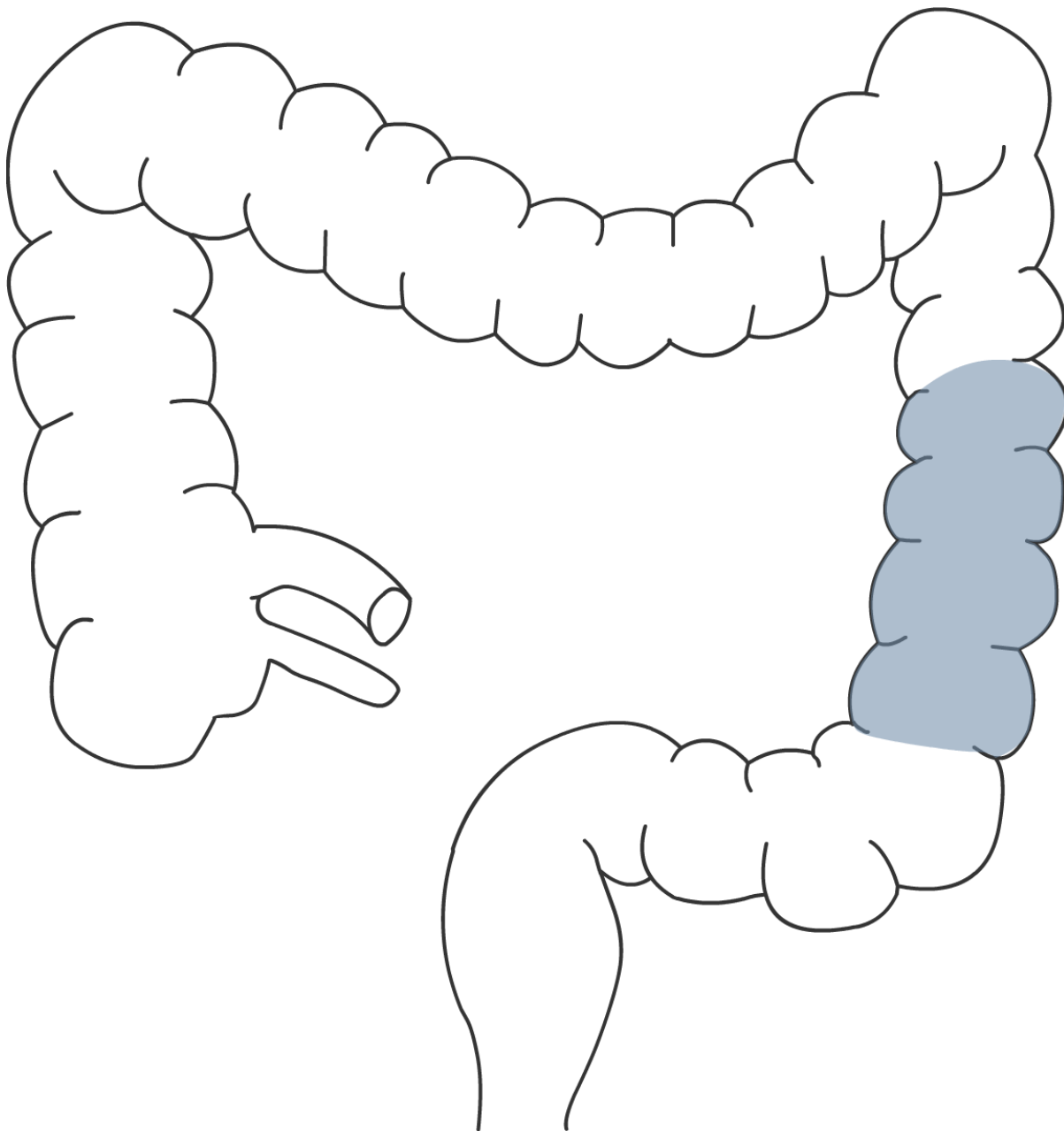
**Explanation:** This is done in lesions affecting the upper third of the rectum. Resection of the upper third of rectum with colorectal anastomosis

**Figure F: Sigmoid Colectomy**



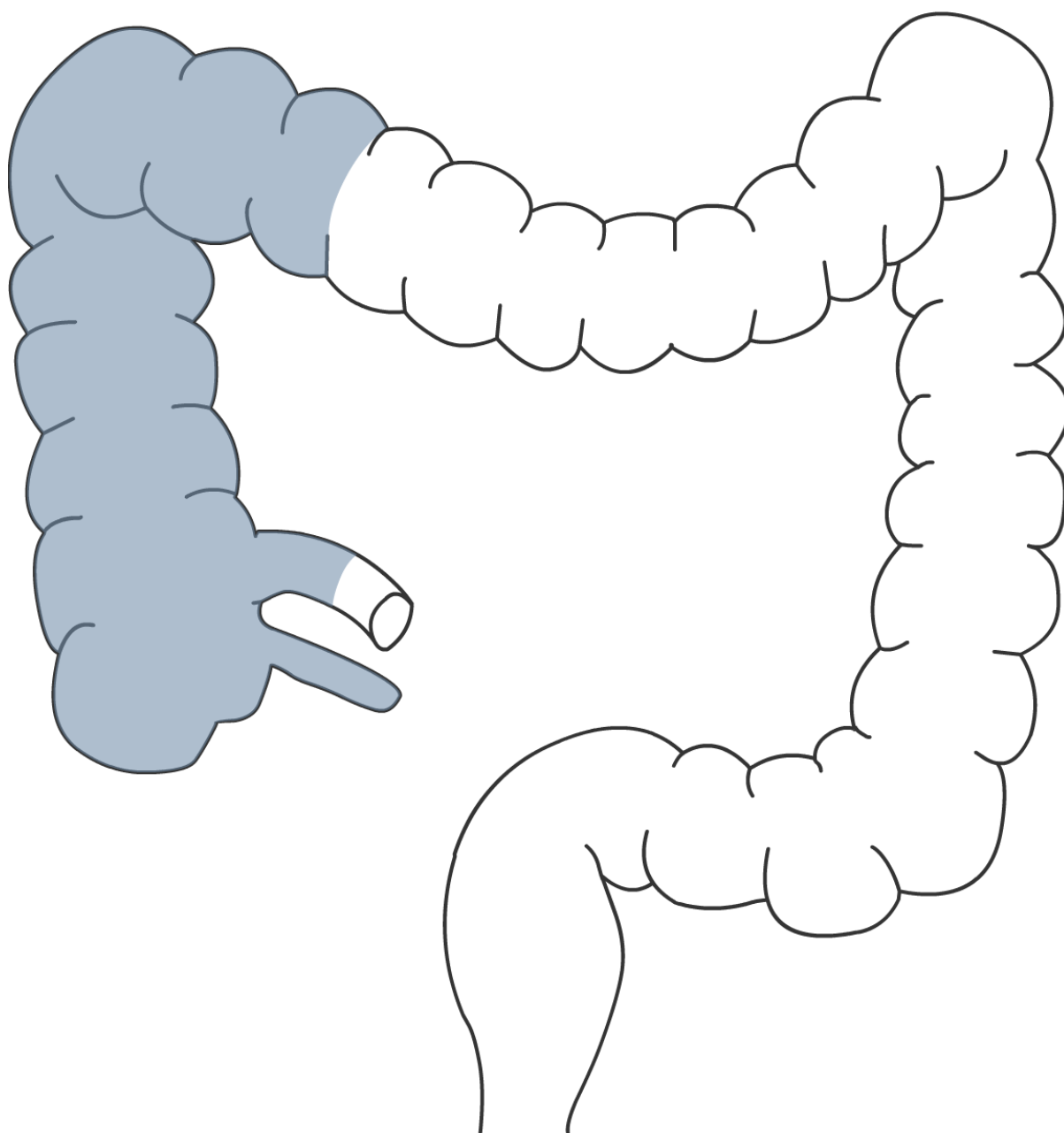
**Explanation:** This is done in lesions of the sigmoid colon. The sigmoid colon is resected with colorectal anastomosis

**Figure G: Left Hemicolectomy**



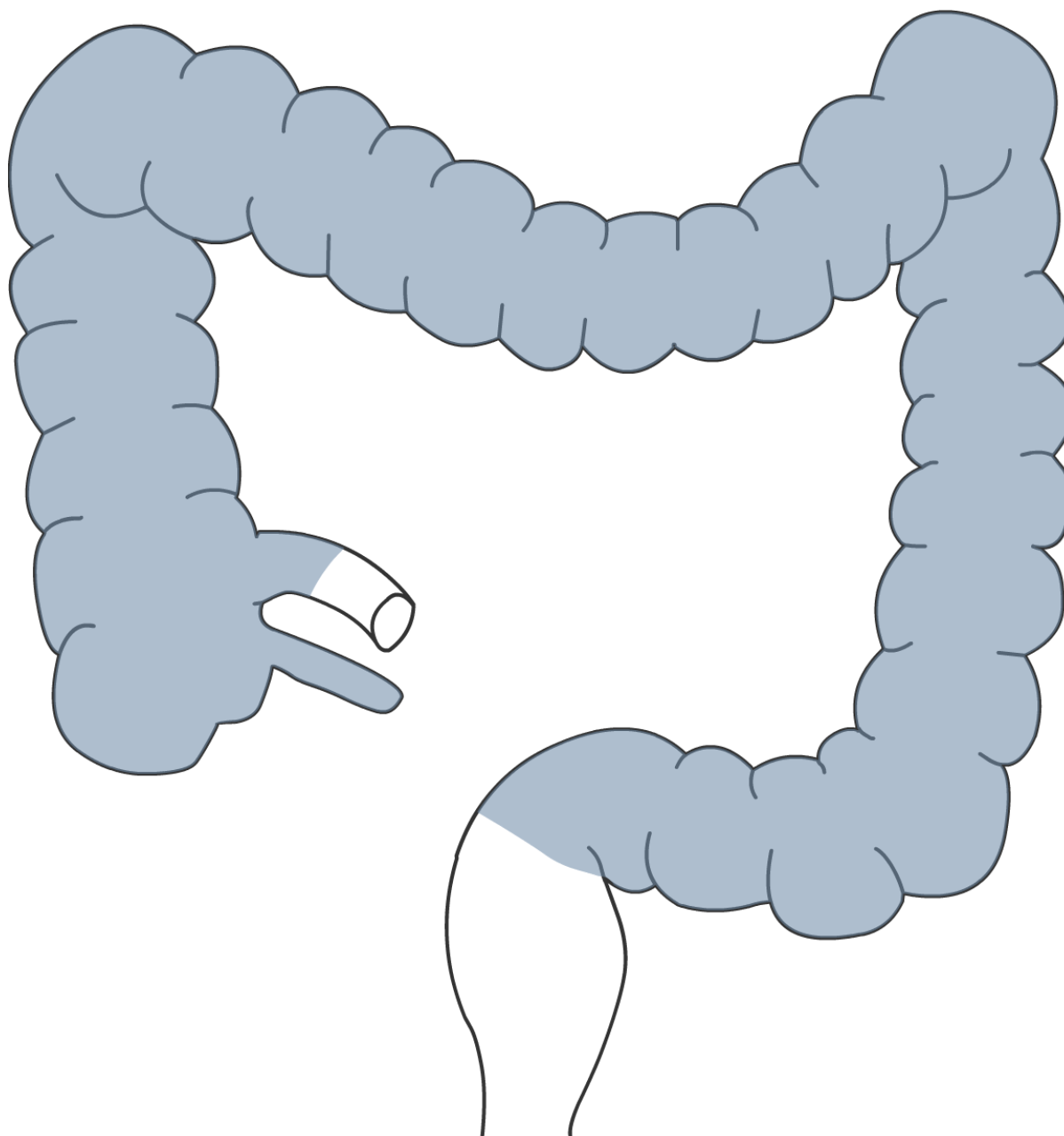
**Explanation:** This is done in lesions of the left hemicolon. The descending colon is resected with colocolic anastomosis

**Figure H: Right Hemicolectomy**



**Explanation:** This is done in lesions of the right colon. The right colon and proximal transverse colon are resected with ileocolic anastomosis

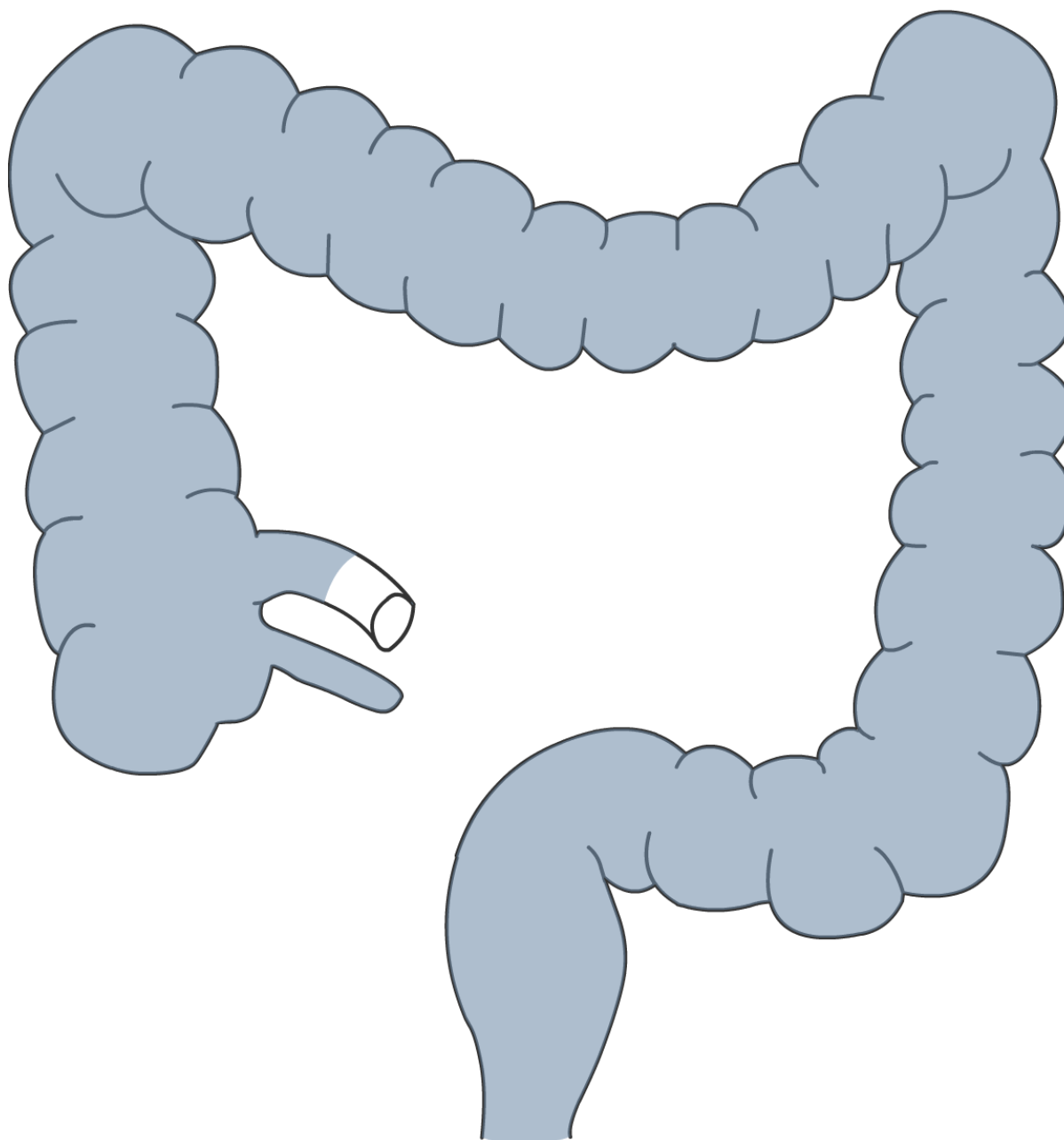
**Figure I: Subtotal Colectomy**



**Explanation:** This is done in lesions affecting all of the colon. The rectum is spared. Resection of all of the colon with end ileostomy formation. Rectum and anus are not resected.

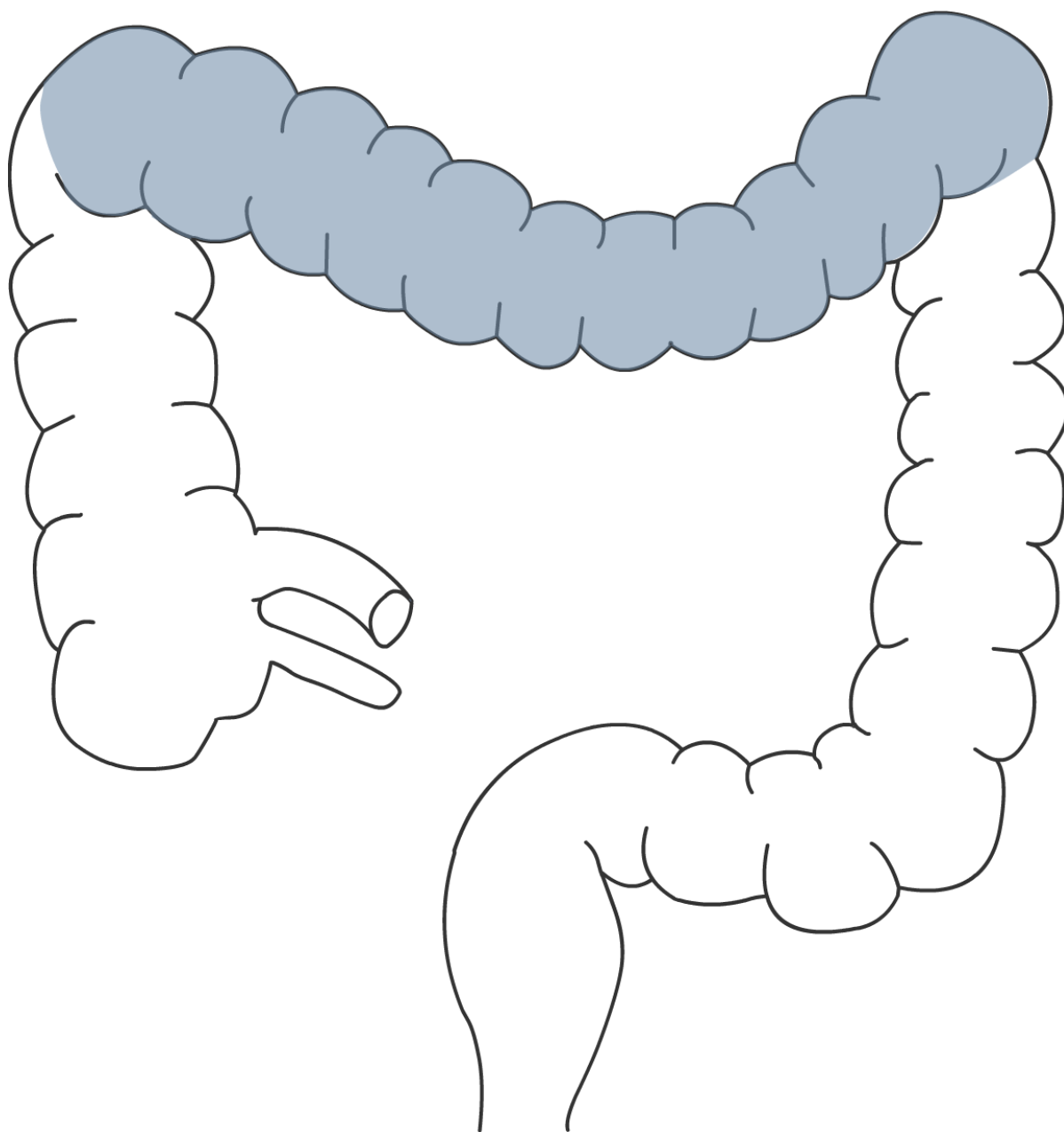


**Figure J: Total Colectomy**



**Explanation:** Done in lesions affecting the colon and rectum. The colon, rectum and anus are all resected with end ileostomy formation

**Figure K: Transverse Colectomy**



**Explanation:** Done in lesions affecting the transverse colon. The transverse colon is resected with colocolic anastomosis

## **1.2 History of Colorectal Surgery**

The advent of colorectal surgery parallels the development of surgery in general. Up until the 19<sup>th</sup> century, the surgical treatment of colorectal cancer was in a deplorable status due to the lack of general anaesthesia and aseptic measures. There are numerous records of treatment of anal and rectal diseases handed down by ancient populations.

### **The Egyptians**

The Egyptians first introduced the Ebers medical papyrus (circa 1700- 1200 BC) which gives 33 prescriptions or recipes for the treatment of anorectal diseases. They include the use of ointments, creams, suppositories, enemas and cathartics. They later introduced the Beatty medical papyrus in the 12<sup>th</sup> and 13<sup>th</sup> century BC which consists of methods and remedies for treating colon and anorectal disease. Those prescriptions contain ingredients such as honey, myrrh, flour and rectal injections which contain honey and sweet beer.

### **The Greeks**

The Greeks were greatly influenced by Hippocrates (460-377 BC) who wrote extensively on the diseases of the anus and rectum. He described the treatment of haemorrhoids by cutting, excising, sewing, binding and cautery. He recognised the relationship between anorectal abscess and the resulting fistula and recommended use of a stent or ligature method for treating fistulae. He recognised the relationship of urinary tract to anorectal diseases and gave prescriptions for both at the same time. The Greeks treated diseases of the anus and rectum by means of suppositories, ointments and enemas in much the same way as the Egyptians. They however, performed more operations.

### **The Romans**

The Romans did not contribute much to the practice of proctology and followed most of the treatments recommended by the Egyptians and the Greeks. Celsus (25 BC -50 AD) stated that wounds of the intestine should be sutured in all layers and advocated use of the knife for anal fistulae. Galen (122-199 AD) who was a famous Roman contributed very little to the management of anorectal diseases.

### **The Byzantines**

Paul Aegina was a 7<sup>th</sup> century surgeon of the Byzantine era. He gave excellent descriptions for procedures for haemorrhoidectomy and anal fistula.

### **The Arabs**

There was not much improvement in treatment of anorectal diseases under the Arabs. However, Maimonides (1135-1204 AD) recommended light diet and sitz bath for the treatment of haemorrhoids.

### **School of Salerno**

Roger Frugardi recommended suture of wounds of the intestine over a stent using the trachea of a large bird or large hollow elder twig. The School of Salerno had rules of hygiene. During this middle age, sufferers from diseases had a patron saint who they could invoke. Saint Fiacre was the patron saint for haemorrhoid sufferers.

### **The 12<sup>th</sup> century onwards**

From the 12<sup>th</sup> century, the barber-surgeons of Europe who were separated from physicians performed operations such as lancing abscesses, tooth extraction and treating wounds. It was not until 1800 with the founding of the Royal College of Surgeons during the reign of King George III in the United Kingdom, that the barbers were separated from the surgeons.

With the practice of colorectal surgery as only surgery of the anus and rectum in Europe, the same applied in America with the establishment of the American Proctologic Society in 1897. However, this was renamed in 1959 to the American Board of Colon and Rectal Surgeons.

Surgery of the colon and rectum became practiced more widely as was general surgery after the discovery of anaesthesia (1846-1849) by the American surgeon Crawford Long and the American dentist William Morton and the introduction of antisepsis in 1867 by the English surgeon Joseph Lister.<sup>(23,24)</sup>

With the onset of colorectal surgery came preoperative, intraoperative and postoperative interventions. Such interventions as use of nasogastric tubes, use of abdominal drains, use of antibiotics and mechanical bowel preparation date back to the same period.

Although the use of nasogastric tube was first described by John Hunter in 1790<sup>(25)</sup> when he stretched the skin of an eel over a whale bone to deliver enteral feeding to a patient with dysphagia, its use in colorectal surgery was first described by Kussmaul in 1884 who used it for decompression of the stomach.<sup>(26)</sup> The use of nasogastric tubes in colorectal surgery was popularised following experiments carried out by Wangesteen in patients with small bowel obstruction in 1932.<sup>(27)</sup> Nasogastric tube in colorectal surgery therefore became standard practice for several years. However, with innovations in surgery and the introduction of the enhanced recovery programme, its use was challenged by a number of trials and it is no longer recommended for prophylactic decompression of the stomach in patients undergoing elective colorectal surgery.

The use of drains was first described by Hippocrates when he used it to release pus from a chest empyema. The prophylactic drainage of the peritoneal cavity was first described by Sims in the mid nineteenth century. Billroth<sup>(28)</sup> who is one of the foremost gastrointestinal surgeons was convinced that drains save lives. Since the study by Billroth, there have been controversies amongst surgeons on the use of drains. While some suggest increased complication rates with use of intraperitoneal drains following colorectal surgery<sup>(29)</sup>, others have expressed a different opinion.<sup>(30)</sup> Current recommendations for elective colorectal surgery in an enhanced recovery programme is for its use only in rectal surgery.

Mechanical bowel preparation was first described during the second world war by the military surgeons who tried to sterilise the colon with the intention of reducing postoperative complications. It became widely accepted in the 1970s following the study by Plumley who described a new regimen for mechanical bowel preparation.<sup>(31)</sup> From clinical experience, many surgeons are aware of poor tolerance of mechanical bowel preparation (MBP) by the patient. In a questionnaire study of 58 patients by Solla et al. 88% found the procedure distressing to some degree and 41% complained of nausea, vomiting and/ or abdominal pain<sup>(32)</sup>. 10 patients stopped taking their preparation due to discomfort and 34% were still passing faecal fluid at the end of the procedure. This highlights the practical problems encountered with bowel cleansing. Several studies have shown complications with mechanical bowel preparation including electrolyte imbalance, significant weight loss, postural hypotension from dehydration and reduction in exercise tolerance<sup>(33,34,)</sup>. The first large randomised controlled trial to investigate the effect of mechanical bowel preparation was by Brownson published in the British Journal of Surgery in 1992<sup>(35)</sup>. They looked at 179 patients undergoing colorectal resection with or without MBP and found a higher leak rate in the group who received MBP with no difference in wound infection rates. A study by Zmora et al. of 380 patients found no differences in infective complications but reported that postoperative diarrhoea was more common in the MBP group compared with those that had no MBP (7% vs.

0.5%,  $p < 0.001$ ). Spillage of bowel content was more common as was the presence of liquid faeces with fluid or semi-solid content reported in over 50% <sup>(36)</sup>. Studies by Miettinen et al. <sup>(37)</sup>, Fa-Si-Oen et al. <sup>(38)</sup> and Ram et al. <sup>(39)</sup> have all failed to show any significant difference in outcome measures between groups with or without MBP. In the last decade, with growing evidence suggesting at the very least no significant benefit and possibly an increase in the rate of anastomotic dehiscence, opinions are starting to change. As in the use of nasogastric tubes and intraperitoneal drains, MBP is no longer favoured by most surgeons for elective colorectal surgery.

The first recorded use of antimicrobial prophylaxis in colorectal surgery dates back to the late 1930s. Garlock and Seley reported the results of 21 patients undergoing colorectal surgery with prophylactic sulphonamides and recorded only one wound infection. <sup>(40)</sup> The first randomised controlled trials on the use of prophylactic antibiotics was carried out in the 1960s and subsequent trials with good results have made this a routine part of surgical practice with the adoption into national guidelines for good practice.

### 1.3 Advances in Colorectal Surgery

Generally all patients undergoing surgery are worried about the operation, the immediate recovery and convalescence to return to normal activities. For cancer patients there is the additional concern relating to issues such as chemotherapy, radiotherapy and survival. As a result of these concerns, surgeons and researchers have made concerted efforts to develop strategies to lessen the impact for patients and their families/carers. Several studies have been conducted in the area of perioperative recovery.

Major recent advances in modern surgery have focussed on processes and pathways relating to perioperative recovery with the aim of improving overall outcome. This interest in perioperative recovery has been driven by a number of factors. First, the demands of an aging population and second the increasing pressure on resources in healthcare systems struggling to meet the cost of new modern medicines and advanced technologies. In the United Kingdom, where the National Health Service is funded through taxation, today's pressures are resulting in more demands for more effective and efficient services.

One of the other areas of interest to most surgeons is the technical aspect of surgery. There is the recognition that advances in training and technology complement perioperative recovery and improve outcomes. Advances such as laparoscopic surgery and endovascular aneurysm repair with patients benefiting from small incisions have improved outcomes by reducing the physiological and psychological stress of surgery.

There are phases to consider when looking at improving perioperative recovery. First, is the preoperative phase as preparation for theatre is very important. There is the assessment of co-morbid conditions and its effect on the wellbeing of the patient. Patients have to be optimised with



respect to nutritional supplementation, fluid balance and psychological preparation as these have an effect on outcome.

The surgical and anaesthetic techniques play an important role in the intraoperative period. The body responds to injury which in this case is surgery by activating the hypothalamic-pituitary axis and the autonomic nervous system which leads to an overall catabolic effect. Interventions which reduce the stress of surgery may well reduce the inflammatory response and improve recovery. Anaesthetic techniques in this phase include fluid management, placing of monitoring devices and analgesic regimes aimed at reducing perioperative pain and stress.

The postoperative phase involves a multidisciplinary team comprising of surgeons, nurses, physiotherapists, nutritionists, occupational therapists and pharmacists. For the patient the support of these team members can be challenging. The team need to work together and agree on joint management plans. This phase has had the most significant advances as interventions such as use of nasogastric tubes, intraperitoneal drains have been challenged and discontinued. There have also been debates about early feeding and mobilisation which have been shown to improve outcomes. With these phases in mind came the idea of an integrated pathway which can combine evidence based practice in a synergistic manner to improve outcomes.

The most significant developments in colorectal surgery in the last decade have been the development of the enhanced recovery programme and laparoscopic colorectal surgery. Several studies have shown improvements in perioperative care when these two strategies are combined. However, for patients to derive the optimal benefits from these, they have to be well motivated and psychological preparation for surgery becomes an important strategy. Dissemination of information and education are key elements in the psychological preparation of patients for surgery. Motivation

can be achieved verbally (face to face) as is the usual practice in clinic, or alternatively through the use of information leaflets or through the use of a video. There is a paucity of data in the literature on the use of audio-visual aids in the preparation of patients for surgery. Patients particularly those presenting with colorectal cancer are more preoccupied with the treatment of the cancer (removing the cancer) and subsequent mortality. Verbal information and education on enhancing recovery after surgery may not be well understood by the patients at this time. Information leaflets with several pages on enhancing recovery may also not be of much interest to the patient. Introduction of the use of a video which tells the patient about the preoperative preparation and postoperative care and expectations as well as advice on discharge could be watched by patients at any time prior to their operation. This could be done in the comfort of their homes with family. This could lead to better understanding and better optimisation of patients.

### 1.3.1 Enhanced Recovery

#### Introduction

Optimising patients preoperatively is essential in improving outcomes. This includes understanding and assessing the patients co-morbidities along with their general health particularly diet and their general wellbeing. Preparing patients psychologically for surgery has been shown in the literature to have a positive impact on short term recovery. Other factors during the preoperative period that may have an impact on recovery in patients undergoing colorectal surgery include nutritional supplementation and mechanical bowel preparation.

Intraoperatively, the insult of surgery leads to an increased catabolic state and interventions at this period focus on reducing the stress of surgery. Strategies include use of short acting anaesthetic agents, maintenance of normothermia and minimal access surgery.

Postoperative care involves a larger number of members of the multidisciplinary team comprising of surgeons, nurses, physiotherapists, nutritionists, occupational therapists and pharmacists. Interventions include fluid management and analgesia which already would have commenced during the intraoperative phase. Others include feeding regimes, surgical drains and nasogastric tubes which have traditionally been guided by practice handed down through an apprenticeship model of training. However, recent advances in perioperative care have provided evidence challenging these practices and significant changes made with the aim of improving outcomes.

There is limited data on the effect of individual interventions in modifying the surgical stress response. Professor Henrik Kehlet introduced the enhanced recovery programme which encompasses different interventions in an integrated pathway.<sup>(41,42)</sup> The enhanced recovery

programme is about improving outcomes and speeding up a patients' recovery after surgery. It results in benefits to both patients and staff. The programme is delivered by the entire clinical and wider inter-professional team. It focuses on making sure that patients are active participants in their own recovery process. It aims to ensure that patients always receive evidence based care at the right time. Interventions include preoperative assessment, consent and information, psychological preparation, discharge planning, anaesthesia, normothermia, surgical technique, care around surgery, effective pain relief and prophylaxis for nausea and vomiting, early mobilisation, minimal use of drips, drains and catheters, oral nutrition and patient held plans. This has led to significant improvements in perioperative care. These programmes reduce the physiological and psychological stress of surgery. This multimodal approach reduces hospital stay to 2-3 days.<sup>(41,42,43)</sup> There is evidence that the clinical improvements resulting from the implementation of an enhanced recovery programme do not cause significant deterioration in quality of life or transfer costs to another component of health care.<sup>(44)</sup>

Fluid and electrolyte balance and the administration of intravenous fluids is an important aspect of the enhanced recovery programme but still poorly understood part of perioperative management. To investigate the effect of intravenous fluid replacement on patient recovery during the perioperative period, one must understand a patient's requirements under normal conditions and with the effect of surgery. Normal water requirements are estimated at around 20-40mls/kg/day which is achieved through drinking (approximately 1200mls), eating (1000mls) and water of oxidation (300mls). Of the 2L of oral intake and 6-8L of gastrointestinal secretions only around 150mls is lost in the faeces. The rest is reabsorbed in the gastrointestinal tract although this may be altered by certain disease processes or following surgery. Many clinicians will agree that there is a fine balance between giving little amount of fluid leading to dehydration and excess fluid administration leading to fluid overload. The argument for fluid restriction is that the metabolic-endocrine response to surgery is water and salt conservation mediated by aldosterone, the renin-

angiotensin system and anti-diuretic hormone. Others would argue that because of the inflammatory response 'third space losses' dictate that you become relatively dehydrated and require extra fluid. This process would presumably be proportionate to the surgical insult and <sup>(45)</sup> may vary depending on the type of surgery. Shoemaker in the 1970's and 80's proposed a policy of resuscitating patients to supra-normal levels of circulatory function however excess fluid in the intravascular space can lead to increased fluid in the interstitial space and in turn to pulmonary and peripheral oedema with reduced systemic and local tissue oxygenation <sup>(46)</sup>. The first to suggest a delay in recovery due to excess fluid was Mecray who carried out an animal study on dogs <sup>(47)</sup>. He found that gastric emptying time was significantly delayed in response to saline and low protein. He also showed that the change in motility was reversible using salt and water restriction and high protein intake. At autopsy dogs were found to have mucosal oedema affecting the gastrointestinal tract in response to excess saline and it was postulated that the oedema was the cause of the motility changes observed.

Lobo randomised 20 patients undergoing colectomy to either 'restricted' intravenous fluids or a 'standard' regime<sup>(48)</sup>. The main difference in fluid administration occurred on the day of operation with a difference of 3L between the groups (3L versus 6L,  $p < 0.0001$ ). Patients in the restricted group gained significantly less weight in the postoperative period. Lobo reported a significant reduction in solid and liquid phase gastric emptying in the restricted group as well as a reduced time to first bowel motion (3 versus 4 days,  $p = 0.001$ ) and a shorter hospital stay (6 versus 9 days,  $p = 0.001$ ). He concluded that reducing postoperative gastrointestinal mucosal oedema was the mechanism for the improvement in GI function. However the weakness of the study was the small number of patients and the lack of blinding of those assessing eligibility for discharge which may have been a source of bias.

Nisanevich randomised 152 patients undergoing elective abdominal surgery to restrictive or liberal intraoperative fluids<sup>(49)</sup>. They reported a significant difference in fluid volumes on the day of theatre (1408 versus 3878mls,  $p<0.001$ ) and also in patient weight gain (0.5 versus 2kg,  $p<0.01$ ). Patients in the restrictive regime were found to have less complications (mainly infectious or cardiovascular), faster return of bowel function and shorter hospital stay (8 versus 9 days,  $p=0.01$ ). Goal-directed fluid therapy incorporates a more invasive assessment of circulatory function using an oesophageal Doppler monitor to calculate cardiac output. This method involves the placement of an ultrasonic probe in the oesophagus to calculate blood flow and cardiac output. Fluid is then titrated until the maximal stroke volume is reached which it is argued gives a more accurate and immediate method for responding to changes in fluid balance. Horgan et al. published a double-blind randomised trial of 108 patients undergoing elective colonic resection<sup>(50)</sup>. They compared Doppler-guided fluid therapy to fluids given at the discretion of the anaesthetist and found shorter hospital stay (7 versus 9 days,  $p=0.005$ ), and reduced postoperative complications (2 versus 15%,  $p=0.043$ ) in the intervention group.

Postoperative analgesia is an important component of any perioperative care regime. Following major abdominal surgery, analgesia can be delivered parenterally or into the epidural space. In a systematic review in the Cochrane Database, 5 out of 8 studies reported that combination epidurals provided better analgesia on day 1 when compared with PCA morphine<sup>(51)</sup>. Those who encouraged the use of epidural analgesia had hoped that with improved analgesia postoperatively an effect on morbidity and mortality would be realised. With the theoretical advantages and the changes in plasma markers suggesting an attenuation of the stress response, as well as improved analgesia allowing deeper respiration and patient mobilisation, a reduction in postoperative complications was expected. These theoretical advantages have not however been supported by clinical evidence. The MASTER trial looked at 915 patients deemed to be at high-risk of postoperative complications because of preoperative co-morbidity<sup>(52)</sup>. It found no overall

difference in major morbidity or mortality when comparing epidurals to other analgesic techniques in patients undergoing major abdominal surgery.

Recent studies have shown use of transversus abdominis plane blocks to reduce pain and morphine use compared with patient controlled analgesia (PCA), expedite recovery of bowel function compared with PCA and epidural, and expedite hospital discharge compared with epidural especially with laparoscopic surgery<sup>(53,54)</sup>.

Preoperative carbohydrate loading reduces the catabolic response induced by surgery. It has been widely adopted as part of the protocol for the enhanced recovery programme. A recent systematic review of the Cochrane database had concluded that preoperative carbohydrate treatment was associated with a small reduction in length of hospital stay when compared with placebo or fasting in adult patients undergoing elective surgery. It was found that preoperative carbohydrate treatment did not increase or decrease postoperative complication rates when compared with placebo or fasting. Lack of adequate blinding in many studies may have contributed to observed treatment effects for these subjective outcomes, which are subject to possible biases<sup>(55)</sup>.

## **The Evidence**

Pritts et al recognised the potential benefits of introducing a clinical pathway that combined different traditional recovery principles.<sup>(56)</sup> They showed that patients could be discharged 2 days earlier from hospital with a saving of about \$6,000. Most of the early evidence was from the Kehlet group in Denmark as the idea of fast track surgery was primarily developed by them.

Kehlet's group in one of their first publications studied 60 consecutive patients undergoing elective colonic resection.<sup>(57)</sup> 20 of the patients were in the American Society of Anaesthesiologists (ASA)

group three to four. Fifty seven had normal gastrointestinal function within 48 hours with a median hospital stay of 2 days. Re-admission rate was 15% with no life threatening complications. They concluded that a multimodal rehabilitation program may significantly reduce the postoperative hospital stay in high-risk patients undergoing colonic resection. Such a program may reduce postoperative ileus and cardiopulmonary complications.

Kehlet's group published a larger series following this early experience.<sup>(58)</sup> They compared 130 consecutive patients receiving conventional care (group 1) in one hospital with 130 consecutive patients receiving multimodal, fast-track rehabilitation (group 2) in another hospital. The ASA score was significantly higher in group 2 ( $P < 0.05$ ). Median hospital stay was 8 days in group 1 and 2 days in group 2 ( $P < 0.05$ ). The overall complication rate (35 patients) was lower in group 2 ( $P < 0.05$ ), especially cardiopulmonary complications (5 patients;  $P < 0.01$ ). Re-admission was necessary in 12% of cases for group 1 and 20% in group 2 ( $P > 0.05$ ).

Several other studies from the same group to date continue to show the benefits of a multimodal rehabilitation programme.<sup>(59-61)</sup>

Whatever the precise components of fast-track programmes, they require an intensive multidisciplinary approach by surgeons, anaesthetists, nutritionists, nurses, occupational therapists and physiotherapists. The surgeons and anaesthetists play a major role in the preoperative and intraoperative phase through strategies such as psychological preparation, use of short acting anaesthetic agents and minimal access surgery. The rest of the team play a major role in the postoperative phase with physiotherapists mobilising patients, occupational therapists ensuring safe discharge, nutritionists involved in nutritional supplementation and nurses involved in the general care of patients.



Many centres around the world have attempted to translate the benefits experienced with fast track recovery in their own practice. Most centres have reported significant reductions in hospital stay with acceptable re-admission rates.<sup>(62,63,64)</sup> A recent meta-analysis which looked at the results from 7 randomised trials with 852 patients showed a significant difference in total length of hospital stay in the enhanced recovery group compared with the conventional group ( $p=0.0003$ ) as well total complication rates ( $p=0.01$ ). There was no statistically significant difference in re-admission ( $p=0.69$ ) and mortality rates ( $p=0.97$ ).<sup>(65)</sup> However, other investigators have found it difficult to replicate hospital stays as short as 2 days as reported by the Kehlet group.

As well as in colorectal surgery, many other branches of surgery have introduced the fast track programmes with good results. Investigators have shown reductions in hospital stay in patients undergoing oesophagectomy<sup>(66)</sup>, hepatobiliary and pancreatic surgery<sup>(67)</sup>, orthopaedic surgery<sup>(68)</sup> and gynaecological surgery<sup>(69)</sup> without an increase in re-admissions or complications.

Initial criticism of fast track surgery studies centres on the selection of the samples with possible selection bias towards fit young patients who have straightforward colorectal resections. There is the issue of hospital stay being the primary endpoint which does not necessarily reflect an improvement in recovery. However, these have been refuted by studies which have shown similar benefits in the elderly<sup>(70)</sup> and in major colorectal, pelvic and re-operative surgery.<sup>(71,72)</sup> There have been studies that have looked at other endpoints rather than hospital stay. Hjort et al, in their study looking at patients after discharge from hospital reported that fast track patients experienced an earlier resumption of normal activities with no increased use of primary care when compared with the control group.<sup>(73)</sup>

In a further study looking at gastrointestinal transit, van Bree et al, randomised 93 patients requiring elective colonic surgery to laparoscopic or conventional surgery with fast-track

multimodal management or standard care, resulting in 4 treatment arms. Multiple linear regression analysis showed that both laparoscopic surgery and fast-track care were significant independent predictive factors of improved colonic transit. Both were associated with significantly faster clinical recovery and shorter time until tolerance of solid food and first bowel movement.<sup>(74)</sup> There is the suggestion that fast-track rehabilitation can lead to improved preservation in cell-mediated immunity post-operatively.<sup>(75)</sup> In addition more objective findings support the claim of a reduction in the surgical stress response.

## **Randomised Trials**

Although there has been a large number of case controlled studies on the multimodal rehabilitation programme, there remains a paucity of randomised trials. Delaney et al, published the first randomised controlled trial.<sup>(76)</sup> They randomised 64 patients to either fast track regime or traditional care following colorectal surgery and showed reduced hospital stay (5.4 versus 7.1 days,  $p=0.02$ ) with no difference in re-admission rates, pain scores and complication rates for both groups. An interesting finding in this study was that patients managed by surgeons experienced in fast track surgery spent significantly less time in hospital irrespective of the group they were randomised into.

Lobo et al, published a meta-analysis of six randomised trials with 452 patients included. This showed a significant reduction in length of hospital stay and complication rates in the fast track surgery group with no statistically significant difference in re-admission and mortality rates.<sup>(77)</sup>

This same result was shown in a more recent Cochrane review which analysed results of 4 randomised controlled trials. There were a total of 237 patients, with 119 in the fast-track group and 118 in the conventional group with comparable baseline characteristics. There was a 3 day reduction in hospital stay in the fast-track group with equal re-admission rates in both groups.

However, other outcome parameters were unsuitable for meta-analysis although they seemed to favour fast-track surgery. The authors concluded that although analysis showed a reduction in overall complications and significant reduction in hospital stay, the quality of trials and the lack of sufficient outcome parameters excluding hospital stay do not justify implementation of fast-track surgery as the standard of care.<sup>(78)</sup>

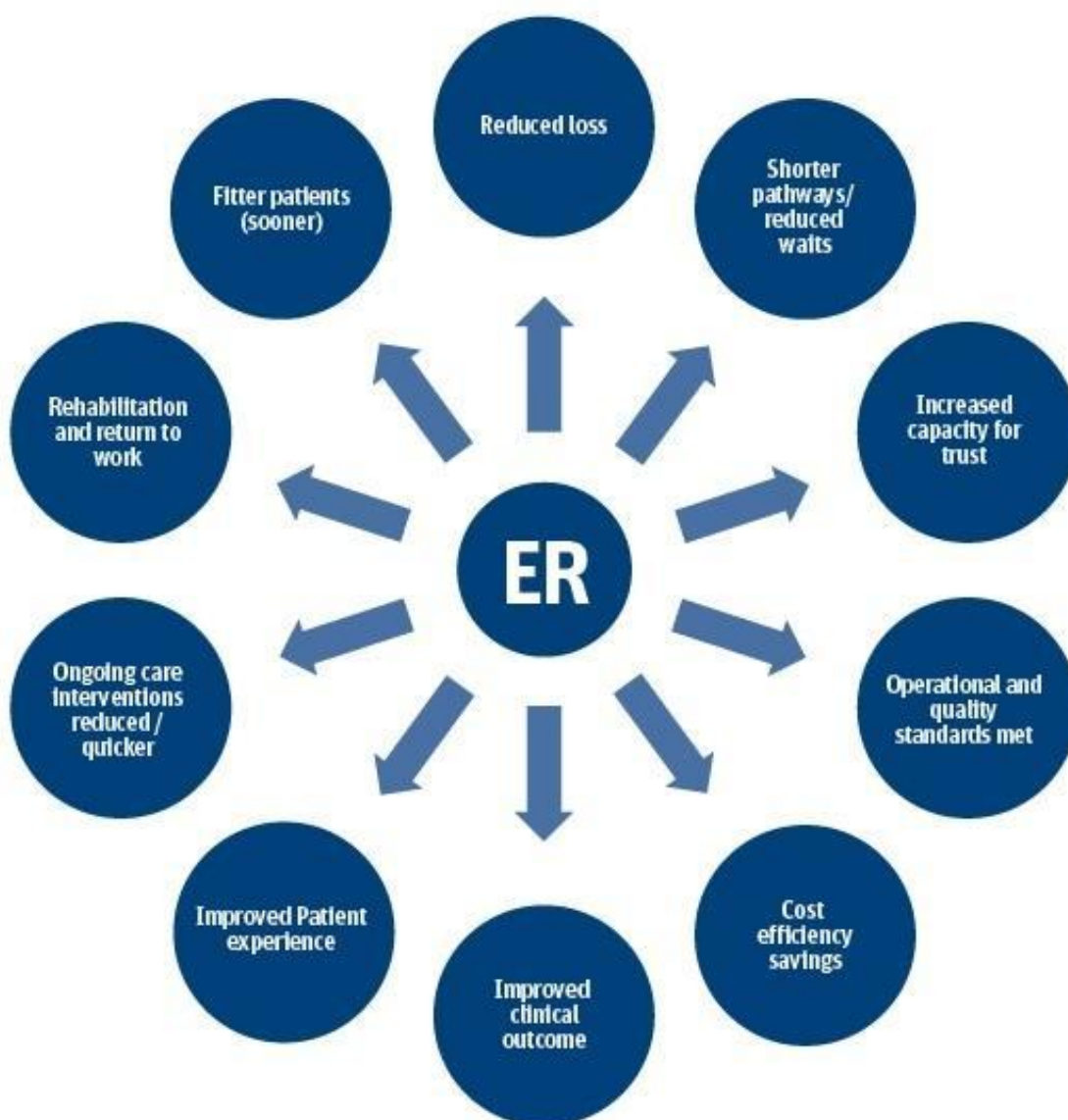
## **Conclusion**

Fast-track recovery protocols have significantly improved perioperative recovery in a range of settings. With respect to colorectal surgery, length of hospital stay has been reduced from the traditional 8 - 14 days to 2 – 5 days.

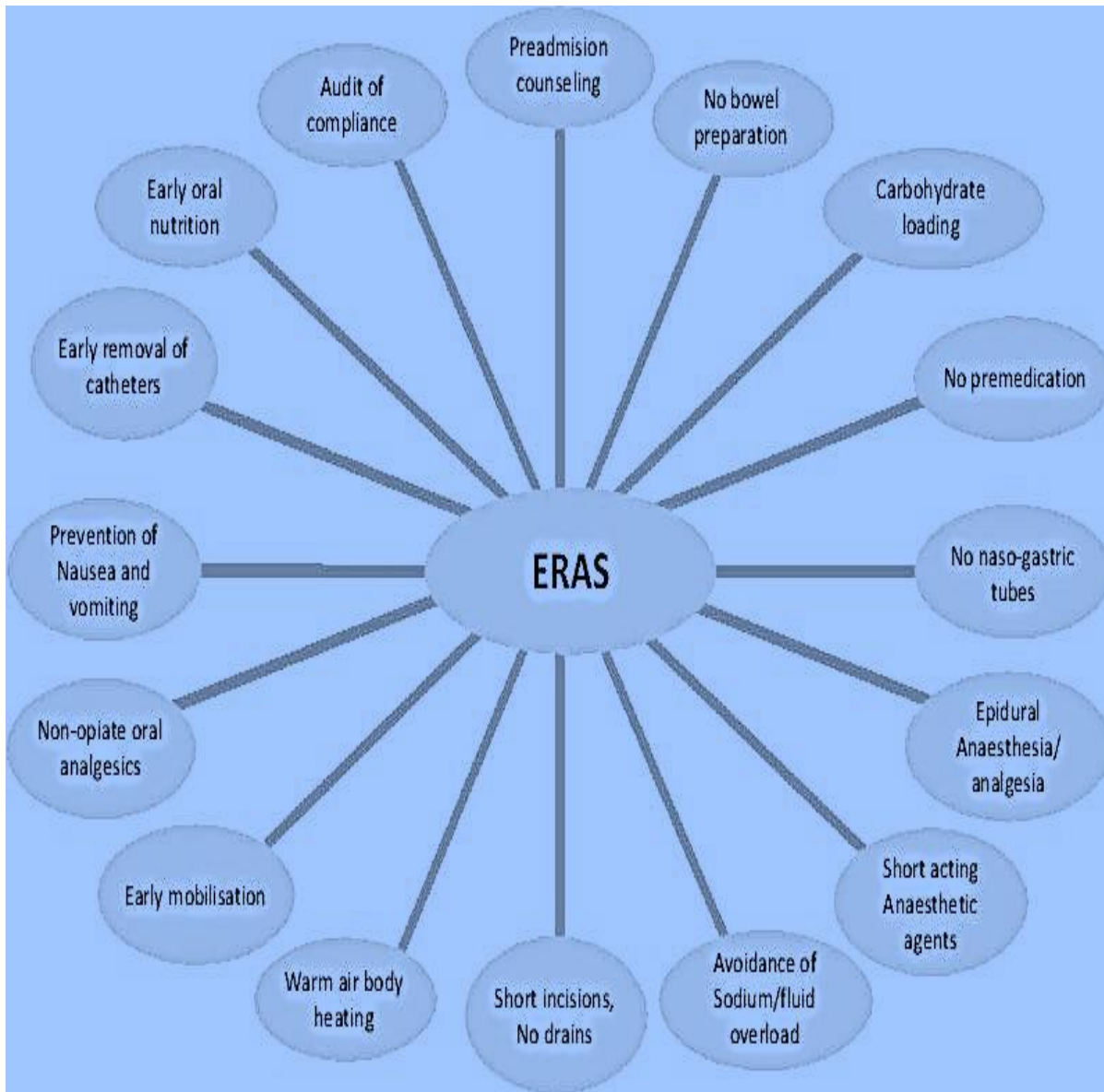
The multimodal rehabilitation regime appears to positively influence surgical stress response with reductions in duration of ileus, pain, complications and activities of daily living. There is the belief that combining fast track surgery with laparoscopic surgery will further enhance recovery. The EnROL trial (Enhanced Recovery Open versus Laparoscopic) which is a phase III, multicentre, randomised trial examines the hypothesis that laparoscopic surgery within an enhanced recovery programme will provide superior postoperative outcomes when compared to conventional open resection of colorectal cancer within the same programme. They intend to recruit 202 patients and results are awaited.<sup>(79)</sup>

With continuing research into perioperative recovery, the different components of the fast track regime continue to be investigated with new strategies adopted to reflect changing knowledge.

In the following pages, the benefits and components of the enhanced recovery programme are shown using diagrams.



**Benefits of an Enhanced Recovery Programme**



**Components of an Enhanced Recovery Programme**

## 1.3.2 Laparoscopic Colorectal Resection

### Introduction

The first experimental laparoscopy was in 1901 by a German surgeon George Kelling who used a cystoscope to examine the abdominal cavity of a dog. Gynaecologists then proceeded to use laparoscopy for diagnosis and tubal sterilisation. Kurt Semm who was a gynaecologist was the first to use a laparoscope in General Surgery when he performed a laparoscopic appendicectomy in 1983.<sup>(80)</sup> The concept of laparoscopic surgery in General Surgery became widespread with the introduction of laparoscopic cholecystectomy which was first performed by Phillipe Mouret in Lyon in 1987.<sup>(81)</sup> Laparoscopic cholecystectomy has now replaced the open procedure due to the benefits of rapid recovery. Most elective cases are now done on a day case basis.

The first reported laparoscopic colectomy was in 1991.<sup>(82)</sup> Conversion rates at this time were high due to a steep learning curve.<sup>(83,84)</sup> There were concerns about port site metastases due to specimen retrieval through the port sites.<sup>(85,86)</sup>

### The Evidence

Studies have shown improved short term outcomes in patients undergoing laparoscopic colorectal resection compared with open resection especially where it is combined with fast track recovery. Scatizzi et al, recently published their results comparing feasibility and safety of laparoscopic colorectal resections in high risk colorectal cancer patients with a similar cohort undergoing open resection in the same time period. They reviewed records of 188 patients of which 68 underwent laparoscopic resection. The laparoscopic group had a shorter length of hospital stay (6 vs 9 days,  $p < 0.0001$ ) and fewer postoperative nonsurgical complications (4% vs 19%,  $p = 0.003$ ). The mortality rate was also significantly lower in the laparoscopic group than in the open group (1.5 vs 7.5%,  $p = 0.038$ ).<sup>(87)</sup> However, these short term improvements have been challenged by other

studies which have shown no short term benefits between laparoscopic colorectal resection and open resection within an enhanced recovery programme. The study by Kehlet's group from Denmark on 60 patients undergoing elective colorectal resection showed no difference between the laparoscopic group and the open group within an enhanced recovery programme in terms of pain score, fatigue, motor activity or cardiopulmonary function. Median hospital stay was two days for both groups of patients.<sup>(41)</sup>

Di Palo et al, published the largest single series on the long term outcomes on 599 patients who underwent laparoscopic colectomy for colorectal cancer.<sup>(88)</sup> Their study showed an overall morbidity of 23.3% with an 81% 5- year survival. Conversion rate was 7% with a 4.4% local recurrence rate for rectal cancers which was comparable to open colorectal surgery.

## **Randomised Trials**

Two large randomised trials as well as two meta-analyses have drawn together all the available information to date.

The COST (Clinical Outcomes of Surgical Therapy) trial randomised 872 patients with colon cancer to open or colorectal surgery.<sup>(89)</sup> For the laparoscopic group, they included patients of surgeons who had performed a minimum of 20 cases. Median follow up was 4.4 years. Median hospital stay was 5 days versus 6 days in favour of the laparoscopic group ( $p < 0.001$ ). They found a significant difference in the length of days in which narcotics were used in favour of the laparoscopic group (3 versus 4 days,  $p < 0.001$ ). They found no difference in complication rates, mortality rates, resection margins or lymph node retrieval rates. Recurrence rates and survival at 3 years were similar for both groups. The trial therefore showed short term benefits with laparoscopic surgery but similar long term outcomes.

The CLASSIC trial (Conventional Versus Laparoscopic-Assisted Surgery in Colorectal Cancer) randomised 794 patients to laparoscopic or open surgery.<sup>(90)</sup> There was a shorter time to resumption of normal diet and shorter duration of ileus in the laparoscopic group. Hospital stay was shorter in the laparoscopic group (9 versus 11 days). There was no difference in complications rates, resection margins, lymph node retrieval and quality of life. Conversion rate in the trial was high at 29% with this group of patients having a delayed recovery and increased complication rates. This therefore showed short term benefits of laparoscopic surgery with appropriate patient selection. However, a weakness of the study was that there was no enhanced recovery. The long term results of this trial have recently been published. At a median follow-up of 62.9 (interquartile range 22.9 - 92.8) months, there were no statistically significant differences between open and laparoscopic groups in overall survival (78.3 (95 per cent confidence interval (c.i.) 65.8 to 106.6) versus 82.7 (69.1 to 94.8) months respectively;  $P = 0.780$ ) and disease-free survival (DFS) (89.5 (67.1 to 121.7) versus 77.0 (63.3 to 94.0) months;  $P = 0.589$ ). In colonic cancer intraoperative conversions to open surgery were associated with worse overall survival (hazard ratio (HR) 2.28, 95 per cent c.i. 1.47 to 3.53;  $P < 0.001$ ) and DFS (HR 2.20, 1.31 to 3.67;  $P = 0.007$ ). In terms of recurrence, no significant differences were observed by randomized procedure. However, at 10 years, right colonic cancers showed an increased propensity for local recurrence compared with left colonic cancers: 14.7 versus 5.2 per cent (difference 9.5 (95 per cent c.i. 2.3 to 16.6) per cent;  $P = 0.019$ ). The authors concluded that long-term results continue to support the use of laparoscopic surgery for both colonic and rectal cancer.<sup>(91)</sup>

Two meta-analyses which have looked at available evidence to date<sup>(92,93)</sup> have confirmed short term benefits of laparoscopic surgery compared with open surgery with similar long term outcomes.



In terms of cost analysis, the increased cost of laparoscopic instruments is countered by savings in relation to shorter hospital stay making the overall cost to the healthcare system similar for both groups.<sup>(93)</sup>

## **Conclusion**

Laparoscopic colorectal resection has now become popular for both benign and malignant colorectal lesions. The initial reluctance to adopt this was based on fears of oncological outcomes. However, several studies have shown similar oncological outcomes with open surgery. There was the issue of a steep learning curve which most surgeons have now overcome. In the UK, the National Institute for Clinical Excellence (NICE) guidelines stipulate that all suitable patients should be offered laparoscopic colorectal resection (NICE technology appraisal guidance 17 issued in August 2006).

With introduction of the enhanced recovery programme at about the same time as the onset of laparoscopic colorectal surgery, there was conflicting evidence on the short term outcome of laparoscopic surgery. While some authors report similar outcomes between both groups with fast track surgery<sup>(41)</sup>, others have reported better outcomes in favour of the laparoscopic group.<sup>(94)</sup> Results of the EnROL trial which is a large randomised multi-centre trial looking at the role of laparoscopic surgery within an enhanced recovery programme are still awaited.

### 1.3.3 Psychological Preparation of Patients for Surgery

#### Introduction

Psychology is the scientific study of the way people behave, think and feel. It has grown at a remarkable rate during the twentieth century from its beginnings in philosophy and physiology. It identifies questions and offers ways to ask them and also points to assumptions about human behaviour that are false and have to be replaced by the results of careful enquiry.

The social sciences, particularly psychology which explores how individuals think and feel and react to situations as well as family support networks can help us to consider the preparation which may be required for any person approaching surgery. Every patient has a perception about surgery and preparation of the patient has an important impact on their postoperative recovery and outcome considering the individual and how they think and feel.

Psychological processes are central to health care and the clinician can use evidence as a technician or scientist. The General Medical Council state that the doctor as a scholar and scientist should apply psychological principles, methods and knowledge to medical practice (GMC Tomorrow's Doctors Outcome 1 Page 15).

Types of evidence include information from questionnaires, statistical information such as from randomised controlled trials, qualitative descriptions of clinician-patient interactions and patient experiences and clinical observations.

Psychological preparation differs from usual clinical practice as it assumes that the body and mind are not separate, people do not just accept challenges but actively manage them, people think about what happens to them and psychological processes affect clinicians as well as patients.

Elements of a psychological framework include holistic care which is an awareness of the indivisibility of mind and body, managing challenge which is an appreciation that people are rarely passive and accepting in the face of events that challenge. Other elements of the framework are making sense of disease and treatment with the realisation that people think and not just accept what they are told to believe and do what they are told to do. Psychological preparation incorporates a range of strategies designed to influence emotions, cognitions or behaviours. Benefits of psychological preparation were identified in a meta-analysis<sup>(95)</sup> which identified different types of preparation to include procedural information, sensation information, behavioural instruction, hypnotic and relaxation training, psychotherapeutic interventions and cognitive behavioural approaches. They were found to be beneficial for a range of outcome variables such as negative affect, pain, pain medication, length of hospital stay, behavioural recovery, clinical recovery and patient satisfaction.

The Self- Regulatory Model of illness and behaviour describes three stages which an individual goes through to identify they are sick and what they do to get better. These stages include:

- interpretation of health threat with cognitive representation such as symptoms, social messages and possible consequences
- an action plan or coping strategy with seeking medical attention, self prescribing, avoidance, discussing with others;
- an appraisal stage which is an evaluation of the success of coping strategies or actions and reflecting on the need for modifications.

Using the Self-Regulatory Model, there are different belief dimensions that make up an individual's illness representation.

- Identity is the diagnostic label that is given by the patient based on beliefs

about the symptoms of illness.

- The cause will influence treatment adherence and expectations as well as emotional responses to the illness.
- The time/longevity which deals with how long the illness will last has an influence on treatment adherence.
- Consequence deals with how the patient believes the illness will impact on other aspects of their life.
- The last factor is control-cure where a patient who believes they can manage an illness will have better adherence to treatment including adapting to the consequences of the illness.

Dissemination of information is one of the key elements of psychological preparation and patients give high importance to the information given to them. Preoperative information can be categorised into sensory, procedural and behavioural. Sensory information describes the experience of the procedure while behavioural instruction consists of telling patients what facilitates the procedure or recovery. Procedural information describes the process which the patient will undergo. Good patient information and education therefore results in patients' being more aware of what to expect culminating in reduced anxiety and pain sensations.<sup>(96)</sup> Information can be given to patients orally (face to face), through printed material or use of audio-visual aid.

## **The Evidence**

Several studies have shown a positive impact after surgery following psychological preparation.<sup>(97,98,99)</sup> Vogeleson et al<sup>(95)</sup> in their meta-analysis evaluated the benefits of psychological preparation for surgery. Different types of preparation were identified.

## **Dissemination of information**

This is very important to patients and influences behaviours such as degree of analgesic use and return to normal activities.<sup>(100)</sup> This can be sensory, procedural or behavioural. Sensory information describes the experience of surgery while behavioural instruction tells patients what to do to facilitate recovery. Procedural information describes the process through which the patients have to undergo.

## **Cognitive Therapy**

This intervention influences how a patient thinks and aims to change the negative aspects of a procedure. Patients coping tendency have been studied in relation to the information they need. People can cope with situations through problem focused strategies or emotional focused strategies. For problem focused strategies, patients make plans to improve the situation and feel better when these are followed. Emotional focused patients tend to alter their own cognitive interpretation of the situation. Mathews et al <sup>(101)</sup> in a randomised trial of procedural information, cognitive coping techniques and general ward information given to patients who had a hysterectomy showed that cognitive coping had the most effect on recovery.

## **Relaxation**

These can be used to reduce anxiety prior to surgery. It could be simple relaxation, muscle relaxation or even imagining a pleasant and relaxing situation. A meta-analysis on use of relaxation training as well as sensory and procedural information giving in patients undergoing cholecystectomy reported less pain and higher levels of activity in those getting this form of preoperative intervention.<sup>(102)</sup>

## **Hypnosis**

Defined as a special psychological state with certain physiological attributes, resembling sleep only superficially and marked by a functioning of the individual at a level of awareness other than the ordinary conscious state. Evidence from a meta-analysis suggest that hypnosis positively affects immune function and may work through psychoneuroimmunological mechanisms.<sup>(103)</sup>

## **Randomised Trials**

Large randomised trials and meta-analysis have shown the benefits of psychological preparation for surgery. One of the largest studies was from the Netherlands. DeWit et al, randomised 223 patients undergoing cardiac surgery into either a two hour information programme in hospital or a two day programme comprising medical information, relaxation exercises and group discussions. They made psychological assessments with the use of questionnaires preoperatively and at 4 month follow up. The study showed that extensive preparation for cardiac surgery has a positive effect on physical wellbeing and anxiety in patients who before their operation had relatively few complaints or were anxious.<sup>(97)</sup>

Vogele et al <sup>(95)</sup> evaluated the benefits of psychological preparation for surgery in their meta-analysis. They identified the different types of psychological preparation including sensation information, procedural information, behavioural instruction, hypnotic and relaxation training and cognitive behavioural approaches. These were found to be beneficial for outcomes such as negative affect, length of hospital stay, clinical recovery, pain scores, pain medication and patient satisfaction.

The method of presentation plays an important role in preparation and impacts on outcome. In a randomised trial by O'Sullivan et al <sup>(104)</sup>, 90 medical students were randomly assigned to verbal information only, verbal information and diagrams, or verbal information and video education on

cataract surgery. The study showed that audio-visual aid significantly improved the ability to remember facts and risks associated with cataract surgery. This was further re-enforced in the randomised trial by Eisen et al <sup>(105)</sup> comparing video education with conventional verbal instructions regarding skin biopsies. 84 participants were recruited and completed a skin biopsy knowledge assessment, patient satisfaction assessment and evaluation of educational medium. The main outcome measures were differences in changes in the pre-study and post-study assessments. The study showed a significant increase in knowledge score following video education but not following oral education.

## **Conclusion**

Psychological preparation is an important factor in a patient's surgical experience. Efficient patient preparation has become an important area with the drive towards shorter hospital stay and enhanced quality patient outcomes. Dissemination of information is a key element and can be verbal, through information leaflets or through the use of audio-visual aids.

With increasing interest in enhancing perioperative recovery, research in this area continues and further strategies adopted to reflect changing knowledge. Recent advances in the field of colorectal surgery including the enhanced recovery programme, laparoscopic surgery and psychological preparation are interventions introduced by clinicians in the last few years and play a crucial role in improving short term outcomes. Despite this, evidence based medicine should remain the foundation on which further advances are built.

The main focus of this research work is in the area of perioperative recovery in patients undergoing elective colorectal surgery. The advent of the enhanced recovery programme brought about remarkable changes in perioperative recovery with the aim of improving outcomes. Several factors influence the successful implementation of an enhanced recovery programme and there

remains a paucity of data on the role individual interventions. This research work was conceived to better understand some of the major factors which may individually influence outcomes in this group of patients.



# **Chapter 2**

## **Methods**

## **2.1 Study Aim**

This research work focussed in the area of perioperative recovery in patients undergoing elective colorectal surgery. The aim was to investigate the factors that influence the implementation of an enhanced recovery programme in patients undergoing elective colorectal surgery.

The study objectives were:

- Feasibility of establishing the enhanced recovery programme in the surgical unit by recruiting patients undergoing an intermediate operation (Reversal of loop ileostomy)
- To consider the role of laparoscopic surgery in postoperative recovery following colorectal surgery
- To consider the long term effects of laparoscopic colorectal surgery
- To consider the role of video education as part of the enhanced recovery programme as first described by Professor Kehlet. In particular to examine the psychological impact of its' use in colorectal surgery
- To analyse the impact of day of surgery on recovery following colorectal surgery.

## **2.2 Methods**

Quantitative research method was used for this work. Numerical data were collected using proformas and questionnaires on outcomes following the different interventions during the study period.

The study was done in four phases. The phases have been published.

### **Phase I: Early discharge following closure of loop ileostomies**

The aim of this phase was to assess the feasibility of introducing fast track surgery in our unit so as to reduce hospital stay from 5-7 days to 1-3 days following elective colorectal surgery. The

research question was if it was possible to discharge patients early following reversal of a loop ileostomy with minimal complication rates and re-admission rates. All our ileostomy reversals were done as open surgery using circumferential incisions around the stoma.

### **Phase II: Short and long term outcomes of laparoscopic colorectal surgery**

The aim of this phase was to see if laparoscopic colorectal resection was associated with shorter hospital stay and reduced complication rates when compared with open colorectal resection.

Both groups (Phase I and II) of patients were followed up over a 2 year period to compare incisional hernia rates.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

In this phase we conducted the main study. The study aim was to see if use of video education in patients undergoing elective colorectal resection prepared them better psychologically for surgery and to determine if hospital stay and complication rates were reduced compared with use of information leaflets and verbal information.

### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery programme**

The final phase aimed to see if operating on colorectal patients earlier in the week (Monday to Wednesday) reduced hospital stay and complication rates compared with operating later in the week.

## **2.3 Ethical Permission**

Ethical approval was obtained from the East Midlands (Derby) Research Ethics Committee (Reference:10/H0401/50) for both parts of the study on the psychological

preparation of patients for surgery using audio-visual aid (Appendix VI). The first part was an observational study to assess patients' perceptions and feedback on the use of a video prior to commencing a randomised trial. The second part was a randomised trial to investigate the effect of the use of video education compared to verbal and written information in the psychological preparation of patients for elective colorectal surgery within a multimodal rehabilitation regime.

## **2.4 Sample**

### **Phase I: Early discharge following closure of loop ileostomies**

This was carried out in the geographical location of Glasgow between February 2003 and February 2004. Consecutive series of patients undergoing reversal of a loop ileostomy in our unit were recruited over this 12 month period. They were verbally informed and a written consent obtained. Patients with physical disability and in long term care were excluded.

### **Phase II: Short and long term outcomes of laparoscopic colorectal surgery**

This was carried out in the geographical location of Glasgow between November 2003 and March 2005. Consecutive series of patients undergoing elective colorectal resection with primary anastomosis at a University teaching hospital were included. Exclusion criteria included those with severe physical disability and in long term care, patients who were medically unfit for surgery and patients undergoing total colectomy, abdominoperineal resection or low anterior resection requiring a covering loop ileostomy. Verbal information was given and written consent obtained.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

This was carried out in the geographical location of Leicester. For the first part of the study, consecutive series of patients undergoing elective colorectal resection were prospectively recruited over a 3-month period (August 2010 and October 2010). The exclusion criteria included

patients with severe physical disability, patients who could not speak or understand English.

Verbal information was given and a written consent obtained.

For the second part of the study, all patients undergoing elective colorectal resection between October 2010 and August 2011 were randomly allocated using sequentially numbered sealed envelopes each with a computer generated random number inside to either verbal, written and video information or verbal and written information only. Exclusion criteria were same as in the first part of the study. All eligible patients were given written information about the study in clinic so that they had enough time before their operation to decide to take part or not. A record was kept of patients who opted out and those who dropped out of the study and the reasons for these.

#### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery programme**

This study was carried out in the geographical location of Leicester between May 2010 and April 2011. Recruitment was from 2 University teaching hospital sites for consecutive patients undergoing elective colorectal resection. Exclusion criteria were patients with severe physical disability and those in long term care.

## **2.5 Intervention**

#### **Phase I: Early discharge following closure of loop ileostomies**

All patients were fasted for surgery from the night before, but bowel preparation was not used. Postoperatively, patients were allowed to commence on light diet immediately after surgery, if tolerated. Diet for the next five days was restricted to soups, ice-cream, yoghurts etc. A more solid diet was introduced after day five. Patients were given written dietary advice on discharge.

**Surgical Technique:** The area of skin around the stoma was infiltrated with 15 - 30 mls of 0.5 % marcaine/adrenaline (1 in 200 000). This reduced intraoperative bleeding and helped clarify the anatomy. The ileostomy was mobilised in an anatomical fashion, preserving the architecture of the sheath and rectus muscle. All intraperitoneal adhesions in immediate relation to the mobilised stoma were divided. Following full mobilisation of the ileostomy, care was taken to preserve the spout which was subsequently reverted. A Cheadle slit (a longitudinal cut in the anti-mesenteric border) was performed occasionally in the distal segment to prevent narrowing of the distal lumen. This had the effect of widening the lumen of the bowel at the anastomosis. The bowel was closed transversely with interrupted sutures, using 3.0 biosyn (monofilament glycomer). The wound was closed with two interrupted sutures to the muscles (No 1 polysorb: braided lactomer), looped maxon(monofilament polyglyconate) to the sheath, and a subcuticular purse string suture (3.0 biosyn: monofilament glycomer) to the skin. This acted as a drainage well.

## **Phase II: Short and long term outcomes of laparoscopic colorectal surgery**

The decision on suitability for laparoscopic-assisted resection was made on a case by case basis by the operating surgeon. This is a weakness of the intervention as there is the potential for selection bias. Both of the participating consultant surgeons carried out both open and laparoscopic procedures and were involved in all operations. A laparoscopic-assisted was defined as an operation where colonic mobilisation and division of the vessels was performed laparoscopically. An extracorporeal anastomosis was fashioned for right sided lesions and an intracorporeal circular stapled anastomosis for sigmoid/ left sided lesions. Transverse, muscle splitting, single dermatome incisions were used for extraction of the specimen.

The unit which is split over 2 sites has experience of around 50 laparoscopic colorectal procedures per annum and is a recognised centre for preceptorship. Patients were given preoperative information and allowed free fluids and high calorie containing drinks for up to hours before

operation. Patients undergoing right hemicolectomy did not receive bowel preparation while those having left sided surgery received a phosphate enema the night before and the morning of surgery. All patients received antibiotic and DVT prophylaxis and no nasogastric tubes or abdominal drains were used. A standardized anaesthetic protocol was used with a conservative perioperative fluid regime consisting of 4 per cent dextrose/0.18 per cent saline at 10mls/kg/hr plus 3 times the measured blood loss. The postoperative analgesic regime was based around PCA Morphine which was continued for 48 hours. Patients were given regular Paracetamol with NSAIDs and Tramadol used for breakthrough pain. Oral fluids were pushed immediately postoperatively and normal diet was encouraged from day 1. Chest physiotherapy and active mobilisation was also commenced on day 1. Urinary catheters were removed on day 2 unless there was a clinical reason for them to remain. Decision on patient discharge was made by the operating surgeon. To be considered fit for discharge, patients had to be afebrile, fully mobile, passing flatus or faeces, using oral analgesics only for pain, and have a healing wound. Following discharge, patients were phoned daily by a research nurse until review at clinic on day 14. At 3 months patients were asked to complete the Short Form 36 health questionnaire.

Between February 2005 and March 2006, a clinical examination was conducted to check for presence of an incisional hernia in both groups. All patients alive at the time of follow up were eligible for clinical examination. An incisional hernia was defined as a bulge visible and palpable at the site of abdominal incision when the patient is standing with spontaneous or pressure induced protrusion of abdominal contents. Diagnosis was made from clinical examination only.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

This was the main study for the project and had an initial part where patients were given questionnaires on their thoughts of the use of video education and a later part which was a randomised trial on the use of video education.

For the first part of the study, patients were given information about their operation and recovery face-to-face in a clinic setting by doctors and nurses, along with printed patient information booklets. The intervention included a 15-minute patient educational video that explained their preoperative assessment and recovery after surgery including postoperative advice on discharge. A questionnaire which was internally validated was used to obtain patient feedback on their perception of the enhanced recovery programme, use of video education and their views on the best medium for patient education. The questionnaire was to be sent back by post or brought by patients to clinic at the 4-week review.

The second part of the study was an observer blinded randomised trial. Randomisation was done as earlier stated in the study sample. All surgeons involved in the trial have a specialist interest in colorectal surgery. All patients were allowed free fluids and high calorie containing drinks for up to 4 hours before operation. Patients undergoing right hemicolectomy did not receive bowel preparation while those having left sided surgery received a low residue diet with three days of senna tablets and phosphate enema on the morning of surgery. All patients received antibiotic and DVT prophylaxis. Patients had to be fully mobile, afebrile, passing flatus or faeces, using oral analgesics only for pain before being considered for discharge. Decision for discharge was made by the consultant surgeon or registrar with responsibility for the patient who was blinded to the treatment group.

#### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery programme**

Two groups were studied based on day of surgery (Monday to Wednesday versus Thursday to Friday). Patients in both groups had either laparoscopic or open colorectal resection depending on patient suitability. Decision for this was made by the operating surgeon. All colorectal surgeons



involved in the enhanced recovery programme in our unit have a flexible rota and so no surgeon was operating on a particular day to avoid bias.

Consecutive patients were recruited to have surgery on the earliest date convenient for both patient and surgeon. A prospective database was maintained for all patients undergoing elective colorectal resection between Monday to Friday. The enhanced recovery protocol was applied for all patients.

## **2.6 Data Collection**

### **Phase I: Early discharge following closure of loop ileostomies**

A proforma was devised to include patient admission details, indication for surgery, complications and readmissions. All patients had pre-operative, operative and post-operative data collected prospectively and entered into a database.

### **Phase II: Short and long term outcomes of laparoscopic colorectal surgery**

For the short term outcomes of laparoscopic colorectal surgery, data on patients' weight, height, blood parameters, analgesic and antiemetic intake, visual analogue pain scores, nausea scores (0-4), time to first flatus and bowel motion and postoperative complications were recorded on the database.

For the long term outcomes of laparoscopic colorectal surgery, data regarding type of operation, risk factors for development of an incisional hernia, incision type and size, patient satisfaction with the wound were obtained and recorded on the database. If clinical examination revealed an incisional hernia, data were obtained on symptoms of discomfort and pain. Treatment modalities were also recorded.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

Answers to questions from the questionnaire given to patients on their perception of the enhanced recovery programme and use of video education were recorded on the database. For the randomised trial, patients' weight, height, blood parameters, analgesic and antiemetic intake, visual analogue pain scores at rest and movement, nausea scores (0-4), time to first flatus and bowel motion and postoperative complications for both groups were recorded daily on the database. All complications prior to discharge were recorded. Patients were sent a Short Form 36 Health Questionnaire at three months.

### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery programme**

Outcomes from a prospectively maintained database of patients undergoing elective colorectal resection from two University teaching hospital sites were studied.

## **2.7 Statistical Analysis**

### **Phase I: Early discharge following closure of loop ileostomies**

Data was entered into SPSS version 15. Statistical analysis was carried out using non parametric statistical tests, the Chi-square test or Fisher's exact test where appropriate with measurements of continuous outcomes analysed by repeated measures linear regression analysis.

### **Phase II: Short and long term outcomes of laparoscopic colorectal surgery**

Data was entered into SPSS version 15. Statistical analysis was carried out using the Chi square test or Fisher's exact test where appropriate with measurements of continuous outcomes analysed by repeated measures linear regression analysis for both studies. Data were analysed both on an intention-to-treat basis and actual treatment received in the long term outcome of laparoscopic surgery study.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

Data were similarly analysed using SPSS version 15. The primary outcome was the length of stay (LOS), and the secondary outcomes were the pain, nausea and patient satisfaction scores.

Comparability of the groups was checked by comparing their age and sex distributions. The statistical significance of the difference in mean LOS between the two groups (study and control) was assessed using a Wilcoxon rank sum test. Data available for a sample of previous patients who underwent comparative colorectal surgery gave a mean LOS of 7 days with a standard deviation of 1 day. The effect size was expected to be approximately 2 days (i.e. a reduction in mean LOS to 5.0 days). Our power calculation showed that a total sample size of 54 patients (27 in each group) was sufficient to detect this effect, allowing for a 5% dropout rate, assessing significance with  $p$  value  $< 0.05$  (significance level of 5% in a two sided test, with power of 90%). The power calculation was made using a two sided T test (appropriate for normally distributed data), which has very similar power to the Wilcoxon test (appropriate for discrete data, such as LOS), and the results were checked using a Monte Carlo simulation of discretely distributed data (applying the Wilcoxon test).

### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery programme**

Data was entered into SPSS version 15. Statistical analysis was carried out using the Chi-square test or Fischer's exact test where appropriate with measurements of continuous outcomes analysed by repeated measures linear regression analysis.

## 2.8 Summary of the stages of the study

Study	Interventions	Sample	Outcomes	Published papers
Closure of loop ileostomies: Is early discharge safe and achievable?	Enhanced Recovery Programme	N=100 Consecutive series	Early discharge is safe and achievable following reversal of loop ileostomy	Scott Med J. 2010 Feb;55(1):27-9
Short term outcomes of Laparoscopic Colorectal Surgery	Laparoscopic Surgery	N=80 Consecutive series	Laparoscopic Surgery does not improve short term outcomes following colorectal surgery compared with open surgery	Colorectal Disease 2007 : 9 : 368-72
Long-term outcomes of Laparoscopic Colorectal Surgery	Laparoscopic Surgery	N=95 Consecutive series	Laparoscopic Surgery does not reduce incisional hernia rates following colorectal surgery compared with open surgery	Surg Endoscopy 2008 : 22 : 689-92
Questionnaire based observational study on use of video education for preparation for elective colorectal surgery	Video Education	N=32 Selected opportunistic ally	Supplementing video education with oral and written information prepares patients better psychologically for surgery	J R Soc Med Sh Rep August 2012 : 3 :58
Psychological Preparation For Colorectal Surgery	Video Education	N=61 Randomised Trial with control group and experimental group	Use of video education does not improve short term outcomes following colorectal surgery	Colorectal Disease 2013 15(11):1436-41
Effect of Day of Surgery on the Enhanced Recovery Programme	Day of Surgery	N=225 Consecutive series	Operating on patients earlier in the week improves short term outcomes	In Press

# **Chapter 3**

## **Results**

**Closure of loop ileostomies: Is early  
discharge safe and achievable?**

### **3.1 Results (Phase I)**

One hundred consecutive patients (57 males) underwent reversal of loop ileostomy between February 2003 and February 2004. The median age at admission was 56 (47 - 67) years. The indications for ileostomy construction are listed in Table 3.3. Over half of our patients presented with colon cancer. Reversal was performed in all the patients after a median period of 133 (120 - 270) days.

The median length of inpatient hospitalisation was two (1-3) days from admission to discharge. Forty-two patients (42%) were discharged home within 24 hours of reversal. Most patients tolerated a light diet, six hours post operatively. Only two of the 100 reversals required surgical resection of the loop ileostomy. Twelve patients (12%) were re-admitted with sub-acute obstruction of which 11 settled with conservative measures (nasogastric decompression and intravenous fluids) while one underwent further surgery. One patient was re-admitted with a late leak and subsequent fistula formation which required surgical resection after failure of conservative management. This patient had gross faecal loading radiologically, due to the prolonged outpatient use of opiate based oral analgesia. One patient had a postoperative anastomotic leak leading to local abscess formation which was drained surgically. There were two cases of urinary retention requiring catheterisation and one case of postoperative ileus which was managed conservatively. One male died due to acute cardiac failure. The post mortem revealed the presence of a hypertensive cardiomyopathy.

Readmissions did not appear to be related to the date of discharge (Table 3.1). There was no difference in readmission rates between patients discharged within 24 hours and those discharged after this. Table 3.2 compares complication rate with time. Patients were grouped chronologically into four sections (25 in each group). The audited complication rate seems to be falling with time. This is due to a learning curve for this operation even in experienced hands.

**Table 3.1: Table comparing time of discharge with readmission rate**

Time of discharge	No of patients	%	Readmission	%
< 24hrs	42	42	5	5
24-48hrs	24	24	2	2
48-72hrs	3	3	1	1
>72hrs	31	31	4	4

The readmission rate is similar irrespective of day of discharge

**Table 3.2: Table comparing complication rate with time**

Patient groups	No complications	%	Complications	%
1 <sup>st</sup> 25 patients	18	18	7	7
2 <sup>nd</sup> 25 patients	20	20	5	5
3 <sup>rd</sup> 25 patients	21	21	4	4
4 <sup>th</sup> 25 patients	23	23	2	2

The complication rate decreased over time probably due to a learning curve



**Table 3.3: Indications for ileostomy construction**

<b>Indication</b>	<b>n</b>	<b>%</b>
Cancer	52	52
Sphincter Repair	15	15
IBD	14	14
Diverticular Disease	12	12
Large bowel obstruction	4	4
Colovesical fistula	3	3

Most patients had an ileostomy formation following surgery for cancer

## **Chapter 4**

### **Results**

**Laparoscopic colonic resection in fast-track patients does not enhance short-term recovery after elective surgery**

## 4.1 Results (Phase II)

During the study period 80 patients who satisfied the inclusion criteria underwent elective colorectal surgery with primary anastomosis. A fast-track recovery protocol was employed in all of these patients. 22 patients underwent laparoscopic assisted colonic resection and 58 had open surgery.

Patients were well matched for demographic data including age, sex, BMI, ASA grade and surgical site (Table 4.1). Median incision size in the laparoscopic group was 9cm (IQR 8-11cm) compared to 21cm (17-24cm) in the open group. None of the patients in the laparoscopic group required conversion to an open procedure for colonic mobilisation. There was no significant difference in the use of morphine, with a median of 70mg (43- 101mg) in the laparoscopic group compared to 67mg (33-91mg) in the open group (mean difference 4(95 per cent confidence interval -14.6, 23.9) mg;  $p=0.69$ ). There was no difference between the groups in use of Paracetamol (Median 15g in the laparoscopic group versus 17g in the open group:  $p=0.63$ ) and Tramadol (900mg in the laparoscopic group versus 1200mg in the open group:  $p=0.96$ ). Patients in the laparoscopic group used significantly more Ibuprofen (4800mg vs 2400mg:  $p=0.036$ ). There was no difference in visual analogue pain scores at rest (Median 2 in the laparoscopic group vs 2.2 in the open group:  $p=0.71$ ) or on movement (Median 4.2 in the laparoscopic group vs 4.8 in the open group:  $p=0.66$ ) between the 2 groups for the duration of their hospital stay. There was no difference in the use of anti-emetics, namely Metoclopramide (Median 70mg in the laparoscopic group vs 90mg in the open group:  $p=0.09$ ), Prochlorperazine (Median 30mg in the laparoscopic group vs 45mg in the open group:  $p=0.24$ ) and Ondansetron (Median 24mg in the laparoscopic group vs 28mg in the open group:  $p=0.28$ ). Nausea scores also showed no significant difference (Median 3 in the laparoscopic group vs 3 in the open group:  $p=0.39$  (morning) and 2 vs 2.5:  $p=0.83$  (evening)). Time taken to passage of first flatus (Median 2.9 days in the laparoscopic group vs 2.9 days in the open group:  $p=0.36$ ) and time to first bowel motion (Median 5.3 days in the laparoscopic group vs 4.2

days in the open group:  $p=0.07$ ) was similar between the two groups. Time to medical discharge and time to actual hospital discharge was not significantly different between the 2 groups with the median day of discharge on the 5th postoperative day (Table 4.2). Two patients in the open group were readmitted following discharge. One patient was readmitted with a late wound dehiscence and a 96 year old patient was readmitted with diarrhoea. Postoperative complications were identified in 6 patients in the laparoscopic group and 13 patients in the open group. There was no difference in infective (3 patients in the laparoscopic group vs 5 patients in the open group:  $p=0.70$ ) or non-infective complications (5 patients in the laparoscopic group vs 9 patients in the open group:  $p=0.73$ ) between the 2 groups (Table 4.3). There were 2 deaths within 30 days of operation. One patient in the laparoscopic group died on day 1 from respiratory failure and another in the open group died on day 4 from a central line infection. There was no difference in short form 36 scores between the two groups for any of the components measured.

**Table 4.1 Baseline Characteristics for patients in the laparoscopic/ open surgery study**

Characteristics		Laparoscopic	Open
N		22	58
Age (years)		72.0(63.7,78.8)	73.2 (66.8, 81.7)
Sex	Male	12 (54.5%)	25 (43.1%)
	Female	10 (45.5%)	33 (56.9%)
BMI		25.1 (23.4, 28.8)	26.2 (22.4, 30.4)
ASA Grade	1	3 (13.6%)	1 (1.7%)
	2	14 (63.6%)	42 (72.4%)
	3	5 (22.7%)	14 (24.1%)
	4	0 (0.0%)	1 (1.7%)
Operation			
Right hemicolectomy		6 (27.3%)	20 (34.5%)
Left hemicolectomy		0 (0.0%)	7 (12.1%)
Anterior resection		16 (72.7%)	26 (44.8%)
Hartmann Closure		0 (0.0%)	5 (8.6%)
Indication			
Benign		2(9.1%)	16 (27.6%)
Cancer		20 (90.9%)	42 (72.4%)
Stoma		7 (31.8%)	16 (27.6%)

Values are median (interquartile range) for continuous or N (%) for categorical data

**Table 4.2 Times to study endpoints for patients in the laparoscopic/ open surgery study**

<b>Endpoints</b>	<b>Laparoscopic</b>	<b>Open</b>	<b>p-value</b>
	Median (IQR)	Median (IQR)	
Time to first flatus	2.9 (2.3, 3.2)	2.9 (2.3, 3.6)	0.36
Time to first bowel movement	5.3 (4.1, 6.2)	4.2 (3.1, 5.8)	0.07
Time to medical discharge	5.8 (4.1, 7.8)	5.9 (4.1, 7.8)	0.99
Time to hospital discharge	6.1 (5.0, 9.0)	6.2 (5.0, 10.0)	0.87

Values are median (interquartile range) for times (in days).

While it was expected that patients in the laparoscopic group will have earlier first bowel movement compared to patients in the open group, the reverse was the case which may be due to a longer operating time in the laparoscopic group.

**Table 4.3 Complications for patients in the laparoscopic/ open surgery study**

<b>Complications</b>	<b>Open (n=58)</b>	<b>Laparoscopic (n=22)</b>
Atrial fibrillation	1	-
Pulmonary oedema	1	-
Myocardial infarct	2	-
Respiratory failure	-	1
Chest Infection	-	1
Wound infection	3	2
Intra-abdominal sepsis	1	-
Central line sepsis	1	-
Wound dehiscence	1	-
Obstruction	1	-
Prolonged ileus	-	1
Intra-abdominal bleed	1	1
Upper GI bleed	1	-
*Acute renal failure	-	1
Rectovaginal fistula	1	-
Femoral nerve palsy	-	1
Death within 30 days	1	1
<b>TOTAL</b>	<b>15</b>	<b>9</b>

\*Occurred following intra-abdominal bleed

# **Chapter 5**

## **Results**

**Incisional hernia rates in  
laparoscopic colorectal  
resections compared with open  
colorectal resections**



## 5.1 Results (Phase II)

During the study period, 104 patients underwent elective colorectal surgery. At a median follow up of 22 (17–26) months for both groups, nine had died and 95 (47 men and 48 women, median age 74) were reviewed. Causes of death included postoperative (2), metastatic colon cancer (3), cardiovascular disease (3), and alcoholic liver disease (1). Laparoscopic resection was attempted in 32 patients while 63 had open surgery. In the laparoscopic group, reasons for conversion included failure to progress (2), adhesions (2), bleeding (1) and bowel injury (1). The median length of the wound in the laparoscopic group was 9 cm (8–11 cm) while in the open group it was 20.8 cm (17–24 cm). Patients were well matched for all baseline characteristics (Table 5.1). Risk factors for the development of incisional hernia were also similar in both groups (Table 5.2). There was no significant difference in hernia rates between the laparoscopic and open groups on an intention to treat basis (3{9.3%} patients in the laparoscopic group vs 10{15.8%} patients in the open group:  $p = 0.533$ ) or actual treatment received (3{11.5%} in the laparoscopic group vs 10{14.5%} in the open group:  $p = 0.520$ ) (Table 5.3). In the laparoscopic group, one patient had a port site hernia, one had a hernia from the pfannestiel incision and one from the transverse incision placed in the right upper quadrant. There was no difference in number of patients with symptomatic incisional hernia in both groups from an intention to treat basis (2{6.2%} patients in the laparoscopic group vs 4{6.3%} patients in the open group:  $p = 0.773$ ) and actual treatment received (2{7.7%} patients in the laparoscopic group vs 4{5.8%} patients in the open group:  $p = 0.909$ ) (Table 5.3). Of the seven patients with symptoms who were listed for repair, one declined, one travelled abroad, while five had their repair. Of three patients who had postoperative wound infection in the laparoscopic group, one developed an incisional hernia while one out of the six in the open group with postoperative wound infection developed an incisional hernia. There were three patients with BMI greater than 30 in the open group of which one developed an incisional hernia.

**Table 5.1 Baseline characteristics.**

Characteristics	Laparoscopic	Open
N	32	63
Age (median: years)	74	74
Sex		
Male	17(53.1%)	30(47.6%)
Female	15(46.9%)	33(52.4%)
BMI	26.3	27.1
ASA Grade		
1	3(9.4%)	1(1.6%)
2	15(46.9%)	41(65.6%)
3	14(43.7%)	20(31.2%)
4	0(0.0%)	1(1.6%)
Operation		
Right hemicolectomy	6(18.8%)	20(31.2%)
Left hemicolectomy	2(6.3%)	7(10.9%)
Anterior resection	24(75.0%)	28(45.3%)
Abdomino-perineal resection	0(0.0%)	2(3.1%)
Hartmann closure	0(0.0%)	6(9.4%)
Indication		
Benign	2(6.3%)	16(25.4%)
Cancer	30(93.7%)	47(74.6%)
Stoma	9(28.1%)	14(22.2%)

**Table 5.2 Risk factors for the development of incisional hernia in both groups.**

<b>Risk factors</b>	<b>Laparoscopic(32)</b>	<b>Open(63)</b>
Previous surgery	2(6.3%)	8(12.7%)
Steroids	1(3.1%)	0(0.0%)
Diabetes mellitus	3(9.4%)	4(6.3%)
Wound infection	3(9.4%)	6(9.5%)
Obesity	0(0.0%)	3(4.8%)
Total	9(28.2%)	21(33.3%)

**Table 5.3 Number of patients with incisional hernia in both groups from an intention to treat basis and actual treatment received.**

Intention to treat				Actual treatment		
Laparoscopic(32)	Open(63)	p-value		Laparoscopic(27)	Open(68)	p-value
3(9.3%)	10(15.8%)	0.533	Incisional Hernia	3(11.1%)	10(14.7%)	0.520

# **Chapter 6**

## **Results**

### **Preparation for elective colorectal surgery using a video: A questionnaire-based observational study**

## 6.1 Results (Phase III)

During the study period, 32 patients underwent elective colorectal surgery and a fast-track recovery protocol was employed in all patients. Of these, 15 patients had laparoscopic assisted colorectal resection (4 right hemicolectomies, 4 left hemicolectomies, 3 anterior resections, 2 abdominoperineal resections, 1 proctectomy and 1 reversal of hartmann's) and 17 had open colorectal resection (3 left hemicolectomies, 7 anterior resections, 2 abdominoperineal resections, 2 proctectomies, 2 subtotal colectomies and 1 hartmann's). There were 20 males and 12 females with a median age of 62 years (Range 25–87). Median BMI was 27.5 (Range 22–35). Median length of stay in hospital was 5 days (Range 3–29 days). 100% compliance rate was recorded for completing the questionnaires. Table 6.1 summarises the results for the various questions asked. All patients (100%) thought they were well informed of the enhanced recovery programme and the provided information was easy to understand. In terms of patient perception about ERP, 14 (44%) patients thought the enhanced recovery programme was excellent, 14 (44%) thought it was good, 3 (9%) thought it was average and 1 (3%) thought it was poor. When asked about the effectiveness of different methods used for providing patient education, 18 (56%) patients found oral information as the most useful while 9 (28%) found the video most useful and 5 (16%) found printed information most useful. In terms of the easiest form of information to understand, 19 (59%) thought it was oral information while 8 (25%) thought it was the video and 5 (16%) thought it was printed information. Overall, 28 (88%) patients thought all the information provided to them about their operation was adequate, 3 (9%) thought it was too much and 1 (3%) thought it was inadequate. In terms of helping them prepare for their operation, 31 (97%) patients thought the video information was helpful, while 1 (3%) patient thought it did not help. A total of 29 (91%) patients thought the video information they got was relevant to their recovery while 3 (9%) did not think so. When asked if the video helped to motivate them to mobilize early, 20 (63%) patients felt well motivated, 10 (31%) patients felt slightly motivated and 2 (6%) patients did not feel motivated.

When asked about confidence levels on discharge, 14 (44%) felt very confident, 14 (44%) felt confident and 4 (13%) felt no change in confidence.

## 6.1 Summary of result from the questionnaire

Well informed of the enhanced recovery programme	Yes		No		
	32 ( 100% )		0 ( 0% )		
Information easy to understand	Yes		No		
	32 ( 100% )		0 ( 0% )		
Thoughts of the enhanced recovery programme	Excellent	Good	Average	Poor	Indifferent
	14(43.7%)	14(43.7%)	3(9.4%)	1(3.1%)	0(0.0%)
Most useful information	Oral		Leaflet	Video	
	18(56.1%)		5(15.6%)	9(28.1%)	
Easiest to understand	19(59.4%)		5(15.6%)	8(25.0%)	
Overall information given	Adequate		Too much	Inadequate	
	28(87.5%)		3(9.4%)	1(3.1%)	
Motivation based on video information	Well motivated		Slightly motivated	Not motivated	Indifferent
	20(62.5%)		10(31.2%)	2(6.2%)	0(0.0%)
Confidence going home based on video information	Very confident		Confident	No change	Unsure
	14(43.7%)		14(43.7%)	4(12.5%)	0(0.0%)



# **Chapter 7**

## **Results**

### **Patient education videos for elective colorectal surgery: Results of a randomised controlled trial**

## 7.1 Results (Phase III)

During the study period, 65 eligible patients were identified. Sixty one gave their consent and were randomised. The main reasons for non-randomisation were anaesthetic cancellations (3) and patient refusal (1). Baseline characteristics were similar in both groups at the trial entry (Table 7.1).

There was no difference in hospital stay between both groups with a median stay of 5 days (IQR 4-6) in the video group and 5 days (IQR 4-7) in the non-video group {  $p=0.239$  } (Fig 7.2). Median epidural use (Epidural consisted of bupivacaine and morphine) in both groups was similar with 207mg in the video group and 245mg in the non-video group { $p=0.984$ } (Fig 7.5). Although in general the non-video group used more epidural analgesia, there was no increased alternative analgesic use by patients in the video group and pain scores were same in the two groups. No significant differences were found between groups in terms of other analgesics: Paracetamol (Median 16g in the video group versus 17g in the non-video group:  $p=0.44$ ) and Voltarol (Median 450mg in the video group and 450mg in the non-video group:  $p=0.506$ ). Pain scores at rest and movement were similar in both groups (Median at rest 2 in the video group vs 2 in the non-video group:  $p=0.989$  and on movement 4 in the video group vs 4 in the non-video group:  $p=0.338$ ) (Figs 7.3, 7.4). Similarly, there was no difference in nausea scores (Median 0 in the video group vs 1 in the non-video group:  $p=0.74$ ). There were no differences observed in complications between the groups (5 patients in the video group vs 6 patients in the non-video group  $p=0.16$ ) although the study was not powered to this endpoint. 1 patient in the non-video group died postoperatively due to cardiorespiratory failure and 1 dropped out due to a necrotic stoma requiring re-operation on the 1<sup>st</sup> postoperative day. Follow up SF-36 scores (Table 7.3) also showed no difference between the groups in any of the components measured.

There were 3 re-admissions within 30 days (1 ileus, 1 high stoma output and 1 perineal wound infection).

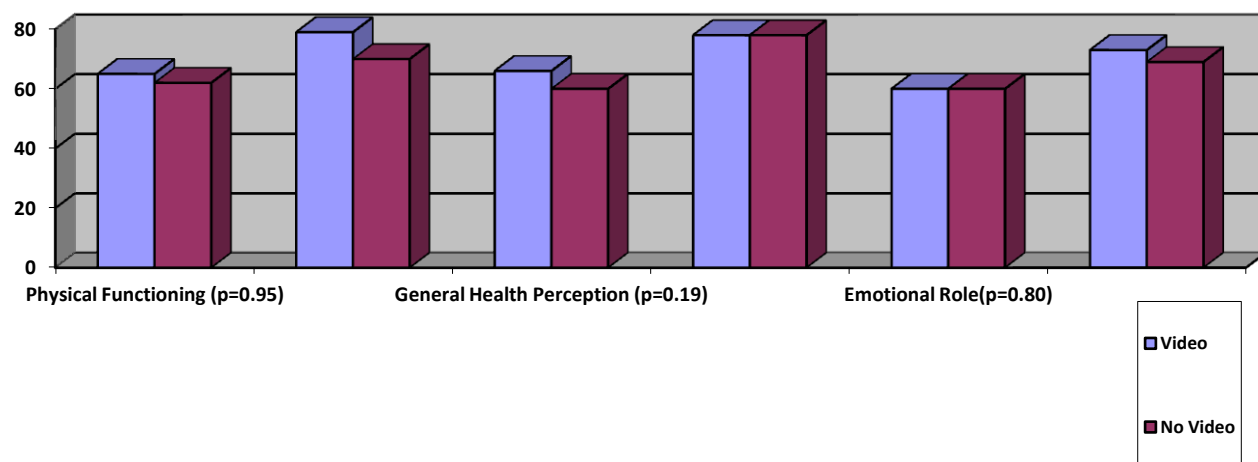
Of the 4 patients who were not randomised into the trial during the study period (non-entrants), follow-up data was available for 3. The main reasons for non-randomisation were anaesthetic cancellations (3) and patient refusal (1). Baseline characteristics for patients not included in the trial were similar to those randomised. The median hospital stay was 7 days (IQR 5-8). 1 patient had a chest infection and 1 had an ileus.

**Table 7.1 Baseline Characteristics for patients in the video trial**

Characteristics	Video	No Video	P value
Sample Size	31	29	
Sex	22 males (71%) 9 females (29%)	19 males (67%) 10 females (33%)	
Age (Median)	65	64	0.964
BMI (Median)	27	27	0.829
Operation :			
Anterior resection	19 (61%)	12 (43%)	
APER	3 (10%)	5 (17%)	
Hartmann's	2 (6%)	1 (3%)	
Right hemicolectomy	2 (6%)	9 (31%)	
Sigmoid colectomy	4 (13%)	1 (3%)	
Proctocolectomy	1 (4%)	1 (3%)	
Technique:			
Laparoscopic	14 (45%)	12 (40%)	
Open	17 (55%)	17 (60%)	
Indication:			
Benign	6 (19%)	8 (27%)	
Cancer	25 (81%)	21 (73%)	

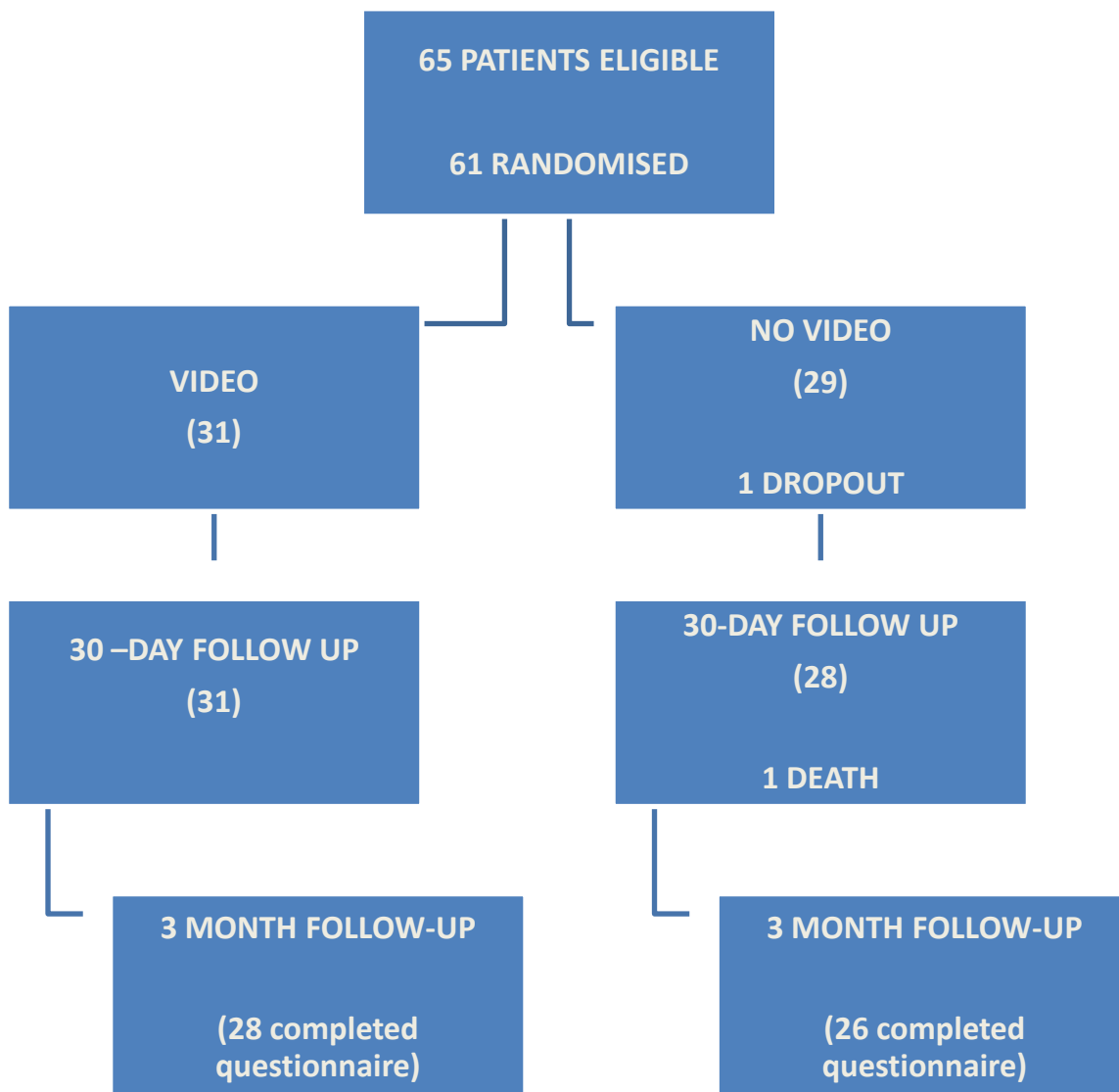
Values are median for continuous or N (%) for categorical data

**Table 7.2 Mean Short Form 36 (SF-36) scores at 3 months after surgery for patients in the video study**



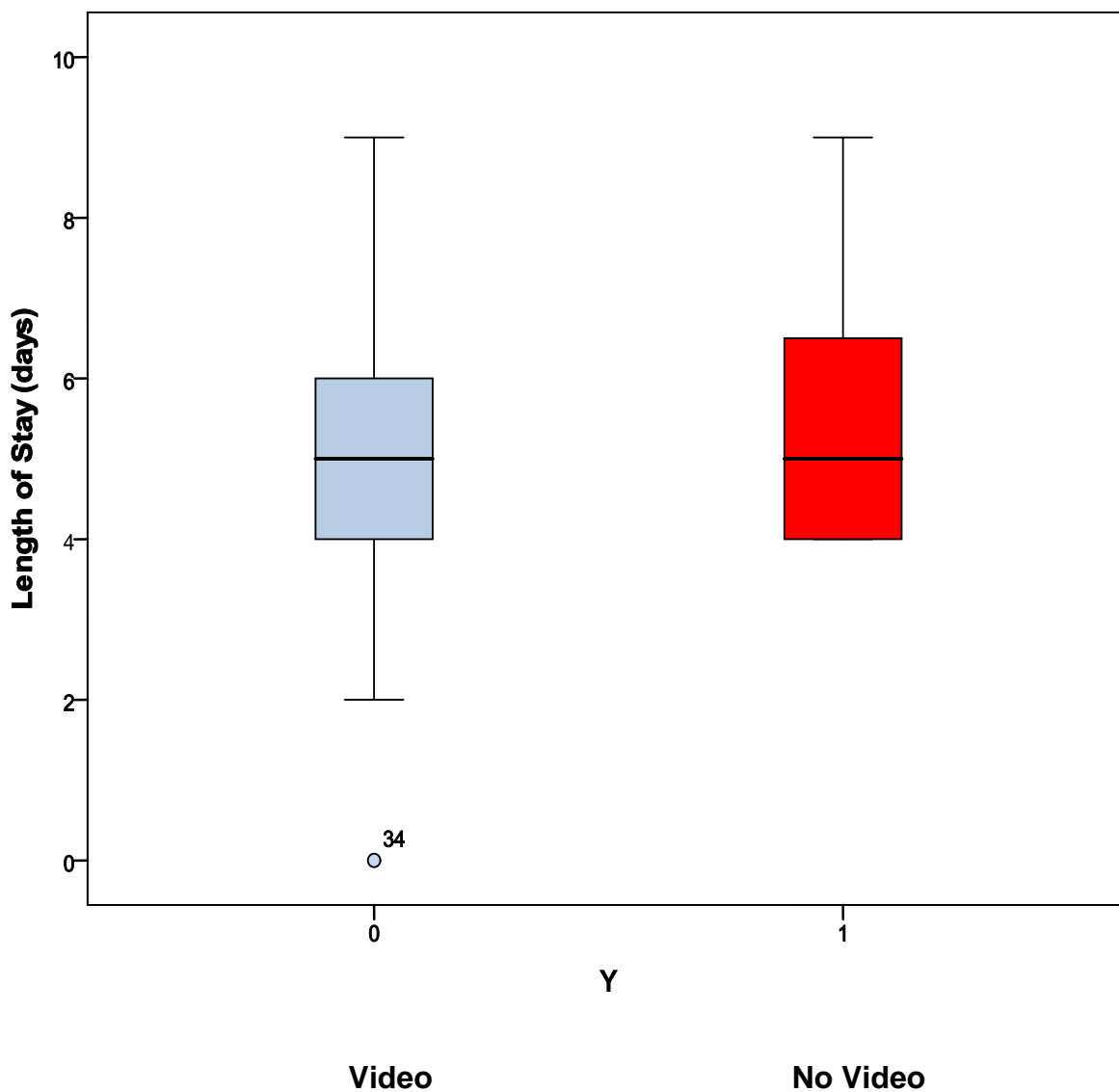
There was no difference in outcomes between both groups in any of the components measured from the SF-36

**Fig 7.1 Trial profile for the video study**



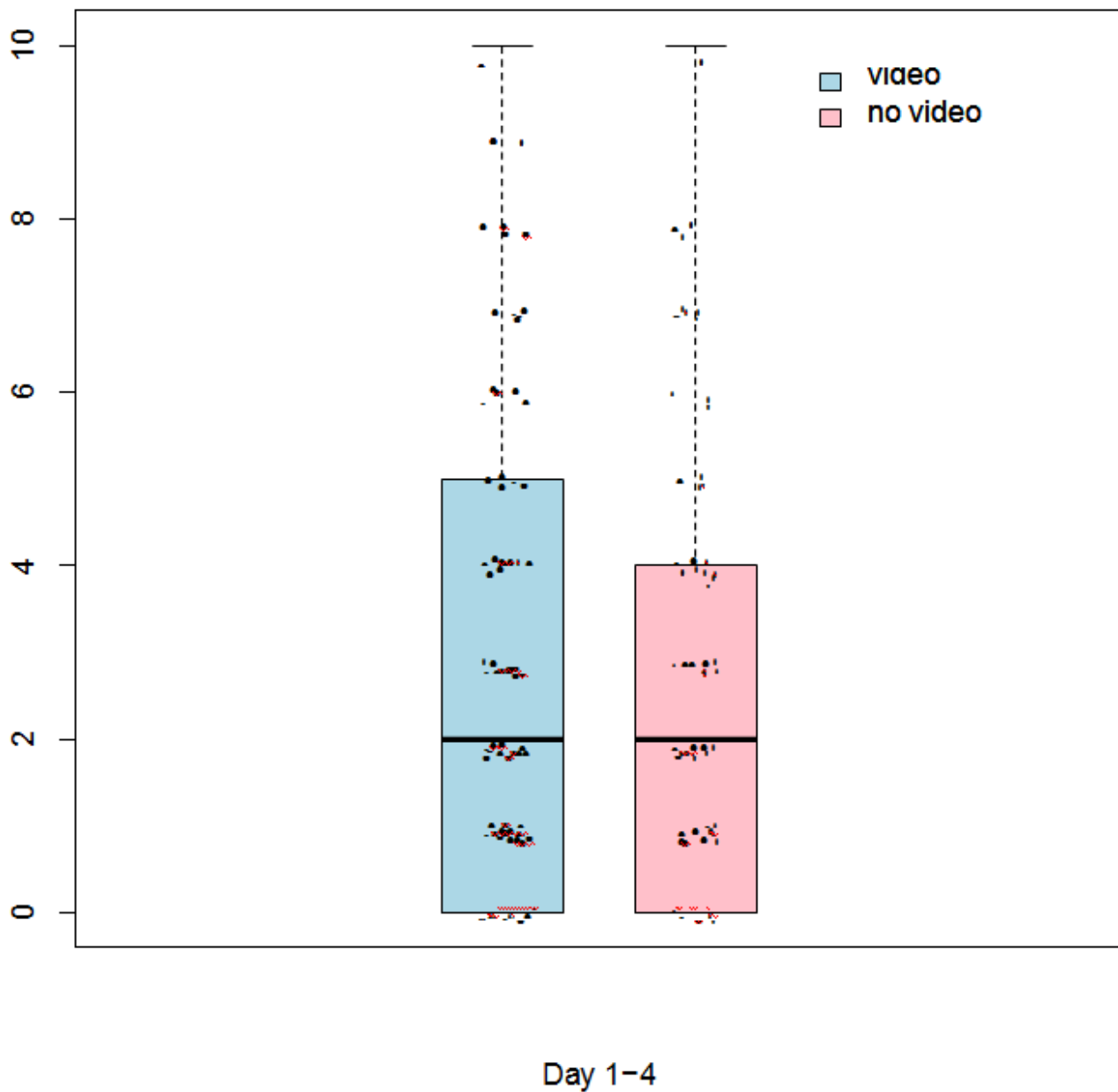
Flow chart of patients from recruitment to end of the study.

**Figure 7.2 Length of hospital stay for both groups of patients in the study (p=0.239)**



The median hospital stay in the video group was 5 days with an inter-quartile range of 4-6 days (Range 2-9 days). In the non-video group, the median hospital stay was 5 days with an inter-quartile range of 4-7 days (Range 4-9 days).

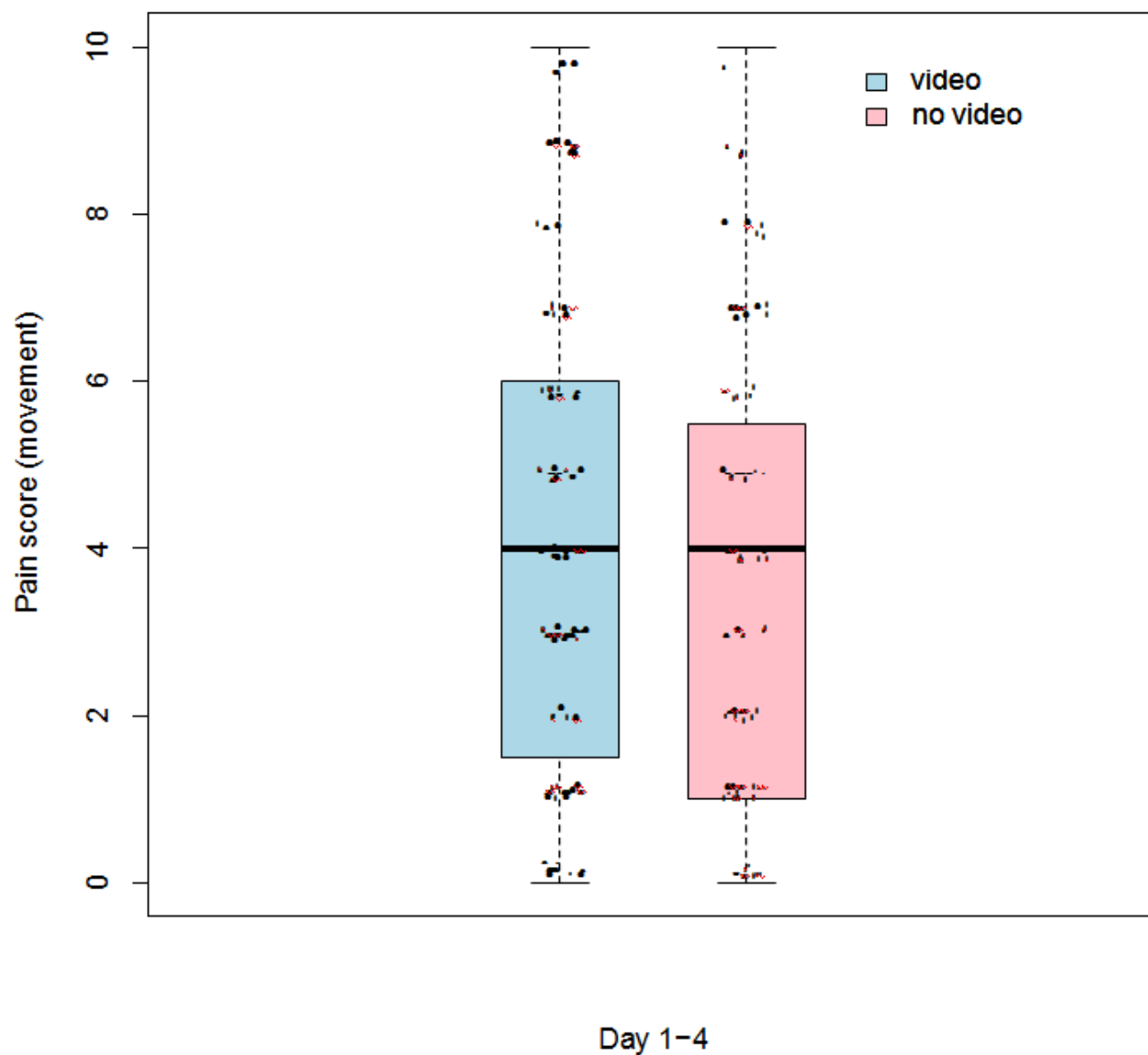
**Figure 7.3 Pain scores at rest from day 1 to 4 postoperative days in both groups ( $p=0.989$ ).**



The median pain score at rest in the video group was 2 with an inter-quartile range of 0 to 5 (Range 0 to 10). In the non- video group, the median pain score was 2 with an inter-quartile range of 0 to 4 (Range 0 to 10).

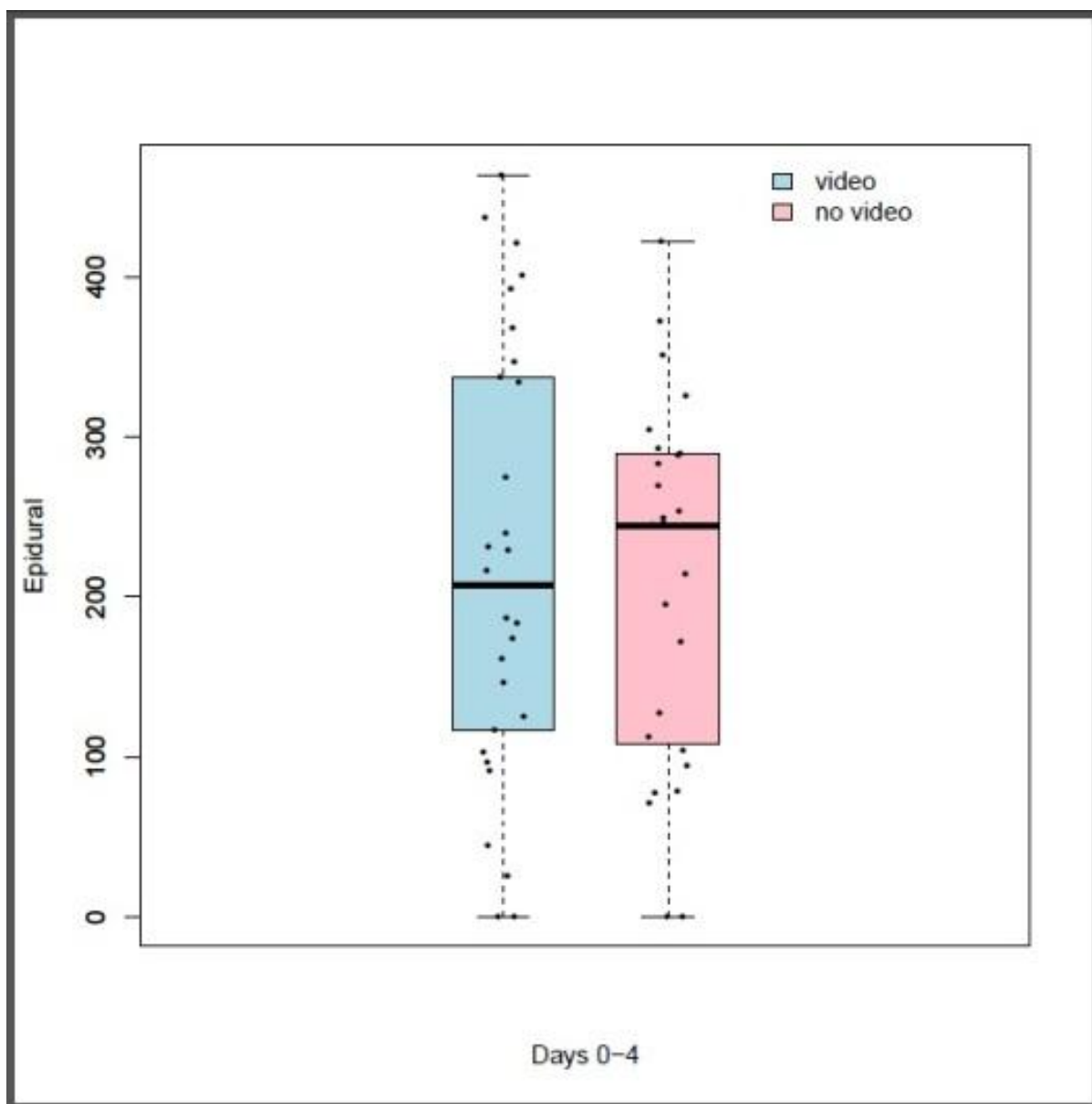


**Figure 7.4 Pain scores on movement from day 1 to 4 postoperative days in both groups (0.338).**



The median pain score on movement in the video group was 4 with an inter-quartile range of 1.5 to 6 (Range 0 to 10). In the non- video group, the median pain score was 4 with an inter-quartile range of 1 to 5 (Range 0 to 10).

**Figure 7.5 Epidural use in both groups (p=0.984)**



The median epidural use was 207mg in the video group with an inter-quartile range of 110mg to 350mg (Range 0mg to 480mg). In the non- video group, the median epidural use was 245mg with an inter-quartile range of 100mg to 280mg (Range 0mg to 430mg).

# **Chapter 8**

## **Results**

**Enhanced recovery programmes in colorectal surgery are less enhanced later in the week**

## 8.1 Results (Phase IV)

The study by Freemantle and co has shown that there is significantly increased mortality rates for weekend admissions.<sup>(106)</sup> This led the Academy of Medical Royal Colleges to introduce standards for 7 day consultant present care. Inpatients now have to be seen by a consultant once every 24 hours, investigations and interventions done and reported 7 days a week and support services available 7 days a week. This study compared short term outcomes between patients operated upon earlier in the week and those operated upon later in the week.

A total of 227 patients (94 females and 133 males) underwent surgery on the enhanced recovery programme (ERP) over the one year period. Median age was 72 years (IQR 63-79). 137 underwent open surgery and 90 laparoscopic surgery.

Analysis of 225 patients included 155 (68%) patients operated Monday to Wednesday and 70 (31%) patients were operated Thursday to Friday. 2(0.9%) patients who had surgery on a Sunday were excluded. Patients in both groups were well matched for demographic data including age, sex, tumour location, operation performed and type of surgery (Table 8.1).

Table 8.2 shows the different complications for both groups of patients studied with no significant difference noted (54 vs 33:  $p=0.428$ ). The overall median hospital stay was 7 days (IQR 6.0-9.75). There was however a significant difference in length of stay (LOS) for both groups with a median LOS for the Monday to Wednesday group at 6 days (IQR: 4 to10) and 8 days (IQR: 5 to11) in the Thursday to Friday group {Mann-Whitney U test  $p=0.045$ }. This could be due to reduced staff availability over the weekend. Whether the resection was right sided or left/rectal resection had no significant association with hospital stay (Table 8.3) {7 days vs 7 days:  $p=0.127$ }.

**Table 8.1 Baseline Characteristics.**

Criteria	Monday to Wednesday	Thursday to Friday	P-Value
Age	72.4(62.1,79.6)	73.1(65.7,80.2)	0.129
Sex	Male 87(56%) Female 68(44%)	43(61.4%) 27(38.6%)	0.555
BMI	26.3 (22.8, 29.1)	26.1 (23.1, 29.3)	0.132
Tumour location	Right sided 54(35%) Left sided 101(65%)	22(31.4%) 48(68.6%)	0.140
Stoma	49(31.6%)	26(37.1%)	0.129
Type of Surgery: Laparoscopic vs Open	Laparoscopic 65(41.9%)	Laparoscopic 27(38.6%)	0.892

No statistically significant difference for patients in both groups (Monday to Wednesday versus Thursday to Friday). Values are median (interquartile range) for continuous or N (%) for categorical data.

**Table 8.2 Complications.**

<b>Complications</b>	<b>Total No of Patients</b>	<b>Mon to Wed</b>	<b>Thur to Fri</b>
	<b>87</b>	<b>54(62%)</b>	<b>33(38%)</b>
Prolonged ileus	20	12(13.8%)	8(9.2%)
Intra-abdominal collection	15	11(12.6%)	4(4.6%)
Acute Renal failure	8	5(5.7%)	3(3.4%)
Anastomotic leak	5	3(3.4%)	2(2.3%)
Wound infection/ dehiscence	10	7(8.0%)	3(3.4%)
Myocardial infarction	2	2(2.3%)	0(0.0%)
Chest infection	12	5(5.7%)	7(8.0%)
Bowel obstruction	2	1(1.1%)	1(1.1%)
Urinary tract infection	7	4(4.6%)	3(3.4%)
Stomal necrosis	1	1(1.1%)	0(0.0%)
Atrial fibrillation	2	2(2.3%)	0(0.0%)
Ureteric injury	1	0(0.0%)	1(1.1%)
High stoma output	1	0(0.0%)	1(1.1%)
Transient ischaemic attack	1	1(1.1%)	0(0.0%)

No statistically significant difference for both groups of patients (Monday to Wednesday versus Thursday to Friday: P=0.428)

**Table 8.3 Operations by day of surgery (p=0.127)**

<b>Mon -Wed</b>		<b>Thur-Fri</b>	
Anterior resection	59(38%)	Anterior resection	28(40%)
Right hemicolectomy	54(34.9%)	Right hemicolectomy	22(31.4%)
Hartmann's procedure	13(8.4%)	Hartmann's procedure	6(8.6%)
Left hemicolectomy	21(13.5%)	Left hemicolectomy	8(11.4%)
APER	8(5.2%)	APER	6(8.6%)

# **Chapter 9**

## **Summary of results**



Results from all the phases of the study show that the enhanced recovery programme is feasible and safe and should be practiced by individual units offering colorectal surgery.

Overall, both studies on the use of video education reveal that although use of video education does not shorten hospital stay nor improve pain and nausea scores, it however, reduces anxiety and improves patients' confidence on discharge from hospital and is viewed as a better source of information on the enhanced recovery programme when compared with information leaflets.

Laparoscopic surgery does not seem to improve short and long term outcomes while operating on colorectal patients early in the week has a positive impact on short term recovery in an enhanced recovery programme.

In summary, patients benefit from pre-conditioning using video education and being operated upon early in the week (Monday to Wednesday) in an enhanced recovery programme. The type of operation (Laparoscopic or open) does not make a difference in outcome.

# **Chapter 10**

## **Discussion**

Perioperative care and recovery have been the major concerns in the development of modern surgery. The focus of interest in recovery has been on both the efficacy of individual interventions as well as processes and pathways to improve outcome. In the last decade, there has been a lot of interest in the medical literature on interventions and pathways relating to recovery.<sup>(44,57,58)</sup> This has been driven by the increasing pressure on resources in healthcare systems and the demand of an ageing population.<sup>(3)</sup> With increasing pressure on the National Health Service to reduce length of hospitalisation, it is important that the preoperative, operative and postoperative periods are managed actively. This research focused in the area of perioperative recovery with the aim of investigating the factors that influence the implementation of an enhanced recovery programme in patients undergoing elective colorectal surgery. It was done in four phases.

### **Phase I: Early discharge following closure of loop ileostomies**

Loop ileostomies have become popular amongst colorectal surgeons because of the apparent ease of formation and closure. It is considered a safe way to achieve faecal diversion.<sup>(106)</sup> Previous reports of loop ileostomy closure conclude that the procedure is associated with low morbidity.<sup>(107)</sup> Complications can occur following construction and closure, most commonly dehydration and intestinal obstruction.<sup>(106)</sup> In our series, the overall complication rate after closure was 18% which is consistent with the published literature. Several authors have reported complication rates ranging from 10 to 30%.<sup>(106,107,108)</sup> Small bowel obstruction was the main postoperative complication recorded in our series (12%), which compares favourably with other reported series.<sup>(107,108)</sup> The reason why patients develop bowel obstruction following ileostomy closure is unclear. Following closure, adhesions may occur at the site, possibly as a result of difficulties in fully mobilising the ileostomy. However, fixation of the small bowel to the deep aspect of the abdominal incision is a common occurrence<sup>(109,110)</sup> and it is this which is probably the cause of obstruction, rather than narrowing of the lumen secondary to swelling of the anastomosis. Some authors have advocated that stapled closure of a loop ileostomy may reduce the complication rate

from bowel obstruction because the lumen created using a stapled side to side technique may be wider than that created by sutured closure.<sup>(111)</sup> We observed a low incidence of anastomotic leak after closure with two patients only developing this complication. Peritonitis is a rare complication that occurs shortly after closure in one to seven per cent of patients.<sup>(107,108)</sup> A proportion of cases are thought to arise from iatrogenic occult enteric tears. None of the patients in this series developed this complication. During surgery, particular attention was paid to oversewing even the most minor serosal tear. The wound infection rate in our series was low (1%) and is probably due to a deliberate policy of not closing the wound. The insertion of a purse string suture, leaves a central drainage well. From these results, it appears that early discharge after ileostomy closure can be achieved with an acceptably low serious complication rate. A pilot study in the Netherlands has shown that further reductions in hospital stay may be achieved by use of local anaesthetic techniques.<sup>(112)</sup> However, a larger randomised, control study on use of local anaesthetic techniques is still awaited.

This study has shown that loop ileostomy closure is a safe and effective procedure which can be carried out with an acceptable complication rate and short inpatient hospitalisation within an enhanced recovery programme.

Complications which occur are unrelated to length of hospital stay. Sound post-operative advice (re: diet) and appropriate analgesia allows many patients to be discharged in the early postoperative phase.

The enhanced recovery programme was successfully introduced in our unit following this study and this led unto the next study.

## **Phase II: Short term outcomes of laparoscopic colorectal surgery**

Laparoscopic colorectal surgery has gained increasing acceptance over the past decade. The arguments made for adopting the technique in spite of higher costs, longer operating times and a steep initial learning curve have been based around the improvements in patient recovery. The perceived advantages of less postoperative pain and a reduction in ileus and length of hospital stay are felt to outweigh any such disadvantages.

With the introduction of fast-track surgery dramatic improvements in perioperative care have been reported with hospital stays of between 2 and 3 days after open surgery.<sup>(113)</sup>

While individual interventions have been validated by randomised clinical trials, their relative importance in the context of a multimodal rehabilitation program remains obscure.

As in the study by Kehlet et al,<sup>(113)</sup> we found no difference in pain scores or analgesic intake between the two groups. These results are obviously quite different from previous large trials and meta-analyses of traditional care which have consistently shown an improvement in analgesia with laparoscopic surgery.<sup>(114)</sup> It may be that altering patients' expectations preoperatively has a significant effect on their perception of pain. We also found no difference in duration of ileus or hospital stay with patients discharged on the 5th postoperative day. This is longer than in Kehlet's group which may be due to the use of PCA morphine rather than epidural analgesia, however a recent randomised trial showed no benefit of thoracic epidural analgesia over PCA morphine when used in a fast-track program for patients undergoing colorectal resection.<sup>(115)</sup> The difference in hospital stay may also reflect the use of different discharge criteria by waiting for the passage of the first bowel motion but it is offset by fewer readmissions in the current study. The only study to show a difference in fast-track patients between open and laparoscopic surgery is the study by Kennedy et al. However this may be due to hospital stays of 7 days in the open group which is longer than those in the current trial.<sup>(94)</sup> While we did not see any difference between the groups in

terms of complications or quality of life when assessed at 3 months, the study is not adequately powered for these specific endpoints.

While this series is non-randomised we would have expected any selection or observer bias to have benefited the laparoscopic group. We did not however see any significant difference in short term outcomes after colorectal surgery in fast-track patients treated laparoscopically. If laparoscopic resection does not improve short term outcomes, then the significantly increased cost of the procedure may become difficult to justify.<sup>(116)</sup>

The short term outcomes of laparoscopic colorectal surgery are not superior to open surgery in an enhanced recovery programme. With the introduction of this programme, the benefits of laparoscopic colonic resection remain to be proven and further large randomised trials are necessary to investigate the current controversy in the literature.

Patients were followed up over a 2 year period to check for incidence of incisional hernias.

## **Phase II: Long term outcomes of laparoscopic colorectal surgery**

With the advent of laparoscopic surgery, the incidence of incisional hernia was expected to be minimal. Lumley et al,<sup>(117)</sup> looked at the intermediate and long-term outcomes following laparoscopic colorectal surgery. In their study on 181 patients, at a median follow up period of 71 months, only one developed an incisional hernia. Regadas et al,<sup>(118)</sup> looked at the complications in laparoscopic colorectal resection and recorded four cases of incisional hernia out of 92 patients reviewed. However, both studies did not check specifically for incisional hernias and it is possible that some cases may have been missed.

Incisional hernia has remained a problem for surgeons following abdominal surgery. Our rate of 15.6% correlates with other studies in the literature.<sup>(119-121)</sup> With the financial burden to the health service which this imposes and the high recurrence rates following repair<sup>(122,123)</sup>, prevention has been of paramount importance to surgeons. Several studies have looked at prophylaxis in high-risk patients. Strzelczyk et al,<sup>(124)</sup> carried out a randomised trial to assess the effects of prophylactic polypropylene mesh in morbidly obese patients undergoing gastric by-pass surgery and concluded that this prevented hernia development. However, this was contradicted by Pans et al. who did not see a significant difference in incisional hernia rates with use of prophylactic mesh in high risk patients.<sup>(125)</sup> Use of transverse incisions in open surgery may make for a better comparison, as at least in high-risk patients there is some evidence that the rate of any subsequent incisional hernia may be reduced.<sup>(126)</sup> Results from better targeted incisions in open surgery may be superior to the laparoscopic approach as the addition of port site hernias would be avoided.

Laparoscopic colorectal resection does not appear to reduce incisional hernia rates significantly when compared with open colorectal resection. While the present study is a selected group of patients, it would be expected that any selection bias would benefit the laparoscopic group. Despite this, there was no difference in hernia rates found and so with the increased cost to the health service with laparoscopic colorectal surgery, the long-term benefits remain to be proven.

### **Phase III: Psychological preparation for surgery using audio-visual aid**

Preparing patients psychologically for surgery is effective in reducing hospital stay, analgesic use, complications and enhances quality of life and immune responses.<sup>(103,127)</sup>

Patient education is an important component of psychological preparation and is done verbally, through use of information leaflets or use of audio-visual aids such as a video (as in the present study).

Studies have shown that preoperative educational video is effective in reducing anxiety and stress associated with surgery as well as reducing individual and overall medical costs.<sup>(128,129)</sup> Good patient information gives confidence and improves overall outcome. The first part of this study had shown that supplementing video education with both oral and printed information may well be better in preparing patients psychologically for surgery and help improve short term outcomes in an enhanced recovery programme. However, this observational study was limited as surveying one's patients can lead to an overstated positive feedback.

The patients who were not randomised into the study had longer hospital stay when compared with patients in the trial. This is unsurprising as this group of patients are expected to have more co-morbidities.

The second part of this study showed that use of video education as an adjunct to verbal and written information does not improve short term outcomes in patients undergoing elective colorectal surgery

Further clinical trials are required to prove the efficacy of video education as a component of the enhanced recovery programme in patients undergoing elective colorectal surgery with comparison done between groups undergoing the same type of surgery.

#### **Phase IV: Effect of day of surgery on outcomes in an enhanced recovery**



Multimodal rehabilitation regimes in association with both laparoscopic and open surgery suggests that the post-operative care package has the more major influence on recovery.<sup>(94,130,131)</sup>

Introduction of the enhanced recovery programme in the last decade has brought about a dramatic improvement in perioperative care. This has allowed many surgical procedures to be performed on a day case basis or with decreased length of hospital stay. This has benefits for the patient, healthcare system and the society.

No studies in the literature have looked at the impact of day of surgery in improving short term recovery in patients in an enhanced recovery programme. Our current audit has not shown any difference between both groups in terms of postoperative complications. However, there was a significant difference in hospital stay in those patients getting their operations earlier in the week. The reason could be due to reduced staff availability over the weekend. This clearly shows that a successful enhanced recovery programme requires a dedicated multidisciplinary team approach and should be available every day of the week. With the National Health Service struggling financially, it may be argued that employing more staff to cover weekends would be costly. However, there will be substantial cost saving when the total bed days saved is calculated. Solly et al<sup>(132)</sup> estimated that if the average length of stay in hospital for patients undergoing laparoscopic cholecystectomy was reduced by one day, there would be an annual saving for the national health service of approximately 35,400 bed days (£8 million, based on a bed day cost of £225). Recent studies have shown significantly increased mortality rates for weekend admissions due to reduced staff and support availability.<sup>(106)</sup> This led the Academy of Medical Royal Colleges to introduce standards for 7 day consultant present care. There is now an increasing trend for consultant review of patients once every 24 hours with investigations and interventions done and reported 7 days a week and support services available 7 days a week.

As our study shows, there is a definite difference in length of hospital stay. On the other hand, units that have a flexible rota could fit in most of their major procedures earlier in the week once it is suitable for both patient and surgeon.

It could be argued that laparoscopic surgery may have contributed to the decreased hospital stay in the Monday to Wednesday group but there was no significant difference found for both groups ( $p=0.892$ ) as was right or left sided resections ( $p=0.127$ ).

Operating on colorectal patients early in the week is associated with reduced in-patient hospitalisation and should be borne in mind by units practising the enhanced recovery programme if the maximum benefit of this is to be attained.

There were **limitations** of this research work. There was a lack of qualitative data. It would have been good to listen to the patient voice one on one using interviews or in focus groups especially with the psychological preparation for surgery using a video. Although patients were given questionnaires on their thoughts, conducting interviews may have been a better way to do this. There were administrative challenges in obtaining large samples as smaller samples may not be an adequate representation of the target population. This may account for the findings in the laparoscopic studies differing from more recent studies with large number of patients recruited. There was no randomisation for the laparoscopic and day of surgery studies which could introduce bias. This research work was done over a prolonged period of time and there was new evidence on improved postoperative analgesia such that our protocols had to be altered. It would have been good to have similar protocol for all the studies.

There were more patients in the video group undergoing left sided resections. This could have influenced hospital stay in both groups. This was unavoidable as it was a randomised trial for all

patients undergoing elective colorectal resection. It may have been better to compare patients undergoing similar resections (Either only right or left sided resections).

# **Chapter 11**

## **Conclusions**

## 11.1 Conclusion

The major advances in modern surgery have been the development of processes and pathways concerned with perioperative care and recovery. With such improvements, many surgical procedures are now carried out on a day case basis.

This is beneficial for both the patient who has a faster recovery and the healthcare systems with reduced costs. With increasing experience in this area of rapid recovery, the principles of enhanced recovery has become popular.

The enhanced recovery programme was first proposed by Professor Henrik Kehlet. The idea was to promote rapid recovery through evidence based protocols which reduce the stress of surgery. This multimodal approach has reduced hospital stay to 2-3 days.<sup>(41,42,43)</sup> There have also been improvements in recovery in other specialties.<sup>(133,134,135)</sup> There were initial criticisms regarding early discharge and the burden on primary care.<sup>(44)</sup> To establish safety of an enhanced recovery programme, 100 consecutive patients who had reversal of loop ileostomy which would be classed as an intermediate procedure as against a major one were studied. This showed that patients could be safely discharged home early with no increased complication rate.

The use of laparoscopic surgery for colorectal resection has continued to gain popularity. There was an early uptake in the 1990's but due to initial reports of compromise in oncological clearance for colorectal cancer, there was a downturn in acceptance. However, this was disputed by several other studies which showed no difference in oncological outcomes compared with open surgery.<sup>(90,92)</sup>

The advantages of laparoscopic surgery have been based on more rapid short term recovery and reduced postoperative complication rates. There are suggestions that applying the same recovery

pathways to open surgery in the form of enhanced recovery can lead to comparable results with laparoscopic surgery. In both studies on the short and long term outcomes of laparoscopic surgery compared with open surgery, there was no difference in the measured variables when same recovery protocols are applied.

Psychological preparation is important in the preoperative optimisation of patients. It incorporates a range of strategies designed to influence emotions, cognitions or behaviours. Dissemination of information is a key factor in the psychological preparation of patients for surgery. The best way to do this remains controversial. The two studies carried out on the use of video education as an adjunct to verbal and written information showed no improvement in short term outcomes. However, when obtaining patients views, it was preferred by patients compared with information leaflets.

From this stepwise project, one can conclusively state that the enhanced recovery programme is safe and feasible and should be practiced by every unit as there is evidence to show improvements in outcome. The programme requires a multimodal approach and no single factor can be said to influence outcome.

Large multicentre randomised trials are required to ascertain the role of laparoscopic surgery, video education and day of surgery on recovery following major abdominal surgery within an enhanced recovery programme

# **Chapter 12**

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# Appendix

**A randomised controlled trial (study) to assess the benefit of a patient information video on recovery after colorectal (bowel) surgery.**

**Patient Information Leaflet**

**Introduction:**

You are being asked to participate in a study to evaluate the usefulness of a patient information video. The video provides information on your recovery after bowel surgery. All patients will get information about their operation and the expected recovery by the doctors and nurses. They will also get written information guides about their surgery.

If you agree to participate you may either be in the arm of the study where you get a video or where you do not get one. Patients will be selected for the study to receive the video randomly and that means you will have a 50-50 chance of receiving the video. Whichever arm of the study you fall into will not affect your treatment.

You can decide not to participate in the study and this will not affect your treatment.

You can also decide to change your mind after initially agreeing to take part and your treatment will not be affected.

**How do we recruit patients to the study?**

All patients who are having planned bowel surgery will be invited to participate in the study.

If you agree to participate in the study, you will be requested to sign a consent form.

When you come to the pre-assessment clinic, depending on the arm of the study you

fall into, you may or may not get a video. You should note that this does not affect your treatment.

### **Information to be obtained from the study and storage of data.**

The information we get about you will not have any of your personal details that could be used to identify you. We will collect information about your length of hospital stay, amount of painkillers you take, levels of pain after you operation, any problems following your operation and how quickly you return to your normal daily activities. All the information will be stored on a hospital computer with a protected password.

There will be no breach of confidentiality.

### **What happens if I get the video?**

If you get the video, you can either watch it in pre-assessment or take it home and watch. You will still be discharged as normal once the doctors are happy that it safe for you to go home.

### **What happens if I do not get the video?**

If you do not get the video, you will still be given adequate information (We will speak to you and give you leaflets). You will still be discharged as normal once the doctors are happy that it is safe for you to go home.

### **What happens when I come for my operation?**

You will be admitted on the day of you operation. You will be seen by the surgeon and the anaesthetist (the doctor who puts you to sleep for the operation) to make

sure you are still okay to proceed with the planned operation. After your operation, we will get you eating and drinking and also getting out of bed as early as possible. This speeds up your recovery and makes it less likely that complications will develop.

### **What happens after discharge from hospital?**

Before you leave the ward, you will be given a telephone number to ring if you have any problems after going home. You will be given a clinic appointment for 4 to 6 weeks after discharge. A questionnaire will be given to you on discharge to find out your thoughts on the information given to you about your recovery. For those who received a video, we will want to know if they watched it. The questionnaire can be filled out before you leave hospital or you can bring it during your clinic review.

### **Who do I contact if I have any problems with the study?**

You can contact the principal researcher: Mr Ugo Ihedioha (Page 3410, Mobile 07985584582) or Mr Sanjay Chaudhri (01162584378)

### **What if I have complaints and want an independent contact?**

You can contact: Mrs Maureen Yardley

Administrator – Clinical Risk and Complaints

Complaints and Litigation

Gwendolen House

Ext 8718

Maureen.yardley@uhl-tr.nhs.uk.

## CONSENT FORM

**Title of Project:** Psychological preparation for colorectal surgery : Impact of video education A randomised trial.

**Names of Researchers:** Mr U Ihedioha Specialist Registrar in General Surgery

Mr S Chaudhri Consultant in General Surgery

Mr J Jamieson Consultant in General Surgery

**Please  
initial  
box**

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study and have had the opportunity to ask questions. ☐
2. I understand that taking part is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

Name of Patient \_\_\_\_\_  
Signature \_\_\_\_\_

Date \_\_\_\_\_

Name of Person \_\_\_\_\_ Date \_\_\_\_\_  
Signature \_\_\_\_\_

taking consent  
(if different from researcher)

Researcher \_\_\_\_\_ Date \_\_\_\_\_  
Signature \_\_\_\_\_

1 for patient; 1 for researcher; 1 to be kept with hospital notes





Operation done :

Weight :

Date of admission :

BMI :

Date of discharge :

Complication :

Hospital stay ( Days )

ASA :

Age :

Sex :

1. Did you get a DVD prior to your operation ? Yes ☐ No ☐

2. If yes, did you get the chance to watch the DVD ? Yes ☐ No ☐

3. Was the information on the DVD easy to understand ? Yes ☐ No ☐

4. What did you find most useful ?

- a) Oral information ☐
- b) Information leaflet ☐
- c) Video ☐

5. Which was the easiest to understand ?

- a) Oral information ☐
- b) Information leaflet ☐
- c) Video ☐

6. Did you think the amount of information was :

- a) Adequate ☐
- b) Too much ☐
- c) Inadequate ☐

7. Did the information help towards preparing you for your operation ? Yes ☐ No ☐

8. Was the information you got relevant to your recovery ? Yes ☐ No ☐

9. Did the information correlate to your path to recovery ? Yes ☐ No ☐

10. Did you get motivated towards early recovery based on the information received ?

- a) Well motivated ☐
- b) Slightly motivated ☐
- c) Not motivated ☐
- d) Indifferent ☐

11. Did you feel confident going home after your operation based on the information you received ?

- a) Very confident ☐
- b) Confident ☐
- c) No change ☐
- d) Unsure ☐

## **PSYCHOLOGICAL PREPARATION FOR COLORECTAL SURGERY: IMPACT OF VIDEO EDUCATION.A RANDOMISED TRIAL**

### **INTRODUCTION**

Since the introduction and favourable early results of enhanced recovery programmes more than a decade ago, they have become increasingly popular following major abdominal surgery. Many elements of these programmes are based on solid evidence and derived from randomised trials or meta-analyses.. These programmes optimize pre-operative, perioperative and post-operative factors to reduce the physiological and psychological stress of surgery with the aim of improving patient outcome and speed up recovery after surgery. Key pre-operative features are conditioning of expectations and the optimization of co-morbid disease. Intra-operative strategies include use of short –acting anaesthetic agents, maintenance of normothermia and minimal access surgery. Post-op care is optimized with epidural analgesia, early mobilisation and early feeding. This multimodal approach reduces hospital stay to 2-4 days ( Basse 2004 ). There is also evidence that the clinical improvements resulting from the implementation of an enhanced recovery programme do not cause significant deterioration in quality of life or transfer costs to another component of health care( King 2006 ).

The relative contribution of each of the single elements in the enhanced recovery programme remains uncertain. Good patient information gives confidence and improves overall outcome. No studies have examined the impact of patient education on enhanced recovery.

The current proposal is to support a prospective randomised trial to compare clinical outcomes between patients given both video and information leaflets and those given information leaflets alone ( control group ) on enhanced recovery.

## **TRIAL DESIGN**

A randomised controlled pilot trial of the impact of patient awareness of the enhanced recovery programme on recovery. Patient recruitment will be from the Leicester General Hospital for all comers undergoing colorectal surgery. A fast track protocol will be established for all patients.

The primary end-points are length of hospital stay, patient satisfaction and return to normal activities and will allow the investigation of the potential implications of incorporating patient awareness of enhanced recovery programmes into routine clinical practice.

## **METHODS**

### **Patients**

All surgeons involved in the trial will have a specialist interest in colorectal surgery. All patients undergoing elective colorectal resection will be eligible unless they were deemed medically unfit for operation, suffering severe physical disability and in long term care, cannot speak or understand english.

### **Preoperative preparation**

Informed consent will be obtained from patients requiring elective colorectal surgery

to be randomised to those given both a video and information leaflet and those given information leaflets alone. All patients will be allowed free fluids and high calorie drinks for up to 4 hours before operation. Patients undergoing right hemicolectomy will not receive bowel preparation while those having left sided surgery will receive phosphate enema on the morning of surgery. All patients will receive antibiotic and DVT prophylaxis. All patients will have baseline haematological and biochemical investigations.

### **Anaesthesia**

A standardised anaesthetic protocol will be used for all patients. Normothermia will be maintained throughout surgery and all operations will be carried out through the smallest incision necessary to complete the procedure. No nasogastric tubes or intraabdominal drains will be used.

### **Postoperative pain and analgesia**

Analgesia will be provided in both groups for 48 hours via PCA, epidural or TAPP block ( Unless changed by the consultant or pain team based on clinical judgement ). Paracetamol will be administered concurrently with NSAIDS and tramadol for breakthrough pain once morphine is discontinued. Visual analogue pain scores at rest and movement will be measured daily until discharge. All analgesia used postoperatively will be recorded including any discharge medication.

### **Diet and Fluids**

Oral fluids will be pushed immediately postoperatively in both groups. In addition,

protein drinks and normal food will be encouraged in both groups from day 1. All intravenous fluid will be stopped by day 2 unless there is a clinical reason to maintain them. Both groups will have daily biochemistry and haematology measurements.

### **Hospital stay**

This will be recorded in hours from the time the patient is admitted to hospital.

Patients for discharge should have normal observations and normal post-operative bloods, free from intravenous lines and drains, be fully mobile, able to get in and out of bed unaided and dress independently. Social reasons for non-discharge such as delay in setting up home help etc will be recorded for both groups of patients.

### **Return of bowel function and complications**

Patients in both groups will be allowed oral fluids immediately after surgery and diet on day one. All patients will have chest physiotherapy and will be encouraged to mobilise on day one with the help of a nurse or physiotherapist. The time to passage of flatus and bowel motion will be recorded for each patient. Episodes of nausea and vomiting will also be recorded as will any post-operative complication up to 30 days post-operatively.

### **Patient satisfaction and return to normal activity**

All patients will complete a questionnaire ( SF-36 ) pre-operatively and at 3 months

post-operatively to assess satisfaction and return to normal activities such as leisure activities and work in the home etc.

## **DATA COLLECTION FORM**

No:

Age:

Sex: M / F

Weight (kg):

BMI:

Date of surgery:

Diagnosis:

ASA grade: 1 / 2 / 3 / 4 Operation:

Date of admission :

Date of discharge :

Date of first bowel motion/ flatus :

Complication :

Outcome :

Reason for delayed discharge :

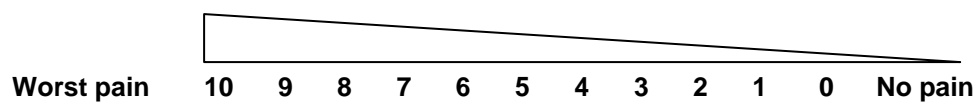
No :

**Day 1 ( Day after surgery )4PM**

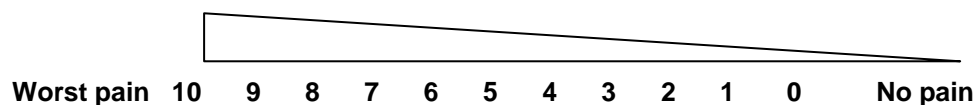


## Pain Score

AT REST



ON COUGHING



## Nausea Score

0 1 2 3 4

0=No nausea  
1=Mild nausea, no treatment  
2=Moderate nausea, response to treatment  
3=Moderate nausea, no response to treatment  
4=Severe nausea

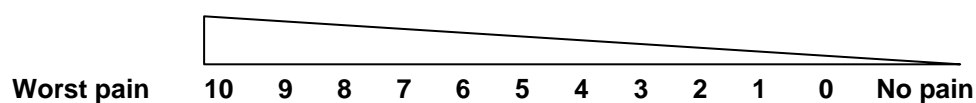
Day 2

4PM

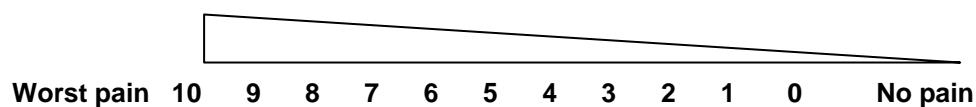
No :

## Pain Score

AT REST



ON COUGHING



## Nausea Score

0 1 2 3 4

0=No nausea  
1=Mild nausea, no treatment  
2=Moderate nausea, response to treatment  
3=Moderate nausea, no response to treatment  
4=Severe nausea

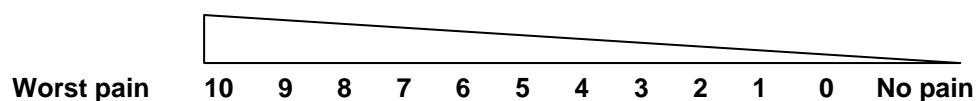
No :

Day 3

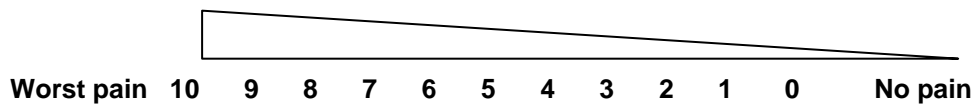
4PM

## Pain Score

AT REST



### ON COUGHING



### Nausea Score

0 1 2 3 4

0=No nausea  
1=Mild nausea, no treatment  
2=Moderate nausea, response to treatment  
3=Moderate nausea, no response to treatment  
4=Severe nausea

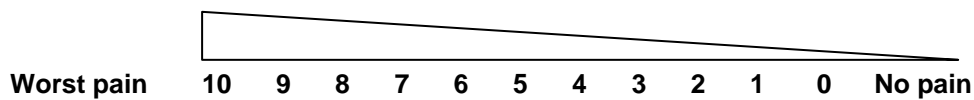
**Day 4**

**4PM**

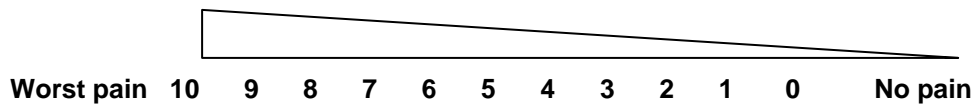
No :

### Pain Score

#### AT REST



#### ON COUGHING



### Nausea Score

0 1 2 3 4

0=No nausea  
1=Mild nausea, no treatment  
2=Moderate nausea, response to treatment  
3=Moderate nausea, no response to treatment  
4=Severe nausea

### Analgesia :

Epidural in-situ                      Day 0.....                      Day 1.....                      Day 2.....

24 hr PCA requirement                      Day 0.....mg                      Day 2.....mg                      Day 3.....mg

**Additional Analgesic Requirement**

	Paracetamol	Ibuprofen	Morphine	Other(name/dose)
Day 0				
Day 1				
Day 2				
Day 3				
Day 4				

# NHS National Research Ethics Service

Derbyshire Research Ethics Committee

1 Standard Court  
Park Row  
Nottingham  
NG1 6GN

Telephone: 0115 8839461  
Facsimile: 0115 9123300

23 July 2010

Mr Ugochukwu Ihedioha  
Specialist Registrar (General Surgery)  
University Hospitals of Leicester  
Dept of Surgery  
Leicester General Hospital  
Leicester  
LE5 4PW

Dear Mr Ihedioha

**Study Title:**

**Psychological preparation for colorectal surgery: Impact  
of video education. A randomised trial.**

**REC reference number:**

**10/H0401/50**

Thank you for your letter of 15 July 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Conditions of the favourable opinion:**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within the  
National Patient Safety Agency and Research Ethics Committees in England

**NRES Committee East Midlands - Derby 2**

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 8839368  
Fax: 0115 8839294

25 July 2011

Mr Ugochukwu Ihedioha  
Specialist Registrar (General Surgery)  
University Hospitals of Leicester  
Dept of Surgery  
Leicester General Hospital  
Leicester  
LE5 4PW

Dear Mr Ihedioha

**Study title:** Psychological preparation for colorectal surgery: Impact  
of video education. A randomised trial.  
**REC reference:** 10/H0401/50

This study was given a favourable ethical opinion by the Committee on 23 July 2010.

Research Ethics Committees are required to keep a favourable opinion under review in the light of progress reports and any developments in the study. You should submit a progress report for the study 12 months after the date on which the favourable opinion was given, and then annually thereafter. Our records indicate that a progress report is overdue. It would be appreciated if you could complete and submit the report by no later than one month from the date of this letter.

Guidance on progress reports and a copy of the standard NRES progress report form is available from the National Research Ethics Service website.

The NRES website also provides guidance on declaring the end of the study.

Failure to submit progress reports may lead to the REC reviewing its opinion on the study.

<b>10/H0401/50:</b>	<b>Please quote this number on all correspondence</b>
---------------------	---

Yours sincerely

**Mr Nick Brooks**  
**Administrative Assistant**

E-mail: [nick.brooks@nottspct.nhs.uk](mailto:nick.brooks@nottspct.nhs.uk)

Copy to: Mrs Carolyn Maloney, University Hospitals of Leicester NHS Trust

DIRECTORATE OF RESEARCH & DEVELOPMENT

**Director:** Professor D Rowbotham  
**Assistant Director:** Dr David Hetmanski  
**R&D Manager:** Carolyn Maloney

Research & Development Office  
Leicester General Hospital  
Gwendolen Road  
Leicester  
LE5 4PW

Direct Dial: (0116) 258 8351  
Fax No: (0116) 258 4226

23/08/2010

Mr Ugochukwu Ihedioha  
University Hospitals of Leicester NHS Trust  
Dept of Surgery  
Leicester General Hospital  
Leicester  
LE5 4PW

Dear Mr Ugochukwu Ihedioha

Ref: UHL 10946  
Title: Psychological preparation for colorectal surgery: Impact of video education.  
A randomised trial.  
Project Status: Project Approved  
End Date: 22/06/2011

I am pleased to confirm that with effect from the date of this letter, the above study now has Trust Research & Development permission to commence at University Hospitals of Leicester NHS Trust.

All documents received by this office have been reviewed and form part of the approval. The documents received and approved are as follows:

Document Name	Version Number	Date
Protocol	2.5	26.05.10
DVD- A patients guide to recovery after colorectal surgery		
Questionnaire – SF36		
Questionnaire – DVD	2.5	14.07.10
PIS	3.0	14.07.10
CF	2.5	26.05.10

*Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.*

Version 5, 20.04.10

**Please Note:** Mr S Chaudri is not currently approved to work on this study. Please submit a non substantial amendment to add Mr Chaudri on.

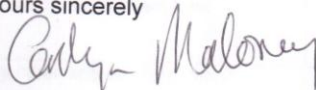
We are aware that undertaking research in the NHS comes with a range of regulatory responsibilities. Attached to this letter is a reminder of your responsibilities during the course of the research. Please ensure that you and the research team are familiar with and understand the roles and responsibilities both collectively and individually.

You are required to submit an annual progress report to the R&D Office and to the Research Ethics Committee. We will remind you when this is due.

The R&D Office is keen to support research, researchers and to facilitate approval. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office.

We wish you every success with your research.

Yours sincerely



Carolyn Maloney  
**R&D Manager**

Encs: .Researcher Information Sheet.

Please note that some of the documents may not apply to your study.



Draft 02

Centre <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	Patient No. <div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>	Initials <div style="border: 1px solid black; width: 60px; height: 20px; margin: 0 auto;"></div>	Date of Visit <div style="display: flex; justify-content: space-around; font-size: 0.8em;"> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> D</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> D</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> M</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> M</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> Y</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> Y<sup>00</sup></span> </div>
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Thank you for completing this booklet. Please follow the instructions.

**Confidentiality:** Your name and address do not appear anywhere on this booklet. The information that you give will not be used in any way that could identify you personally.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

#### GENERAL HEALTH

For questions 1 and 2, please circle the number that best describes your health.

- |   |   |   |   |   |   |
|---|---|---|---|---|---|
|   | Excellent   | Very good   | Good  | Fair  | Poor  |
| 1. In general, would you say your health is:                                | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">5</div> |
|   |   |   |   |   | 06  |
|   | Much better   | Somewhat better   | About the same  | Somewhat worse  | Much worse  |
| 2. Compared to one year ago, how would you rate your health in general now? | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">5</div> |
|   |   |   |   |   | 06  |

#### HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do in a typical day. Does your health limit you in these activities? If so, how much? Please circle one number on each line.

- |   | Yes, limited<br>a lot   | Yes, limited<br>a little  | No, not<br>limited at all   |
|---|---|---|---|
| a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.  | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| c) Lifting or carrying groceries.   | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| d) Climbing several flights of stairs.  | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| e) Climbing one flight of stairs.   | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| f) Bending, kneeling or stooping.   | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| g) Walking more than a mile.  | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| h) Walking half a mile.   | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| i) Walking 100 yards.   | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |
| j) Bathing or dressing yourself.  | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">3</div> |

4. During the past 4 weeks, have you had any of the following problems with your work or other daily activities as a result of your physical health?

Please circle 1 for Yes or 2 for No on each line.

- |  | Yes   | No  |
|--|---|---|
| a) Cut down on the amount of time you spend on work or other activities                        | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> |
| b) Accomplished less than you would have liked.  | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> |
| c) Were limited in the kind of work or other activities.                                       | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> |
| d) Had difficulty performing the work or other activities (for example, it took extra effort). | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">2</div> |



Draft 02

Centre <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	Patient No. <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	Initials <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	Date of Visit <div style="display: flex; justify-content: space-around; font-size: 0.8em;"> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> D</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> D</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> M</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> M</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> Y</span> <span><div style="border: 1px solid black; width: 20px; height: 20px;"></div> Y<sup>04</sup></span> </div>
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5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any **emotional problems** (such as feeling depressed or anxious)?

Please circle 1 for Yes or 2 for No on each line.

- |  | Yes   | No  |
|--|---|---|
| a) Cut down on the <b>amount of time</b> you spend on work or other activities | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> |
| b) Accomplished less than you would have liked.                                | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> |
| c) Did not do work or other activities as <b>carefully</b> as usual.           | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> |

For questions 6, 7 & 8, please circle the number that best describes you and your health.

- |   | Not at all  | Slightly  | Moderately  | Quite a bit   | Extremely   |
|---|---|---|---|---|---|
| 6. During the <b>past 4 weeks</b> , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or other groups? | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> |

- |   | None  | Very Mild   | Mild  | Moderate  | Severe  | Very Severe   |
|---|---|---|---|---|---|---|
| 7. How much bodily pain have you had over the <b>past 4 weeks</b> ? | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |

- |   | Not at all  | A little bit  | Moderately  | Quite a bit   | Extremely   |
|---|---|---|---|---|---|
| 8. During the <b>past 4 weeks</b> , how much did pain interfere with your normal work (including both work outside the home and housework)? | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> |

#### YOUR FEELINGS

9. The following questions are about how you feel and how things have been with you **during the last month**. For each question, please circle the number that best describes the way you have been feeling.

Make sure that you circle one number on each line.

- |   | All of the time   | Most of the time  | A good bit of the time  | Some of the time  | A little of the time  | None of the time  |
|---|---|---|---|---|---|---|
| How much time during the <b>past month</b> :  |   |   |   |   |   |   |
| a) Did you feel full of life?   | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| b) Have you been a very nervous person?   | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| c) Have you felt so down in the dumps that nothing could cheer you up?                        | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| d) Have you felt calm and peaceful?   | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| e) Did you have a lot of energy?  | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| f) Have you felt downhearted and low?   | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| g) Did you feel worn out?   | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| h) Have you been a happy person?  | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| i) Did you feel tired?  | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |
| j) Has your health limited your social activities (like visiting friends or close relatives)? | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">1</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">2</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">3</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">4</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">5</div> | <div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px;">6</div> |

Centre <div style="border: 1px solid black; width: 40px; height: 15px; margin: 0 auto;"></div> <small>01</small>	Patient No. <div style="border: 1px solid black; width: 60px; height: 15px; margin: 0 auto;"></div> <small>02</small>	Initials <div style="border: 1px solid black; width: 40px; height: 15px; margin: 0 auto;"></div> <small>03</small>	Date of Visit <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 15px; margin: 0 2px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 8px;"> <span>D</span><span>D</span><span>M</span><span>M</span><span>Y</span><span>Y<sup>04</sup></span> </div>
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**HEALTH GENERAL**

10. Please choose the answer that **best** describes how **true** or **false** each of the following statements is for you.  
*Please circle one number on each line.*

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a) I seem to get ill more easily than other people.	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">1</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">2</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">3</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">4</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">5</div> <small>05</small>
b) I am as healthy as anyone I know.	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">1</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">2</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">3</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">4</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">5</div> <small>06</small>
c) I expect my health to get worse.	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">1</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">2</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">3</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">4</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">5</div> <small>07</small>
d) My health is excellent.	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">1</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">2</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">3</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">4</div>	<div style="border: 1px solid black; width: 20px; height: 20px; line-height: 20px; margin: 0 auto;">5</div> <small>08</small>

Investigator's Name

Investigator's Signature

Date